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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

5 (ACMUI)

6 + + + + +

7 MONDAY

8 OCTOBER 29, 2001

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10 ROCKVILLE, MARYLAND

11 The ACMUI Advisory Committee on the Medical Uses
12 of Isotopes met at the Nuclear Regulatory Commission,
13 Two White Flint North, Room T2B3, 11545 Rockville
14 Pike, at 9:00 a.m., Dr. Manuel Cerqueira, Chairman,
15 presiding.

16 Committee Members Present:

17 Dr. Manual Cerqueira, Chairman, Nuclear Cardiologist

18 Ms. Nekita Hobson, Member, Patient Advocate

19 Dr. Subir Nag, Member, Radiation Oncologist

20 Dr. David A. Diamond, Member, Radiation Oncologist

21 Mr. Ralph P. Lieto, Member, Medical Physicist

22 Dr. Leon S. Malmud, Member, Healthcare Administration

23 Ms. Ruth McBurney, Member, State Representative

24 Ms. Sally Wagner Schwarz, Member, Nuclear Pharmacist

25 Dr. Jeffrey Williamson, Member, Therapy Physicist

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1 Committee Members Present:

2 Dr. Richard J. Vetter, Member, Radiation Safety
3 Officer

4 NRC STAFF PRESENT:

5 Donald A. Cool, Ph.D

6 Angela Williamson

7 Donna-Beth Howe, Ph.D

8 Frederick D. Brown

9 Patricia Holahan, Ph.D

10 Marjory Rothschild

11 Susan Frant, Ph.D

12 Robert Ayres, Ph.D

13 Mark Sitek

14 Melanie Galloway

15 GUEST SPEAKERS

16 Dr. Jeffrey A. Brinker, Society of Cardiac Angiography
17 & Interventions

18

19 Dr. Geoff Ibbott, American Association of Physicists
20 in Medicine

21

22 Dr. Prabhakar Tripuraneni

23

24

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

(9:03 a.m.)

1
2
3 DR. CERQUEIRA: I'd like to welcome
4 everyone to the meeting. My name is Manuel Cerqueira,
5 and I'm the Chairman of the committee. We have two
6 new members who are joining us. Are they both
7 official now, Angela?

8 MS. WILLIAMSON: Yes. It's done.

9 DR. CERQUEIRA: Well we have American
10 Association of Physicists in Medicine Ralph Lieto
11 who's a medical physicist, who's the newest member of
12 the committee; and Dr. Leon Malmud, who's a well-known
13 entity, but he's here as the Healthcare Administration
14 representative, which is a new role for him. And then
15 we have one vacancy which we're still recruiting for.

16 A couple of people have informed me that
17 they have flight changes, and so we will definitely
18 try to get through the meeting in a timely fashion.
19 Maybe we should just go on to the remarks that were to
20 be delivered by John Hickey who was unable to make it,
21 and Angela will make some comments and then we'll have
22 Dr. Donald Cool is going to make some comments as
23 well. Angela.

24 MS. WILLIAMSON: Good morning everyone.
25 I'm going to read the official opening remarks for the

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1 meeting.

2 I am pleased to welcome you to Rockville
3 for the public meeting of the ACMUI. My name is
4 Angela Williamson. I'm the Project Manager and I am
5 standing in today for John Hickey who is the Branch
6 Chief of the Material Safety and Inspection Branch.

7 Mr. Hickey is the designated Federal
8 official for this committee. Normally, he would
9 present these introductory remarks, but unfortunately
10 Mr. Hickey is ill today.

11 This is an announced meeting of the
12 committee. It is being held in accordance with the
13 rules and regulations of the Federal Advisory
14 Committee Act and the Nuclear Regulatory Commission.
15 The meeting was announced in the Federal Register on
16 September 19, 2001 for the October 29, 2001 meeting.

17 The function of the advisory committee is
18 to advise the staff on issues and questions that arise
19 on the medical use of by-product material. The
20 committee provides counsel to the staff but does not
21 determine or direct the actual decisions of the staff
22 or the commission. The NRC solicits the opinions of
23 the council and values the opinions of the committee
24 very much.

25 I do request that whenever possible, we

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1 try to reach a consensus on the various issues that we
2 will discuss today or at any other ACMUI meeting. But
3 I also do value stated minority or dissenting
4 opinions. I do ask that if you have dissenting
5 opinions, that we read those into the record.

6 As part of the preparation for this
7 meeting, Mr. Hickey reviewed the agenda for members
8 and employment interests based upon the very general
9 nature of the discussion that we are going to have
10 today. He did not identify any items that will pose
11 a conflict. Therefore, I see no need for an
12 individual member of the committee to recuse
13 themselves from the discussion.

14 However, if during the course of our
15 business, you determine that you have some conflict,
16 please state it for the record and recuse yourself
17 from that particular aspect of the discussion. And
18 now I'd like to turn it over to Dr. Cool.

19 DR. COOL: Thank you and good morning. I'm
20 Donald Cool. I'm the Director of the Division of
21 Industrial and Medical Nuclear Safety, and I would
22 like to welcome you here to White Flint and the
23 meeting today. I'd also like to extend a welcome to
24 the various members of the public representatives from
25 a number of the medical societies and others that we

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1 have here in the room with us today.

2 Let me particularly welcome Dr. Malmud and
3 Mr. Lieto. Welcome to the committee. We are very
4 pleased that you have been able to join us today. We
5 look very much forward to your being part of this
6 committee, sharing with us your insights, experience,
7 advice as we address a variety of topics, both today
8 and over the coming meetings in your term.

9 We are in interesting times. The world
10 changed on September 11th. It certainly changed for
11 those of us here at the agency in a variety of ways.
12 I think it has probably changed for each of you in
13 maybe very tangible ways, perhaps more intangible
14 ways.

15 For the Nuclear Regulatory Commission, we
16 have been on a heightened state of alert and security
17 since minutes after the first plane went into the
18 World Trade Towers. We have had our operations center
19 under continuous activation and staffing since that
20 time, as we have with our regional offices.

21 We have had the reactor facilities, our
22 fuel facilities under heightened security and
23 safeguards, and have been pursuing aggressively a
24 variety of reexaminations of our current security
25 posture and security of various vulnerabilities and

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1 issues, trying to look forward at the possible ways
2 that other mischief or misuse could take place, and to
3 have in place additional measures that might be
4 necessary or appropriate in order to deal with those
5 threats. Obviously a great deal of that is classified
6 and is not something that we could discuss openly
7 around this room, but there has been a great deal of
8 activity that has gone on here.

9 As well, there's been a great deal of
10 activity involving the agency with other various
11 Federal agencies and interactions with the Department
12 of Energy, the FBI, the Federal Emergency Management
13 Agency, and you can just keep on going down the list.
14 Add now the Homeland Security office with which we
15 have someone participating, not quite around the clock
16 in their staffing activities, to try and stay involved
17 and be part of the various activities of the Federal
18 family in response to the various events that have
19 taken place.

20 There certainly have been a number of
21 questions that have been raised about vulnerabilities
22 of various radioactive materials. You've seen a lot
23 of discussion in the press about what people could do.
24 You've seen various viewpoints expressed.

25 We have, let me assure you, been examining

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1 various issues, interacting with our licensees,
2 providing information to them, as may be necessary
3 providing specific threat information under a couple
4 of circumstances in which we have had at least, over
5 brief periods of time, threats made that we could not
6 determine the exact nature thereof.

7 We were pleased that they turned out not
8 to have any substance behind them, but it does, as you
9 might expect, get the pulses racing just a little bit
10 when you can't exactly figure out what's going on and
11 you're continuously trying to sift through enormous
12 quantities of information in order to understand
13 exactly what may be going on out there.

14 I'm sure you're aware that the Federal
15 Government overall continues to believe that the
16 threat in a general threat sort of environment remains
17 high in the United States. You hear that from
18 Governor Ridge who's now the head of Homeland
19 Security, and various other folks on a daily basis, so
20 that should not come as any particular surprise to
21 you.

22 There have been a variety of issues more
23 recently with regards to anthrax, bioterrorism and
24 including the issues associated with whether radiation
25 has a potential role to play. I'm guessing that a

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1 number of you probably saw the news over the weekend
2 with the Postal Service looking to purchase various
3 radiation pieces of equipment to irradiate the mail.
4 We have been interacting with the Postal Service and
5 the Department of Energy and FDA and AFFRI.

6 We've been looking into these issues, not
7 directly involved because the technologies that they
8 appear to be looking at and entering into contracts
9 through Ruth McBurney and the states will get the
10 opportunity out as opposed to the by-product materials
11 that are under the NRC's jurisdiction, but we
12 certainly had questions tossed at us early on, how
13 much radiation? What else might it do? And we have
14 interacted with a variety of those folks to try and
15 help pull together an understanding of what is taking
16 place in that area.

17 So there have been a lot of things that
18 have gone on. There has been a lot of normal
19 activities that would otherwise have been expected to
20 have been worked on and been moving forward, which
21 would have been put on the back burner or worked only
22 very slowly as a result of a very heightened focus
23 within the agency on some of the immediate issues.

24 Nevertheless, it is with recognition that
25 some of the day-to-day issues and activities need to

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1 continue to be examined that we are here today.
2 Medical care needs to continue. New technologies and
3 activities need to be examined, and we need to make
4 sure that we continue to be in the right place in
5 terms of providing proper oversight, allowing the
6 kinds of activities and developments that are ongoing
7 to be involved, taking a look at some of the emerging
8 issues that are taking place.

9 Your agenda today has several of those
10 topics, intravascular brachytherapy and some of the
11 things related to mixtures of doses between atomic
12 energy materials and non-atomic energy material,
13 particularly the x-ray fluoroscopy, which at one level
14 ought not to seem to be a problem, but when you start
15 drawing the nice little legal lines and bright boxes
16 that inevitably happen anytime you write down a
17 regulation, suddenly draw you into potential conflicts
18 of how you calculate things and why you calculate
19 things and why that's okay and that's not okay where
20 the two points seems to be essentially side-by-side
21 with each other. So we look forward to some of those
22 discussions early this afternoon.

23 Likewise, we continue to be in a position
24 where we do not, in fact, have the revised Regulation
25 35 in place. Dr. Patricia Holahan is going to be

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1 talking about that in just a few moments, so I will
2 not go into detail on those, but she'll give you a
3 review of the current status of the activities there
4 and the various things that are going on and how we
5 are moving forward.

6 I believe that summarizes the sort of
7 brief overview that I wanted to give you today. I
8 recognize this is a shorter meeting. A number of the
9 topics that we probably would have wanted to discuss
10 were the new regulations going into effect. We're not
11 in the position to discuss these because we really
12 have no idea of exactly how that will all transpire,
13 but we do very much appreciate all of you taking the
14 time and effort, braving the flights or the very other
15 things in order to spend some time with us today.

16 Dr. Cerqueira, I will be glad to answer
17 some questions or entertain a discussion if some of
18 the members of the committee would like. Thank you.

19 DR. CERQUEIRA: Dr. Diamond can ask some
20 questions about a discussion we had earlier today to
21 Dr. Cool.

22 DR. DIAMOND: A few moments before your
23 arrival, we were having a discussion regarding a lot
24 of questions that we members are being asked in our
25 home communities, specifically what type of education

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1 and materials do we have with respect to counseling
2 the public or treating patients, God forbid should
3 there be an intentional release of radioactive
4 materials.

5 I, as a radiation oncologist despite all
6 my years of medical training, have never received
7 formal training on how to handle these patients. I do
8 know that our professional society's now starting to
9 develop some training materials, but I certainly think
10 it would be useful and productive if the NRC did play
11 a role in helping to coordinate this dissemination of
12 training material in a fashion that does not seem
13 alarmist, and perhaps coordinate those activities with
14 constituencies that we generally don't work with,
15 namely the American Society of Hematology, because of
16 course, they would play an important role should
17 patients be exposed in large numbers.

18 So, those were some of the thoughts we
19 were ruminating about.

20 DR. COOL: I think those are some excellent
21 ideas. One of the things that I failed to mention, as
22 I was trying to go through MMI and some of the
23 activities that are going on is that there is an
24 effort within the Federal community to look at and try
25 to have prepared some materials and information

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1 should, as I agree God forbid, someone chooses to use
2 radioactive materials or a nuclear warhead of some
3 type of yield and magnitude.

4 We have been participating with FEMA and
5 the other agencies. My deputy, Dr. Susan Frant, was
6 at a meeting of Friday of last week with those various
7 groups that are working to try to have some templates
8 in basic pieces of information available for Governor
9 Ridge and others.

10 So at one level, and a very high level at
11 this moment, there is some work being done to try and
12 have some materials in place. But I would also agree
13 that at a very different level, at your individual
14 levels, it would be useful to have that. I do not
15 have a handy dandy card in my pocket that I can yank
16 out and suggest the three or four things. What little
17 bit of media training I've had, you always try to have
18 your two or three messages and you want them to be
19 fairly short and crisp because CNN will never give you
20 more than five seconds of sound time anyhow.

21 I think it would be good to be trying to
22 work on some of those things, and we would be pleased
23 to try and reflect on that with you to the extent that
24 the committee either here want to discuss that a
25 little bit, or to interact separately to try and have

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1 some of those things and build upon each other's
2 ideas. So that would be a wonderful thing.

3 DR. NAG: Don, one thing. You would be
4 able to use your offices to have a more formal
5 training for handling nuclear accidents for the
6 members of the ACMUI and other staff because not just
7 how to respond to the media but if any type of
8 accident happened, whether intentional or not, what
9 are the things that we should be doing? Because we
10 are the ones who are more likely to be called to
11 handle those, and we are basically unprepared to
12 handle them.

13 DR. COOL: A couple of very good points
14 there. We will have to explore the extent to which we
15 can provide, either providing locations or more
16 directly be involved in providing some training and
17 information. Within the Federal family, there are
18 some other groups that specialize in this down at Oak
19 Ridge REAC/TS Group and some others. I know the
20 Health Physics Society has been doing some things.

21 At the moment, I'm drawing a blank as to
22 whether you already have some materials that are out
23 there and available. Certainly there are some
24 materials in our operations center that we have
25 available for those within the agency, that the agency

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1 would be looking to as spokespersons to deal with
2 members of the public and some things which our public
3 affairs folks have.

4 If we can explore, probably not within the
5 scope of the meeting time today, the extent to which
6 we might be able to get some of those and provide some
7 of that to you, we can certainly take that as a
8 possible follow-up item.

9 DR. CERQUEIRA: Other questions for Dr.
10 Cool?

11 I think the discussion we had this morning, and again
12 there's a lot of professional medical societies that
13 are involved in there. There's a lot of government
14 agencies, but ultimately I mean, we as physicians
15 working in these areas will probably be contacted, and
16 if we're not that well informed, I'm sure most of our
17 colleagues are probably less informed.

18 So to try to coordinate the effort would
19 be important, and it would be nice if we could somehow
20 get follow-up on this to try to identify some tangible
21 things that can even be provided to the committee or
22 some sessions, or if those things don't exist, to try
23 to come up with a structure to develop them. And I
24 think the feeling of the committee is we would really
25 like to work with the NRC on some of these issues in

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1 whatever way would get it accomplished.

2 DR. COOL: Very good. I welcome that
3 suggestion. We'll see what we can do in terms of
4 laying our hands on bits and pieces that are here, and
5 if it pleases the committee, see about getting those
6 to you and get some reflections from you on gaps,
7 omissions, suggestions to try to refine it, because I
8 think it would be useful to us in terms of advanced
9 preparations and certainly useful to various groups in
10 the community. Ruth is waving over there.

11 MS. McBURNEY: There may be some materials
12 that REAC/TS has prepared and Dr. Ricks (phonetic) or
13 somebody there that could be disseminated to expand.

14 DR. COOL: Yes, that's what we need to
15 explore, what's already out there.

16 DR. CERQUEIRA: Would it be possible to get
17 somebody from the NRC staff to sort of help coordinate
18 some of these efforts, or at least a preliminary look
19 to see what's out there or what needs to be done?
20 Could there be a contact person identified?

21 DR. COOL: We will do that. For the
22 moment, why don't you work through Angela, who's the
23 Project Manager for this committee.

24 DR. CERQUEIRA: Okay.

25 DR. COOL: We may modify that at some point

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1 down the line, but that will be a good place to start
2 and someone that you're already familiar with.

3 DR. CERQUEIRA: Do you have a time line on
4 this? It won't be today, we realize that.

5 DR. DIAMOND: Yesterday would be fine.

6 DR. COOL: Yesterday would be fine, okay
7 thank you.

8 DR. CERQUEIRA: Hopefully the relevance
9 will disseminate over time, but at the same time to
10 sort of get into periods of months before anything
11 gets done doesn't really meet the needs of the
12 committee.

13 DR. COOL: No, I think this is one which,
14 consistent with the pace of a number of other things
15 we've got going, I would hope would be measured in
16 days to small number of weeks, not in terms of months
17 or the next committee meeting.

18 DR. CERQUEIRA: Right, because ultimately
19 these bioterrors have medical consequences, and I
20 guess in terms of radiation, this is the advisory
21 committee. Jeffrey, you had a comment?

22 DR. WILLIAMSON: Yes, I suggest maybe we
23 take some of elective time for new agenda items at the
24 end of the meeting and try to make a more specific
25 focused list of requests from the commission and their

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1 staff, what we as a group would like from them.

2 DR. CERQUEIRA: That's good. Other
3 questions for Dr. Cool?

4 DR. COOL: If not, I thank you. I will not
5 be able to stay with you for the majority of the day.
6 In fact, the daily briefing of our senior managers in
7 our operations center up just two floors is in
8 progress and I'm going to go join them next.

9 DR. NAG: The meeting with the commissioner
10 that was postponed, have we been able to reschedule
11 that at any point?

12 DR. COOL: It has not been formally
13 rescheduled as in locked down with some new dates.
14 Once we know a little bit more about the time line
15 with Part 35 and looking to see what your schedule may
16 look like in terms of interacting with us on that for
17 the spring meeting, our thought at this point was we
18 would try to arrange that to be more or less
19 coincident with take advantage for a single travel
20 opportunity with the commission at that time. The
21 commission indicated its desire for that to be in the
22 spring.

23 DR. CERQUEIRA: Okay. We'll work with
24 Angela to try to firm up a date. Obviously getting
25 the five commissioners together is more difficult than

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1 getting the committee today. So, we'll work around
2 their schedule.

3 DR. COOL: One never knows.

4 DR. CERQUEIRA: Okay, well thank you very
5 much Dr. Cool. Let's see. We can go on to the next
6 item, which is the follow-up from the April ACMUI
7 meeting.

8 MS. WILLIAMSON: Dr. Cerqueira, I was
9 wondering if you wanted to briefly introduce the
10 members around the table very briefly.

11 DR. CERQUEIRA: Of the committee, sure.
12 Okay. Why don't you start Nekita.

13 MS. HOBSON: I'm Nekita Hobson, and I am
14 the Patient Advocate and my organization is the
15 National Association of Cancer Patients.

16 DR. NAG: Subir Nag, Association of
17 Oncology, representing radiation oncology and brachial
18 therapy immunity.

19 DR. DIAMOND: David Diamond, radiation
20 oncologist, also representing the radiation oncology
21 and brachial therapy communities.

22 MR. LIETO: Ralph Lieto, I'm the new member
23 representing the medical nuclear physicists community.

24 DR. CERQUEIRA: Manual Cerqueira. I'm a
25 nuclear medicine physician and a cardiologist, and I'm

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1 representing the nuclear cardiology community.

2 DR. MALMUD: Leon Malmud, the Dean of
3 Medicine at Temple University and the President of
4 Temple University Health System, representing
5 healthcare administration.

6 MS. McBURNEY: I'm Ruth McBurney with Texas
7 Department of Health. I'm the State Government
8 representative on the committee.

9 MS. SCHWARZ: Sally Schwarz, representing
10 nuclear pharmacy. I'm from Washington University in
11 St. Louis.

12 DR. WILLIAMSON: Jeff Williamson, also from
13 Washington University in St. Louis, representing
14 radiation oncology physics.

15 DR. VETTER: Dick Vetter from Mayo Clinic,
16 representing radiation safety officers.

17 DR. CERQUEIRA: So, Mr. Brown will do the
18 presentation in place of Mr. Hickey.

19 MR. BROWN: Yes, absolutely. My name is
20 Fred Brown. I am a Section Chief in John Hickey's
21 branch and I will be trying to cover for him today.
22 So, for instance, I took the requests for information
23 on medical recommendations in the event of a
24 radiological attack, and I'll try to have some
25 information this afternoon during the opening period

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1 for you.

2 I'm actually going to empower Angela to go
3 over the minutes from the last meeting and the
4 recommendations that you made to us.

5 MS. WILLIAMSON: Okay, I'll just bend down
6 a little. I have in front of me some recommendations
7 that ACMUI made at our April 18th, 2001 meeting and
8 I'm going to speak to the staff response to those
9 recommendations.

10 The first recommendation, ACMUI thought
11 that the procedure or felt that the procedure for
12 recruiting and appointing ACMUI members be done more
13 expeditiously to get vacancies on the ACMUI filled
14 sooner. The staff response to that recommendation, we
15 agree with it and we have put into place procedures
16 for filling the vacancies more expeditiously. So,
17 we're addressing that continuously.

18 The second recommendation that ACMUI made
19 --

20 DR. CERQUEIRA: Angela, so I guess right
21 now we've got one vacancy, the nuclear medicine
22 physician, and I know that some of the professional
23 medical societies have sent in information. I don't
24 think they've heard, or gotten any feedback to date.

25 MS. WILLIAMSON: Well when people send in

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1 for the --

2 DR. CERQUEIRA: Nominations?

3 MS. WILLIAMSON: When they send in
4 nominations, it's not our procedure to write back
5 every organization that sent in a nomination. What we
6 do is we just collect the nominations and then we
7 proceed with trying to fill the vacancy from there.

8 DR. CERQUEIRA: All right.

9 MS. WILLIAMSON: The next thing everyone
10 will hear, the next notice will be a Federal Register
11 -- excuse me, the next thing that will happen after we
12 get the recommendations or the nominations rather, we
13 will proceed to have a panel to screen the
14 recommendations and the commission will make a
15 decision. But we don't reply to everyone.

16 DR. CERQUEIRA: Well, maybe you could give
17 us an update in terms of when was the deadline for
18 submitting? How many have we gotten to date?

19 MS. WILLIAMSON: We have five, if my memory
20 serves me correctly, we have five nominations that
21 came in by the deadline and I'm sorry but I don't
22 remember the deadline off the top of my head. We will
23 be having a screening panel meeting in early December
24 -- excuse me, that's wrong, in November, the middle of
25 November. We changed it.

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1 But in any case, in the middle of November
2 we will be having a screening panel meeting and at
3 that screening panel meeting, there will be
4 recommendations made to the commission as to who
5 should fulfill that vacancy. So, by spring of next
6 year, definitely by then we should have the person
7 selected and probably before then as a matter of fact.

8 But whoever is selected should be able to
9 attend the spring meeting. That's what I want to make
10 clear.

11 DR. CERQUEIRA: And we have no other
12 vacancies then right?

13 MS. WILLIAMSON: No, that's the only
14 vacancy that we have.

15 DR. CERQUEIRA: And in terms of people
16 going off the committee, anticipating another cycle?

17 MS. WILLIAMSON: Yes, we do look at who's
18 due to rotate off and we address it at that point. If
19 the person is eligible and willing, then of course as
20 you know Dr. Cerqueira, they can serve again, or we
21 can go out and --

22 DR. CERQUEIRA: Right, but I think Dr.
23 Williamson's point last time had been if we know, and
24 I don't recall who's going to be going off the
25 committee, but if they're going off a year from now,

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1 then if we could start doing some of the leg work for
2 that six months at the latest before that, that would
3 guarantee that we would have somebody in place.

4 So I think the discussion last time was to
5 try to really have operational definitions of how to
6 do it. Maybe, you know, in terms of follow-up, maybe
7 at the next meeting we could get a listing of when
8 people are rotating off the committee and some time
9 lines for when we're going to -- because we have to
10 publish a Federal Register notice.

11 MS. WILLIAMSON: Right.

12 DR. CERQUEIRA: Give a period and so it
13 would be ideal to have the schedule.

14 MS. WILLIAMSON: I can give you a schedule
15 of rotations.

16 DR. NAG: Anyone here getting off in April
17 of the people who are here? No.

18 DR. CERQUEIRA: Does anyone know?

19 DR. WILLIAMSON: I don't know. I think the
20 major suggestion was recruit in advance.

21 MS. WILLIAMSON: Yes.

22 DR. WILLIAMSON: And publish the Federal
23 notice, Federal Register notice well in advance of the
24 member rotating off. So, have you changed your
25 procedures to reflect that?

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1 MS. WILLIAMSON: We have. I mean,
2 sometimes understand that there are snafues, things
3 that just occur that are out of our control. We would
4 have had the nuclear medicine -- we might have been
5 able to fill it sooner, but we have to wait for people
6 to send us nominations and we really have no control
7 over that sort of thing.

8 DR. WILLIAMSON: No, my point was that if,
9 for example, I am to rotate off in twelve months for
10 example, you would publish the Federal Register notice
11 for my position six months before I rotate off and
12 have basically the selection made by the time my term
13 ends. Have you changed your procedures to do that?
14 That was the major suggestion that was made at the
15 last meeting.

16 MR. BROWN: Let me interject that we
17 understood the suggestion. We agree with it. That's
18 our plan. As you're aware, there was a change in the
19 management of the committee function about a year ago.
20 We've been in the process of trying to fill the
21 existing vacancies and to get caught up and to get
22 ahead.

23 We have not updated our internal
24 procedures, but we understood the recommendation. We
25 agree with it. That's our intent and we're moving in

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1 that direction.

2 DR. CERQUEIRA: Okay, good.

3 MS. WILLIAMSON: Okay, let's move on to the
4 next recommendation. The recommendation involves a
5 risk-informed reporting limit in which the ACMUI
6 recommended that this risk-informed reporting limit of
7 5 rem be limited to the reporting of errors made in
8 the release of patients and/or the reporting of errors
9 made in the delivery of instructions to the patient.

10 The staff in response to this
11 recommendation included it in a paper that --

12 MR. BROWN: And actually what I'd like to
13 do, Trish Holohan's our next speaker. She can speak
14 to this issue in detail for you. She's the most
15 knowledgeable person. So if we could just defer on
16 that until the next speaker. And actually, the
17 following two recommendations, one dealt with
18 intravascular brachytherapy and we're going to have a
19 speaker shortly in that area.

20 MS. WILLIAMSON: And the other one is the
21 broad authorizations for --

22 MR. BROWN: Board authorizations and I'd
23 like to do the same thing, defer the detailed
24 discussion for those speakers.

25 MS. WILLIAMSON: Okay. For the training

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1 requirements for authorized medical physicists, the
2 ACMUI recommended that the staff involved such
3 qualified member as specialist, consultants or the
4 ACMUI itself in approving these supplementary training
5 requirements that allow Board-certified radiation
6 oncologists and medical physicists to become
7 authorized medical physicists.

8 In response to this recommendation, the
9 staff agreed with it and will involve outside parties
10 as necessary when guidance is developed.

11 MR. BROWN: And Dr. Ayres will be speaking
12 to that.

13 MS. WILLIAMSON: And Dr. Ayres will be
14 speaking to that.

15 MR. BROWN: And the same with Donna-Beth
16 Howe will be speaking on the last item. So, that was
17 basically all we had for introductory information
18 before we moved into the first presentation, Dr.
19 Cerqueira, unless there are any other ACMUI process
20 questions for us at this time.

21 DR. CERQUEIRA: No, I guess the minutes are
22 not in the book, are? Or, did I just miss them
23 somehow?

24 MS. WILLIAMSON: The minutes, I did pass
25 those out. You should have them.

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1 DR. CERQUEIRA: Where?

2 MS. WILLIAMSON: They may not be in the
3 book but I did pass them out.

4 MR. BROWN: If there's trouble finding
5 them, we'll certainly get them to you.

6 MS. WILLIAMSON: We'll get them to you.

7 (Background conversation.)

8 DR. CERQUEIRA: Okay yes, it's under Tab,
9 response to April recommendations. That's logically
10 where it should be, yes. Okay, I guess those items
11 are there. We can probably follow up. Angie, you did
12 a great job being put on the spot like that.

13 All right, so we'll move on with the other
14 items.

15 (Background conversation.)

16 DR. CERQUEIRA: Yes, these are just the
17 action items, yes.

18 DR. WILLIAMSON: The NRC response. There's
19 no minutes.

20 MS. HOLAHAN: Good morning. I know a
21 number of you but for those of you who don't know me,
22 I'm Trish Holahan. I'm the Chief of the Rule-making
23 and Guidance Branch. No, I'm not John Hickey.

24 Anyways, I was asked this morning if I
25 could cover the status of Part 35, and some of the

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1 other outstanding issues, so let me walk quickly
2 through that. I was at Cathy Haney's talk at your
3 last meeting in which she gave you some of the status,
4 at which time she had indicated that the Part 35
5 package had gone down to OMB on March 14th, and on
6 September 19th we did receive OMB approval of the
7 information collection requirements within the Part
8 35, the new Part 35 package.

9 We have incorporated all the changes that
10 were in the staff requirements memorandum from the
11 commission in the new Part 35, and there were some
12 minor adjustments based on discussions with OMB to
13 clarify that we were not looking at duplicate records
14 in terms of labeling. Those changes were made.

15 The OMB did include a number of terms of
16 clearance, which is their phraseology for things that
17 must be addressed at the next time the package is
18 renewed. So, the current clearance expires on
19 September 30th of 2004, and at the time that we submit
20 the renewed package, assuming that we can get the
21 current package out and published, the OMB would like
22 us to first of all consider any new information
23 regarding risk information on uses of medical by-
24 product material and how that new information could
25 then impact the burden imposed by information

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1 collection.

2 So, they haven't asked us to revisit all
3 the existing risk information, but if new information
4 becomes available, they've asked us to consider and
5 address it in the renewal package.

6 Also, the second term of clearance
7 requests the NRC to consider whether alternatives,
8 including the use of a third-party accrediting
9 organization would achieve the same purpose, and I do
10 know that in a number of the public meetings and the
11 meetings with the committee here, as Cathy Haney did
12 address the use of third-party accrediting
13 organizations and that was something at that time was
14 put aside for later consideration.

15 But I think over the next three years,
16 it's going to be something that we are going to be
17 coming to the committee to see whether or not that is
18 a viable alternative, recognizing can you require the
19 use of third-party, and that in and of itself may be
20 a burden.

21 DR. CERQUEIRA: I don't fully understand
22 what you mean by third-party accrediting
23 organizations.

24 MS. HOLAHAN: This was a proposal that
25 originally came in, I believe it was from the ACNP and

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1 SNM and I stand corrected if I'm wrong on that, where
2 a third-party such as JCAHO or some other third party
3 put together by the medical organizations would go in
4 and inspect a facility to see if they were in line
5 with the regulations, rather than NRC coming in to
6 inspect.

7 DR. CERQUEIRA: Okay.

8 MS. HOLOHAN: Finally, the third term of
9 clearance was focusing on the reporting thresholds we
10 have for a medical event and looking at again whether
11 there is any new information regarding the risks
12 imposed by variation from the prescribed dose, and
13 whether a different threshold would better satisfy the
14 regulations. It may also impose less burden, so they
15 want us to revisit what the actual reporting
16 thresholds are if there is additional risk information
17 available at that time.

18 They've also requested that we consult
19 with licensees or relevant stakeholders and that would
20 certainly include the ACMUI as we're pulling together
21 that next renewal package.

22 So that's where the actual rule stands is
23 to say we do have the OMB approval; however, we have
24 not gone forward to publish the rule at this point
25 because, you may be aware that there has been some

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1 discussions up in Congress and the Senate has proposed
2 some language that would impact our expending
3 resources to implement the new Part 35 that is
4 currently in conference session between the House and
5 the Senate.

6 The House version did not include the
7 language, whereas the Senate version did, so that they
8 are continuing now to negotiate and I know that
9 several of the medical organizations have communicated
10 with both the House and the Senate.

11 So at this point, we are holding the new
12 Part 35. We have not forwarded it for publication
13 because if we can not go forward and implement it,
14 then we would have superceded the old Part 35 and have
15 nothing on the books, so.

16 DR. CERQUEIRA: So what are the possible
17 scenarios that could result for this? I mean, so far
18 there's a deadlock and there's no budgetary approval,
19 so where do we go from here?

20 MS. HOLAHAN: I guess it will depend in
21 part as to what the language finally comes forward,
22 whether or not they are looking for additional
23 information from NRC before we can go forward and
24 publish it or whether we would look to continue with
25 the existing Part 35. At this point, I think they're

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1 negotiating on the Hill and you know, I don't have
2 more insight than that right now.

3 DR. CERQUEIRA: What if they request a cut
4 and paste? I mean, implement some but not all, would
5 that be something that would be acceptable?

6 MS. HOLAHAN: That's a possibility, but it
7 would take us again some time to go back through the
8 rule and identify which aspects would be cut and paste
9 and then make sure throughout the statements of
10 consideration in the regulatory analysis that the
11 issues that are moved forward are accurately reflected
12 and referenced. So there would be some work on our
13 part to do that.

14 DR. CERQUEIRA: We'll come back to get a
15 time line. Dr. Williamson has this.

16 DR. WILLIAMSON: I wanted to, if you do
17 make a revision of the regulations at the request of
18 Congress, you have to essentially repeat the whole
19 regulatory rule-making process of public comment and
20 so on, don't you?

21 MS. HOLAHAN: I think it would depend on
22 what they were requesting, because if they were asking
23 us to completely go through and revise Part 35 or
24 aspects of Part 35, yes we would have to go and re-
25 notice it. If it was a matter of just moving forward

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1 with certain aspects that have already gone through
2 the public comment period --

3 DR. WILLIAMSON: I see.

4 MS. HOLAHAN: -- that may be a different
5 issue and I think that's what Dr. Cerqueira was
6 focusing on in the cut and paste if I'm correct.

7 DR. CERQUEIRA: Right.

8 MS. HOLAHAN: Okay. So anyways, we are on
9 hold at least at this time and as a result, there are
10 a number of other actions that are on hold. Angela
11 addressed that one of the issues that was raised at
12 the last ACMUI was a secondary follow-up rule to Part
13 35 that would modify 35.3075 which are the reporting
14 requirements if an individual that was released under
15 35.75, the patient release criteria inadvertently gave
16 an exposure to another individual greater than 5 rem.

17 I know again in her discussion with you in
18 April, I believe, as Cathy Haney had gone through some
19 of the draft ruling which she had then forwarded you
20 some suggested draft ruling which we received your
21 comments, the comments have been incorporated into a
22 draft commission paper and the draft proposed rule,
23 but right now that action is also on hold and has not
24 gone forward to the commission until such time as we
25 see which way we're going with Part 35.

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1 So, we appreciate your comments. We have
2 incorporated them and we've included them, and we'll
3 certainly get them up in front of the commission when
4 the package goes forward. There are also a couple of
5 other petitions for rule-making that we had hoped that
6 we could move forward to close out, but we are now
7 holding until we see which direction we go with the
8 new Part 35.

9 So anyways, that's the current status. I
10 apologize and it's very brief, but it's what we have
11 today and as I say, we did make progress. We have
12 moved forward and received the OMB approval, and we
13 are in a -- that's where we are today.

14 DR. CERQUEIRA: In a holding position.

15 MS. HOLAHAN: Yes.

16 DR. CERQUEIRA: I think Dr. Williamson was
17 an instructor when this whole process started out,
18 which kind of dates it and I think for some of us that
19 have been involved, it's a little bit frustrating
20 because the package did sort of go through. But let's
21 -- I sort of time lines and so let's say that if it's
22 -- it could just totally be rejected, correct? Not
23 funded?

24 MS. HOLAHAN: That's a possibility yes,
25 that it could be totally --

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1 DR. CERQUEIRA: And the consequences of
2 that would be?

3 MS. HOLAHAN: The existing Part 35 would
4 continue on the books.

5 DR. CERQUEIRA: So all those years worth of
6 work and Dr. Siegel's time and everything would be
7 lost? Yes?

8 MS. HOLAHAN: I wouldn't like to say lost.
9 I mean there's still a lot of value there but we
10 wouldn't be able to move forward.

11 DR. CERQUEIRA: So that's one alternative
12 that I don't think any of us would really look forward
13 to. The other one is it could be approved, correct?
14 That's still a possibility or?

15 MS. HOLAHAN: That's true. There could be
16 that there is no, I mean the resolution could be such
17 that there is no language in the appropriations bill
18 specific to Part 35, and if that is the case then we
19 could move forward with the Part 35 as it is.

20 DR. CERQUEIRA: And if that were to happen,
21 what's the time line on that? It has to be published
22 and what would be the time line between Congress'
23 approval and publication in the Federal Register?

24 MS. HOLAHAN: Realistically, I mean by the
25 time we would go through and do the, I mean we have

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1 the package ready as it would go forward. It would
2 have to be signed off by the secretary of the
3 commission and then forwarded to the Federal Register,
4 so, and the Federal Register could take up to three
5 weeks. That's their time line. I mean, typically
6 they take less time, so I would say within a month or
7 two.

8 DR. CERQUEIRA: So eight weeks, and then
9 six months after that it would be implemented?

10 MS. HOLAHAN: And then six months after
11 that would be the implementation date, the effective
12 date of the rule, yes.

13 DR. CERQUEIRA: Okay, so we've covered both
14 extremes. What about somewhere in the middle? What
15 if there is a compromise in the sense that some things
16 are, you know, approved and implemented and others are
17 not? What constitutes enough of a change that it has
18 to go back through the public notice process?

19 MS. HOLAHAN: I think if we were changing
20 specific language in the rule, that would have to go
21 back through the public notice comment. If we were
22 moving forward with already approved language, but
23 certain sections, we would have to go back and re-look
24 at the entire rule to make sure that we haven't
25 referenced pieces in certain sections and not

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1 referenced others.

2 DR. CERQUEIRA: I think the issue comes up
3 is what to do with diagnostic nuclear medicine, I
4 believe, and if that were the only things that were
5 kind of held from implementation, would that require
6 a change or?

7 MS. HOLAHAN: Well, yes it would because
8 there are several sections within the new Part 35,
9 Subpart A, B and I think C that are general
10 requirements that will apply to all licensees.

11 So to specifically not have them and then
12 there may be some issues that if you did not move
13 forward with the regulations, you wouldn't have
14 specific regulations; for example, allowing release
15 of patients and things like that for diagnostic, and
16 so you would be in a situation that you may not have
17 applicable regulations to be able to do certain
18 activities.

19 DR. CERQUEIRA: And what would that mean,
20 so that it would basically have to be republished? It
21 would have to come back to this committee or to the
22 NRC, which would then have to rework the language?

23 MS. HOLAHAN: Yes. Yes, NRC would have to
24 rework the language on which way we went forward.

25 DR. CERQUEIRA: And then published Federal

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1 meetings announced, public hearings?

2 DR. NAG: No public hearings.

3 MS. HOLAHAN: Well again, the meetings, it
4 would depend on whether or not we went forward with
5 more public meetings on the direction that we would
6 go. And so, you know, until we actually see what the
7 language is, it's sort of difficult to sort of predict
8 which direction we're going to go.

9 DR. CERQUEIRA: Okay. Jeffrey had a
10 comment.

11 DR. WILLIAMSON: I wanted to ask about the
12 existence and status of the regulatory guide for the
13 new Part 35.

14 MS. HOLAHAN: Okay, the guide has been
15 finalized in line with the existing -- no, I'm sorry
16 not the existing, the new Part 35. We have completed
17 the revision of Volume 9 of the 1556 series based on
18 the final rule that's waiting for publication.

19 DR. WILLIAMSON: So is that available for
20 this committee to look at for example, because I don't
21 recall that we've ever had any input into that. I
22 have never, with all my years of involvement with this
23 process, really ever seen except at very early times
24 a draft of that regulatory guide.

25 MS. HOLAHAN: Okay, you mean you saw the

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1 draft guide that was published for comment? Is that
2 the one you're referring to?

3 DR. NAG: I guess so.

4 MS. HOLAHAN: So then you haven't seen the
5 final guidance document?

6 DR. NAG: No.

7 DR. WILLIAMSON: That's right and there's
8 a substantial change.

9 DR. CERQUEIRA: Is that available on your
10 web site or?

11 MS. HOLAHAN: No it is not. It's the draft
12 that was published is the one that is still available
13 on the web site; again, because with the rule still
14 not being final, we hadn't published the final guide.

15 DR. NAG: If we're optimistic and
16 everything went through, what we would like to see is
17 the latest version you have now, so that if everything
18 went smoothly, we would know what is being published.
19 I think that would be rather helpful for us.

20 MS. HOLAHAN: Okay, you're asking before it
21 was published the committee would like to see it?

22 DR. NAG: Yes.

23 DR. WILLIAMSON: Yes.

24 MS. HOLAHAN: Okay.

25 DR. WILLIAMSON: In fact, I have a concern

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1 that we've never been asked to look at it because
2 there was substantial changes in the draft rule
3 language since the time, I think, we looked at a draft
4 of the regulatory guide and I believe that must have
5 been two or three years ago.

6 MS. HOLAHAN: Okay.

7 DR. WILLIAMSON: So I'm concerned that we
8 have never had an opportunity to have input into the
9 regulatory guide associated with this version of the
10 rule that went to OMB.

11 DR. CERQUEIRA: Ralph had a question.

12 MR. LIETO: Yes, I would like to echo
13 Jeff's comments because I think the devil's in the
14 details and that's where a lot of the so-called
15 conditions and what the inspection and enforcement
16 people are going to be looking at is compliance with
17 that regulatory guide if it's adopted by licensees.
18 And so, I think it's really important that we have a
19 change to take a look at this before it goes out.

20 MS. HOLAHAN: Okay.

21 MR. LIETO: Because we've never seen it.

22 MS. HOLAHAN: All right. Well as I say is
23 -- okay, Marjory may I turn to Marjory Rothschild
24 there?

25 MS. ROTHSCHILD: Yes, I'm with the Office

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1 of General Counsel, and I just wanted to clarify
2 something, kind of put it in perspective. Getting
3 first to the rule, we have a proposed rule that was
4 published for comment. We received comments from the
5 public on it.

6 Based on those comments, you know, certain
7 changes might have been made. And so, the status of
8 the rule is, it was published for comment or any
9 changes in the final rules of such a nature so
10 significant that you would have to go through notice
11 and comment. I mean it's anticipated that when you
12 publish a proposed rule and see comments, you're going
13 to get out of that process, you know, changes to the
14 rule language.

15 So, that's a given and not all changes
16 would require, in fact it's just a question of degree.
17 You evaluate changes between proposed and final, and
18 if they are so significant that you feel there wasn't
19 adequate notice, then you may have to republish for
20 notice and comment.

21 But in a typical rule there are going to
22 be changes in language from proposed to final, and
23 aside from whatever's going on now in terms of
24 Congressional action, the rule still has that status
25 of a proposed rule on which there was comment and you

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1 would only have to republish for notice and comment if
2 you decided that the changes were of such a magnitude
3 between proposed and final that, you know, you didn't
4 give adequate notice. The other comment I had as far
5 as the --

6 DR. CERQUEIRA: Just in follow-up to that
7 now, is that decision to be made by this committee?

8 MS. ROTHSCHILD: No. When you say
9 committee, the ACMUI whether you'd have to republish?

10 DR. CERQUEIRA: Yes.

11 MS. ROTHSCHILD: That's a legal question.

12 DR. WILLIAMSON: Would we be able to have
13 -- I guess maybe a more appropriate question is, would
14 we be consulted and be able to express an opinion,
15 since I don't think we have any decision-making
16 authority whatsoever in this agency?

17 MS. ROTHSCHILD: Yes, I'm sure if you had
18 views you wanted to express, you know, that's
19 certainly a prerogative you have. But whether you re-
20 notice from proposed to final is a legal question.
21 There may be policy considerations also.

22 DR. CERQUEIRA: Dr. Nag said --

23 MS. HOLAHAN: I was very actively involved
24 in the development of the draft final rule.

25 DR. CERQUEIRA: Right.

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1 DR. NAG: I'm not saying that you have to
2 consult us. What I'm saying is that we would like to
3 be consulted upon when you make changes. I know
4 you're getting comments from a lot of people and the
5 staff is going to make the changes. Sometimes some of
6 the changes may be unintentional. It may have some
7 consequences that you may not have thought of.

8 Even a simple thing like and, and all,
9 make sometimes a big difference, and I think some of
10 you know what I'm talking about. Even a single word,
11 changing an and to an or makes a really big
12 difference, and I think we would like to see that
13 rather than waiting and having the whole thing
14 published and then suddenly be surprised.

15 MS. HOLAHAN: And you're talking about the
16 guidance rather than the rule-making?

17 DR. NAG: Yes.

18 MS. ROTHSCHILD: You're talking about just
19 reg guide?

20 MS. HOLAHAN: Okay, because I was going to
21 say I was very involved in the finalization as we move
22 forward with the rule. They're asking about the reg
23 guide.

24 MS. ROTHSCHILD: Okay, well I just wanted
25 to clarify this in terms of the rule, but make it

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1 clear that the ACMUI, as well as members of the
2 public, did have an opportunity to come in on the
3 draft regulatory guide and I know we received a lot of
4 comments. But ultimately what that will say will, you
5 know, depend on: 1) what those comments were; and, 2)
6 what the final rule language is.

7 MS. HOLAHAN: Right.

8 DR. CERQUEIRA: Neki, you have a comment?

9 MS. HOBSON: Well, yes. I think that it
10 would be very useful for us to have the guidance
11 language that we can look at, you know, in connection
12 with Part 35 since some of the comments that I've
13 heard is that the guidance documents that are actually
14 establishing new regulations without going through a
15 regulatory process, and I don't think that's what we
16 intended to do here.

17 Secondly, and this is nothing new to the
18 members of this committee, but I have expressed in the
19 past my kind of frustration that we seem to spin our
20 wheels and, you know, we give advice and nothing
21 happens. I mean I'm sure we've had some impact on the
22 final Part 35, but I think it's far less than I would
23 have liked to have.

24 MS. ROTHSCHILD: Okay, we can get copies of
25 the draft guidance for the committee, but I'd just

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1 like to say as one of the things that the guidance
2 does do, and we have taken a very careful look to
3 insure that we're not putting any new requirements in
4 the guidance than is what is in the rule. I mean I
5 think we have to look at that also from an OMB
6 perspective to make sure that there's no additional
7 burden in the guidance other than what is in the rule.

8 MS. HOLAHAN: But we can check it out.

9 MS. ROTHSCHILD: We also since the new Part
10 35 doesn't require the submittal of procedures, we do
11 have model procedures in the guidance, but that's what
12 they are. They are model procedures and licensees can
13 develop their own procedures to meet the requirements.
14 But I think we find sometimes there are some cases
15 where licensees would like to have the model
16 procedures to follow.

17 DR. WILLIAMSON: So we can count on seeing
18 the regulatory guide soon or do we need to make a
19 motion to the chair?

20 DR. NAG: At night time please.

21 MS. HOLAHAN: I think we can get you a copy
22 of the guide.

23 DR. NAG: Can we have it at night time on
24 that?

25 MS. HOLAHAN: Pardon me?

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1 DR. NAG: Can we have it at night time on
2 that? When?

3 MS. HOLAHAN: I don't know if I can get the
4 copies made today but I can get them out to you. We
5 can put it in motion today and get it to you, but I
6 can't --

7 MS. ROTHSCHILD: Trish, is that the draft
8 final guide you're talking about?

9 MS. HOLAHAN: Yes.

10 MS. ROTHSCHILD: Okay.

11 MS. HOLAHAN: Yes, the draft final.

12 MS. ROTHSCHILD: Okay, that's fine.

13 DR. WILLIAMSON: I just had an information
14 question. What version of the rule was the draft
15 guide that we had a chance to comment on based?

16 MS. HOLAHAN: The proposed rule.

17 DR. WILLIAMSON: The proposed rule that was
18 published in the Federal Register?

19 MS. HOLAHAN: Correct.

20 MS. ROTHSCHILD: Yes, they were both
21 published.

22 DR. CERQUEIRA: You said you had another
23 comment?

24 MS. FRANT: I'm Susan Frant and I guess Don
25 mentioned my name and now this is me. I was out

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1 running around trying to find some medicine for
2 impacted sinuses, so I apologize.

3 Anyway, what I was going to say about the
4 web is our web is down and the only thing on it now
5 are employment kind of things, contract kind of
6 things, the name of the agency, who we are, what our
7 mission is, and how to report a safety concern. So
8 all of the other information that you might send
9 somebody to the web site to get is not available.

10 The rule-making, proposed rules will go up
11 but the comments are no longer going to be available
12 on the web site. So I wanted you to know that. We
13 decided to do that a couple of weeks ago. The
14 Department of Defense, in fact, asked us to take down
15 our web site and it was more related to the reactors,
16 but there's also some issues related to, and I think
17 Don discussed this, related to radioactive material.

18 So while we work that through, for
19 instance the Sealed Source and Device Registry is now
20 password protected, and only the states and NRC staff
21 and our master material licensees have access to the
22 Sealed Source and Device Registry when before it was
23 a public registry.

24 So I heard the conversation "well, what's
25 on the web and what's not on the web." Nothing's on

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1 the web that's related to Part 35.

2 MS. HOLAHAN: I'm sorry, you're right. I
3 didn't address that.

4 MS. FRANT: But that doesn't mean that's
5 not available so people can ask for it, but we want to
6 keep track of who's getting what material.

7 MS. ROTHSCHILD: I just wanted to clarify
8 as far as OMB, the rule doesn't go down to OMB for
9 approval as a whole. What they're looking at is,
10 under Paperwork Reduction Act, the information
11 collection requirements. So, I just want to clarify.

12 MS. HOLAHAN: Okay, I thought I'd said
13 they'd approved the information so I'm sorry.

14 MS. ROTHSCHILD: I'm sorry in some of the
15 discussion that might have been blurred.

16 MS. HOLAHAN: I'm sorry, I meant to say
17 that they -- okay. Doctor Diamond?

18 DR. DIAMOND: I'd just like to say that
19 when I first learned about this action to go and
20 debate the final rules in Congress, I can not tell you
21 how frustrated and disappointed I was.

22 Two of the NRC principles with good
23 regulation, I'm reading from the little chart back
24 here, are efficient and clear and we've spent a
25 tremendous amount of time and work on this and I'm

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1 sorely disappointed that this was the method decided
2 by one constituency to go and try and change the final
3 regs. They have the right to do it of course, but
4 that was sorely disappointing to me and just dragging
5 the process that's taken years and years and making it
6 even longer.

7 The second point is, I would like to fully
8 and very clearly enunciate that when guidance
9 documentation is being promulgated, that this
10 committee have access to this beforehand for comment.
11 The memo that was sent out dated June 12, 2001
12 regarding IVB, because of a simple use of an operative
13 term, and versus or, as we'll discuss later has
14 generated for me a tremendous amount of questions and
15 confusion which again violates one of your principles.

16 So the two points I'd like to share: 1)
17 I'd like to see these guidance documents before they
18 go out for discussion; and 2) I was very, very
19 disappointed regarding the type of action that's been
20 taken and it questions the valuable use of my time
21 serving on this committee.

22 DR. CERQUEIRA: Good comments. Neki?

23 MS. HOBSON: Is the only OMB report
24 available anywhere?

25 MS. HOLAHAN: The terms of clearance?

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1 MS. HOBSON: Yes.

2 MS. HOLAHAN: I can get you copies of
3 those. I didn't get copies made before I came down
4 here. That is to say I stepped in very quickly this
5 morning, but I will get copies and we will get those
6 to you today.

7 DR. DIAMOND: That's an excellent idea.

8 MS. HOLAHAN: I can tell you the time line
9 for that. The other thing I would like to say is
10 depending on where we do go is we certainly would like
11 to continue to keep the ACMUI engaged as we see where
12 the final language goes and what the next steps are.
13 So we'll certainly look to the committee as we move
14 forward.

15 DR. CERQUEIRA: Okay, other comments?

16 MS. HOLAHAN: Because I appreciate Dr.
17 Diamond's comments and I recognize that you have
18 expended a tremendous amount of effort on the rule
19 that stands today, the new rule.

20 DR. CERQUEIRA: Okay, well we're at break.
21 Should we take a break and then come back. Let's try
22 to reconvene in ten, fifteen so we stay on time.

23 (Whereupon, the above-entitled matter went
24 off the record.)

25 DR. CERQUEIRA: If Mr. Ayres could come

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1 forward we'll get started.

2 MR. AYRES: Well, thank you. I notice that
3 I'm scheduled for an hour. My presentation is not
4 anywhere near that long, but depending on the
5 questions, we'll see how it goes.

6 DR. CERQUEIRA: Bob, let me just ask a
7 procedural question. Since some of the people do have
8 to leave early, if we can get through some of these
9 discussions, can we move some of these items up on the
10 agenda or are we committed to doing it at the time
11 that they're on the schedule?

12 DR. COOL: We should be able to move
13 everything up as we have time available.

14 DR. CERQUEIRA: Okay.

15 MR. AYRES: What my purpose here today is
16 to update you on the status. This is my third
17 presentation on board recognitions and my intent is to
18 report on those things we've done and sent the April
19 report to you, and answer any questions that you might
20 have.

21 DR. CERQUEIRA: Bob, before you get
22 started, I have a question. After the last
23 discussion, you know, on the Part 35 revision, if that
24 doesn't get implemented what's the status of the board
25 recognition?

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1 MR. AYRES: Well the same thing as
2 everything else. We're continuing to work on them but
3 we're holding putting out any formal responses. If
4 you will, we're preparing at a reduced pace, I guess,
5 to continue with the board recognitions, but we're not
6 actually executing the letter.

7 DR. CERQUEIRA: So, you know, sort of
8 expressing some of Doctor Diamond's frustration, it's
9 been a long process and --

10 MR. AYRES: It's a shared process and
11 frustration I guess is my comment to that.

12 DR. CERQUEIRA: Okay.

13 MR. AYRES: But we are continuing to work
14 on them. Just a quick review. These are the ones
15 that we've talked to you about in the past that have
16 submitted, and what I want to do is now update the
17 status on the individual boards.

18 American Board of Health Physics, we've
19 come to you several times with the problem we perceive
20 with their application. It's still under review and
21 the two problems we've discussed with you quite a bit
22 in the past are both they come up under board
23 certification process as not mandating the one year of
24 full time radiation safety experience with similar
25 types of by-product materials, and they don't have the

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1 specified written certification of experience signed
2 by preceptor radiation safety officer.

3 What they do have is six years of
4 professional experience and a code of ethics. What
5 they're trying to do is say, well we put those two
6 together and we get the equivalent. It doesn't seem
7 to quite work out that way. Any discussion on the
8 American Board of Health Physics? I'll happily take
9 comments on the individual items or wait until the
10 end.

11 DR. CERQUEIRA: Jeffrey?

12 DR. WILLIAMSON: So has the American Board
13 of Health Physics actually submitted a letter claiming
14 that they meet at least the intent of the rule, or
15 exactly -- I understand they had actually sent a
16 letter saying they don't meet the rule.

17 MR. AYRES: They've submitted several
18 pieces of correspondence, one of which says that they
19 don't meet the letter of the language but they feel
20 they meet the intent through their six years plus
21 their code of ethics. But unfortunately with rule
22 language, intent usually doesn't quite get you there.

23 DR. CERQUEIRA: Neki, you have a comment.

24 MS. HOBSON: How is this going to be
25 resolved? From your comments, it almost sounds like

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1 you've kind of made up your mind that they don't
2 qualify?

3 MR. AYRES: That's correct. That's the way
4 it looks at this time but the letter hasn't gone out
5 so that's subject to change. But basically as a role
6 of staff member, my position is to determine whether
7 they do or do not meet the rule requirements.

8 MS. McBURNEY: And that's only for the RSO?

9 MR. AYRES: I'm sorry?

10 MS. McBURNEY: This is only for the RSO?

11 MR. AYRES: That score yes, of 35.50 for
12 radiation safety officer, and in particular in the
13 past the board has been the main source of your large
14 institution radiation safety officers, broad scope
15 medical licensees and multi-disciplinary treatment
16 facility.

17 What's the out? The out is to go back to
18 the training and experience and maybe another possible
19 way is American Board of Health Physics board
20 certification plus the preceptor statement showing
21 that they have met the one year of full-time radiation
22 training and experience in a medical facility, so they
23 have the requisite experience.

24 DR. CERQUEIRA: Ralph -- go ahead Dick.

25 MR. LIETO: If I could just go Dick. Yes,

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1 if I could comment on that since I'm on the board.

2 DR. CERQUEIRA: Yes.

3 MR. LIETO: One of the reasons the board
4 has resisted going that direction is because that
5 would force it into a sub-specialization and they're
6 just trying to keep one single certified health
7 physicist which is comprehensive, certifies across all
8 areas, and then the ethics force you to practice in an
9 area of expertise. So the board recognizes they do
10 not meet the letter of the law and they were simply
11 commenting to the NRC they thought that the way they
12 practiced met the spirit of the law and so it's in a
13 state of discussion.

14 MR. AYRES: Yes, I think we come up with
15 some unattended consequences in the rule language and
16 the public comment period and the whole process maybe
17 didn't get where everybody thought they were.

18 But now we have the language, and assuming
19 it goes forward, what we're doing in our letters and
20 you have one of them in your package, the one we did
21 send out recognizing the American Board of Nuclear
22 Medicine, but not totally, I'll point that out in a
23 moment, we say you appear to meet all of our
24 requirements and we'll grant recognition for this and
25 then we ask questions about those things. We don't

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1 say we're denying recognition. We haven't been able
2 to resolve whether they do or do not meet the rule
3 language.

4 So often our letters, once they start
5 going out, will go out with questions and there are
6 several areas. More of them will come up as we go
7 through the different boards, but the American Board
8 of Nuclear Medicine, that letter of June 29th is in
9 your package.

10 DR. CERQUEIRA: We had another question
11 from Ralph.

12 MR. LIETO: Mr. Ayres, back with the
13 American Board of Health Physics, a question. You
14 made a point that most of the RSOs with broad scopes,
15 large medical centers and so forth are RSOs that were
16 approved meeting certification requirements under the
17 current Part 35.

18 MR. AYRES: Right and the board is
19 recognized under the current Part 35.

20 MR. LIETO: Right, now assuming that the
21 new Part 35 is approved and goes into effect, are
22 those --

23 MR. AYRES: They'll be grandfathered.

24 MR. LIETO: Okay.

25 MR. AYRES: Yes, everybody that holds an

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1 existing appointment, authorized user, medical
2 physicist, RSO, et cetera, grandfathers. If they're
3 listed an authorized user, that authorized user status
4 will transfer. I know there may be some questions on
5 that.

6 So, the only thing else with the American
7 Board of Nuclear Medicine as well as three or four
8 other boards come in asking for recognition under
9 35.50-A. Maybe they didn't understand the ruling, but
10 35.50-A is for the full broad scope RSO type of
11 appointment that's traditionally done by AB, the
12 American Board of Health Physics right now, and it has
13 the same requirement.

14 I mean the requirements are the same.
15 They don't change. That one year of full-time
16 experience in the RSO statement, plus the other
17 training experience issues. So it didn't look like to
18 us that the American Board of Nuclear Medicine met
19 that, but there's an alternate pathway for almost all
20 authorized users, 35.50-C which says if you're an
21 authorized user, a physician or a medical physicist or
22 a radiation pharmacist, you can be an RSO of a
23 facility working as an RSO for those materials for
24 which you have experience.

25 So a nuclear medicine authorized user

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1 could readily be appointed under 35.50-C as the RSO
2 for a diagnostic nuclear medicine facility. I don't
3 know if their request for broader authorization was an
4 error or not, but what we did in the letter and it's
5 in your package is said "well, it doesn't look like
6 you meet, we won't recognize you under 35.50-A, but
7 you're already granted the authority and recognition
8 under 35.50-C."

9 The Board of Pharmaceutical Specialties,
10 that's also under review. It looks like we've got to
11 go back to them and ask some questions about their
12 written certification of training and signed preceptor
13 statement. Those seem to be an issue at least in the
14 letters that we've got and looking on their web sites,
15 on their board processes, that we don't see evidence
16 that they exactly meet the rule on this and we have to
17 go back and ask. Yes.

18 DR. WILLIAMSON: I guess I have a general
19 question. What sort of verification do you subject
20 these written claims to?

21 MR. AYRES: Written certification from the
22 board officers.

23 DR. WILLIAMSON: But if the board officers
24 say "we certify X" do you just accept that or do you
25 have some sort of a procedure for validating that

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1 claim against independent information?

2 MR. AYRES: I'm speculating here but I
3 think the way it works, we accept it. If somebody
4 questioned or complained to us that this board you
5 approved and it doesn't meet this requirement, we're
6 probably going to go out and inspector check.

7 So the policy now, as I understand it,
8 we'll accept their verification but we reserve the
9 right to question it if it becomes an issue.

10 DR. WILLIAMSON: Okay.

11 MR. AYRES: I think that's a fair way. So
12 that's the status of radio pharmacy. One of the more
13 problematical ones, this one really applies as we
14 later get on to ABR and their certification of medical
15 physicists also. The exact same issues exist. It's
16 currently under review. We in fact have a letter
17 drafted, but again pending the outcome of Part 35,
18 we're sort of sitting on that one.

19 We also have a letter that we got on these
20 issues from AAPM and that is in your package. And
21 like I said, it's under review. The central issue is
22 the lack of a requirement to complete the training for
23 specific modalities, such as -- well, not such as,
24 specifically remote afterloader teletherapy and the
25 gamma knife. Like I said, the AAPM letter is in your

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1 package.

2 There are certainly some alternatives here
3 to go and maybe we might end up in a position that
4 might not be too different from what we are doing now
5 in that we again recognize board certification plus,
6 and that's kind of what the letter addresses, plus
7 evidence of specific training experience in these
8 modalities. So you could be an authorized medical
9 physicist for remote afterloaders or remote
10 afterloaders and gamma knives or any combination of
11 the three.

12 I expect that that's probably the way
13 we'll grandfather if a person is currently authorized
14 for teletherapy and remote afterloaders that would be
15 their authorization and grandfathering. It would not
16 include gamma knife until they come in to demonstrate
17 specific training and experience which we really need
18 on the gamma knife.

19 DR. WILLIAMSON: What's your basis of that?
20 35.51 does not express any such qualification.

21 MR. AYRES: Well, it's a training and
22 experience requirement. What I'm saying is I'm
23 hoping. There's two ways to go, to not recognize the
24 board whatsoever, okay -- well, three ways, recognize
25 the board and that would give them all the

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1 authorization.

2 DR. WILLIAMSON: I think there's two issues
3 maybe being collapsed into one issue. I guess I heard
4 you addressing both in the same sentence, 35.51 which
5 is the perspective credentialing for medical licensees
6 and 35.51 which is the grandfathering clause for those
7 currently on licenses and it seems to me they're very
8 different.

9 MR. AYRES: Right. Well, they are. They
10 may be. They could be very similar and they could be
11 very different. There's two issues and one, you've
12 raised the points in correspondence.

13 One is what does grandfather? How do we
14 grandfather authorized users and medical physicists
15 that have current authorizations that do not encompass
16 the full range of the board certification process?
17 And as written now, 35.51 if we recognize and granted
18 recognition for board certification, we say that the
19 board certification encompasses all of these
20 modalities and the medical physicist is authorized to
21 perform them all, which is the problem that we're
22 running into.

23 What we have with current medical
24 physicists, we have them authorized for one or two or
25 there may be some where they're authorized for all

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1 three. None come to mind, but it's certainly
2 possible. And so how do we -- do we just have a
3 general title of authorized medical physicist or do we
4 grandfather authorized medical physicists for modality
5 A, B and not C that they currently are authorized for.

6 DR. CERQUEIRA: I'd like to hear, you know,
7 comments from Jeffrey and Ralph on these points
8 because it's a critical issue.

9 MR. AYRES: Yes, there's certainly a lot of
10 correspondence going on.

11 DR. WILLIAMSON: Well, I think the 35.51
12 and 57 have to be clearly distinguished from one
13 another and I think that we have a system that's in
14 place now where there basically is only a definition
15 in the regulations of teletherapy physicists.

16 MR. AYRES: That's correct.

17 DR. WILLIAMSON: And in some cases by
18 license amendment, radiation safety committees and so
19 on have had to review the credentials of individual
20 physicists to do high dose rate and gamma knife.

21 MR. AYRES: Exactly.

22 DR. WILLIAMSON: And perhaps in even some
23 specific scope licenses there might be a commitment to
24 provide certain QA functions for gamma knife and for
25 high dose rate therapy by someone who meets the

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1 teletherapy physics requirements.

2 MR. AYRES: Yes, there's usually some --

3 DR. WILLIAMSON: So I think it's a rather
4 confused situation.

5 MR. AYRES: Yes.

6 DR. WILLIAMSON: I think now you're
7 starting a new system and the system's not going to
8 function very well unless you create artificially a
9 pool of authorized medical physicists who can provide
10 the preceptor function. So --

11 MR. AYRES: Well.

12 DR. WILLIAMSON: Let me finish. My strong
13 advice would be that 35.51 should be interpreted
14 without qualification, that if someone is named or
15 endorsed as a teletherapy physicist on an agreement
16 state license or NRC license or via act of a radiation
17 safety committee for any modality whatsoever, that
18 credential should be accepted, that person should be
19 accepted as a fully qualified AMP without restriction,
20 thereby creating the pool of individuals you need to
21 do the credentialing prospectively.

22 MR. AYRES: Well.

23 DR. WILLIAMSON: Every board or
24 certification mechanism faces this problem, and I
25 think the fact that qualifications were not written

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1 into the rule language gives you the option to
2 prevent, I think, what could be a catastrophe in the
3 community.

4 MR. AYRES: I'm not sure on that. At a
5 minimum, and I didn't want to really get into the
6 grandfathering issue, but at a minimum everybody would
7 retain their authorizations they currently have, at a
8 minimum. But I hear and I really didn't intend to
9 address, except for some similar issues, the
10 grandfathering.

11 DR. CERQUEIRA: But this is an opportunity
12 to hear from two respected physicists in this area.
13 Ralph.

14 MR. LIETO: I agree that you got to keep
15 the two issues separate. I think the grandfathering
16 has to occur across the board, because you're going to
17 end up disenfranchising a lot of physicists from
18 performing duties that either they assumed that
19 they're qualified by their board certification, and
20 their institution to perform. The main population
21 that's going to suffer is the patient population that
22 may not be able to get the medical physics support
23 that's needed for that modality.

24 You're already stating that you're going
25 to be grandfathering the RSOs and the authorized users

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1 as they're approved right now. This sub-
2 specialization so to speak of subcategories are being
3 created by the new rule, okay. It's not something
4 that exists in the old rule.

5 MR. AYRES: Well it's something that exists
6 in policy because the old rule only covers
7 teletherapy.

8 MR. LIETO: Right, but if a teletherapy
9 physicist was approved on a license or by a radiation
10 safety committee or so forth, to my knowledge I know
11 of none that have not been approved to perform remote
12 afterloading and some of these other new modalities as
13 they're coming up.

14 MR. AYRES: The way we do it now so it's
15 the same way, basically we've always viewed the
16 teletherapy physicists and their involvement in manual
17 break therapy was a given and we never had any
18 questions about that. But we required specific
19 authorizations and training for them to be authorized
20 to work with remote afterloaders, high dose rate
21 remote afterloaders and stereotactic radiosurgery.
22 They did have to come in and have a specific
23 authorization put on their license for that, and
24 provide training and experience, any additional
25 training and experience requirements.

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1 DR. WILLIAMSON: Did you require that for
2 authorized users in the license?

3 MR. AYRES: No, don't believe so. Don't
4 hold me to that. I'm not absolutely certain on
5 something like stereotactic radiosurgery.

6 DR. WILLIAMSON: But they didn't.

7 MR. AYRES: I don't think they did at all.

8 DR. CERQUEIRA: Maybe we can get some
9 comments from Dr. Nag and Dr. Diamond on this issue.
10 I mean, how would you propose to deal with the issue
11 of specific modality.

12 DR. NAG: Yes, I think again I agree that
13 the grandfathering should be kept separate from the
14 new one. For the new one yes, you can go ahead and do
15 it the way of the posting. But in the grandfathering,
16 the way we have our medical physicists if they are
17 doing teletherapy, let's say we never had remote
18 afterloader in our department and we bought one today,
19 they would get the short training course from the
20 manufacturer on how to use that but they would not
21 require any other separate 500-hour job training.

22 The way it's written, the 500 hours is not
23 taking into account the overlap of the training that
24 you already had for taking care of your other
25 radioactive material. So, my suggestion is anyone who

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1 is currently a medical physicist should be allowed to
2 use any of those modalities.

3 MR. AYRES: Well, what you said what they
4 do is what -- basically we require primarily for
5 remote afterloader is our main additional requirement
6 for a teletherapy medical physicist to be named as a
7 remote afterloader or a high dose rate brachytherapy
8 authorization is to get the manufacturer's training.
9 We require it for the authorized user too, so there is
10 a case there where we do it in policy, okay. I'm not
11 absolutely current on the stereotactic radiosurgery,
12 but we do have a little more extensive requirements.
13 There's an apprenticeship training program run by the
14 manufacturer and that includes both the authorized
15 user and the medical physicist.

16 DR. WILLIAMSON: So why are you singling
17 out the physicists for special treatment like this?

18 MR. AYRES: We're not. We haven't got to
19 the authorized users. There's some places in there,
20 okay.

21 DR. CERQUEIRA: David, do you have a
22 comment?

23 DR. DIAMOND: Yes.

24 MR. AYRES: Okay.

25 DR. DIAMOND: Every time I hear these

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1 discussions, I keep on asking myself how can we not be
2 enslaved to regulations that are well-intentioned but
3 not perhaps worded the exact way they were intended?
4 And this would be an example of it. What I'd like to
5 explore is whether, just like we've done in other
6 areas, without our advice and consent I may add, some
7 type of guidance document be promulgated that exactly
8 reflects the spirit of this discussion.

9 MR. AYRES: Well, generally we issue
10 guidance documents in the absence of regulatory
11 language.

12 MR. DIAMOND: This would be an example of
13 a guidance documents in the place of bad regulatory
14 language.

15 MR. AYRES: When we have regulatory
16 language, we can't issue guidance language that gets
17 around the regulatory language requirements. We can
18 only issue -- we can and do and that's a reg guide
19 that you want to review, issue language in how to meet
20 the regulatory requirements, but there's no way we can
21 alter the regulatory requirements through guidance.

22 DR. DIAMOND: Well, I don't know. I think
23 one of the most productive at last meeting was a
24 methodology in the guidance document that allowed us
25 to use IVB for indications off label without that

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1 being mis-administration. I would consider this to be
2 in exactly the similar vein.

3 MR. AYRES: No, because there's no
4 regulatory requirements relating IVB, so we're free to
5 regulate it and we do and we must because there's no
6 other mechanism through guidance. Once it's in the
7 rule, we don't have any flexibility anymore. Well,
8 the only flexibility we have is granting requests for
9 exemption, specific requests for exemption on a case-
10 by-case basis.

11 DR. CERQUEIRA: Neki had a comment.

12 MS. HOBSON: Yes, from a patient
13 perspective what we are really talking about here is
14 a transition period of a few years I'm assuming.

15 MR. AYRES: No, if the new rule becomes
16 effective, it becomes effective completely on the
17 date, which would be six months from publication.

18 MS. HOBSON: But you're grandfathering
19 everyone who's current licensed.

20 MR. AYRES: Only on training and
21 experience.

22 MS. HOBSON: Oh, on training and
23 experience.

24 MR. AYRES: So anybody new applies the day
25 after the new rule becomes effective has to meet the

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1 new requirements.

2 MS. HOBSON: Okay, but the currently
3 licensed or authorized medical physicist, even though
4 his certification doesn't include specifically remote
5 afterloader teletherapy and gamma knife, he would be
6 able to conduct those efforts?

7 MR. AYRES: Well it does right now. It is
8 specific to what he's authorized for. If he's been
9 there a long time and has done nothing else, it's for
10 teletherapy only. Then, you have to come in to be
11 added either, well through a master material license
12 broad scope and through ourselves for the other
13 modality, yes.

14 MS. HOBSON: I'm concerned that the patient
15 is going to be caught in a situation here where, you
16 know, they'll just fall through the cracks because
17 there won't be anyone at that particular institution
18 or facility who can give them the treatment that they
19 need if the license is so restrictive.

20 MR. AYRES: There's no change in the
21 authorization -- when the new rule becomes effective,
22 there's no change in the authorization of the medical
23 physicist from what exists now, and exactly how the
24 grandfathering will be done, we've kind of gotten in
25 to that which I'm not addressing and there's two

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1 routes, full recognition or recognition for the
2 modalities that they currently have.

3 MS. HOBSON: That's my concern.

4 MR. AYRES: I'm not sure. I would have to
5 review the rule language a little myself.

6 MS. HOBSON: I think there's a --

7 DR. CERQUEIRA: The recommendations of the
8 committee are to basically grandfather them
9 generically for all of those modalities for the people
10 that are currently licensed. Does anybody disagree
11 with that?

12 DR. WILLIAMSON: No. I think we need a
13 motion.

14 DR. CERQUEIRA: All right, do you want to
15 make a motion Jeffrey?

16 DR. WILLIAMSON: Yes. The ACMUI moves,
17 recommends to the commission that 10 CFR 35.57 be
18 interpreted to mean that medical physicists listed as
19 teletherapy physicists on any agreement, state or NRC
20 license, be understood to be fully qualified
21 authorized medical physicists without limitation to
22 modality.

23 MS. HOBSON: I'll second that.

24 DR. CERQUEIRA: Second that. Any further
25 discussion?

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1 MR. AYRES: The rule is quite clear on it.

2 MS. HOBSON: Yes.

3 MR. AYRES: They can be authorized only for
4 those medical uses which they're authorized on the
5 date the new rule goes in effect. I wasn't prepared
6 to talk on 35.51, so I hadn't reviewed the language,
7 but it's quite clear. So, it's kind of a moot point.

8 MR. NAG: I'm not quite sure, what does
9 that mean?

10 MR. AYRES: Well, it means if they're only
11 authorized for teletherapy, that's all they're going
12 to get grandfathered for.

13 MR. NAG: Right, but not here today. We
14 have Dr. Williamson who is taking care of the
15 teletherapy at his institution, but tomorrow he goes
16 to an institution that has teletherapy and a remote
17 afterloader. The manufacturer provides usually a
18 three or four-day course on how to run the remote
19 afterloader. Would he be able to use it or not?

20 MR. AYRES: No, he'd have to submit to be
21 named as authorized user for remote afterloaders based
22 on the training he received and that would probably be
23 readily granted.

24 DR. WILLIAMSON: Could I read the
25 regulation just to make sure I understand the

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1 consequences.

2 MR. AYRES: Sure.

3 DR. WILLIAMSON: An individual identified
4 as a radiation safety officer, a teletherapy or
5 medical physicist or a nuclear physicist on a
6 commission or --

7 MR. AYRES: Pharmacist.

8 DR. WILLIAMSON: Well, it says "or medical
9 physicist."

10 MR. AYRES: Well they should have nuclear
11 -- well, never mind.

12 DR. WILLIAMSON: "Medical physicist or a
13 nuclear pharmacist on a commission or agreement state
14 license or master material license permit or by a
15 master material license permittee," a broad scope,
16 "before insert date six months from publication of
17 final rule need not comply with the training
18 requirements of 35.51 or 55."

19 MR. AYRES: Right but then the language I
20 was referring to is in B. "Physician then or
21 authorized user" and you go on down and it says --

22 DR. WILLIAMSON: Where does it say
23 physicist?

24 MR. AYRES: "To perform only those medical
25 uses for which they are authorized on the date need

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1 not comply with the training requirements of Subparts
2 B and A."

3 DR. WILLIAMSON: Where does it say
4 physicist? It says physicians, dentists, or
5 podiatrists.

6 MR. AYRES: Okay.

7 DR. WILLIAMSON: It doesn't say physicists
8 in there.

9 MR. AYRES: All right, I wasn't prepared to
10 talk on this but we -- clearly on the physician all
11 right.

12 DR. CERQUEIRA: We're not going to be able
13 to resolve all this.

14 MR. AYRES: Yes. I certainly understand
15 your recommendation and certainly review it in looking
16 at the rule. I wasn't prepared to discuss the
17 grandfathering which seems relatively straightforward
18 in most cases.

19 DR. CERQUEIRA: So we still have a motion
20 on the floor. Is it still relevant Jeff? Do you want
21 to keep it?

22 DR. WILLIAMSON: I think it's relevant.

23 MR. AYRES: Oh, it could be. Well,
24 certainly advice we'll take it and look at it.

25 DR. WILLIAMSON: I would like to say one

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1 thing in it's defense or it's articulated rationale
2 for it. I think that the idea of grandfathering is to
3 basically for a population of professionals that are
4 working before a certain date is to be able to
5 guarantee that they will be able to pursue their
6 livelihoods under the existing training and experience
7 regulations as of that date.

8 MR. AYRES: Yes.

9 DR. WILLIAMSON: And as of that date, you
10 know, right now if someone is a teletherapy physicist
11 doing just teletherapy, all they have to do is satisfy
12 the conditions of the license to be an authorized HDR
13 physicist which in this case simply means undertaking
14 the, you know, accepting a commitment to have vendor-
15 supplied training or perhaps, you know, annual
16 training provided by another physicist within the
17 institution. It depends how your license is written
18 really.

19 MR. AYRES: Yes.

20 DR. WILLIAMSON: So I think the intent
21 clearly is, is that that's the rule that should be
22 followed in the future for somebody that's listed as
23 a teletherapy physicist prior to the changeover.

24 MR. AYRES: Yes.

25 DR. WILLIAMSON: I'm not trying to suggest

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1 that this should be a way of getting around license
2 commitments.

3 MR. AYRES: Traditional grandfathering is
4 you retain the rights you had when the rule changes,
5 and on that basis they are --

6 DR. WILLIAMSON: To say that somebody who's
7 just a teletherapy physicist who's board certified and
8 so on can only be a teletherapy physicist without
9 satisfying the new 35.51 for HDR and gamma is actually
10 then imposing an additional and different set of
11 requirements which are rather different than the ones
12 they work under now.

13 MR. AYRES: What I'm saying is not really
14 because we have that type of requirement as part of --
15 only it's in guidance --

16 DR. WILLIAMSON: But I don't think it's
17 identical to the one that's in 35.51-B. It's not the
18 same.

19 MR. AYRES: Well, I understand your
20 recommendation.

21 DR. CERQUEIRA: I think we should vote on
22 this and move on. You said an hour was too long.

23 MR. AYRES: I was hoping it would be.

24 DR. CERQUEIRA: Training and experience is
25 never.

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1 MS. McBURNEY: I can support what Jeff is
2 saying if the license conditions are going to stay the
3 same after the new rule goes into effect.

4 MR. AYRES: They won't.

5 MS. McBURNEY: Right, so if they're not
6 going to stay the same, I mean there needs to be some
7 commitment that they have that additional training
8 from the manufacturer.

9 MR. AYRES: In the therapy area they're
10 fairly similar but there is of course changes.

11 DR. CERQUEIRA: Do I have a motion for a
12 vote on this, because what I'd like to do, and Jeff
13 has brought up this point a couple of times. We have
14 a lot of discussion.

15 MR. NAG: And nothing goes.

16 DR. CERQUEIRA: Sometimes we don't make
17 motions. Well now, we're going to try to make the
18 motion and what I'd like Angela to do is, at the next
19 meeting give us follow-up. And by follow-up, I want
20 like what's been done, when it was completed, and if
21 it hasn't been done, what's the problem?

22 DR. WILLIAMSON: Not that we're thinking
23 about it or we heard what you said.

24 DR. CERQUEIRA: Okay, so --

25 DR. VETTER: One more, I just would like to

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1 support what Ruth said. If the conditions of the
2 license change, then that becomes problematic.

3 MS. MCBURNEY: Right.

4 DR. VETTER: Relative to the motion.

5 MS. MCBURNEY: Right, so he can add.

6 MR. LIETO: You're going to change all the
7 licenses when the new Part 35 goes through? I mean,
8 that's kind of what it sounds like.

9 MR. AYRES: You're getting a little outside
10 my area. I've never made this major transition on a
11 rule, but there is rule language in there on how the
12 rule transitions the new part and what governs if you
13 have more restrictive license conditions in the new
14 rule, those stay. Yes.

15 MR. BROWN: What I'd suggest is that the
16 committee go ahead, make the recommendation. As with
17 all recommendations, the staff will take that, look at
18 how implementable it is and we'll get back to you with
19 the decisions that we've made.

20 DR. CERQUEIRA: So Ruth, one final comment.

21 MS. MCBURNEY: I would like to amend the
22 motion to include that when transitioning to a new
23 modality that they still be required by license
24 condition to receive the manufacturer's training on
25 the new modality.

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1 DR. WILLIAMSON: I guess I would like to
2 maybe suggest that we have an alternative amendment.
3 Instead of that, basically include in the motion that
4 not only teletherapy physicists' qualifications as
5 articulated in the current Part 35, but also the
6 training and experience guidelines in the existing
7 regulatory guidance for gamma stereotactic and HDR,
8 which would be more general and would pin it down to
9 a document that is now in place.

10 MS. MCBURNEY: That's exactly it.

11 DR. CERQUEIRA: So why don't you --

12 MS. MCBURNEY: Restate the motion.

13 DR. CERQUEIRA: So what are we voting on?

14 DR. WILLIAMSON: Okay, I think we are
15 voting on a motion which reads as follows: The ACMUI
16 recommends that NRC interpret 35.57 to mean the
17 following; that medical physicists who are listed as
18 authorized teletherapy physicists on any agreement,
19 state or NRC license, or by any act of a radiation
20 safety committee within a broad scope licensee, be
21 allowed to be authorized medical physicists for all
22 modalities without qualifications, provided that they
23 satisfy the supplementary training requirements
24 contained in the current regulatory guides for those
25 modalities extent on that date.

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1 DR. CERQUEIRA: He doesn't have John's
2 knack for resolutions.

3 DR. WILLIAMSON: I'm sorry. He is sorely
4 missed.

5 DR. CERQUEIRA: But I think you'll get the
6 gist of it. We should take a vote. All in favor.
7 Opposed? Okay, and then Angela if you could
8 transcribe that off the transcript.

9 MR. AYRES: Yes, that actually sounds
10 pretty workable.

11 DR. WILLIAMSON: I would be happy to help
12 edit my motion before I leave.

13 DR. CERQUEIRA: Okay Bob, what's next. The
14 American Board of Radiology.

15 MR. AYRES: A similar one and the American
16 Board of Radiology, ABR, has applied for recognition
17 under all three of their disciplines which are
18 diagnostic radiology. They've applied for 31.190, 290
19 and 390 and they've stayed away from the specific
20 applications for thyroid work on their applications,
21 and 392 and 394 they didn't ask for.

22 Under radiation oncology, 392 and 94,
23 which they are putting the thyroid cancer ablation
24 applications under, 490 the brachytherapy, 491's the
25 stronium I applicator, and 690 which encompasses all

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1 the high-dose stuff, the gamma stereotactic
2 radiosurgery and the high dose rate and teletherapy
3 and so forth.

4 Under radiological physics, they again
5 applied for the broad 35.50 and the 35.51. Again,
6 we're reviewing that. We have some issues. Again,
7 with all the board, we're looking at and confirming
8 that they do, as part of the board application
9 process, have a preceptor statement requirement.

10 Now Jeff raised an issue under 35.690 on
11 our specific modality requirements for authorized
12 users, and under 693 at the bottom of the page here,
13 B-3, it says it has obtained written certification
14 that the individual has satisfactorily completed the
15 requirements above in this section and has achieved a
16 level of competency sufficient to function
17 independently as an authorized user in each type of
18 therapeutic medical unit for which the individual is
19 requesting authorized user status.

20 So there is a requirement for the
21 authorized user to demonstrate experience with gamma
22 stereotactic and radiosurgery, high dose rate,
23 standard manual brachytherapy, teletherapy, et cetera.
24 Yes.

25 DR. NAG: What is the language requirement

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1 on this? Is this the same? For example, like 30
2 years or 20 years ago --

3 MR. AYRES: I think the grandfather
4 requirement on this is much more straightforward
5 because we do not at present put authorized user
6 radiation oncologists in bins as we do medical
7 physicists. So, there's no bins to sort the existing
8 pool and they would just get the full authorization.

9 DR. WILLIAMSON: I'm not sure you really
10 have that for physicists. I mean, you only have the
11 one legal category which is teletherapy physicists,
12 and there's a requirement in guidance that for HDR and
13 gamma stereotactic that you have a physicist do these
14 things who satisfied the definition of teletherapy
15 physicists in the current Part 35, plus has these
16 additional trainings. I think you do exactly parallel
17 language for the authorized user if I'm not mistaken.

18 MR. AYRES: We have authorized for 35.600,
19 35.400, and 35.300. There's three bins if you would
20 for a therapy authorized user. For authorized medical
21 physicists we have the same three bins. They're
22 authorized for either teletherapy, high dose rate or
23 gamma stereotactic radiosurgery. That's how they're
24 currently binned. Now how it ends up, well let's not
25 go back there.

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1 DR. WILLIAMSON: It currently refers to the
2 current Part 35. I mean, how they will be binned is
3 what you mean.

4 MR. AYRES: Under the current Part 35,
5 there's no binning of the authorized user for therapy
6 except in the broad 600, 400, 300. The medical
7 physicists are usually not involved in 300, the ones
8 that are working in therapy, they may or may not be.
9 There's no requirement that a medical physicist be
10 there, so that's not an issue. But they are binned
11 400, 600, and 300 in six bins. We heard your
12 recommendation and hopefully we can move on here.

13 DR. CERQUEIRA: We've got to think about
14 the physicist and Dr. Nag do you have a comment?

15 DR. NAG: Yes. We had a long discussion in
16 the last meeting and since I'm not clear what portion
17 of our discussion was acted upon, I would like
18 clarification here. One of the major discussions we
19 had was what the radiation oncologist, the 500-hour
20 requirements and those 500 hours, it was not clear
21 were they to be 500 hours separately for high dose
22 rates, separately for gamma knife, and separately for
23 --

24 MR. AYRES: I can head that off quickly.
25 The answer's in your book, the letter from the

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1 chairman to Dr. Hendee I believe. It gives our
2 position on that and it's that they will be aggregated
3 in a single 500 or whatever expansion task that is to
4 meet the necessary training.

5 DR. CERQUEIRA: While people are looking at
6 that so they can comment, since they haven't seen it,
7 the confirmation of preceptor statement, that's been
8 something that showed up on all of these, but if you
9 make that an eligibility requirement for the board,
10 shouldn't that satisfy your requirements as well?

11 MR. AYRES: Yes, and the issue is whether
12 the boards require it or not. It's not certain that
13 ABR does. The draft letter back to them will ask them
14 "well, what do you require in the way of meeting this
15 objective of the rule?" Their initial submission
16 didn't go into that.

17 DR. CERQUEIRA: Okay.

18 MR. AYRES: They may or may not. We'll get
19 down to the bottom and then there's the broader
20 issues, but you're already getting into most of those.

21 The medical physicists we have the same
22 issue that we had with the Board of Medical
23 Physicists, which is the three specific modalities.
24 Again they ask for the RSO qualifications. It's the
25 same issue. They really don't meet the one year

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1 specific training and experience requirement and the
2 preceptor statement under 35.50-A but they come in
3 under 35.50-C again.

4 And the letter from the chairman to Dr.
5 Hendee really does give our position I think quite
6 clearly on the 500-hour, whether it sums for 400, 500,
7 600, 300 you end up with 2,000 hours and their answer
8 is no. It's 500 plus and the plus would be if you
9 couldn't stuff it all for all those modalities in 500.
10 Yes.

11 DR. WILLIAMSON: Could you go back to the
12 radiation oncology slide application?

13 MR. AYRES: We're still on it.

14 DR. WILLIAMSON: No, there was one where
15 you listed all the things that ABR had requested.
16 That's the one I wanted to just make a comment on.

17 MR. AYRES: Oh, okay.

18 DR. CERQUEIRA: Just go backwards for the
19 sake of time.

20 MR. AYRES: There we go, okay. I was
21 figuring out if it was up, down, right or left.

22 DR. WILLIAMSON: Under radiation oncology,
23 Dr. Kapp's (phonetic) letter, you know, December 26,
24 2000 actually includes 35.390 which is the general
25 radiopharmaceutical authorized user status.

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1 MR. AYRES: Yes, you mean under oncology?

2 DR. WILLIAMSON: Under oncology, yes.

3 MR. AYRES: Okay, I may have -- if it
4 includes it, it includes it and it's just an error on
5 my preparing the slide. But certainly addressing
6 everything that's asked for, and I just omitted one.
7 I had it up here. I didn't move it down here.

8 DR. CERQUEIRA: So Dr. Nag, did you get a
9 chance to look at the letter?

10 DR. NAG: Yes.

11 DR. CERQUEIRA: And you're in agreement
12 with the response?

13 DR. NAG: Yes.

14 DR. CERQUEIRA: Okay.

15 DR. NAG: That includes now.

16 DR. CERQUEIRA: Right. Now Bob, where do
17 you stand? I mean, you know the ABR was preapproved
18 in the past, so have you responded to them with these
19 issues and have they gotten back to you?

20 MR. AYRES: Well, we're holding the
21 response.

22 DR. CERQUEIRA: So you haven't sent
23 responses out to any of the boards at this time?

24 MR. AYRES: Well, only two communications
25 went out, yes, the letter out to the American Board of

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1 Nuclear Medicine which went out before we found out
2 there was a problem with getting the rule out in a
3 timely fashion, and the letter from the chairman to
4 Dr. Hendee which partially clarified some of the ABR
5 issues.

6 DR. CERQUEIRA: Right. Well, I think the
7 suggestions of the committee would probably be that
8 once this gets resolved that hopefully we'll be able
9 to go forward with this. We'd really need to notify
10 them because to make some changes in the eligibility
11 requirements for preceptorship statements and
12 everything can take a year or two. I wouldn't hold up
13 boards pending the actual language in their
14 eligibility requirements.

15 MR. AYRES: Well understand there's no
16 deadline on this. If the rule becomes effective and
17 they haven't met the requirement and it's the decision
18 of the board whether they choose to alter the board.
19 We're getting ahead in the discussion item, where they
20 wish to alter their requirements in a sometimes major,
21 or sometimes minor way to meet the requirements.
22 There's no deadline. There might be a period of
23 months or weeks or years that they wouldn't be
24 recognized, but once they do they can go on the list.

25 DR. CERQUEIRA: But I think you can

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1 minimize that. It would be in everybody's interest to
2 do that.

3 MR. AYRES: Yes it would be --

4 DR. CERQUEIRA: It would minimize the
5 transition period.

6 MR. AYRES: It would be a big
7 administrative burden on us. This guy was certified
8 in this time period which means he's not eligible for
9 this time. That would be really -- it would be nice
10 to avoid.

11 DR. CERQUEIRA: I guess what we're
12 suggesting is once the decision's been made and you've
13 already done the work and there's issues, and if these
14 boards don't know that there's issues, they're not
15 going to be able to respond.

16 MR. AYRES: The boards know the issues
17 because they in fact identified them themselves in
18 their letters to us.

19 MR. BROWN: This is Fred Brown. I can
20 speak for John Hickey. We agree, Dr. Cerqueira, these
21 need to go out as quickly as they can once we know the
22 status of the final rule and that's our plan.

23 MR. AYRES: Yes, we're continuing to work
24 on them and; in fact, I have several of them all
25 drafted and ready to go once we know which direction

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1 we're going.

2 DR. CERQUEIRA: Hopefully that will be
3 soon. MR. AYRES: Yes.

4 DR. CERQUEIRA: Why don't we go on to,
5 what's the next board? Go ahead Jeff.

6 DR. WILLIAMSON: What are your responses to
7 the radiation --

8 MR. AYRES: We did --

9 DR. WILLIAMSON: -- excuse me, what are
10 the responses, your proposes responses in the letters
11 for radiation oncology?

12 MR. AYRES: Well, they're draft right now.

13 DR. WILLIAMSON: Can I ask what they say?

14 MR. AYRES: I basically reviewed them and
15 we got to go back with questions, particularly with
16 regard to the preceptor statement. I got to look at
17 -- I haven't prepared that letter yet. That one's
18 under preparation, but I need to look a little more
19 closely about their training and individual modalities
20 too, whether they certify that.

21 The American Board of Cardiology is under
22 review. It looks like, well they meet everything. It
23 looks like it's no problem, no outstanding issue, one
24 clarification. I talked with their manager.

25 There is a -- in the preceptor language it

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1 says a preceptor has to have training -- or be an
2 authorized user for 35.190 and 290 and the question
3 came up, do I need the 190 authorization if I'm
4 serving as a preceptor to only grant 290? It seems
5 obvious that you wouldn't if you're only going to
6 write a preceptor statement for 290, 290 would be all
7 that you should need.

8 I think the rule more or less anticipated
9 that the nuclear, the pure diagnostic nuclear medicine
10 side where almost all of them ask for both 190 and 290
11 and many of the 300s. So there's no outstanding
12 issues that we can see there at this time.

13 The American Board of Science and Nuclear
14 Medicine look like they have a lot of problems because
15 they're -- well, I don't want to go into what the
16 composition board -- they're only asking for
17 authorization under 35.50-A. They have no other
18 available authorized user path, so 35.50-C is not
19 available to them and they clearly look like they have
20 difficulties in meeting the one year and the RSO
21 preceptor statements.

22 So right now I've got to write back to
23 them and, you know, ask for clarification on this.
24 But if they don't meet that, it looks like they would
25 not gain recognition.

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1 DR. CERQUEIRA: Is anybody familiar with
2 this board?

3 MR. AYRES: It's kind of affiliated with
4 SNM or the American Board of Nuclear Medicine, and
5 it's a board of science professionals, Ph.D. chemists,
6 electrical engineers and other related medical
7 professionals that are kind of aggravated into this
8 one board.

9 DR. VETTER: I'll give you an example of
10 the type of person who might be certified by them who
11 then practices radiation safety, and that would be a
12 consultant. They've never actually practiced at a
13 medical center but they consult for many medical
14 centers, so there's no way to get the one year of
15 experience under a certified RSO.

16 MR. AYRES: Unless you go back in their
17 training which is by the board by now. Anyway, they
18 would certainly, those of their individuals who
19 currently are authorized as RSOs would retain that
20 under the grandfather provision. But it looks like
21 they will have difficulty gaining recognition.

22 Points for discussion. I think we hit
23 most of them. Those are the boards the work's been
24 done on since I last spoke to you.

25 DR. CERQUEIRA: How many others have

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1 submitted?

2 MR. AYRES: I had the whole list at the
3 start. There's seven boards I believe that have
4 submitted.

5 DR. CERQUEIRA: So and we went over all
6 seven of those?

7 MR. AYRES: It's in the handout. The first
8 two slides are all of the boards that have submitted.

9 DR. CERQUEIRA: All right, so there are no
10 others then. Then basically you're up to date?

11 MR. AYRES: Yes, there are other boards
12 that haven't submitted and, in fact --

13 DR. CERQUEIRA: Well, if they haven't
14 submitted then --

15 MR. AYRES: Two osteopathic boards I've
16 spoken to. I didn't put slides on them because they
17 have not submitted. They intend to submit once the
18 rule goes out.

19 DR. CERQUEIRA: Okay.

20 MR. AYRES: So there's others that plan to
21 submit but have not.

22 DR. CERQUEIRA: So we had discussions in the
23 past that there might be hundreds of boards that would
24 be applying, but the reality is the number has been
25 relatively small.

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1 MR. AYRES: Yes, in fact the number of
2 boards that have currently applied are far less than
3 the number of boards that are currently recognized. I
4 think we currently recognize twelve, seven have
5 applied, and one of those is a new board.

6 MR. LIETO: But aren't some of those foreign
7 boards, like the Canadians and the British?

8 MR. AYRES: Yes.

9 MR. LIETO: So they wouldn't --

10 MR. AYRES: There are two British we list
11 and I'm not too sure that hasn't co-listed a single
12 British board. The Canadians, there's three foreign
13 boards in there. The Board of Nuclear -- the
14 Certification Board of Nuclear Cardiology is a new one,
15 and so we have six -- well four -- basically six
16 currently longstanding boards that have applied to us
17 for recognition.

18 DR. CERQUEIRA: Good, well maybe we could
19 save five minutes for the intravascular brachytherapy
20 discussion which I'm sure will be. Any other questions
21 for Bob?

22 MR. AYRES: I think we've dealt with these.

23 DR. CERQUEIRA: Jeffrey.

24 DR. WILLIAMSON: I understand this issue's
25 going to come up again this afternoon, is that right?

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1 MR. AYRES: I'm going to be at -- this
2 afternoon, so I won't be here. I'm scheduled to give
3 a talk this afternoon.

4 DR. CERQUEIRA: Come up in what way? Under
5 new business?

6 DR. WILLIAMSON: Well I understood there was
7 going to be a speaker from the AAPM who was going to
8 address the issue again with a proposal.

9 MS. MCBURNEY: That's correct.

10 DR. WILLIAMSON: Since Bob won't be here to
11 hear that person, you know, it might be appropriate to
12 discuss what the AAPM speaker has said. We have the
13 slides distributed here.

14 DR. CERQUEIRA: What are the wishes of the
15 committee, do it now rather than part of new business?

16 DR. NAG: We can do it now. It's the same
17 line.

18 DR. DIAMOND: I think it would be fine to do
19 it now. Bob is here.

20 DR. CERQUEIRA: Do we have the
21 representative then?

22 PARTICIPANT: He was told he wasn't on until
23 2:00, so he left.

24 DR. DIAMOND: So wait until 2:00.

25 DR. CERQUEIRA: Okay.

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1 MR. AYRES: I managed to get dual scheduled.
2 Jeff is familiar with the competing meeting. One of the
3 items there is, Jeff is on the committee, but we're
4 working on, I think it's an important point to note
5 when you review the guidance document is one of the
6 things NRC is encouraging in the new regulations is
7 adopting of industry standards.

8 I have a committee working with Jeff on one
9 and there certainly could be more. Unfortunately, APM
10 does a lot of good work but they don't develop industry
11 consensus standards, and I think they're looking
12 towards doing something in that area. And so what, for
13 example, was pointed out in the guidance, you can
14 accept the model program, develop your own, or accept
15 an industry standard.

16 DR. CERQUEIRA: Good. Well, thank you very
17 much. The next discussion is on update on
18 intravascular brachytherapy and Donna-Beth Howe.

19 MS. HOWE: I don't have a microphone. Okay,
20 can you hear me? I'm essentially going to be giving
21 you an update on the guidance that we put out for
22 intravascular brachytherapy. I don't have any slides
23 because I'll be speaking to the handouts in your
24 notebooks, and at the end I'll give you just a quick
25 update on mis-administrations that have occurred since

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1 the last time we met.

2 What you have in your handout is the June
3 12, 2001 letter memorandum to the regions from Don
4 Cool, giving updates on guidance. It supercedes two
5 memos that went out, one was February of 2001, which
6 was addressing the Novoste beta cath and the other was
7 January 26th which was discussing the Cordis system.

8 The major differences are that we have kind
9 of written things in a little bit more general and
10 concise manner. Primarily in training and experience,
11 that's the same. We're still requiring 35.940 for
12 intravascular brachytherapy for these particular
13 devices. Intravascular brachytherapy is not one field.
14 It may be many different field depending on what the
15 device is. So, what I say for these two devices may
16 not apply for the next device coming down the road,
17 okay.

18 We're still requiring vendor training for
19 the authorized user, the interventional cardiologist
20 and the medical physicist. We are no longer really
21 defining things as a team but we're saying that the
22 authorized user is responsible for the procedure and
23 that the authorized user will consult with, an
24 intravascular cardiologist or that could also be an
25 interventional radiologist, and the medical physicist.

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1 And then instead of requiring in the
2 earlier memos all three members of the team to be
3 physically present during the procedure, we've
4 indicated that you must have the physical presence of
5 the authorized user or the medical physicist. That in
6 sort, we assume the cardiologist will be there, but
7 there is some optional leeway there. Dr. Nag?

8 DR. NAG: I think I have very strong
9 reservations about that. We had a lot of discussion at
10 the last meeting.

11 MS. HOWE: You did.

12 DR. NAG: And there was no final consensus
13 that this should be an or. Just changing that one word
14 from and to and/or makes a huge difference without
15 consulting or without talking back to the ACMUI.

16 The reason I have great reservation is that
17 by changing this to an or, you would have a scenario
18 that you are having an interventional cardiologist
19 present who is very good in putting in catheters and
20 taking care of the interventional part of it, and you
21 may have a physicist very good in calculation, but does
22 not have the anatomical know-how of blood vessels
23 inside, and if there is a problem you don't have that
24 one person there who has both the radiation safety
25 knowledge in their head as well as the medical training

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1 required to intervene with that second part. That very
2 much concerns me.

3 So this should not have remained an or
4 without getting back to us. This should have remained
5 as an and and not an or. So it's that one word. And
6 the other thing that concerns me is that you can make
7 -- this is not a regulation, but this is what, an
8 amendment? No.

9 MS. HOWE: This is a guidance.

10 DR. NAG: Yu can make a guidance where you
11 make a slight change of the word and that changes the
12 entire meaning and entire substance of the whole ruling
13 and that very much concerns me, and I would like to
14 have some feedback from some of the other members of
15 the committee about this.

16 MS. HOWE: I reviewed the transcript from
17 the last meeting several times before in preparation
18 for this and it appeared to us that in the last
19 meeting, there was pretty much a consensus that the
20 committee did not want to require all three individuals
21 to be there and that the flexibility of two individuals
22 would be more acceptable to the committee members.

23 What we tried to do in specifying the
24 authorized user and the medical physicist is to insure
25 that we will always have someone there that has

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1 radiation safety knowledge and the ability to do dose
2 calculations in brachytherapy.

3 It can either be the authorized user or if
4 the authorized user is not available and it's just the
5 interventional cardiologist, the interventional
6 cardiologist has substantial experience in, or the
7 interventional radiologist because it may not be the
8 coronary arteries, has extensive experience in the
9 medical aspects, can recognize when the patient's
10 having a medical problem, can take care of that, while
11 at the same time, the medical physicist can supplement
12 that information as far as the dosimetry, so he can
13 know pretty quickly whether he's got a radiological
14 concern in addition to whatever the problem is.

15 DR. NAG: But the concern that I have, you
16 don't have that one person who has them both. Because
17 in an emergency what you need is somebody who's
18 familiar with both.

19 Let me give you a scenario. The major
20 scenario I'm worried about is the fact that source is
21 now inside the patient. The physicist can do the
22 calculation and say well the set amount. But the
23 physicist is not familiar or not very competent about
24 handling anatomical stuff.

25 So now it goes back to the interventional

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1 cardiologist who is very good at the interventional
2 procedure but is not very comfortable with handling
3 radioactive material. So who is going to handle it
4 now?

5 DR. CERQUEIRA: Dr. Brinker is in the
6 audience and he was actually at the last meeting.
7 Maybe we could get him to come to the microphone and
8 make some comments as well. But while we're waiting to
9 do that, maybe Dr. Williamson, you wanted to make a
10 comment?

11 DR. WILLIAMSON: I think we didn't come to
12 a consensus that there should be an and, and some of
13 the considerations that were involved is that the
14 radiation oncologist is still the authorized user. The
15 regulations are very clear that that individual has
16 responsibility for the conduct of the procedure and has
17 the ability to be there, require himself or herself to
18 be there, or designate a resident of, if appropriate,
19 if the physician has confidence in the physicist and
20 the rest of the team to handle it, then just that
21 group.

22 I think the intent was to provide some
23 flexibilities to licensees, recognizing that the
24 devices have very different levels of complexity, very
25 different levels or probabilities of error and problems

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1 and that one size doesn't fit all. And we did have
2 quite an extensive discussion.

3 DR. CERQUEIRA: Yes, we did.

4 MS. MCBURNEY: I don't think it was a
5 consensus one way or the other.

6 DR. WILLIAMSON: Yes, I think we couldn't
7 achieve a consensus on the and, that's for sure.

8 DR. CERQUEIRA: Dr. Brinker, do you want to
9 make any comments?

10 DR. BRINKER: Well obviously I appreciate
11 the opportunity to speak to you all again and I
12 configured myself between my colleagues, radiation
13 oncologists. I'd just like to say that the logistical
14 problems that we discussed at the last meeting were
15 accompanied by a suggestion and that is that we don't
16 preclude situations where there is an agreement between
17 all three members of the team that a cutting edge
18 approach to this might be taken to solve a potential
19 logistical -- not a potential, a real logistical
20 problem in many areas.

21 This by no means meant to disenfranchise
22 any member of the team, all three of which we consider
23 to be very important. The background of some of this
24 is the fact that this scenario of having a radiation
25 oncologist aware of a particular case or situation but

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1 not necessarily physically present has been used pretty
2 frequently in Europe, which operate under a number of
3 constraints, some of which don't pertain to us.

4 But, the concept is not unreasonable. My
5 thought when I proposed this the last time was that in
6 certain institutions where you have the three members
7 of the team agree to this configuration, and who will
8 put the necessary monitoring and checkpoints in motion,
9 that this could be done. I don't think in proper
10 reflection that this should be a problem for anybody,
11 because if the radiation oncology arm of the team
12 doesn't agree at that institution, that should be
13 respected, and that was the gist of the comments.

14 I thought actually when I left that people
15 pretty much agreed to that concept. The wording may be
16 a little bit less precise and it could certainly be
17 corrected by just saying when all three members of the
18 team agree, and I hope everybody would be happy.

19 MS. McBURNEY: I think I'd also like to
20 point out that just because we say the authorized user
21 or the medical physicist have to be physically present,
22 that does not exclude the cardiologist from being
23 physically present.

24 DR. NAG: I don't think that answered my
25 question at all. My concern was somewhat different.

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1 MS. HOLAHAN: You want the authorized user
2 there at all times?

3 DR. NAG: If the authorized user, like now
4 the authorized user is the only person who is most
5 confident, familiar with both components, the radiation
6 component as well as the medical anatomical component.
7 I would like to invite Dr. Tripuraneni who has been
8 doing interventional brachytherapy longer than I have
9 and see what you think this would do to your practice.
10 He's a pioneer in this, and I invite -- Manny, can I
11 invite Dr. Tripuraneni to say a couple of words?

12 MS. HOLAHAN: I would like --

13 DR. NAG: It is very important.

14 MS. HOLAHAN: I'd like to point out that in
15 the last meeting, one of the major concerns, and I
16 think the committee discussed it for a significant
17 amount of time was the fact that, at many of the
18 hospital, they could not get the radiation oncologist
19 for 24/7 coverage. They couldn't get the medical
20 physicist for 24/7 coverage and so there was tremendous
21 discussion about the fact that all three members of the
22 team at many hospitals weren't available for 24/7. So
23 there needed to be some kind of flexibility, some kind
24 of compromise that the team could go ahead and treat
25 patients without all three being present.

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1 DR. NAG: Except that it's much easier
2 because radiation oncology and medical personnel and
3 who are already on medical standby, it's much easier to
4 get a radiation oncologist immediately than to get a
5 medical physicist immediately. The other thing is, if
6 you have a situation where they are so understaffed and
7 they can not have center coverage, then that center
8 should not be doing treatment with high dose radiation
9 where there's a potential for severe problems.

10 DR. CERQUEIRA: Well, I think that some of
11 the discussion related to the fact that some of these
12 devices are much more straightforward in terms of the
13 administration, the dosing and everything else. There
14 was a lot of discussion, I think Neki made some points,
15 that if you're going to be denying access to some
16 patients for a technique which is valuable, then that
17 really kind of limits the care.

18 I certainly would entertain, make a three-
19 minute comment period if you'd like to make it about
20 your experience with intravascular brachytherapy. This
21 is obviously a difficult question. We'd like to get
22 everybody's viewpoint and I think what the staff was
23 trying to do was just trying to be pragmatic to make
24 the service available in a way that would help the
25 patient and clinicians. If you could come to a

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1 microphone. Do we have one back there?

2 DR. TRIPURANENI: Thank you for recognizing
3 me.

4 DR. CERQUEIRA: I'm going to watch the
5 clock, so I don't want to be rude, but this is an add-
6 on, so three minutes.

7 DR. TRIPURANENI: We started vascular
8 brachytherapy in March, 1995. We have done about close
9 to 1,200 cases of it so far. We have experience with
10 just about all systems that are currently approved and
11 also currently going through the investigational
12 procedures. I think it's probably important to have
13 all three members of the team and this was the point of
14 Dr. Nag.

15 I do agree that there are multiple systems,
16 and even though some systems may seem straightforward
17 and simple, some of the difficulty in administering and
18 mis-administration seems to happen with one system more
19 than the other. It's probably the design of the system
20 rather than actually the isotope, et cetera, right in
21 there.

22 That's when I think it's important to have
23 all members of the team for the safety of the patient
24 more than anything else. By giving the leeway, I think
25 what you're doing is you're really not asking the

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1 institutions to develop policies and procedures.

2 I do respectfully disagree that actually
3 the this is really not a 24 hour and 7 days procedure.
4 Most of the institutions have developed policies and
5 procedures how to actually integrate there day-to-day
6 practice between interventional cardiology and
7 radiation therapy. For example, we have not denied a
8 single patient so far, even though technically we do
9 only two periods of this procedure, and then we're
10 doing corporate emergencies that come in because it's
11 for instant regional cell only.

12 So I don't think it's really a 24/7. We
13 can work out these things into the day-to-day
14 procedures sir. I think the European candidate
15 training is somewhat different and actually they are
16 much more broad-based. In some of the European
17 countries, you really don't even need a radiation
18 oncologist, and in fact, to give chemotherapy, you
19 don't need a chemotherapist, a radiation oncologist can
20 give chemotherapy. So you really can't extrapolate
21 experience from there to here.

22 So in summary, I think from our experience
23 having used all systems, I do think actually having all
24 three members at the table is helpful.

25 MS. HOLAHAN: What facility are you from?

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1 DR. TRIPURANENI: Scripps Clinic in La
2 Jolla.

3 MS. HOLAHAN: Okay.

4 COURT REPORTER: I'm sorry, could the
5 speaker identify himself for the record please.

6 DR. TRIPURANENI: Prabhakar Tripuraneni and
7 I'm a radiation oncologist at Scripps Clinic in La
8 Jolla, California.

9 DR. NAG: For your information, Scripps
10 Clinic was the first institution and that institution
11 has a long list of experience in intravascular
12 brachytherapy in this country.

13 DR. CERQUEIRA: Dick?

14 DR. VETTER: I have just a little bit of
15 problem with the patient who is on the table. You're
16 doing angioplasty and the cardiologist decides that
17 this patient would be ideal for IVB. The cardiologist
18 can get a hold of the physicist and the radiation
19 oncologist but both can't come there immediately to do
20 the procedure. They agree on what the prescription
21 should be, but the only way they can do the procedure
22 is to pull the catheter and do the patient again
23 tomorrow, and that introduces more risk.

24 DR. NAG: I think I'd like to -- you've had
25 several of these. Can you tell me how you responded to

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1 this situation?

2 DR. VETTER: And while he's on the way to
3 the phone or to the microphone, it introduces more risk
4 and we're asking the regulator to make a decision about
5 that risk. Personally, I think it ought to be the
6 medical team that's making the decision about whether
7 or not to reintroduce a catheter tomorrow.

8 DR. CERQUEIRA: I'd like to add as a
9 clinical cardiologist, for me to take a patient out of
10 the cath lab, a lot of these people come in with
11 instent restenosis with an unstable course. They're
12 having symptoms and to basically have to leave them on
13 anticoagulation for 18, 24 hours adds a certain amount
14 of risk, leaving the sheaths inside add some additional
15 risks, taking the sheaths out and then having to put in
16 new sheaths adds even more risk on the anticoagulation.
17 So it's not an ideal situation.

18 If you can basically get somebody there who
19 has the experience and the knowledge to calculate a
20 dose and do the procedure, that's optimal for patient
21 care.

22 DR. NAG: And I have had that situation
23 happen to me much more frequently with the intra
24 operative radiation where the surgeons are taking too
25 much out and they need me immediately, and that happens

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1 at a much higher frequency than ever happened to me in
2 intravascular brachytherapy. Radiation oncologists
3 because they are doing so much brachytherapy for cancer
4 work, are much more readily available than apprentices.
5 Apprentices at night are more difficult. Radiation
6 oncologists are always available for radiation
7 emergency. If in twenty minutes you can not remove
8 radiation from an implanted patient, that hospital
9 should not be doing any brachytherapy at all.

10 DR. WILLIAMSON: But do the Federal
11 regulations require you to be present to do an
12 intraoperative implant?

13 DR. NAG: We are the one doing the
14 intraoperative, no one else.

15 DR. WILLIAMSON: You are the one doing it,
16 but you're able to staff that in the way you want
17 without a Federal regulation that requires only you and
18 you alone to be there.

19 DR. NAG: For high dose rate brachytherapy
20 yes. The authorized user has to be present and
21 intravascular brachytherapy at the dose rate is
22 apparently given this high dose rate brachytherapy.

23 DR. WILLIAMSON: Yes, but the treatment for
24 high dose rate brachytherapy yes, but not for laying
25 down the catheters in the operating room. There's no

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1 NRC requirement that requires --

2 DR. NAG: That's fine. You can lay the
3 catheter for intravascular brachytherapy, just don't
4 put the radiation source in.

5 DR. CERQUEIRA: Some of the discussion that
6 occurred last time also related to the fact, we're
7 talking right now about very specialized centers with
8 expertise with a lot of bodies around, but if you're
9 really going to do this, in not such a prestigious
10 institution and especially as you identified the fact
11 that radiation oncologists are getting busier. They're
12 doing more things in the operating room which makes
13 availability more of an issue for clinical sites.

14 I can tell you at our center, we have to
15 electively schedule these two days a week and sometimes
16 we've got patients coming in and the radiation
17 oncologist has an emergency of some sort that we
18 basically can't do the procedure. So I think the
19 discussion last time was, if you're going to have a
20 technique that's been official and you're going to make
21 it available to do the greatest good for the patients,
22 you need to streamline the process in such a way that
23 you can make it available, while at the same time
24 guaranteeing safety.

25 DR. TRIPURANENI: The great majority of the

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1 patients with instent restenosis, at least in our
2 institution, are scheduled procedures. That's where
3 this has been approved to use in radiation therapy. I
4 would say in excess of 95 percent of them.

5 We do an occasional emergency that actually
6 could not wait. For example, somebody comes in let's
7 say on a Friday morning, we certainly don't wait until
8 next week. We actually go in and do the case at Friday
9 noon or whatever. We do want to take care of the
10 patients first there.

11 The second thing I think is one the
12 situations that the chairman talked about is somebody
13 at their periphery. For example, several small centers
14 where they do a diagnostic angiogram find an instent
15 restenosis and actually ship the patient as of that
16 point in time, we actually accommodate them within the
17 next several hours to actually take care of those
18 patients.

19 And as they're getting comfortable, they
20 actually go into angioplasty at that point so that the
21 patient is unstable. However, they do not have
22 radiation therapy available at that center. They
23 actually ship the patient to regional centers such as
24 our site and elsewhere.

25 In the beginning we did not know what to

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1 do, but I think with the recent June 12th NRC guidance
2 document, we actually decided to go ahead and offer
3 radiation therapy at that point, within the first 48
4 hours, rather than wait for the next instant
5 restenosis. Where there is a way, you can find ways to
6 actually do it and I think having to do this vascular
7 brachytherapy with the two members should be an
8 exception rather than the rule.

9 DR. NAG: The other thing that concerns me
10 is that if you having the procedure being done in
11 centers that are doing very few of them, in centers
12 that are not well equipped to do this, you are going to
13 end up with poor results. And once you start getting
14 poor results, you tend to wipe out an extremely good
15 technique because it's not done well.

16 So, I would prefer these to be done in
17 centers that have the experience, that have the know-
18 how and that have the safety to back them up. If
19 you're doing only it only once in a blue moon, you can
20 not respond to emergency.

21 The other thing that concerns me, I am
22 doing intravascular brachytherapy and let's say at my
23 center, because of a new ruling, the cardiologist says
24 well, we will be doing this with a physicist only.
25 Now, I'm the authorized user. It is going under my

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1 license. If there's a problem, I'm not doing it but
2 I'm responsible for it but I have no way of
3 supervising, no way of knowing what is going on under
4 my own license. I am not prepared to have things done
5 under my license when I have no control over what's
6 going on.

7 And also, if I don't do it often enough,
8 let's say the cardiologist says well, we have to do it
9 now, they don't call me. They do it with a physicist.
10 I would not be keeping abreast and later on when I have
11 to go into it, I will just like a hospital where I'm
12 doing one a year and I have no idea what I'm doing.

13 DR. CERQUEIRA: Let's sort of go around the
14 room. This is obviously a complicated issue and we
15 haven't heard from some people. Why don't we sort of
16 start at this end and float around. Dick.

17 DR. VETTER: Number 1, I am a firm believer
18 in efficacy but I do not believe that's within the
19 purview of the NRC and I don't think we want it there.
20 Number 2, at any institution the authorized user is
21 responsible, and if the authorized user's uncomfortable
22 with the way things are done or proposed, the
23 authorized user simply must say no.

24 DR. WILLIAMSON: I think the other thing I
25 would like to point out is we have a long debate during

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1 the development of the new Part 35 over the staffing of
2 remote afterloading procedures and the community pushed
3 very hard to relax the attendance requirements for high
4 dose rate brachytherapy, from requiring a medical
5 physicist and an authorized user to be present during
6 the whole treatment, to medical physicist plus a
7 physician trained to undertake emergency applicator
8 removal under the supervision of the authorized user.

9 So you know, we do have precedents where we
10 attempted to sort of put in place a guidance that was
11 a little more balanced, that respected patient safety,
12 but gave some flexibility in staffing so that in an
13 institution. Where you have a senior resident that you
14 trust to delegate this responsibility to, you don't
15 have to be there every minute and you can write the
16 written directive, have your designee be there.

17 So I think this kind of a guidance allows
18 you to, I think, tailor the staffing policy to the
19 complexity of the procedure and the risk.

20 DR. NAG: I'm telling you not the way this
21 guidance is written, not saying that you must have less
22 than -- it doesn't allow me to have a designee there.

23 DR. WILLIAMSON: Sure it does.

24 DR. NAG: I have no problem if I have a
25 designee there.

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1 DR. WILLIAMSON: It's consistent with that.

2 DR. CERQUEIRA: Let's sort of go around and
3 we'll give everybody a chance to -- Sally.

4 MS. SCHWARZ: I believe that within an
5 institution certainly, you have to have guidelines and
6 I think for the NRC to regulate all of these issues, I
7 think it becomes more inflexible. I understand your
8 concerns but I think each institution will have to
9 essentially -- I think that the regulation can't be so
10 constrictive and that it's better to allow within the
11 institution you to make choices and set up a guidance
12 that allows you to operate safely and effectively,
13 rather than to be regulated.

14 DR. CERQUEIRA: Okay. Ruth do you have
15 anything?

16 MS. MCBURNEY: Yes. Right now most of the
17 states, agreement states, are requiring the three-
18 person team approach. I think leaving it in guidance
19 will allow more flexibility than certainly to put any
20 rule in place. This is a relatively new area and we
21 need to see how that approach is going to go and
22 whether we can pull back and be a little more flexible
23 as was mentioned, a delegated type approach for the
24 medical end.

25 In some cases, not this particular case,

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1 but we've allowed for the supervision to be available
2 in the facility in case of an emergency type situation
3 rather than to be actually, physically present in the
4 room at all times. But what I think that we need to do
5 is kind of see how we're going and what sort of
6 problems arise and how to address those, but leaving in
7 guidance.

8 DR. CERQUEIRA: Leon, do we have enough
9 time?

10 DR. MALMUD: I'll be very brief. I think
11 that the credentialing process of the Joint Commission
12 for Accreditation of Health Organizations is one which
13 gives this responsibility to the medical staff of the
14 hospital, and this should be a credentialing issue
15 within the institution.

16 It would be a mistake for us to assume that
17 the NRC with all of its wisdom should be the party to
18 declare who should and who should not participate.
19 Having said that, it would be extremely wise for each
20 healthcare institution that will be doing brachytherapy
21 to have participating in the process someone who is
22 either the licensee or the designee of the licensee to
23 make certain that your concerns are addressed. But I
24 don't believe it should be through the NRC. It should
25 be through the individual institution.

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1 DR. CERQUEIRA: Okay. Ralph.

2 MR. LIETO: I feel that with the guidance
3 that it should remain guidance. I agree that it
4 shouldn't be a rule, that the authorized user
5 determines the team components. I think having it
6 stated that the cardiologist or interventional
7 radiologist be there is really kind of a moot point.
8 They're going to be there no matter what because of
9 the fluoroscopy that's done.

10 And so basically what I think it comes down
11 to is the authorized user and/or the physicist aspect
12 and I think that depending on the facility that the
13 authorized user is the guy in charge. He's the one
14 that's accountable to the radiation safety committee or
15 the NRC and they should determine the team components.

16 In some institutions, they physicist is
17 mainly there. He's not there to do treatment planning
18 or time and so forth. That's all been done beforehand.
19 They're mainly there to handle if there's an emergency
20 removal that things are done safely, that surveys are
21 taken care of, and it very well could be that you could
22 have in some institutions a very qualified dosimetrist
23 that could perform that aspect that's been trained.

24 So to say that it has to be the specific
25 team players, I think that the authorized user should

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1 be the person that's placed in charge and determine
2 what those team components are and who needs to be
3 there and so forth. I agree, I mean if the facility
4 staffing does not allow 24/7 coverage, they shouldn't
5 be doing 24/7 coverage, okay. But it's the authorized
6 user that has the say in that.

7 DR. DIAMOND: I agree with a lot of the
8 statements that were just mentioned. We discussed this
9 at our hospital at great length. We're the largest
10 cardiovascular hospital in the country, and in the past
11 year I myself have done 300 of these cases.

12 Basically what we decided is that our
13 policy will be that we would wish that all three
14 members be present at all the cases unless there is
15 some circumstance which made it physically impossible,
16 some extenuating circumstance, and that allows us this
17 flexibility if a person's coming on in for an emergency
18 case and either the physicist or the radiation
19 oncologist, you know, has an accident or has a problem.
20 It gives you flexibility to proceed without incurring
21 some type of therapeutic misadventure.

22 But again, this was an issue that we
23 discussed amongst our medical staff. We have our
24 bylaws for the Department of Cardiology reflective of
25 this, and we feel very comfortable. I myself would not

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1 feel comfortable treating a person with a high dose
2 rate procedure without having an opportunity to discuss
3 the risk and benefits with the patient in advance. And
4 again, this is just how we decided to do it at our
5 institution. We feel very comfortable with this
6 approach, and this flexibility.

7 My one reservation regarding this whole
8 process was that the guidance document which was
9 promulgated on June 12th, I don't think reflected that
10 sense. I don't think it reflected the sense that: 1)
11 we had not reached a consensus at the last meeting or
12 that, 2) if one allowed this to proceed without all
13 three members present, perhaps the best argument would
14 be some sort of an exceptional circumstance.

15 But in any event, I think most of the
16 discussion is moot in that the authorized user is the
17 ultimate person responsible for the management of the
18 procedure and that each medical staff needs to discuss
19 this and develop policies that are commensurate with
20 what they feel comfortable with. I should also say
21 that of the 300 cases that I myself have helped
22 perform, only one has been a middle-of-the-night case
23 thus far.

24 I guess one other thing that perhaps would
25 be useful for the advisory committee to know is that my

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1 personal sense is that this field is going to continue
2 to evolve in that what we're seeing is that perhaps in
3 the next year or two, these new coded stents may be a
4 wonderful boon for our patients in reducing the primary
5 rate of restenosis.

6 Many individuals think that perhaps what
7 we're going to be seeing is a shift from many of our
8 patients having fairly straightforward lesions, meaning
9 big vessels, large diameters, that's to say short
10 lesions, non-diabetics, to a shift towards treating
11 these folks with the most complex of lesions
12 bifurcations repeat treatment, patients that have had
13 perhaps radiation procedures before.

14 So the field really continues to evolve
15 and, if anything, I think we're going to be leveling
16 off on the number of cases that we perform at our
17 institution on an annual basis, but shifting it toward
18 the high-risk patients.

19 DR. BRINKER: I don't have anything to add
20 to the cogent comments made by everybody else here. I
21 think that the key is flexibility and leaving the
22 responsibility to the authorized user for his or her
23 appropriate delegation when they're confident it can be
24 carried out.

25 I would just like to take the opportunity

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1 to thank the commission for two other pieces that were
2 in that guidance that have greatly facilitated all of
3 our work in terms of not feeling bound to the specific
4 FDA indications, and the step back procedure. I think
5 that that has done a great service to us all, and I
6 want to thank you for that.

7 DR. NAG: Well, I think now having heard
8 from all of you, I think what people are saying is
9 reasonable but then the wording that you have here has
10 to be changed slightly to reflect that, just like the
11 and and or wording. I think this should be changed so
12 that it's authorized user or designee and the designee
13 could be under exceptional circumstances, and I have no
14 problem with that.

15 The other thing is that this has to be
16 recognized that interventional brachytherapy is nothing
17 but high dose rate brachytherapy because the definition
18 of high dose rate brachytherapy is 12 mR per hour.
19 Anything more than 12 mR per hour is high dose rate
20 brachytherapy and if we did not have the specific
21 technically staff for brachytherapy, this whole thing
22 would have been under the definition of high dose rate
23 brachytherapy and that's how we would have managed it.

24 So, almost everything that's under high
25 dose rate brachytherapy should be applied to this as

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1 well, and therefore it is nothing but high dose rate
2 brachytherapy.

3 MS. HOWE: I think that was Jeff's point is
4 that in the HDR, in our guidance required all three
5 people to be there.

6 DR. WILLIAMSON: I think there's a technical
7 difference between many of the systems available for
8 intravascular brachytherapy and conventional high dose
9 rate brachytherapy.

10 The latter is photon emitting, has
11 extremely high activity sources, and involves an
12 entirely different overlay of technical complexity,
13 having to do with the single stepping source device,
14 the need to have a remote afterloading versus -- so the
15 35.600 section was crafted very carefully to be focused
16 on existing high dose rate devices.

17 And, I think if one of those devices were
18 used for intravascular brachytherapy, such as in the
19 peripheral vessels, I think you'd be absolutely right
20 that NRC, you know, without question should use the
21 35.600 guidance in determining what the attendance and
22 various technical restrictions are. But I don't think,
23 for example, the Novoste device that would be
24 completely appropriate.

25 DR. NAG: But then intravascular

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1 brachytherapy under which all of these things go, also
2 include iridium at more than 500 millicurie and that
3 will be the problems with a high energy gamma emitter,
4 the same or similar as iridium.

5 DR. WILLIAMSON: But it's not remote
6 afterloading, so --

7 DR. NAG: It's manual.

8 DR. WILLIAMSON: It's manual.

9 DR. NAG: Yes.

10 DR. CERQUEIRA: Okay, we'll give Neki the
11 last word.

12 MS. HOBSON: Okay, you know my stand on
13 this. I do not want to see treatment of the patient
14 denied or delayed on some technical regulatory
15 technicality. I mean, I think it's the medical care,
16 the medical profession is obligated to give that
17 patient the very best care, and if that involves three
18 people or two people, you know, I'm not going to be
19 counting heads.

20 I would assume, and I agree with the
21 comments that have been made around the table, that the
22 medical institution and in this case the authorized
23 user, would be responsible enough to make sure the
24 expertise is available to do the procedure. But I
25 don't want to leave the patient dying on the table

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1 while we go run for someone else.

2 DR. CERQUEIRA: I guess a lot of what we're
3 saying is the practice of medicine is something that's
4 already regulated at the hospital level, and
5 radiation's covered under a lot of that. But obviously
6 there's inherent risks and so we want to stay within
7 those guidelines provided that we can give the patients
8 what they really need. Now Ralph, you wanted to make
9 a comment?

10 MR. LIETO: Yes, I was just going to say
11 that when we consider this guidance, Dr. Nag's point is
12 well taken that we can't separate, you know, beta
13 midicurie versus gamma midicurie because of the
14 guidances being written to apply to all the systems.
15 So, I think this is one thing we need to be careful of
16 there.

17 MS. HOWE: I think as you look through the
18 guidance, you'll see that for those things that are
19 common --

20 MR. LIETO: I'm referring to the issue of
21 the team presence.

22 MS. HOWE: Yes, those particular issues.

23 DR. CERQUEIRA: Yes, Neki.

24 MS. HOBSON: Well is it too late to, you
25 know, maybe Dr. Nag has some substitute language that

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1 would clarify the guidance if it isn't too late.

2 DR. NAG: My suggestion would be as I said,
3 authorized user or designee. If you put that in there,
4 I have no problem. Then if the authorized user in
5 charge, if he feels that a certain person has a similar
6 level of expertise, he can ask that person to come and
7 I have no problem with that. For example, if I'm busy,
8 I'm doing an intraoperative case, I can ask a senior
9 resident, who is most expert in radiation and expert in
10 the anatomy, to be there to be able to take that out if
11 necessary in an emergency. That's not the problem.

12 But the way this language is, it leaves
13 open that in one center, you may not have authorized
14 users in any of the cases and that center would be in
15 severe trouble if there was an emergency and neither of
16 those personnel were very familiar to handle an
17 emergency in that circumstance.

18 DR. WILLIAMSON: I think if that's so, you
19 know, it should be amended in such ways to make it
20 symmetrical between the physicist and the physician so
21 that it's one or the other, or designee.

22 DR. NAG: Or designee, yes.

23 DR. WILLIAMSON: Or designee of either. I
24 mean, because you know, as Ralph pointed out, it would
25 be appropriate under some circumstances for the

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1 physicist to designate a therapist or dosimetrist to
2 cover the case.

3 DR. NAG: I agree with you.

4 DR. CERQUEIRA: But I guess the one thing is
5 so that means -- I think some of the gist that came up,
6 you obviously need the cardiologist there, and if the
7 medical physicist is there and can deal with some of
8 the issues, can the team just be the medical physicist
9 and the cardiologist? Could that designee be the
10 cardiologist who's appropriately trained?

11 DR. NAG: No, because the cardiologist is
12 appropriately trained in the anatomical positioning,
13 the isotope positioning, but is not adequately trained
14 in the radiation safety and handling of radiation
15 material in an emergency. We do this as a team in our
16 department. If I were not there, the cardiologist
17 would have a difficult time trying to assess under what
18 situation they could take it out, when they could take
19 it out, handling radioactive material.

20 I have great regard for them in that
21 adequately placing the catheter. I depend on them to
22 do that, but I would not depend on them to be taking
23 out the source in an emergency. I have no problem
24 having a senior resident do that because I have taught
25 him for three years.

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1 DR. WILLIAMSON: I agree completely with Dr.
2 Nag on this point. I think first of all, there's a
3 problem of having sort of a board certified individual
4 in another field being the designee, because I'm not
5 sure it satisfied the supervision requirement. And
6 secondly, there's a virtue in having redundant
7 personnel available whenever you're doing, I think, a
8 procedure like this.

9 So I think it would be surely a mistake not
10 to have one person who is in a formal sense under the
11 supervision of the authorized user and who has mainly
12 sort of a technical safety background that can be a
13 counterbalance and a separate pair of eyes and hands to
14 the cardiologist.

15 DR. CERQUEIRA: Maybe I misunderstood some
16 of the discussion because I think some of the points
17 that were made was that we're dealing with a
18 cardiologist who's been through three years, four years
19 of medical school, three years of internal medicine
20 training which includes oncology, three years of
21 cardiology which includes a lot of radiation and
22 nuclear cardiology, nuclear medicine, and then he's got
23 a fourth year of training in interventional cardiology,
24 which is very extensively involved.

25 So we've got four years, plus three of

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1 internal medicine, that's seven; three years of
2 cardiology is ten and an extra year as an
3 interventional cardiologist, that's eleven years beyond
4 college, can't we train that person somewhere in there
5 to deal with some of these issues or -- I mean, what
6 have they learned during all that?

7 DR. WILLIAMSON: Why don't you count up the
8 years of training of a radiation oncologist and an
9 authorized physicist as well and then ask, is the
10 cardiologist going to, you know, absorb that additional
11 training?

12 DR. BRINKER: Can I just make one point --

13 DR. CERQUEIRA: Go ahead.

14 DR. BRINKER: -- that I think is germane to
15 this? I think that if we're interested in supplying
16 the best service and the greatest flexibility, I think
17 it's naive to think that if the authorized user feels
18 that the cardiologist at his or her institution is
19 adequately trained in bailout technique, that he could
20 designate that person.

21 In some places, there is no resident and in
22 other places it's an affront to have, you know, an
23 interventional cardiologist. I've done hundreds of
24 these procedures and for them to be -- and at none of
25 them as there ever been a radiation oncology resident

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1 in when a time when the authorized user can't be there
2 for him to say "well, I'm sending this resident to be
3 there." It just doesn't make the same sense.

4 So I want to take this away from a turf
5 issue and make it more a patient safety and patient
6 efficacy oriented issue, and I think that putting too
7 limiting a wording on this will not really change the
8 issues which prompted our concern about this.

9 DR. WILLIAMSON: So are you arguing that the
10 existing wording should remain or some additional
11 modifying the word as it sits.

12 DR. BRINKER: I wouldn't mind the existing.
13 I want to keep the authorized user in the place that he
14 is, but I want --

15 DR. NAG: It is all.

16 MS. HOWE: The authorized user --

17 DR. BRINKER: No, what I'm proposing --

18 MS. HOWE: The authorized user, it says in
19 the beginning that the procedure will be conducted
20 under the supervision of the authorized user who will
21 consult with the interventional cardiologist,
22 physician, medical physicist prior to initiating
23 treatment. So the authorized user is still
24 responsible. He is still providing the supervision.
25 It's his decision whether that supervision is in the

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1 physical present or more remote.

2 DR. DIAMOND: I think that this last two or
3 three minutes of discussion truly is moot with respect
4 to what Dr. Malmud has said and what I have said. I
5 think this gives the flexibility for unforeseen or
6 exceptional circumstances for the procedure to go
7 ahead.

8 And I think it also makes it very clear
9 that the authorized user is the ultimate responsible
10 party, and that that institution under the direction of
11 the authorized user needs to develop policies on how
12 they wish to proceed with regard to this technique and
13 this technology. And, I feel comfortable at this
14 point, keeping it the way it is because I don't think
15 the language we could come up with is going to be any
16 better.

17 DR. CERQUEIRA: Let's go around. Richard,
18 what do you?

19 DR. VETTER: I'm comfortable with the way it
20 is.

21 DR. CERQUEIRA: Jeffrey?

22 DR. WILLIAMSON: I think under the
23 circumstances, yes I'm comfortable the way this
24 guidance documents reads. It might be appropriate to
25 add some more sort of, I wouldn't say paragraphs --

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1 explanatory paragraphs, thank you, that would be the
2 word, maybe getting the spirit across. But, I think to
3 sort of have hard and fast rules with more teeth and
4 more different details and options is probably
5 inappropriate at this time.

6 So, I just want to say two more things.
7 You know, I would like to echo the comment that I think
8 the added flexibility in using the device for stepping
9 for slightly different indications and so on, I think
10 is a great boon to the medical community and to the
11 ability of the community to develop, you know, new and
12 different indications for this technique and improved
13 techniques for treating the existing indications.

14 And secondly, I think also to echo the
15 comment to leave this is guidance phase for awhile so
16 that the results of this approach can be observed,
17 because I think it's going to be really very difficult
18 to get a consensus what we should do in terms of a
19 final regulation at this point.

20 DR. CERQUEIRA: Sally?

21 MS. SCHWARZ: I agree. I think the
22 authorized user has to be the individual in charge.
23 The institution at hand has to be able to develop
24 policies that fit. That's where I think it should
25 stay, the way it is.

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1 DR. CERQUEIRA: Okay. Ruth.

2 MS. MCBURNEY: I agree.

3 DR. CERQUEIRA: Ralph.

4 MR. LIETO: I guess I was trying to figure
5 out a way to maybe improve this along the lines, and
6 I'm wondering if that last sentence and the guidance,
7 if that was just struck out, and just leave it as
8 "procedures will be conducted under the supervision of
9 the authorized user who will consult with the
10 interventional cardiologist, physician and medical
11 physicist prior to initiating a treatment," and then he
12 determines whether he's going to be there or the
13 physicist because the cardiologist is going to be there
14 anyhow.

15 To say that they're going to be there or
16 not is really immaterial. They're going to be there
17 regardless period, whether you do the procedure or not.
18 They're going to be the one putting in the catheter and
19 taking it out. They're going to be there from beginning
20 to end. So the issue really sounds like it's the issue
21 between whether the physicist and/or the authorized
22 user is going to be present. And I think just striking
23 that last sentence might, you know, solve that issue.

24 DR. CERQUEIRA: Well, we'll come back to
25 that.

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1 DR. DIAMOND: Again, for the reasons I
2 explained, I feel comfortable with the language within
3 the guidance document. I wasn't happy with the way it
4 was promulgated, but I'm happy with the way it is,
5 given the reasons I expounded upon a few moments ago.

6 DR. CERQUEIRA: Jeff.

7 DR. WILLIAMSON: I have nothing to add.

8 DR. NAG: What I'd like to know is after
9 this was sent out in June, how many centers are doing
10 interventional procedures without an authorized user
11 being present? Do we have any idea? That would give
12 me an idea whether it can be routinely done or whether
13 even though we have that, it's not been used, and that
14 would be of interest to me to know. And, you know, if
15 it's not being done that's a moot point what we have in
16 here anyway.

17 DR. WILLIAMSON: Yes. At Washington
18 University, the radiation safety committee took it upon
19 itself to basically say "we want both to be there, you
20 know, for the time being."

21 DR. NAG: All three you mean?

22 DR. WILLIAMSON: All three, well yes
23 essentially all three.

24 DR. NAG: Yes.

25 DR. DIAMOND: It's always been all three at

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1 my institution. I'm not aware of it being done with
2 just the cardiologist and one or the other in the State
3 of Florida.

4 DR. VETTER: The Mayo Clinic also requires
5 all three, but I'm not so sure we'd want the NRC
6 dictating that to us.

7 DR. CERQUEIRA: Yes. Neki?

8 MS. HOBSON: I guess I'm comfortable with
9 the way it's worded but I do think this is an issue
10 that we should review periodically to see are we having
11 any problems.

12 DR. CERQUEIRA: Yes, I think that's an
13 important point because it's only been in the last year
14 that these devices, two of them, have been approved
15 certainly for cardiac applications, and you've got a
16 couple of problem cases of details.

17 Now, do you have any numbers how many of
18 these are being done?

19 MS. HOWE: NRC always has difficulty getting
20 the denominator.

21 DR. BRINKER: I called, I took it upon
22 myself to call the vendors and it's roughly 20,000
23 since approval between the two of them. That's what
24 they said.

25 MS. HOWE: 20,000?

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1 DR. BRINKER: 20,000.

2 DR. CERQUEIRA: Since March `99?

3 DR. BRINKER: This is since approval.

4 DR. NAG: November.

5 MS. HOBSON: November of 2000.

6 DR. CERQUEIRA: And of those 20,000 do we
7 have any information on those outcomes or adverse
8 events?

9 MS. HOWE: We have the individual case
10 studies and the in med and Bob Ayres is keeping track
11 of them, so he has the preceding mis-administrations
12 and then I've got the next four mis-administrations
13 here. We don't have a lot of mis-administrations, but
14 we don't tend to have a lot of mis-administrations
15 period, and mis-administrations are in order to see
16 trends or to identify problems before they get out of
17 hand.

18 DR. CERQUEIRA: Right. I guess the feeling
19 of the committee was to keep the language as is, is
20 that it? Okay. And basically we feel it's being done
21 at institutions and certainly it sounds like at least
22 the two that you've reported on, it's being done as
23 prescribed, but it does give sort of the medical
24 community the opportunity to regulate itself.

25 MS. HOWE: And that essentially was our

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1 intent.

2 DR. CERQUEIRA: I think Dr. Brinker --

3 MS. HOWE: That essentially was our intent.

4 The other parts I think are pretty easy to go through.

5 We have the written directive follows more the HDR type

6 brachytherapy. We have to give the site and the dose.

7 It is high dose. We require independent measurement

8 prior to being used on a patient. We have emergency

9 procedures. The idea that -- in the earlier guidance

10 we had that it was for native coronary arteries for

11 instent restenosis.

12 We talked about it last time. We were

13 going to go to a much more general authorization and

14 you'll see that under the Cordis and also under the

15 Novoste, we have gone to that general authorization

16 where it says "for the use of" and then lists the

17 device for intravascular brachytherapy. So, it's not

18 tied to the specific approval given by the FDA.

19 In the Novoste, we had required an

20 introducer sheath. Now we've said they shouldn't use

21 it unless it's contraindicated for the individual

22 patient. And we had the same thing for the dual

23 syringe system, unless it's contraindicated for the

24 patient.

25 And we've noted that in the mis-

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1 administrations, those two aspects come to light as
2 being our most prominent mis-administrations. They run
3 out of fluid. They have a kink where the valve is and
4 the sheath would have prevented a number of these mis-
5 administrations and the dual syringe would have
6 provided an extra safety margin also.

7 We were a lot more specific on the source
8 train and size and also the stepping. We said, we've
9 put the stepping up into the quality management
10 program. We have concerns whether you can provide a
11 high confidence that what you're prescribing can be
12 done in some of these systems with stepping, because
13 it's difficult to tell where you are. But if the
14 facility can come up with a procedure that gives them
15 high confidence that they can do stepping, then that's
16 part of 35.32, the Quality Management Program.

17 I think that's probably about all that I
18 had. Any other comments on the guidance? And the
19 guidance was put out because we are dealing with
20 licensees everyday and applications everyday. This is
21 not rule-making. Our licensees don't have four years
22 for us to figure out a rule and go out, so we needed
23 some guidance to help patients be treated with these
24 devices. So that's why a guidance letter went out in
25 June, as soon as we felt we pretty much knew what the

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1 committee was thinking in terms of it and if we could
2 come up with the flexibility.

3 DR. CERQUEIRA: One last final short comment
4 Jeff.

5 DR. WILLIAMSON: I understand the guide in
6 P32 System, approval by FDA is imminent. So what are
7 your plans for developing product-specific guidance for
8 that device?

9 MS. HOWE: We'll look at it and we'll see
10 how it fits into the scheme, where it fits with things
11 that are common to practices already done. We'll leave
12 those as is. If it needs additional, we'll add it. If
13 it doesn't we'll delete.

14 DR. WILLIAMSON: Can you consult this
15 committee with your proposal, at least entertain our
16 feedback?

17 MS. HOWE: We can always entertain your
18 feedback.

19 DR. WILLIAMSON: Not if you don't ask for
20 it, you can't.

21 MS. HOWE: The committee meets --

22 DR. WILLIAMSON: I guess I'm asking, can you
23 make a commitment to share your preliminary guidance
24 once you've drafted it but before it's finalized, for
25 this committee to review, if nothing else remotely?

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1 MS. HOWE: We can consider it.

2 DR. NAG: The remote afterloader, it will be
3 a stepping source. It has basically no difference from
4 any other HDR afterloader other than the energy and I
5 think it highly appropriate if at least the people, the
6 apprentices and the radiation oncologists who deal with
7 this every day at least get the chance to look at it
8 before you send it out to the whole world.

9 DR. WILLIAMSON: Have a conference call with
10 a subcommittee. No, you can't do that I guess. We have
11 to announce it.

12 MS. HOWE: We have certain requirements for
13 the government advisory committees and we'll have to
14 work with those and we'll try to be as flexible as we
15 can.

16 DR. CERQUEIRA: We have in the past, we've
17 actually broken up into two separate committees.

18 MS. HOWE: Yes, that was when you were
19 working on rule-making, right.

20 DR. CERQUEIRA: Right.

21 MS. HOWE: This isn't quite rule-making, but
22 within the guidelines of the Federal advisory
23 committees, we'll work something out.

24 MR. BROWN: This is Fred Brown. I guess I
25 would request and I believe you are probably more

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1 knowledgeable than we are about the new treatment
2 system. If you have recommendations for us today,
3 please give them to us, either now or after 2:00. You
4 know, we can include that going forward as we try to
5 respond promptly to the request for licensing actions.

6 DR. CERQUEIRA: Sure.

7 MR. LIETO: I know that people are antsy to
8 hit the food line, but I got two issues regarding this
9 that I'd like to bring up regarding how licensing is
10 being done and being approved. They've created I think
11 some real issues at the license amendment stage at the
12 regional levels, and I'd like to address that if we can
13 at a later point.

14 MS. HOWE: I won't be here this afternoon,
15 so if you --

16 MR. LIETO: Well, I guess my quick question
17 is why does everybody have to go back and get their
18 license amended when the sources are FDA approved? For
19 example, the Novoste. You approved the sources. They
20 were in the source registry and just simply because of
21 the source linked to the training, everybody's got to
22 go back and amend their license and it created a huge
23 bottleneck at the licensing regional level. And to say
24 that there were a lot of short fuses being lit is an
25 understatement.

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1 DR. CERQUEIRA: What did they do at the
2 agreement state, do we know? Because right now, you're
3 only regulating what, 18 states, 17?

4 MS. HOWE: It's a small number.

5 DR. CERQUEIRA: Ruth, do you know what they
6 did at the agreement states?

7 MS. McBURNEY: I don't know with all the
8 states. We don't have the same configuration in the
9 rules, so all of these devices are, for specific
10 licensees, would be separately authorized.

11 DR. CERQUEIRA: So people have to apply for
12 an amendment then in Texas?

13 MS. McBURNEY: Yes, right.

14 DR. CERQUEIRA: Yes.

15 MR. LIETO: Well, I mean for the device, but
16 --

17 MS. McBURNEY: For the device.

18 MS. LIETO: Whether they got a source of x-
19 strength or y-strength, as long as they were under
20 their possession limit, it's not an issue.

21 MS. McBURNEY: We didn't have to amend for
22 that.

23 MS. HOWE: That was an issue to start out
24 with because one of the manufacturers did not have all
25 of their sources in the original PMA, and so not all of

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1 the sources that were in the device registry had FDA
2 approval, so those that didn't had to be under INDs.

3 MS. LIETO: No, the issue specifically has
4 to do with Novoste okay, and that the sources were
5 approved, and that basically the issue is whether how
6 many sources you have in the train, whether it's 20
7 millimeters or 40 millimeters.

8 And when the FDA approved the 20 millimeter
9 source strength in the original device configuration,
10 when they got the FDA approval for the longer source
11 strength, everybody had to go back and amend their
12 license to get that longer source strain, although the
13 sources, the individual source type had not changed.
14 It was just the number of them. That's really, I
15 think, inconsistent.

16 I mean, you didn't have brachytherapy
17 departments going back if they wanted to get so many
18 seeds for Iodine ¹²⁵, they didn't have to have approval
19 based on the number of seeds they had. It was a
20 possession limit issue.

21 MS. HOWE: I think probably Dr. Ayres can
22 address that since he was more actively involved.

23 DR. AYRES: Those two different length
24 trains were not approved at the same time. Otherwise,
25 if we'd incorporated, they'd have been the same

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1 guidance, first the 30, then the 40. The 60 is not yet
2 approved.

3 MR. LIETO: But you have given specific
4 guidance to them to state that they can not license it
5 based on the condition that it's FDA approved. In
6 other words, it would save a hell of a lot of problems
7 with licensees and time and with the regional staff if
8 you would just state and allow them to state on the
9 license that they could have any FDA approved source.
10 So when the 20 came out, boom it's approved. When the
11 40 came out and it was approved, automatically they
12 could use it. And they are under specific guidance not
13 to do that, and I think that's wrong.

14 MR. BROWN: I think I understand the point
15 and we'll take that for follow-up.

16 MS. HOWE: I think we have another issue
17 though and that's that our General Counsel a number of
18 years ago, in looking at the sealed sources, indicated
19 that we used to have a very general way of writing on
20 a license what sealed sources you can use, and this is
21 not just medical, this is gauges, this is radiography,
22 this is everything.

23 So they said we have to list specific
24 manufacturer model numbers on the license, and so that
25 gets you into the concept that as something gets

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1 approved you got to change model numbers. But we'll
2 look into the issue, but I just wanted you to know
3 that's another complexing factor.

4 DR. CERQUEIRA: Maybe you could look into it
5 and then, you know, provide Ralph with some feedback
6 and I think the feeling of the committee is whatever we
7 could do to simplify it, especially since the states
8 seem to have kind of resolved the issue without
9 additional paperwork. So, I think we should break for
10 lunch now because we're going to try to quit early.

11 DR. NAG: When do we come back?

12 DR. CERQUEIRA: 1:00.

13 (Whereupon, the above-entitled matter went
14 off the record.)

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(1:03 p.m.)

DR. CERQUEIRA: The first presentation's going to be on regulation of mixed occupational doses involving both NRC-regulated material and fluoroscopy. Mr. Brown will be doing the presentation.

MR. BROWN: Thank you, yes. Before I jump directly into the technical aspects of the issue, I'd like to start by saying I know that this is the first time we've brought this to you. You don't have detailed copies of the regulations or any of the procedures I'm going to discuss.

So what I'm really interested in is feedback from you on how in your facilities you deal with mixed dose issues, and then the practical ramifications of some of the various options or the options that you have in place. What I'm really looking for, as we work our way through the mixed dose regulatory issue, is a better understanding from you about what impact we're having in the license community.

So I guess I'll start by saying, obviously the NRC regulation is limited to by-product material. The states typically, well the NRC and agreements

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1 states limited the by-product material. The states
2 have regulatory jurisdiction over fluoroscopy and other
3 sources of radioactive material used in the medical
4 community.

5 There is certainly no intent in this area
6 to change that or modify it in any way, but on the flip
7 side, the human body that's absorbing the radiation is
8 indifferent to what its source is. It knows only the
9 biological effect from that radiation.

10 So Part 20 is written to apply dose limits
11 as they're applicable to NRC licensees to a cumulative
12 dose for the individual from both licensed and
13 unlicensed sources. If you look at the history of Part
14 20 at the time of the revision, and it was quite an
15 extended period that Part 20 was being revised, there
16 were several issues of concern.

17 One was workers at DOE facilities where the
18 dose is not NRC regulated, coming to NRC regulated
19 facilities and doing work. Another was that employees
20 on a contract basis could go from an NRC regulated
21 facility to NRC regulated facility, and if each were
22 limited to 5 rem during the time of employment, then
23 you could obviously end up with much greater doses over
24 the course of a year.

25 So Part 20 encompasses all dose received

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1 during the year by an individual for comparison to the
2 5 rem limit. We've looked at this as a pretty simple
3 thing with the blinders on, that people do NRC
4 regulated work and they may do work regulated by
5 somebody else, but the licensee could always add the
6 values together to come up with a dose of record.

7 What we've become aware of recently this
8 year, is that there are applications, especially in the
9 medical field, where doctors and other professionals
10 are exposed to NRC regulated dose, they're exposed to
11 state regulated dose, and for instance in intravascular
12 brachytherapy, especially with the Iridium sources,
13 they may be exposed or they will be exposed to both
14 sources at the same time. The concept was always easy.
15 Now though, we're trying to deal with the practical
16 ramifications of how the employer or the licensee
17 attributes or assigns dose for the individuals.

18 Quickly where we are at today, we became
19 aware of a couple of hospitals in NRC regulated states
20 or jurisdictions where doctors had received greater
21 than 5 rem whole body dose as computed under the NRC
22 regulations, which is basically the TLD at the collar,
23 even when fluoroscopy is performed with a vest. The
24 doses that the hospitals were assigning were less than
25 5 rem because of methodologies approved by the states

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1 relative to the fluoroscopy dose.

2 As the regulations, Part 20, are written
3 that is a violation of NRC requirements because we
4 require deep dose equivalent for the part of the whole
5 body receiving the greatest dose. That's not a
6 consequence that we had intended, so we have informed
7 at least two licensees that we are exercising
8 discretion for those violations, and that the staff is
9 working on a methodology that will be communicated to
10 the industry on how to avoid this unintended
11 consequence.

12 So the issue before the staff is to work
13 through the legal mechanism for doing that, and we've
14 been doing that internally very aggressively. Once we
15 have worked through the legal mechanism to achieve the
16 desired results within Part 20, we will issue guidance
17 to all of our licensees on acceptable methodologies to
18 look at an effective dose equivalent approach for whole
19 body dose when fluoroscopy is involved and aprons are
20 worn to reduce the dose.

21 The hope today is to get your input, I
22 said, on practical ramifications of this issue and
23 recommendations that you would have on how we proceed
24 with issuing a guidance.

25 DR. WILLIAMSON: Can I just ask a question

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1 of clarification?

2 MR. BROWN: Certainly.

3 DR. WILLIAMSON: I think I'm just sort of
4 confused what the technical issue is. As I understood
5 in Part 20, the 5 rem equivalent is in terms of the
6 quantity EDE, Effective Dose Equivalent. It's not --

7 MR. BROWN: I know.

8 DR. WILLIAMSON: And so the definition
9 that's in Part 20 is something more like the maximum
10 dose of penetrating radiation is the one that's
11 supposed to be carried as the quantity that's supposed
12 to be accumulated for the body dose?

13 MR. BROWN: Right, the limit for whole body
14 is stated in terms of total effective dose equivalent.
15 The definition of total effective dose equivalent is
16 the deep dose equivalent plus the committed effective
17 dose equivalent, and the deep dose equivalent is
18 further limited to that portion of the whole body
19 receiving the greatest dose.

20 Just for context to help you understand
21 that, on the other side of the NRC regulated fence for
22 a worker in a nuclear power plant entering a steam
23 generator, the radiation field on the portion of the
24 body inside the generator may be orders of magnitude
25 greater than the proportion outside of the steam

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1 generator. So, the standard has always been, deep dose
2 equivalent portion of the whole body receiving the
3 greatest dose, and that's actually consistent also with
4 OSHA's approach and other Federal approaches for
5 external radiation.

6 DR. WILLIAMSON: How does that agree with
7 ICRU and ICRP and NCRP?

8 MR. BROWN: Looking at Part 20 when it was
9 issued, the ICRP 60 guidance had not been finalized.
10 Right in the statements of consideration we addressed
11 the absence of recognized Federal waiting factors for
12 external radiation sources. And, in the rule we do
13 indicate that as we move to an accepted standard for
14 waiting factors, that the agency will look at adopting
15 those or responding to them. That's actually the
16 approach that we're looking at now from the legalistic
17 end.

18 MS. MCBURNEY: Just to explain just a little
19 bit about how the states are addressing this. In the
20 suggested state regulations in what we've adopted, if
21 there are two film edges, one under the apron, one
22 outside the apron, there is a waiting factor to
23 actually determine the effective deep dose equivalent.
24 This was based on some work, I think the AAPM or
25 somebody did.

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1 DR. VETTER: I think it was published by
2 NCRP.

3 MS. McBURNEY: It was in the NCRP, right.

4 DR. VETTER: Originally it was Rosenstein &
5 Webster.

6 MS. McBURNEY: Right.

7 DR. VETTER: It was work originally
8 conducted by Rosenstein & Webster and it's now in NCRP.
9 I've forgotten the report number.

10 MR. BROWN: 122.

11 DR. VETTER: 122, thank you.

12 DR. CERQUEIRA: Other comments? Dr. Nag.

13 DR. NAG: No comment but a question. I'm
14 not very familiar with this so I need some
15 clarification from the witnesses. How are you
16 differentiating, by having one film under and one over?
17 I mean, if I have to go and do a procedure, I have to
18 have three films then, one for my ring because I'm
19 handling the radioactive material in my hand, one
20 because I'm also at the same time doing fluoroscopy.
21 I have one that I wear over my lab apron and one under
22 my lab apron?

23 MS. McBURNEY: That's correct.

24 DR. NAG: And minusing the two that you
25 have, can you explain one of you?

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1 MS. McBURNEY: There's a calculation.

2 DR. VETTER: NCRP 122 also allows a single
3 whole body badge in which you can estimate the fraction
4 that penetrates the apron, but the apron if you're
5 looking at like 80 to 100 KBB (phonetic) stops almost
6 98 percent of the scattered radiation. If you're at
7 100 and above, it's 95 percent. So, the apron is very
8 effective at stopping x-rays.

9 DR. NAG: No, it will stop the fluoroscopy
10 but not the Iridium.

11 DR. VETTER: That's correct but not the
12 Iridium, right.

13 DR. WILLIAMSON: Can you give us an idea
14 what would be, for a typical say interventional
15 cardiologist or other person that made extensive use of
16 fluoro, what could be the discrepancy between the two
17 measures, the deep dose equivalent as defined by NRC
18 and NCRP 122?

19 DR. VETTER: Just talking practical levels,
20 what really happens at our institution, the
21 interventional radiologist receives zero from Iridium
22 because they leave the room. So, it's easy.

23 DR. WILLIAMSON: That's what we do too.

24 DR. VETTER: Yes, so it's easy. But we do
25 have several who exceed 5 rem per year on their badge

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1 but the state allows us to use the NCRP 122 methodology
2 to estimate the effective dose.

3 DR. NAG: Where do they wear their badge,
4 outside or inside the lab coat?

5 DR. VETTER: Outside the apron.

6 MR. BROWN: The reduction factor, in looking
7 at the doses we've seen, is approximately 5-1 when you
8 compare the deep dose equivalent at the part of the
9 whole body receiving the greatest dose which would be
10 the collar badge, and the assigned dose using what's
11 been referred to as the Webster Formula, which is one
12 and a half times the value of the badge under the apron
13 and .04 times the value at the collar added together.

14 DR. WILLIAMSON: Will this eventually, are
15 you planning a rule-making initiative to adopt
16 something equivalent to the NCRP 122 methodology?

17 MR. BROWN: We feel at this point that there
18 is latitude within the regulations for us to adopt
19 guidance and publish it uniformly that will not require
20 a rule-making change. A rule-making change may long-
21 term be the best way to go, but what I'm interested in
22 right now again is the practical inputs on especially
23 any facility that's counting doses differently for
24 different regulators to be able to get the quickest
25 response out, which is not rule-making.

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1 DR. VETTER: A very practical way to handle
2 that is to require the issuance of a separate badge
3 when they are being exposed to Iridium, and that badge
4 not then be worn for the fluoro portion.

5 DR. NAG: But the problem is many times you
6 are doing both, you are checking, you are putting the
7 Iridium in. I'll be putting the Iridium in and then
8 I'll be checking with fluoro to make sure that the
9 Iridium is going in, so I'm exposing both at the same
10 time. And immediately after that I might be doing a
11 case with Iridium and another case with fluoroscopy and
12 Iodine.

13 DR. VETTER: In that case, then you have to
14 wear a badge under the apron.

15 MS. McBURNEY: Yes.

16 DR. WILLIAMSON: You have to wear three
17 badges I guess, one for the non by-product material,
18 one for the by-product material and one for both, so
19 you could do the appropriate subtractions. I guess we
20 handle it typically in radiation oncology as we do have
21 some non by-product sources that we are concerned with,
22 we have fluoro because we have simulators. We have
23 linear accelerators which contribute a small amount of
24 whole body exposure to our personnel, and we have other
25 radionuclides, such as Paladium ¹⁰³, which is largely a

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1 cyclotron-produced radioisotope.

2 But I think in general these are well
3 managed sources of exposure. The exposures are quite
4 small and we simply, as a matter of practice, we don't
5 make a distinction. We just sort of report one
6 quantity which is the sum of all these radiations, and
7 we don't attempt to distinguish it. But I think there
8 are different settings in our institutions, such as the
9 cyclotron. Maybe Sally might want to address where
10 this approach is not possible.

11 Certainly I think in the cath lab it's a
12 problem, and our solution has been to try to separate.
13 And as long as the cardiologist is willing to stand in
14 the control area, you know, where the Iridium sources
15 are being used, we've not had the problem.

16 MS. SCHWARZ: We have produced isotopes and
17 our personnel that handle all of our accelerated
18 produced isotopes are badged and essentially similar to
19 NRC-regulated materials. But they're looked at
20 separately when we are inspected, because we're
21 maintaining a single exposure for the individuals but
22 certain individuals are only exposed to cyclotron
23 produced and some are exposed to both and those people
24 are under NRC auspices. So essentially, the records
25 are kept separately for those who are essentially

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1 accelerator produced individuals, but it's the same
2 badging technology.

3 MR. BROWN: Right, thank you.

4 MS. MCBURNEY: I don't think that you'd want
5 to separate for an individual the dose that they got
6 from by-product versus non by-product sources, because
7 the rules are talking about total occupational dose.

8 MS. SCHWARZ: If our individuals are exposed
9 to both, it is a single badge.

10 MS. MCBURNEY: Right.

11 DR. WILLIAMSON: But we would have different
12 levels of concern in terms of ALARA investigations,
13 wouldn't we? Potentially for somebody that was exposed
14 just to by-product material who has very relatively low
15 exposures versus somebody that has the potential of
16 higher exposures from the accelerator, plus some
17 exposures to by-product material, we might adjust the
18 ALARA level. So we wouldn't in that sense manage it as
19 sort of a compromise between the sort of working
20 standards that I guess prevail in the accelerator world
21 versus the by-product material world.

22 DR. CERQUEIRA: Ralph.

23 MR. LIETO: As far as ALARA reporting, I
24 guess it kind of might vary from institution to
25 institution how they maybe make their reporting and so

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1 forth, but most places pretty much have a standard
2 reporting level. It's usually around 10 percent of the
3 dose limit or some other fraction, like 30 or 50
4 percent. So I don't think it will affect ALARA
5 reporting that much.

6 I think the practicality of having like
7 three badges to try to separate the radioactive
8 component from the fluoroscopy component with no fence
9 to our cardiologists is really, I don't think they're
10 going to buy into that. I think with a lot of times
11 it's real difficult just getting them to wear badges
12 period.

13 So, to get into issues of trying to
14 separate the components -- but I think you could
15 probably do that by looking at, you know, overall
16 trends of areas. There's going to be a fair number of
17 them that just do fluoroscopy and granted there might
18 be certain expertise differences, but I think on the
19 average you can get some idea of what fraction of their
20 exposure is from just fluoroscopy.

21 And by the same token, looking at just your
22 radioactive material handling side, say your nuke-med
23 techs for example, they're going to probably be an
24 upper estimate though in terms of whole body exposure
25 from that side.

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1 So I think there's ways you could get an
2 idea as to what fractions are from radioactive material
3 handling versus the fluoroscopy end, especially in the
4 cardiac area.

5 MR. BROWN: So that approach which would be
6 to look at the dosimeters at the end of the year, and
7 then assign fractional values for whole body using deep
8 dose, and then whole body using computational methods,
9 such as Webster. Is anyone doing that?

10 MR. LIETO: Probably not according to that.
11 I think probably the method that Dick mentioned earlier
12 is doing it on an individual basis, based on the fact
13 of the two dosimeters that are worn. But then there
14 are some states that don't allow it.

15 MR. BROWN: Right.

16 MR. LIETO: And that can be a problem. But
17 I think if the NRC came out with guidance that this was
18 an acceptable methodology to follow, using NCRP as
19 maybe a precedent, I think it might be easier for those
20 states that don't allow it to justify the individual
21 licensees to do it.

22 MR. BROWN: Ruth, do you have a comment on
23 that or is the NRC going to be in the position of --

24 MS. McBURNEY: I don't think that they'll be
25 forcing the states to do that, but I think they will

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1 be, I mean we'll kind of encourage those that haven't
2 adopted the methodology to go ahead and do so.

3 Because if on one hand, you know, the state
4 is coming in to review the occupational doses under
5 their x-ray registration and are using a different
6 methodology than the NRC is allowing when they come in
7 to do their radioactive material inspection in a non-
8 agreement state, that could be problematic. So
9 hopefully, it will encourage states to become a little
10 more uniform if it becomes a national standard.

11 DR. CERQUEIRA: Yes. Jeff.

12 DR. WILLIAMSON: Well, you know, I guess the
13 solution for most of us is we really try to avoid the
14 problem where we have to apply a different sort of
15 correction to one whole body dose than another, but
16 clearly intravascular brachytherapy and maybe a few
17 other applications maybe make that very difficult to do
18 and we're left with this quandary.

19 So, I suppose a technical question is, does
20 there exist a single badge which has some filter in it
21 or something and could distinguish between diagnostic
22 quality exposure and a gamma, which would be higher
23 energy and hence bear the maximum, as you call it, body
24 dose? It would be a good indication of the whole body
25 dose.

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1 MS. McBURNEY: I think there are some energy
2 compensated badges.

3 DR. WILLIAMSON: I think that's a question
4 for the physics people.

5 DR. VETTER: The current badges will
6 distinguish extremely low-energy photons and that adds
7 to the skin dose. It's a shallow dose.

8 MS. McBURNEY: Right, but I don't think
9 there's incremental things.

10 DR. VETTER: But whether or not -- how far
11 up in energy they could go, I don't know.

12 MR. LIETO: I think it's mainly for the
13 algorithm that's used for converting the dose into a
14 dose equivalent.

15 DR. WILLIAMSON: So there's, other than a
16 dual badging procedure, there's no technical solution
17 to this problem?

18 DR. VETTER: There might be. We just don't
19 know. We would need LCN or Landau or somebody like
20 that here to answer that question.

21 MS. McBURNEY: Right.

22 MR. LIETO: And even if the technology's
23 there, then you'd have to have the vendor adopt that.

24 DR. WILLIAMSON: Ralph, you think there
25 isn't such a technology that's been developed by a

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1 vendor at this point that's widely available.

2 DR. VETTER: Well the other complication is
3 a Nav-Lab. They have to process their badges in
4 accordance with Nav-Lab.

5 MR. BROWN: Going back to the comment,
6 thinking through it a little further, if we adopted an
7 approach that said for the portion of the exposure
8 that's fluoroscopy and even the portion that's a
9 combination of fluoroscopy and Iridium intravascular
10 brachytherapy, use two badges. Calculate them under
11 the state standard that's applicable. Add that value
12 to a separate badge that would be worn only with by-
13 product material alone. Do you see practical concerns
14 with getting a second set of dosimetry put into use in
15 some cases or not?

16 MR. LIETO: I don't. I think you're
17 probably doing it as a standard anyhow for physicians
18 or workers using fluoroscopy, table-side fluoroscopy.
19 Just thinking out loud here, you could maybe use, if
20 you can demonstrate that there's a high likelihood that
21 less than 10 percent of it is from radioactive
22 materials, that you could use this as a methodology.

23 Now, if you're above that, I don't have an
24 answer for you. But, that might make it easier,
25 because generally speaking, if they're getting dual

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1 exposure, just a very small fraction of it is due to
2 the radioactive material aspect of their work.

3 DR. CERQUEIRA: Okay.

4 MR. BROWN: I guess I would comment as an
5 inspector following up and doing the end-of-the-year
6 dose reviews, trying to decide whether it was 9.5 or
7 10.5 though is the dreaded task. But that is actually
8 something that we're looking at as well.

9 MS. HOBSON: I have a question. Say you
10 found a situation where the combined dose exceeded the
11 NRC standard, would the licensee get a violation or
12 would they be cited for that?

13 MS. McBURNEY: Yes.

14 MR. BROWN: yes.

15 MS. HOBSON: So you're really bringing
16 fluoroscopy kind of in under the NRC mantle of
17 regulation?

18 MR. BROWN: Well, I would say no. What
19 we're doing is insuring for the health and safety of
20 the individual, in this case the doctor or the medical
21 worker, that they aren't exposed to more than the legal
22 limit in an annualized period. As I said, the body
23 really is indifferent to the source, the nature of the
24 source, so if it's occupational exposure we apply the
25 5 rem limit without regulating the non by-product

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1 material, but in essence by reducing the allowable dose
2 from by-product material.

3 So in simple math, if the limit is 5 and
4 you've received 4 rem annual exposure from non by-
5 product material, what you really have is an annual
6 dose limit of 1 rem for NRC regulated material.

7 DR. CERQUEIRA: Dr. Williamson.

8 DR. WILLIAMSON: Well, you know, I think
9 that maybe it's not quite fair to call this mixed
10 exposure. It's really -- the only problem is when one
11 exposure is relatively superficial and governed by a
12 different set of rules than is in Part 20 and the other
13 component is a more penetrating component.

14 So your proposal, you know, is to offer
15 some regulatory relief to those people so that they can
16 apply, you know, the what would the word be, I guess
17 the less conservative methodology in a sense, which is
18 now a well-regarded and how should I say, is not just
19 sort of a procedure that's been dreamed up, but the
20 various advisory bodies such as NCRP stand behind it.

21 So since you're accommodating them by
22 allowing them to use this more liberal strategy, it
23 seems that it's incumbent upon those that avail
24 themselves of this strategy to develop a method of
25 keeping track of the two. And perhaps, in cases which

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1 Ralph has mentioned where one can come up with a
2 ballpark estimate that demonstrates that the
3 penetrating component is quite low, maybe dual badging
4 might not be necessary.

5 But if in a sort of rare scenario where you
6 have somebody that's doing a whole bunch of fluoro plus
7 a significant amount of brachytherapy with Iridium 192
8 or some other penetrating field, you know, then I think
9 they simply are going to have to bite the bullet and
10 wear two badges and have one under the apron and one on
11 the collar, and apply a set of corrections and they
12 will just have to accommodate themselves. And, I think
13 that's not an unreasonable demand to make on the part
14 of an institution, because I think it's probably a
15 small cohort of workers.

16 DR. CERQUEIRA: Any other comments for Mr.
17 Brown?

18 MR. LIETO: Well, I've got one related to
19 this dose limit issue and maybe I have this wrong, but
20 it relates to extremity monitoring and that I seem to
21 recollect that reactor people have said that exposures
22 to the upper arm would be considered like whole body
23 limit values, and I'm just wondering if you would be
24 running into a similar issue, let's say they're wearing
25 an extremity monitor and because the lead aprons don't

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1 cover any portion of the arm, would we be running into
2 a similar issue here also?

3 MR. BROWN: Actually, the way the Webster
4 formula was developed applies the whole body exposure
5 portion as part of -- the upper arm, excuse me, is
6 considered within the whole body for EDE as calculated
7 or as determined by Webster.

8 MR. LIETO: It's in the correction factor.

9 MS. McBURNEY: Right.

10 MR. BROWN: Yes.

11 MS. McBURNEY: The portion of the body
12 that's still exposed, even with the lead apron on, is
13 taken into account in those calculations.

14 MR. LIETO: Right, okay.

15 MR. BROWN: Well, thank you very much. This
16 helps considerably.

17 DR. CERQUEIRA: Thank you. I guess the next
18 item is new business.

19 MR. BROWN: Yes new business and I guess --
20 let me go over a couple of things. We have available
21 for the members of the committee, copies of the Volume
22 9 guidance for Part 35, and I'll warn you Melanie
23 Galoway can probably hold up a visual to help you
24 appreciate the scope of the package.

25 MS. GALOWAY: So if anybody would prefer to

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1 have it mailed to them, we can do that. I do have ten
2 copies available for anyone on the committee who would
3 like to take one home with them. They're not too
4 heavy. The staff and I were able to sweet-talk the
5 xeroxing department to make it a priority today for
6 you. Does anybody else prefer to have theirs mailed?

7 (Background conversation.)

8 MR. BROWN: I'd like to just kind of
9 introduce a concept as you look at that too because
10 there's been a fair amount of discussion at the last
11 two meetings around the role of guidance, and the
12 regulations and licensing. I'm sure you all know this
13 better probably than I do, but just to reiterate. The
14 regulations are enforceable and we inspect against the
15 regulation. Licenses are enforceable and we inspect
16 against the licenses.

17 This guidance document is to facilitate the
18 licensing process so there are pre-approved standards
19 in this guidance document that will facilitate rapid
20 issuance of licenses, but it does not preclude any
21 licensee from choosing an alternate means to
22 demonstrate compliance. So if you see, for instance,
23 it was mentioned the model procedures. If you see
24 model procedures that you don't think are consistent
25 with how the new rule should be applied, that does not

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1 mean that we have placed a new regulatory requirement
2 in place via this guidance. Go ahead.

3 DR. WILLIAMSON: I was going to actually
4 comment on the licensing guidance for remote
5 afterloading brachytherapy which is FC 86-4. My own
6 personal experience is that license reviewers are
7 loathe to entertain any alternatives to those
8 procedures. So I find your comment rather difficult to
9 reconcile with my own personal experience.

10 MR. BROWN; Well, I on the other hand deal
11 with the requests for alternate methodologies as a
12 major portion of my job so I know that they do come in
13 and we, in fact, end up approving not a small share of
14 those requests, and I think both are probably true.
15 That I think license reviewers would prefer to have
16 licenses that come in that they can turnaround in a
17 very short period of time without any additional
18 headquarters review. But by the same token, where
19 licensees feel strongly that they do not want to
20 proceed in exact conformance with the guidance, we do
21 approve many of those.

22 DR. WILLIAMSON: Well, you know, I think
23 it's one thing to state that. It's another to make
24 your administrative structure and procedures be
25 friendly and not make it an intolerable burden so that

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1 in practice the licensees really don't have access to
2 that benefit.

3 That is the concern I'm stating, and I
4 think this is not just the way, you know, a matter of
5 how these things are written, but it's a sort of a
6 function of the roadblocks, procedures that you set up
7 to implement these. You can either make it sort of
8 something nice you can say which you sort of show, or
9 you really could have a system set up that is fairly
10 robust and does, in fact, seriously entertain
11 alternatives without imposing substantial burdens or
12 costs upon the licensee to have access to alternatives.

13 MR. BROWN: I think it's a good point and I
14 don't disagree, and then getting to the practical
15 application of it is, of course, the devil in the
16 details.

17 DR. CERQUEIRA: Exactly. Any other
18 comments?

19 MR. BROWN: There was at least one other
20 follow-up from this morning as well. We've had a staff
21 member looking into existing guidance and
22 recommendations on medical follow-up for anyone exposed
23 to radioactive material that might seek medical
24 attention. At 2:00, I hope to be prepared to give you
25 a quick overview of the NRC role, the existing

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1 documentation that we have, one or two references that
2 you might find useful, and then some discussion about
3 where we can go to address the more specific interests
4 that you had. So that should be ready in about 20
5 minutes or so.

6 DR. CERQUEIRA: Okay. So in the meantime
7 we're probably going to go on with new business. Yes,
8 Geoffrey.

9 (Pause.)

10 MR. IBBOTT: Thank you and good afternoon.
11 I appreciate your giving me this opportunity to speak
12 with you this afternoon. I'm representing the two
13 organizations listed on this slide, the AAPM and the
14 ACR, and I'm a member of both.

15 My name is Geoff Ibbott. I'm a medical
16 physicist at the Anderson Cancer Center in Houston and
17 I have a number of years of experience in medical
18 physics, and I'm here to relay concerns to you in two
19 areas regarding Part 35.

20 First let me explain to you that our
21 organizations recognize a term we've dreamed up called
22 "qualified medical physicist" and all three of the
23 organizations listed here, the AAPM, the ACR, and the
24 American College of Medical Physics, have agreed on
25 essentially identical definitions. Our definition of

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1 a qualified medical physicist is somebody who is board
2 certified and who then meets certain continuing
3 educational requirements.

4 We believe that board certification is
5 important and under the board certification pathway in
6 the new Part 35, the NRC would expect board
7 certification to address all of the training and
8 education requirements that are specified in 35.51-B.
9 And, we're concerned that strict interpretation of this
10 requirement could ultimately diminish the importance of
11 board certification.

12 Let me explain to you why we believe that.
13 Firstly board certification is, in our field, the only
14 widely-accepted credentialing system for clinical
15 medical physicists. For 50 years, medical physicists
16 have been certified by the American Board of Radiology
17 and the American Board of Medical Physicists, and it is
18 a process that indicates a certain level of competency
19 that people in our field have come to recognize and
20 take confidence in.

21 Unlike with physicians, a residency program
22 is not a requirement for board certification. In
23 addition, the demographics of our field require that
24 physicists be able to transfer from traditional physics
25 fields into medical physics by getting some additional

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1 training and then board certification.

2 We are very concerned that board
3 certification be preserved as a key element of any
4 other credentialing requirement through the NRC. But
5 as has been discussed earlier, I believe the
6 certification boards do not require specific experience
7 with Cobalt 60, gamma stereotactic radiosurgery or
8 remote afterloading brachytherapy.

9 We believe that any move that diminishes
10 the importance of board certification, could ultimately
11 jeopardize public health. This is because
12 certification is recognized as an indicator of
13 competency. We have a number of examples. In Texas,
14 I'm licensed by the state, essentially by virtue of
15 being board certified. MQSA is another example, where
16 great importance is placed on board certification.

17 We would hope that the NRC would accept
18 board certification as a default or accepted pathway
19 for demonstrating some of the individual requirements
20 in Part 35.51, such as the existence of an advanced
21 degree and of certain training.

22 There's also been some discussion about
23 grandfathering earlier today I understand. We believe,
24 again, that previously and currently licensed medical
25 physicists should be recognized as meeting the

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1 requirements for an authorized medical physicist. This
2 is consistent with NRC practices. We believe it to be
3 appropriate that this authorization be awarded without
4 limitations, and we think it's essential that this be
5 done to build up a cohort of authorized medical
6 physicists to continue the process of awarding
7 authorization to other medical physicists.

8 Now, the existing wording proposes a single
9 AMP category. We think this could be a problem. Our
10 estimates are that there are approximately 100 Cobalt-
11 60 teletherapy units in clinical use. That's clearly
12 about two per state, but they're not distributed that
13 way and so there are many folks who are quite some
14 distance from a Cobalt ⁶⁰ teletherapy unit.

15 Similarly, there are only a few dozen gamma
16 stereotactic units, not enough for potential AMPs to
17 get experience with these devices. So we propose that
18 subcategory AMPs be defined, that again emphasize the
19 importance of board certification but enable the
20 awarding of the AMP authorization.

21 So our proposed solution to this is to
22 define three subcategories of AMP. As shown here, the
23 teletherapy AMP, remote afterloading AMP and a gamma
24 stereotactic AMP.

25 Now for the teletherapy authorized medical

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1 physicist, a physicist who is already board certified,
2 could then show his special skills with Cobalt⁶⁰
3 teletherapy by performing a complete calibration, a
4 full annual calibration of a Cobalt unit and then a
5 monthly spot check which would then be scrutinized by
6 an AMP who would then sign off to indicate that the
7 procedures were in agreement with the AMPs own
8 procedures.

9 I'd like to point out that, while my slides
10 says "under the supervision of", this is not intended
11 to mean a sort of teacher-student relationship. It may
12 well be that the person seeking the authorization is
13 more experienced and more capable than the AMP, but the
14 point is that the AMP who has first calibrated the unit
15 to meet with the NRC requirements then compares the
16 measurements of the person seeking accreditation with
17 his own to insure that the procedures were done
18 correctly and the results are in agreement.

19 Now, this is a physicist who is not already
20 certified. A physicist who is not board certified
21 would have to have a graduate degree and have a year of
22 full-time training in therapeutic radiological physics,
23 and an additional year of experience under the
24 supervision of an AMP physicist at a facility using a
25 Cobalt teletherapy unit. This would bring us into

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1 agreement with the legal requirements established by
2 35.51.

3 Similarly, for remote afterloader system,
4 a board certified physicist would demonstrate his
5 ability to operate and calibrate the unit by performing
6 a full calibration and a spot check, and that would be
7 signed off by an AMP and a non-certified medical
8 physicist would go through the pathway I described just
9 a moment ago, with the appropriate degree and training,
10 followed up with experience on that particular device.

11 And likewise for the gamma stereotactic
12 AMP, a board certified physicist would demonstrate his
13 ability to calibrate the unit appropriately. A non
14 certified physicist would have again the degree and
15 training requirements, followed up by experience at an
16 institution with such a device.

17 So I'd like to conclude by stating that
18 I've intended to make two points here. One is that we
19 believe certification is a very important credential in
20 our field and that the requirements for an authorized
21 medical physicist should not in any way detract from
22 the importance of certification, and should take
23 advantage of the certification processes we have in
24 place.

25 Second, that we propose that there be three

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1 subcategories of authorized medical physicists to make
2 it more practical to bring people in under this
3 credential. And I'd like to finish by saying that the
4 AAPM and ACR are both willing to work with the NRC in
5 any way we can to help with this ruling and with
6 regulations that would follow. Thank you and I'd be
7 happy to answer any questions.

8 DR. CERQUEIRA: Dr. Nag.

9 DR. NAG: You mentioned three subcategories.
10 Where would you put the category that exists in many
11 places where the physicist is certified and handles
12 Caesium, Iridium, has not had training in either gamma
13 knife or high dose rate or cobalt teletherapy? How
14 would you characterize that person?

15 MR. IBBOTT: Well, if that person is not
16 working with cobalt teletherapy or cobalt gamma knife
17 or the remote afterloading devices, then it's my
18 understanding that the AMP criterion doesn't come into
19 play.

20 DR. NAG: No, but then how would you handle
21 caesium and iridium? What will you call him? He's not
22 a teletherapy AMP. He's not a gamma knife AMP and he's
23 not a high dose rate AMP. So, what kind of an AMP is
24 he?

25 DR. WILLIAMSON: I think the answer is, is

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1 that in 35.400 the only requirement for the involvement
2 of an AMP is to perform decaic calculations for
3 strontium⁹⁰ I applicators and that's it. So
4 essentially, the role of the AMP is limited to 35.600
5 devices, except for that one indication.

6 DR. CERQUEIRA: I don't think that's what he
7 was asking.

8 DR. NAG: No, how are you handling, you
9 know, many patients are using a lot of caesium,
10 iridium.

11 DR. WILLIAMSON: But the NRC basically does
12 not regulate the role of a physicist in those
13 modalities with the exception, you know, the NRC staff
14 can correct me, but my understanding is, is that the
15 AMP is not required for 35.400 modalities except for
16 the strontium⁹⁰ I applicators and in the case where low
17 dose rate sources are used in a remote afterloading
18 device.

19 DR. DIAMOND: Jeff, I don't think you
20 understand what Subir was asking. I think his question
21 is, with the new rubric that Geoff just explained,
22 whether it be an AMP with these three different
23 qualifications for the individuals coming through the
24 training now, I think Subir was asking what about those
25 individuals who are grandfathered in. Would there be

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1 specialized designations indicating their training? Is
2 that what you're asking?

3 DR. NAG: No, I was saying what about those
4 physicists who have training in low dose rate, all
5 right, but do not have training in any of these three.
6 You only have three top categories. What about the
7 fourth category which will be applicable to a lot of
8 physicists who don't have training in any of these
9 three.

10 DR. CERQUEIRA: So he's saying a general
11 physicist who wouldn't be specifically trained in those
12 three but --

13 DR. NAG: That means they can't handle
14 radioactive material if they don't have a category.

15 DR. WILLIAMSON: NRC doesn't have such an
16 entity, that's the answer Subir is there is no AMP for
17 manual afterloading brachytherapy with the exception of
18 strontium⁹⁰ decay calculations.

19 DR. NAG: Oh.

20 DR. WILLIAMSON: If you read the definition,
21 it basically says AMP has this degree and so on, and
22 gets the experience at an institution and then there's
23 a list of section numbers out of Part 35 and they refer
24 to all of the things Dr. Ibbott mentioned, which are
25 the full, basically full calibrations and spot checks

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1 of the three 35.600 modalities, plus I think leak
2 testing and strontium⁹⁰ decaic calculation.

3 DR. NAG: No, if someone is doing
4 interventional brachytherapy and does not have any of
5 these three, he's not an authorized medical physicist.

6 DR. WILLIAMSON: I think he can become one
7 depending upon the proposal that's used. Now, in Dr.
8 Ibbott's proposal, if this person were board certified,
9 he would have to go and fulfill these supplementary
10 training requirements that he just mentioned in this
11 scenario, and then he could become an authorized
12 medical physicist.

13 DR. NAG: No, but -- okay, under the
14 interventional brachytherapy procedure, it has to be
15 done in the presence of a physicist or authorized user
16 and so forth. Now, if it is not high dose rate, since
17 this is not gamma and this is not cobalt⁶⁰ he's not a
18 physicist.

19 DR. WILLIAMSON: Well, it says actually in
20 this guidance, I hate to be argumentative, but it just
21 says medical physicist. It doesn't say authorized
22 medical physicist.

23 DR. NAG: Oh, okay.

24 DR. WILLIAMSON: So there still is a concept
25 of medical physicist and there still is a concept of

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1 board certified medical physicist and that is quite
2 separate from the current category of teletherapy
3 physicist which is going to turn into the category of
4 authorized medical physicist.

5 So, I think the way to see this is in the
6 old regulation that we now have, the only mention of
7 the physicist in the regulations is for calibrating
8 cobalt⁶⁰ teletherapy and that's why he's called a
9 teletherapy physicist. And there are other mentions or
10 other references to the physicist, but only in
11 regulatory guides.

12 DR. CERQUEIRA: Dick, you understand this.
13 You're going to explain it, right?

14 DR. VETTER: Oh yes, Jeff is absolutely
15 right and I do understand the question. But it's sort
16 of like the old cliché, when is a dose a dose? Now we
17 have a new one. When is a physicist a physicist?

18 DR. NAG: Right.

19 MR. IBBOTT: And I have to say we were
20 responding to the wording in the revised ruling, and
21 sort of took it point by point.

22 DR. NAG: Thank you for the clarification.
23 Now I know when you're a physicist and when you are an
24 authorized physicist.

25 DR. VETTER: And a qualified medical

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1 physicist.

2 DR. NAG: And a qualified physicist.

3 DR. WILLIAMSON: I mean it really is
4 confusing. We have actually the same trouble in our
5 radiation safety committee. We had nearly an identical
6 discussion. It was very confusing because we even had
7 a third definition which was authorized by the
8 radiation safety committee to do such and so which is
9 different yet. So, it's very confusing.

10 DR. CERQUEIRA: Any other questions for Dr.
11 Ibbott? Yes?

12 DR. WILLIAMSON: If I can make a comment and
13 I think what this proposal amounts to is accepting the
14 rule language as it is and is suggesting a procedure
15 which would be implemented more in guidance space
16 rather than rule space. The essence of the idea is to
17 make board certification cover as many of the 35.51-B
18 requirements as possible, so from a regulatory point of
19 view, there would be desirability of board
20 certification, and the willingness of physicists in the
21 field to undergo the rigors required to earn this
22 certification would not be diminished.

23 So you know, I think in view of how
24 controversial this is, I think it would be maybe a good
25 idea if this committee considered a motion to support,

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1 you know, this type of proposal.

2 DR. CERQUEIRA: Well, why don't you work on
3 a short motion and Dick you wanted to make a comment?

4 DR. VETTER: Yes, just one brief comment
5 more or less in support of the whole discussion here,
6 and that is we all together hold some responsibility
7 for the dilemma we find ourselves in relative to the
8 interpretation of the requirements, not the
9 requirements to be uncertified, but the requirements
10 for certification to be recognized. So anything we can
11 do in guidance phase to try to clarify that to
12 encourage, at least to not discourage board
13 certification will help improve the safety of patients
14 in my opinion.

15 DR. CERQUEIRA: Yes, I think that's true for
16 not just medical physicists, for all the groups we've
17 addressed today. Dr. Nag.

18 DR. NAG: I would like to know if, I know
19 there has been some problem between certified
20 physicists from the American Board of Radiology
21 certified physicists and I think the American Board of
22 Medical Physicists. Would this involve both or would
23 it resolve the issue for both or not? I'm not really
24 up to date with the two, but I know that there was a
25 controversy. Someone who is either a member of both,

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1 or not a member of either, I think should address this
2 position.

3 MR. IBBOTT: Well, I think I can address it
4 if you will. There are two answers. One is that we
5 are saying board certification without specifying ABR
6 or ABMP.

7 But the second response is that an
8 agreement has been worked out between those two boards
9 and physicists certified by the ABMP can request and
10 will receive a letter from the ABR stating that their
11 certification is equivalent to ABR certification. It
12 will be a time limited certificate and at the
13 appropriate interval, they will then be able to become
14 recertified by the ABR if they so choose. Otherwise,
15 they can become recertified by the ABMP. But the
16 boards have recognized the equivalency of the two
17 mechanisms, so I deliberately did not state which board
18 I was talking about. We consider them equivalent.

19 MS. HOBSON: I assume you've discussed this
20 proposal with NRC staff?

21 MR. IBBOTT: We have written to the NRC
22 staff.

23 MS. HOBSON: Right, have you had any
24 indication as to what their position might be?

25 MR. IBBOTT: Not to my knowledge.

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1 DR. CERQUEIRA: How's the motion coming
2 Jeffrey?

3 DR. WILLIAMSON: Oh, I'm working on it here.
4 It's three pages long, so.

5 DR. CERQUEIRA: Good grief.

6 DR. WILLIAMSON: It's hard for me to write
7 it down. I'm not nearly as good as our departed
8 colleague at this.

9 DR. CERQUEIRA: That's right.

10 DR. NAG: You're better on your computer
11 typing.

12 DR. WILLIAMSON: I'm better at just ad-
13 libbing it actually. Maybe I should just do that.
14 Well, I think the motion would read: ACMUI recommends
15 that NRC accept ABR or ABMP certification in radiation
16 oncology physics as prima facie evidence for satisfying
17 as many of the 35.51-B training requirements as
18 possible.

19 DR. CERQUEIRA: That doesn't -- it has to
20 translate into the boards, you know, the application
21 process that we talked about earlier.

22 DR. NAG: Yes, the three subcategories.

23 DR. WILLIAMSON: Okay, well we could make it
24 more --

25 DR. CERQUEIRA: But there seems to be a

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1 mechanism in place, although --

2 DR. WILLIAMSON: It's really sort of three
3 components to it, I guess. We've already had one
4 motion which endorses the idea of broadening the
5 grandfathering.

6 DR. CERQUEIRA: To grandfather it in in
7 three levels.

8 DR. WILLIAMSON: We need to have essentially
9 two recommendations. One recommendation would be that
10 NRC utilize a modality specific definition of AMP which
11 allows separate credentialing of teletherapy AMP,
12 remote afterloading AMP, and gamma stereotactic AMP.
13 That would be one component of the recommendation.

14 DR. CERQUEIRA: But shouldn't part of this
15 be incorporated as part of the board approval process
16 because in a sense that's what we're -- I mean, how
17 would that be -- I mean, we could make the motion.

18 DR. WILLIAMSON: No, this first part is
19 independent of the board certification to some extent
20 I think, the idea of having multiple modality AMPs is
21 not necessarily, I think, connected with the board
22 certification.

23 DR. CERQUEIRA: But it's a concept of --

24 DR. WILLIAMSON: The second component would
25 be is that I think to sort of iterate the essence of

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1 Geoff's proposal, you know, the basic idea is that:
2 ACMUI recommends that NRC accept ABR or ABMP
3 certification in radiation oncology physics as evidence
4 for complying with all of the requirements of 35.51-B
5 except the modality specific requirements not covered
6 by the board eligibility criterion, which is in essence
7 the various types of calibration. Would that cover it?

8 MS. McBURNEY: Rather than this being a
9 motion, could it just be kind of a consensus that we
10 support the idea outlined by Jeff?

11 DR. CERQUEIRA: Dick?

12 DR. VETTER: I agree. In fact, I think in
13 the material that was in our packet, I think it's
14 pretty well outlined, board certified physicist plus
15 demonstrating the modality specific training. It's
16 really well-outlined there and if we could simply
17 transfer to the NRC our consensus that we support this
18 concept, it doesn't have to be the exact words, this
19 concept. I think that would work.

20 DR. CERQUEIRA: I think consensus opinion is
21 probably right.

22 DR. WILLIAMSON: I think it would be
23 interesting to hear what the NRC reaction to this
24 proposal is.

25 MR. BROWN: Well I tried to operate by the

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1 standard. If I don't know what I'm talking about, I
2 shut up, and unfortunately in the room right now, you
3 don't have any of the people dealing directly with this
4 issue, so I can't offer you anything more than that.
5 I would observe that if the issue is trying to modify
6 the rule language for blanket recognition of the board
7 certification, that's more difficult than if how this
8 is implemented is as a standard acceptable for license
9 amendment request to add an authorized medical
10 physicist to a license which is quite simple and
11 readily amenable.

12 DR. WILLIAMSON: I think it's guidance for
13 identifying those physicists that comply with 35.51-B
14 that basically, if a candidate comes to you that has
15 one of the two specified certifications, you don't have
16 to ask them where they got their degree and what it was
17 in.

18 You don't have to ask them about their year
19 of training and their year of experience, because you
20 have already concluded that the board certification
21 adequately covers those requirements, and the only
22 additional ones you have to go after are those that the
23 board does not include.

24 So I think this is the idea and that the
25 idea is this would be something that exists in guidance

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1 space and would not require a reworking of the
2 regulatory language itself, which requires a rule-
3 making initiative which I think should be discussed
4 sometime soon, I hope, to rectify the problem long-
5 term.

6 So I guess what it would require is, is
7 that the boards would basically write to NRC and say
8 our requirements include this, this, this and this but
9 not this, and that could be used as the base by
10 radiation safety committees of broad scope licensees
11 for credentialing AMPs and I guess would be used by NRC
12 license reviewers in assessing the suitability of
13 applicants offered as authorized medical physicists
14 file license amendment.

15 DR. CERQUEIRA: The more you keep talking
16 about it, the more confused I'm getting here. Again,
17 I understand the point that you're making, but I'm not
18 certain why we shouldn't make this point for all the
19 other authorized users, whether it's physicians or
20 whatever. So and I think this is covered adequately
21 within the certification board review process. I think
22 that would get it into, you know, out there and
23 enforced much sooner than anything else we could do.
24 Dick, am I misperceiving it?

25 DR. WILLIAMSON: I'm not sure I understand

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1 your point.

2 DR. CERQUEIRA: I understand your points
3 though.

4 DR. VETTER: See I think one of the problems
5 is the way the language has been finalized. There's
6 nothing in the language that prevents someone from
7 becoming a qualified medical physicist or radiation
8 safety officer apart from being certified. Just fill
9 out all the paperwork. You send it in to the NRC and
10 you get approved. I think what Dr. Ibbott is saying is
11 that there is value in the certification process in
12 helping to assure safety of the medical use of
13 radioisotopes, because certification is one very strong
14 indication of competency, and the more competent our
15 physicists are, at least we would hope, the safer --
16 this is true for physicians as well, I assume.

17 DR. CERQUEIRA: See but that's kind of a
18 generic.

19 DR. NAG: I think one way or the other, for
20 the authorized user, for the radiation safety officer.
21 I think the only difference I can see here is that in
22 addition to you having a certification, they should
23 show competence in these three --

24 DR. VETTER: Right, and his proposal does
25 that.

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1 DR. NAG: Right.

2 DR. CERQUEIRA: Right, but the way to get
3 this through is part of the application process that
4 they've already initiated that we discussed this
5 morning. I mean, isn't that correct? I mean, David
6 help me out here? I mean, what am I missing?

7 DR. DIAMOND: Well, I was just laughing to
8 myself. Perhaps if the Society of Nuclear Medicine has
9 its way and this whole Part 35 rule-making is scrapped,
10 we have now learned some important lessons next time we
11 do this as to how to write these regulations.

12 DR. CERQUEIRA: Dick?

13 DR. VETTER: The problem that we have is
14 that the current language requires the board to certify
15 that the person has had the appropriate training and
16 experience. And the boards don't do that.

17 DR. CERQUEIRA: Well, they do in their
18 eligibility requirements and that's one of the things
19 that the board review process is looking at is they're
20 looking at the requirements for those candidates for
21 certification, and they're supposed to meet the NRC
22 requirements.

23 I know that the cardiology community
24 basically changed their rules to be in compliance with
25 the proposed changes. Now unfortunately, it's already

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1 been done and if it just doesn't go through, they're in
2 trouble. But Jeff, briefly, how am I going to, what am
3 I missing?

4 DR. WILLIAMSON: Well, I think three points
5 I'll try to make.

6 DR. CERQUEIRA: Quick points.

7 DR. WILLIAMSON: I think what you're saying
8 is why can't this comment be generalized or essentially
9 this recommendation of Dr. Ibbott's be generalized to
10 cover all of the various individuals that are mentioned
11 in the regulation.

12 Well, I think the first reason is, is aside
13 from the health physics certification, I think medical
14 physics has been the sort of only individual where it
15 appears that we definitely know for sure the board
16 certification process has failed to meet the NRC
17 definition. I think at this point in my mind, all I've
18 heard it's very cloudy.

19 DR. CERQUEIRA: Wasn't the discussion this
20 morning that we would basically break it down into
21 categories, and shouldn't that meet the board's
22 eligibility requirements?

23 DR. WILLIAMSON: Let me try to finish my
24 answer.

25 DR. CERQUEIRA: Okay.

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1 DR. WILLIAMSON: So that's one point. The
2 medical physics, the definition for authorized medical
3 physics very clearly does not agree with the board
4 eligibility requirements that exist now. There
5 probably is no practical way ever to make it agree
6 completely with those requirements due to the
7 demographics and how people enter the field and the
8 distribution of some of these modalities, which is
9 actually quite rare.

10 I think the second point is, is that board
11 certification is especially important to, I think,
12 quality of radiation medicine delivered because it's
13 sort of really the only credentialing tool we have. If
14 board certification in radiation oncology, you know,
15 ceases to have the significance that it does now,
16 that's not as serious I would argue because there is
17 the residency requirement, which is the sort of real
18 teeth of the regulation.

19 And again, due to the fact that residency
20 programs are a new concept in medical physics and do
21 not have the market penetration, it is not practical at
22 this time to insist on a uniform training experience.
23 So we really have to rely on the board certification
24 mechanism in order to weed out people, and it does have
25 teeth. It's rather difficult to pass in the sense that

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1 30 or 40 percent of those who take the exams flunk
2 them. So it is an effective tool I think.

3 I think those are really the two main
4 points. I've lost track of what the third is, so I
5 think the idea was to make -- the third idea is or the
6 third argument was, is that the fact that board
7 certification for physicists has been the criterion
8 used in the current Part 35, I think has been very
9 important in making it have the universality of
10 acceptance that it now has and the concern is, if it
11 completely disappears as a tool for selecting who can
12 be an authorized medical physicist, that they'll be
13 little motivation for physicists in the future to
14 become board certified and there will be an influx of
15 people into the field who do not have the certified
16 credentials.

17 DR. CERQUEIRA: I'm president of a
18 certification board, so I understand a need and a
19 concept of why we want to do it. I'm just not certain
20 how this committee's going to advance it. But tell me
21 what you would like to do and we should probably take
22 a vote and move on.

23 DR. WILLIAMSON: The proposal is that I
24 think this committee should pass a motion which
25 endorses the separate modality AMP concept and I think

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1 the second proposition I think this committee should
2 support is the idea that, even though board
3 certification at this time can not be accepted as sort
4 of the sole credential for getting through the process,
5 it should be utilized as much as possible in
6 determining who has satisfied the alternative pathway
7 requirements in 35-1B.

8 So, the board certification is not evidence
9 that the person has had specific experience in gamma
10 stereotactic, but it is evidence that the person has
11 the two years of training, the Graduate Degree.

12 DR. CERQUEIRA: See, that's just too many --
13 you got to make it simple.

14 DR. WILLIAMSON: What is your point?

15 DR. DIAMOND: The point is you made a very
16 good case just now that this is a special situation in
17 which there's a disconnect or dichotomy between
18 current training with respect to the board and what the
19 new regs have, a special case in that there's no
20 residency training so that the certification is really
21 integral, and number three, it's a special case because
22 it's the historic certification which has carried
23 weight.

24 So you made a very good argument with these
25 three points. How do we get these points over here and

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1 make it workable so for the next three years, we don't
2 have to spend a lot of time dealing with this?

3 MR. BROWN: I think that I suggest that
4 there was a proposal brought to the committee in the
5 form of the slides which will be part of the record.

6 DR. CERQUEIRA: Plus the letter.

7 MR. BROWN: And the letter. And I think if
8 the intent of the committee is to suggest to the staff
9 that we pursue this avenue to achieve a methodology of
10 getting authorized medical physicists into hospitals,
11 then you could simply so recommend to us and then we'll
12 work out the mechanism on how to make it work.

13 DR. WILLIAMSON: The recommendation is this,
14 that the NRC accepts board certification as having
15 satisfied all of the 31-1B requirements, except for the
16 specific experience with remote afterloading, gamma
17 stereotactic and Cobalt⁶⁰.

18 DR. MALMUD: I have a question.

19 DR. CERQUEIRA: Yes.

20 DR. MALMUD: Are there enough board
21 certified physicists to handle the clinical load
22 nationally or are we creating a possible obstruction to
23 patients getting care?

24 MR. IBBOTT: I don't believe there's any
25 evidence that there are not sufficient numbers.

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1 DR. MALMUD: But I was asking the other
2 question. Is there evidence that there is a sufficient
3 number?

4 DR. NAG: You have the alternative pathway.
5 The pathway is there. I mean, this is a way to
6 streamline or make it faster, so you don't have to go
7 through and examine every training requirement. If you
8 don't have a board, you can always use the alternative
9 pathway with equivalence.

10 DR. WILLIAMSON: I think one answer is, I'm
11 not sure if there's direct evidence, but certainly the
12 current regulation and the current licensing guidance
13 basically requires board certification as the sole
14 criterion essentially for being authorized to do all of
15 these things. So this represents actually a change
16 where board certification is no longer going to be used
17 as part of an assessment.

18 MR. IBBOTT: But Jeff, could I follow up on
19 that? At the moment, yes board certification is
20 recognized as that level of competency in practice. In
21 institutions that have say a gamma knife, a physicist
22 does get training administered by the manufacturer or
23 by a practitioner of that field that's acknowledged by
24 the manufacturer, and so does get some special training
25 in that field.

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1 So, I think the answer is that yes, we do
2 have people out there now who are meeting the needs
3 because there isn't a clamoring for four people. Now,
4 we're experiencing some shortages just like all other
5 medical specialties are, but the fact is that hospitals
6 aren't prevented from delivering these treatments
7 because they don't have qualified and experienced
8 medical physicists to calibrate the equipment.

9 DR. CERQUEIRA: I'm not sure we're going to
10 get consensus, so unless somebody feels very strongly
11 that we need to take a vote on it, I think we've gotten
12 information to the NRC staff. I also think, you know,
13 in terms of Dr. Malmud's point, we should get some
14 numbers. I mean, how many certified physicists are
15 there out there? How many people are currently
16 employed as medical physicists were certification would
17 be a necessity? That would give us some idea of the
18 numbers and the scope of the problem, and I think that
19 could be discussed at the spring meeting.

20 So, unless somebody feels really strongly,
21 I vote --

22 DR. WILLIAMSON: Well, I feel quite strongly
23 and I think this is a seminal point in time which, you
24 know, the role of physics board certification in the
25 regulatory process is really in doubt, and I think it

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1 would behoove this committee to send a strong signal to
2 the NRC staff that this is an important credential and
3 should be used.

4 DR. CERQUEIRA: Maybe let's go around the
5 room and just short comments in terms of whether you
6 feel we need to have sort of a motion or whether we
7 need more information.

8 DR. NAG: I felt that, the way the ruling
9 now addresses that and that's true for all the others,
10 I mean authorized user a board requirement is there and
11 all the others and we have an alternative pathway for
12 those who are not board certified.

13 DR. CERQUEIRA: Yes, Neki?

14 MS. HOBSON: Well, it seems to me that if we
15 endorse Dr. Ibbott's proposal, it would just hopefully
16 give it more weight when it's being considered by the
17 NRC staff and hopefully, eventually a commission. So,
18 I would agree with Jeff that I think it's something
19 that we could go on record now as being in favor of it.

20 DR. CERQUEIRA: As endorsing, okay. David.

21 DR. DIAMOND: As I suggested, I'm in favor
22 of endorsing Jeff's points.

23 MR. LIETO: Same.

24 DR. MALMUD: I agree.

25 MS. MCBURNEY: I too am in favor.

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1 DR. CERQUEIRA: All right. So, shall we
2 take a vote for endorsement?

3 MS. McBURNEY: Yes.

4 DR. CERQUEIRA: All in favor? Opposed?
5 It's unanimous, good. Thank you very much.

6 MR. IBBOTT: Thank you.

7 DR. CERQUEIRA: Any other new business
8 before we --

9 MR. BROWN: We are prepared.

10 DR. CERQUEIRA: To do?

11 MR. BROWN: To talk about the other subject.

12 DR. CERQUEIRA: All right, some people have
13 to jump ship momentarily, don't they?

14 DR. NAG: Yes, actually right now.

15 DR. CERQUEIRA: Okay, well maybe I think we
16 could let the three jump ship and then this is -- is
17 there any way we could send in the material?

18 MR. BROWN: We certainly can hand you what
19 we have.

20 DR. WILLIAMSON: What is the topic that's
21 being proposed, I'm sorry?

22 MR. BROWN: This is the follow-up to your
23 request this morning for information on recommended
24 treatment.

25 MS. McBURNEY: Medical update from accident?

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1 MR. BROWN: Accident, right.

2 MS. MCBURNEY: And non accidents.

3 MR. BROWN: Mark Sitek from our staff will
4 go through the slide. I'd like to just introduce the
5 topic by pointing out that within the NRC obviously, is
6 as you have pointed out to us quite often, we're not
7 involved with the practice of medicine or recommended
8 medical efficacy issues with respect to patients.
9 We're interested in radiation safety occupational
10 specifically, as well as to the patient from the
11 treatment.

12 So we don't have a large in-house medical
13 capability to make the sort of recommendations or
14 provide you directly with the information on how you
15 would treat citizens who came to you with specific
16 concerns or specific exposures. Having said that
17 though, we do have some things that we can share with
18 you, including who we think the best people in the
19 Federal Government to address the issue are.

20 So, I'm going to let Mark go through that,
21 and then I'll kind of wrap it up at the end by letting
22 you know how we intend to proceed based on your
23 concerns.

24 MR. SITEK: Again, my name is Mark Sitek and
25 I work for Fred. I quickly went through some of our

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1 internal documents and did a couple searches for other
2 Federal agencies or government entities that can offer
3 assistance. Internally, in one of our inspection
4 manuals, we have very brief and generic guidance on
5 when we recommend individuals exposed to radiation be
6 referred to a physician. This procedure is currently
7 under review, but as it stands now, we have basically
8 two group.

9 Group A, those women that are pregnant that
10 receive or are believed to receive in excess of 500
11 millirem, we recommend that they see a physician. The
12 second group is everybody else, men, children and non-
13 pregnant females when they receive greater than 5 rem,
14 we recommend that they see a physician, and these dose
15 limits are based on Part 20 dose limits. Five rem is
16 of course the occupational worker limit and 500
17 millirem is the limit for pregnant females.

18 MS. MCBURNEY: Question, this is a single
19 dose?

20 MR. SITEK: Acute, yes.

21 MS. MCBURNEY: Acute instantaneous.

22 MR. SITEK: Yes. And then if anybody
23 receives greater than 20 rem, we recommend that the
24 physician follow up with cytogenetic studies. But in
25 all cases when we refer it to the physician or ask the

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1 individual to see a physician, we recommend that they
2 contact REAC/TS which is through the Department of
3 Energy and is the Radiological Emergency Assistance
4 Center/Training Site, for those individuals are truly
5 the world experts in all aspects of assessing radiation
6 exposure and have the state-of-the-art and the most
7 current expertise on how to deal with and treat
8 internally, externally wounds associated with
9 radiological contamination.

10 Their web site is pretty good in providing
11 very general or generic guidance on how to treat
12 externally contaminated individuals, externally exposed
13 and internally contaminated individuals, but it does
14 not go into great detail on how to step through the
15 process like in a cookbook format. It doesn't say,
16 Step 1, administer 100 milligrams of potassium iodide
17 for example. It's just very general and provides to
18 some degree various drugs or blocking agents and
19 chelating agents that are in existence that can be
20 used.

21 This center is available 24 hours a day,
22 and like I said, they are the world experts and are
23 called upon all the time. They also provide training
24 to physicians on how to treat and recognize signs of
25 radiation.

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1 But the underlying message from them is,
2 these types of events and these patients should be
3 treated on a case-by-case basis, and if you don't know
4 what you're doing, then you should definitely contact
5 the experts, which in this case is this group of
6 people.

7 They also refer you to, there's a national
8 counsel on radiation protection and measurements report
9 which is #65 which goes into a little more detail on
10 the recommendations and on how to treat, and other
11 drugs that have been used in the past. But again, it's
12 also a very general and the overall recommendation is
13 to seek expert advice.

14 MR. BROWN: This obviously goes hand-in-hand
15 with the function that we have more directly, which is
16 in the event that there is either an industrial
17 accident or a terrorist event, we'll be working with
18 the other Federal agencies involved and key players,
19 the states, to make recommendations on protective
20 actions and over the course of the long-term,
21 decontamination of any exposed area.

22 So, that effort is actually right now being
23 coordinated through the Homeland Security Office and I
24 believe FEMA is the lead agency. So what we plan on
25 doing is to recommend to the commission and senior

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1 agency management that we forward to that organization
2 the issue that you raised, that the medical community
3 in general may expect to be asked about what are
4 protective action guidelines, what should they do if
5 they're directed to a physician. And so that we'll
6 propose that those branches of the government with the
7 lead on this be responsive, and then we'll keep you
8 informed as the ACMUI as we hear back to that need.

9 So, I guess I should first ask whether we
10 scratched your itch at all here, or if we're totally
11 off target.

12 DR. CERQUEIRA: I think this is a start in
13 terms of once again -- I think the point we were
14 getting at this morning again, is just some general
15 information. Again with the anthrax concerns, our
16 medical center has been having almost daily briefings
17 for staff and physicians on what knowledge do we have
18 about anthrax? What are some of the issues that are
19 going to come up? How do we treat it? And just try to
20 keep it very current with what's going on in the public
21 media, because that's what patients come in and ask
22 about.

23 So, the whole issue is, you know, obviously
24 sort of nuclear bioterrorism is a concern and how do we
25 sort of alert ourselves and the other physician

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1 communities. It sounds like REAC/TS is the group that
2 we need to go to. Leon.

3 DR. MALMUD: There is a rich literature on
4 the subject. It tragically evolved in the same way
5 that the literature for anthrax evolved. Anthrax came
6 out of the Swerdlovsk incident in the Soviet Union, and
7 our information has come from our own effort to close
8 World War II at Hiroshima and Nagasaki and then with
9 one or two radiation accidents that have occurred.

10 The individuals who would be involved in
11 treatment would be certain radiation oncologist,
12 environmental health and safety people, radiation
13 safety people. But then hematologists, burn
14 specialists and then the areas that are affected would
15 require intensive -- for patients who were subjected to
16 large radiation burdens externally but may or may not
17 be externally burned, they would have the typical
18 reaction of patients who got too much whole body
19 radiation, begin sloughing their gastrointestinal tract
20 and have bone marrow shutdown.

21 But there's rich literature on it. It's
22 not timely, fortunately, and we hope it will never have
23 to be timely, but it is available and I suspect it's
24 probably accessible through those numbers that you've
25 given us in that page. The data will be updated as the

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1 Federal Government gets to work on preparing us for
2 possible nuclear terrorism.

3 We have the largest emergency service in
4 the City of Philadelphia at Temple, and we've begun the
5 process of preparing for both biologic, chemical and
6 nuclear incidents. We're further ahead with biologic
7 and chemical than we are with nuclear because we wanted
8 to deal with those two first.

9 We would be remiss in a facility of our
10 size, treating the volume of patients that we do in the
11 city, not to be prepared for this as well. And I
12 suspect as you well know, that's why we have the itch.
13 I could respond to you that you did help scratch it a
14 bit. That list is very useful. Thank you.

15 MR. BROWN: Thank you.

16 DR. CERQUEIRA: Ruth.

17 MS. McBURNEY: For those, as I mentioned
18 this morning, for those facilities that are in the
19 vicinity of nuclear power plants, they are geared to
20 treating exposures and contaminated individuals from
21 the plant. But in the case of a large-scale attack,
22 you're talking about having to take people to higher
23 populated because most of the power plants are in lower
24 populated areas and having to go into bigger facilities
25 in the city, which may or may not have had the training

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1 to deal with that.

2 DR. CERQUEIRA: Ruth, or Neki?

3 MS. HOBSON: Aside from, you know, the
4 technical and professional problems that the medical
5 community would need to address, and maybe someone's
6 already done this, but there should be put together by
7 some very credible organizations a packet of basic
8 information on radiation and radiation exposures that
9 you can hand to the media and try to keep -- you know,
10 the media just goes hysterical and I think it would be
11 really helpful if we had that kind of information
12 available that we can just distribute to dampen that
13 hysteria a little bit at least.

14 DR. CERQUEIRA: Yes, I think that would be
15 very important, and obviously even if word got out that
16 some government committee had started asking about
17 these questions, then there would be concern it's
18 imminent.

19 But I think just having information is
20 useful, and whatever the NRC could do to come up with
21 it. Maybe, you know, the REAC/TS people seem to have
22 all the information but maybe it needs to kind of be
23 distilled and made available for the medical community
24 as well as for the general public. Certainly, I think,
25 that's within sort of the mission of this committee to

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1 advise you that that's a need, that people are going to
2 come to the NRC and to committee members in general to
3 address.

4 MR. BROWN: And we took our web site down
5 where we had some of that general information. So, I
6 guess the other option --

7 DR. CERQUEIRA: Well, if it was there, maybe
8 you could provide, I mean -- it wasn't closed because
9 of that type of information. So if that could be made
10 available, that would be useful.

11 MR. BROWN: I guess the other obvious
12 reference are the BEIRs studies to go back to the best
13 science as we know it for dose effect relationship, but
14 your point's well taken Dr. Cerqueira. I think that's
15 what we'll pass on.

16 DR. CERQUEIRA: Yes.

17 DR. MALMUD: The Soviet literature too from
18 Chernobyl.

19 DR. CERQUEIRA: Chernobyl, yes.

20 MS. MCBURNEY: The Conference of Radiation
21 Control Program Directors is putting together a sort of
22 a series of links or referenced web sites for the
23 general public and on different topics, one of these
24 being general information on radiation. Also, even
25 terrorism type links that they've -- anyway, I'm on the

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1 committee that's putting this together for public
2 information type information that people can go to to
3 find information on the various related -- you know, to
4 get information, general information on radiation and
5 radiation effects.

6 DR. CERQUEIRA: The information is there.
7 All these things that have been mentioned have all the
8 information, but it's not distilled in a form that can
9 be easily presented to, certainly to lay people or even
10 to medical physicians. Okay. Thank you, that was very
11 useful. Other new business? I guess the next meeting
12 is?

13 MS. WILLIAMSON: Before we discuss that, I
14 just want to mention to the committee members that if
15 I can get specific travel information and other
16 information. This is really committee business, more
17 than public business, but I just want to remind the
18 committee members that if I can get all of your travel
19 information, your professional pay information before
20 you leave, that will expedite the process of getting
21 those reconciled. So, if you can get those to me that
22 will be helpful to us both.

23 DR. MALMUD: Is there a standard form?

24 MS. WILLIAMSON: Yes. I might have to speak
25 with you and Mr. Lieto offline since you're new to the

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1 process, but the other members know exactly what I'm
2 talking about.

3 MS. McBURNEY: It's just the little expense
4 form, or do we need to have a voucher to sign as well
5 or would we be sent that?

6 MS. WILLIAMSON: Well, I thought -- if you
7 don't have both of the forms that you need, I can get
8 you both the forms.

9 MS. McBURNEY: Okay.

10 DR. WILLIAMSON: We might not have all of
11 the receipts and some of our expenses are yet to be
12 incurred, so it's sort of difficult to.

13 MS. WILLIAMSON: Okay.

14 MS. McBURNEY: Yes, the end of the night
15 tonight.

16 DR. WILLIAMSON: I think all we have to do
17 is fill out the simple form and give you the receipts
18 that are required, including the airfare information
19 and such, and then as I understand, your office
20 generates some more complicated voucher that comes back
21 to us and then we sign and then we send it back to you.

22 MS. McBURNEY: Is that right?

23 DR. WILLIAMSON: That's how it works.

24 DR. CERQUEIRA: Good, okay. So the next
25 meeting, I think everyone felt it was important to have

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1 the meeting with the commissioners which we tried to
2 schedule this time but were unable to do so. But, we
3 were supposed to meet in April and hopefully we will
4 have some resolution on Part 35 by then, the revisions.
5 We should probably get availability for the
6 commissioners in April?

7 MR. BROWN: We'll use April as a target to
8 work with the commission staff.

9 DR. CERQUEIRA: Okay, they can't project
10 that far I guess. I think otherwise first to try to
11 settle on a date without knowing when they're available
12 is futile and a waste of time.

13 Okay, any comments from the staff? Well,
14 then I'd like to thank everyone for coming and
15 participating and giving us their input. And I'd like
16 to again welcome Ralph and Leon to the committee and
17 hope they weren't too discouraged by this first
18 meeting. It gets better I think. And with that, we'll
19 adjourn. Thank you.

20 (Whereupon, the above entitled matter was
21 adjourned at 2:39 p.m.)
22
23
24
25

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