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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 MEETING

6 OPEN SESSION

7 + + + + +

8 Tuesday

9 October 28, 2008

10 + + + + +

11 The meeting came to order at 8:00 a.m. in T2B3
12 of White Flint 2. Richard J. Vetter, PhD, Vice
13 Chairman, presiding.

14 ACMUI MEMBERS PRESENT:

15 RICHARD J. VETTER, PHD, VICE CHAIRMAN

16 DOUGLAS F. EGGLE, MD, MEMBER

17 DARRELL R. FISHER, PHD, MEMBER

18 DEBBIE B. GILLEY, MEMBER

19 RALPH P. LIETO, MEMBER

20 STEVEN R. MATTMULLER, MEMBER

21 SUBIR NAG, MD, MEMBER

22 ORHAN H. SULEIMAN, PHD, MEMBER

23 BRUCE R. THOMADSEN, PHD, MEMBER

24 WILLIAM A. VAN DECKER, MD, MEMBER

25 JAMES S. WELSH, MD, MEMBER

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1 PRESENT: (cont.)

2 MICKEY GUIBERTEAU, MD, DIAGNOSTIC RADIOLOGIST

3

4 NRC STAFF PRESENT:

5 KIMYATA MORGAN BUTLER

6 CHRIS EINBERG, DESIGNATED FEDERAL OFFICER

7 CINDY FLANNERY, ALT DESIGNATED FEDERAL OFFICIAL

8 OSSY FONT

9 VINCENT HOLAHAN

10 DONNA-BETH HOWE, PHD

11 HARRIET KARAGIANNIS

12 DORIS LEWIS

13 ROBERT LEWIS, DIRECTOR

14 JIM LUEHMAN, DEPUTY DIRECTOR

15 ANGELA MCINTOSH

16 GRETCHEN RIVERA-CAPELLA

17 TERRY REIS, DEPUTY DIRECTOR

18 ASHLEY TULL

19 DUANE WHITE

20 RONALD ZELAC, PHD

21

22 MEMBERS OF THE PUBLIC PRESENT:

23 ROY BROWN, CORAR

24 TOM BURNETT, MDS NORDION

25 WILL DAVIDSON, UPENN

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1 PRESENT (cont.):
2 RICHARD EATON, MITA
3 LYNNE FAIROBENT, AAPM
4 EMILY GARDNER, ASNC
5 MIKE PETERS, ACR
6 DOUG PFEIFFER, AAPM
7 RICHARD MARTIN, ASTRO
8 REED SELWYN, UNIF SVCS UNIV OF HLTH SCI
9 HARRY SKENE, GEISINGER
10 ANN WARBICK-CERONE, MDS NORDION
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P-R-O-C-E-E-D-I-N-G-S

8:07 a.m.

VICE CHAIR VETTER Good morning, everyone.
My name is Richard Vetter. I'll be chairing the
meeting this morning. Dr. Malmud was called away on
a family emergency.

Yesterday was a long day for us, so if the
weather is any indication this morning, we're going to
breeze right through the agenda, but we do want to,
before we begin -- and let me explain, we will be
moving things around a little bit in order to pick up
those papers -- those presentations that we missed
yesterday. We'll deal with that as we go.

First, as you know, yesterday, we had a
presentation on the shortage -- the shortage of
medical isotopes and it was toward the end of the day
and we were all rather tired and we sort of left it on
the table after the presentations. So just to go back
for just five minutes, we would like to put a motion
on the table indicating our support of the issue.
Steve Mattmuller has the motion.

MR. MATTMULLER: Steve Mattmuller. "The
US moly supply for technetium 99 M generators
currently is extremely fragile. The ACMUI strongly
encourages the NRC to; one, continue supporting the

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1 exportation of H highly enriched uranium material for
2 Moly-99 targets used by international suppliers."

3 MS. TULL: Will you read the beginning?

4 Sorry.

5 VICE CHAIR VETTER Read it a little slower
6 and they'll type it as we go.

7 MR. MATTMULLER: Okay.

8 VICE CHAIR VETTER Why don't you just read
9 it and then give her the notebook?

10 MR. MATTMULLER: All right, and then
11 number two, "Provide all possible help towards the
12 development of US suppliers of Moly-99."

13 VICE CHAIR VETTER That's a motion. Is
14 there a second?

15 MS. GILLEY: Second.

16 VICE CHAIR VETTER Debby Gilley seconds.
17 Discussion? I don't think it's very controversial.
18 It's just basically saying we support continued use of
19 HEU and the -- encourage the agency to provide
20 whatever help it can in moving the issue forward. Dr.
21 Welsh?

22 DR. WELSH: We're saying that we're
23 encouraging the continued shipment of HEU for the
24 production of the moly which is a critical aspect for
25 us as medical practitioners that the technetium 99 is

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1 available but the HEU remains a concern and there have
2 been petitions put forth to encourage suppliers to
3 switch from HEU to LEU. It may not happen. It may
4 not be as easy as just asking for it, but I think that
5 we should continue to encourage that ultimately these
6 international producers use LEU rather than HEU.

7 VICE CHAIR VETTER Dr. Fisher?

8 DR. FISHER: I'd like to comment on that.
9 Earlier this year in May, I attended the Sixth
10 International Conference on Isotopes in Seoul, Korea.
11 There was substantial discussion of the production of
12 Moly-99 using high and low enriched uranium targets
13 and one of the most interesting comments made in the
14 opening plenary session by the representative from
15 South Africa, his laboratory name I can't quite
16 remember. His name is difficult to pronounce. But he
17 made the comment that although it's feasible to
18 produce Moly-99 using low enriched targets, it is not
19 commercially viable without substantial federal
20 subsidies.

21 You're looking at much larger costs to
22 produce Moly-99 using low enriched uranium for reasons
23 mentioned yesterday. It cannot succeed on a
24 commercial scale without substantial federal subsidies
25 from the host country.

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1 VICE CHAIR VETTER Other discussion? Yes.

2 DR. GUIBERTEAU: I know the --

3 VICE CHAIR VETTER Your name again,
4 please?

5 DR. GUIBERTEAU: I'm sorry, Mickey
6 Guiberteau. I'm a diagnostic radiologist
7 representative. I know there's a subtle difference
8 about this and to provide support for the development
9 of US suppliers of Moly-99. There are a number of
10 suppliers but the producers actually are overseas. So
11 having more suppliers doesn't necessarily help us and
12 I would like to see, perhaps, that word "supplier"
13 changed to "producers."

14 MS. GILLEY: Do you accept that as a
15 friendly amendment?

16 MR. MATTMULLER: I accept that, yes.

17 MS. GILLEY: I accept that as a second.

18 VICE CHAIR VETTER It's been accepted as
19 a friendly amendment to the motion to change
20 "suppliers" to "producers".

21 DR. GUIBERTEAU: Actually, I was thinking
22 in the second part, but both would be fine.

23 VICE CHAIR VETTER Other discussion? All
24 those in favor of the motion, raise one hand. One,
25 two, three -- it is unanimous? It is unanimous.

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1 Thank you very much. Okay, now back to the agenda,
2 we'll be starting on Tuesday, October 28th the agenda
3 beginning at 8:00 o'clock. We welcome Dr. Donald Cool
4 and then the 9:00 o'clock presentation by Cindy
5 Flannery will be cut from the agenda and we will deal
6 with that by teleconference. And then we will go
7 back, pick up Dr. Zelac's presentations from yesterday
8 and he will have those two presentations plus item 14.
9 So we'll have Dr. Zelac for three in a row.

10 And meantime, back to Agenda Item Number
11 1. Most of you have met or are -- or know Dr. Donald
12 Cool. If you've been on the committee long enough, he
13 was our boss for awhile and then since then, we've had
14 a couple of generations of changes. But in the
15 meantime now, he's back here to visit with us about
16 Revisions of the NRC Radiation Protection Requirements
17 and Potential Impacts to the Medical Community.
18 Welcome, Dr. Cool.

19 DR. COOL: Thank you, Dr. Vetter. Good
20 morning. Hopefully my voice will hold up with
21 sufficient volume for this discussion. Standing on a
22 rather cold wind-swept train platform as the MARC
23 commuter train system this morning decided to have a
24 little issue with a freight train which resulted in us
25 standing on the platform for over an hour is never

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1 good for your throat.

2 So it's been an interesting morning.
3 Things can only go up from there, I assume. So what
4 I'm here to talk about this morning for you is the
5 things that the NR staff is currently looking at and
6 considering and looking at the radiation protection
7 framework that the NRC has. Now, we talk about this
8 mostly when we do this as just Part 20, but there's
9 actually, of course, considerably more than that as
10 there are radiation protection criterion standards
11 sprinkled all through the requirements.

12 This process got started at the direction
13 of the Commission, this year following the publication
14 by the International Commission on Radiological
15 Protection, that's ICRP who published their revised
16 recommendations, Publication 103. Back in 2001, the
17 staff, the NRC staff, had gone to the Commission with
18 some options for whether to start proceeding to look
19 at Part 20 and other parts at that point. One of the
20 options that we gave the Commission was since we knew
21 ICRP was beginning to work on doing an update of the
22 revisions, we actually suggested to them that it might
23 be a nice idea this time around to wait for ICRP to be
24 done rather than doing like we did last time, get all
25 done with the rulemaking just as ICRP puts out a new

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1 set of recommendations and immediately being behind
2 the eight ball once again.

3 So the Commission agreed with that. The
4 Commission told us, however, not to work on any
5 technical basis and underpinnings, so we've just been
6 commenting on the ICRP draft as they took seven years
7 to do a document, almost as long as the rulemaking,
8 perhaps not quite. So we are not in the position to
9 start considering what to do next as a result of that
10 publication.

11 I will note to you that the International
12 Atomic Energy Agency is already in the process of
13 revising the international basic safety standards.
14 The European Union is in the process of revising the
15 Euratom basic safety standards. So internationally,
16 there are already moves to incorporate ICRP
17 Publication 103 into the regulations and requirements
18 that most of the rest of the world deals with.

19 So, we are taking a look at the
20 regulations. Our task is to provide the Commission
21 with options for consideration. That paper is due to
22 the Commission in December or due to the Executive
23 Director on December 15th and it goes to the
24 Commission shortly thereafter. We've been working
25 this with a senior technical group and a steering

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1 committee involving all of the offices of the agency
2 and we have started by taking a look at all of the
3 portions of the regs. Now, most of you remember when
4 we did the revision of Part 20, it came out in 1991
5 and you know, there were a whole raft of parts. It
6 was -- the actual CFR citation was 10 CFR Part 1920 et
7 al.

8 What was interesting about that was all of
9 those parts were cross-references. We, in fact, did
10 not at that point go and change regulations where
11 there were separate explicit criteria in place. They
12 were independent from Part 20. So there are, in fact,
13 portions of the regulations in particular some of the
14 things that the reactors have to deal with and the
15 reactor effluence in Part 50, Appendix I, some of the
16 things in Part 30, the low level waste criteria which
17 go all the way back to ICRP publications 1 and 2, the
18 maximum organ burden, maximum commercial concentration
19 values from 1959.

20 Though the might be just considered a wee
21 bit out of date, and in fact, the 800 pound gorilla,
22 the reactor power industry, has gotten just a little
23 bit frustrated with having to take all the bright
24 young HP's and physicists that come out of
25 universities and go back and teach them how to do the

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1 old calculations so they can actually continue to
2 demonstrate compliance.

3 As a result, there is a fair bit of
4 pressure around to do something, at least for those
5 portions of the regulations which are really, really
6 old and they would prefer to do everything in one
7 sweep and have everything come up to speed. So
8 there's a certain logic to that. And of course, the
9 reactors also have to deal with this little rule
10 called the backfit rule which means you have to do a
11 demonstration of whether or not there is an adequate
12 basis for change, whether the cost benefit is
13 appropriate. There's a lot of criteria that go into
14 that.

15 Some of that may come into play in terms
16 of adequate protection, which is the obvious way that
17 you could step forward with that, but there's also
18 issues about updating scientific information. A lot
19 has happened in the last 25 years. There are a number
20 of transboundary implications, some of which I'm sure
21 you are very familiar with. You're in fact, probably
22 the only folks that actually deal with SI units
23 because that's the only way you can export your
24 materials.

25 Achieving consistency in approach, workers

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1 are moving back and forth across borders, materials
2 are moving back and forth across borders. So there
3 are a lot of reasons that are floating around out
4 there to consider changes and updates. We are in the
5 process of developing this options paper. This slide,
6 because we needed to provide it to Ashley a month in
7 advance for you, is just a wee bit out of date in that
8 the regulatory options, the administrative options
9 part of the papers have now sort of been combined
10 together. I'll be talking about the sets of things
11 that we're considering.

12 So what are we thinking about? Obviously,
13 the first option could be to do nothing. That's
14 always an appropriate option. We're protecting public
15 health and safety. Things haven't changed
16 substantially. The risk coefficients from that which
17 were known in 1990 have not significantly changed. If
18 anything, they've come down a little bit. You might
19 want to put just a bit of a parenthetical in there.
20 The actual risk coefficients which underlie the
21 existing Part 20 come from ICRP Publication 26 in 1977
22 and those risks were actually predicted lower at that
23 time. So the risk estimates have come up to five
24 times 10^{-4} per rem fatal cancer risk from 1.25 times
25 10^{-4} per rem which is what the current Part 20 is

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1 based on. So again, you can make an argument that
2 there is an underlying basis for change should you
3 wish to do so.

4 The second option or actually a sub-option
5 of that, would be since the reactors have the really
6 burning platform, let the reactors work on doing some
7 updates and leave everything else alone. That
8 certainly isn't as resource intensive as trying to
9 attack the entire spectrum or we could start the
10 process of moving towards some degree of alignment
11 with the new recommendations and updated factors and
12 of course, you could just look at Part 20. You could
13 look at Part 20 and Part 50 or you could think really
14 globally and you could think about trying to take
15 everybody all at once.

16 Now, that's sort of an interesting
17 proposition. As you might guess, the amount of
18 resources necessary as you would step through with
19 each of these options, gradually climbs. You start to
20 think about what would be necessary to do all of the
21 different places and all of the regulations and all of
22 the correlated issues that would go along with that,
23 you would see that that is a really daunting
24 challenge.

25 Now, let's talk for a minute or two about

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1 some of the technical options. I will tell you at
2 this point that these are issues to be placed on the
3 table. That staff at this point has not firmly come
4 to a particular solution for each one of these
5 technical options. That is in part because we have
6 not been developing any technical basis. The
7 Commission was just see what ICRP was going to do
8 before we moved forward. So there is a lot of
9 information that remains to be needed in order to
10 understand the details, my slide went away, for these
11 -- for a number of these options.

12 Furthermore, some of the information that
13 we would need for this particular last item, the
14 numeric values which we'll talk about in a little bit,
15 is not yet available. ICRP in Publication 103 put out
16 new weighting factors for tissues, new weighting
17 factors for radiation. The next step in their process
18 is to go through and take that material and use the
19 new biological models for distribution of material in
20 the body, et cetera, updated information on the
21 physics of the different isotope decay change because
22 the nuclear data has been changing and go through to
23 calculate a new set of dose coefficients. That's what
24 you use to calculate annual limits of intake drive the
25 concentrations, that's what's in Appendix B.

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1 The first of those calculations, as we
2 understand it to this point, will be available in
3 2011. So that's like not now, that's not like not
4 even manana as in not today. It's a fair bit away.
5 So there are some things that we still need to wait
6 on. That, in fact, gives us, we believe, as the
7 staff, the opportunity now to pick back up from where
8 the Commission had told us to wait and watch to
9 consider looking at and developing a technical basis
10 and understanding the issues and implications that
11 would go along in our revision. This discussion with
12 you today is one of the starting points in that steps
13 in terms of what's on the table and what might be
14 appropriate.

15 So to quickly walk through these, total
16 effective dose, actually, from a Part 20 standpoint,
17 this would be an editorial change. Part 20 today
18 reads "total effective dose equivalent". Okay, so
19 they change the terminology a little bit. With each
20 of the succeeding generations they've updated the
21 tissue weighting factors, radiation weighting factors,
22 so the process of calculating it is a little bit
23 different. You'd get slightly different numbers.

24 But, in fact, Part 20 today already uses
25 the underlying concept of combining internal/external

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1 exposures into a single value that we'd use for
2 compliance and in fact, with a change that was final
3 in February of this year, effective dose can be
4 calculated from external exposures.

5 Some people have not actually picked up
6 that that provides a significant change. Instead of
7 it just being the badge on the lapel, the deep dose
8 equivalent, the dose measure that deploys the highest
9 exposure, it cannot be a calculation of effective
10 dose. So if you're an intervention radiology or
11 cardiology or doing a number of other things and you
12 have the lead aprons and other shielding, you can use
13 the two batching approach, some of the algorithms that
14 are out there. A number of those have, in fact, been
15 endorsed by the NRC and are available as regulatory
16 information summaries. All that's already in place.
17 So from a Part 20 standpoint, this could almost be
18 considered as editorial to bring the terminology up so
19 that when we talk the same language, we're all using
20 a consistent standpoint. This is the really big deal
21 with you look at some of the other portions of the
22 regulations such as Part 50 Appendix I because they
23 still talk about organ doses and whole body doses, and
24 of course, they would want to move to an effective
25 dose or effective dose. That's why this one is on the

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1 table because this would be the place where you would
2 finally get a consistency in the approach to radiation
3 protection.

4 Constraints, the biggest thing which
5 happened in the ICRP recommendations was an increased
6 focus upon the process of optimization, we call it
7 ALARA. They also use the phrase ALARA, and the use of
8 what they refer to as constraints as a boundary in the
9 optimization process. Now, as ICRP lays this out, a
10 constraint is any value that you would use in the
11 planning of your program and your activities to help
12 decide what protection options were viable or not
13 viable. It helps make sure that you don't actually
14 approach the dose limits. It helps make sure that if
15 you have multiple sources of other activities, that
16 the combination of those two would not result in
17 receiving the dose limit but a constraint as
18 envisioned by ICRP is not a dose limit. It's a
19 planning value, the value that we'd use in setting it
20 up.

21 So in fact, as the process of developing
22 their recommendations went along, it got fairly clear
23 differentiating what they consider to be a constraint
24 from that which we would consider as a limit, where
25 the Office of Enforcement comes down and bangs a

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1 hammer over your head.

2 Now, in fact, Part 20 today has the word
3 "constraint". It's defined as a value which requires
4 some licensee action. Very nice, okay. There is, in
5 fact, a constraint already in Part 20. Most of you
6 sort of have to live with it at least because it
7 applies to the airborne effluents from a material
8 facility. It was put in place as a result of some
9 rather interesting negotiations with our friendly
10 Environmental Protection Agency on the Clean Air Act.
11 It has a numeric value at 10 milirem.

12 The requirement is if you set to exceed 10
13 milirem, you need to figure out what to do. You need
14 to try and bring those effluents back in. It also
15 requires a report to the NRC. But simply because your
16 effluents went over 10 milirem, doesn't mean it's a
17 violation. It's only a violation if you don't do
18 anything about it.

19 So the staff consideration on this in the
20 occupational exposure area, would be do we consider
21 putting in a requirement that licensees use such a
22 concept in their programs? Now, the reality is most
23 programs of any significant size and complexity
24 probably already have planning values, reference
25 values, action levels, a variety of different things

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1 that you would have in your system which are less than
2 the limit that you're using for planning, that you're
3 using as targets as part of your process. So if the
4 Commission were to put in a requirement like that,
5 that would be exactly what you would use. There would
6 really not necessary need to be any particular change.

7 On the other hand, we know that there are
8 some folks around for whom this is not a concept of
9 his employ, industrial radiographers form an example,
10 and so there is the possibility that adding this
11 structure to the requirements would help to improve
12 radiation protection, would help to improve ALARA,
13 would help to reduce the top end of the dose
14 distribution, those within the occupational system
15 that are getting very high exposures.

16 So this is a consideration. It's a
17 consideration, do you put in such a requirement and
18 then do you put in a numeric value for it or not, or
19 do you simply say that they have to pick one and it
20 has to be less than the limit? So there are some
21 possible implications there. Obviously, the impact
22 would depend on how you wrote it. That's one of the
23 issues that we're seeking feedback on.

24 That correlates to the next issue which is
25 the dose limits. The United States is the only

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1 country in which the occupational dose limit remains
2 at 5 rem per year. Everyone else has gone to either
3 a 10 rem over five years which is an average of two
4 rem per year with a caveat of a maximum of five in any
5 one year. So you could have five, then you'd have to
6 be substantially less in any five-year period, or
7 they've made it simpler and they've gone to a straight
8 two rem per year.

9 We are an outlier from the standpoint of
10 where our occupational dose limit is at. So a
11 question clearly on the table for consideration is
12 whether the NRC should, in fact, move to change the
13 occupational dose limits. We could do nothing. We
14 could leave it at five and we could sit here and argue
15 probably with a perfectly straight face, no, ICRP has
16 said maximum of five in any year. We have five,
17 what's the problem? In fact, the average dose in most
18 of the occupational categories is down in the few
19 hundred milirems range. So if you change the dose
20 limit would you actually change the average for
21 occupational exposures? Probably not.

22 Would you change the upper tail of the
23 distribution? Absolutely, because we know that there
24 are people that are getting over two rem per year in
25 each of the categories, reactors, medical,

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1 radiography, you name it, you've got some distribution
2 up there. We are right now looking at a draft NCRP
3 update in Publication 93. There has been some
4 discussions here and there. I will tell you that that
5 says that there's actually more people above that two
6 rem number than you might have suspected and in more
7 job categories. Maybe that doesn't surprise you,
8 maybe it does. But you could leave it at two.

9 You could move -- leave it at five. You
10 could move to a straight two, very simple,
11 straightforward, record the doses. Of course, that's
12 reducing the dose limit by a little over a factor of
13 two, goes from five to two and the screaming starts
14 ensuing. How can you possibly do that? Look at all
15 of the impact. What are we going to do with all these
16 people? You're impacting patient care. We can't do
17 the procedures and on and on and on. Okay.

18 The third possibility, of course, is what
19 the actual recommendation is, make it 10 rem over five
20 years, a maximum of five in a year. It has a little
21 more flexibility, has potentially a lot more burden in
22 terms of record keeping and otherwise, because you'd
23 have to go back to collecting dose histories and
24 keeping track of people over five year terms to figure
25 out how much you can have this year, Dr. Vetter,

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1 because you got five last year. So you can't have
2 nearly that much this year, but, you know, Dr. Van
3 Decker, oh, he's good. He only had minimal on his
4 badge, so he's good to go. So it would make for much
5 more complication and impact on the system.

6 Again, this is an issue which we want to
7 explore with you and the other licensee categories to
8 try and understand the impacts and implications of the
9 proposal. As I said, this needs to be considered with
10 the concept of constraints because constraints from
11 one mechanism to move the top end of the distribution
12 of doses down, moving the dose limits is the second
13 level.

14 Now, if you really want to do it up right,
15 you can move the dose limit to two and then tell them
16 to set -- tell licensees to set a constraint lower
17 than that because that's sort of the way to maximize
18 the impact on licensees if that's what you wanted to
19 do. On the other hand, you could deliberately set a
20 numeric value of a constraint at two rem per year or
21 something less than that and effectively require
22 licensees to take some actions to get their programs
23 so their people were not exceeding two rem and not
24 necessarily have to move the limit off. This is part
25 of what we want to try and explore.

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1 Public exposure; current recommendations
2 is 100 milirem per year. Part 20 is 100 milirem per
3 year. Actually, not much of an issue here, except
4 where you're talking about the dose of the
5 embryo/fetus or perhaps young children. Occupational
6 dose provisions have a provision for a dose limit of
7 the embryo/fetus upon declaration of pregnancy. Right
8 now that sits at 500 milirem per year for the
9 gestation period, which means that when the individual
10 declares her pregnancy, you have to go back, assess
11 what has been the dose to the embryo/fetus already,
12 figure out how much is left, put it in the control
13 program. It's actually a potentially complicated
14 process. ICRP's recommendations now are actually a
15 bit simpler. They've said 100 milirem per year. They
16 want to have protection equivalent to that of a member
17 of the public, but their recommendation actually is
18 make it 100 milirem per year and make it from the
19 standpoint of which the individual makes known her
20 pregnancy, in our legal parlance, as in the
21 declaration.

22 Now, as you can immediately deduce,
23 depending on when she decides to declare, a provision
24 for 100 milirem from the point of declaration for the
25 remainder of the gestation period could be more

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1 protective, or less protective. Of course, the woman
2 has the option to not declare at all. It's not a
3 matter that it may be very visible at eight, nine
4 months she has the right not to declare. So this is
5 a protection that's provided at that standpoint, but
6 again, there are a couple of options. They do pose
7 differences in terms of protection.

8 One of the things that you might even toss
9 out is well, okay, they've said 100, maybe we should
10 pick some slightly less value so that we know that
11 even if the individual declares a little bit later on
12 in the pregnancy that there's less of a chance for the
13 dose to the embryo/fetus over the entire gestation
14 period to have exceeded 100 milirem. So again, there
15 are a variety of options that we want to try and look
16 at and consider what the implications are.

17 As I already mentioned, there are numeric
18 weighting values, the tissue weighting factors, organ
19 weighting factors are already available. The
20 calculations per dose coefficients, annual limits of
21 intake drive their concentration are not yet available
22 and we will have to await those. So what are the
23 administrative possibilities? We could begin
24 rulemaking activities now. We could pretend that we
25 know enough and start the process and work on

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1 developing the information as we go along in a
2 rulemaking.

3 Of course, there's a couple of problems
4 with that. We don't like starting a rule without
5 really having a technical basis and it's not all that
6 good to say you've started a rulemaking when you
7 really still need to understand issues and
8 implications on some rather important issues. You can
9 delay the discussions and continue to work on the
10 basis of interactions. That's what the staff believes
11 is an appropriate approach. Do not say, we're going
12 to initiate rulemaking but rather to start by saying
13 we believe that it's appropriate to start moving
14 towards considering some greater degree of alignment
15 and we need to spend the next two to three years at
16 least because some of the technical information is
17 going to be available in that time, understanding and
18 vetting out working with the various constituencies so
19 that when we get to that point, there is a better
20 understanding of the issues and implications so that
21 you can write a statement of considerations, a
22 regulatory analysis, backfit analysis, and all of the
23 pieces that would be necessary to go along with the
24 rule.

25 Obviously, you can package these still as

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1 Part 20, Part 50, all the parts. I'll tell you
2 frankly at this point, the resource implications of
3 trying to go do everything are really, unless somebody
4 found an enormous quantity of money, too much to
5 really consider. So the staff at this point is
6 looking at ways that this could be packaged since
7 there is not an unlimited amount of resources, since
8 there are a few other things that the Commission would
9 like us to do in rulemaking besides just this over the
10 next few years, security for example.

11 So some points to ponder. There changes
12 can be very significant. As Debby, I think would
13 certainly agree with me, what we start to do here
14 will, because of the adequacy and compatibility
15 considerations, also need to be looked at by the
16 states. The states, in general, don't like to have
17 different sets of regs for different portions of
18 radiations that they regulate. So the reality is that
19 we need to, from the get-go consider the implications
20 of some of these major issues all across the board,
21 all across the activities, all across the types of
22 radiation because this will be a move to try and
23 realign our framework and in fact, the US Federal
24 framework. The staff is also working with the
25 Environmental Protection Agency, the Department of

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1 Energy, Occupational Safety and Health Administration
2 to try and look at using this as an opportunity over
3 the next few years to move everyone back in the
4 consistent framework. You can probably say I'm crazy
5 and I should get a drug test because I've obviously
6 been smoking something. That might be true, but
7 that's what we would like to try and do, but there are
8 major implications. There's lots of effort that's not
9 part of the rulemaking. There's all sorts of
10 guidance. There's computer code activities and all
11 sorts of other things, particularly in the reactor
12 side of the house because all of those codes are still
13 on ICRP 2 type methodology.

14 That's going to take a bunch of time to do
15 the development, V&V and everything necessary for a
16 licensee to actually demonstrate compliance. The
17 reality is that being able for licensees to have the
18 materials necessary to comply is probably out 2014,
19 2015, 2016, even if you start some of this work today.
20 The technical basis is it is still working. When will
21 we have enough to move forward? Is it the ICRP dose
22 coefficient the first set, the most common
23 radionuclides, most of what we use, we expect some
24 time in 2011.

25 Some of the more esoteric things in the

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1 complete set which corresponds to everything that's in
2 Appendix B right now, probably won't be available
3 until maybe 2014. To do we wait all the way to '14 to
4 start? Is there a mechanism to try and start some of
5 it earlier and catch up some of the other pieces?
6 That's another one of the implications. How do we
7 gauge benefits and impacts? How do we best figure out
8 what is the right combination of things here for
9 protection.

10 We're providing adequate protection today
11 but we know we want to update scientific information.
12 We want to update calculation about -- how do you go
13 about packaging and understanding what all those
14 implications are around such a diverse set of
15 activities from the things that you have and the whole
16 diversity that you have to the reactors to the new
17 reactors, to gases diffusion plants, all the other
18 facilities?

19 And with that, that's a quick synopsis of
20 where we're going and I will be glad to entertain
21 questions. Thank you very much, Dr. Vetter.

22 VICE CHAIR VETTER Richard Vetter, Chair.
23 Thank you very much, Dr. Cool, for that very clear
24 presentation, laying out the issues for us. If I may
25 ask the first question, how do you plan to solicit

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1 stakeholder input in this process very early on in
2 order to stimulate, perhaps, some people in the
3 licensed community to do some research, collect data
4 and so forth that might be useful to you?

5 DR. COOL: A very good question. Step one
6 is to get the options paper to the Commission and have
7 the Commission and have the Commission actually agree
8 that we can do this. That's actually not a given.
9 Although we would think this is -- it might seem very
10 reasonable, the Commission needs to tell us to do
11 that. Presuming that would happen, we would then
12 start to use special society meetings. I've already
13 been talking with a number of the folks to try and get
14 a least placeholders for various medical communities
15 that otherwise we would be looking to try and perhaps
16 establish some convened facilitated discussions around
17 particular licensee groups.

18 I would actually hope that we could use
19 your committee and the context that you could generate
20 to start to engage in some of those to come and talk
21 with some of your particular subsets and specialties
22 to do a presentation like this with some of the issues
23 to get them thinking. The process that we're thinking
24 about is actually to use the first six, nine months in
25 a first round to get people really thinking, asking

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1 the questions and asking them what are your questions
2 and issues? What else is out there? I mean, this
3 presentation has been at 50,000 feet. The details are
4 always in the detail. Now, all those issues in there,
5 what are the implications? Get people thinking about
6 it and engaging the second round a little bit later
7 this year and into the early part of next year to
8 bring people set back and say, "Now that you've
9 thought about it," to do some iterative interactions
10 because we have enough time to do that process to be
11 able to build the information.

12 With Commission agreement, the staff I
13 think also will look to try and update some of the
14 information that is available. There was, for example
15 a NUREG that was done in the mid-`90s which took a
16 first look at the implications of moving from five rem
17 to two rem. We would probably ask our Office of
18 Research to move to contract to do an update on that
19 so there would also be other mechanisms that were
20 being use to develop the materials.

21 VICE CHAIR VETTER Thank you. Dr.
22 Suleiman?

23 DR. SULEIMAN: Yeah. First of all, I want
24 to commend the NRC for actually approaching this. I
25 think it's long overdue. I'm always embarrassed --

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1 M. GILLEY: So am I.

2 DR. SULEIMAN: -- speaking we're so far
3 behind the times. I think, you know, you're still
4 using the 1977 effective dose equivalent, you know,
5 metrics. I don't see it as gloom and doom as you do
6 because I don't think these numbers ultimately are
7 more than one significant figure in terms of accuracy,
8 I mean, when you look at the underlying risks.

9 DR. COOL: I very much agree with you.

10 DR. SULEIMAN: Okay, number 2, it's
11 something we've done at FDA on a hit or miss basis but
12 you may want to adopt by reference scientific
13 standards, in other words, some of the dose weighting
14 metrics, you don't necessarily need to codify that as
15 a regulation. Maybe say you use the most current ICRP
16 published tissue weighting factors or whatever in
17 terms of calculating the dose so you adopt some sort
18 of standardization. Recognize that the rest of the
19 world understands the science.

20 We participate in these meetings, you
21 know, with the ICRP and other organizations as well.
22 Then you don't have to go ahead and publish a whole
23 set of you know, metrics and even if there's newer
24 data, five years from now, it's probably not going to
25 be a whole lot different. You know, science is

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1 science. Physics is physics. Some of these dose
2 constants get revised, but they're not going to change
3 dramatically.

4 So I wouldn't use that as an excuse to
5 hold up the process. The five-year business, we used
6 to keep track for lifetime, so I don't think that's a
7 -- that's a big challenge. Having been trained
8 originally as a health physicist and being very aware
9 of the doses, I think going to two and this is the
10 more philosophical thing, probably won't impact on
11 most facilities, most users, but it will impact, I
12 think on the occupational group that's pushing the
13 five rem or the 50 miligray, you know, limit.

14 So I think that's an important concept to
15 go through but I think -- again, I think there's a
16 need to standardize with the rest of the world that
17 it's embarrassing for me, many, many -- I mean, 10, 20
18 years ago I was told by my colleagues overseas saying
19 that we don't even bother with the old units, and here
20 we are 20 years later still doing that. So I think
21 it's an important move. I think there are some places
22 where you can be much more efficient in how the
23 process goes and clearly, you open it up with the
24 stakeholders, but I think rather than just have this
25 ongoing endless dialogue, if you were to plan it in

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1 such a way, you could probably have done it a whole
2 lot more efficiently and with -- we're not reinventing
3 everything from scratch. I think most of this
4 information is out there.

5 DR. COOL: Two notes, if I could, Dr.
6 Vetter. First, I should probably have you talk with
7 our colleagues in the General Counsel's office.
8 Legally, according to the Federal Register and the
9 Administration Procedures Act, as I understand it, we
10 cannot incorporate by reference that which has not
11 gone through an Administrative Procedure Act process.
12 Because the ICRP recommendations and the dose
13 coefficients are not a public commented process, we in
14 fact, cannot at this point simply do as you suggested,
15 although I would love to do that and simply reference
16 the latest set of values that have been done by the
17 ICRP.

18 I would not with quite interest, that is
19 exactly the approach the International Atomic Agency
20 is currently talking about for the international basic
21 safety standards but legally, we're not allowed to do
22 so.

23 VICE CHAIR VETTER Ms. Gilley?

24 MS. GILLEY: Debby Gilley. I just wanted
25 you all to be aware of the 35 agreement states. To my

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1 knowledge, they do not treat occupational exposure
2 from x-ray sources and material sources any
3 differently. So the impact of this particular change
4 in these occupational dose limits will have impact on
5 all medical users, the individual radiologist and some
6 of the other ones that we typically see have a little
7 higher occupational doses than some other activities.
8 And it's something to be very conscious of as we go
9 forward. We don't treat them differently.

10 VICE CHAIR VETTER Dr. Fisher.

11 DR. FISHER: Yeah, Don, you did a really
12 nice job of summarizing the main issues. I think this
13 50,000 foot perspective is really quite good to have
14 at this time and you've certainly keyed in on the key
15 issues. The NRC has, I think, been wise not to try to
16 change regulations with every new ICRP publication.
17 It's like trying to shoot at a moving target and just
18 as sure as there's an ICRP 103, there will be in a few
19 more years another set of recommendations slightly
20 modified from those that we have today. I mean, and
21 the NRC just can't be jumping each time NRC comes out
22 with a new set of regulations. But I do agree that
23 it's time for an update and it will require an immense
24 amount of work.

25 One thing to keep in mind as a member of

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1 this committee is that the concept of effective dose
2 does not apply to medical patients and you spoke to
3 this -- the new concept of constraints. Constraints
4 for public exposure would generally be those under the
5 ICRP 103 philosophy, would usually be those that are
6 set by the regulator. However, constraints for
7 occupational exposure would be those that would be
8 established by individual licensees with guidance from
9 the NRC or the states. And I think if you're going to
10 strictly follow the new recommendations, you certainly
11 recognize that there's a difference between dose
12 limits and regulated dose constraints. That would get
13 you in some difficult areas.

14 I think the scientific evidence for -- the
15 scientific rationale for moving from a five rem to a
16 two rem annual dose limit is pretty well justified and
17 would not greatly impact on most licensees. It could
18 be challenging for some occupations, those that
19 receive the highest dose during nuclear power plant
20 operations upgrades, maintenance, operations, I mean,
21 those are the -- so it will have some impacts on
22 select occupations and -- but for the purposes of
23 planning occupational exposure, even a five rem annual
24 dose limit provides a substantial level of protection.
25 I think we all need to recognize that.

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1 So I won't say anything more than that,
2 but I commend the NRC for its, in one sense, lack of
3 action over the years, as it carefully evaluates these
4 options and also the planning to update regulations to
5 be more consistent with international guidance.

6 VICE CHAIR VETTER Yes, Dr. Cool.

7 DR. COOL: For everyone's benefit, Dr.
8 Fisher mentioned quite correctly the constraints in
9 the context of public exposure and you're correct, and
10 ICRP 103 and generally viewed that in the public
11 exposure area constraints are usually due to something
12 that a regulatory organization would more likely set.
13 The staff, in looking at this, has looked at the
14 variety of things that are already out there because
15 there are, in fact, not constraints but other limits
16 and requirements that are in place for most every kind
17 of facility from decommissioning to a variety of
18 things, such that the staff's view at this point is
19 that there would not be a need for the agency to put
20 yet another layer of constraints that the regulatory
21 structure in place today already has the function of
22 constraints with Part 20 and a limit and other limits
23 in other places, the regulations serving as de facto
24 constraints and other restrictions on public dose.

25 I would also note just for all of your

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1 benefit, the concept of the constraint is not
2 applicable to medical exposure according to ICRP. You
3 have to deliver that which is most appropriate for
4 your patient. So that concept as the limits simply
5 would not apply in the actual treatment of the
6 patients. This would be dealing with the occupational
7 individuals doing the work, et cetera. Thank you.

8 VICE CHAIR VETTER Ms. Gilley?

9 MS. GILLEY: I just wanted to ask some of
10 the radiation safety officers in the room, are you
11 seeing some of your individuals approaching five rem
12 per year or is this -- some of you deal with both
13 interventional radiologists and all that and I'm
14 getting mixed emotions from my state as to whether how
15 difficult this will be for some subsections of the
16 medical community to be able to be in compliance with
17 this.

18 VICE CHAIR VETTER Well, Richard Vetter.
19 As the radiation safety officer representative and a
20 radiation safety officer, I could give you my reaction
21 to the question which is that it's not uncommon at all
22 for a few interventional radiologists to well exceed
23 five rem to the badge. Now, they are covered in lead
24 and so the debate we get involved with, with the state
25 is what protection factors can we apply to the badge

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1 reading.

2 But I mean, it's clear -- and if you put
3 too much pressure on interventional radiologists about
4 that they simply forget their badge in their desk
5 drawer because to them, the number one priority for
6 the day is the patient. And many of them, they don't
7 care what they're getting. I mean, they certainly are
8 using proper protective equipment but they're not
9 worried about that badge reading, they're worried
10 about their patient.

11 So it is an issue in interventional
12 radiology and one other issue is, I'm not arguing one
13 way or another on this, I'm just saying that it's
14 important to get stakeholder feedback on this, Dr.
15 Cool, that the average nuclear medicine technologist
16 gets two, 300 milirem a year. If you set a pregnancy
17 limit of dose to the fetus of 100, you know, you can't
18 expect them to be wearing lead aprons all day. That's
19 simply not very effective. So the point I want to
20 make is stakeholder input on this issue is going to be
21 very, very important.

22 MS. GILLEY: May I ask one more question?

23 VICE CHAIR VETTER Yeah.

24 MS. GILLEY: Do you do the weighting
25 factors that described in one of the NCRP publications

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1 for your individual radiologists where you wear a
2 badge under the apron and a badge at the collar?

3 VICE CHAIR VETTER We would certainly like
4 to utilize the weighting factors in NCRP 122.

5 MS. GILLEY: 122, okay. But you don't --

6 VICE CHAIR VETTER But not all states
7 allow that, that's the point.

8 MS. GILLEY: Thank you.

9 VICE CHAIR VETTER Mr. Lieto?

10 MR. LIETO: Yes, Ralph Lieto. To answer
11 Debby's question, most certainly interventional
12 radiology, cardiology areas are going to exceed two
13 rem in a year. It's almost a given, especially in
14 teaching programs as the -- where fellows are learning
15 the trade. It's expected, almost, that they're going
16 to approach that five rem in a year, so in terms of
17 the highest reading to the badge. So I think that
18 definitely needs to be taken into consideration.

19 MS. GILLEY: I was going to ask you if you
20 used the weighting factors that are described in NCRP
21 122.

22 MR. LIETO: I'm from Michigan, no. The --
23 to just as a follow-up on DR. Vetter's point about
24 pregnant occupational workers, as we see increased use
25 of the PET radiopharmaceuticals, you're not going to

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1 be putting lead aprons on these women. It's
2 absolutely useless. And so we are seeing that in
3 busier departments, especially cardiology with
4 cardiology use be a predominant type of procedure and
5 the large activities that are used there, you can
6 almost expect that a pregnant technologist is going to
7 exceed 100 milirem over the gestation period. So it's
8 -- this is going to be very problematic to go down to
9 100 milirem for these individuals, whether it's
10 declared or not in the situation.

11 But the -- I have a question for you, Dr.
12 Cool. Correct me if I'm wrong. In your discussion
13 about the total effective dose, you were mentioning
14 that the NRC has come out with a regulatory issue
15 summary about wearing multiple monitors and taking
16 into account -- or using weighting factors for the two
17 dosimeters for coming up with an effective dose.

18 My understanding is that those weighting
19 factors are based -- in order to use those, they're
20 based on ICRP weighting factors from ICRP Report, I
21 think, 26 or whatever, but my understanding is that
22 those factors have to be approved by the lead agency
23 for dose limits which is the EPA. So to change the --
24 to change those factors, it requires a change by the
25 EPA to approve those weighting factors and dose limits

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1 as a national standard or am I -- have I got something
2 that's off base here?

3 Because my premise on this is we were
4 looking at trying to get our state to adopt this and
5 one of the issues that came up with adopting the more
6 recent weighting factors, is that one of the leading
7 monitoring companies said that the national standard
8 for these weighting factors is based on the values set
9 by the lead agency for setting these limits which is
10 the EPA.

11 DR. COOL: Okay, it's in one sense more
12 complicated, in one sense more simple. EPA certainly
13 has federal guidance which is available. There is the
14 federal guidance itself for occupational exposure and
15 then there are various federal guidance reports, which
16 have all sorts of dose coefficients specific for the
17 US. Those are guidance to the federal agencies. It
18 is not a legal mandate that the NRC use the EPA
19 values. In fact, you will find that the values that
20 are in Appendix B are not exactly the same as the
21 values that are in EPA Federal Guidance Report 11.

22 What I suspect and whomever it was, was
23 telling you, was that the current weighting factors in
24 the NRC regulations are ICRP Publication 26. The
25 weighting factors upon which the formulation for this

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1 two-batch calculation are actually ICRP 60. The NRC
2 actually recognized those as valid for use for
3 external exposure. So yes, we have validated
4 something making us inconsistent.

5 There is already at least one article out
6 in the Health Physics Journal which has updated some
7 of those formulations to use the new ICRP 103
8 formulations. Part of what we would be looking to do
9 as part of this process would be to try and move and
10 hopefully be able to endorse, adopt a system that
11 would be based on the most recent set of weighting
12 factors. But what you have today based upon the NRC
13 regulation, now, and our regulatory information
14 summaries would allow you to calculate to badge
15 effective dose and it would actually be using
16 weighting factors that come from 1990 ICRP Publication
17 60.

18 VICE CHAIR VETTER Okay, try to get the
19 discussion back up to the 50,000 foot level and Dr.
20 Cool's presentation. DR. Thomadsen.

21 DR. THOMADSEN: Well, I would -- before
22 you go back up, while we're in the nitty gritty, I
23 would like to give a different opinion than the two
24 that have been given. We do use two badges and we
25 have no problem, we would have not problem with

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1 keeping our interventionalist, our cardiologist or
2 anybody below the two level. They don't come close.
3 They don't come close.

4 DR. COOL: Because you're calculating
5 effective dose.

6 DR. THOMADSEN: That's exactly correct.
7 That's exactly correct. So that would not be a
8 problem if you guys could come out of the Dark Ages in
9 the states. The -- I agree fully. Well, Michigan has
10 quite ways to go. I'm from Michigan. I agree fully
11 with Ralph. I don't remember if DR. Vetter had also
12 said that, that the pregnancy limit for nuclear
13 medicine technologist would be a problem for that to
14 be lower. There isn't much you can do about that.

15 VICE CHAIR VETTER Okay, other questions?
16 We have a question from a member of the public.
17 Please identify yourself.

18 MR. PFEIFFER: Doug Pfeiffer with AAPM.
19 Thank you very much. First I would like to echo what
20 DR. Thomadsen just said. That is also my experience,
21 that our interventionalists using the two-badge system
22 we have no problems keeping them under the two rem
23 limit. Without that capability, though, they would be
24 well exceeding the five nuclear medicine
25 technologists, that pregnancy limit would be an issue

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1 particularly for out PET technologists, so keep that
2 in mind.

3 One other thing I would like to add in is
4 when you start thinking about dose constraints, the
5 implication of that will also go into the design of
6 facilities when you start using it for public exposure
7 limits and the additional shielding required to meet
8 some constraints beyond what the regulatory limits
9 are, can be very high with potentially very limited
10 positive impact from that. So I would encourage you
11 to be very careful when you start talking about
12 constraints because they will impact shielding designs
13 also, greatly increasing the amount of shielding that
14 could be required. Thank you.

15 VICE CHAIR VETTER Thank you. Dr. Fisher?

16 DR. FISHER: If we have time, just a
17 couple of quick comments and one question. In my
18 experience, of course, I work at a Category 2. My
19 office is in a Category 2 nuclear facility at a
20 national laboratory. And we already -- we already
21 function under a system of dose constraints. We're
22 limited institutionally to about 500 milirem per year
23 as workers. But my understanding of the ICRP 103
24 philosophy is that it -- the focus is moving from
25 intervention and process such as would apply to

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1 nuclear cardiologists, interventional radiologists and
2 perhaps even astronauts, to one of planning and
3 preparing for emergency situations or accidents and
4 instituting dose limits and dose constraints to
5 minimize those situations. I wondered if you'd
6 comment on that, perhaps a system that would allow a
7 higher exposure to interventional radiologists and
8 cardiologists doing critical patient care and to
9 astronauts who are fulfilling a deep space mission for
10 example, where occupational exposure limits do not
11 prohibit certain essential work activities but are
12 designed to limit accidental exposures. And my
13 question is, do these occupational limits apply to
14 astronauts?

15 DR. COOL: I can answer the question first
16 which is no, they do not apply to astronauts. There
17 is currently working in the international framework of
18 things, a framework document to deal with protection
19 and safety aspects for space missions, et cetera. And
20 the limits do not apply. They have a whole set of
21 different considerations and some very unique
22 circumstances with very heavy ion radiations and
23 things.

24 So that's one short answer. The second
25 piece of this very quickly, yes, ICRP 103 moved from

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1 a process system of practices and intervention to a
2 situation based approach where you had a planned
3 situation, that is you were planning to do something
4 and you could do all the planning in advance, an
5 emergency situation where something has happened and
6 you have to react to it right now or an existing
7 situation which like radon and other things, it exists
8 and you have to decide what you want to try and do
9 about it. You couldn't really plan for it. It's
10 there. Now, ICRP's philosophy was to -- in 103 is now
11 to attack that always the same way. And that is to
12 establish a boundary, an optimization boundary, either
13 a constraint or what they call a reference level for
14 emergencies in existing situations and then to
15 optimize protection below that. So it's always the
16 same system trying to optimize protection, whatever
17 the situation you're in.

18 My understanding of ICRP 103 that they
19 would not -- that document would not have endorsed a
20 separate or unique dose limit for a particular
21 occupational category. All of that activity would
22 assume to be a planned exposure situation where you
23 could do that planning and the optimization and that
24 is the only situation in which dose limits apply.

25 VICE CHAIR VETTER Any other final

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1 questions? Dr. Cool, we very much appreciate your
2 coming here well in advance of any regulatory action,
3 rulemaking, et cetera, explaining what the issues are
4 and I think on behalf of the ACMUI, I'd also like to
5 encourage you to update us on a regular basis as this
6 -- which may be every other year, I'm not sure how
7 long this will take, but we expect it will be more
8 frequently than that, to keep us apprised of these
9 issues as they move forward.

10 DR. COOL: Thank you very much. As --
11 presuming for a moment that the Commission agrees that
12 we should start taking these next baby steps towards
13 technical basis, I would actually hope that this
14 committee would be willing to work with the staff to
15 help us establish some of the stakeholder interactions
16 with your particular groups of users so that we can
17 get to the next levels of information over the next
18 few months. Keep those cards and letters coming.

19 VICE CHAIR VETTER I'm sure each one of us
20 would be happy to work with you on that, either as a
21 co-author at a meeting or as a sponsor for you to
22 present at a meeting or whatever the case, we are very
23 interested in facilitating stakeholder input. Thank
24 you again.

25 Okay, the next item on our agenda is to go

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1 back to yesterday. We scratched DR. Zelac's
2 presentations from the agenda in order to allow more
3 time to discuss the issues that were on the agenda
4 yesterday. So DR. Zelac.

5 (Discussion off the record.)

6 MS. TULL: I have the -- this is the same
7 draft risk that was sent to the committee but it's a
8 hard copy of the comments that Ralph provided. It's
9 a redline strike-out version. So keep what's in your
10 binder because that's the original one and this one
11 contains ACMUI comments.

12 VICE CHAIR VETTER Okay, so we're going
13 back to agenda item number 9 from yesterday, Potential
14 Rulemaking and Associated Regulatory Information
15 Summary Regarding Multiple RSO on a Medical Use
16 License. DR. Zelac, the floor is yours.

17 DR. ZELAC: Thank you. Before I begin, I
18 think this is an opportunity, I think it really
19 depends on all of you, to one, stay on schedule and
20 two, possibly even pick up a little time on the
21 schedule because what I'm trying to do with this is
22 simply to bring you up to date as to where we are with
23 three ongoing processes. There are three things that
24 we're doing that are not completed at this point but
25 are moving along and this is simply to let you know

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1 where we are in the process, what's being done and
2 what will be done.

3 The first of these has to do with the
4 issue of multiple RSOs on medical use licenses. As
5 you all know, that issue went to our Office of General
6 Counsel and the decision that we received was, no, it
7 cannot be done. It's against regulations. So on that
8 basis, we will be moving ahead with consideration in
9 the next round of modifications to Part 35 to include
10 that as an issue.

11 First, of course, it's going to be
12 considered and part of that consideration will depend
13 on the responses that we get to this regulatory issue
14 summary, if any, that's being sent out. This RIS, of
15 course, has gone to all of you. You've all had an
16 opportunity to comment and your comments have been
17 received and will be considered when this document is
18 reworked. It is still a draft.

19 It has also gone out to our regional
20 offices and we have received comments from the
21 regional offices. Again, those comments as well will
22 be considered when this draft is reworked before the
23 document becomes final. And lastly, on your
24 recommendation and with good practice as well, because
25 this would impact all of the agreement state programs,

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1 it is being sent out with an all agreement states
2 letter to all of the agreement states for their input
3 and comment. Depending on when Mr. Lewis has the
4 opportunity to take a look at the covering letter, the
5 all agreement states letter, it will be going out
6 relatively soon I suspect and there will be a 30-day
7 opportunity for feedback from the -- all of the
8 agreement states.

9 So in summary, for this particular draft
10 RIS, one we have comments from you, two we have
11 comments from the regions, and three, we anticipate
12 receiving comments from the agreement states. When
13 all of those are received, we'll take them all into
14 consideration at the same time and come up with a
15 revised document that would be the final.

16 If you are so inclined and so recommend,
17 this document, once it is revised, can come back to
18 you for a second look.

19 VICE CHAIR VETTER Questions for DR. Zelac
20 regarding this draft RIS? I have a question. Richard
21 Vetter, I have a question. Regarding the
22 interpretation by the OGC, they have concluded that
23 although there may be policy reasons for allowing a
24 medical use license to include multiple RSOs, the
25 current regulations do how allow, could you please

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1 cite the regulation that says we -- it says the
2 regulations do not allow. In other words, there must
3 be somewhere in the regulations where it specifies
4 only one RSO.

5 DR. ZELAC: The opinion we get, the
6 interpretation we get covers the whole gambit of
7 information relating to the issue which means all of
8 the Federal Register notices relating to publications
9 of the rule, it relates to the rule itself. I can't
10 speak for Office of General Counsel except to say that
11 there are multiple places in Part 35 where it speaks
12 of an RSO or the RSO in contrast to all of the other
13 authorized individuals where it speaks of them in
14 plural. That could well be the basis and I suspect
15 it is.

16 MR. LEWIS: There is also 3524(b) but it's
17 not so much the regulation itself, it's the statement
18 of considerations that form the regulation which made
19 it very clear that the intent of that regulation was
20 to name one and we provided all of that info to the
21 committee as an action item from our last meeting.

22 VICE CHAIR VETTER Okay, thank you. Mr.
23 Lieto?

24 MR. LIETO: Yes. On the issue with the
25 statement that came from the Office of General

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1 Counsel, and the comments that were incorporated into
2 the draft RIS that DR. Zelac had sent out earlier to
3 the committee, the citation is a -- was from the
4 Federal Register was sent to the committee. It's an
5 answer to a question in the Statements of
6 Consideration. There is absolutely nothing in there
7 that references any previous regulation, NRC
8 directive, headquarter policy, OGC directive from
9 before 2002. This has been an ongoing process at
10 least from the 1980s maybe even precedes that time
11 period. And so again, to cite something in 2002 as
12 for the ongoing policy and -- of naming one RSO for
13 the past 25, 30 years, you know, just doesn't seem to
14 get to the gist of the -- or to the answer to the
15 question.

16 So I really -- you know, to me it's still
17 does not get to why there is a single RSO. Your
18 comment about in the rules that it references a RSO or
19 the RSO well, it does the same thing for authorized
20 users for AMPs and so forth. So you know, it doesn't
21 -- and there's nothing in -- if you look in the
22 definition for RSO, it does not say that it's singular
23 to the license. So again, I mean, I'm willing to
24 accept something that states that there's -- that it's
25 prohibited but it's -- there's -- again, there's

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1 nothing that's been provided from OGC in their
2 reference document or in the regulations that say it's
3 prohibited. The fact that there's a reference to the
4 RSO you know, again, maybe stems from historical
5 language or whatever but again, I'd like to see
6 something and I would hope that the committee would
7 like to see something that says it's prohibited from
8 being done and there was nothing that was provided.

9 The introduction and the background to the
10 RIS gives the implication that the training and
11 experience criteria is what's at question and we're
12 not questioning that. I mean, we're not asking for
13 changes to that. What we're asking for is those
14 individuals that do meet the current RSO training and
15 experience okay, why can't they -- you know, what
16 prohibits them from being named on a license?

17 And I think there's a very real and
18 serious practical reason and concern for this. With
19 broad scope licenses, there's, you know, a
20 practicality of transition and so forth, and it's
21 probably a little more straightforward and less
22 problematic. But what we're finding out there in the
23 real work with community hospitals and so forth with
24 multi-modalities of therapy, nuclear medicine,
25 diagnostic radiology, an extreme reluctance for a

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1 singular individual who is usually a physician, to
2 assume responsibility for all modalities, either
3 because of time commitments just you know, from the
4 standpoint of their concern about not being involved
5 in those other modalities, yet having a licensee
6 responsibility for those radiation safety duties. I
7 think the RIS also ignores the transition of the
8 regulations over time to management responsibility for
9 the license. It's true back in the '70s and '80 that
10 pretty much that the RSO -- early '80s that the RSO
11 was the end all and be all responsible person for a
12 license. But during that time at least for medical
13 use licenses, there was the NRC focus on the person
14 who controls the purse strings and personnel control
15 making management overall responsibility for the
16 license.

17 And over time, I think these two things
18 have been continued on a parallel separate track and
19 I think we're seeing this come to a head a little bit
20 because of the fact that why not let management decide
21 if they want to have RSOs who meet the training and
22 experience in that modality as the designate on their
23 license and the management decide who has overall
24 responsibility.

25 I use that analogy and it may not be

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1 accurate, I mean, we have a Commander in Chief who's
2 called the President but yet doesn't necessarily mean
3 that he has to have all the military training and
4 experience that's equal to the best individual that
5 makes those decisions. And that management is the one
6 that's ultimately held responsible for the license.
7 If the management wants to have RSOs designated for
8 individual areas, if that would serve the best
9 purpose, and have a -- and wants someone with overall
10 responsibility, I don't see why that's prohibited in
11 the license. I'll leave it right there.

12 VICE CHAIR VETTER Mr. Lewis?

13 MR. LEWIS: Mr. Lieto, I think the NRC
14 staff, we're sympathetic to the point you're making
15 and that times have changed and what should be done
16 and allowed and the RIS reflects that and suggests a
17 path forward through the rulemaking. But I think that
18 our Office of General Counsel has the sole
19 responsibility for interpretations of the regulations
20 and as the regulations are currently written, they are
21 very convinced that the regulatory history that is the
22 Commission record, even if it's in response to a
23 comment that was on the proposed rule, that the
24 Commission endorsed that entire rulemaking package as
25 our policy.

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1 And the last thing on record, in many
2 cases in regulatory interpretations is 30, 40 years
3 old, but it's the last thing on record and until it's
4 changed, that's the policy. So we have a case where
5 the lawyers are convinced and I don't think we have a
6 success path arguing with them that the regulations do
7 in fact, allow more than one because they've made
8 their decision. We do have, though, a success path
9 that I think will satisfy the issues. Maybe we need
10 to discuss if that's in a timely way or not but we are
11 sympathetic to the need that you're demonstrating.

12 VICE CHAIR VETTER DR. Zelac, is there
13 still time for members of the committee to comment on
14 this and if so, what would be the deadline?

15 DR. ZELAC: I thought that what had been
16 received already was the combined input from the
17 committee. However, if you wish to add additional
18 comments, the letter to the agreement states has not
19 yet been sent, which means there is at least 30 days
20 from when it is sent for us to be receiving comments.
21 So if there are more comments to be provided from
22 members, I would prefer, if possible, to get the
23 overall opinion from the committee as opposed to that
24 from individual members and I hope that's what the
25 document that had been received represented. However,

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1 if you wish to modify that, add to it, augment it
2 whatever, just so indicate and --

3 MR. LEWIS: If I could ask, actually, did
4 we -- we did provide the OGC's e-mail and their second
5 e-mail where they found additional arguments in the
6 Statement of Considerations to the committee? If you
7 want us to resend that, we will be happy to do that.

8 VICE CHAIR VETTER Yeah, Richard, if I may
9 make excuses for the committee, this fall has been an
10 extremely busy professional fall with many, many
11 meetings and I'm afraid Mr. Lieto got very little
12 feedback from members of the committee on this issue
13 when he sent out his e-mail. And I'm just making
14 excuses. It's been extremely busy, most -- not most of
15 us, several of us on this committee just got back from
16 the IRPA meeting in Argentina and there were earlier
17 meetings of other society matters earlier in the
18 month. It's been an extremely busy fall.

19 So if you'd indulge us and give us a
20 little more time to provide feedback and if Mr. Lieto
21 would be willing to solicit one more round of
22 comments, we may be able to provide some additional
23 input.

24 MR. LIETO: I'm always open to
25 solicitations.

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1 VICE CHAIR VETTER Okay.

2 DR. ZELAC: And we are always open to
3 receiving the comments.

4 VICE CHAIR VETTER Thank you very much.
5 Ms. Gilley.

6 MS. GILLEY: Debby Gilley, agreement
7 states, there are agreement states that list more than
8 one Radiation Safety Officer on a license. We do have
9 corporate Radiation Safety Officers for certain
10 activities. And we have not experienced any problems.
11 But we are very specific in those licensing activities
12 to make sure there is responsibilities and
13 accountability and my concern with listing multiple
14 Radiation Safety Officers on a license is that we get
15 into the finger-pointing when an incident happens.
16 And so we need to be very clear that there is direct
17 chain of command as to who ultimately is responsible
18 for the radiation safety activities at a facility or
19 licensee.

20 VICE CHAIR VETTER Any other comments or
21 questions?

22 DR. SULEIMAN: She just answered my
23 question.

24 VICE CHAIR VETTER Thank you. Mr. Lieto?

25 MR. LIETO: Just I think Debby, you know,

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1 answered one of the points that I had made or tried to
2 make in this document. Regarding the OGC comments,
3 the only thing that was provided or that I had was
4 distributed to the committee was a single statement
5 referencing a Federal Register citation which I then
6 pulled and sent to the committee as attachments to the
7 comments incorporated into here. So if there are
8 other OGC comments and specific citations, those were
9 not available when I formed this --

10 MR. LEWIS: Well, we'll make sure you have
11 whatever we have. I remember there was about a
12 paragraph long e-mail. There was a subsequent e-mail
13 where they dug further into the statement.

14 MR. LIETO: Okay, so Part 2 we don't have.

15 VICE CHAIR VETTER DR. Zelac?

16 DR. ZELAC: Just to conclude, if my memory
17 serves me properly, although the principal issue that
18 originated had to do with multiple RSOs, there was
19 also the sub or side issue of the ability of
20 individuals to be named as RSOs, impediments that
21 existed in that process. And part of that had to do
22 with the availability of preceptors. That's why this
23 particular document is trying to lay out exactly where
24 we are in the whole process at the moment of being
25 able to have individuals named as RSOs.

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1 It speaks to some things that have
2 occurred recently in terms of regulatory
3 interpretations. It's speaks to things that we intend
4 to do and it lays out hopefully, a path forward for
5 all of us to reach the achieved goal.

6 VICE CHAIR VETTER Thank you. Okay, so
7 where we're leading this is Mr. Lieto is going to send
8 us an e-mail reminding us of this draft RIS. If you
9 are not a Radiation Safety Officer, please feel free
10 to solicit comments from your Radiation Safety Officer
11 or equivalent at your institution and try to provide
12 some feedback. And if you have no feedback, simply
13 indicate that to Mr. Lieto, so that he can proceed
14 with his proposed revisions to the RIS. Thank you,
15 DR. Zelac.

16 We now move to Item Number 10 which will
17 be Status of Technical Basis for Follow-up to the
18 Ritenour Petition.

19 DR. ZELAC: Just as a reminder, the
20 Ritenour Petition sought to have specifically medical
21 physicists who are certified and individuals that were
22 certified as health physicists are able, based on
23 those certifications alone, to be named as authorized
24 medical physicists and Radiation Safety Officers as
25 long as they met the ancillary additional training

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1 requirements that exist in the regulations.

2 That petition was settled out. It was
3 completed in terms of its consideration and the
4 outcome was that the Commission decided that there was
5 possibly a group of individuals who were adversely
6 effected by the modifications in the training and
7 experience requirements that came into play in 2005.
8 On that basis, they suggested that we, staff, should
9 consider further modifications of the training and
10 experience requirements, not only limiting it to those
11 persons seeking authorized status as medical
12 physicists or Radiation Safety Officers, but opening
13 it up to all individuals who might be seeking
14 authorized status, meaning authorized users,
15 authorized nuclear pharmacists, in addition.

16 The one caveat towards doing that was to
17 receive adequate information from the user community
18 to form what we need to form in order to move ahead
19 and that's the technical basis. If we get information
20 from the user community, which suggests that there --
21 in fact, there have been individuals adversely
22 effected by the current requirements, in sufficient
23 numbers to justify moving ahead with rulemaking, then
24 that's exactly what will happen.

25 Now, the question, of course, is well, how

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1 does this information get to us and to form this
2 technical basis document which is required? And what
3 we had decided to do with your input was to contact
4 the boards, the certification boards and to give them
5 specific requests for information. That is what you
6 see in your notebooks under Item 10. This is the
7 letter that in fact, was sent to the eight
8 certification boards that are listed as having
9 recognized certification processes on the NRC public
10 website plus one additional board that was listed
11 previously in Sub-part J but has not yet received
12 recognized status for their certification process.

13 Now, you had also recommended that this
14 same request for information be sent out to the
15 various professional societies. And that we were not
16 able to do because in order to do that, in order to
17 seek information for more than it turns our
18 fortuitously nine organizations or nine individuals,
19 you need clearance for that process from the Office of
20 Management and Budget. That process of requiring this
21 approval, takes multiple months.

22 On that basis, in order to move ahead
23 adequately in a time frame with what we intended to
24 do, we have elected to send this to the certification
25 boards themselves. That is indirect contact, of

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1 course, with all the professional societies and I
2 don't think we're going to frankly be losing any
3 information or any input by this process. This letter
4 that you see which says addressed to certification
5 board, as I said, was sent out to the eight boards
6 that have recognized processes listed on the website,
7 plus one additional board, the American Board of
8 Medical Physics, which was in Subpart J and up until
9 this point it time has not yet achieved recognized
10 status.

11 These letters were sent out on October
12 15th. Our intent, our hope, was that we could get
13 input back by mid-January. The first intent is that
14 when the current rulemaking process involving Part 35
15 is concluded, that we can then move forward with
16 additional changes to Part 35 and this would be one of
17 them.

18 VICE CHAIR VETTER Ms. Gilley? I'm sorry,
19 are you done, DR. Zelac?

20 DR. ZELAC: I am finished.

21 MS. GILLEY: I was just wondering if it
22 might be possible for the organization of agreement
23 states or the conference of radiation control program
24 directors to contact the professional associations to
25 provide information, since we would not have the

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1 constraints of the Federal Government for impacting
2 us.

3 DR. ZELAC: The best that I can tell you
4 is that the feedback that we have received on this
5 very issue because clearly we would like to have as
6 much input as possible, was that if the letter that's
7 sent out is essentially soliciting in some way the
8 collection of information from further individuals,
9 you automatically have exceeded your limit of nine.
10 If you want to as a person, take this letter and do
11 what you wish with it, that's --

12 MS. GILLEY: So you would receive one
13 letter from the organization of agreement states or
14 the CRCPD with the comments from nine professional
15 associations attached to it. It would not be in non-
16 compliance with the federal requirements?

17 DR. ZELAC: My only problem is that you
18 are a special employee of the NRC and as such, if a
19 letter requesting the same information that we have
20 sent out and it is sought by you, even if it isn't in
21 your official capacity, but it's a result of your
22 official activities, that may raise an issue.

23 MS. GILLEY: Okay, thank you.

24 DR. ZELAC: I can't --

25 MS. GILLEY: But this is a public meeting,

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1 correct?

2 DR. ZELAC: This is a public meeting and
3 everyone knows that we seek information can respond
4 accordingly.

5 VICE CHAIR VETTER Mr. Lieto?

6 MR. LIETO: I have a question for DR.
7 Guiberteau in terms of his activities with the ABR.
8 Does the ABR have the type of information where if
9 they were contacted that they would know whether their
10 diplomates were RSOs or AU's on licenses or AMPs on a
11 license or is it pretty much once they get their
12 certificate as a diplomate, it's God's speed and best
13 wishes?

14 DR. GUIBERTEAU: The short answer is, no,
15 they would not have that information and if they do
16 have it, it would be exceptional.

17 VICE CHAIR VETTER Yes, DR. Eggli?

18 DR. EGGLI I think though, one of the
19 things that ABR and the other certifying boards could
20 provide is the number of people potentially
21 disadvantaged between the time that the regulation
22 went into effect which would be October 2005 and the
23 time at which the Board was recognized, because during
24 that gap, none of the diplomats of the Board could
25 become AU's by the Board's certification process.

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1 So although it doesn't get to quite what
2 you're looking for, it does give you some concept of
3 the potential order of magnitude and I think that's
4 one of the things that the certifying boards could all
5 provide is the numbers of potentially disadvantaged
6 individuals and that might in part, serve as your
7 technical basis. So ABR certifies nearly 1500 people
8 every year in that ball park, so if you look at 2006,
9 diplomates and 2007 or I guess it's primarily the 2006
10 diplomates, there are potentially 1500 diagnostic
11 radiologists out there who are disadvantaged who may
12 not be able to get an alternate pathway preceptor
13 statement. Would that kind of information be helpful,
14 Ron, if you had that kind of numbers?

15 DR. ZELAC: Certainly, anything of that
16 kind would be helpful and, in fact, that was part of,
17 you know, what we anticipated receiving from the Board
18 based on this letter that went out. It speaks to that
19 in terms of it asking about those diplomates that were
20 certified prior to the time when their process was
21 recognized by NRC.

22 DR. EGGLI: So that's certainly something
23 that all of the certified boards can provide because
24 those are hard numbers and hard dates. It doesn't say
25 that they were disadvantaged but they were potentially

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1 disadvantaged.

2 DR. ZELAC: That's correct.

3 VICE CHAIR VETTER That's -- Richard
4 Vetter, that's a very, very significant point and I
5 personally think it would be helpful to the process if
6 each of us contacted the principal board in our areas
7 simply to relate that information. I will do that in
8 my case for the American Board of Health Physics. Any
9 other questions or comments on this issue?

10 If something occurs to you in the
11 meantime, DR. Zelac is looking for information between
12 -- looking to receive information before mid-January,
13 so please don't hesitate to contact him if there's any
14 questions or additional information that you might
15 have. Thank you, DR. Zelac for updating us on the
16 status of the Ritenour petition and actions that are
17 being taken to solicit data for the technical

18 14. STATUS OF COMMISSION PAPER FOR MODIFYING
19 TRAINING AND EXPERIENCE ATTESTATION REQUIREMENTS

20 DR. ZELAC: Last but not least, --

21 VICE CHAIR VETTER: Item 10? Let's see.
22 Where are you?

23 DR. ZELAC: -- if you haven't tired of
24 hearing about things from me yet is the number 14, --

25 VICE CHAIR VETTER: Number 14.

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1 DR. ZELAC: -- which is the one that is
2 actually scheduled for now. That has to do with the
3 status of the Commission paper, which is seeking
4 Commission's input on modifications of the training
5 and experience attestation requirements.

6 This, of course, results from the
7 recommendations that we received from the Advisory
8 Committee through the presentation that was made by
9 Dr. Eggli at the last meeting of the Committee with
10 the Commission in April.

11 What you see in your handout is an all
12 agreement states letter that was sent out, as you can
13 see, in mid September and requesting input from the
14 agreement states as to their support or lack of
15 support for the three recommendations that you have
16 made.

17 The first page of that is the actual
18 letter itself. And you can see -- in fact, I think
19 that was the only page that was in your handout and
20 the questions that were asked of the agreement states
21 on page 2.

22 And I think probably the best way to tell
23 you where we are is to indicate that we did receive
24 responses from nine agreement states plus Conference
25 of Radiation Control Program Directors. And I will

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1 summarize what those responses were.

2 We also sent the same letter to our
3 regional offices for input from regional staff. So we
4 have at this point in time input from agreement
5 states, including from the Conference of Radiation
6 Control Program Directors and from the regions.

7 This information is being incorporated in
8 a draft Commission paper, which will use this as part
9 of the basis for making recommendations to the
10 Commission as to what modifications appear to staff to
11 be appropriate to address this issue.

12 So let me first I think read the question
13 and then tell you what, first, the agreement states
14 and, secondly, the region's positions are. And let me
15 also tell you before I even start where these
16 responses came from. It might be useful for you to
17 keep in mind.

18 We did receive responses from California;
19 from Florida; from Illinois; from Iowa; from Kansas;
20 from Louisiana; from Minnesota; from North Carolina;
21 and from Wisconsin; plus, as I said, the Conference of
22 Radiation Control Program Directors.

23 So the first question, do you support the
24 recommended, meaning from you, the recommended,
25 elimination of the attestation requirement for

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1 individuals seeking authorized status via the board
2 certification pathways; i.e., eliminate attestations
3 for anyone that wants to become an authorized
4 individual via a board certification pathway?

5 The answers, from the agreement states,
6 the respondents strongly supported, meaning 80 percent
7 were for elimination of the attestation requirement.
8 We had an unconditional yes from seven of the ten
9 respondents plus a conditional yes from one of them,
10 making the eight.

11 The one that was conditional suggested
12 that that elimination of attestations was only
13 appropriate for 10 CFR 100 and 200 users. But in
14 other situations, it would be appropriate to retain
15 it.

16 Any time that you have a question, you
17 know, about any of these things that I am saying,
18 please feel free to just jump right in.

19 From the regions, regional staff
20 unanimously supported elimination of the attestation
21 requirement. You can see the agreement states, 80
22 percent for, regional staff, 100 percent for. I think
23 you get the flavor of where our recommendation might
24 be going to the Commission.

25 Second question --

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1 DR. NAG: What about CRCPD? You said
2 that agreement states --

3 DR. ZELAC: CRCPD, again there were ten
4 responses totally. And they were included in this
5 summary, speaking of the agreement states.

6 DR. THOMADSEN: Was there any comments
7 with the negative ones other than where you had the
8 conditional as to why they were against that?

9 DR. ZELAC: No. The nos were
10 unconditional and unexplained, simply no.

11 Now, the second question, do you support
12 the recommended modification? Again, the
13 recommendation is coming from you, the Committee. The
14 recommended modification of the attestation
15 requirement for individuals seeking authorized status
16 via the alternate pathways and that modification being
17 to delete text associated with preceptors attesting to
18 individuals' competency being sufficient to function
19 independently as authorized persons for those medical
20 uses for which they sought, again the key word being
21 the one that you have always objected to: competency.

22 Responses from the agreement state. The
23 respondents that we got marginally opposed, I mean 60
24 percent were against, modification of the attestation
25 requirement in this way.

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1 Let me give you a breakdown of where these
2 went. We had an unconditional yes, no comments,
3 simply unconditional yes, for four of the ten. Forty
4 percent favored such a change.

5 We had an unconditional no for five of the
6 ten. And for one of the nos, there was a suggestion
7 that, again, because of the relatively common
8 interpretation of competency having to do with medical
9 practice, as opposed to what was meant and intended by
10 the Commission, as stated multiple times, that this
11 did not relate to medical competency but to the
12 ability to fulfill the responsibilities relating to
13 radiation safety of the position which was sought, one
14 organization suggested replacing has achieved, which
15 has a future -- excuse me?

16 DR. EGGLI: Yes. When you finish your
17 comment, I would like to add something in addition.

18 DR. ZELAC: Certainly. One organization
19 suggested replacing the word "achieved," which is kind
20 of an open-ended suggesting future and, therefore,
21 possible liability, with "demonstrated," means this
22 person has in the past shown that they can do this
23 without making any presumptions as to their ability to
24 continue doing this in the future, you know, making
25 that essentially a prior time-limited endorsement of

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1 that person's qualifications in order to reduce
2 liability concerns.

3 So the response from the agreement states,
4 again, 60 percent against doing it, 40 percent doing
5 what you had suggested.

6 VICE CHAIR VETTER: Dr. Eggli?

7 DR. EGGLI: I think that in the
8 alternate pathway that we had offered substitute
9 language that it's not clear went out to the agreement
10 states for their consideration, which that substitute
11 language was "have demonstrated mastery of a body of
12 knowledge" or, actually, it was "completed the
13 requirements for licensure."

14 There were words to that effect that we
15 recommended as substitute terminology in the alternate
16 pathway. And I don't see that as having gone out to
17 the agreement states. And would that have impacted
18 the decision the agreement states made if they had
19 been offered simply to remove the part of the
20 attestation if they weren't offered the substitute
21 language?

22 DR. ZELAC: The current regulation -- I
23 don't have it right in front of me, but basically asks
24 for the person, the preceptor, who is providing an
25 attestation statement to attest to the individual

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1 having completed the training and experience
2 requirements and then the competency statement.

3 The recommendation was to get rid of the
4 competency statement. So what would remain, then,
5 would be training and experience, which I think is
6 exactly what you are referring to.

7 DR. EGGLI: Now, can I ask again, maybe
8 toward Debbie, would the agreement states have seen
9 that as the context that we weren't asking for a
10 complete removal of attestation but that we are
11 willing to see an attestation of completion of
12 requirements of all the training and experience
13 requirements? If that were not emphasized, would that
14 have been missed?

15 MS. GILLEY: It's possible. It's hard
16 to read the mind of 35 states, but this was as short
17 turnaround time document also for us. So some states
18 weren't probably able to mobilize to give it full
19 consideration.

20 VICE CHAIR VETTER: Dr. Nag had a
21 question?

22 DR. NAG: Yes. Dr. Zelac, when you
23 said demonstrate what that state said is the best
24 thing about achieving, you said there was a case,
25 demonstrate. Demonstrate what? Demonstrate

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1 competency or --

2 DR. ZELAC: Well, that wasn't really. I
3 don't have the letter right in front of me, but the
4 sense was that use of the word "demonstrated" would
5 suggest that this is something that the person has in
6 the past shown.

7 Now, what words followed "demonstrated,"
8 that's really left open to us. There is no suggestion
9 that the words that followed had to be inclusive of
10 the word "competency" because we all have made some
11 different suggestions for different words to achieve
12 the same objective.

13 DR. ZELAC: Dr. Welsh?

14 DR. WELSH: I'm not clear on whether
15 the question that went out emphasized that the concern
16 of the Committee was the use of the specific word
17 "competency." Was it underlined? Was it italicized?
18 Was there a comment saying that this is the specific
19 concern? Because if the question is --

20 DR. ZELAC: The question again was, do you
21 support the recommended modification of the
22 attestation requirement for individuals seeking
23 authorized status via the alternate pathways to delete
24 text associated with preceptors attesting to
25 individuals' competency being sufficient to function

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1 independently as authorized persons for the medical
2 uses associated with the authorization sought?

3 DR. WELSH: If the question was as
4 written here, then I would not be convinced that the
5 casual reader without the background of all the
6 discussion, that the place here understands that the
7 word "competency" to a medical practitioner is a very
8 key word. And unless it was italicized, underlined,
9 put in quotes, they might have missed the specifics
10 for the general concept.

11 DR. ZELAC: If I can respond, the
12 discussion, which was part of the letter, said, "ACMUI
13 also recommended that the attestation requirements
14 associated with more prescriptive alternate pathways
15 to authorized status be modified to delete text
16 associate with preceptors attesting to individuals'
17 radiation safety-related competency being sufficient
18 to function independently," et cetera.

19 VICE CHAIR VETTER: Dr. Eggli?

20 DR. EGGLI: Again I would wonder if
21 they went back and looked, if everybody went back and
22 looked, to see what was left. There is a subliminal
23 message in the request that suggests that we want to
24 remove all attestation.

25 And unless you go back to the original

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1 regulation and see that there is a nice piece left
2 that says we are still attesting to the completion of
3 the training and education requirements and experience
4 requirements, I think there's a subliminal message
5 that suggests that we drop that, too.

6 And I think our concern as a Committee is
7 to create a viable alternate pathway that preceptors
8 will actually use. And if the language doesn't get
9 adjusted, then effectively the alternate pathway
10 withers and dies because preceptors won't take that
11 legal risk of writing that statement that looks like
12 an attestation of competency because there's just too
13 much risk.

14 So my concern is that the alternate
15 pathway be salvaged as a viable pathway for people who
16 are not able or because of their training not part of
17 organizations that have a board certification pathway
18 available to them.

19 DR. ZELAC: I think there are two things
20 to be said here. First is you haven't heard what our
21 original staff has said.

22 DR. EGGLI: Okay.

23 DR. ZELAC: And, secondly, both of those,
24 what the agreement states have said and what the
25 regional staff have said, and, plus, we who are

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1 involved with the formulation of recommendations to
2 the Commission fully understanding exactly what you
3 are saying and the objective to be achieved. And
4 being sympathetic to that, you don't know what the
5 recommendations will be to go to the Commission.

6 So you are hearing something that doesn't
7 agree with what you have recommended. That doesn't
8 mean that that is the end of it.

9 DR. EGGLI: No. And I apologize for
10 jumping the gun and not waiting for the regional
11 recommendations.

12 DR. ZELAC: That is perfectly all right.

13 VICE CHAIR VETTER: If we could hear the
14 regional recommendation, please?

15 DR. ZELAC: I would be more than happy to.
16 The regional staff unanimously supported modification
17 of the attestation requirement, et cetera.

18 DR. EGGLI: I am much happier.

19 DR. WELSH: Okay. We are all happy.
20 You obviously hit a hot button there. Okay.

21 VICE CHAIR VETTER: Please proceed, Dr.
22 Zelac.

23 DR. ZELAC: Yes. There was a comment from
24 regional staff that is probably worth noting, but this
25 is more of an administrative thing than anything else.

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1 Staff noted that if the attestation text
2 "uncompetency" was deleted, the attestation itself
3 should probably be renamed to "recommendation for
4 authorized status" or something similar to that.

5 Last question, at least the last of these
6 three that were sent out, do you support additional
7 methods for attestations, such as the attestation
8 being provided by consensus of an authorization group;
9 for example, a residency program faculty represented
10 by a residency program director?

11 Response from the agreement states plus
12 CRCPD very strongly supported this recommendation. In
13 fact, 90 percent of the responses favored this
14 recommendation.

15 We had an unconditional yes for five of
16 the ten respondents. We had conditional yeses for
17 four of the ten. And let me just give you a rundown
18 of what those conditions were.

19 From one state, the recommendation was
20 that the signer, the attester, or a cosigner be an
21 authorized individual.

22 In other words, there should be somebody
23 that is contributing to this attestation who, in fact,
24 has knowledge of the responsibilities that this person
25 is seeking to achieve. In fact, there were two of the

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1 states that said the same thing.

2 Another comment from the yes group was
3 that the signer must have actual knowledge of the
4 candidates' work experience. That makes sense.

5 And another comment was that, for sure,
6 the wording of the regulation needed to make it very
7 clear that this attestation represented a group
8 consensus, the person who is representing the group.
9 And there should be a consensus among the group that
10 this recommendation is appropriate. In addition, we
11 had one probable no. So 90 percent, 9 of 10, were
12 for, one probable no.

13 The regional staff strongly supported but
14 not unanimously allowing additional methods for
15 attestations. The staff noted that since residency
16 program directors are typically not authorized users,
17 to accept attestations from them, multiple training
18 and experience sections of Part 35 would require a
19 modification. Again, that is kind of an
20 administrative matter, and it really is not of much
21 concern.

22 So strongly supported but not unanimously.
23 There are several comments that came in from the
24 regions which said, "This is not the way to go. We
25 should not permit this."

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1 So we have got the input. And that's
2 really what I wanted to bring to your attention, where
3 we stood in terms of what we asked and what we got in
4 the way of input from these two separate groups on the
5 same questions.

6 And the next step, of course, is the
7 Commission paper with the recommendations to the
8 Commission for modifications to these attestation
9 requirements in Part 35 dealing specifically with
10 these three recommendations that you had made to them
11 and that they obviously for anyone who was there or
12 read the transcript was favorably impressed with for
13 good reason.

14 DR. EGGLI: I can say personally I am
15 pleased with the outcome.

16 (Laughter.)

17 VICE CHAIR VETTER: That was Dr. Eggli.

18 DR. ZELAC: Any additional questions?

19 VICE CHAIR VETTER: Yes, Mr. Lieto?

20 MR. LIETO: I guess it's more
21 semantics. I have a question for Dr. Zelac. And then
22 I would like to ask Debbie Gilley also. In question
23 number 3, when you wrote "additional," was your intent
24 alternate or supplement?

25 DR. ZELAC: No. Additional, exactly the

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1 way we got the directive from the Commission,
2 additional, not to replace but as a supplement to what
3 is there already, multiple ways to acquire the same
4 information.

5 VICE CHAIR VETTER: So those would be
6 alternate ways to have acceptable attestation, not
7 additional to what is already there or supplemental to
8 what is there? Supplemental means what is there plus
9 what you recommended. Alternate means what is there
10 or these other ones.

11 PARTICIPANT: I think the agreement states
12 -- I've not seen their comments or just specifically
13 knowing who made what
14 attestation. We're looking at it as multiple
15 alternative ways to get to the same finish. But I
16 can't speak on behalf of all the --

17 MR. LIETO: This is Ralph Lieto. I am
18 sure Dr. Eggli's intent and the Committee's intent was
19 alternate acceptable methods of attestation.
20 Additional, again, it may be semantics, but I am just
21 wondering looking at this now and seeing it for the
22 first time if others were hopefully taking it as the
23 alternate pathway, as opposed to being --

24 VICE CHAIR VETTER: This is Richard
25 Vetter.

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1 I think that is the way they took it or we
2 wouldn't have seen 90 percent yes from the states and
3 strong support from the regions.

4 MR. LIETO: As long as that is the way
5 we are all taking it, that is fine.

6 VICE CHAIR VETTER: Yes.

7 MR. LIETO: Okay.

8 DR. ZELAC: I can't speak for the
9 Commission, by interpretation, I thought, was that
10 that was what they were thinking. And that is what
11 was reflected in the staff requirements memorandum,
12 which was the basis for this letter. We tried to use
13 what they had specifically asked us to consider.

14 VICE CHAIR VETTER: Dr. Guiberteau?

15 DR. GUIBERTEAU: Just in terms of
16 clarification since this is my first meeting, this in
17 no way would impact the attestation that the boards
18 get from program directors in terms of the potential
19 candidates have completed all of their required
20 training.

21 DR. ZELAC: That is correct.

22 DR. GUIBERTEAU: And, two, if I may, to
23 bring up since we're on the board pathway and I
24 believe this has been discussed before, but I would
25 like to suggest that it is a matter that needs some

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1 determination from this Committee.

2 And that is the extensive reworking of the
3 training pathways and the certification process by the
4 American Board of Radiology and the diagnostic
5 radiology RRC changing from a pattern where at the
6 time our candidates take their examination, they have
7 completed the training, they have been attested to to
8 the board, and they have received an examination and,
9 therefore, get a certificate if they pass that portion
10 of the examination that says that they are
11 AU-eligible.

12 In the future, they will complete their
13 training. They will receive the attestation. And
14 they will take an examination on the curriculum set by
15 the Nuclear Regulatory Commission at the end of their
16 four-year residency. But they will not be eligible to
17 take their exam until 15 months after that. So that
18 there will be a considerable gap of 1,250 to 1,300
19 people who cannot be AUs if they do not have their
20 certificate.

21 I mean, my point here is that there needs
22 to be some consideration of solutions to allow those
23 people perhaps to become AUs since they have completed
24 all of the requirements. They have taken the test.
25 The only thing they don't have is their final

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1 certificate for everything else.

2 VICE CHAIR VETTER: Dr. Zelac?

3 DR. ZELAC: I think the response to that
4 concern is the fact that all of the authorized
5 individual training and experience requirements
6 include an alternate pathway that has requirements
7 which are more spelled out but not necessarily more
8 rigorous by any means than those in the board
9 certification pathway.

10 And the expectation is that if an
11 individual has not fully completed their certification
12 process because they have not yet taken the
13 examination but have completed all of the training and
14 experience requirements that have led up to their
15 being in that position, that they could and would be
16 expected to be applying for authorized status via the
17 alternate pathway.

18 DR. FISHER: So in order to be truthful
19 to those who are actually applying to the board to
20 take their examination, we would have to insist that
21 all of our programs train to the alternate pathway.

22 DR. ZELAC: This is something that Dr.
23 Eggli has brought up numerous times, the fact that
24 programs need to do this.

25 DR. EGGLI: That was one of the

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1 impetuses in my commenting on having a viable
2 alternate pathway available, but the effect of this is
3 that essentially no diagnostic radiologist will ever
4 again achieve authorized user status by board
5 certification. That essentially forces all diagnostic
6 radiologists down the alternate pathway and eliminates
7 functionally board certification as a mechanism to
8 achieve authorized user status for these individuals,
9 which I see as actually problematic.

10 I understand there is a remedy in the
11 alternate pathway. The alternate pathway is more
12 prescriptive than the board certification pathway.
13 Preceptors I think, at least having been in that
14 position for many years, are more comfortable with the
15 board certification pathway than the alternate pathway
16 and not because we don't think we're training people
17 adequately. But when you have a more prescriptive
18 regulation, if you miss it by a little bit, you have
19 missed it by a mile, even if you have covered all of
20 the necessary material.

21 I would hate to see American Board of
22 Radiology because of this alteration in training,
23 which actually brings them into closer alignment with
24 all the rest of the medical boards in the United
25 States, which is not certifying people immediately on

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1 completion of training. I would hate to see the board
2 certification pathway disappear for diplomats of the
3 American Board of Radiology, which functionally would
4 occur unless this training gap of 15 months between
5 completion of the requirements and final achievement
6 of the certificate can be dealt with.

7 And, actually, there is more there than
8 just the American Board of Radiology. If I could
9 speak to the cardiology boards because right now the
10 people who are beating up on me are actually
11 cardiologists, rather than radiologists.

12 Once they complete their training and take
13 their certification exam, they can't immediately get
14 their authorized user status until they actually get
15 their cardiology board certificate from the American
16 Board of Internal Medicine.

17 And there is a time gap between when they
18 complete their training and they can get their actual
19 board certification. In core cardiology, the
20 certifying Board of Nuclear Cardiology will not
21 release that board certificate until they get their
22 core certifying board in underlying cardiology. So
23 they have a gap between when they complete training
24 and when they can become authorized users.

25 I don't know if Dr. Van Decker experiences

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1 it, but I have cardiology fellows who are struggling
2 in the employment market by not being authorized
3 users. And I am personally one of the people
4 reluctant to write an alternate pathway preceptor
5 statement.

6 So it's not just the American Board of
7 Radiology. It's others as well.

8 DR. ZELAC: The best that I can say is
9 that the requirements in the board certification
10 pathway go through, as you all well know, including
11 examination. You're not certified until you're
12 certified. You don't get certified until you have
13 taken the exam. So that --

14 DR. EGGLI: I understand that point,
15 but the --

16 DR. ZELAC: That's part of it. The other
17 side of it is that while the recommendation that was
18 made in terms of additional persons that might provide
19 attestation requirements is pointed towards residency
20 program directors, I don't see why it couldn't just as
21 well apply to fellowship program directors. You know,
22 that would kind of get these people off the hook.

23 DR. EGGLI: Right. But it does
24 functionally eliminate board certification as a
25 pathway for the individuals who have a gap between

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1 completion of training and when they actually get
2 their board certificate.

3 In some cases, they have already taken and
4 passed their exam. They just don't have that
5 certificate in hand yet because of other requirements
6 of the board that aren't necessarily related to
7 passing an examination.

8 DR. ZELAC: Couldn't such an individual
9 seek a letter from the board that said, "You have
10 passed the examination. You have completed all the
11 requirements"; i.e., effectively a certificate?

12 DR. EGGLI: Well, recently I was told
13 that I had to submit a copy of the certificate, as
14 opposed to the letter. I actually did try. And I
15 don't know which regional office it went to. It was
16 someone who is now working out of state. I did ask
17 them to.

18 I attached the letter that said that they
19 had passed the examination, but, unfortunately, the
20 letter also says, "You're not considered
21 board-certified until you get your underlying
22 cardiology board." And that individual was unable to
23 get authorized user status based on that letter.

24 VICE CHAIR VETTER: A comment from Dr.
25 Howe?

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1 DR. HOWE: Dr. Eggli, I have a basic
2 question. You're training radiologists and
3 cardiologists. And you're giving them the training
4 and experience that is required in the regulations.
5 Why is it you don't feel your program is such that you
6 can sign off that these individuals have completed
7 their training and experience and can function
8 independently without having a board certification?

9 It seems like it's your decision not to
10 allow them to be authorized users until they get the
11 certification process. What is it about the
12 certification process that your program doesn't meet?

13 DR. EGGLI: Our program does meet the
14 board certification process. Again, for the boards,
15 the --

16 DR. HOWE: I mean the alternate pathway.
17 What is it about your program?

18 DR. EGGLI: The alternate pathway is
19 more prescriptive than the board examination. The
20 concern is that I will be challenged to document every
21 component of the training, where in the board
22 certification pathway, as long as I comply with the
23 training program, as outlined by the American Board of
24 Radiology and the RRC as far as the training
25 requirements go, I don't have to keep records that

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1 document these experiences.

2 The only records that I think we're
3 required to keep is documentation of therapy
4 experiences, but as long as the training program meets
5 the board's and the RRC's requirements, I don't have
6 to keep records that detail individual experiences.

7 If I go down the alternate pathway, it is
8 conceivable that I will be required to produce
9 documentation that I didn't keep that these people
10 have actually sort of dotted all the i's and crossed
11 all the t's in that training and experience. Even
12 though I am personally comfortable with it, I don't
13 have documentation that proves it.

14 VICE CHAIR VETTER: Dr. Guiberteau?

15 DR. GUIBERTEAU: I think that Don has done
16 a very good job of framing this correctly. I can't
17 tell you how many calls I get from AUs who are
18 reluctant to sign attestations. And it's becoming
19 rampant. It's almost a panic. I get at least two
20 calls a week through the American Board of Radiology.

21 I have a personal interest in this because
22 I am responsible from the ABR perspective in terms of
23 providing the examination that the candidates will
24 take, which at the moment is spread out through
25 multiple examinations because we have both a written

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1 and an oral exam and a physics exam, et cetera, et
2 cetera.

3 I guess what I am getting at is that our
4 consideration is taking all of these components into
5 one radiation safety, radioisotope safety, NRC
6 curriculum examination that would be given before the
7 end of residency but not before the end of
8 certification for two reasons. Now, we haven't done
9 this yet, but it would be simple for us to do.

10 One is that perhaps it might provide a
11 justification, a technical basis for some change in
12 allowing program directors or, for instance, the ABR
13 to write a letter saying they passed the exam, they
14 have been attested to, and they have completed the
15 training and basically they're applying to you. They
16 haven't gotten their complete clinical certificate
17 yet, but they have completed the entire curriculum and
18 demonstrated a mastery of the basis of knowledge that
19 the NRC wishes them to have.

20 The other perspective on that is that it
21 might also provide an external measure by which
22 preceptors might be more willing to write their
23 letters. I don't know that.

24 But we're trying to find some way. I
25 mean, if we are going to go to this model if there is

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1 any way that that could in terms of the board
2 certification process, if that could provide an
3 additional way to do this?

4 VICE CHAIR VETTER: Any final comments,
5 Dr. Zelac?

6 DR. ZELAC: Just a question. Could you
7 indicate the principal reason that these individuals
8 have for their reluctance to sign attestation
9 statements?

10 DR. GUIBERTEAU: I think primarily it's
11 medical/legal and it's a matter of their -- it's also
12 the competency issue. Now, if that changes, that
13 might change things.

14 I might also add here when our residents
15 get their certificate, as Dr. Howe pointed out, they
16 get a certificate in diagnostic radiology. And if
17 they pass the AU portion, they get AU-eligible. All
18 right?

19 Some don't pass and don't get it. Some
20 programs don't attest. So they're not eligible to get
21 it on those certificates. So, in truth, the
22 certificate contains two pieces of information.

23 The question is, if we could give you that
24 piece of information that's pertinent to you before
25 this clinical certificate, could that be acceptable?

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1 And, to be honest, I don't expect this to
2 be resolved today, but I think this deserves
3 considerable consideration. It's not going to happen
4 tomorrow, but these examinations take years to
5 develop. And we would really like to have some
6 further consideration of this at some point.

7 VICE CHAIR VETTER: Dr. Eggli?

8 DR. EGGLI: I guess Dr. Guiberteau can
9 speak to it probably better than I can, but I believe
10 this new process starts for in-bound residents in the
11 year 2010. Is that correct?

12 DR. GUIBERTEAU: That is correct.

13 DR. EGGLI: And so by 2013, I would
14 personally like to see a solution that maintains board
15 certification process as a viable process for
16 diagnostic radiologists becoming authorized users.

17 But at the same time, maybe we can address
18 some of the issues that are associated with the
19 cardiology board exam, which creates a similar gap,
20 during which time individuals cannot become authorized
21 users by the board certification process because in a
22 sense, these gaps in here end up throwing the baby out
23 with the bathwater because the intent was that board
24 certification should prepare people to be authorized
25 users.

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1 But, yet, now we have a situation where we
2 can't do that because of this lag between when the
3 individual completes all of these requirements and
4 when the board certification goes.

5 I guess to again further address Dr.
6 Howe's question, we live in a very litigious world.
7 And there is sort of safety in numbers. The board
8 certification process gives me great comfort that not
9 just me personally feels this person has crossed the
10 threshold but that a certifying body agrees with that
11 impression.

12 And there is a real comfort for individual
13 preceptors that although I am still accepting an
14 individual liability by writing that preceptor
15 statement because NRC could if they choose hold me
16 personally responsible for that statement if the
17 individual turns out not to perform up to standard.

18 I am more comfortable when the board also
19 says that this individual has crossed the threshold.
20 And maybe it's just that they come down to "It's just
21 not me," but there are more people out there who agree
22 with the assessment. And, again, that addresses the
23 third part of the training and experience attestation
24 is it's not just me.

25 Other people who are professionals and who

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1 have observed the performance and tested the
2 performance of these individuals agree that they have
3 crossed the threshold.

4 So maybe you can say it's the safety in
5 numbers, but I am far more comfortable when I have
6 that other level of backing before I put my signature
7 on that preceptor statement.

8 DR. ZELAC: Of course, the follow-up to
9 that position is the fact that what we have heard so
10 far from the agreement states; from regional staff;
11 and, of course, from you is that those attestations
12 should be eliminated entirely for board-certified
13 individuals.

14 DR. EGGLI: Right. But, see, now what
15 happens, then again, Dr. Zelac, is we take that board
16 certification pathway away from diagnostic
17 radiologists and cardiologists because of this time
18 gap.

19 So what I would like to do is somehow find
20 a way to make board certification a relevant process
21 for the authorized user status again.

22 DR. HOWE: Dr. Eggli, it sounds as though
23 in your program you have taken away the alternate
24 pathway because you're not going to sign a preceptor
25 attestation until the person is board-certified.

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1 So you haven't negated the board
2 certification pathway. You have said at your program,
3 that is the only pathway.

4 DR. EGGLI: Our program has made that
5 decision, yes, that the board certification pathway is
6 the only pathway.

7 VICE CHAIR VETTER: Dr. Thomadsen?

8 DR. THOMADSEN: We also have had
9 problems, and it's interesting that it's with new
10 nuclear cardiologists coming into our program. We
11 have not been able to get attestations for them.

12 VICE CHAIR VETTER: Okay. Any final
13 questions or comments. Dr. Zelac?

14 DR. ZELAC: No.

15 VICE CHAIR VETTER: Okay. I am hearing
16 Dr. Guiberteau and Dr. Eggli. Is there a
17 recommendation or is there something that the
18 Committee needs to do at this point? Dr. Eggli?

19 DR. EGGLI: I want to do two things.
20 First of all, I want to say that this in no way
21 diminishes the work that has already been done. A
22 very good thing has happened, I think. But then,
23 secondly, we need to develop a way of looking at this
24 question and coming up with a solution.

25 I hate the concept of another

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1 subcommittee, but maybe the Committee as a whole
2 should think about the process. We should engage the
3 affected stakeholders in the form of American Board of
4 Radiology, in the form of the certifying Board of
5 Nuclear Cardiology.

6 American Board of Nuclear Medicine is a
7 little bit less effective because they only have a
8 three-month gap between the completion of training and
9 when the person can get a board certification.

10 But I think we should engage the
11 stakeholders into the process of trying to develop a
12 solution that both satisfies the training needs of the
13 program and may help satisfy the NRC requirements of
14 achieving authorized user status through the board
15 certification process and keeping that process
16 relevant.

17 VICE CHAIR VETTER: Dr. Guiberteau?

18 DR. GUIBERTEAU: I agree wholeheartedly.
19 And I also think the time is right for some sort of
20 decision on this, whether to stick with what we have
21 or to make it a bit different.

22 I do think the American Board of Radiology
23 because of this large number of diplomates every year
24 would be flexible in terms of perhaps considering
25 providing a certificate for AU eligibility at the end

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1 of residency if that would make a difference. Now, it
2 wouldn't make them board-certified, but it would
3 complete the process with a piece of paper from the
4 board.

5 I think the Committee knows best how to
6 approach this, but it really is an important question.
7 And we are doing all of our budgeting and all of our
8 planning for this examination process. It is set,
9 really, in terms of radiologic education and turmoil
10 because it is going to change the training pathways
11 considerably.

12 And I think once it gets on track, we
13 won't have another opportunity to change this in a
14 timely manner.

15 VICE CHAIR VETTER: Well, if I may
16 suggest, I don't think this is something the Committee
17 as a whole should be discussing here. It is way too
18 complicated.

19 But perhaps Drs. Eggli and Guiberteau
20 could think about this, possibly even proposing an
21 agenda item for the next meeting that would be a
22 little bit more thought out.

23 I also want to point out that the time gap
24 exists for all of these specialized individuals, for
25 AMPs, for RSOs. No physicist can graduate from a

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1 program and become an authorized medical physicist
2 until they practice for whatever the board requirement
3 is, two or three, five years before they can even take
4 the board.

5 In the meantime, they need to work under
6 the direction of an authorized medical physicist. The
7 same thing can happen with physicians, although I
8 understand that it is much more problematic for
9 physicians. But those things I think need to be taken
10 into consideration in trying to come up with a
11 proposed solution.

12 So if you could think about that, Dr. --

13 DR. EGGLI: Is this a subcommittee,
14 then, or --

15 VICE CHAIR VETTER: No, I am not proposing
16 a subcommittee at this point unless you want a
17 subcommittee. I think because we have some time, it's
18 a few years before this becomes effective, it would be
19 good to be very thoughtful about it. And perhaps, Dr.
20 Eggli, you could more or less take the lead in terms
21 of discussing this with boards and possibly coming up
22 with a solution.

23 DR. EGGLI: For Dr. Van Decker, is this
24 something that would be of interest to the cardiology
25 community as well?

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1 DR. VAN DECKER: Yes. I think that we
2 share some of the same pragmatic issues involved in
3 all of this. Obviously alternate pathway was
4 something that was a big piece of cardiology in the
5 past. And so we have had more experience that way as
6 well.

7 But certainly for our certification
8 pathway right now, which is our preferred pathway as
9 well in a lot of different ways, you know, we do have
10 interest in this.

11 VICE CHAIR VETTER: Dr. Zelac?

12 DR. ZELAC: This is more of an
13 administrative comment, but I think everyone
14 recognizes that Part 35 was modified in 2002, training
15 and experience were modified in 2005. And, of course,
16 each time that we do that, besides the effort that
17 goes into doing that, it is the agreement states which
18 have to make modifications to their requirements as
19 well.

20 Now, with that in mind, I know that the
21 position of previous Commissions and perhaps carried
22 over to this one is that Part 35 should be something
23 that is relatively stable when at all possible so
24 people know what to expect and move ahead with their
25 plan and their programs and with their expectation

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1 that reasonably there will not be significant changes
2 at the time that they want to use some part of that
3 regulation.

4 Since we are now talking through the
5 attestation to additional modifications to the
6 training and experience requirements in Part 35, I
7 think it would be very beneficial, personal opinion,
8 if there were going to be further changes to those T&E
9 requirements, that they be lumped and packaged
10 together so that we don't have to go back again and
11 then again later.

12 As I noted earlier, the intention at the
13 moment is to make changes to Part 35 dealing with a
14 variety of subjects, including the attestation for
15 T&E, in the next rulemaking that will begin when the
16 current one completes, which is expected to be
17 sometime in the spring, I believe. We'll find out in
18 a few minutes.

19 So on that basis, it would be very nice if
20 whatever input we were getting from the Committee
21 could get to us in time to incorporate into, personal
22 opinion again, the next rulemaking.

23 VICE CHAIR VETTER: Mr. Lieto?

24 MR. LIETO: Just a final question. Dr.
25 Zelac, just to be explicit, do you feel, then, waiting

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1 until the next spring meeting of ACMUI might be a
2 little bit too long of a wait for getting the input of
3 Dr. Eggli, Dr. Guiberteau, and Dr. Van Decker?

4 DR. ZELAC: If it were possible to get
5 input sooner, I think that would be beneficial.

6 MR. LIETO: Thank you.

7 VICE CHAIR VETTER: Dr. Nag?

8 DR. NAG: With these in mind, I would
9 make a motion that we do have a subcommittee and the
10 subcommittee comes up with a recommendation that can
11 be passed by the entire Committee by phone before the
12 next meeting. That's the motion I'm putting forth.

13 VICE CHAIR VETTER: Is there a second to
14 that motion? Dr. Thomadsen. Discussion of the motion
15 to appoint a subcommittee to address the training and
16 experience issues for physicians with --

17 DR. NAG: Not just physicians,
18 physicians and --

19 MS. GILLEY: Authorized users.

20 DR. NAG: For all the --

21 VICE CHAIR VETTER: For authorized users?

22 MS. GILLEY: Authorized individuals.

23 VICE CHAIR VETTER: Authorized
24 individuals?

25 DR. NAG: And through that, that it be

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1 an ACMUI -- that the conference sets up before the
2 next meeting.

3 VICE CHAIR VETTER: With a teleconference
4 sometime this winter. Is there a second to that
5 motion? Oh, there was. Sorry. Yes. Discussion of
6 the motion?

7 (No response.)

8 VICE CHAIR VETTER: All in favor of the
9 motion raise one hand.

10 (Whereupon, there was a show of hands.)

11 VICE CHAIR VETTER: All those opposed?

12 (Whereupon, there was a show of a hand.)

13 VICE CHAIR VETTER: Seven for, one
14 opposed, and --

15 PARTICIPANT: I abstain.

16 VICE CHAIR VETTER: And more than one
17 abstention? One abstention. Sorry. I was voting
18 for. So that's --

19 MS. TULL: There are nine.

20 MR. LEWIS: I think you miscounted.

21 VICE CHAIR VETTER: Okay. For again,
22 please?

23 (Whereupon, there was a show of hands.)

24 VICE CHAIR VETTER: Nine for. Opposed?

25 (Whereupon, there was a show of a hand.)

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1 VICE CHAIR VETTER: Abstaining?

2 (Whereupon, there was a show of a hand.)

3 MS. TULL: That adds up.

4 VICE CHAIR VETTER: Thank you.

5 And, Dr. Eggli, would you be willing to
6 chair that subcommittee?

7 DR. EGGLI: Sure.

8 VICE CHAIR VETTER: Who else would like to
9 volunteer to be on that subcommittee with Dr. Eggli?

10 DR. EGGLI: Well, I would like to
11 volunteer Dr. Guiberteau and William Van Decker.

12 MR. LEWIS: Dr. Guiberteau is not a member
13 of the Committee.

14 DR. EGGLI: Okay. Can we use him for
15 technical assistance?

16 MR. LEWIS: Yes.

17 DR. EGGLI: Okay.

18 DR. NAG: I would like to help on the

19 --

20 VICE CHAIR VETTER: Dr. Nag? Okay.

21 DR. NAG: The next time I will still be
22 here.

23 VICE CHAIR VETTER: Okay. And so the
24 subcommittee can coordinate its activities through
25 Ashley. And Ashley will schedule a conference call

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1 for the Committee sometime this winter to discuss this
2 issue.

3 Okay. Thank you, Dr. Zelac, for getting
4 us almost back on schedule. So we are scheduled for
5 a break now at this time. If we could please be back
6 at 10:45? We're still a little behind schedule.

7 (Whereupon, the foregoing matter went off
8 the record at 10:34 a.m. and went back on
9 the record at 10:48 a.m.)

10 VICE CHAIR VETTER: Okay. First an
11 administrative announcement by Ashley.

12 MS. TULL: During one of Ron's
13 presentations we were talking about the one RSO issue
14 and there's a question of what documentation had been
15 sent from OGC and I have a copy of the email that I
16 sent to you guys back in May as well as the second
17 document is what was provided during the April meeting
18 that was also justification from OGC. So those are
19 these copies that are coming around.

20 (Off the record comments.)

21 15. STATUS OF CURRENT AND FUTURE

22 10 CFR PART 35 RULEMAKING

23 VICE CHAIR VETTER: Okay. We are back on
24 the agenda item number 15, Status of Current and
25 Future 10 CFR Part 35 Rulemaking. Ms. Bhalla and Mr.

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1 Lohr will be presenting that.

2 MR. LOHR: Thank you. We are from the
3 actual Rulemaking division within the NRC and Neelam
4 and I do most all of the medical petitions and
5 rulemakings. And currently we want to discuss what is
6 out in the public right now as you know the proposed
7 rule and we want to also talk about future Part 35
8 rulemaking from the Rulemaking perspective. This will
9 be a short presentation we hope.

10 As I said, we have two Part 35 rules that
11 we want to talk about or two pieces if you will,
12 what's currently out in the public as you know right
13 now for public comment on the medical event
14 definitions and then we want later in this
15 presentation to talk about future Part 35 rulemakings
16 as we project them which, of course, as you know are
17 subject to change.

18 The other day I believe this committee and
19 this group has gone over very well in-depth of what
20 the Part 35 medical event proposed rule encompasses.
21 This is just a short brief piece if you will. You
22 have discussed this in great depth and we do not
23 intend to do so, just to point out to those who may
24 not be familiar with this as to what the rulemaking
25 entailed.

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1 To give you a status, the proposed rule
2 actually published in the Federal Register on August
3 6th. Our public comment period was originally
4 supposed to expire on the 20th of October. Based on
5 this committee's request, we moved it forward to
6 November 7th so that all the public comments and such
7 could be vetted here in a public forum and this group
8 could then send the recommendations to the NRC.

9 Do understand that everything that we
10 receive in the public comment period will be reviewed
11 by the working group and we will resolve what we call
12 public comments and those resolutions will appear in
13 the final rulemaking.

14 To give you a little bit of a time frame
15 involved, it's approximately a year to develop and
16 publish this final rule. It's very dependent on what
17 these public comments have to say and what this group
18 will put in writing and send to the NRC. Sometimes
19 when we receive information that we didn't have when
20 we started the proposed rule, we will have to go back
21 and do additional analysis, additional research.

22 But we anticipate that this will publish
23 in 2009 pending Commission approval and that's a point
24 I want to bring out is that all rulemakings are
25 approved by the Commission or their representative

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1 before they're ever published. So this is not done in
2 a vacuum. This is done with upper management's
3 approval.

4 There's always a question of why the
5 process is so lengthy and my supervisor, Mark
6 Delligatti, came before this group I believe last year
7 and laid out the process and I wanted to reiterate
8 that it is a delivered process and it's a
9 collaborative process. Everybody gets to bring their
10 viewpoint to the table and all viewpoints are
11 considered whether they come from a group such as
12 ACMUI or from individual practicing or just a citizen.
13 Each one carries the same weight of consideration
14 within the working group at the NRC.

15 And again, we must resolve these comments.
16 And the Commission does take its role very seriously
17 in reviewing and approving of these regulations. So
18 there is, of course, as you know, multiple
19 rulemakings going on at the agency not only on the
20 material side which is what we represent but also on
21 the reactor side the funnel through the Commission's
22 office. So this is part of what takes so long in the
23 process. But it's a deliberate process so that things
24 do not -- nobody gets run over shall we say in the
25 process. Everybody has their say in it.

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1 MS. BHALLA: I just want to add on that
2 that comments are also received from the agreement
3 states. So when we send our proposed rule, we also
4 include the agreement states for their comments.

5 MR. LOHR: I want to talk a little bit
6 about our next Part 35 rulemaking. As I said, we
7 anticipate the current 35 rulemaking to finish up late
8 in the summer in August. There will be numerous
9 amendments that have already been identified by the
10 NRC medical team and all these proposed changes to the
11 35 either have been reviewed by ACMUI or will be
12 before they come to us in rulemaking.

13 I want to reiterate that things do not
14 come to rulemaking unless the medical team brings them
15 to us. And so the medical team is our client, if you
16 will, and us in Rulemaking our role is then to take
17 what they bring to us and get it through the
18 rulemaking process, make sure it stays legal, make
19 sure all the inputs are handled properly and all the
20 viewpoints are brought to the table and resolved.

21 I do want to emphasize that and this was
22 brought up by Dr. Zelac that the Ritenour petition
23 should be included in the next rulemaking. But as you
24 have read in the Federal Register from the petition
25 resolution it is very clear that there is not a

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1 technical basis at this point that data would have to
2 come in from the community for the medical group to
3 form that technical basis to bring to the rulemaking
4 group. But the plan is and we have it in our
5 schedules and rulemaking is to have the Ritenour
6 petition as part of the next Part 35.

7 So I just wanted to reemphasize that if it
8 is not a technical basis formed by the medical group,
9 it will not come to rulemaking. There will not be a
10 rule. And the petition said that and we want to make
11 sure that's very clear that it's not misinterpreted as
12 automatically goes into rulemaking space. That
13 technical basis must be developed and brought to us.

14 Again, I want to talk about our time
15 lines. We anticipate beginning next summer at the
16 finish of this current Part 35. But these are
17 schedules. Many things affect our schedules, anything
18 from empower to budget to whatever. We then
19 anticipate taking approximately a year to do the
20 proposed rule and put it up for public comment just as
21 we've done this one and then another year then to
22 resolve the comments and go through the concurrence
23 process to do a final rule in 2011.

24 In summary, if we have any questions on
25 the actual process, we can answer that. If there are

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1 any questions as to what will appear in those rules,
2 that's really the medical team. They will bring us
3 those. We can address what's, of course, in the
4 current rulemaking because we have that. But anything
5 into the future I believe Dr. Howe is going to talk
6 about some of that at the next presentation. But
7 understand we already have some items that they have
8 brought to us in a user need memo and I believe all
9 those have been before the ACMUI already. Is that
10 correct, Dr. Howe?

11 DR. HOWE: I believe so, yes.

12 MR. LOHR: So at this point, I'll just
13 open up if you have any questions on the process.

14 VICE CHAIR VETTER: Any questions on the
15 process? Dr. Eggli.

16 DR. EGGLI: Technical basis, I guess
17 that's one of the concepts that I'm a little bit
18 confused about. I guess that means the justification
19 for making the rule essentially.

20 MR. LOHR: Essentially.

21 DR. EGGLI: Are there standard components
22 of that or is it just you simply lay out the
23 justification and you lay out how many people are
24 affected? I mean, what does it take to make a
25 satisfactory technical basis for a rule?

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1 MR. LOHR: We actually have guidance from
2 the Rulemaking group that goes to all our customers,
3 if you will, within NRC including the medical team
4 that spells out what must be in a technical basis and
5 I don't think there's anything unclear to the medical
6 group as to what they need and I think that they have
7 asked for from the community what they need for that
8 data piece. I think the other pieces they have that
9 are administrative in nature, how does it fit the NRC
10 goals and those sort of things, that all appears in
11 the technical basis.

12 MS. BHALLA: Could I just add to it?
13 Basically, as Ed said, technical basis is really our
14 customers are going to bring to us the basis and one
15 of the main things is what is it in the rule that's
16 not working right now. That is the foremost thing.
17 And then because rulemaking is a very expensive
18 process, rulemaking is also a lengthy process. So
19 then we also ask in this technical basis is are there
20 other avenues. Is rulemaking the only avenue that's
21 left to you or could you do it in terms of some other
22 ways that you could? Then, of course, comes the
23 question of how many people will be affected by this.
24 Is there a burden on the licensees? What are we going
25 to achieve and that's the first thing why the rule is

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1 needed.

2 So even for within NRC, I think there used
3 to be a little bit of I won't say a misunderstanding,
4 but people didn't have -- like they didn't quite know
5 exactly what our technical basis is. So recently in
6 our Rulemaking division we have come up with a paper
7 so to speak where we are defining or we are explaining
8 what our technical basis is and that came from the
9 Commission and now when we give our rulemaking
10 courses, little seminars and so on, we also include
11 this paper technical basis and it is available if
12 ACMUI would like to have that. We would be very happy
13 to send a copy of that.

14 MR. LUEHMAN: Dr. Vetter.

15 VICE CHAIR VETTER: Yes.

16 MR. LUEHMAN: Just to add on to what
17 Neelam and Ed have said, I think one of the key, to
18 answer Dr. Eggli's question, statements has to be in
19 the technical basis and Neelam touched on it is what's
20 the problem. But I think we want a very definitive
21 statement of the problem. A lot of times having
22 worked in rulemaking you know the effected branches or
23 divisions will come and say, "This rule is no good."
24 "Well, we have to have to have a little bit more than
25 that." "Okay. This part of the rule is no good."

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1 "Well, you're getting warmer." And you really have to
2 get it defined. Because as you have in earlier
3 discussions, one of the things that you find out in
4 rulemaking is you only want to change what you
5 absolutely have to change what is exactly the problem.

6 Because if you make changes too broadly, then you
7 have the potential for unintended consequences when
8 you start going and changing words or sections that
9 are outside what you immediately have to change. Then
10 you create one of the big dangers in rulemaking which
11 is to create unintended consequences to fix one thing
12 but then through inaccurate wording create problems in
13 other areas.

14 So one of the major goals of the documents
15 that Ed and Neelam are talking about is to get a
16 precise, as precise as we can, problem statement from
17 the users that want the rule changed and then some
18 precise to the extent that it's available data that
19 supports why that it's a problem and what could fix
20 it. And in the past, I think that rulemakings have
21 gotten hung up when the Rulemaking group then gets a
22 less than precise statement of the problem, embarks on
23 the rule, goes to the first stage of the rule.

24 And, for instance, if we started with an
25 advanced notice for rulemaking or a proposed rule and

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1 it's very unfocused and you get a lot of comments back
2 "Well, you guys are changing way too much. You're
3 creating all these problems," I think that we've
4 learned that lesson the hard way. So what we're
5 trying to do in the rulemaking area is really force
6 the groups that are asking for the change to be very
7 focused in their comments. It results in a better
8 rulemaking and, as Neelam said, it's a very resource
9 intensive process.

10 VICE CHAIR VETTER: Okay. Dr. Thomadsen.

11 DR. THOMADSEN: Could we get a copy of
12 that document please?

13 MR. LOHR: Sure.

14 VICE CHAIR VETTER: That would be helpful.
15 Thank you. Dr. Nag.

16 DR. NAG: Yes. I would like to mention
17 again that you have from the ACMUI some information
18 that it gives to medical group I believe.

19 MR. LOHR: That's correct.

20 DR. NAG: Right. And then there's always
21 some loss of communication when it goes from one group
22 to the other to the other to the other. So it goes
23 from ACMUI to the medical group and then from the
24 medical group, they make the technical basis and then
25 it goes to the rulemaking group and then from the

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1 rulemaking group it goes out for the public comment.
2 In between there can be some losses of details. There
3 can be perhaps even miscommunication or there can be
4 because of the time sequence that can be dangerous in
5 overall situations or overall techniques that by the
6 time that the rulemaking is done some of the things
7 are not appropriate.

8 So I would like once this tentative
9 rulemaking has been done to then instead of going for
10 the public comments first to then come back to the
11 ACMUI to say, "Yes, this is what we are tentatively
12 doing. Do you have any comments before it goes out
13 for public comment?" You may be able to shut down
14 some of the problems. Could you comment on that? Is
15 that plausible or is that something that's even
16 doable?

17 MR. LOHR: That is not a process, Dr. Nag.
18 We in Rulemaking have a process that we have to
19 follow. The APA spells out the -- I can't remember
20 what the APA stands for. Administrative Procedures
21 Act.

22 MS. BHALLA: Administrative Procedures
23 Act.

24 MR. LOHR: Thank you. It spells out the
25 process. We have to follow this process or our

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1 regulations are not legal. Part of the process is, of
2 course, to get input as we start down the road for the
3 technical basis. This is where your committee fits
4 in. As I understand, you're an advisory committee to
5 the medical group. Okay. So you would make advice to
6 the medical group. They in turn take that advice and
7 then they put that in their technical basis such as
8 they bring to us.

9 Once it's in our hands we then are
10 following process. Our process then for your feedback
11 is the public comment period. So it's not closed, but
12 there is -- In process if we were then to bring you
13 back in, we would have to bring the whole public back
14 into it in fairness and if we don't follow a process,
15 then our regulations are not legal and subject to
16 challenge.

17 DR. NAG: In that case can the feedback be
18 at the earlier stage, that is, when the medical group
19 gives its recommendations to you to make the rules,
20 can we be seeing a copy to make sure that that is what
21 we really intended?

22 MR. LOHR: That's between you and the
23 medical group, sir. Once it comes to us --

24 DR. NAG: Well, a member of the medical
25 group, is that possible?

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1 MR. EINBERG: I believe that's possible.

2 MR. LEWIS: I hate to walk in the room and
3 jump in the conversation. But the process by which we
4 get back to the committee is something that I admit we
5 need to work on and Dr. Malmud and I have taken an
6 action to talk about that. We haven't gotten to it
7 yet. That's actually one of the action items on our
8 list.

9 Your point is right. We need to do a
10 better job of telling you how we took or did not take
11 your comments and whether the process is what we have
12 to define. We know what we have to do. We just have
13 to get it in the right process.

14 VICE CHAIR VETTER: Dr. Suleiman.

15 DR. SULEIMAN: Yes, I raised this question
16 earlier, but I'm going to raise it again. Basically,
17 I think it would help streamline or it would be one
18 little tiny step in the right direction. When you
19 write some regulations, why can't you adopt scientific
20 constants for example? I'm not saying you adopt the
21 ICRP standards or guidelines on dose limits, but let's
22 say you've defined pi, 3.14, whatever, and all of a
23 sudden somebody comes up with a slightly different --
24 you don't have to codify that every time the number
25 changes. Why can't you say using the most

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1 scientifically available equilibrium constants or
2 whatever and not have to take those constants and
3 republish them in the CFR? Wouldn't that make some of
4 the part of your rulemaking easier?

5 MR. LOHR: I think part of that answer
6 lies in the answer that you received earlier on the
7 legalities of doing that and part of the answer lies
8 in what's brought to the working group or to the
9 rulemaking group from the customer or in this case the
10 medical team. We would not add. We may suggest to
11 them that they want to add some things, but we would
12 not add to their want or desire to change a particular
13 piece.

14 And if they brought to the rulemaking
15 group a reference if you will, we're just going to
16 incorporate this as reference I believe is what you're
17 referring to, that would be considered under -- Of
18 course, we would then go to our Office of Legal
19 Counsel and say, "Can we do this" and they may say yes
20 or no. So it's really up to the customer who brings
21 that to rulemaking to whether or not they would want
22 that.

23 DR. SULEIMAN: I mean, I'm trying to make
24 the differentiation between something that has been
25 politically or administratively decided versus a

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1 scientific value, you know, a scientific methodology.
2 Let's see how you calculate dose for example.

3 (Off the record comments.)

4 DR. ZELAC: In response to what you're
5 saying, I should note that our attempt is to do
6 exactly what you are asking for whenever possible and
7 I give as examples several places in the current Part
8 35 where rather than refer to some particular standard
9 we tried to put language in which is general enough so
10 that when that standard is revised individuals using
11 that particular section of the regulations can use the
12 revised version immediately.

13 DR. SULEIMAN: Without having to --

14 DR. ZELAC: As an example, 35.432,
15 Calibration Measurements of Brachytherapy Sources says
16 "Before the first medical use of a brachytherapy
17 source on or after this date a licensee shall have..."
18 and then number three down the step is "... used
19 published protocols currently accepted by nationally
20 recognized bodies to meet the requirements of
21 paragraphs one and two above."

22 DR. SULEIMAN: So you actually do that.

23 DR. ZELAC: It's an example. We try to do
24 it whenever we possibly can. We also certainly try
25 not to develop any standards of our own. If there is

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1 something in the regular user community which is
2 recognized and accepted by that community, we will
3 adopt it.

4 VICE CHAIR VETTER: Okay. Dr. Howe.

5 DR. HOWE: My comment was very similar to
6 Ron's response and I think another important part of
7 this picture is in some cases we have specific
8 regulations that you have to meet. In other cases for
9 Part 35, you don't have to provide your procedures.
10 You have to provide a commitment that you will do
11 something. So generally for those sections where you
12 provide a commitment that will do something, we allow
13 you to adopt, to use, a nationally recognized
14 standard.

15 So it depends on whether the regulation is
16 very prescriptive or we can take that section and make
17 that more performance based. There is a mixture in
18 there depending on where we are. Part 20, I don't
19 think we have that flexibility on doses, things that
20 Dr. Cool was talking about.

21 DR. SULEIMAN: I think there are so many
22 other societies and organizations in play that maybe
23 you need to make more of an effort to incorporate that
24 style because maybe there's some benefit to be gained
25 by adopting work that some other organization or

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1 society has already done.

2 VICE CHAIR VETTER: Dr. Nag.

3 DR. NAG: I think in that respect we, the
4 members of ACMUI, can be of help because we are
5 working with these organizations and publications all
6 the time. So if we are aware of certain standards,
7 certain obligations, we should forward that to the
8 medical team to be of assistance to you.

9 VICE CHAIR VETTER: Is there any other --
10 Yes.

11 MR. LUEHMAN: I just want to comment on
12 that, Dr. Vetter. I think that as Ron said that we
13 attempt to do that. But then in response to the
14 question when does a standard become a standard, I
15 mean, there are lots of different standards out there.
16 There are lots of different standard setting type
17 organizations and we not only have to look at not only
18 the medical community. But as Donna-Beth said when
19 you have some of the regulations which not only affect
20 the medical community but go over into the other
21 effected communities that we have, the reactor
22 community, the materials community, the type of
23 standard setting bodies and the processes that
24 different standard setting bodies use, can be
25 different.

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1 And so we have to be careful that as I
2 said in the beginning what is a standard and it may be
3 very defined and clear in a medical context how those
4 standards and whether they're adopted in other
5 communities may not be exactly the same. So we have
6 to be careful when we write our regulations because
7 again getting back we may have unintended consequences
8 because the standards that are set in other areas
9 aren't using, you know, they have draft standards.
10 There's a lot of different ramifications and so we
11 have to do that very carefully. We try to do it, but
12 it's not going to be universal. It's never going to
13 be universal.

14 VICE CHAIR VETTER: Mr. Lewis.

15 MR. LEWIS: I would also add that we do
16 try to consider standards wherever possible as part of
17 a rulemaking. There is a trick to that though.
18 Rulemakings are defining the minimum regulatory
19 acceptable practice and standards often are written
20 towards best practices especially standards by
21 consensus organizations. And we often find this in a
22 situation where we don't necessarily want to put the
23 best practice in the regulation because it's one way
24 of doing things. But in terms of our mission and
25 safety, defining the level of safety, it is not

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1 necessarily appropriate from a regulatory perspective
2 to have such language in a regulatory requirement.

3 DR. SULEIMAN: I understand. I mean, one
4 size doesn't fit all and there are some organizations
5 that are recognized as being able to generate
6 standards. FDA recognizes some voluntary standards,
7 but recognizing them doesn't mean the same thing as
8 saying, "If you meet it, you comply with our
9 regulations." I understand that.

10 And sometimes I would argue a voluntary
11 standard in terms of a public health standard is not
12 a very good standard because it's not mandatory. I
13 mean, if you're trying assure safety, then it has to
14 be mandatory. What I'm getting at is don't duplicate
15 work that may have already been done elsewhere.

16 VICE CHAIR VETTER: Any final questions or
17 comments for Ms. Bhalla or Mr. Lohr.

18 (No verbal response.)

19 If not, thank you very much. We
20 appreciate your updating us on the status of current
21 and future 10 CFR rulemaking.

22 16. POTENTIAL CHANGES TO 10 CFR PART 35

23 VICE CHAIR VETTER: Dr. Donna-Beth Howe
24 will now update us on potential changes to 10 CFR Part
25 35 and seek our advice. We don't have much advice of

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1 course.

2 DR. HOWE: You always have. Okay. Ed was
3 talking to you about the fact that the medical group
4 brings things to the ACMUI and then eventually takes
5 them off into rulemaking and over the years I've been
6 presenting to you potential changes because we're
7 getting you involved very, very early on. For one
8 reason or another, the NRC has realized that we have
9 a problem with the regulation or we need an additional
10 regulation to clarify something.

11 And so I bring these to the ACMUI. What
12 we pass on in the user need memo which is our document
13 that goes over to rulemaking is generally an exact
14 duplicate of what you're seeing or if you make a
15 motion that changes some wording, then we put the
16 revised wording in.

17 In some cases, we don't know what the rule
18 would look like. So we propose a generic type of
19 change, where we want to go. We don't know how to get
20 there, but this is where we want to be. So in those
21 cases you're not going to see rule language going to
22 the Rulemaking group and it will be the group that's
23 working on the rule that works out the specific
24 language.

25 Now I just have a few items for us today.

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1 You probably have to follow along on the printouts
2 because these are kind of small to see.

3 (Simultaneous speakers.)

4 Okay. In this particular issue, we're
5 looking at certificates of financial assurance. Most
6 medical licensees don't trigger certificates of
7 financial assurance for sealed sources. But we've had
8 a few cases where we've got people that are getting
9 new Perfexion Gamma Knife units. They still have the
10 existing Gamma Knife unit that has a fairly high
11 activity. So it's not a case that it's about ready to
12 source exchange, but they're going to the new
13 technology and we can see this happening more
14 frequently with the Gamma Knife and maybe other cases
15 in the future.

16 So for a very short period of time the
17 activity for the sealed source and the cobalt may
18 exceed the level of which you need a financial
19 assurance statement that may be higher than what you
20 have. And so what we're recommending is that the
21 financial assurance requirements in 30.35(b) be
22 revised so that we have an addition that says if you
23 have byproduct material for half-life greater than 120
24 days of quantities specified in paragraph D of the
25 section except we're going to allow licensees to

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1 exceed those limits for a short period of time,
2 60days we think is more than adequate, due to source
3 exchange for very large sources.

4 VICE CHAIR VETTER: Is there a motion to
5 support that?

6 DR. EGGLI: So moved.

7 DR. NAG: Second.

8 VICE CHAIR VETTER: Dr. Eggli and Dr. Nag
9 seconds. Discussion?

10 (No verbal response.)

11 All in favor? Yes, I'm sorry.

12 DR. EGGLI: One discussion question and I
13 have no knowledge of it, but if you're installing a
14 new Gamma Knife and have the old one side-by-side is
15 60 days a resonable time to get the new one calibrated
16 and online?

17 VICE CHAIR VETTER: Yes.

18 DR. EGGLI: Okay. Good. All in favor?

19 DR. NAG: One comment on that. On the --
20 we have to ensure that having the two sources together
21 would not exceed the radiation exposure of -- That's
22 something.

23 MS. GILLEY: That's different. Release
24 them from any other regulatory requirement.

25 DR. EGGLI: That's a different matter.

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1 This is just financial.

2 VICE CHAIR VETTER: Okay. One more time.
3 All those in favor?

4 I believe it's unanimous. Thank you very
5 much, Dr. Howe. Next item.

6 DR. HOWE: Part 35.40, in this case it
7 says the part of the regulations that deals with the
8 written directive and in the current proposed
9 rulemaking they've dealt with the fact that for
10 permanent brachytherapy there are two components to
11 the written directive. There is the before
12 administration and then there is before completion of
13 the procedure and, in the propose rule, they made it
14 clear that the authorized user needs to sign. If
15 there are changes, the authorized user needs to sign
16 both documents if there are changes.

17 So what we're doing is we're extending
18 that concept to all other brachytherapy and HDR
19 procedures that also have a before administration and
20 before completion of the procedure components to the
21 written directive. And so where in this case we don't
22 have specific rule language, but we're recommending
23 that 35.40 be revised to clarify that the AU needs to
24 sign and date both before administration and after
25 implementation parts of any written directive for all

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1 modalities that have the two parts.

2 VICE CHAIR VETTER: Is there a motion to
3 support that recommendation? Dr. Eggli.

4 DR. EGGLI: So moved.

5 VICE CHAIR VETTER: Dr. Thomadsen second.
6 Discussion? Yes, Mr. Lieto.

7 MR. LIETO: What is the impetus for this,
8 Dr. Howe? Had there been medical events or I should
9 say potential medical events that have created this?
10 In other words, what's the health and safety issue
11 that we're also trying to address if it's not a
12 medical event issue?

13 DR. HOWE: I can't give you a specific
14 medical event. But the issue is to make sure that the
15 authorized user is aware of any changes made to the
16 written directive especially when you have two part
17 written directives to make sure that things were in
18 accordance with the authorized user's wishes.

19 VICE CHAIR VETTER: Dr. Nag.

20 DR. NAG: It would be permanent
21 brachytherapy that would fall under these two parts
22 because if it does then it's really easily solved when
23 you think about the things we were discussing
24 yesterday. Is that a two part issue?

25 DR. HOWE: This particular clarification

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1 is already in the proposed rule for permanent
2 brachytherapy. So we're just extending to those other
3 parts with the two part directive.

4 DR. NAG: Okay. So it includes now the
5 HDR and --

6 MS. GILLEY: No, it only includes manual
7 brachytherapy. That's 400.

8 DR. NAG: Also HDR. No?

9 MS. GILLEY: 35.40. Excuse me.

10 DR. HOWE: HDR does not have a two part
11 written directive. So this would be all other parts
12 of manual brachytherapy.

13 VICE CHAIR VETTER: Mr. Lieto.

14 MR. LIETO: So we're talking that this is
15 to address low, medium and pulse dose rate remote
16 after loaders in permanent brachytherapy. Is that
17 correct?

18 DR. HOWE: I don't think so. I'm looking
19 right now to make sure. High dose rate, remote
20 afterloading, radionuclide therapy, dose fractions,
21 all other brachytherapy, yes, including low, medium
22 and pulse rate afterloaders. Yes, you're right.

23 MR. LIETO: So it includes all because I
24 agree with Dr. Nag. This would resolve that very
25 lengthy discussion we had yesterday on permanent

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1 brachytherapy. But this would also then apply to Part
2 1000 or would this also apply to the Part 1000 Y-90
3 microspheres because that's considered a brachytherapy
4 device?

5 DR. HOWE: It's considered a
6 brachytherapy. When you -- it's kind of difficult to
7 answer across the board for Part 1000 because 1000 is
8 1000 because it doesn't necessarily fit. If your
9 particular 1000 device fit everything in the written
10 directive requirements, we would in the guidance say,
11 "You should meet the written directive requirements
12 for the basic device."

13 DR. NAG: But the Part 1000 Yttrium-90,
14 that is already -- It is No. 1 in the guidance. No.
15 2 in the guidance is already written that if there
16 were stasis, then you would face it and you sign it.
17 It's already there.

18 DR. HOWE: So for the Yttrium-90 we took
19 the -- we recognize that you might have stasis as a
20 different method and an endpoint. So we added that
21 and that's a case where the written directive is
22 modified for the particular device. But if we had
23 even the written directive for the Perfexion was
24 modified for the Perfexion because the written
25 directive for the Perfexion you need to specify which

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1 sectors you're going to have on each treatment because
2 you don't have just one collimation. Right now, I
3 can't think of one that we haven't modified the
4 written directive for but it could be.

5 MR. LIETO: Is the intent of this proposal
6 that the authorized user that does the first part is
7 the same authorized user who does the second part?
8 Because I could see an authorized user writing it,
9 writing a written directive, which may be a day or two
10 in advance or maybe even that morning and then another
11 AU would be the one that is actually there during the
12 procedure and could sign off and I guess I would ask
13 my colleagues at the table is that acceptable.

14 DR. HOWE: I think I would want to defer
15 to Ron and Ed as to what the proposed rule says. I
16 don't think it got to this level of thought, but it
17 doesn't mean it doesn't address it.

18 DR. ZELAC: This is Dr. Zelac. I believe
19 the general expectation is that the physician that
20 gives the directive, makes the directive available. is
21 in fact the person that would sign the concluding
22 directive, that what he or she wanted initially in the
23 initial directive was in fact carried out or modified
24 and acknowledged what those modifications were.

25 DR. NAG: From a technical standpoint

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1 although most of the time the one who started was the
2 one who ended is the same. Many times it is not. For
3 example, I may implant a patient and I have to be out
4 of town. So the implantation for the dose length can
5 be three days or five days and I may not be the one
6 available to take it out. But I assign it to an
7 authorized user and it's perfectly legal and right now
8 we are doing it that way. So you are going to change
9 an established procedure if you say that same person
10 has to be signing it before and after. So I don't
11 think that should be acceptable.

12 DR. HOWE: Dr. Zelac.

13 DR. ZELAC: If I can interject, I don't
14 think there's anything that's being proposed here
15 which is going in that direction. No one said
16 anything in particular in this writing that says it
17 had to be the same person. That's wasn't an issue.

18 VICE CHAIR VETTER: Mr. Lieto was simply
19 requesting a clarification.

20 Dr. Thomadsen.

21 DR. THOMADSEN: I was going to make the
22 same point that Dr. Nag just made.

23 VICE CHAIR VETTER: Okay. Any other
24 comments on this recommendation or on the motion to
25 support this recommendation?

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1 Dr. Eggli.

2 DR. EGGLI: I have a run going here. Yes,
3 but I move to support.

4 VICE CHAIR VETTER: You've already done
5 that. We're discussing the motion to support. All in
6 favor, raise one hand.

7 Unanimous.

8 MS. GILLEY: I'm much more agreeable
9 today.

10 (Laughter.)

11 VICE CHAIR VETTER: We appreciate that.
12 All right. Thank you, Dr. Howe. Next recommendation.

13 (Off the record comments.)

14 DR. HOWE: Okay. In this case, we're
15 looking at 35.65 and 35.590. 35.65 has traditionally
16 been those sources that are used in medical use for
17 calibration, for various purposes, that are associated
18 with medical use but not with patient irradiation.

19 In 2002, we added transmission sources to
20 it not totally appreciating that we may have been
21 adding a transmission source that involved patient
22 irradiation into a section that has no authorized user
23 associated with it and isn't normally set up for
24 patient irradiation. And so the recommendation here
25 is that the transmission sources would stay in 35.65

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1 if there's no patient irradiation. We'd move them to
2 35.500 authorization which is very minor
3 authorization, diagnostic sources because you would be
4 irradiating the patient in the scan and we'd make the
5 training and experience very minimal as it goes with
6 the 35.590.

7 Most of these transmission sources are
8 used by 35.200 authorized users and so we were also
9 proposing that if you're a 35.200 user you're
10 automatically authorized to use these transmission
11 sources. So that was the problem.

12 The recommendation is to revise 35.65 so
13 that it does not apply to byproduct material that used
14 intentionally to administer radiation for byproduct
15 material to patients or human research subjects and
16 that 590 would be revised to say that an authorized
17 user under 35.280 requesting use of a transmission
18 source in administering radiation to a patient or
19 human subject would be covered under the training and
20 experience of 35.590.

21 VICE CHAIR VETTER: Is there a motion to
22 support that recommendation? Dr. Egli. Is there a
23 second? Mr. Lieto. Discussion?

24 DR. HOWE: Ralph, do you have discussion?

25 VICE CHAIR VETTER: Ms. Gilley.

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1 MS. GILLEY: What is the purpose of a
2 transmission source if it's not to image the patient
3 for the purposes of nuclear medicine to do some type
4 of anatomical --

5 DR. EGGLI: It may be a semantic thing,
6 but we use the same source often for quality control.
7 We put it across the collimator and flood a camera
8 with this same source that we use for transmission
9 purposes. So there is no difference between a cobalt
10 sheet source and a transmission source. It's the same
11 thing. It's just how you're using it.

12 MS. GILLEY: But for SPEC capabilities and
13 all I think it's SPEC that they use a transmission
14 source to an anatomical location and then they do the
15 nuclear medicine component and lay it over in a
16 computerized fashion.

17 DR. EGGLI: There are some cameras that do
18 attenuation correction that use transmission sources.

19 MS. GILLEY: I think of the cobalt-57 not
20 as a transmission source but a quality assurance for
21 your camera source. So I guess I have --

22 DR. EGGLI: That's not what this is
23 referring to.

24 MR. FISHER: Are they talking about x-ray
25 here?

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1 DR. EGGLI: No.

2 MR. FISHER: Germanium sources and PET
3 scanners.

4 DR. EGGLI: Right. It's primarily PET
5 scanner.

6 MR. FISHER: But would this not also
7 include an iodine-131 transmission flood source used
8 for patient dosimetry?

9 DR. HOWE: If you were using the flood
10 source to calibrate your device that would be under
11 35.65. If you put a patient between a flood source.

12 MR. FISHER: For the patient to determine
13 attenuation factors, that would be the 590.

14 DR. HOWE: That would be the 590 for this
15 proposal because you are deliberating irradiating a
16 person.

17 VICE CHAIR VETTER: Dr. Van Decker.

18 DR. VAN DECKER: I think I need a
19 clarification I guess. When we talk about
20 transmission sources, I assume that one of the ones
21 that we're talking about here is gadolinium line
22 sources that are used for attenuation maps and SPEC
23 and obviously these are common and used in the 200
24 uses all the time for improving image quality and
25 making better diagnoses. So I guess my question is

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1 how does this affect that current use right now.

2 DR. HOWE: It should not affect it. It
3 just moves the source into the parts of the regulation
4 35 that deal with patient delivered administration of
5 radiation to patients. It's diagnostic because it's
6 diagnostic. We have very limited requirements on
7 training and experience and because it is normally
8 used in 200, the concept was to in here recognize that
9 a physician authorized user that's authorized for 290
10 would automatically be recognized as a user for these
11 sources. So there is a connection.

12 VICE CHAIR VETTER: If I may ask Part D is
13 an authorized user under 35.290 requesting use.
14 Requesting could simply be built into the procedure.
15 Correct? So when a procedure is ordered the procedure
16 describes the use of the transmission that is in
17 essence the request. You're not looking for a
18 specific written request each time a patient is
19 scanned.

20 DR. HOWE: No, that's more intended to be
21 it would be added to the license. In other words, we
22 would add transmission sources to the license and say
23 any time you had a 200 authorized user you'd say for
24 35.200 uses and 35.500 and many times our regions will
25 automatically add 500 because it's eight hours of

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1 training and experience on a device and they'll
2 automatically put it in.

3 Yes, Ralph.

4 MR. LIETO: If I'm understanding this
5 right regarding the Item D, you're adding this to
6 training and experience requirements. Is that
7 correct?

8 DR. HOWE: I've made it --

9 MR. LIETO: As opposed to an authorized
10 use.

11 DR. HOWE: It's added to the authorized
12 use because it's not included in -- If you're exposing
13 patients or human research subjects, it won't be in
14 35.65. 35.500 does not prescriptively list things
15 that are in it. So that automatically moves it to
16 35.500 and then you look at the training and
17 experience requirements to use a device under 35.500
18 and you have all of these requirements. You're either
19 (a) and I would have to look to see what (a) is or
20 you've completed training and use in the device for
21 uses requested or another alternative is that you are
22 an authorized user under 290. So if you're already an
23 authorized user you are automatically authorized to
24 use this 500 device.

25 VICE CHAIR VETTER: Dr. Eggli and then Ms.

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1 Gilley.

2 DR. EGGLI: I think to try to restate that
3 is if you are already authorized for Part 200 uses
4 having met the training requirements of 35.290, then
5 these sources are automatically included and you are
6 deemed appropriately trained for their use if you are
7 authorized for Part 200 uses. Is that correct?

8 DR. HOWE: That's correct.

9 DR. EGGLI: Okay.

10 MS. GILLEY: I'm going to get into
11 implementation of this. Is the intent of this change
12 to have transmission line item on licenses because
13 right now if they're less than 30 millicuries, we're
14 not having to have line item them.

15 The second issue is for those authorized
16 users that have 290 capability. Are we now looking at
17 also including the line item for these transmission
18 sources to be added to their authorization?

19 DR. HOWE: Our regional experience is that
20 if we have sources under 35.65 under the 30
21 millicuries that they will include it in the automatic
22 authorizations in the regulation.

23 MS. GILLEY: That's correct.

24 DR. HOWE: If they exceed 30 millicuries,
25 then they take them out.

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1 MS. GILLEY: It's line item.

2 DR. HOWE: The intent here would be if you
3 use any source that's being used to irradiate a
4 person, it will come under 500. Now we also have a
5 revision in that you haven't seen because you weren't
6 on the ACMUI earlier and that was using a notification
7 process to identify when you have sources that might
8 have been line itemmed before for sealed sources.

9 MS. GILLEY: Okay.

10 VICE CHAIR VETTER: Just to clarify, we're
11 not -- Again, even under 500, we're not talking about
12 line itemming these sources, are we? Because they
13 come automatically with a camera basically. So then
14 we'd have to demand a license every time we buy a new
15 camera or change out the sources.

16 DR. HOWE: We can make that clearer.

17 MS. GILLEY: I hate to be the idiot here
18 but I do need to ask one more question of the
19 professional group here. Is there any time you would
20 do a transmission source that you weren't also doing
21 a nuclear medicine procedure because I think it's
22 already covered by the fact that it is included in the
23 nuclear medicine procedure? Fill me in. I don't know
24 all the new technology out here.

25 DR. EGGLI: Moving the transmission images

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1 always accompany a clinical study.

2 MS. GILLEY: So we already have authority
3 to image the patient with a transmission source.

4 VICE CHAIR VETTER: Steve.

5 MR. MATTMULLER: This is Steve Mattmuller.
6 To build on what Debbie is saying, technically I can
7 understand where you're -- what's driving this. But
8 you can blame your co-workers on educating us on
9 technical analysis. Practically, I don't see any
10 advantage to going through this whole rulemaking
11 process because as Debbie suggested anyone who would
12 use one of these sources is already authorized under
13 200 and there would be no advantage in my mind to
14 going through all these steps.

15 So I guess the real question I have for
16 you is is there a situation that I'm not thinking of
17 where an authorized user for a transmission source
18 isn't an authorized user under 200.

19 DR. HOWE: Part of our problem is the
20 transmission sources are not over in a category that
21 all the other sources in that category are quality
22 control, quality assurance. There is no patient
23 radiation. There are no authorized users. This is an
24 attempt to recognize that these transmission sources
25 are really used in medical use because they are used

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1 to administer radiation to patients for a purpose.
2 The purpose is generally to get better images, etc.
3 and to put this under the authorized user that normal
4 uses it and that would be the 200 authorized user.

5 VICE CHAIR VETTER: Mr. Lieto.

6 MR. LIETO: To answer Steve's question,
7 there is no circumstance where this would not be done
8 as a part of the imaging procedure. I understand in
9 terms of revising 35.65 to clarify the use and the
10 existence of these sources.

11 I would object to adding a line item under
12 590 requiring this additional training and experience
13 in order for 590 use. Because what you're saying is
14 that to be authorized under 590, although there are no
15 sources listed under that, generally speaking it would
16 be another requirement for radiation biology,
17 radiation protection, mathematics. You're saying that
18 if there is something that comes down the pike that
19 would not be a transmission source this would be an
20 additional line item under the training and experience
21 that they would have to have. I think it's just
22 unnecessary.

23 DR. HOWE: What I gave was an or. You're
24 either (a) or you're coming down the pathway in (b) or
25 you are already authorized for 200. So I'm just

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1 giving three different ways you can use this. There
2 is no additional training.

3 MR. LIETO: But it's unnecessary. There
4 is no procedure where all you do is a transmission of
5 a patient.

6 MS. GILLEY: Dr. Vetter, behind you.

7 VICE CHAIR VETTER: Dr. Zelac.

8 DR. ZELAC: Thank you. I think it's
9 important to point out that the authorizations given
10 under 200 which is what we're talking about are for
11 unsealed material. If there are sealed sources that
12 are used in conjunction with that unsealed material
13 for nuclear medicine and other studies, then there has
14 to be something that says it's okay to do this. Right
15 now, it's 35.65 and the point being made is that these
16 sources are simply in the wrong place because 35.65
17 doesn't involve -- was not initially intended to
18 involve human application and this clearly is human
19 application. So it's being put into a place 500 which
20 is meant for diagnostic use of sealed sources.

21 VICE CHAIR VETTER: Mr. Mattmuller.

22 MR. MATTMULLER: Steve Mattmuller. Again
23 I would agree. Technically you're absolutely right
24 about how you're describing these sources and how
25 they're actually used. But practically I would argue

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1 and I think the Committee agrees that anyone who is
2 going to use this is already licensed under 200. So
3 you would put this through the whole expense as we've
4 been reminded rulemaking process. But in the end
5 there would be no benefit to the community.

6 DR. HOWE: Dr. Eggli.

7 VICE CHAIR VETTER: Dr. Eggli.

8 DR. EGGLI: I actually don't have a
9 problem with this as a 200 user. What this says is
10 basically you have to be a 200 user or better to use
11 these on a human subject and the regulation doesn't
12 say that currently. So I don't have a problem with
13 this being added. It's not going to cost me an ounce
14 more training. These are the little administrative
15 rulemaking things that I don't believe are horribly
16 expensive to accomplish and it kind of cleans up the
17 regulation.

18 And as a Part 200 user I don't have a
19 problem with that being there because it imposes no
20 additional burden on me whatsoever and I don't know
21 that it's a bad thing to say that any source that's
22 used for human imaging, in this case a sealed source,
23 has to be done under the authority of someone licensed
24 for human imaging as opposed to calibration.

25 And if you look at Part 65, the title says

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1 "Authorization For Calibration, Transmission and
2 Reference Sources" and the implication is that's not
3 for human use. It's for purely calibration and I
4 think reclassifying these sources as intended for
5 human use is not a bad thing and imposes no additional
6 burden.

7 DR. HOWE: So when you look at the types
8 of medical use in the definitions you see that it's
9 100, 200, 300, 400, 500, 600 and 1000. There is no
10 65. So it is cleaning up the regulations.

11 VICE CHAIR VETTER: Dr. Van Decker.

12 DR. VAN DECKER: I'm sorry. And so there
13 would be a listing of these transmission sources in
14 this category. So Americium would be in there as well
15 as Gadolinium. How would -- Other ones showed up.

16 DR. HOWE: We also have as part of our
17 rulemaking package looking at how we list sealed
18 sources on the license and when you need an amendment
19 to do it, etc. And so I think we can cover some of
20 these issues that you're concerned about under that
21 part of the user need memorandum what we talked about
22 making some revisions.

23 VICE CHAIR VETTER: Dr. Eggli.

24 DR. EGGLI: Aren't those covered under the
25 possession requirements? For instance, we brought in

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1 a camera that had a barium source. We didn't have
2 barium on our license. We had to add it to our
3 license. Doesn't that cover the issue that Dr. Van
4 Decker is talking about? I mean, as long as the
5 source is listed, as long as you're allowed to possess
6 that amount of radioactivity, that you can use it for
7 calibration purposes. I'm not sure what the issue is
8 here.

9 DR. HOWE: We have some general ways of
10 writing authorizations and it really is up in the
11 authorization section and in the authorization section
12 we can either write specific isotopes in maximum
13 amount or in some medical use, especially the unsealed
14 materials, we'll say for any isotope authorized under
15 35.200. So we don't list the isotopes. We know what
16 those isotopes are. They don't just change that much
17 and it also allowed us when we went into the NARM rule
18 not to have to revise everybody's license because if
19 it was previously NARM material used under 200 it was
20 automatically authorized.

21 We have other sections where you did list
22 them singly. Now we have an OGC interpretation that
23 for sealed sources we have to list them singly. We
24 have a lot of medical community uprising on that that
25 doesn't want to list some of these sources

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1 independently because it's a burden. So we're looking
2 at revising that section in the regulation in one of
3 the previous things that I brought before the ACMUI
4 that's currently in the user need memo. So I think we
5 can address if you have real concerns about having to
6 list them on a license.

7 VICE CHAIR VETTER: Richard Vetter. Yes,
8 we do not -- it's very important that this not be line
9 itemmed. An example is Dr. Fisher's example where
10 he's using I-131. Tomorrow it could be any source
11 that would be used as a transmission source. It has
12 to be written in a general fashion.

13 Other comments or questions?

14 (No verbal response.)

15 So the motion is support this
16 recommendation. It's been moved and seconded.
17 Discussed. All in favor, raise one hand.

18 (Show of hands.)

19 Eight in favor. Opposed?

20 (Show of hands.)

21 Three opposed. Thank you.

22 Dr. Howe, if we could move to the next
23 item.

24 DR. HOWE: Okay. This one is generator
25 elution. In January - February time frame of this

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1 year, we discovered that one of the major generator
2 manufacturers had generators that were exceeding the
3 moly-breakthrough values but not on the first elution,
4 on subsequent elutions.

5 This is not the situation that prior to
6 2002 the rule said you have to elute the -- on each
7 elution you had to check for moly-breakthrough. In
8 2002, based on prior history, there was a
9 determination that the only real problems that they
10 were seeing for decades literally were transportation
11 issues and if the generator was made incorrectly, that
12 would show itself on the first elution and patients
13 would be protected because the material would not be
14 used on patients.

15 What we discovered in January and February
16 was that Mallinckrodt was having a tremendous increase
17 in moly-breakthrough that was not picked up on the
18 first elution, may not be picked on the second
19 elution, but would be picked up later on. They're
20 still trying to determine the root cause for this.
21 They believe that maybe some of the materials that
22 went into the generator production were different than
23 they were before and they're trying to figure out how
24 to stabilize this.

25 So it became very obvious to us that our

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1 current rules that say you cannot administer material
2 that exceeds the moly-breakthrough value to patients
3 and that we considered measuring moly-breakthrough on
4 the first elution, meeting that criteria was not
5 sufficient. There are other with molybdenum
6 generators that are not being caught on the first
7 elution. So what we're recommending is that we go
8 back to what we had prior to 2002 because we now have
9 a technical basis and knowledge that this can be an
10 issue and we're recommending that the moly-
11 breakthrough be performed on each elution.

12 VICE CHAIR VETTER: Is there a motion in
13 support of this recommendation? Dr. Eggli? Is there
14 a second?

15 MR. MATTMULLER: I'll second it.

16 VICE CHAIR VETTER: Mr. Mattmuller
17 seconds. Discussion? Dr. Eggli.

18 DR. EGGLI: I have old dose calibrator
19 software. It won't let me administer a dose unless I
20 do moly-breakthrough on every elution anyway. I don't
21 see requiring. All you simply do is you put the
22 elution vial in a shield and put that in your dose
23 calibrator. I don't see how that poses much of a
24 burden to any enduser and I do it on every elution we
25 elute in our own pharmacy and if I'm going to buy bulk

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1 tech from a commercial supplier, I would like to know
2 that that was done there, too. So I think this is a
3 very reasonable move.

4 VICE CHAIR VETTER: Mr. Lieto.

5 MR. LIETO: I would like to ask Steve. Is
6 this something where patients were administered moly
7 in excess of the limits?

8 MR. MATTMULLER: Steve Mattmuller. It's
9 my understanding they were not. The higher moly
10 levels were caught in the moly assay before the
11 product was released and the other comment I would
12 like to make is that I see this more as an
13 FDA/practice of pharmacy issue. In the package insert
14 for the generators, it requires you to do a moly assay
15 on every elution. In fact, this problem was brought to
16 light because people were doing the moly assay on
17 every elution.

18 To me, this somewhat goes back to the
19 previous discussion that it's already being done. So
20 what is the value to the NRC to go through the expense
21 of rulemaking process to change this regulation so
22 it's in compliance or so it's stated the same as
23 current practice and its current FDA requirements and
24 FDA labeling?

25 DR. HOWE: I can answer that. Originally,

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1 NRC had regulatory authority over all radioactive
2 drugs and then FDA came in and put radioactive drugs
3 under the MDA and when FDA entered into the picture,
4 NRC wrote in its regulations that you could not use a
5 kit. You would not do anything unless you followed
6 the FDA-approved labeling. We required it. And if
7 you didn't follow the FDA-approved labeling, it was a
8 violation of NRC.

9 In the Radiopharmacy Act rulemaking in
10 1994, there was a petition for rulemaking that came in
11 that said, "NRC, you are inhibiting the practice of
12 pharmacy. We don't necessarily follow the FDA package
13 inserts. We have all kinds of reasons for not doing
14 it. You are enforcing FDA regulations and FDA is not
15 enforcing them." So at that point, we took out the
16 requirement that you follow the package inserts.

17 We did say nothing in our rule relieves
18 you from FDA, other state and federal requirements for
19 drug elution or drug management, drug preparation.
20 The requirement to measure moly-breakthrough has been
21 an NRC requirement from almost day one of technetium.

22 The problem was identified at those
23 facilities that do measure the elution each time. But
24 our licensees are not required to measure it each
25 time. So at a commercial pharmacy I might expect them

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1 to measure it each time. But at a smaller facility,
2 they're meeting regulatory requirements. They don't
3 necessarily have to.

4 Do we know that every patient that
5 received moly did not receive a moly-breakthrough
6 value that exceeded what they were supposed to see?
7 I don't think we can say that. I think we can say
8 that a number of them were identified across the
9 country. The problem was identified to the
10 manufacturer. We had increased inspection.

11 But was every patient given moly under the
12 breakthrough? I don't think we can go there because
13 we don't know if everybody followed the FDA and the
14 FDA labeling may or may not be followed. There are
15 many reasons not to follow it. There are many reasons
16 to follow it. It's not an absolute requirement on the
17 enduser. It's part of the approved labeling.

18 VICE CHAIR VETTER: Dr. Suleiman.

19 DR. SULEIMAN: The label for this specific
20 product says after every elution you do a breakthrough
21 test. I also understand it's good practice for
22 pharmacists to do it on a regular basis and so that's
23 how it got caught. So it gets back to it's being
24 covered by two specific requirements. Do you want to
25 codify it? I mean, it's just a question.

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1 VICE CHAIR VETTER: Dr. Eggli.

2 DR. EGGLI: I understand that a commercial
3 pharmacy is going to follow all of the FDA
4 regulations. Outside of a commercial pharmacy,
5 offlabel is considered a practice of medicine issue.
6 Many drugs, not just radioactive drugs, but drugs of
7 all kinds are routinely used offlabel as part of the
8 practice of medicine.

9 So I do not think that the FDA regulation
10 covers those users who conceptually have no problem
11 with offlabel use. So I think it's reasonable for NRC
12 to put it back into the regulation.

13 VICE CHAIR VETTER: Mr. Lieto.

14 MR. LIETO: I don't know if I share Dr.
15 Eggli's comment that there's no added exposure. There
16 are some types of devices for doing moly checks that
17 does require the transfer of the elution vial into
18 another container to do that. So there are --

19 DR. EGGLI: I think I said no added
20 exposure.

21 MR. LIETO: There are some added extremity
22 exposure that's going to occur with doing this for
23 every elution as opposed to doing it for the first
24 elution which is the current requirement.

25 I guess I do have an issue with putting

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1 this back into the regulation. Since it's been out.,
2 there has been no reports either in N Med or any place
3 else of any patients being dosed as a result of moly-
4 breakthrough and I guess I'd again have to ask Steve
5 for his expertise. If there was moly-breakthrough and
6 they go to make a kit or something of that nature,
7 wouldn't that immediately show up on it being a very
8 compromised quality exam?

9 MR. MATTMULLER: No. Absolutely not.

10 DR. HOWE: If it's not required, you would
11 never catch it.

12 VICE CHAIR VETTER: Dr. Eggli.

13 DR. EGGLI: Yes, the point on the no N Med
14 is you don't know what you don't know. If you're not
15 determining that moly-breakthrough either did or
16 didn't occur and you're not looking for it, there's
17 nothing to report and I can make a kit that's going to
18 QC at 99 percent with moly-breakthrough or aluminum
19 breakthrough in excess of the regulatory limit. How
20 am I going to know if I don't measure it? So again,
21 you don't know what you don't know.

22 DR. HOWE: And, Ralph, you're supporting
23 the concept that not everybody measures the elution,
24 every elution. So those that aren't don't know and
25 because where we're ending up with the new technical

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1 problems with generators that were not foreseen
2 before, you are having failures and they're not --
3 Some of them are not just marginal failures.

4 They're really significant breakthrough on
5 subsequent elutions and those that were caught were
6 caught. They were brought to NRC's attention because
7 the person didn't receive the right answer from the
8 manufacturer and they wanted a new generator and there
9 wasn't another one available. So they came to the NRC
10 and said, "What's going on here" and we started
11 looking into it and we found that they were having
12 significant quality control problems that they
13 couldn't identify before they sent them out and users
14 couldn't identify on the first elution.

15 VICE CHAIR VETTER: Dr. Guiberteau.

16 DR. GUIBERTEAU: I think consistency is a
17 good thing. I do think that the teaching standard for
18 radiologists are the Nuclear Regulatory Commission
19 documents. We don't really teach to FDA standards and
20 whatever in the labs. The radiopharmacists do teach
21 this. But out in the communities and people who
22 aren't able to get radiopharmaceuticals from a central
23 pharmacy have generators and I do believe, although,
24 Ralph, I think you made a good point, that if the
25 requirement basically is to elute after every -- to

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1 measure moly-breakthrough after every elution, I think
2 to keep this consistent and not confusing for those
3 people who do some nuclear medicine but also general
4 radiology that this would be a good thing.

5 DR. SULEIMAN: I want to clarify. These
6 aren't FDA standards. What these are when the drug
7 gets approved by FDA the manufacturer agrees to put
8 this in this label. So it's part of their labeling
9 instructions. It's not a separate FDA standard per
10 se. But it's one of the conditions of approval for
11 the drug and they probably included because of the
12 pharmacopeia, the pharmacy standards.

13 DR. VAN DECKER: Which the user then
14 promptly ignores.

15 DR. SULEIMAN: Yes.

16 VICE CHAIR VETTER: Okay. Other questions
17 or comments? The motion is to support this
18 recommendation to require a moly-breakthrough test on
19 every elution. All those in favor of the motion?

20 (Show of hands.)

21 Nine in favor. Opposed?

22 (Show of hands.)

23 One. Is there an abstention?

24 (Show of hands.)

25 One abstention. Okay.

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1 Dr. Howe, next.

2 (Off the record comments.)

3 DR. HOWE: This was just our proposal.

4 VICE CHAIR VETTER: That was part of it.

5 DR. HOWE: This was just to say we want to
6 say on each elution.

7 VICE CHAIR VETTER: Yes. Okay.

8 DR. HOWE: Okay. You're not going to
9 believe this one. Okay.

10 MS. GILLEY: Is this one in here?

11 DR. HOWE: There's a new page. Ashley
12 should have passed out a new page.

13 MS. GILLEY: Okay.

14 MS. FLANNERY: Dr. Vetter, I just want to
15 add something else on the same topic of the moly
16 generators. I don't think it made it into the slides,
17 but there's been a lot of discussion with NRC staff to
18 also include in the rulemaking to make measurements of
19 moly-breakthrough that failed to be reportable because
20 right now it is not reportable.

21 We happened to find out about these cases
22 before by chance. But in this whole process we
23 learned that it is not a requirement for people to
24 report moly-breakthroughs. So I am interested in
25 getting ACMUI input on this issue as well.

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1 DR. HOWE: And it was my oversight in not
2 making an additional slide. So we wanted to make a
3 report in Part 30. Well, we would probably make a
4 report in Part 30 and also in 35 because Part 30 would
5 cover the commercial compliances and Part 35 would
6 cover the medical users that are using generators.

7 So we would make an addition to Section
8 Subpart M Reports and we would add a reporting
9 requirement that if the generator elution exceeded the
10 moly-breakthrough values specified in the earlier part
11 of the section that it would be reported to the NRC.

12 VICE CHAIR VETTER: NRC or agreement
13 states?

14 DR. HOWE: We can only write the rules for
15 NRC.

16 VICE CHAIR VETTER: So it wouldn't be
17 written in such a way that agreement states would have
18 to report to NRC. They would report to the agreement
19 state.

20 DR. HOWE: Yes. It would be written that
21 NRC would report to NRC and then depending on the
22 level of compatibility it might be the agreement
23 states reporting to the agreement states.

24 VICE CHAIR VETTER: Okay. So just to
25 clarify, the proposal is to require moly-breakthroughs

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1 that exceed the specs specified in the regulations
2 reportable.

3 DR. HOWE: Yes.

4 VICE CHAIR VETTER: Discussion? Well,
5 first of all, is there a motion to support that
6 recommendation? Yes, Dr. Eggli. Thank you. Is there
7 a second? Yes, Dr. Welsh seconds.

8 Discussion? Dr. Eggli?

9 DR. EGGLI: I would have thought this was
10 unnecessary. But hearing what Dr. Howe said about the
11 experience of an enduser who couldn't get a vendor to
12 make it right is one level. It's a financial level
13 and if the vendor -- Do I take it then that the vendor
14 did not report this to NRC?

15 DR. HOWE: No, they did not report it to
16 NRC.

17 DR. EGGLI: I wouldn't have thought that
18 this would be necessary. But it looks like it
19 probably is. And if the vendor isn't going to
20 remediate it under good faith, then maybe the
21 regulators have to make sure that the problem is
22 remediated.

23 DR. HOWE: I don't believe the vendor
24 reported it to the FDA either because I believe we
25 were the first ones to find out and then we passed the

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1 information on.

2 DR. SULEIMAN: This was another thing.
3 It's still in place. So I don't want to comment too
4 much, but I argued internally saying that the system
5 works. I mean the elution picked up the problem. It
6 got reported. But the reporting mechanism isn't very
7 clear. I mean, it was unfortunate. We had to learn
8 it from the NRC. We should have heard it first from
9 the company.

10 DR. HOWE: And we heard just in passing
11 from our licensee because there was no reporting
12 requirement.

13 VICE CHAIR VETTER: Mr. Lieto.

14 MR. LIETO: I was just going to ask. This
15 is a device failure, is it not?

16 DR. SULEIMAN: That's not a device.

17 DR. HOWE: It's an interesting issue.
18 It's not a device.

19 DR. SULEIMAN: That is a drug
20 manufacturing kit. It's regulated by the Center for
21 Drugs.

22 DR. HOWE: And we have gone through OGC to
23 determine if it's reportable under -- Cindy can talk
24 more to that.

25 MS. FLANNERY: We actually looked at two

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1 regulations, 30.50 as well as Part 21, and it was
2 determined to not be reportable under either one. So
3 that's why NRC staff is really interested in putting
4 it under Part 35.

5 DR. HOWE: And put it under Part 30 also
6 to capture coming from the pharmacies.

7 VICE CHAIR VETTER: Based on our own
8 collective experience, I might be safe in saying that
9 it would be very rare that this would have any impact
10 on a licensee because it's simply really rare to
11 happen. Is that correct?

12 DR. HOWE: There's been an increased
13 frequency.

14 VICE CHAIR VETTER: Sorry.

15 DR. HOWE: There's been quite an increased
16 frequency for one manufacturer of this happening.

17 VICE CHAIR VETTER: Okay. So it would
18 catch if it's in the best interest of patient safety.
19 It would catch when there's a manufacturing problem
20 with generators.

21 DR. HOWE: Yes.

22 VICE CHAIR VETTER: Okay. Any other
23 discussion or questions regarding this issue?

24 (Off the record comment.)

25 The motion is to support the

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1 recommendation that when there's moly-breakthrough
2 exceeds the threshold as included in the regulations
3 that this would be reportable. All those in favor of
4 the motion, raise one hand.

5 (Show of hands.)

6 Ten. Opposed?

7 (Show of hands.)

8 One. Thank you all very much.

9 The next one which you -- let's see.

10 DR. HOWE: Yes. This one you're really
11 going to like. It has to do with training and
12 experience, one of your favorite topics.

13 (Off the record comments.)

14 And it essentially goes across almost all
15 the training and experience requirements. For those
16 sections that require supervised work experience under
17 the supervision of an individual who meets the
18 requirements in that particular section, we more
19 recently looked at the way it was written and our
20 general counsel pointed out to us that that meant the
21 supervising individual had to meet the requirements in
22 that particular section, not that they were authorized
23 for that use which would have grandfathered all of the
24 authorized users, authorized medical physicists,
25 authorized nuclear pharmacists and RSOs but that they

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1 had to meet the requirements in this particular
2 section.

3 I will tell you that none of the regions
4 have interpreted it this way. So we haven't had a
5 outcry, but we believe that we need to clean the
6 regulation up and make it state what we intended it to
7 state and that is that if you're getting supervision
8 you're getting supervised by someone who has
9 experience and is authorized for that particular use.

10 So that was the problem. And we've stated
11 the recommendation in very general terms because it
12 would be worded differently for each section and that
13 would -- Right now, we're think we have maybe two ways
14 of going at it. One is that we could include 35.57
15 for individuals without authorization, state it and
16 put 35.57 in because that's experienced authorized
17 users, medical physicists, RSOs, etc. or we could just
18 clearly say that someone that meets the training
19 experience in this section or is identified on a
20 license for this particular use. We don't know what
21 the wording will look like, but we do believe we need
22 to clean it up.

23 VICE CHAIR VETTER: Dr. Thomadsen.

24 DR. THOMADSEN: I'm a little bit confused
25 about this. Would this be, for example, if an

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1 authorized user was being trained? Would an RSO be
2 able to provide the training in things such as safety
3 handling of radioactive materials?

4 DR. HOWE: The supervising individual in
5 most of the medical uses is an authorized user that is
6 authorized for that particular use. In, say, 35.200,
7 you have to have training and experience with
8 generator elution. We had the issue before of the
9 authorized nuclear pharmacist doesn't meet the
10 criteria there. How are they doing this? Well,
11 they're doing it because they're under the supervision
12 for this particular part of 200 AU. So if the
13 physicist is training someone and the requirement in
14 the regulation is the supervising work experience
15 comes under the physician, then the physicist training
16 is being provided because the physicist is actually
17 operating under the AU in providing that training
18 because we recognize the AU doesn't have to provide
19 every single minute of the training. They are the
20 supervising individual.

21 Does that help, Dr. Thomadsen?

22 DR. THOMADSEN: That clarifies exactly
23 what my question was. I don't particularly like the
24 answer, but that answered the question.

25 VICE CHAIR VETTER: Dr. Nag.

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1 DR. NAG: Dr. Howe, I understand your part
2 two and I think that's quite clear. Maybe I don't
3 understand what 35.57 is because I don't understand
4 the meaning of the part one and is that part one
5 needed in fact?

6 DR. HOWE: No, this is an either or. We
7 don't know exactly how we wanted to word it. One
8 thought was if we brought in the grandfathering
9 provisions of 35.57 in each one of these sections,
10 then that would make it clear that if the rules change
11 the person was grandfathered for this section would be
12 able to provide the training. So this was kind of an
13 or type of thing.

14 Another easy way would be to have someone
15 identified on a license or a broad scope permit or an
16 MML permit or an agreement state license, the whole.

17 DR. NAG: I think it would be -- If 35.57
18 is the grandfather clause, I think we should just add
19 in that who are grandfathered under 35.57. It makes
20 it a little more clear.

21 DR. HOWE: That gets down into the exact
22 wording which is what the Rulemaking group in
23 connection with the medical group will determine. The
24 basic thing I'm bringing to you is the concept.

25 VICE CHAIR VETTER: Right. Mr. Lieto.

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1 MR. LIETO: I would like to table this
2 specific item until we get the -- I would like more
3 information on what is the issue that's being
4 addressed and you said that there was an OGC
5 determination.

6 DR. HOWE: Yes.

7 MR. LIETO: And I'm assuming in response
8 to maybe a region or somebody asking for -- In other
9 words, what was the motivation for the OGC to make
10 this determination and so forth because I think this
11 has the potential things extremely convoluted and
12 difficult for preceptors and even more so than what we
13 already have in terms of a problem for documenting and
14 attesting to training and experience?

15 DR. HOWE: Mr. Lieto, I would be reluctant
16 on tabling this because it really is an issue we have
17 to address as soon as we can address it and, Cindy,
18 can you give us more background?

19 MR. LIETO: This is a proposed rulemaking,
20 right?

21 DR. HOWE: Yes, but --

22 MS. FLANNERY: The reason why this is
23 coming up today and it wasn't in your binders, this
24 literally is an issue that came up in the last couple
25 days. And the history behind this is we were

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1 developing some procedures on recognizing foreign
2 trained physicians and physicists and what we found is
3 that the supervising AUs and the preceptor AUs it
4 would not be acceptable for grandfathered individuals
5 to be supervisors and preceptors which is not the
6 intent of the regulations.

7 So essentially if you have somebody who
8 got listed on the license say ten years ago the way
9 the regulations are currently written, that individual
10 could not be a supervising AU for somebody proposed to
11 get their work experience under. That same individual
12 also cannot be a preceptor AU. Somebody who is going
13 to be a preceptor AU or a supervising AU has to meet
14 NRC's current training and experience criteria.

15 DR. HOWE: Now it's clear that --

16 MS. FLANNERY: And that was not the intent
17 of the regulations.

18 DR. HOWE: -- was not the intent of the
19 regulation, but that is how the regulations are
20 written.

21 MR. LIETO: I have to be sure I
22 understand. So let's say Dr. Guiberteau is named on
23 a license as an AU, has been and continues to be
24 named. He is training residents and physicians to be
25 AUs. All right. I'm assuming that he was on a

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1 license more than ten years ago. You're saying that
2 he cannot sign as an AU for training and experience of
3 those individuals under whom he's trained?

4 DR. HOWE: That's the way the regulation--

5 MS. FLANNERY: You are correct.

6 DR. HOWE: That's not how we have been
7 taking licensing actions.

8 MR. LIETO: This is just to clean it up.

9 MS. FLANNERY: We just learned this the
10 other day and as Donna-Beth just explained, we have
11 not interpreted it that way and that's not been the
12 practice in how the regions have been allowing
13 supervisors and preceptors to be AUs.

14 DR. HOWE: And I think to make clear how
15 I've interpreted it, I have essentially translated
16 what was said in the regulations. So let's look at
17 35.290, Section (e)(ii). It says, "Work experience
18 under the supervision of an authorized user who meets
19 the requirements and 35.290(c)(1)(ii)(G) and 35.390 or
20 equivalent agreement state requirements involving..."
21 I have translated that in my mind as has everybody in
22 the NRC to say that's one way of saying you're an
23 authorized user for 200 or 300 uses. But OGC says,
24 "That's not what we said."

25 MR. LIETO: That seems to negate the whole

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1 grandfathering clause, doesn't it? I mean --

2 DR. ZELAC: For training purposes.

3 DR. HOWE: For training purposes and
4 that's what we're trying to tell you is this is a
5 major problem.

6 MR. LUEHMAN: For training purposes,
7 you're right but not for being an authorized user or
8 something.

9 VICE CHAIR VETTER: Dr. Nag.

10 DR. NAG: Yes. I would not be in favor of
11 tabling this. I think this is something that needs to
12 be fixed now. It is more of a legalistic issue and I
13 would like to make a motion that the ACMUI approves
14 this in spirit. The final wording of that may be
15 tweaked a little bit to meet legal standards, but in
16 spirit we should --

17 VICE CHAIR VETTER: There's a motion on
18 the table that says exactly that. I mean, we're --

19 DR. NAG: Who made that motion?

20 VICE CHAIR VETTER: Dr. Eggli.

21 DR. NAG: Oh, you did.

22 VICE CHAIR VETTER: I forget who seconded
23 it. Didn't we have a motion?

24 MS. TULL: I don't have a motion.

25 VICE CHAIR VETTER: Then I accept your

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1 motion, Dr. Nag.

2 DR. EGGLI: I'll give him a second.

3 VICE CHAIR VETTER: Dr. Eggli will second.

4 Okay.

5 MS. GILLEY: This appears to be an
6 extremely critical issue. Is there any other way
7 besides rulemaking that we could implement this pronto
8 at least through a guidance? I mean, what recourse do
9 we have because this has some --

10 DR. HOWE: Major implications.

11 MS. GILLEY: Major implications. That's
12 a good term.

13 DR. HOWE: I think once we have your vote
14 on the issue and we recognize we will also try to see
15 if we can come up with something that can handle it
16 before we go through a rulemaking process.

17 MS. GILLEY: This is a compatibility B
18 issue. This affects all 35 agreement states as well
19 as NRC. So this is not something that we have any
20 flexibility or regulatory relief from the agreement
21 states.

22 VICE CHAIR VETTER: Okay. So this is
23 something that absolutely must be fixed.

24 DR. HOWE: We believe so.

25 VICE CHAIR VETTER: If OGC is saying that

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1 their interpretation is different, yes, we need to fix
2 it. Other questions or discussion on the motion?
3 We're approving this but not specific wording. Mr.
4 Lieto.

5 MR. LIETO: I would ask what other
6 landmines are there out there that you have OGC coming
7 up with these shall I say extremely unusual
8 interpretations of the rules when -- I guess I would
9 say I would go back to the Statements of Consideration
10 which were stated before to be the policies and so
11 forth and I'm sure it's quite -- it's in those
12 Statements of Consideration that the grandfathering
13 applied to all.

14 DR. HOWE: Ralph, in this case, in some
15 cases, we have OGC taking maybe a different read on
16 what is written. But none of us are able to say what
17 is written is not what is written and that's why we
18 have this issue.

19 VICE CHAIR VETTER: Dr. Nag.

20 MR. LEWIS: There probably is other
21 landmines in all honesty, but we wrote what we wrote
22 trying to be as generic as possible and as specific
23 situations arise, we find out that some course
24 corrections need to happen. That's just the
25 regulator.

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1 VICE CHAIR VETTER: Dr. Nag.

2 DR. NAG: That's confirmation that there
3 are lawyers and there are lawyers and one lawyer may
4 interpret it one way. Another lawyer may interpret it
5 another way. Is it possible to go back to OGC and
6 say, "This is what we meant" and can you interpret it
7 in that light? Sometimes it depends how you ask the
8 question.

9 DR. HOWE: Dr. Nag, I understand what
10 you're saying and I will tell you that the senior
11 experience medical staff once we were aware of it we
12 read it and we went "Oh, my gosh, she's right."

13 DR. NAG: Okay.

14 DR. HOWE: This is not one of those
15 equivocal "can I maybe read it this way or maybe read
16 it that way." It says flat out you meet the training
17 and experience requirements in 290.

18 VICE CHAIR VETTER: Okay. So let's make
19 it legal. So Drs. Eggli and Guiberteau can, in fact,
20 train their residents.

21 DR. HOWE: It's not only those. It's
22 you.

23 VICE CHAIR VETTER: I know.

24 DR. HOWE: And me. Dr. Nag.

25 VICE CHAIR VETTER: I know it's everyone.

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1 Any final discussion? Final comments?

2 MR. LIETO: I have a question. Does this
3 effect I mean past or ongoing --

4 VICE CHAIR VETTER: We don't even want to
5 ask that question.

6 DR. NAG: Don't ask. Don't tell.

7 VICE CHAIR VETTER: Don't ask this.

8 Okay. All those in favor of the motion to
9 support this change.

10 (Show of hands.)

11 Unanimously supports. Thank you.

12 MS. GILLEY: Can we say strongly
13 unambiguously supports this thing?

14 VICE CHAIR VETTER: One hundred percent
15 unambiguous.

16 DR. HOWE: And that is my last.

17 VICE CHAIR VETTER: That concludes your
18 report.

19 Dr. Welsh.

20 DR. WELSH: If we're finished with this
21 section, then in the spirit of what we just discussed,
22 I would like to quickly revisit 35.40, the proposed
23 change there, where the question was raised by Ralph
24 about can you have two different authorized users.
25 Dr. Nag pointed out the answer is yes. We've heard

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1 others saying the answer is yes. So the problem would
2 go away. The question will be asked again. The
3 problem would not be asked again if we change the word
4 "the authorized user" to "an authorized user." Just
5 a suggestion.

6 DR. HOWE: I would include it in your
7 comments on the proposed rulemaking.

8 DR. WELSH: Okay. You will include that?

9 DR. THOMADSEN: Yes.

10 DR. HOWE: I believe someone here should
11 make that.

12 VICE CHAIR VETTER: Why don't you make
13 that as a motion?

14 DR. WELSH: I would like to make it aa a
15 motion that the word --

16 DR. NAG: Put it as a motion.

17 DR. WELSH: So you can replace the word
18 "the" --

19 VICE CHAIR VETTER: And that's in the
20 discussion on 10 CFR 35.40.

21 DR. WELSH: Correct.

22 DR. THOMADSEN: Yes, at the bottom of the
23 slide.

24 VICE CHAIR VETTER: Is there a second to
25 that motion?

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1 DR. THOMADSEN: Yes.

2 VICE CHAIR VETTER: Dr. Thomadsen. All in
3 favor?

4 (Show of hands.)

5 It's unanimous. Good catch.

6 Does that complete your report, Dr. Howe?

7 DR. HOWE: That completes my report. Let
8 me just ask a quick question to Mr. Lohr back there.
9 Do you accept this as a public comment?

10 MR. LOHR: Please clarify what you mean by
11 accept by public comment.

12 DR. HOWE: The ACMUI has voted unanimously
13 that they believe that the "the" -- that "the
14 authorized user" needs to be changed to "a authorized
15 user."

16 DR. NAG: "An."

17 MR. LOHR: Are you talking about the
18 current proposed rule?

19 DR. HOWE: The current proposed rule.

20 MR. LOHR: Then I would suggest that they
21 put it in their letter during the public comment
22 period which is ongoing right now and we will receive
23 it and we will take it into consideration. Anything
24 that comes in through public comment will be
25 considered during the rulemaking.

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1 VICE CHAIR VETTER: Mr. Lieto.

2 MR. LIETO: I am a little confused. The
3 things that we just addressed right now are not --

4 DR. HOWE: Potential.

5 MR. LIETO: Right. These are potential.
6 These are not out there for public comment right now.
7 Is that correct?

8 DR. HOWE: One of them was to bring the
9 rest of the regulation into conformance with the
10 proposed rule and that's the issue that Dr. Welsh is
11 addressing now. He's addressing the one that will
12 bring it into conformance. So he's saying that he has
13 essentially a comment on the proposed rule to ensure
14 that it is "an authorized user," the same authorized
15 user.

16 MR. LUEHMAN: Because the language that we
17 were considering there was when you were considering,
18 the language that you were considering was an addition
19 to some proposed language and what's being proposed by
20 Dr. Welsh to change is something that was already
21 proposed language, not the additional language that
22 you were adding. You're not changing the additional
23 language. You're changing the existing language of
24 the proposal.

25 DR. HOWE: It goes to both.

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1 MR. LOHR: If I may, I believe what they
2 are referring to is -- This is from the Federal
3 Register. It says, "... require the AU to sign the
4 written directive after administration." You want to
5 change that to "... require an AU to sign..." Is that
6 correct?

7 MR. LUEHMAN: Yes.

8 MR. LOHR: So that would be appropriate
9 then to put it in your comments in this public period
10 back to us on this proposal.

11 MR. LEWIS: For the permanent implant
12 brachytherapy.

13 DR. NAG: Yes. Anyway, I would be
14 including that in my comment anyway.

15 VICE CHAIR VETTER: So how can we make
16 sure -- Cynthia or Ashley, how can we make sure that
17 that comment gets from ACMUI into public comment?

18 DR. HOWE: Dr. Nag.

19 VICE CHAIR VETTER: Dr. Nag will do that.

20 DR. NAG: Yes.

21 VICE CHAIR VETTER: Thank you.

22 MS. TULL: Dr. Nag is revising the
23 Committee's comments as a whole based on discussions
24 yesterday.

25 VICE CHAIR VETTER: All right.

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1 MS. TULL: So he would include that in his
2 report.

3 VICE CHAIR VETTER: Terrific. Thank you.

4 Now are we --

5 MR. LIETO: I'm sorry.

6 VICE CHAIR VETTER: Mr. Lieto.

7 MR. LIETO: In a more general nature, the
8 next Part 35 rulemaking that Ed discussed in his
9 previous presentation, he said we'll include numerous
10 amendments identified by the NRC medical team which
11 now those numerous amendments obviously will include
12 not only these but my recollection is that we started
13 doing this, I remember the meeting being back in 2006
14 at the NIH meeting.

15 DR. HOWE: I think probably 2002 - 2003.
16 We've been running a long time.

17 MR. LIETO: Okay. So I know there's
18 probably dozens. Is the intent that these dozens of
19 things that we've discussed are all going to be part
20 of this --

21 DR. HOWE: Yes. We have a --

22 MR. LIETO: -- major Part 35 rulemaking ed
23 talk?

24 DR. HOWE: We have a very long list and
25 some items on that list have already been handled

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1 through administrative rule changes and are already
2 part of Part 35. We've had one direct final rule that
3 put changes in Part 35. So some of the items that we
4 could handle more quickly have come off of that list.
5 Those that were a little more controversial and will
6 take more time to develop remain on the list and those
7 are the items that they will be considering for the
8 next rulemaking.

9 MR. LIETO: Thank you.

10 VICE CHAIR VETTER: Okay. Are we done now
11 with Dr. Howe for now?

12 (Laughter.)

13 She will be back right after lunch. Okay.
14 Now recognizing that we're a half hour behind
15 schedule, how much time would you like for lunch?

16 DR. NAG: Forty-five minutes.

17 VICE CHAIR VETTER: Is 45 minutes
18 adequate? 1:15 p.m. Can you please be back promptly
19 at 1:15 p.m. so that we get through the agenda this
20 afternoon and remember if we can we want to back and
21 capture Cindy Flannery's presentation. If we can't
22 we'll address that on teleconference. If we can work
23 her in this afternoon, that would be good. So 1:15
24 p.m. Thank you very much. Off the record.

25 (Whereupon, at 12:29 p.m., the above-

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1 entitled matter recessed to reconvene at 1:15 p.m. the
2 same day.)

3 VICE CHAIR VETTER: It's 1:15. If we
4 could call the meeting to order, please? The next
5 item on our agenda is number 17, "Medical Nuclear
6 Materials Events." And this will be presented to us
7 by Dr. Howe and Ralph Lieto. Dr. Howe?

8 17. MEDICAL NUCLEAR MATERIALS EVENTS

9 DR. HOWE: I am the first parts of the
10 team tag. Okay. I am going to be going through the
11 medical events for F.Y. 2008. Just as a refresher, we
12 had 40 medical events in 2007, 1 in 200, 6 in 300, 10
13 in 400, 15 in 600. And then we had eight
14 microspheres. So that is where we are last year.

15 In 2008, we have dropped down nine medical
16 events. This -8 here is because I can't subtract.
17 That's really a -4.

18 DR. NAG: I was wondering.

19 DR. HOWE: So we went from 40 medical
20 events last year to 31 medical events this year.

21 You will also see that I have numbers in
22 parentheses. In most cases when we have a medical
23 event, we have one patient. When you see a number in
24 parentheses, that's an indication we had multiple
25 patients for one or more events.

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1 So in 200, we had three medical events.
2 And I'll get into the causes for those. So we had two
3 more than we had last year. In 300, the therapy on
4 unsealed material, we had four. We were down two.
5 But we had ten patients involved. So that gives you
6 an indication we had one medical event with multiple
7 people.

8 In the manual brachytherapy, we had the
9 same number of medical events that we had last year.
10 You will see that there are 109 patients involved.
11 And I think you can guess which medical event has a
12 significant number of patients involved.

13 In 35.600, which I have broken it down
14 into HDR and a subset of HDR because I am just kind of
15 following what our experience is with the MammoSite
16 and other breast balloon cases because they are not
17 our typical HDR uses, although they're becoming more
18 and more prevalent, and then gamma knife. And you
19 won't believe it, but we actually had a teletherapy
20 missed medical event. There can't be more than a
21 handful of these units in the United States, but we
22 still managed to have a medical event with one.

23 And then for 35.1000 use, we have got four
24 yttrium microsphere events. We had eight last year.
25 There should be a difference. And we're down four

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1 this year.

2 So now let's look at detail on the 200.
3 It's not a surprise to you that our 200 medical events
4 are those events in which a diagnostic procedure was
5 requested or intended. And I-131 greater than 30
6 microcuries was given.

7 We had two cases that involved I-123. In
8 the first case, the physician didn't specify the
9 isotope. He asked in general for a whole body scan.
10 So someone checked off on the I-131 whole body scan.

11 In the second one, there was a verbal
12 order for I-123. I-123 was written down. But when
13 they scheduled it, they scheduled I-131.

14 The third case was the typical case that
15 you have where there are multiple capsules to give a
16 therapy dose. In this case --- oh, no. That's not
17 this one. That is another one. Okay.

18 In this one, what we had was we had an
19 authorized user or referring physician that intended
20 to have a ten-millicurie dose. He didn't write ten
21 millicuries. He wrote ten microcuries.

22 Then when it was ordered, it ended up
23 being ordered. Even though everything in writing was
24 in microcuries, it was ordered in millicuries. The
25 written directive was in microcuries. They gave ten

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1 millicuries.

2 It's a medical event because it wasn't
3 what was in the written documentation, but it ended up
4 in this particular case it's what the patient was
5 supposed to get. But a medical event is when you
6 depart from whatever the written documentation was.
7 And they did not have a written directive in this case
8 for the ten millicuries.

9 So that was kind of two errors make a
10 right. So that gave us our third medical event for
11 35.200. And then we get into -- Dr. Nag?

12 DR. NAG: That last one is basically a
13 technical medical event because --

14 DR. HOWE: It is technical.

15 DR. NAG: -- it's really not a medical
16 event because, you know, most people would be giving
17 ten millicuries. And that was ordered, and that was
18 given.

19 DR. HOWE: It's a technical medical event.

20 DR. NAG: It's just like saying, "You
21 did not have a prescription, but you gave the right
22 quantity. But you are cited for a medical event
23 because you didn't have the prescription." Basically
24 it's similar.

25 DR. HOWE: Yes. This was one of those

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1 cases where two errors brought it back around to where
2 it was intended, but it met our requirements for being
3 a medical event.

4 And then in the unsealed materials
5 requiring a written directive, we have the typical one
6 where the therapy procedure is given in multiple
7 capsules. It comes from the pharmacy in multiple
8 capsules in one vial. One capsule is given to the
9 patient. They don't see that there are two more
10 capsules inside. So they send it back to the
11 pharmacy. And then they got it back again and finally
12 treated the patient. So we had a medical event.

13 Another one was -- let me go back.

14 DR. WELSH: Can I ask a question going
15 back to the previous slide?

16 DR. HOWE: Which one?

17 DR. WELSH: The previous event Dr. Nag
18 was just talking about.

19 DR. HOWE: Yes.

20 DR. WELSH: That didn't require a
21 written directive or did it?

22 DR. HOWE: Well, this was one of our
23 problems with 200.

24 DR. WELSH: Yes.

25 DR. HOWE: Once you administer something

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1 with 30 microcuries of I-131, you should be looking
2 for that written directive to say, "This is what you
3 are supposed to be giving."

4 And we have routinely had cases where
5 people are giving I-131 greater than 30 microcuries.
6 And they're not looking for that written directive to
7 do that final check to say, "Is this what I should be
8 doing? I need a written directive for it."

9 DR. WELSH: I wasn't even thinking
10 whether it did or it didn't, but you switched to 300
11 and said, "Now things requiring a written directive."
12 The last one did require a written directive?

13 DR. HOWE: We wrote ten microcuries.

14 DR. WELSH: That required a written
15 directive?

16 DR. HOWE: Ten microcuries did not require
17 a written directive.

18 DR. WELSH: No, no, no. But the ten
19 millicuries?

20 DR. HOWE: The fact that they administered
21 ten millicuries --

22 DR. WELSH: Right.

23 DR. HOWE: -- did require a written
24 directive.

25 DR. WELSH: Okay.

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1 DR. HOWE: But they did not go back and
2 check and ask to see if there was one, which would
3 have prevented the medical event.

4 Okay. For the Bexxar, that was kind of a
5 complicated one. The patient was supposed to be
6 getting Bexxar. Bexxar wasn't sent from the pharmacy.

7 There was a therapy I-131 dose that came
8 in, I think maybe the day before. It wasn't given.
9 And so when this patient showed up for the Bexxar,
10 they had a syringe with I-131. It wasn't Bexxar, but
11 it was a syringe there. So they picked up the
12 syringe, and they gave the dose.

13 And in this case, they realized it almost
14 immediately. So they did a thyroid block. They
15 mitigated some of the effect, but they did not
16 mitigate it to the point where it wasn't a medical --
17 well, it was a wrong radiopharmaceutical anyway.

18 DR. WELSH: Was that a therapeutic dose
19 of the --

20 DR. HOWE: They received an uptake, I
21 believe, of -- let me get the right one here. I
22 provided you with the NMED reports. So it's page 6.
23 So in this case, they received 100 millicuries. No,
24 that's not the right one. It's the next one over.

25 They had an uptake of two millicuries. So

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1 we have about 2,000 rads to the thyroid. And then
2 they had a whole body exposure with ten millicuries.

3 DR. SULEIMAN: And they were supposed
4 to give the five millicuries?

5 DR. HOWE: Of Bexxar, --

6 DR. SULEIMAN: Of the Bexxar.

7 DR. HOWE: -- which would not have gone to
8 the thyroid.

9 DR. SULEIMAN: To the thyroid.

10 DR. HOWE: And then if you looked at my
11 summary slide, you would see that we had a total of 10
12 patients with the 300 medical events. And the reason
13 we did was because we had a Samarium-153, where the
14 dose calibrator was set up for vials. They measured
15 it with a syringe. It was off by 30 percent.

16 They had at least eight patients that were
17 potentially affected by this. Some of the patients
18 had died, some patients are still alive. They
19 couldn't go back and absolutely confirm which ones
20 they measured a syringe in and, therefore, gave the
21 wrong dose. So they decided that they would call all
22 of them medical events because they could not confirm
23 one way or the other that they weren't medical events.

24 This is an issue that we have seen before
25 with licensees that measure P-32, Samarium, Strontium.

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1 They calibrate for a vial. They measure in a syringe.
2 They calibrate for a syringe. They measure in a vial.
3 They believe that they can measure things more
4 accurately than the manufacturer. So they put it in
5 the dose calibrator and adjust the dose. And they
6 cannot do that with a dose calibrator. So we end up
7 with a lot of medical events for a particular licensee
8 when we have these kinds of situations.

9 Okay. Now, moving on to 35.400, which are
10 the manual brachytherapy, we had one case -- and
11 Ashley should be passing out a new page because we had
12 this review. And the region pointed out some
13 inaccuracies of the write-up. This is the 300-400.
14 So just pass out both pages together, I think.

15 We still have a couple of more errors in
16 here. There is a right point A. And then it says a
17 left point B. Well, that should be a right point A
18 and a right point B.

19 We had two patients involved. It appears
20 as if they were implementing a new method of including
21 geometric data. And in the process, they put in the
22 wrong magnification factor. And the magnification
23 factor that they used ended up delivering
24 significantly less dosage than the patient was
25 prescribed. So we had two medical events.

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1 We always have a large group of prostate
2 medical events. And in this case, we had 109
3 patients. The first, we had two cases of leaking
4 sources. This was pretty interesting because one case
5 of leaking sources involved two patients.

6 But the manufacturer was called. And they
7 actually had three sets of seeds that they were
8 running to give to three different patients. In the
9 first patient, they recognized contamination on the
10 needles. And they did a careful review of the next
11 set of seeds that were supposed to be given.

12 There didn't appear to be any
13 contamination. They gave the material. And then they
14 looked at the needles when they were through, and they
15 had contamination again.

16 So they went back. And they decided that
17 they were not going to give it to the third patient.
18 So they went back to the manufacturer. And the
19 manufacturer actually found a problem in the wells.
20 The wells weren't totally sealed. So that was a
21 manufacturing problem.

22 The other leaking source medical event was
23 our typical Mick applicator where possibly a source
24 gets jammed, they put too much pressure, the source
25 gets sheered. In this case, part of the source goes

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1 into the patient.

2 Dr. Nag?

3 DR. NAG: On that first case, where the
4 manufacturer welding or something was a problem, if
5 that happened, then the entire batch should be looked
6 at because it's not only that center but that whole
7 batch of seeds that may have a problem.

8 DR. HOWE: Yes. And what we have in the
9 NMED report was it was determined that the problem was
10 isolated. So this could have been the entire batch
11 because there were three patients being treated at
12 this one facility.

13 Then we get to treatment-planning failure.
14 In this case the treatment computer planning didn't
15 function correctly. And so it defaulted to the
16 default values, which did not give the right dose to
17 the patient.

18 We had three different licensees that had
19 less than 80 percent of a dose given to the treatment
20 site or we had wrong treatment site. These are three
21 Department of Veterans' Administration facilities.

22 We had 57 patients with less than 80
23 percent to the prostate and 35 patients with excess
24 dose to the non-treatment site. And those are
25 independent cases. So that's not 35 of the 57.

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1 That's a total of 92. And then we had another VA
2 facility with seven and three.

3 Some of these may end up not being medical
4 events because they may have been called potential
5 medical events because of the issue of drawing to the
6 dose, iso-dose curves. One physician draws them one
7 way, another physician draws them another. But that
8 will all work out in the inspection process. You will
9 be getting more information on that in another
10 meeting.

11 And then we had three wrong treatment
12 sites, where they were aiming for the prostate and
13 they didn't get them in the prostate. One claims that
14 the prostate was --

15 MS. GILLEY: Did you misplace a
16 prostate?

17 (Laughter.)

18 DR. NAG: The prostate was misplaced?

19 DR. HOWE: Yes. That was a misplacement
20 of the prostate. I suspect most of these had to do
21 with ultrasound and not being able to accurately
22 visualize where they wanted to with the seeds.

23 Dr. Nag?

24 DR. NAG: I know I had investigated two
25 of them. And the two of them that I knew about were

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1 that when they did the ultrasound, one was when they
2 did the ultrasound, they thought that the bulb of the
3 penis was the prostate until they implanted that.

4 And the other one I think was in the
5 middle, the patient moved. And then they went on with
6 the implantation without reverifying that the needle
7 had moved to that point. They implanted part of the
8 prostate at the wrong site.

9 DR. HOWE: Right. And there was one that
10 said the seed had moved.

11 Okay. Now moving into 35.600, I will
12 start with the HDR units. We had eight HDR cases.
13 These are five. The three that we will talk about on
14 the next slide are all MammoSite or new devices that
15 function similarly to MammoSite.

16 You had an equipment malfunction halfway
17 through the procedure. An error message came on. The
18 device just would not send the source back out again.
19 So we had a medical event there.

20 There were some problems with putting in
21 dwell times. They wouldn't go across properly in the
22 computer system. And so the physicist put them in
23 manually, and he put the wrong dwell times in, wrong
24 spacing.

25 And in one case, in the wrong dose

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1 reference point, the authorized user wanted to deliver
2 the dose at the surface. This was a gynecological
3 one. They wanted it delivered at the surface of the
4 ovoid. And when they manually put it into the
5 treatment planning center, they put it at five
6 millimeters away.

7 Everybody followed the treatment-planning
8 system. Nobody went back to the original written
9 directive. And so the dose was resulted in a medical
10 event.

11 The wrong source length and wire
12 applicator, in this case they had multiple catheters.
13 And they were using the simulation tool. The
14 simulation tool had a kink in it. So it only went out
15 to a certain distance. So that meant they inputted
16 the distance that the simulation tool went out to,
17 which was much shorter than the source should have
18 gone. So they ended up delivering the source outside
19 the patient.

20 And the final one is the problem. You end
21 up with fractionalization. You write a written
22 directive for ten fractions, a certain dose per
23 fraction. The next person that reads it thinks it is
24 ten fractions, that dose total, divides by ten, gives
25 one-tenth of what is required. We have seen those

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1 over the years.

2 DR. NAG: Question. I would like to
3 know more about the equipment malfunction on 12 of 29
4 fractions. Two things. Number one is 29 fractions,
5 I mean, I have done HDR. I haven't had a situation of
6 doing 29 fractions. So I would question that.

7 And equipment malfunction on 12 times, you
8 know, up to the first time that should become --

9 DR. HOWE: No. It didn't malfunction 12
10 times. It got up to the 12th catheter. And at the
11 12th catheter, it didn't work.

12 VICE CHAIR VETTER: So it's not the
13 fraction. It's the catheters.

14 DR. NAG: It's 12 --

15 DR. HOWE: And they didn't treat from 12
16 to 29.

17 DR. NAG: So it's not fraction. It's
18 29 catheters.

19 DR. HOWE: Yes.

20 DR. NAG: Okay. Because 12 fraction to
21 me means that you are treating the patient 29 times.
22 Twenty-nine catheter I can understand. Okay.

23 DR. HOWE: We end up -- I would have to
24 look at it carefully, but we end up with, you know,
25 kind of descriptions that might not be right on the

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1 market. You can get the flavor of what they are
2 talking about. And I believe this one was they had 12
3 catheters and they --

4 DR. NAG: Can you send me the report of
5 that?

6 DR. HOWE: We have the NMED in here.

7 DR. NAG: Oh, yes, yes, yes. Okay.

8 DR. HOWE: Okay. And then the next three
9 are the balloon, the breast balloon procedures. It
10 used to be they were all MammoSites, but now we have
11 got a new manufacturer out there, SenoRx.

12 In one of them the simulator was checked.
13 The catheter was kinked. The wrong length was used.
14 We may have described that one for an earlier case.
15 But the other case they used the wrong length
16 catheters.

17 And then we had an error message that
18 showed up on the second one. And the physicist
19 mistakenly read that the error message indicated that
20 the source was off by two millimeters. So he decided
21 to override the error message and give the treatment.
22 But the error message really said it was off by two
23 centimeters. And so the dose was given two
24 centimeters away from where it was supposed to be.

25 And in the third one, we have the HDR unit

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1 was attached. And the technologist accidentally put
2 the source into the saline balloon part of the
3 catheter. And then when they took it out, all the
4 saline leaked out. And then when they connected it
5 correctly, there was no volume there. The balloon was
6 now deflated. And so the sources were too close to
7 the tissue. And we ended up with a medical event.

8 So we have seen other cases where people
9 have ended up removing fluid and pricking the balloon
10 and having deflated. In this case, they did not go
11 back and check to make sure the balloon was inflated
12 properly before they gave the procedure.

13 We had one gamma knife incident. In this
14 particular case, it ended up it was an MRI issue. The
15 MRI tech inputted that the image was taken, I believe,
16 feet first when, in fact, it was taken head first.
17 And because he inputted that it was feet first, the
18 lefts and rights were reversed.

19 And you wouldn't know this unless you went
20 way down deep into the MRI electronic report to see
21 how it was entered. And so most folks are now looking
22 at little more carefully at the images and the
23 information that comes through with the additional
24 images.

25 DR. FISHER: How was it discovered?

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1 DR. HOWE: I'm not sure we get a good
2 description of how it was discovered. A lot of times
3 these things are, well, gee, it was really on the
4 left. Why are you slightly over on the right? Here
5 is my gamma knife.

6 And it was close to the center margin, but
7 I think when they went back, they had discovered that
8 they had put it in the wrong place. And then they
9 went back to see why they had put it in the wrong
10 place. And they realized that the MRI image was
11 mistakenly left right. And we actually had a
12 teletherapy medical event.

13 In this particular case, the authorized
14 user wanted two shots or the AP view. And he wanted
15 two shots for the PA view. And they were both similar
16 times. And so the person that provided the dose
17 believed that it was one shot for AP, one shot for PA.
18 So they gave 50 percent of what was --

19 DR. THOMADSEN: What do you mean by
20 "shot"?

21 DR. HOWE: Orientation.

22 DR. THOMADSEN: Treatment?

23 DR. HOWE: Treatment, yes.

24 DR. THOMADSEN: A beam?

25 DR. HOWE: Yes, a beam.

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1 DR. THOMADSEN: Okay. A shot would be
2 for a gamma knife. Here it sounds like you are
3 talking about films when you talk about shots.

4 DR. HOWE: No. I am not talking about
5 films. They were supposed to give a 17-minute
6 exposure. And then they were supposed to give another
7 17-minute exposure. And then they were supposed to
8 flip over to the PA view and give another similar time
9 exposure. And they only gave one each.

10 DR. NAG: It's a field within a field.
11 So you have a smaller field, like we do what's
12 something like -- this same thing has happened with
13 the linear X generator, where you are using multiple
14 fields. And it would not be a medical event. I mean,
15 it would be like forces but not be a medical event,
16 right?

17 MS. GILLEY: Only in California.
18 That's not true through all states. Some states treat
19 medical events with linear accelerators the same as
20 they would radioactive materials.

21 DR. HOWE: It would not be an NRC medical
22 event because we do not regulate the accelerators
23 providing therapy treatment.

24 And in 35.1000, we had 4 medical events
25 involving the yttrium microspheres. And in all cases,

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1 we had the dose didn't go into the patient. It went
2 into the wrong vial. It generally went into the waste
3 vial. So we had that they put the stopcock in
4 backwards. It caused a kink. They set up the
5 stopcock wrong. So the dose went into the vent dial.

6 They didn't turn the stop cock on the
7 delivery device. And so everything went into the
8 waste vial.

9 And the fourth one we didn't get enough
10 description to know exactly what they did, but there
11 is a good assumption that it had to do with stopcocks
12 and vials and the dose did not go to the patient.

13 Okay?

14 Debbie?

15 MS. GILLEY: Are we not seeing a trend
16 with these stopcocks and microspheres? And should we
17 not be looking at some alternatives, technology, or a
18 different -- I mean, I realize there's a lot of them
19 being done, but this seems to be very preventative.
20 Is it not?

21 DR. HOWE: We are seeing some
22 manufacturers actively working on the device delivery
23 systems. And we have seen it evolving with time to
24 try to eliminate some of these problems.

25 DR. THOMADSEN: The waste vial

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1 indicates it was a theradose --

2 DR. HOWE: TheraSpheres.

3 DR. THOMADSEN: -- a TheraSpheres
4 patient. And they have just come out with their Mark
5 III delivery system, which is we are getting trained
6 on that next week. But the point is to address all of
7 these stopcock issues.

8 So they have taken it seriously, and they
9 have redesigned it. That's what they said.

10 MS. GILLEY: Excellent.

11 DR. HOWE: Two of these we know are
12 TheraSpheres. We don't know the other two. We have
13 had a more recent medical event with stopcock and
14 errors. And that has been a SIR-Sphere. So it's not
15 exclusively TheraSpheres.

16 And we have from day one, one of the major
17 problems with the microspheres has been the delivery
18 system, making sure that things get --

19 VICE CHAIR VETTER: Dr. Nag has a
20 question.

21 DR. HOWE: Dr. Nag?

22 DR. NAG: There is more of a comment.
23 I think the increased number you are saying, that's
24 two things. Number one, when initially this was done,
25 it was done by a small group who was doing so many of

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1 them. And, therefore, they were the one who started
2 the program and they had the training and they were
3 doing it.

4 And now you are seeing this going to a
5 larger number of centers, many of whom are doing it
6 for the first time, perhaps with inadequate training.
7 Well, I have seen most of the time inadequate training
8 that leads to error, not so much faulty equipment.
9 You know, you blame faulty equipment, like more of the
10 training that I have seen.

11 DR. HOWE: Well, the faulty equipment is
12 part of the training. In other words, if you aren't
13 properly trained to set it up correctly and if you
14 don't turn the dials in the right places -- and I'm
15 not sure I would go so far as it's a difference in
16 where the devices are now because from day one, we had
17 medical events in some of the big facilities because
18 you do have delivery problems with these devices. And
19 we have a higher percent. I mean, it's not a lot of
20 them, but we have quite a few medical events with
21 them.

22 Yes?

23 DR. SULEIMAN: Who reports these, the
24 manufacturer or --

25 DR. HOWE: No. The licensee has to report

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1 them to NRC. They're medical events.

2 DR. SULEIMAN: Because if the user
3 reports it, it's a device problem. If the
4 manufacturer reports it, it's a user problem.

5 (Laughter.)

6 DR. THOMADSEN: By definition.

7 VICE CHAIR VETTER: Dr. Thomadsen had his
8 hand up.

9 DR. THOMADSEN: I was just going to say
10 three of the four events were at large places, who
11 probably have done -- I know two of them at least have
12 done lots of these.

13 DR. HOWE: Yes.

14 DR. THOMADSEN: The fourth one I just
15 don't know about. So it may not be --

16 DR. HOWE: I think I had a few more
17 slides.

18 MS. GILLEY: I just would encourage if
19 we are seeing these trends that we have some
20 recommendation, either additional training is needed
21 or we need to at least go back to the manufacturer and
22 encourage them to find a better delivery system or
23 improvements to the delivery system to prevent such
24 events which I felt like could be corrected and we
25 should --

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1 DR. HOWE: Well, one of the things we did
2 in the beginning was we changed the sealed source and
3 device registry because in the initial sealed source
4 and device registry, it was just the microspheres.
5 And we when back and we said, "No. This device is the
6 delivery system, too."

7 So we have tied the delivery system into
8 the sealed source and device so that we have a handle
9 for improvements. And because of the medical events,
10 we are seeing engineering improvements.

11 MS. GILLEY: Good.

12 DR. HOWE: And the companies are taking a
13 look at what is happening and they are trying to
14 figure out a root cause and trying to address it. We
15 had some pressure issues. So they put a pressure
16 syringe on we had.

17 And now the new TheraSphere device doesn't
18 have any stopcocks. So as long as they connect the
19 tubes up in the right places, it should be okay.

20 Okay. And then I have a few cases that
21 were reported to us, but they really weren't medical
22 events. And I thought they might be of interest to
23 the ACMUI.

24 The first one was we had an I-131 patient
25 that came in for a 150-microcurie I-131 thyroid

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1 ablation. And this particular facility has them come
2 back about a week later and does a whole body scan
3 without giving any additional I-131.

4 The patient came back. They were given
5 five millicuries of I-131 because somebody didn't
6 realize that wasn't on the written directive. It ends
7 up this is not a medical event because at this point
8 the thyroid was ablated and the dose was not high
9 enough to bring it up to a medical event.

10 And even once in a while we had a patient
11 intervention. And we had a patient that pulled the
12 needles out and put them at her feet. And the nurse
13 comes in and finds them. So that's not a medical
14 event.

15 The strontium eye applicator, this one
16 came in from the agreement state. We believe it's not
17 a medical event. We're still tracking down specific
18 information.

19 What happened in this case is the device
20 was calibrated in '92, I believe '91-'92. They
21 changed ownership. The device was being used in
22 accordance with good decay correction.

23 And then because the agreement state now
24 has to implement them at 35, they had to get the
25 device recalibrated. They got the device recalibrated

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1 with the new calibration system that NIS is proposing.
2 And so the value of the activity in the strontium eye
3 applicator changed.

4 So when then the inspector went out, they
5 said, "You've got three medical events because you
6 don't have the right activity for the eye applicator."

7 And so we went back out with our
8 information notice and sent that to the agreement
9 state. And we said, "If you think it is a medical
10 event just because the activity changed" --

11 (Whereupon, the foregoing matter went off
12 the record briefly.)

13 DR. HOWE: So this is an issue that the
14 ACMUI addressed a number of years ago. When they
15 change the calibration, the authorized user, if they
16 are getting good results should keep the time the
17 same, change the dose, and continue on.

18 And so we think that the activity changed
19 because of the calibration, but the physician was
20 getting good results. And the previous events that
21 were called medical events we believe were not really
22 medical events.

23 Yes, Dr. Welsh?

24 DR. WELSH: Regarding that first one on
25 your list there, five millicuries were administered.

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1 Maybe I'm still confused about which ones require and
2 which ones do not require written directive.

3 As Bruce asked earlier when you talked
4 about the diagnostic medical event where ten
5 millicuries were intended, ten microcuries were
6 written, ten millicuries were actually given, that was
7 a medical event. Here it's five millicuries. Didn't
8 that require a written directive? It doesn't sound
9 like there was a written directive.

10 DR. HOWE: It did require a written
11 directive, but to get it to a medical event, you have
12 to also go over some dose limits. And in this case
13 because it was a thyroid person, the dose limits
14 weren't exceeded. So there are a number of factors
15 that you have to meet.

16 MS. GILLEY: The second organ of
17 interest of iodine-131 is the stomach. So if you
18 don't have a thyroid to get the organ dose of a
19 thyroid because it's ablated, the next choice is the
20 lining of the stomach. And it has to meet the
21 threshold for a medical event.

22 DR. THOMADSEN: I thought something
23 such as treating the wrong patient didn't require a
24 threshold. I mean, that was by definition a medical
25 event. I thought not having a written directive when

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1 you're supposed to is automatically a medical event,
2 regardless of thresholds.

3 DR. HOWE: Dr. Thomadsen, that was the
4 discussion yesterday --

5 DR. THOMADSEN: Exactly.

6 DR. HOWE: -- on making a change to the
7 rules.

8 DR. THOMADSEN: Right. What is the
9 current rule, though?

10 DR. HOWE: The current rule is if you
11 don't have a written directive -- well, generally
12 there is something in writing. In this case they
13 wrote. There was a written directive for a whole body
14 scan. Okay? The technologist interpreted that to be
15 "Okay. I need five millicuries" and gave the five
16 millicuries. But in this particular case, the
17 physician didn't ask for five millicuries.

18 Then you have to go to dose because what
19 we go back to in this case is what was the intended
20 dose. Intended dose was zero. He had a written
21 directive. The intended dose was zero. He gave
22 material that wasn't supposed to be given.

23 Then you have to go and see if that
24 material resulted in a dose to the patient that
25 exceeds our limits. It's the same as if you expected

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1 technetium and you gave the wrong technetium.

2 Yes, there was something that said, "You
3 were going to get a bone scan. You got a kidney scan.
4 Do you exceed the dose threshold?" And the answer is
5 no. It's not a medical event. So you have to do
6 multiple things.

7 MR. LUEHMAN: That doesn't mean there
8 wasn't a violation. There may have been violation.
9 It's just not a medical event.

10 DR. HOWE: Yes.

11 MR. LUEHMAN: That was the discussion
12 yesterday where you had the medical --

13 DR. THOMADSEN: Actually, I thought the
14 discussion yesterday because yesterday's discussion
15 was about changing things -- the discussion today is
16 about what exists currently.

17 DR. HOWE: Right.

18 DR. THOMADSEN: Okay.

19 DR. HOWE: So what we are looking at is we
20 are looking at a diagnostic procedure because this
21 person was athyroid and did not raise up to the dose
22 levels that would be required for a medical event. So
23 it's immaterial.

24 We had to be careful because there was a
25 presumed -- the procedure was a zero dose, a zero

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1 activity for the second part of the procedure. They
2 gave the material. Okay? But once you give the
3 material, you then go over the dose issues.

4 VICE CHAIR VETTER: Mr. Lieto, you have a
5 question?

6 MR. LIETO: Yes. I am a little
7 confused because you are saying that there was a
8 written directive, which to me means there was a
9 script saying that they are to give the patient five
10 millicuries from the authorized user. That's a
11 written directive.

12 DR. HOWE: There was a written directive
13 for the 150 millicuries.

14 MR. LIETO: Right.

15 DR. HOWE: And then we went back and asked
16 what the licensee's procedures were for people coming
17 back. Was it understood from their procedures that
18 the whole body scan after the therapeutic required an
19 administration? And they said they had procedures.
20 It said no administration.

21 MR. LIETO: Okay.

22 DR. HOWE: Now, once they gave the five
23 millicuries, should they have asked for a written
24 directive? Yes.

25 MR. LIETO: Okay.

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1 DR. HOWE: And they didn't have one. So
2 should they have given it? No. Did it become a
3 medical event? No because it didn't reach the dose
4 threshold.

5 MR. LIETO: Okay.

6 DR. HOWE: And then the last case was a
7 fluorine-18 infiltration. And Cindy was going to talk
8 more about that. But we have essentially some
9 questions that we asked, but we had been on record
10 earlier, and I mean much earlier, before the 2000
11 rule, probably before the '80 rule, that said
12 essentially infiltration was something that happens
13 and it would not be called a misadministration. And,
14 therefore, it still wouldn't be called a medical
15 event.

16 So those are the four cases that I thought
17 you might be interested in.

18 VICE CHAIR VETTER: Thank you. Thank you,
19 Dr. Howe.

20 DR. HOWE: Very well.

21 VICE CHAIR VETTER: Mr. Lieto?

22 MR. LIETO: My portion addresses the
23 other material events that are reported involving
24 medical radioactive material use. These are based on
25 events from the NMED database.

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1 I have on here through October of this
2 year, but, in actuality, because of the timing of
3 providing the reports, there may be events during the
4 month of October that we did not capture at the time
5 making these reports and so forth.

6 As Donna-Beth reported, there were 31
7 medical events involving patients. There were 32
8 other reportable medical use-related material events.

9 There are a couple of changes on the
10 slides because we found that after submitting the
11 slides, that there was an event in the database that,
12 in actuality, did not exceed the reportable threshold
13 involving a lost source. And I will describe that as
14 we go along.

15 First of all, I want to express my
16 appreciation to Duane White from NRC staff for his
17 assistance because he was very helpful in explaining
18 some of the nuances in doing searches on the NMED
19 database to capture these other events.

20 In terms of categories of events, there
21 were for lost sources, both sealed and unsealed, 11
22 events. For leaking sealed sources, there were seven
23 events. And fetal embryo dose, there were two events.

24 For landfill alarms, which is something
25 that we reported in the past, which were either due to

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1 decay in storage waste being disposed of improperly,
2 unknown origin, as well as patients who had been
3 released under 10 CFR 35 whose waste gets into the
4 general waste stream and sets off landfill alarms.
5 There were four events that were reported into NMED on
6 this situation.

7 And, therefore, the final category was
8 what I will call "miscellaneous," which is to capture
9 everything else, which included in this report
10 equipment malfunctions, which were three events;
11 packaging problems and contamination, which were four
12 events; and an overexposure of the extremities.

13 One of the things that I do want to kind
14 of as a preliminary is that the reports that both
15 Donna-Beth has presented and what I am going to be
16 presenting actually provide the input to a more
17 detailed report of the Materials Event Subcommittee,
18 which makes a report in the spring, which addresses
19 all the events that we described here plus any that
20 might have been reported in this last month and a
21 slightly more detailed analysis as well as specific
22 recommendations will be made from that subcommittee.
23 It is an ongoing I guess action item or Committee
24 program. So, actually, next spring will be our second
25 subcommittee report.

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1 First of all, I will start off with some
2 of the specifics. Regarding the lost sources, this is
3 somewhat in a chronological order. The first event
4 was an iodine capsule that was used as a calibration
5 quality control check in a neck phantom.

6 The source was there. Some counting was
7 done. But sometime between doing the calibration and
8 quality control and getting back to the hot lab for
9 storage, the capsule was lost.

10 A second event was an iridium-192 seed, a
11 ribbon that was removed after treatment to a patient.
12 I think there were a number of ribbons, I think about
13 eight or nine ribbons, involved in the treatment.

14 Sometime between removal and inventory
15 back in radiation oncology, one of the ribbons was
16 found to be missing. A search of the patient's room
17 and area was negative and subsequent search of the
18 off-site laundry three days later found the ribbon,
19 and it was returned into storage.

20 The next event was an iodine-125 seed use
21 for breast tumor localization sometime. During the
22 tumor removal process during suction of the breast
23 site, the seed was thought to have gotten sucked into
24 the canister of the suction device and later disposed
25 of via that route before a survey was completed.

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1 And next was again another iodine-125
2 seed. There was a batch of seeds obviously being
3 autoclaved prior to for implantation in a patient.
4 The pig in the autoclave overturned, spilled the seeds
5 out. And during the recovery process, only 19 of the
6 20 seeds were recovered.

7 In another case, 18 seeds, which were
8 unused after an implant, were transferred to the
9 nuclear medicine technologist for storage and
10 disposal, which was really the standard procedure for
11 this licensee.

12 The nuclear medicine technologist was not
13 very well-trained in their procedure and process, took
14 the seeds, dumped them into a NucMed decay and storage
15 bin.

16 And ultimately this made its way out as
17 general nuclear medicine decay and storage waste. So
18 apparently it was not surveyed properly before
19 disposal, but this was the route of, shall we say,
20 transfer to the local landfill.

21 Two seeds in another application,
22 iodine-125 seeds, were unused after implant, were left
23 in an applicator, which was not their standard
24 process. And during cleaning, it is presumed that the
25 seeds were ejected during the cleaning process of the

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1 applicator and subsequently flushed down the drain.

2 Again, another I-125 seed situation became
3 lost after implant during the post-implant inventory.
4 One of these seeds was determined to be missing and
5 was not able to be found. And it was suspected that
6 somehow it got disposed of via the general trash route
7 and was not recovered.

8 The next incident here -- I should
9 probably point out that one of the incidents that may
10 still be on your handout is an I-123 capsule that was
11 supposedly not returned to inventory after use in an
12 uptake phantom for calibration and quality control for
13 an uptake procedure.

14 It was reported as being 200 millicuries.
15 When we were reading the narrative on this, we asked
16 that NRC staff follow up on this event. And
17 subsequently it turned out that it was a
18 200-microcurie capsule, which put it over the
19 threshold. And I believe subsequently that report has
20 been removed from the reportable criteria for the NMED
21 database as lost sources.

22 The next event was two gadolinium-153
23 transmission sources. Basically a gamma camera was
24 being disposed. It had had two gadolinium-153
25 transmission sources, the type that was described

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1 earlier in our proposed rulemaking changes. And
2 subsequently when the camera was disposed by simply
3 transferred to a scrap recycler, these two
4 transmission sources went with it and were not
5 recovered.

6 The next event was five iridium seeds in
7 a ribbon that were lost, became lost. The inventory
8 -- this was done, I believe, after inventory of the
9 implant and upon removal became lost, it's suspected
10 that they went out in the trash/laundry prior to
11 proper survey and were not recovered.

12 The next incident was a large batch of
13 palladium-103 seeds, which were unused for an implant.
14 I believe this was an implant that was intended to be
15 done.

16 And there was an area undergoing
17 renovation where these seeds were being stored. It
18 was presumed that they were put into a lockbox at the
19 time for storage prior to their disposal and/or use.

20 When they went to go back and get this,
21 the so-called lockbox area was not locked up. The pig
22 containing the seeds was gone. And it is again
23 presumed that this went out into the general trash
24 during the renovation process of the area.

25 The next and last incident or event

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1 regarding lost sources was again another 125 seed that
2 was unused after implant, during inventory was
3 discovered that was one of -- the inventory, the six
4 unused seeds at the time became lost, presumably --
5 again, I think this one was -- was this flushed down
6 the drain also? -- but, anyhow, became lost during the
7 process of the post-inventory evaluation of the unused
8 seeds and was not recovered.

9 There were seven events involving leaking
10 sealed sources. Now, these are not leaking sources
11 that were reported under the medical event process
12 that Donna-Beth discussed earlier.

13 One event involved five seeds that were
14 unused after implant. The licensee did white testing
15 of the storage pig cartridge and one of the seeds and
16 found removable contamination significantly above an
17 action level.

18 They returned the cartridge and seed to
19 the vendor, who did analysis. The vendor said based
20 on the analysis of the damage to the seed, that it
21 likely occurred during the seed being used in the
22 applicator and the leakage occurred during that time.
23 There was no patient contamination in this event.

24 In the second event, a seed became jammed
25 in the applicator. The technician, who did not use

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1 any gloves, unloaded the seed from the cartridge. And
2 after the technician unloaded the seed, did a survey
3 immediately afterwards, found both the cartridge and
4 her hands contaminated. And so it was obviously a
5 leakage caused by the process of using the seeds in
6 the applicator.

7 The decontaminated the technician. And
8 calculations were done in terms of dose due to the
9 contamination and was below any reportable level.

10 In another incident, the vendor during
11 seed assembly of iodine-125 seed strands damaged the
12 seed during this process, severely contaminating the
13 working and crimping tool used to make these seed
14 assemblies.

15 I think this is noteworthy because, as I
16 will report in a subsequent one, this has a very high
17 potential for the contamination if not caught to
18 contaminate other seed assemblies and these being
19 distributed to licensees.

20 The next event was five seeds from two
21 different lots that were unused after implant. In
22 other words, there were two different implants
23 involving a total of five unused seeds that the
24 licensee did white testing of and were found to be
25 leaking and in one of the situations visibly damaged.

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1 There was no patient or work area
2 contamination that was found by survey and also I
3 think a survey of the patient's thyroid.
4 thyroid. It was thought that the cause was that as
5 these seeds were being shipped, they were stacked in
6 the shipping container. And it was thought that some
7 excessive force caused damage to the seeds and that
8 during the cartridge loading, the leakage resulted.

9 The next event, a patient was brought back
10 after proper seed implantation. And during the
11 process of trying to open up the ureter with a
12 cauterization tool, a seed became damaged and resulted
13 in contamination of both the patient and the
14 equipment. A thyroid bioassay was done of the
15 patient. And the dose to the thyroid was estimated at
16 less than a rem.

17 The last two events, a vendor reported a
18 leaking I-125 seed, which was estimated to
19 cross-contaminate potentially over 1,500 seeds that
20 were shipped to multiple customers, both in the United
21 States and internationally.

22 The vendor did follow up with all of these
23 customers. And so one thing that wasn't clear is
24 whether this event is related to any of the previous
25 events that were reported earlier.

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1 We suspect not because that there were no
2 follow-up. At least there was not any indicated in
3 the narrative on this, any reports from customers on
4 these potentially contaminated seeds.

5 In the last incident, a licensee reported
6 one seed being leaking. It was found to be leaking
7 after survey of a group of seeds that were found after
8 autoclaving and cartridge loading but prior to patient
9 implantation.

10 They were returned to the vendor for
11 analysis. And the vendor found surface contamination
12 also but no defects in either of the welds or
13 encapsulation. So it's not clear where this
14 contamination originated from.

15 There were two events reported on fetal
16 embryo dose. I think that is kind of noteworthy in
17 that obviously the licensee was following standard and
18 very good measures to assess the pregnancy status of
19 the patient.

20 In both incidents, these were patients
21 that were receiving I-131 sodium iodine for thyroid
22 ablation. In the first case, the patient had a serum
23 pregnancy test done two days prior to administration,
24 and in the second incident, the patient had a negative
25 test that was done within five days prior to

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1 administration.

2 So obviously the licensee was following
3 good standard procedures to try to assess that the
4 patient was not pregnant. And obviously the patient
5 didn't think she was pregnant at the time.

6 In the first incident, the event was
7 discovered. And the estimate to the embryo dose was
8 32 rads. I believe it was the medical consultant that
9 was called in on this case who stated that there were
10 no adverse effects expected to the embryo fetus
11 because of the stage of pregnancy during the exposure.

12 In the second incident, the patient
13 informed the licensee three weeks after administration
14 that she was pregnant. The dose was estimated to be
15 35 rads or Centigray to the embryo. And I don't
16 remember what the medical consultant's report on this
17 was other than that they were going to, I believe,
18 follow the pregnancy and monitor the patient and the
19 child. Obviously the patient failed to follow written
20 instructions to avoid becoming pregnant.

21 Very briefly, there were four landfill
22 alarms, all involving agreement state reports. They
23 all involved I-131 waste. In two of the events, the
24 waste origin was unknown. And in the other two
25 events, it involved one improper disposal of hospital

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1 waste that got into the general waste stream.

2 MS. GILLEY: May I interrupt? I want
3 everyone to know that agreement states do not have to
4 report landfill alarms. That's no longer a reporting
5 requirement for us. And in the State of Florida, we
6 have about 100, 130 of these landfill alarms every
7 year. This is voluntarily reporting that you're not
8 really reflecting what's happening out there in the
9 profession.

10 MR. LIETO: Regarding miscellaneous, there
11 were three machine malfunctions, one involved a gamma
12 knife, doors that failed to close after treatment. At
13 the end of the treatment fraction, the patient couch
14 moved out withdrawing the patient from the treatment
15 helmet, but the source door -- the shielding doors
16 failed to close on the sources. The medical physicist
17 entered the room and manually closed the doors,
18 receiving negligible dose, and patient dose did not
19 deviate above a level requiring -- being outside the
20 written directive guidelines.

21 The next two events involve HDR sources.
22 Both of these occurred during source servicing, source
23 exchange, and occurred with the manufacturer's field
24 engineers. The first, during an emergency retraction
25 test, the source failed to retract properly. Part of

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1 the source became disconnected, and the top of the
2 source capsule was clipped off within the vault door.
3 The vendor sent out a team to assess the situation,
4 and the recovery of the source, and its evaluation was
5 done all under the vendor's, what I'll say - I don't
6 know if I should -- emergency response team, but their
7 response team trained to assess this.

8 The source was clipped off. Part of it
9 was found I think in the inner vault, because the
10 surveys were found to be extremely high as they were
11 assessing the situation, so it did require some
12 specialized recovery efforts. During the other, the
13 next event, the field engineer was trying to get the
14 old source to exit into the source exchange container
15 and failed to do so. The cause was determined to be
16 that both the dummy and the active, or the old source
17 exited at the same time, and because stuck. The
18 vendor -- the manufacturer told the field engineer to
19 clip -- to cut the source wire, and put the source
20 into the emergency storage container, and await
21 further action. The engineer cut the dummy source
22 instead, and placed that into the emergency shielded
23 container, so subsequently the vendor had to send out
24 a specialized team for the source recovery and
25 exchange.

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1 In terms of the packaging events, there
2 were four events. The first event involved a licensee
3 returning an unused block of seeds that were not used
4 for an implant. It was not packaged properly, such
5 that the pig became open during transit. The seeds
6 spilled out of the pig container within the inner
7 packaging. The exposure levels significantly exceeded
8 the limits for the package labeling. The manufacturer
9 received the sources, determined there was no
10 contamination or loss, and they did estimates on
11 expected exposures, and these were found to be -- that
12 none had occurred.

13 The next incident were three packages of
14 cobalt sources, flood sources being received by a
15 licensee, found the surface contamination to
16 significantly exceed the acceptable guidelines. The
17 contamination was determined to be Technetium, so it
18 was not determined where the origin of the Technetium
19 was.

20 DR. VETTER: Ralph, we just have a couple
21 of more minutes for you.

22 MR. LIETO: Okay. All right. There were
23 two others, both involving Technetium packages with
24 significant contamination on the surface. Again,
25 there were -- in one case there was significant cross-

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1 contamination by a courier picking up several
2 contaminated packages going to the next stop, and then
3 contaminating -- it was discovered that the packages
4 there were contaminated upon receipt. And also, his
5 hand and vehicle were significantly contaminated. And
6 the last event was a significant over-exposure to the
7 extremities of two manufacturers, radio pharmacy
8 technicians who were making I-131 capsules for human
9 use.

10 In summary, they're comparing the events
11 over the last three years that I've been making these.
12 The landfill alarms have significantly gone down, for
13 the reasons I think Debbie has alluded to. We're
14 seeing a significant increase, I feel, in the number
15 of leaking sources being reported. Lost sources over
16 the last year, I won't say that they've increased, but
17 there is, I think, an increasing trend there, also.
18 But I think we need to look at this a little bit
19 farther in the Subcommittee report. And that's it.

20 DR. VETTER: Thank you. I am going to
21 just take one or two questions, comments, now. And if
22 it appears we need more time, we'll do that later,
23 because the next presentation has some problems with
24 flights. We need to get moving. Dr. Thomadsen.

25 DR. THOMADSEN: Well, it's not a question

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1 on this. It's a question as to how does hearing these
2 now differ from what we do in the spring when we go
3 over these events? And why is it we're doing the
4 events twice a year, as opposed to just doing them
5 once?

6 MS. GILLEY: We don't have all of them.

7 DR. VETTER: Dr. Howe could perhaps add
8 something to that.

9 DR. HOWE: I think the original intent was
10 that in October, we would give you an overview of all
11 the events that happened in the past year. And that
12 if you discovered something that was a trend of
13 interest, then your spring group would have delved
14 more into that particular area, and develop a more
15 detailed report on whatever was of interest to the
16 ACMUI. So, originally, it wasn't intended that you
17 got the same information in October and in the spring.
18 It was that you got a more detailed look at some
19 aspect of what was going on that you thought was of
20 particular interest.

21 DR. THOMADSEN: Actually, I think in the
22 spring we are going through the details of each of
23 these events.

24 DR. HOWE: But you don't have to.

25 DR. THOMADSEN: Right. Or we wouldn't

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1 have to do it now, if we're going to be doing that as
2 part of the analysis in the spring.

3 DR. VETTER: Dr. Welsh.

4 DR. WELSH: Was there any difference in
5 the way you acquired the information this time through
6 the database, or is it identical to what -

7 MR. LIETO: It will be the same. There
8 may be some additional events that were not captured
9 between the time that we had to submit our report for
10 the Committee and the end of the fiscal year, so there
11 could be a few added events. Hopefully not, but there
12 could be.

13 The report that we've done in the fall
14 actually predates the forming of the Subcommittee that
15 was established -- well, actually, the first report
16 was this past spring, so I could see where we could
17 just roll these both into one.

18 MS. TULL: This is Ashley. Just to add
19 some perspective on this. Medical events have always
20 been reported in the fall. It's been a standard thing
21 that Donna-Beth and Ralph have done. And what came
22 out of it is this is just a brief overview, and I
23 think Dr. Nag may have actually brought this up, and
24 wanted more information, more detailed analysis. And
25 then if there is a bigger issue, or we do see a trend,

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1 then you, as a Committee, could make some sort of
2 recommendation to the NRC so that we could maybe get
3 a message back to the licensees. So it's a more in-
4 depth, if needed, type thing.

5 DR. HOWE: And this is Dr. Howe. You also
6 have at the bottom of all the NMED reports that you've
7 seen a series of references, and those are documents
8 that may or may not give additional information. And
9 there's time between October and the spring to go back
10 and get more additional information if you thought a
11 case was interesting, but you didn't really have
12 enough information to see what was going on with it.
13 So the information presented in the spring can be
14 different than what's in the fall, and I hope it is.

15 DR. VETTER: Okay. So I guess, I don't
16 hear any recommendations at this point.

17 DR. THOMADSEN: Well, I'll make a motion
18 that we do -- we review the events in the spring. We
19 can start looking at them earlier so we can -- if we
20 need more information, we can go to those references
21 and have things ready for the spring meeting.

22 DR. VETTER: Okay. Is there a second to
23 that? Ms. Gilley?

24 MS. GILLEY: Second.

25 DR. VETTER: Discussion? Yes, Dr. Eggli.

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1 DR. EGGLI: Given the large number of
2 medical uses and the very small number of events, I
3 don't see any obvious trends here. To me, it looks
4 like noise in a very small number. I don't know that
5 this needs to be repeated in the spring.

6 DR. VETTER: This year.

7 DR. EGGLI: This year.

8 DR. VETTER: Dr. Thomadsen.

9 DR. THOMADSEN: The only reason to repeat
10 it in the spring is to have a consistent database that
11 we're looking at over the years. I agree that we
12 probably don't need to go over everything in detail
13 again.

14 DR. VETTER: Dr. Eggli.

15 DR. EGGLI: Again, when the numbers are so
16 small compared to the total number of events that they
17 begin to look like noise in the system, I'm not sure
18 that the fact that we may not have captured 100
19 percent of what occurred in October of this year is
20 going to have any dramatic change, unless there's a
21 huge surprise in there. The one event that may be of
22 note is the VA system event, but that's being looked
23 at intensively. And the question is, does this
24 Committee have anything to add to that?

25 DR. VETTER: Ralph.

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1 MR. LIETO: Well, I guess I would -- we do
2 try to put a little more statistical, shall we say
3 numerical validity to the conclusions maybe that
4 you're stating. In other words, are these very small
5 number events that are occurring? We don't make
6 recommendations at this time period. I was going to
7 say that if we do -- are only going to do it once, I
8 guess I would tend to agree with Bruce, that we would
9 do it in the spring when we have all the data in for
10 the fiscal year, and any final -- hopefully, current
11 reports, and make either recommendations that there's
12 no recommendations, or we may have some
13 recommendations to be made, especially in light of the
14 event that's coming out regarding the I-125 seeds,
15 because that should be the Subcommittee that makes any
16 recommendations.

17 DR. VETTER: Dr. Suleiman.

18 DR. SULEIMAN: First off, these are always
19 going to be soft data. I mean, it's trying to put a
20 whole lot of effort to get more statistical certainty
21 is a wasted effort, but it's interesting to follow on
22 a routine regular basis, so from that point of view,
23 I think it's good to monitor it more regularly so we
24 get more experience in doing it. Which brings me to
25 my second point; why are we doing this? I mean,

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1 doesn't the NRC staff do this, and just give us this
2 information? I mean, why are we doing this? I think
3 it's interesting information, but -

4 DR. VETTER: Dr. Nag.

5 DR. NAG: I had made the original
6 suggestion last year. My suggestion would be that in
7 the fall, it be a standing report in the fall, so
8 every year automatically we would get this report in
9 the fall. And then if we see some significant need,
10 for example, for this year if we find that by February
11 or something we have more data on the VA event, that
12 would be a single time, we asked for that time, not a
13 standing event.

14 DR. VETTER: Mr. Lewis.

15 MR. LEWIS: To answer the direct question,
16 yes, the NRC does analyze all of these events in many
17 ways, but one of the more visible ways is our annual
18 NMED report, which we issue in the spring, and our
19 annual Agency Action Review Meeting, which is
20 specifically for the Commission -- it's a Commission
21 meeting where they look at trends across the industry.

22 All of that being said, the Committee's
23 work in this area is invaluable to us, because you
24 bring a medical perspective on the trends, especially
25 on the trends issue, and how things are practiced that

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1 the NRC staff can't bring to the issue.

2 DR. VETTER: Dr. Welsh.

3 DR. WELSH: One other point that I think
4 might have been brought up at previous meetings was
5 that by having this data on material events and
6 medical events, we could, perhaps, publish a paper
7 that would be disseminated to the end-users so that
8 they could get feedback about what has been going on.
9 And regardless of whether there is a trend or not a
10 trend, at least they would have an idea, if there was
11 a trend, how do we correct it?

12 MR. LEWIS: And the difference between
13 this industry and some of the other industries that we
14 regulate, particularly reactors, is the amount of
15 communication between the licensees. In the materials
16 world, and in the medical world, there's very little
17 in terms of user groups and cross-communication on
18 event response compared to what's done in the reactor
19 world, so the work that the Committee does serves a
20 critical function in that cross-cutting look.

21 DR. VETTER: So the motion was to have
22 another report in the spring.

23 DR. THOMADSEN: Each year have one report,
24 that being in the spring, and including any analysis
25 that's going on.

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1 DR. VETTER: Okay. This motion was to
2 have one report in the spring. So the next report
3 would be next spring.

4 DR. NAG: The following year there will
5 not be a report in the fall.

6 DR. VETTER: Unless someone makes a motion
7 that there's some particular issue we want to look at
8 in more detail. We need to move along here. I'd like
9 to halt discussion of this, unless it's really
10 critical. All those in favor of the motion for one
11 report in the spring. One, two, three, four, five,
12 six. Opposed? Abstentions? One, two, three, four
13 abstentions. Okay. The motion passes. 6-4, 4
14 abstentions. Six in favor, four abstentions. Is that
15 correct?

16 MS. TULL: Somebody didn't vote.

17 DR. VETTER: Somebody didn't vote, or I
18 miscounted. All right. Those four, one, two, three,
19 four -

20 DR. THOMADSEN: I'm sorry. What?

21 DR. VETTER: Those for the motion, those
22 in favor of the motion. Two, four, six. Those
23 against the motion, those abstaining. One, two,
24 three, four, five. Thank you. Thank you, Ralph.

25 The next item on the agenda is a

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1 presentation by Dr. Jeff Heier of NeoVista on
2 interocular Strontium-90 eye applicator. Please, Dr.
3 Heier. Am I pronouncing it correctly?

4 DR. HEIER: You have it exactly right.

5 DR. VETTER: All right. So if you would
6 introduce your team.

7 DR. HEIER: Absolutely. My name is Jeff
8 Heier. I'm a vitreal retina specialist from
9 Ophthalmic Consultants of Boston in Boston,
10 Massachusetts. This is John. I'll actually let you
11 introduce yourself.

12 MR. HENDRICK: I'm John Hendrick. I am
13 the President and CEO of NeoVista, and this is Bill
14 Vermeere. He is our Radiation Safety Officer for
15 NeoVista.

16 DR. HEIER: I'd like to thank you for the
17 opportunity to speak with you this afternoon. I'd
18 also like to acknowledge right off that I have
19 received research support from Neo Vista, and served
20 as a consultant, but I have absolutely no financial
21 equity in NeoVista or any other company involved in
22 ophthalmology. My interest here is purely scientific
23 and clinical.

24 I'm going to take just a moment to --
25 okay, great. I'm going to take just a moment to

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1 explain the disease state that we're talking about.
2 Many of you know of, or have family members or friends
3 who have macular degeneration, and exudative macular
4 degeneration is the devastating form of it. In
5 exudative macular degeneration, you get a growth of
6 new blood vessels coming up from layers underneath the
7 retina. They grow into the layer just underneath the
8 retina, and into the retina, and they leak and they
9 bleed, and they often cause devastating loss of visual
10 acuity.

11 The U.S. has roughly almost 2 million
12 people with advanced age-related macular degeneration,
13 of which about 200,000 develop wet macular
14 degeneration annually. As our aging population is
15 increasing, this number is expected to increase
16 exponentially. The World Health Organization
17 estimates that will be in epidemic proportions in
18 about 20 to 25 years.

19 That's the bad news. The good news is
20 we've had dramatic advances in the treatment of
21 macular degeneration over the past couple of years.
22 In particular, intravitreal injections of agents
23 called anti-VEGF agents have led to us being able to
24 stabilize this disease. And in many patients, result
25 in significant improvements in their vision. And we've

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1 seen visual recovery in many of these patients. That
2 visual recovery occurs in upwards of 30 to 40 percent,
3 but there is a cost to that recovery.

4 First of all, it requires multiple
5 intravitreal injections. If you have family members
6 or friends involved in this, you've seen that they may
7 get injections every month for a period of a couple of
8 years. This, obviously, results in a tremendous
9 burden on the patients, on their families, and on
10 clinicians. That's the physical burden.

11 There's also a very significant financial
12 burden in this. The drug that is most effective, and
13 that has been approved by the FDA is a drug called
14 Lucentis. It costs \$2,000 an injection. Patients may
15 get 12 in a year, and so they could get upwards of
16 \$24,000 worth of injections in a year. That's just
17 the drug itself. So there is a need for additional
18 therapies, although we've made tremendous headway.

19 Why do we look at radio therapy? Well,
20 there's been a great deal of radio therapy exploration
21 with macular degeneration in the past with variable
22 results. We know it has efficacy. We know it can
23 work in this disease, but we've been harmed by the
24 collateral damage to surrounding tissues in the
25 application of the radio therapy. We know ionizing

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1 radiation is significantly anti-angiogenic, anti-
2 fibrotic, and anti-inflammatory, all effects that are
3 important in the treatment of this disease.

4 We also have seen synergism demonstrated
5 with radio therapy, and the exact anti-VEGF agents
6 that have shown such promise in AMD. And, in fact,
7 Avastin in radiation therapy are used in colon cancer,
8 and now many other cancers, as well.

9 The diagnosis and treatment of this
10 disease is done when a patient comes in. They're
11 referred to a retina specialist. They're examined,
12 various types of diagnostic evaluation are ordered.
13 This called the fluorescein angiogram, and this is
14 critical to our diagnosis and management of these
15 patients. And it's also critical to the delivery of
16 radiation therapy to these patients. We look for
17 various signs in these patients, such as leakage
18 that's seen here right off of the center, that enables
19 us to determine what treatment is best for these
20 patients, and how to apply that treatment.

21 Once we've decided on a treatment
22 approach, we then have to analyze the different
23 components of that grouping of neovascular blood
24 vessels. We look right, this is an area of leakage,
25 but there is an area here that is also involved in the

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1 neovascular process, and so truly, the complicated
2 part of treating these patients is in the diagnosis,
3 the evaluation, and the determination of management of
4 these patients.

5 Once we've made that decision, if, in
6 fact, we determine that the brachytherapy approach
7 might be ideal for these patients, then our
8 orientation is guided by these fluorescein angiograms.
9 And they're determined by other factors, things like
10 lesion size, lesion safe, proximity to the optic
11 nerve, surrounding structures to there all play a
12 role, and there are other diagnostic evaluations that
13 may help us in guiding that therapy.

14 And here you see actually the device is
15 put into the eye, and it goes directly over the
16 lesion. And that's what's unique about this device,
17 it's placed directly over the lesion minimizing
18 collateral damage to the surrounding tissues. And
19 that's been the very difficult part in the past.

20 This is an animation of the NeoVista
21 procedure, and so what happens when we decide to do
22 this is, first of all, the patient is consented about
23 the risk of the procedures. And the biggest risk in
24 these patients is the risk of the surgical approach to
25 the delivery of the brachytherapy. It's not the

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1 brachytherapy itself, it's the surgical approach,
2 which has a complication rate of about 3-5 percent.

3 This is -- an angiogram is brought in with
4 us, and we use that to, again, reconfirm how we're
5 going to deliver the therapy. We administer it
6 through a surgical approach, which is the most common
7 surgery we all perform in retina surgery today, this
8 initial approach. The NeoVista device is then
9 introduced into the eye in the mid-vitreous position.
10 At that point, one of our assistants would come in and
11 transfer, or actually move the edge of the device, and
12 Bill has an example of it here, that would engage the
13 radiation while we're in the mid-vitreous cavity, so
14 we're holding the device, our assistant engages the
15 device, and then we place the device right down on the
16 eye. We then time the delivery of the device, which
17 is roughly in the four minute range, so the retina
18 specialist holds this actually touching a small part
19 of the retina for four minutes, keeping it stable
20 during the delivery of the device.

21 At the conclusion of the delivery, the
22 device is again lifted back into the mid-vitreous
23 cavity, and the system then retracts the device, or
24 retracts actually the radiation back up into the
25 handle, and the radiation source is then pulled back

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1 after the lever has been placed, and it's pulled out
2 of the eye. And then the eye is closed with sutures.

3 Here you see again the delivery of the
4 device positioned over the lesion. And one of the
5 true benefits of Strontium-90 in this case is the
6 rapid fall-off. So here we see the device being
7 delivered to an area of corneal vascularization, and
8 the fall-off is roughly 10 percent for every .1
9 millimeters when delivered from the point source. So
10 if we look at various regions, we're delivering 24
11 gray to the center of the lesion, the edge of the
12 lesion, again, that will be dependent upon the size of
13 the lesion, which can vary anywhere from less than a
14 millimeter to 7, 8, 10 millimeters in size.

15 We see delivery to the lens is far less
16 than 1 gray. Delivery to the optic nerve, again
17 dependent upon positioning, is roughly about 2.4 gray.
18 And here we see a threshold for clinically observable
19 damage. And, again, this is one of the beauties of
20 the delivery of this device. We see for corneal edema
21 it's 30 to 50 gray, and the dose delivered to the
22 cornea is extremely low. The conjunctiva shown here,
23 cataract, which was a significant complication of
24 previous deliveries were getting far less than the
25 dose that would cause a cataract, far less than the 2

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1 gray.

2 Radiation retinopathy is a significant
3 finding in previous cases. The threshold is somewhere
4 between 35-55 gray, and delivery of 24 gray, again, is
5 only to the point source, only to the source where
6 there's the neovascular membrane. And then one of the
7 most important complications in the past has been
8 optic neuropathy. And, again, we're delivering far
9 less than would be toxic to the optic nerve.

10 As a retina surgeon, I'm trained to handle
11 the radiation device in the eye. NeoVista procedure
12 has basic treatment planning requirements as it
13 pertains to the radiation dose, and to the delivery of
14 the dose. The placement and orientation of the device
15 is the only changing component of the procedure, and
16 it's very dependent upon the retina surgeon's
17 evaluation of the angiogram, the other testing, and
18 then his evaluation for the patient of how this should
19 be delivered. And considerations there in terms of
20 size and orientation also have to do with where you
21 want the tip of the device that's actually going to
22 touch the retina to go into position in the retina.
23 You'll do things to avoid the optic nerve,
24 vasculature, or other areas of the retina.

25 In the case of a device malfunction, we

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1 would withdraw the delivery dice from the eye, we
2 would move it immediately away from the eye. We would
3 place the cover back on the device. We would return
4 the device to the shielded box which it comes in, and
5 then have notification of the appropriate personnel.

6 It's my understanding that there were
7 concerns of the procedure from a meeting last year,
8 and as best as I can, from my appreciation of them,
9 I'd like to address those concerns. Here were the
10 concerns, used by ophthalmologists with little or no
11 radiation treatment, little or no radiation oncology
12 input, primitive dosimetry, and questions about
13 technology that may fade with inadequate multi-
14 disciplinary approaches.

15 With regards to the training, this
16 training is the training that was recommended for
17 Strontium-90 for the surface applicator, and I
18 underwent this same training with regards to delivery
19 of the NeoVista device. I had training both at
20 Harvard, in terms of radiation training, and then I've
21 actually -- this is a -- I've been involved in
22 previous radiation studies for macular degeneration,
23 and I had proctorship in those, and delivery of the
24 radiation training for that delivery. I feel that
25 that training was more than adequate for the delivery

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1 of what we're doing here. There are complications and
2 risks associated with this that all have been -- have
3 fallen under the concern of a retina specialist, and
4 all of the complications that we perceive with this
5 would fall under things that I would need to diagnose
6 as a retina specialist, and I would need to treat as
7 a retina specialist.

8 If we look at the input of radiation
9 oncology, Strontium-90 utilization in the NeoVista
10 device, the dosimetry, the determination of the
11 radiation is absolutely fixed here. The only
12 component that has any degree of change is the
13 delivery or the positioning of the device. This is
14 very unique from the other types of radiation
15 applications into the eye. The application of
16 radiation for tumors, for the oncologic applications
17 with the eye are extremely different. There's dosing
18 that has to be determined, there's placement that
19 requires very significant coordination.

20 In the previous radiation study I was in,
21 there was significant coordination that needed to go
22 on between the radiation oncologist and the retina
23 specialist. This is very unique, that all of the
24 components here need to be determined by the retina
25 specialist.

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1 With regards to dosimetry, again, the
2 dosimetry is fixed. That's determined. We actually
3 receive the dwell time periodically from NeoVista, but
4 that is fixed. It is the application of the device
5 that's critical here in the positioning.

6 Finally, with regards to technology that
7 may fade, the Strontium-90 has had very significant
8 success in the Phase II studies. It's now undergoing
9 enrollment in their Phase III studies, and that
10 enrollment is proceeding nicely. If the results of
11 the Phase III studies replicate the results of the
12 Phase II studies, there is no question that this would
13 have application to many patients with exudative
14 macular degeneration, and it's awaiting the results of
15 those Phase III studies that are critical. Right now,
16 there are patients being enrolled in 45 sites across
17 the country.

18 There are a couple of points that I feel
19 are important. The repetity of this disease onset, as
20 many of you know, this is not a disease that
21 progresses in a very slow manner. Usually, patients
22 will present overnight with loss of vision. They'll
23 come into the clinic having lost vision the previous
24 day. The need to deliver treatment to these patients
25 in a timely manner, that treatment often has to be

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1 delivered within days to certainly within a week to
2 allow the best outcomes. Across the board, it is felt
3 that the sooner treatment can be delivered, the more
4 likely you are to achieve good outcomes in these
5 patients.

6 In addition, the urgency with which we try
7 to schedule these, this is delivered in an operating
8 room. When we try to schedule these in the hospital
9 outpatient departments, you have far more rigid
10 requirements to get these scheduled. In our
11 ambulatory surgery center, we have far greater
12 flexibility to schedule these. And they're often
13 scheduled, for instance, if I have a patient today
14 that I see and determine they need this, I can often
15 get them on the schedule for the next day, or the day
16 after, with the caveat that there may be a block.
17 They may say you're probably going to go between 12
18 and 2. From the previous studies I was in, I
19 recognized that the ability to coordinate a retina
20 specialist, an OR, and a radiation oncologist in that
21 time frame was virtually impossible. And it was
22 actually the reason that I initially didn't do this
23 study, because I felt it wasn't doable. The ability
24 to do that in a timely manner is critical to the
25 success of these patients.

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1 If we look at why else these are best
2 suited for ASC as opposed to a hospital outpatient
3 department, again, the frequency of the cases, the
4 potential to see these regularly. I have a fairly
5 typical busy retina practice. I see 45-50 patients a
6 day, as is very typical for retina specialists, and of
7 these patients, 1 to 3 of them have newly diagnosed
8 wet macular degeneration. That means you are going to
9 be routinely trying to schedule these patients if, in
10 fact, you determine that this is the best treatment
11 for those patients.

12 The need for efficient operation is
13 critical. There is a significant push, trend, however
14 you want to look at it, of retina surgery moving to
15 the ASC because of advances in our technology,
16 advances in our ability to deliver treatment in the
17 ASCs, this enables more efficient treatment for these
18 patients. And in a treatment like this, that would be
19 absolutely critical.

20 Finally, I'd like to point out that prior
21 utilization of Strontium-90 applicators for the
22 treatment of -- post-treatment pterygium is something
23 that is not new. There have been a number of reviews
24 of large retrospective series of Strontium-90
25 delivered to post-ptyerygium treated patients, and all

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1 of the complications in these large reviews, all of
2 the complications have fallen into the purview of the
3 ophthalmologist. They've all been complications that
4 have been diagnosed, and then managed by the
5 ophthalmologist.

6 Here we see the extra vitreal Strontium-90
7 eye applicator, that which was used in the past for
8 the treatment of pterygia. And here is actually a
9 pterygia device that NeoVista is looking at that is
10 actually before the FDA right now.

11 Here you see the Strontium-90 applicators.
12 And, again, you'll notice that the dosimetry, the
13 delivery is very similar between the superficial
14 device and the intravitreal device. Again, the main
15 difference is, one is delivered externally, and is
16 always -- it's unshielded, essentially, and one is
17 delivered intraocularly where it's shielded until it's
18 opened. And, to me, that's actually a much safer
19 approach to it. It's shielded until I'm right where
20 I want to be. In the worst case scenario, it has the
21 same exposure as the surface delivery.

22 Finally, I'd like to point out that this
23 therapy is unique with regards to the interaction
24 between specialists in both ophthalmology and
25 radiation oncology. This application is very

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1 different than the application we've seen in other
2 diseases. Again, 100 percent of the planning in this
3 case is done by the retina specialist, and the
4 complications are those that are going to have to be
5 seen, diagnosed, and dealt with by the retina
6 specialist.

7 The safety of this device in terms of
8 surface delivery has been supported by 30 years of
9 work in thousands of patients. The only complications
10 have been ophthalmic, and they've been managed by the
11 ophthalmologist. The level of recommended training is
12 fully adequate to justify the use of this applicator
13 inside the eye, again, which by all accounts should be
14 safer than that delivery outside of the eye.

15 Finally, to end with this slide, which
16 just compares the characteristics of the surface
17 applicator and the intravitreal applicator, and they
18 are extremely similar. Dosimetry, delivery is the
19 same, positioning is the same other than one is on the
20 cornea, one is in the retina. The radiation
21 management component is the same, the recognition of
22 delivery and treatment by the eye care specialist is
23 the same.

24 I would like to respectfully request that
25 the Commission consider the training that is

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1 appropriate for the surface applicator be considered
2 appropriate for the delivery of the retinal therapy,
3 as well. Thank you for your time.

4 DR. VETTER: Thank you for a very succinct
5 and clear presentation. Are there questions from
6 members of the Committee? Yes, Dr. Nag.

7 DR. NAG: Thank you for an excellent
8 presentation, going into far greater detail than I had
9 done last year on the details of the technique. Have
10 you done the I-125 eye plat? Okay. There, again,
11 most of the things are very similar. You have a
12 radiation -- here is the Strontium leg in I-125 dose.
13 It's placed directly on, in your case, a lesion, in
14 the other case, a tumor. The application is a surface
15 application in both case, so why would you think that
16 in the NeoVista you would want a different set of
17 training requirements than you would for I-125
18 brachytherapy? Because they all have very, very
19 similar -- and I think you did reference the Finger
20 paper, and I know Paul Finger very well. I have
21 worked with him.

22 DR. HEIER: Yes, I was actually on the
23 phone with him yesterday about a patient. It's a good
24 question, but I think, in fact, they are different.
25 I think that the training that goes into positioning

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1 of plats, the complications of plats are certainly
2 more widespread than you see with this delivery. The
3 timing and the side -- the delivery of radiation to
4 the surrounding tissues is certainly different. In
5 fact, there is a complete separate fellowship for
6 treatment of tumors and delivery of that type of
7 therapy to those types of patients; whereas, when you
8 look at the delivery of this, say a surface applicator
9 in corneal disease, it's a much more basic delivery.
10 I think that the delivery to a point source, as we are
11 here, in that time frame is much less. You may be
12 delivering it to a certain area, but you're delivering
13 it outside the retina. You're not delivering it over
14 the retina. You're outside the sclera, and the amount
15 that you need to deliver outside the sclera to
16 actually treat retinal tissues and elevated tissues
17 underneath the retina is much greater, with much more
18 surrounding collateral damage, and a much higher
19 complication rate. So I think they are very
20 different.

21 DR. NAG: The other question, or other
22 comment I had is that, do you feel you have enough
23 knowledge of radiation effects, long-term effects, and
24 dosimetry? Because right now, you are correct that
25 you are having a single dosimetry. However, as we

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1 have seen with any other radiation modality, once you
2 go into more detail, you then have to modify your
3 dose, to be able to tailor your dose to the disease.
4 And do you feel you have enough knowledge of that to
5 be able to do all the fine tuning? So in the short
6 line, it might be easier for you, because you don't
7 have to wait and try to coordinate a multi-
8 disciplinary -- two people can go to the OR. But in
9 the long line, do you not think that you are damaging
10 a very useful treatment, because you won't have the
11 ability to do all the fine tuning and so forth that
12 you could once you have a radiation oncologist who
13 knows the details of what the effects of both the
14 dosimetry and the effects of the radiation are.

15 DR. HEIER: Well, I can't argue that I'm
16 nowhere near trained to the level of a radiation
17 oncologist for dosimetry. And, in fact, one of the
18 beauties of this technology is right now, it is a
19 fixed dosimetry delivered right over the lesion. And,
20 in fact, I would absolutely not have any role in
21 increasing the dosimetry there, or changing the
22 dosimetry.

23 It seems to me as if, if you are going to
24 have attempts at changing that dosimetry, that is a
25 site where you'd have interaction. But that's a whole

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1 different study from this approach. This study, and
2 this therapy, as it's being described right here is
3 absolutely fixed, as it was in the surface
4 application. And I think if you're talking about
5 modifying dosimetry, and changing dosimetry based on
6 lesion size, or other issues like that, you're talking
7 about a different therapy. So I wouldn't argue with
8 that, I would say that that's not an intention here.
9 And that certainly doesn't fall under the guidelines
10 of the training that I've had to-date.

11 DR. VETTER: I have a question, perhaps
12 for the NRC. Under 35.491, "Training for Ophthalmic
13 Use of Strontium-90", the first paragraph, "Except as
14 provided in 35.57, the licensee shall require the
15 authorized user of Strontium-90 for ophthalmic
16 radiotherapy to be a physician who", and then it goes
17 down and gives the training and so forth. So the
18 question I have relating to that first statement, an
19 authorized user of Strontium-90 for ophthalmic
20 radiotherapy, how is this application any different
21 from the surface applicator relative to this
22 requirement for training?

23 MR. LEWIS: Dr. Zelac.

24 DR. VETTER: Is there a difference?

25 DR. HOWE: We believe there is. We

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1 believe that the training that you get for the eye
2 applicator, the external eye applicator is not
3 sufficient to use this device. One of the proposed
4 changes we have in our user need memo is to retitle
5 35.491 to surface ophthalmic therapy. We think that
6 there are other things he has to know that if he was
7 doing the external he would not have to know.

8 DR. VETTER: Like what?

9 DR. HOWE: Well, for the external one, you
10 also are able to visualize, and many cases they use
11 treatment output to determine when to stop the
12 procedure. In other words, you may go back for
13 several fractions, because you're not getting the
14 treatment output. This appears to be a one shot, and
15 it's very high dose rate delivery. We think there are
16 significant differences between this.

17 DR. VETTER: Dr. Fisher.

18 DR. FISHER: A comment. However, there
19 are some simplicities involved here in the delivery of
20 radiation by virtue of using a beta emitter rather
21 than an Auger emitter. And, in fact, as Dr. Heier has
22 mentioned, the dosimetry is actually more simple,
23 owing to the constant source, and the distinct energy
24 range cutoff of these beta particles. It's very
25 predictable over a short range. And beyond a certain

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1 distance, the dose is essentially zero from this
2 source.

3 DR. VETTER: Dr. Welsh is next.

4 DR. WELSH: Just to start with a quick
5 editorial. There appears to be a disproportionate
6 number of medical events with the Strontium-90
7 ophthalmic applicator, so rather than lump this with
8 491, my reflexive answer, if that's what was being
9 proposed would be add it to 491 to make it safer.

10 But moving on to the other issues. I know
11 you said that only ophthalmic complications are seen,
12 but this is an eye treatment, so you wouldn't expect
13 anything other than ophthalmic complications, for the
14 most part. I think what you're implying is that there
15 are no radiation-related complications. Yet, scleral
16 malacia is seen there. Is the scleral malacia
17 believed to be physical, or is it possibly a
18 radiation-related effect, as an example of some of the
19 possible complications?

20 DR. HEIER: You're talking about the
21 surface application -

22 DR. WELSH: No, with this particular
23 treatment.

24 DR. HEIER: There has not been a case of
25 scleral malacia with this. So, currently, in the

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1 Phase I and II studies, there are I believe now over
2 100 patients treated. The only instance of any source
3 of retinopathy seen was in a patient with pre-existing
4 diabetic retinopathy, who actually should have been
5 excluded from the study, and it wasn't even felt that
6 was consistent with radiation retinopathy. And there
7 are patients who are out to I believe the three-year
8 time frame now. But even if you see radiation
9 retinopathy, which our belief is we're not going to
10 because of the delivery to the point source; even if
11 you do, you're still talking about a disease state
12 that in the majority of patients without treatment has
13 them legally blind within a year. And radiation
14 retinopathy actually today is best treated with anti-
15 VEGF agents, where the plan is to combine
16 brachytherapy with the anti-VEGF agents.

17 DR. WELSH: So it sounds like this is an
18 important treatment that needs to be made available
19 for those who need it, but you did say that one
20 complication was in a patient with diabetic
21 retinopathy, and maybe that patient shouldn't have
22 received the treatment. As a radiation specialist, I
23 would argue that when we have patients who need
24 treatment for their cancer, or a patient who needs
25 this treatment to prevent blindness, rather than

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1 withhold the treatment and let them die of the cancer,
2 or go blind, a dose adjustment might be appropriate.
3 And I would think that with clinical experience, this
4 24 gray to the center, and 6 gray to the periphery may
5 need adjustments; and, therefore, the one dose fits
6 all model may not hold up in the long run. Therefore,
7 radiation specialists might have more of a role than
8 you're initially proposing here.

9 DR. HEIER: They may not, but right now
10 the Phase III study is ongoing, so I think we -- it's
11 important to see those results. In the Phase II
12 study, the results were excellent. Now, as we've
13 seen, Phase II studies don't always replicate at Phase
14 III. That's certainly been the history of most
15 treatments. In fact, the anti-VEGF treatments are the
16 first Phase III results I've seen that have outdone
17 Phase II results, but I think you have to wait to see
18 that.

19 If the results in Phase II are replicated
20 in Phase III, this treatment would be delivered just
21 as it is right now. If those results are not
22 replicated, then it may turn out that this treatment
23 does require modification, and it may require more
24 input. But as it's designed right now, and as the
25 studies are going forward, and as the Phase III

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1 studies are going, this is the delivery.

2 DR. VETTER: Dr. Nag, and then Suleiman.
3 Dr. Suleiman.

4 DR. SULEIMAN: Medical applications, the
5 medical use are clear, to me. I mean, there are some
6 differences. That's going to be incorporated in the
7 training. It will come out in the trials, and so on.
8 I'm concerned about why does the training have to be
9 so different? Is the training, from a radiation
10 safety point of view, that it would warrant a
11 completely different set of training? In other words,
12 it's a beta emitter. It's slightly different than --
13 it is different than the other -- than the Strontium-
14 90 applicator, but why would we want -- this is my
15 argument I was making earlier. Do we have a subset of
16 specialized training? I mean, are the risks and the
17 needs to be addressed by the radiation safety
18 sufficient to be handled by the existing training?

19 DR. HEIER: Actually, I think, in fact,
20 it's very similar to the Strontium-90 surface
21 applicator.

22 DR. SULEIMAN: What I'm saying is, I don't
23 see why you'd need -- you could probably modify the
24 training so it would address both devices. But,
25 again, I'm trying to segregate the radiation safety

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1 application from the vendor's training that would be
2 applicable to the device itself.

3 DR. HEIER: And I want to be very clear.
4 These were all concerns that I had as we look forward
5 here. I'm a clinician. I see these patients all the
6 time, and I'm heavily involved in clinical research.
7 I want what's best for these patients. My initial
8 response when asked to look at this, because of my
9 involvement with previous radiation treatments was, I
10 didn't want to be involved. I didn't want to have to
11 deal with the safety issues. As I saw this, as I
12 spoke to other investigators, as I became involved in
13 it, and now as I've performed eight of these on
14 patients, I'm very comfortable with the safety issues
15 as it's delivered under these parameters, as it's
16 delivered this way.

17 DR. VETTER: Dr. Thomadsen.

18 DR. THOMADSEN: Are you proposing that you
19 would still have the same types of interactions with
20 the medical physicist?

21 DR. HEIER: We have had interactions.
22 They're the ones who helped to determine the
23 parameters going forward, and so I do think those are
24 important.

25 DR. THOMADSEN: Do they come to the

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1 operating room with you?

2 DR. HEIER: They do not. And I truly
3 don't mean this disrespectfully, what would their
4 interaction be in the OR?

5 DR. THOMADSEN: Either in case something
6 happens, as a radiation specialist, dealing with -

7 DR. HEIER: We have the radiation safety
8 officer there.

9 DR. THOMADSEN: Okay. You have the
10 radiation safety officer.

11 DR. HEIER: Absolutely.

12 DR. THOMADSEN: Well, they could do that,
13 too. Who deals with the checking of the device?

14 DR. HEIER: The radiation safety officer.

15 DR. THOMADSEN: So, in this case, the
16 radiation safety officer is acting sort of like a
17 medical physicist.

18 MR. HENDRICK: If I could make a comment
19 here. The issues that we, as a company, are trying to
20 deal with here, is that trying to keep the cost down.
21 As we all are aware, next year there are going to be
22 significant changes by CMS. The budget process and
23 how they deal with reimbursement of fees for different
24 particular practices we all know it's going to change.
25 And our particular procedure will probably start to

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1 move more towards an outpatient setting, much as ACS,
2 as Dr. Heier has. Currently today, the market is the
3 vast majority of these cases are done inside a
4 hospital, where a physician has his clinic outside.
5 He comes to the hospital. There's already a radiation
6 oncologist employed by the hospital, and that's all
7 worked out.

8 What we feel is going to happen, and this
9 is why this is extremely important to us to
10 understand, is that that is going to start to move
11 into ASC environment. And if we create a process that
12 is required more than what we're saying has already
13 originally been analyzed, and said this is the amount
14 of training required, that it's going to start to, and
15 it will affect the cost of this treatment being given
16 to patients. So when we looked at that whole process,
17 we're pretty confident, they are almost identical. In
18 fact, our particular procedure is even safer because
19 of a protective device that we have. And so, what has
20 come back recently, the guidance document that came
21 out, that put this into a new technology, basically
22 said you have to be a radiation oncologist now to do
23 the procedure. And I think that that is clearly not
24 warranted in this particular case.

25 DR. VETTER: Dr. Eggli.

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1 DR. EGGLI: I agree with the statement
2 made about where these procedures will be done. With
3 the exception of tumors, all of our eye surgery now is
4 done in the ambulatory surgery center environment. If
5 we make an assumption of fixed dosimetry, which is to
6 say that the time is not going to be varied, except as
7 adjusted for source strength by the manufacturer, this
8 looks like a very safe procedure from a radiation
9 safety point of view, where, in fact, the
10 complications are primarily related to the surgery,
11 not the application of radiation. If the device is
12 unable to deliver either excess or under-dose the
13 patient, unless you alter the time, then this looks
14 pretty straightforward from my simplistic point of
15 view.

16 DR. VETTER: Dr. Nag. I'm sorry. Dr.
17 Howe, and Zelac both had their hands up.

18 DR. ZELAC: Just for my own edification,
19 I have a couple of procedural questions that I'd like
20 to ask about what's actually done.

21 How do you actually place the tip of the
22 device onto the lesion? I mean, what guides you? Are
23 you simply looking through the eye?

24 DR. HEIER: So you're doing it through an
25 operating microscope. There is a point mark on the

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1 device which tells you what you treat as the point
2 source. That is actually held .1 millimeters above
3 the lesion. The device is angled in such a way that
4 the very tip rests on the retina. To put that in
5 perspective, the retina has the texture of wet toilet
6 paper, so the ability to tear the retina is extremely
7 high, which is why we say the training for this is
8 highly retinal in nature, and not something that from
9 a retina standpoint, you don't do without training.

10 DR. ZELAC: So the tip is actually making
11 contact with tissue, and that's when you know you're
12 in the right spot, as long as it's visually at the
13 right spot.

14 DR. HEIER: Right, so that it's not the
15 tip that you care about. That's where the analysis
16 comes ahead of time, making sure that you align it in
17 such a way that your entry point into the eye is such
18 that the tip can be placed where it's not endangering
19 important tissues, but the cross-hairs of the delivery
20 is right over the main component of the lesion.

21 DR. ZELAC: I have two more. Is there
22 time? The second question, with one entry, one
23 surgical entry of the device, can you treat multiple
24 lesions?

25 DR. HEIER: We never would. It's delivery

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1 of 24 gray to one lesion. So if you have a patient
2 who has -- first of all, you might have a patient that
3 has a large contiguous lesion, and that might be
4 something you're still ready to treat, but you would
5 not treat multiple lesions with this device. If you
6 have that type of patient, that's not a good candidate
7 for this therapy.

8 DR. ZELAC: And third and final question,
9 you mentioned in your presentation that the surgeon
10 needs to hold this device in position for four
11 minutes. That sounds challenging.

12 DR. HEIER: Not for an experienced retina
13 specialist.

14 DR. ZELAC: Okay. Thank you.

15 DR. VETTER: Dr. Thomadsen.

16 DR. THOMADSEN: Sort of following up on
17 one of his questions, one thing that concerns me about
18 this treatment when you were saying you just give a
19 fixed dose to -- fixed volume, et cetera, is similar
20 in ways to the beginning of intravascular
21 brachytherapy, which was driven by vascular
22 cardiologists as opposed to radiotherapists. Without
23 regard to the effect of the dose distribution, and the
24 attempt was being given to just have a single dose
25 regardless of the size of the lesion, and without

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1 paying attention to the penumbra of the beam. And
2 that accounted for many of the early failures.
3 Whereas, the experience when brought in from radiation
4 oncologists looked at the dose distribution compared
5 to the lesion to adjust the dose to fit the lesion, as
6 opposed to using one-size-fits-all. And I would think
7 that after the trial is over, you wouldn't want to
8 change this in the trial, it would probably be useful
9 to be able to go from this fixed dose, fixed volume
10 approach to one which would be customized to the
11 patient to the size and shape of the lesion, or
12 possibly number of lesions.

13 Similar arguments would hold for the
14 Itrium-90 microspheres, which is driven by
15 intravascular interventional radiologists; although,
16 I will say that they have a lot more training in
17 radiation, so they do have -- they fall not exactly
18 towards the extreme.

19 I would hate to, at this point before the
20 studies have come to their conclusion, and enough data
21 has been gathered with respect to size, shape,
22 positions of lesions, and the results of the therapy,
23 to cut out those people who are very experienced in
24 customizing radiation treatments to the patient.

25 MR. HENDRICK: If I could answer that. If

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1 there is going to be a change such as that in nature,
2 it would require that I would have to go back to the
3 FDA and start a whole new IDD application and PMA.
4 And if we were to have a product or a device that
5 would say, for some example, allow us to have
6 significant modifications, then, of course, at that
7 particular time, we're talking about a different
8 device. And we're talking about a device that has to
9 have significant treatment planning protocols. But
10 that's not the device that we have today, that's not
11 the device, if we get through this current trial, that
12 will have the labeling that will be very specific,
13 that will say that this device has only one type of
14 radiation -

15 DR. THOMADSEN: A question for Dr.
16 Suleiman, if I may.

17 DR. VETTER: Okay.

18 DR. THOMADSEN: A follow-up question on
19 that. Would this device, once it got through the
20 trials and approved, be something like intravascular,
21 which would not be allowed to be used off-label, or
22 would this be something that could be used off-label?

23 DR. SULEIMAN: When you do a trial, you
24 pretty much define what you're going to do. You go
25 through, and it's your final exam. It either passes

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1 or it fails based on your criteria.

2 DR. THOMADSEN: But afterwards, could a
3 physician -

4 DR. SULEIMAN: Off-label use?

5 DR. THOMADSEN: -- use it otherwise?

6 DR. SULEIMAN: Yes. That's an easy
7 answer.

8 DR. HEIER: If I may, I think, again,
9 that's an important concern. From a practical
10 standpoint, as a clinician, if that's what this
11 treatment comes to, and I have to coordinate treatment
12 patterns with a radiation oncologist, this isn't going
13 to be a practical application, because the need to
14 deliver this treatment quickly, coordinate the OR,
15 coordinate sitting with the radiation oncologist,
16 describing the lesion, going over -- I mean, we have
17 two-year fellowships to learn to read angiograms, and
18 OCTs, and how to determine what type of lesions they
19 are. If it's going to require that, from my
20 standpoint, that's not going to be a practical
21 application. It may be that you'll do another study
22 to find certain patients that it will, but you're not
23 going to be able to do that practically speaking.

24 DR. VETTER: Dr. Welsh.

25 DR. WELSH: So what Dr. Thomadsen was

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1 alluding to regarding the 24 gray to the center, 6
2 gray to the periphery, is a concept that we use
3 frequently in radiation medicine, which is GTV, Gross
4 Tumor Target, Gross Target Volume. The clinical
5 target volume where you might want to provide a
6 certain dose that would take care of anything that you
7 cannot visualize, or know for a fact is diseased. And
8 then, finally, the planning target volume, which is
9 the dosimetric margin, which accounts for the
10 penumbra. So in the clinical trial, what are the
11 parameters? Are you saying 24 gray to the center, and
12 6 gray to the visible edge, or is there a dosimetric
13 penumbra margin that is being accounted for, just for
14 our education.

15 DR. HEIER: So there are -- there is a
16 wide variety of lesion sizes that are eligible. There
17 is no small size that would make it ineligible. There
18 are large sizes that would make it ineligible. From
19 the standpoint of the trial, there's no
20 differentiation of those lesion sizes from the
21 smallest to the largest that's allowed. And the
22 delivery is based on the one fixed dosimetry. And the
23 trial, the Phase II trial results were excellent based
24 on this wide variety of lesions.

25 If you need to change that, I think you're

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1 looking at an -- if it turns out that, say for 40
2 percent of the lesions work really well, and you do a
3 sub-analysis, and you find that's the smaller lesions,
4 which I think you could certainly assume that would be
5 the case, 40 percent of the lesions working well with
6 this will not get this treatment passed, because right
7 now we can do that with our injections.

8 MR. HENDRICK: In our trial, though, we
9 only allow treatment up to 5-1/2 millimeters, and so
10 in our documentation, we will only have in our sheet
11 that goes along with the product the ability to say
12 you can treat up to 5-1/2 millimeters. That's the
13 cut-off range.

14 DR. WELSH: My question is not so much
15 about size per se, but minimum dose to the periphery
16 of the lesion. So if you say minimum dose to the
17 lesion periphery is 6 gray, you then say plus X number
18 of microns, millimeters to account for dose fall-off
19 to minimize dosimetric concerns.

20 MR. VERMEERE: Yes, I have developed
21 target dose volume histograms that take us out to 10
22 millimeters, so we've done that analysis.

23 DR. WELSH: And that's 6 gray to that -

24 MR. VERMEERE: No, 6 gray, the definition
25 is, John said is to 5.4 millimeter diameter. But I

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1 did the calculations both with Monte Carlo and
2 radiocarbon film, took that out, and then did the
3 calculations for the dose volume histograms, and we
4 ran those out to 10 millimeters, so we do have that
5 database.

6 DR. WELSH: So in the clinical trial, what
7 is the prescription?

8 MR. VERMEERE: It's 5.4 millimeter max
9 lesion.

10 DR. WELSH: You ascribe 24 gray to that.

11 MR. VERMEERE: To the centroid, yes.

12 DR. VETTER: Dr. Nag. I'm sorry.

13 DR. WELSH: If, in your analysis of the
14 trial, you get some disappointing results, surprising
15 results, it might be over-simplifying by saying that
16 it's due to the lesion size if the dosimetry to the
17 periphery of those lesions hasn't been fully worked
18 out in each and every case.

19 MR. VERMEERE: We've worked it. I'm
20 saying 5.4 millimeters, you are working at a 6 gray
21 level, and that's what we define as that outer
22 perimeter.

23 DR. VETTER: Dr. Nag.

24 DR. WELSH: It would just be sad to see if
25 it doesn't work because of something similar, but it

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1 sounds like you -- something simple, but it sounds
2 like you've put a lot of thought and effort into it.

3 DR. VETTER: Dr. Nag.

4 DR. NAG: Yes. A couple of points. Dr.
5 Heier, you said they're difficult to coordinate, and
6 you are not -- likely, you're not going to any of
7 these further if radiation oncologists are involved.
8 I have done not just -- you have done eight. I have
9 done several hundred of interocular procedures with
10 the I-125 plats with ophthalmologists. I don't claim
11 to have the expertise of the ophthalmologists, so I
12 let them do the dissection, and they don't claim to
13 have the expertise with the radiation that I have.
14 And they value my input tremendously. And it's
15 because of our close interaction that we have been
16 able to develop ocular brachytherapy to the level it
17 is now, where you are having over 90 percent control
18 rates. So that was one.

19 And you said it was hard to do it in the
20 outpatient setting. I have done these both in
21 hospital settings, and in outpatient settings, so
22 there is no reason why radiation oncologists cannot
23 come in the hospital setting, as well.

24 The third point I would like to make, that
25 radiation dosimetry, especially at close distance, you

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1 are distant in the order of millimeters, sub-
2 millimeters, the dosimetry changes so rapidly that
3 unless you have someone who knows all of the different
4 things about how the dose is spreading in the
5 longitudinal direction, the vertical direction and so
6 forth, you are not getting the full benefit of the
7 treatment. And I think for NeoVista, I would like to
8 say I think you are being short-sighted, that you have
9 the convenience of having this time over it, and
10 having a higher turn over basin, you are more likely
11 to fill the procedure because if a certain dose is not
12 effective, you don't know what is the reason, was it
13 because of placement it retained, or the angle it
14 retained, or the distance it retained, or whether you
15 needed to have multiple applications. All of these,
16 you are going to lose all of this, and in the long run
17 you are going to be shooting yourself in the foot.

18 DR. HEIER: I think if it comes to that,
19 and if it turns out that the study shows that we need
20 that degree of coordination, it may be that that's
21 something that has to be looked at. The large
22 majority of retina specialists in this country will be
23 unable to deliver it in that manner. And I'm speaking
24 solely from a practical application. From the
25 previous study where we had people very gung ho about

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1 looking at that study, could never coordinate all of
2 those schedules within a week, and that was in the
3 hospital setting. In an ambulatory surgery center,
4 which are often separate from the hospitals, I would
5 be surprised if a radiation oncologist is going to be
6 willing to take a two or three hour gap out of his
7 day, because that will be the time frame there, come
8 over, wait in the ambulatory surgery setting for what
9 is going to be a five-minute application of radiation,
10 and take that time and arrange that in a couple of
11 days span. So if this requires the degree of
12 collaboration that you are discussing, and I
13 understand. I'm waiting to see the results of the
14 study. If it does, you may be absolutely right, and
15 I fully recognize that that may be the case. The
16 results of the Phase II have given us hope that for
17 the majority of patients, delivery of these exact
18 parameters will work. And if they do, this is
19 something that we'll be able to practically offer to
20 a number of our patients. If they don't, I think
21 you're looking at a whole different paradigm, and that
22 will need to be worked out. And it will certainly be
23 different than what's been proposed today.

24 DR. VETTER: Dr. Howe.

25 DR. HOWE: I think one issue that hasn't

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1 really been addressed yet is the fact that it's very
2 difficult to measure the activity in the dose from the
3 source in an accurate method. And one difference
4 between this device and the eye applicators that we
5 see for the external eye, is that the authorized user
6 for the external eye applicator has an eye applicator,
7 uses it to a medical endpoint, and continuously uses
8 that applicator. So once they're familiar with it,
9 they don't change eye applicators.

10 This particular device gets changed out at
11 a routine frequency, and so your experience with it -
12 first of all, the dose is not as accurate as being
13 said, so you have a potential for one coming in at a
14 high dose level, the next one that you get comes in at
15 a low dose level, a lower dose level, so there really
16 is a big range here.

17 MR. VERMEERE: Excuse me. Let me speak to
18 that, if I could, please. We have a clinical device
19 that we've designed for the clinical study, and we've
20 made sets that are at 45 different institutions around
21 the world. Every set will be there for the full
22 period of the study. Every device has been analyzed.
23 Chris Kasors and I have been working dosimetry. Chris
24 has created the standards for us. Also, DNK in
25 Germany has made their standards, and we've cross-

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1 referenced to that. Everything has been done with
2 radiocarbon film, everything is done with Monte Carlo
3 coding, making sure that all the dosimetry is
4 accurate. We go through and do every six months an
5 update in the decay function, so we give them an
6 accurate time. They get two sources at each location
7 in case they drop one. As you'll notice, that little
8 20-gauge needle is fairly fragile, to push on it might
9 break off, but each pair is matched, and so there's no
10 change-out, there's no routine change. The decay of
11 the Strontium is 1 percent every five months. We do
12 a six months correction just to make sure we're
13 staying accurate, so those aren't quite right.

14 DR. HOWE: I think what I'm saying is that
15 during your clinical trial, yes, you have that
16 control. When your clinical -- but we have to
17 regulate for the long run. And in the long run, once
18 you're beyond the clinical trial, just as Dr. Welsh is
19 alluding to, and Dr. Nag is alluding to, you're going
20 to be seeing different patients coming through that
21 you'll want to treat. Then you're going to have your
22 change-out of sources. You're not going to have the
23 matched sources each time, so you're going to have
24 more variability. And that's all I'm bringing in is
25 the -

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1 MR. HENDRICK: Let me answer that for a
2 second, Ma'am.

3 DR. HOWE: And I know you have the
4 precision that you're trying to get, and you have the
5 best you can for what's available.

6 MR. HENDRICK: One of the ways that we
7 control this specific thing is that these devices are
8 never sold. The reusable portions are in control of
9 the company forever. We do not allow a hospital to
10 buy them. And the reason for that is specifically
11 that, is that we keep absolute control of the
12 dosimetry that is out there in the devices, so there
13 can't be any of that kind of issue, where a device
14 might go someplace else, or they start to use it, and
15 they don't do the proper validation of the device
16 after a year. And the devices that we send out, we
17 always make sure that they are within a couple of
18 seconds of each other at each site, so there isn't a
19 significant difference there.

20 DR. HOWE: So you're matching the sources
21 for the site.

22 MR. HENDRICK: Absolutely. Absolutely.

23 DR. VETTER: Dr. Suleiman.

24 DR. SULEIMAN: Just to clarify, I think
25 some of the suggestions you've heard from the

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1 Committee probably are valuable, but your trial has
2 already been launched. And it's obvious to me that
3 you seem to know what you're doing, so you've put all
4 your eggs into this basket, and let the trial finish.
5 And it may succeed, it may not. That, I don't think,
6 is the issue here, necessarily. I think the issue here
7 is the training that's appropriate for the Strontium-
8 90 applicators, sufficient to address the radiation
9 safety issues that you would want for your device.

10 The off-label question, just to clarify,
11 when FDA approves a medical product, it allows it to
12 enter commerce. It's been shown to be safe and
13 efficacious according to some standards depending on
14 our various regulatory authorities. After that, how
15 it's used in the field of medicine, it can be used for
16 other indications. That's a different issue. But a
17 lot of the scientific points you're making I think are
18 valid, and would be useful to you, but I think at this
19 point isn't really relevant to this discussion.

20 DR. VETTER: Dr. Eggli.

21 DR. EGGLI: I would like to ask another
22 irrelevant question then. I don't remember hearing
23 what you said about the number of patients in your
24 Phase II trial, and your success rate in your Phase II
25 trial.

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1 DR. HEIER: There has been a Phase I and
2 Phase II. The Phase I was NeoVista device only. The
3 Phase II was in combination with anti-VEGF therapy.
4 In that study, there were 34 patients, and we've got
5 18-month follow-up on them. And the most interesting
6 part about that is, what we're looking at is overall
7 success rate. The success of that has been comparable
8 to what we saw with the anti-VEGF patients who were
9 delivered monthly therapy for a year in terms of
10 significant visual gain.

11 DR. EGGLI: That's approximately?

12 DR. HEIER: Right. Because you can't
13 compare the -

14 DR. EGGLI: What's the number that goes
15 with that roughly?

16 DR. HEIER: Thirty-four. Oh, no, 30 to 40
17 percent.

18 DR. EGGLI: Okay. The 30 to 40 percent
19 that you see here.

20 DR. HEIER: A three-line gain.

21 DR. EGGLI: Okay.

22 DR. HEIER: More important is that roughly
23 70 percent of patients at 18 months had not required
24 further therapy.

25 DR. EGGLI: There was no progression of

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1 the lesions.

2 DR. HEIER: Not only no progression, but
3 stabilization and in case improvement where fluid
4 dried up. If that's replicated in the Phase III, and
5 the Phase III study is going to be 450 patients.
6 That's a large study, 450 patients, 300 in the
7 treatment arm, 150 in the Lucentis arm. It's being
8 compared to standard of care, Lucentis.

9 DR. VETTER: Dr. Thomadsen.

10 DR. THOMADSEN: One thing that hasn't been
11 said here is that the authorized user, as far as
12 coordinating, the radiation oncologist doesn't have to
13 be in the operating room. This has come out in the
14 other Part 1000 treatments that we've been discussing,
15 so the coordinating doesn't have to involve having a
16 radiation oncologist in the operating room. But it is
17 involved -- so then, again, I'm not sure what -- as
18 it's designed here, I'm not sure what the coordination
19 is. There's a fixed dose delivery. The positioning
20 is determined solely by the retina specialist, as you
21 suggest. If we require that modification of
22 dosimetry, that's going to require coordination, but
23 that's going to be an entirely different study, an
24 entirely different approach.

25 DR. THOMADSEN: Right. But right now, if

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1 you were to change anything about your study, like the
2 use of a radiation oncologist, that's a different
3 study, too. You really can't change that in mid-
4 study.

5 DR. HEIER: What would -- and I'm truly
6 not trying to be difficult on this, but what would
7 that gain the patients?

8 DR. THOMADSEN: At the moment, only
9 finishing your study. As you've described, I'm not
10 disinclined to say that there is really no role of the
11 radiation oncologist to be the authorized user. I
12 don't think we're quite ready to decide that yet. I
13 think you need to analyze in your study what has
14 happened to the patients, what might be a variable
15 that could be changed, and what the future is going to
16 look like. The future may or may not look like
17 exactly your trial, and as such, I don't know that we
18 can say, but in the middle of your trial, you can't
19 stop and say these patients have had the involvement
20 of radiation oncologists suddenly, these patients
21 don't. I don't think you can. That would have to be
22 an amendment to your trial.

23 MR. HENDRICK: Currently, there is no
24 requirement in the trial -

25 DR. THOMADSEN: For a radiation

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1 oncologist?

2 MR. HENDRICK: For a radiation oncologist.

3 DR. THOMADSEN: You need an authorized
4 user. Correct?

5 MR. HENDRICK: Yes.

6 DR. THOMADSEN: So you've had an
7 involvement of a radiation oncologist so far.

8 MR. HENDRICK: We were following the laws
9 of the NRC, or the regulations of the NRC, in which
10 the NRC -

11 DR. THOMADSEN: That is correct.

12 MR. HENDRICK: -- at that point in time,
13 we said that we're an optical applicator, and they
14 said yes, you're an optical applicator. That's how
15 Dr. Heier was able to fall into that realm. And so,
16 we have hospitals where they have radiation
17 oncologists, sometimes they are, sometimes they're
18 not. In his particular case, he has his radiation
19 safety officer there, so we have kind of a lot of
20 combinations.

21 And what I want to emphasize is, I don't
22 want to change any of the regulations. I just want to
23 make sure that we're in the right regulation, so that
24 we aren't impacting the fact of -- as CMS was talking
25 to me two weeks ago, it is clear, in my industry, in

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1 our industry, we have to -- we must develop products,
2 but also reduce the cost. That must happen, and it's
3 going to force us into that scenario if we choose, if
4 we choose to ignore it, those companies won't exist.
5 And so, what we're trying to do here, and that was the
6 whole purpose of trying to focus in on what could give
7 us the highest probability, that could also minimize
8 the cost, but give us the best clinical output. And
9 yes, if something comes along in the trial that says
10 maybe we should do something different. Certainly, as
11 a company, we would probably look at that. But,
12 again, we still have to focus on the fact, is that I
13 have to deliver to your families, and to the
14 hospitals, and to the patients a treatment that is
15 going to be cost-effective, but that is also
16 clinically significant. And if we don't allow an ASC
17 environment to operate, and also like a hospital or
18 university to operate, and we start to enforce other
19 restrictions on it, it will start to impact the
20 patients.

21 DR. VETTER: Mr. Lieto.

22 MR. LIETO: A quick question. How much
23 activity is roughly in one of the devices,
24 millicuries?

25 MR. VERMEERE: The nominal activity is 555

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1 mega becquerel, which translates to about 11.1
2 millicuries for reality. It would be 15 millicuries
3 at 555, and right now with the chemistry we're at
4 11.1.

5 MR. LIETO: And each site has two of
6 these. Correct?

7 MR. VERMEERE: That's correct.

8 MR. LIETO: How many sites in the U.S. are
9 you expecting to use this in your Phase III? Because
10 you say 45 globally -

11 MR. HENDRICK: Thirty.

12 MR. LIETO: Thirty in the U.S.

13 MR. HENDRICK: Thirty sites now have the
14 device.

15 DR. VETTER: Dr. Eggli.

16 DR. EGGLI: It seems to me that this
17 device is designed to deliver the therapy one way,
18 and one way only. And that modification of the
19 therapy would require modification of the device, with
20 the exception of, you can't move it around because of
21 the approach to the eye. All you can do is change the
22 time that you expose the retina to with this device.

23 DR. THOMADSEN: Not so.

24 DR. EGGLI: You can't -- we've already
25 heard him say you can't move it around.

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1 DR. THOMADSEN: You can. You can position
2 it differently. They have to be able to position it
3 differently to hit the target.

4 DR. HEIER: You can position it
5 differently, but how would that change -- the decision
6 for positioning is based on the lesion
7 characteristics.

8 DR. THOMADSEN: And that's exactly the
9 point, that if the lesion were elongated, or if it
10 were circular, just like with the pterygium, you may
11 have a different treatment pattern.

12 DR. EGGLI: But how is the presence of a
13 radiation oncologist going to change that?

14 DR. THOMADSEN: In the planning of where
15 the device would be to cover the target.

16 DR. HEIER: I don't think so. That I
17 truly do not believe.

18 DR. THOMADSEN: That's what we do.

19 DR. VETTER: So in an elongated lesion,
20 how would you do the treatment?

21 DR. HEIER: You would try to place it in
22 the borders of that elongated lesion, but your going
23 to have other parameters which are going to guide
24 that. So we always look at that. We always look at
25 the characteristics of the lesion, and try to base the

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1 device based upon that. But we're guided by other
2 things, we're guided by entry into the eye, we're
3 guided by vessels, we're guided by the nerves, so
4 that's something -- that's what we've been looking at
5 for years in terms of our fellowship with angiograms.
6 That's what we train our fellows to do, and so it's
7 how we look at laser application, it's how we look at
8 photodynamic therapy applications, it's how we look at
9 other approaches to the eye.

10 And, again, I truly am not trying to be --
11 I recognize the value of radiation physicists, and
12 oncologists, and if this has to be modified, they're
13 going to play an instrumental role, and it's going to
14 completely change the dynamics of this procedure, from
15 my standpoint. I can apply it when it's delivered
16 like this. And if it turns out that the parameters
17 you're talking about are important, those are going to
18 become manifest in the outcomes of the trial. And if
19 the trial shows success, as it did in Phase II, then
20 the means we're applying it are fitting these
21 dynamics.

22 DR. VETTER: Dr. Nag.

23 DR. NAG: From what I'm hearing, I think
24 if you are using this tool more like a laser, you
25 apply on the surface, you burn it, and that's all you

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1 are doing, then you are using it more or less blindly.
2 Whereas, if you are going to be able to modify it, and
3 you are able to sculpt it, then you would need to know
4 more details about not only the isodoses, but also the
5 details of what happened at the sub-millimeter level,
6 so it depends. I think right now if you are -- are
7 you trying to use it just like a laser, a burning
8 tool, or more like a radiation device that can be
9 modulated? If you need the modulation portion, then
10 I think having it in the hands of an ophthalmologist
11 may not be to the best advantage to the company.

12 DR. HEIER: Then that will be manifest in
13 the outcomes of the trial.

14 DR. SULEIMAN: I think it's more the form.
15 I don't think -

16 MR. VERMEERE: There is no intent to
17 modulate the beam, shape the beam, or use IMRT, but
18 it's placed in a single location, there's a single
19 field, calculate the field dynamics which is going to
20 be X dimension at 2.5 millimeters from the surface,
21 and get a set field, and those values are all
22 calculated.

23 DR. NAG: That's why I'm saying, I think
24 you are being short-sighted, and you are using a
25 highly advanced tool in a very simplistic way, and you

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1 are sort of hindering the growth potential of this
2 device.

3 MR. VERMEERE: Right now, we try to use
4 the device under the 491 clause as a surface
5 applicator, which restricts us from doing a lot of
6 other things. And we felt this is the level that we
7 need it from the early Phase I, Phase II study. We
8 got the results that we were hoping for, and the Phase
9 III will confirm those results, using a simple field
10 as we've defined, and providing us 24 gray centroid
11 value.

12 DR. VETTER: Mr. Mattmuller.

13 MR. MATTMULLER: It seems like a lot of
14 this discussion has been based on how they can improve
15 their product, or its use, and I don't know if that's
16 appropriate. I'm thinking we ought to be focusing on
17 what they're proposing is safe, and the training
18 they're proposing that the ophthalmologist has is
19 adequate for the use of this device.

20 DR. VETTER: Dr. Fisher.

21 DR. FISHER: I agree. Just to finish
22 Steve's thought. He reminded me earlier how important
23 this is from a patient perspective. And I think we
24 need to consider that first and foremost. If this is
25 a successful, workable solution, then that should take

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1 some priority. And, again, as my role as patient
2 rights advocate, I may need this device some day. And
3 my father needed it at one time, and it wasn't
4 available, and he's blind as a result, with this
5 disease. I think that's what's important here. We
6 need to keep that in mind.

7 DR. VETTER: Any other questions or
8 comments? Dr. Eggli.

9 DR. EGGLI: I would like to second what
10 Steve and Darrell just said. We're not here to help
11 the company design a product. We're here to determine
12 whether the product as presented can be used safely
13 from a radiation safety point of view. And I think,
14 to me, the answer to that, again, from a very
15 simplistic point of view, is already obvious.

16 DR. VETTER: So the question really before
17 us is, do we, as a Committee, feel that the training
18 as specified in 35.491 is adequate for use of this
19 device. Dr. Eggli.

20 DR. EGGLI: I would like to move that the
21 as providing in 491 is adequate for the use of this
22 device.

23 DR. VETTER: Is there a second?

24 DR. FISHER: Second.

25 DR. VETTER: Dr. Fisher seconds. Further

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1 discussion? Dr. Howe.

2 DR. HOWE: Dr. Vetter, if you make that
3 statement flat out, then that means anyone using the
4 external eye applicator is now good to go with this
5 eye applicator. And I think there are differences
6 between the external applicator and the internal that
7 you may want to apply the same topics, but you want to
8 make the topics specific to the device.

9 DR. VETTER: 491 does not talk
10 specifically about the external applicator, or
11 internal applicator, or anything. It talks about -

12 DR. HOWE: But what you're saying is that
13 once a person has authorization for 491, and we have
14 a number of people out there with 491 with the
15 external applicator, those people now can use this
16 device without any additional training. I don't think
17 that's your intent. I think your intent is to have
18 maybe the same level of training with the same topics
19 that are focused on this device and its use.

20 DR. EGGLI: I would like to modify my
21 motion to include with specific device-appropriate
22 training.

23 DR. VETTER: Is that -

24 DR. FISHER: Yes.

25 DR. VETTER: Okay. So motion now reads -

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1 can you review that for us, again?

2 DR. FISHER: That 491 is an appropriate
3 training requirement for the use of the NeoVista
4 Strontium-90 device, accompanied by appropriate device
5 -specific training.

6 DR. VETTER: Dr. Nag.

7 DR. NAG: You were mentioning that 491
8 does not mention superficial and deep, because at the
9 time when that was written, there was no deep device.
10 And, in fact, it is now in the rulemaking that these
11 are going to be separated, and this would now be
12 called - 491 would be called for superficial
13 ophthalmic use, so 491 will be superficial ophthalmic
14 application.

15 DR. EGGLI: That actually doesn't have to
16 happen. And that's what we're talking about right
17 here, right now, is that doesn't have to happen. 491
18 does not have to be changed.

19 DR. VETTER: Mr. Lieto.

20 MS. GILLEY: Was there a second? I'm
21 sorry.

22 MR. MATTMULLER: There was.

23 MS. GILLEY: Okay.

24 MR. LIETO: Do we need to be concerned in
25 terms of who the team -- terms of who is going to be

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1 the authorized users for this? I mean, I guess what
2 I'm kind of looking at, does this need to kind of -- I
3 know I'm going to hate for saying this, moving this
4 into 1000 to specify that there are certain authorized
5 user credentials to be -- well, I guess what I'm
6 trying to think about is, it would be like -- I'm
7 looking at Dr. Heier's credentials, and I'm thinking
8 could some optometrist or somebody come in with an
9 authorized user credential, in terms of wanting to
10 use, because we're looking a lot at the situation I
11 think that you're talking about, of doing this in an
12 ambulatory setting.

13 DR. EGGLI: There has to be a retinal
14 surgeon.

15 DR. HEIER: Yes. So there are credentials
16 already to get credential to do retinal surgery that
17 require a certain level of training, which is a
18 minimum of a one-year fellowship, most require a two-
19 year vitreoretinal fellowship, so the requirements to
20 do those, to be able to deal with the complications of
21 this are extensive.

22 DR. VETTER: Dr. Nag.

23 DR. NAG: No.

24 DR. VETTER: Dr. Zelac.

25 DR. ZELAC: Kind of a question I'm just

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1 putting out to the floor. If the retinal surgeon is
2 the authorized user, who's the radiation safety
3 officer?

4 DR. HOWE: It would be the same person.

5 DR. ZELAC: I understand that. We're
6 talking about this 10 or 15 millicurie Strontium
7 source in a rather delicate needle. There is the
8 possibility, if not the likelihood, that this is going
9 to break off at some facility, so my question is,
10 who's the radiation safety officer?

11 MR. VERMEERE: Every facility that we
12 currently use has a staff medical physicist, such as
13 Dr. Thomadsen or Dr. Vetter, or has a RSO, somebody
14 who has been recognized by the Nuclear Regulatory
15 Commission or an agreement state. Some of us are
16 professors in radiology, some of us are medical
17 physicists and board certified, but there is a class
18 of people who have been recognized, either through the
19 American Health Physicists Society, or the AAPM, or
20 the NRC by grandfathering, or the states by
21 grandfathering. So those people will be involved.
22 You've even stated such in your initial guidance
23 document, that either an oncologist or a medical
24 physicist, or radiation safety officer will be there.
25 And we would expect that the support team would always

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1 require to have such trained individual along with the
2 authorized user if it's a retinal surgeon.

3 DR. VETTER: Mr. Lewis.

4 MR. LEWIS: Dr. Vetter, given the motion
5 on the table, and recognizing some of the comments of
6 Dr. Thomadsen and Dr. Welsh before he left, about the
7 different techniques that might be used for different
8 shaped or sized lesions, wouldn't the -- and I'm not
9 well-informed, so I guess my question is, is the
10 Committee really in a position to judge the radiation
11 safety before the results of the trial? I recognize
12 the radiation safety issue of the users may not be an
13 issue, but there is also the radiation safety issues
14 of the patient.

15 DR. VETTER: Dr. Eggli.

16 DR. EGGLI: I think the Phase II study
17 with 18 months of follow-up provides that level of
18 reassurance. And, again, we're not talking about what
19 Dr. Welsh was talking about, which is modifying or
20 modulating the therapy. We're talking about a very
21 rigidly constructed therapy. And I think 34 patients
22 with 18 months of follow-up, given the time course of
23 typical radiation complications, is adequate to
24 demonstrate the safety from a patient use point of
25 view.

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1 DR. VETTER: Dr. Nag.

2 DR. NAG: Yes. A couple of points. I
3 think -- in fact, I know the new ophthalmic applicator
4 under 35.1000. Am I right?

5 DR. HOWE: Yes, it is. It's under
6 35.1000.

7 DR. NAG: Therefore, you would now move it
8 to 35.491? Is that -

9 DR. EGGLI: I think the motion says that
10 the training as prescribed is appropriate training.
11 It doesn't say to move the device from Part 1000 to
12 Part 400. But what it's saying is that as you develop
13 training requirements, if you leave it in 1000, then
14 these are adequate training and experience
15 requirements.

16 DR. VETTER: Dr. Thomadsen.

17 DR. THOMADSEN: One of the issues that's
18 coming up, which may be that's subtle on this, is
19 administratively, once the person is an authorized
20 user, at the moment, they can't not be allowed to be
21 radiation safety officer. That's adequate, if they're
22 listed on there. So if you have a clinic, an
23 outpatient clinic somewhere that's open, that the
24 ophthalmologist is the authorized user, they can also
25 then designate that they are the radiation safety

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1 officer, even though they do not have the training
2 that most radiation safety officers would have.

3 MR. VERMEERE: That's not quite right,
4 because you and I both know that the radiation safety
5 officer position has to be a recognized position. To
6 get yourself written onto that line 12 of the license,
7 normally there's a recognition either by training,
8 past experience, or meeting the obligations of the
9 various radiation safety -

10 DR. THOMADSEN: Or by being listed on the
11 license as the authorized user. Is that correct?
12 Once you're on, you're on.

13 DR. HOWE: Yes. Once you're recognized as
14 an authorized user, you're eligible to be a radiation
15 safety officer for the same types of uses.

16 DR. VETTER: If someone signs the
17 preceptor statement.

18 DR. HOWE: The preceptor statement, yes.

19 DR. VETTER: And right now, that might be
20 difficult.

21 DR. EGGLI: Identifying the training
22 requirements for an authorized user, leaving the
23 device in Part 1000 does not exclude the requirement
24 of the presence of a radiation safety officer, or
25 someone who provides that functionality. All we're

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1 talking about are what the training requirements for
2 an authorized user, so I have no problem leaving this
3 in Part 1000, saying for the time being it requires a
4 radiation safety type skill present. But what we're
5 talking about is defining the training and experience
6 requirements for an authorized user as that will be
7 constructed within the confines of Part 1000.

8 MR. VERMEERE: And I think we totally
9 agree with you.

10 DR. HEIER: I have no desire to be a
11 radiation safety officer.

12 DR. VETTER: Ashley, did you happen to
13 capture that motion? Oh, you didn't. The earlier one
14 by Dr. Eggli.

15 MS. TULL: Oh. I have 491 is an
16 appropriate training requirement for the use of the
17 NeoVista Strontium-90 device, if accompanied by
18 appropriate device-specific training.

19 DR. VETTER: Okay. That's the motion
20 before us.

21 MS. TULL: Yes.

22 DR. VETTER: Any further discussion? Dr.
23 Nag.

24 DR. NAG: Now, you are saying that you are
25 having a radiation safety officer when you are doing

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1 your treatments. And at the same time you are saying
2 that you would not be able to get a radiation oncology
3 back-up person. Now, how is it your are able to get
4 the radiation safety officer in the outpatient
5 setting, but not the radiation oncologist?

6 DR. HEIER: They're cheaper, and more
7 plentiful. They're readily available to whenever we
8 say.

9 MS. GILLEY: They have patients that
10 they're seeing every hour, every half hour, like a
11 radiation oncologist is.

12 DR. HEIER: And think that's infinitely
13 easier.

14 DR. VETTER: Okay. Are you ready for the
15 question?

16 (Chorus of yeses.)

17 DR. VETTER: All those in favor of the
18 motion, please raise one of your hands. One, two,
19 three, four, five, six, seven. Opposed, raise your
20 hand. One opposed. And abstentions? Two
21 abstentions. And we're down one number because Dr.
22 Welsh has left, so the motion passes.

23 Dr. Heier, recognize please that we are
24 advisory, so we simply pass the motion advising the
25 NRC that we would recognize the training as

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1 equivalent, basically, but device-specific, so that
2 doesn't necessarily change anything. It's advice that
3 we are providing to the Agency. Dr. Thomadsen.

4 DR. THOMADSEN: I just wanted to explain,
5 I'm not adverse to the change at all. I just think
6 it's a little premature to make this decision. That's
7 all.

8 MS. GILLEY: One more question. I think
9 there's some guidance document that came out on this.
10 Will that be reconsidered?

11 MS. FLANNERY: Yes, the guidance is
12 published and posted on the website, so what happens
13 in a case like this is we take ACMUI's recommendation
14 and make a decision whether we want to change the
15 guidance, and consider it under 491. So a decision
16 will have to be made on that.

17 DR. VETTER: Ms. Flannery wanted to make
18 a statement before we go on break. Is it related to
19 this subject?

20 MS. FLANNERY: No.

21 DR. VETTER: Okay.

22 MS. FLANNERY: So I'd rather just wait
23 until this discussion is closed.

24 DR. VETTER: Yes. Dr. Howe.

25 DR. HOWE: This is Dr. Howe. I'd just

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1 like a clarification. In 35.491, it is a physician
2 who. Is your recommendation to be any physician who,
3 or are you thinking in terms of a -- not an
4 ophthalmologist, but a retinal surgeon?

5 DR. EGGLI: I guess, if I might speak to
6 that.

7 DR. HOWE: Is that too prescriptive?

8 DR. EGGLI: It is -- no, I think that's
9 presumptive, because in any institution you're not
10 going to get the credentials to open up an eye and get
11 down to the level of the retina unless you can prove
12 that you have the credentials to be a retinal surgeon.
13 So I don't think there's any risk that me, as a
14 diagnostic nuclear medicine physician, is going to go
15 to the OR and open up an eye, and try to stick a
16 device down to the retina. So that I don't -- in any
17 one institution, you have to be credentialed to do
18 retinal surgery.

19 DR. THOMADSEN: Would that be true in a
20 freestanding office?

21 DR. EGGLI: If you don't want to spend the
22 rest of your life broke from the first malpractice
23 suit.

24 DR. THOMADSEN: Well, we never let tort be
25 the defining -

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1 DR. EGGLI: And I understand. I don't
2 know the answer to that question, but if the
3 freestanding clinic is associated with any kind of an
4 institution, then there would be a credentialing
5 process. I would assume that the American Board of
6 Ophthalmology has guidelines as to who can and who
7 cannot perform retinal surgery. Is that correct?

8 DR. HEIER: Every surgery center that I've
9 ever -- every accredited surgery center, and that's
10 all we can attest to, are accredited surgery centers,
11 every accredited surgery center I've ever been aware
12 with, has very specific requirements as to the
13 training that you go under before you can do any
14 retinal procedure.

15 DR. THOMADSEN: What is your reticence to
16 including those qualifications in the motion?

17 DR. EGGLI: I'm not reticent to include
18 those qualifications. At this point, since the motion
19 passed, we would have to do an amendment, and I'm
20 happy to do that. I'm happy to amend my prior motion
21 to say that the authorized individual must be a
22 qualified retinal surgeon. I'm happy to add that
23 modifier to that.

24 DR. VETTER: So that's -- we'll take it as
25 a new motion then.

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1 DR. EGGLI: All right.

2 DR. VETTER: Dr. Nag.

3 DR. NAG: Yes, I think we are going to
4 relish the principle. We haven't reviewed the entire
5 491 to see what other unforeseen consequences we are
6 going to land into. I think it would be wise of the
7 Committee to look over -- to table this for the time
8 being, look over the entire section.

9 DR. EGGLI: It's already passed.

10 DR. THOMADSEN: Except for defining what
11 physician would qualify.

12 DR. VETTER: You're going to make it more
13 restrictive. Ms. Gilley.

14 MS. GILLEY: I simply want to ask a
15 question of NRC. How many licenses do you have out
16 there for ophthalmologists that only do 491? If I
17 have five out of 1,700 I would be surprised, and none
18 of them are general practitioners. They're all people
19 with board certification in ophthalmology, so I wonder
20 if we're not opening up a can of worms that doesn't
21 really exist by the nature of what we've already got
22 going on. The commitment to have a license to do
23 Strontium-90 eye application requires all the other
24 requirements of a license, not just the T&E of the
25 individual. There's inventory control, there's

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1 radiation safety, ALARA, occupational -- I mean, this
2 is not a fly in the dark-type operation. There is
3 serious consideration when you get radioactive
4 materials in the eye surgery-type environment.

5 DR. VETTER: Mr. Lieto.

6 MR. LIETO: I would speak against the
7 motion, and I think we've done enough, and I don't
8 think we need to add any more -- there's not any
9 indication that we need to add more restrictions at
10 this time. My recommendation to the Committee is to
11 vote against this, this added restriction.

12 DR. VETTER: Any other comments? The
13 motion is to add another requirement to the training,
14 that it only -- that the individuals must be retinal
15 surgeons.

16 DR. FISHER: Was that seconded?

17 DR. EGGLI: It was by Dr. Thomadsen. I'm
18 willing to withdraw it, if Dr. Thomadsen is willing to
19 agree.

20 DR. THOMADSEN: No, I'm not. I'm not
21 willing to withdraw that.

22 DR. VETTER: All right. All those in favor
23 of the motion raise your hand. One, two, three, four.
24 All those opposed? One, two, three, four, five. And
25 abstentions? So the motion fails. Are we done with

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1 this discussion for now for this meeting? Okay. Thank
2 you very much. We appreciate your coming.

3 Ms. Flannery has something to say.

4 MS. FLANNERY: Thank you. I'm hoping that
5 this will be quick, because I know everybody is ready
6 for a break. This just has to do with the discussion
7 right before we broke for lunch. I think there was a
8 concern by ACMUI about the supervising AUs and the
9 preceptor AUs, that the current regulations don't
10 allow them to be -- don't allow grandfathered
11 supervisors and preceptors. And I guess i just wanted
12 to make a clarification here. Right now, we are
13 seeking a higher level opinion from OGC, so we're
14 going through that right now, and still trying to get
15 this issue straightened out.

16 Now, we just want ACMUI to realize that
17 you can still continue your practice for supervising
18 and preceptoring the proposed authorized individuals
19 while we still work with OGC on this matter. Now,
20 when this issue is resolved, and we find that we do
21 need to do a rulemaking, something like this can be
22 expedited. So I know that there was a concern here
23 that this would take years, and the issues that would
24 be involved, but there are certain circumstances, and
25 I think this would qualify, where we could expedite

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1 it. And it wouldn't have to go through normal
2 rulemaking, so I just want to clarify that. But I
3 also want to state for the record that we're still
4 trying to get this issue straightened out.

5 DR. VETTER: Dr. Eggli.

6 DR. EGGLI: In a sense, this is a
7 technical error with respect to the intent. Did this
8 go through the administrative rulemaking process?

9 MS. FLANNERY: We're still trying to get
10 that straightened out with OGC. OGC would have to
11 answer that question, and we have posed that question
12 to them, so we're still trying to get that resolved.

13 MS. GILLEY: Could I just request the
14 urgency that when you all do get an answer to
15 correspond with us, and let us know. The agreement
16 states, a lot of them are in the process of rulemaking
17 and rule developing, and instead of recreating the
18 same mistake, it would be good for them to be able to
19 go ahead and make some of those administrative
20 changes, so they're not having to go back through the
21 rule promulgation process in two years.

22 MS. FLANNERY: Absolutely.

23 DR. VETTER: Okay.

24 MS. FLANNERY: Thank you for giving me a
25 minute.

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1 DR. VETTER: Yes, you're welcome. Thank
2 you for clarifying that for us.

3 So we have an hour and a half left on the
4 agenda with a break here. It looks like we're bumping
5 up against 6:00. Are there any concerns with flights
6 or anything like that?

7 DR. EGGLI: I'm concerned that Marriott is
8 going to tow my car.

9 DR. VETTER: Send the bill to Mr. Lewis.

10 MR. LEWIS: I have to leave. I have to
11 get to the day care.

12 DR. VETTER: You have to leave. Okay. So
13 I think we need to have a break, but we just need to
14 recognize that the remaining agenda is going to take
15 us a little while. We may lose a few people along the
16 way.

17 MS. TULL: Can I ask who does have a
18 flight this evening? Are all of you staying here?

19 MS. GILLEY: Somebody say yes, so we can
20 get out of here before 8:00.

21 DR. VETTER: So let's -- can we get by
22 with a five-minute break? Will that work?

23 DR. EGGLI: Just a bio-break.

24 DR. VETTER: Just a bio-break, so we can
25 keep things moving along. Okay. Please try to be

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1 back, we'll make it quarter after. You get seven
2 minutes.

3 (Whereupon, the proceedings went off the
4 record at 4:08 p.m., and resumed at 4:17 p.m.)

5 VICE CHAIRMAN VETTER: I'll call the
6 meeting to order. Okay. Do we have a quorum here?
7 One, two, three, four, five, six, seven, eight. Do we
8 still have eight? All right.

9 MS. GILLEY: This is higher math, I'm
10 not sure.

11 DR. EGGLI: Yes, we're ready. Yes, we
12 have a quorum.

13 VICE CHAIRMAN VETTER: We're at ten now?

14 DR. EGGLI: Yes, we have a quorum.

15 We're speaking to ourselves but we have a quorum.

16 VICE CHAIRMAN VETTER: Okay. We have the
17 next item on the agenda, the last item on the agenda.
18 Dr. Fisher is going to provide us some information
19 from a patient's perspective on a patient's needs,
20 concerns, and rights.

21 DR. FISHER: Thank you, Dr. Vetter.

22 This presentation is informational and
23 does not request any action or changes on the part of
24 the Nuclear Regulatory Commission but primarily for
25 the benefit of this committee.

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1 I appreciate the opportunity to work with
2 you and serve on this committee. It is a real honor.
3 And my special role is as a patients' rights advocate.
4 And there are some important history associated with
5 this role.

6 And as I will show you, there are some
7 other concepts that are critical to this committee
8 that have evolved over time, including the concept of
9 the Human Subjects Committee and the Institutional
10 Review Board. They are all kind of tied together in
11 an interesting way.

12 Patients want the best possible medical
13 care when faced with illness and disease. A good
14 example of this is a friend of mine whose funeral is
15 being conducted at this very hour, one o'clock Pacific
16 time, very close friend died of metastatic prostate
17 cancer with extensive involvement to the skeleton,
18 multiple skeletal lesions.

19 One of the drugs that he wanted more than
20 anything else for his particular condition was alpha
21 radiating radium-223 chloride, which is not available
22 yet in the United States as clinical trials are just
23 beginning at two institutions this year.

24 And it wasn't possible for him, because of
25 lack of availability, to get perhaps the one treatment

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1 that could have helped him the most. And so that's
2 kind of what this position is all about.

3 DR. NAG: Dr. Fisher, can you tell me
4 what the isotope was?

5 DR. FISHER: Radium-223.

6 DR. NAG: As what form?

7 DR. FISHER: Chloride. And I won't go
8 into that particular isotope and treatment at this
9 time but it is in extensive clinical trials in Europe.

10 In particular, patients want access to the
11 latest scientific advances. They want protection from
12 poor health care practices. They don't want to be
13 ripped off.

14 They want to understand their options for
15 treatment and they want good clear information.
16 They're not specialists. They don't understand the
17 medical jargon. But they do want to know what is
18 best.

19 They want to be treated with dignity and
20 respect. And they are concerned about the long-term
21 consequences of their disease, in particular about the
22 financial aspects.

23 The role of the patient rights advocate is
24 quite important. And if you look at the first four
25 bullets on this list, these are the same

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1 responsibilities that each of you have as members of
2 this committee. And I'll try to make this
3 presentation, in the interest of time, I'll shorten it
4 up just a little bit so that we can be finished soon.

5 But I did want to add that in addition to
6 the four responsibilities we all have, the patient
7 rights advocate must be cognizant of the impact of NRC
8 actions on patient access to health care and,
9 therefore, represent the concerns of patients and
10 patients' rights stakeholders.

11 Regulations have impact on patient care
12 and access to best health care practices. The factors
13 that may impact on patient rights are the tradeoffs
14 between regulations that restrict or limit the
15 availability to or patient access to new treatments.

16 For example, in the case of the
17 presentation that we just had. I was quite agitated
18 during that entire discussion because I'm genetically
19 disposed to the disease being discussed. It's a
20 family trait in our family and so I really -- I have
21 personal interest in it.

22 But I'm also aware of other people who
23 have interest in these and other treatments.
24 Incidentally, I spend about four hours a week in a
25 patient rights advocacy role as a volunteer. And so

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1 I have a passion for this subject that extends beyond
2 my professional responsibilities.

3 It is obvious that the slow process for
4 new drug or device regulatory approval impacts on
5 patient access to best health care. Regulations that
6 restrict hospitals and physicians ability to provide
7 the most effective treatments do not work in the best
8 interest of patients.

9 So the patient rights advocate must pay
10 particular attention to rulemaking process to ensure
11 that NRC regulations do not adversely impact patient
12 access to health care.

13 The history of patient rights advocacy
14 parallels the history of this advisory committee. I'm
15 not sure to the degree you are aware of this but the
16 concept of patient rights did, in fact, evolve as a
17 fundamental part of the operating philosophy of this
18 committee, which dates back to the Manhattan Project.

19 The next few slides show the evolution of
20 federal regulations concerning patients' rights in the
21 context of radio isotope research and the practice of
22 medicine. This goes back to -- actually the
23 experimentation with radiation predates the 20th
24 century but specifically there was an important event
25 in 1946 when recognizing the value of radioisotopes in

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1 medicine, the Manhattan Project announced the
2 availability of radioisotopes for medical research
3 and, in particular, the treatment --

4 MS. TULL: Oh, I'm sorry. I just grabbed
5 the wrong one.

6 DR. FISHER: -- the treatment of
7 disease. And there was first a memorandum from
8 Colonel Stafford Warren, the Medical Director of the
9 Manhattan Project, who was at that time at Oakridge
10 National Laboratory.

11 It was followed up by a journal article
12 June of 1946, published in science written by Paul
13 Abersold, on the availability of radioactive isotopes
14 in an announcement to universities, hospitals, and
15 clinicians.

16 In 1946, the Manhattan Engineering
17 District formed the Interim Advisory Committee on
18 Isotope Distribution Policy. That's the predecessor
19 to this committee.

20 The Atomic Energy Act of 1946, you are all
21 familiar with the Atomic Energy Act or the enabling
22 act that started the Atomic Energy Commission. But
23 really the first act was in 1946. In 1947, the Atomic
24 Energy Commission formed its committee on isotope
25 distribution policy, which was a slight change in the

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1 form it formed in 1946. It had two parts. It had a
2 subcommittee on allocation and distribution and a
3 subcommittee on human applications. It is really
4 interesting how this was set up.

5 The first subcommittee decided who would
6 receive isotopes and for what purpose. And whether
7 the government should make an investment in their
8 production for that particular research. And the
9 second subcommittee determined whether it was
10 appropriate to use those in human subjects.

11 In 1950, this committee's name changed to
12 the Atomic Energy Commission Advisory Committee on
13 Isotope Distribution. In 1953, we had President
14 Eisenhower's famous speech on atoms for peace to the
15 United Nations in New York.

16 Then we had the Atomic Energy Act of 1954
17 with focus on nuclear power, nuclear weapons, and the
18 third leg of the Atomic Energy Commission was peaceful
19 applications of isotopes. That was the third
20 important mission of that agency.

21 In 1974, the Energy Reorganization Act
22 split the Atomic Energy Commission into two parts, the
23 Nuclear Regulatory Commission and the Energy Research
24 and Development Administration. This committee stayed
25 with the Nuclear Regulatory Commission and today the

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1 Advisory Committee, of which you are a member,
2 provides advice on policy and technical issues that
3 arise in regulating the medical use of byproduct
4 material for diagnosis and therapy. Short history of
5 this committee.

6 Back to 1946, this particular slide
7 indicates recognition that radiation therapy is not
8 without risk of normal tissue injury. Local isotope
9 committees were formed to review the use of
10 radioisotopes. It was a two-tiered system. It had
11 both local review and federal review or federal
12 oversight for each project.

13 Experimental protocols were reviewed at
14 the local level before being approved at the federal
15 level and receiving permission to receive isotopes
16 through this national distribution policy.

17 And in the documents that I have reviewed
18 on this subject, patient safety was of "paramount
19 importance." And also I found that risk-benefit
20 analysis was an integral component of the policy on
21 the use of isotopes in humans.

22 I found this statement, "it is not wise in
23 any way to inhibit investigators with ideas." In
24 other words, let's try to utilize this new tool as
25 best we can. And yet the safety of the patient must

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1 come first.

2 The concept of patient informed consent
3 originated with this committee. In 1949, the
4 responsibility for the use of radioisotopes was
5 assumed by a special committee of at least three
6 competent physicians belonging to the institution
7 where the work was to be performed.

8 The rule said that a subject must consent
9 to the procedure and there should be no reasonable
10 likelihood of producing, through this experiment or
11 this treatment, manifest-producing injury by the
12 radioisotopes to be employed.

13 Paul Abersold was the AEC Director of the
14 Isotope Program and this is part of the minutes of the
15 Subcommittee on Human Applications in 1949. These
16 rules on human use of isotopes were first codified in
17 1951, part of 10 CFR -- what was then 10 CFR 30.50, a
18 supplement to the 1949 edition.

19 And these contained not the full set of
20 rules but a very primitive set of rules with
21 administrative facility and personnel requirements for
22 receiving and using isotopes. It did not include dose
23 limits or patient consent requirements. A very crude
24 set of rules at that time.

25 In 1956, the Atomic Energy Commission

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1 issued guidelines for the use of isotopes in
2 terminally-ill patients. The interesting part of this
3 was the requirement for preclinical studies in
4 laboratory animals before isotopes could be tested in
5 humans.

6 And the use of isotopes was limited to
7 patients suffering from disease conditions with a life
8 expectancy of one year or less with no reasonable
9 probability of the radioactivity employed producing
10 manifest injury. So here we had the concept of
11 compassionate use, which is common today in FDA
12 nomenclature.

13 In 1956, there was a more formal statement
14 presented on patient informed consent in research
15 subjects. And guidelines for informed consent became
16 more formal. Informed consent was required for all
17 use of radioisotopes in normal, healthy subjects.

18 A radioactive tracer could not exceed what
19 was under ICRPT the permissible body burden.
20 Experiments should not normally be conducted on
21 infants or pregnant women.

22 Subjects were limited to volunteers to
23 whom the intent of the study and the effects of
24 radiation had been outlined. And that these
25 guidelines required that both the purpose and the

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1 effects of radiation be explained to volunteer
2 subjects.

3 Also in 196, the Medical Isotope Committee
4 became more formal and these requirements updated the
5 1949 requirements, again three or more physicians plus
6 a qualified radiation physician were required to serve
7 on the Medical Isotope Committee. This committee
8 reviewed and permitted the use of radioisotopes within
9 the institution from the standpoint of radiation
10 health physics.

11 The committee prescribed special
12 conditions that must be used, such as physical exams,
13 the training requirements, designation of limited
14 areas or locations of use, disposal methods for waste,
15 et cetera. Records and reports were to be provided by
16 the radiation safety officer.

17 The committee recommended remedial action
18 when a person failed to observe the safety
19 recommendations and rules. And these guidelines also
20 required that medical isotope committees maintain
21 adequate records.

22 So just another comment, in 1965, the
23 Atomic Energy Commission produced its guide for the
24 medical use of radioisotopes. This document described
25 the application process and specific policies for the

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1 non-routine medical uses of byproduct material.

2 It reiterated the exclusion of pregnant
3 women as subjects, required that subject selection
4 criteria be clearly delineated, and, again, required
5 the consent of human subjects or their representatives
6 except where this would not be feasible or where
7 consent would be contrary to the best interest of the
8 subjects. A little caveat there which we don't any
9 longer have.

10 The 1960s were characterized by the
11 emerging role of the Food and Drug Administration
12 which developed, at this time, a more active role in
13 supervising the discovery, the development, and the
14 commercialization of radiopharmaceuticals. And
15 through this process, the oversight of radioisotopes
16 research began to change.

17 And the history of this shift in
18 regulatory authority from the Atomic Energy Commission
19 to the FDA is complex and beyond the scope of what I
20 want to say other than that the FDA now has assumed
21 many of these roles.

22 So we jump forward 30 years in time to the
23 Clinton administration in 1997. President Clinton
24 created the Advisory Commission on Consumer Protection
25 and Quality in the Health Care Industry and charged it

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1 with recommending such measures as may be necessary to
2 promote and assure health care quality and value and
3 protect consumers and workers in the health care
4 systems, laid the foundations for the Patient's Bill
5 of Rights in medicare and medicaid.

6 And he asked the commission to develop a
7 Patient's Bill of Rights. So the commission did. And
8 this Patient's Bill of Rights was codified in 42 CFR
9 482.13 on medicare conditions of participation, dated
10 1999.

11 The federal statement on patient's rights
12 -- I'm going to go back -- the goals of the bill of
13 rights were to strengthen consumer confidence that the
14 health care system is fair and responsive to consumer
15 needs, to reaffirm the importance of a strong
16 relationship between and health care providers, and
17 reaffirm the critical role that consumers play in
18 safeguarding their own health.

19 The main aspects of the patient bill of
20 rights are usually adopted by most medical
21 institutions. The seven or eight primary aspects of
22 the patient's bill of rights from 42 CFR 482 are the
23 right to information, the right to choose, access to
24 emergency services, being a full participant in health
25 care decision, care without discrimination, the right

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1 to privacy, and the right to speedy resolution of
2 complaints.

3 In addition, the commission added one
4 responsibility for the patient. And that was to
5 maintain good health. In a health care system that
6 affords patient rights and protections, patients must
7 also take a greater responsibility for maintaining
8 good health.

9 In summary, by recognizing the importance
10 of patient rights advocacy and by sustaining the
11 position of the patient rights advocate on this
12 committee, the U.S. Nuclear Regulatory Commission
13 continues the pattern established more than 60 years
14 ago by the predecessors of this committee.

15 The NRC demonstrates its longstanding
16 commitment and sensitivity to issues that are of
17 concern to patients. So this position has its
18 foundations in the historical development of this
19 committee.

20 Concerns for protection of patient rights
21 are based on that history that parallel the
22 evolutionary history of this committee. And the most
23 important elements of patient rights are established
24 in federal law.

25 And with that, I would open it to the

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1 committee or the audience for any questions.

2 VICE CHAIRMAN VETTER: Dr. Fisher, may I
3 say first of all that the committee appreciates the
4 importance of the patient rights advocate. And we
5 appreciate your presentation on patient needs,
6 concerns, and rights. And I think we've heard that
7 before. It is very helpful to us. And we also
8 appreciate the role that you serve in that regard.

9 So questions or comments for Dr. Fisher
10 from either the committee or the audience?

11 (No response.)

12 VICE CHAIRMAN VETTER: Thank you very
13 much.

14 And to the last item on the agenda, the
15 one we've been working real hard to get to, Ashley,
16 the administrative closing.

17 MS. TULL: I have several things to go
18 over. The first is for the presentation -- for
19 Cindy's presentation on F-18 infiltrations that we
20 skipped today, we have some background information
21 that came in from the regions.

22 We are moving that item to a
23 teleconference. And we'll discuss teleconference
24 dates here in a minute. But if you want to read over
25 this, you will have some prep time before the

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1 teleconference.

2 Okay, the first thing I'm going to do is
3 go over the recommendations that the committee made
4 during today's meeting. I'm going to pass around a
5 one-page sheet and I'll wait for these to go around
6 before I start. And on all of these, these are just
7 a draft. This is what I tried to frantically type
8 while the committee changed its mind repeatedly and
9 revised recommendations.

10 MR. EINBERG: Ashley, we only have -- we
11 ran out of the recommendations. Oh, are they coming
12 around that way? Oh, okay.

13 MS. TULL: Half and half.

14 PARTICIPANT: We all had three over here.

15 MS. TULL: Okay, so these are draft
16 recommendations from today's meeting. When I get the
17 transcripts, we will put together the official
18 recommendations per ACMUI's exact wording in those
19 transcripts.

20 So for number 18, this actually wasn't a
21 recommendation but we took it as an action item. NRC
22 staff should transmit information from the ACMUI
23 fingerprinting subcommittee report to licensees. A
24 good example would be through the Q&As on the website.

25 Number 19, NRC staff should accept the

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1 permanent implant brachytherapy subcommittee report
2 recommendation on pre-implantation. This was
3 recommendation number one of the bullets that were
4 listed. And it had to do with medical events based on
5 the written directive at the time the patient leaves
6 the postoperative treatment area.

7 Number 20, NRC staff should accept the
8 second, third, fourth, and fifth recommendations of
9 the permanent implant brachytherapy subcommittee
10 report, as indicated on the slide.

11 And 21, NRC staff should accept the sixth
12 recommendation of the permanent implant brachytherapy
13 subcommittee report. This recommendation was later
14 amended to read when a written directive is required,
15 administrations without a prior written directive are
16 to be reported as regulatory violations and may or may
17 not constitute a medical event.

18 Number 22, ACMUI should form a
19 subcommittee to draft a set of proposed qualifications
20 to be satisfied by interventional radiologists to
21 become authorized users for Yttrium-90 microspheres.
22 Dr. Thomadsen will be the chair. And Drs. Eggli, Nag,
23 Welsh, and Mr. Mattmuller will all serve on that
24 subcommittee.

25 Number 23, there was a recommendation for

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1 NRC staff to move the Yttrium-90 microspheres from
2 guidance to regulation space.

3 Number 24, ACMUI endorsed the permanent
4 implant brachytherapy subcommittee report as a whole.

5 Number 25, ACMUI strongly encourages NRC
6 to continue supporting exportation of highly-enriched
7 uranium material from moly-99 targets used by
8 international producers and to provide support for
9 development of U.S. producers of moly-99.

10 Number 26, ACMUI should form a
11 subcommittee to develop recommendations for
12 individuals to achieve authorized user status using
13 the board certification pathway. The subcommittee
14 will provide feedback to the full committee during a
15 future teleconference. The subcommittee includes Dr.
16 Eggli as the chair, Dr. Guiberteau will provide
17 technical assistance, and Dr. Nag.

18 DR. VAN DECKER: I'm not convinced that
19 this engenders the theme of what was talked about. But
20 Dr. Eggli can help me. I think the concept was to
21 discuss the specific problem of somebody completing
22 training until the time they take the board and their
23 ability to be an authorized user in that interim
24 period.

25 I believe that is the specific question

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1 that is to be addressed. And if that is the specific
2 question to be addressed, then I think I also need to
3 be a piece of this.

4 DR. EGGLI: And you were.

5 MS. TULL: Okay. So I will add Dr. Van
6 Decker. And then I'll make a note to specifically
7 look at the transcript on this one to get a good
8 subcommittee charge. And send that to you guys.

9 DR. VAN DECKER: Right. Right.

10 MS. TULL: Okay?

11 Number 27, NRC staff should revise 10 CFR
12 35.30, 35(b) as proposed. All of the following are
13 going to come from Donna-Beth's presentation so they
14 are kind of vague and out of context. But I'll put
15 them into better words when you get the formal
16 recommendations.

17 Number 28, NRC staff should revise 10 CFR
18 35.40 to clarify that the authorized user should sign
19 and date that the pre-implantation and after-
20 implantation portions of the written directive for all
21 modalities with two-part written directives.

22 Number 29, NRC staff should revise 10 CFR
23 35.65 to clarify it does not apply to sources used for
24 medical use; however, NRC should not require licensees
25 to list the transmission sources as line items on the

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1 license.

2 NRC staff should also revise 10 CFR 35.590
3 to permit the use of transmission sources under 10 CFR
4 35.500 by authorized users meeting the training and
5 experience requirements of 10 CFR 35.590 or 35.290.

6 Number 30, NRC staff should revise 10 CFR
7 35.204(b) to read that a licensee that uses molybdenum
8 and technetium generators for preparing technetium-99m
9 radiopharmaceuticals shall measure the moly-99
10 concentration of each eluate after receipt of a
11 generator to demonstrate compliance with paragraph (a)
12 of this section. Okay?

13 Number 31, NRC staff should add
14 reportability to the regulations when moly
15 breakthrough is measured.

16 Number 32, NRC staff should --

17 MR. LIETO: Wait a minute.

18 MS. TULL: Yes?

19 VICE CHAIRMAN VETTER: Ralph?

20 MR. LIETO: I think you mean when moly
21 breakthrough limits are exceeded.

22 MS. TULL: Yes. That exceed limits -- the
23 limits. Okay?

24 Number 32, NRC staff should approve the
25 proposed change for grandfathered authorized users as

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1 supervisors and preceptors for the purposes of T&E.
2 This is the urgent issue that we are dealing with with
3 OGC as well.

4 NRC staff should revise -- this is number
5 33 -- NRC staff should revise 10 CFR 35.40 to clarify
6 that NAU has to sign both the pre-implantation and
7 after-implantation portions of the written directive
8 for all modalities with two-part written directives.
9 Dr. Nag will include this clarification in the
10 permanent implant brachytherapy subcommittee report.

11 Okay, 34, the ACMUI subcommittee should
12 review events and provide analysis to the full
13 committee in the spring meeting instead of the fall.

14 If you'll turn the page over, number 35,
15 10 CFR 35.490(1) is an appropriate training
16 requirement for the use of the NeoVista strontium-90
17 device if accompanied by appropriate device-specific
18 training.

19 Number 36, NRC should add another
20 requirement to the training that the individuals must
21 be retinal surgeons. This is in reference to the
22 previous recommendation.

23 VICE CHAIRMAN VETTER: That was withdrawn.
24 Oh, no, I'm sorry. Oh, no, I'm sorry.

25 MS. TULL: It did not pass, yes, I noted

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1 a four-five-one vote so the motion --

2 VICE CHAIRMAN VETTER: Failed.

3 MS. TULL: -- didn't carry.

4 VICE CHAIRMAN VETTER: Yes, thanks.

5 MS. TULL: Yes.

6 Number 37, NRC staff should notify ACMUI
7 when OGC makes a determination on the availability of
8 grandfathered authorized users to be supervisors and
9 preceptors for the purposes of T&E.

10 Any questions or comments on the
11 recommendations?

12 (No response.)

13 MS. TULL: Okay.

14 VICE CHAIRMAN VETTER: Excellent. Thank
15 you. Very good.

16 MS. TULL: Last year, we had over 50
17 recommendations. So 30-something, I'm happy with. I
18 can follow 30.

19 Okay, next we're going to set dates for
20 the upcoming teleconference and meetings. So I'm
21 going to pass around some calendars so you can
22 actually be looking at days and we're not guessing
23 what is a Monday, what's a Wednesday.

24 DR. EGGLI: You don't, by chance, have
25 a copy of my calendar?

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1 (Laughter.)

2 MS. TULL: No, I don't have copies of your
3 calendar. I'll call Debbie really quick.

4 (Laughter.)

5 MS. TULL: Oh, actually I need one, too,
6 please. Thanks.

7 MS. GILLEY: Oh, good, you took care of
8 all of May.

9 MS. TULL: Yes. So for the December
10 teleconference, typically we do one to two hours, 1:00
11 to 3:00 p.m. east coast time has worked. For those on
12 the west coast, that's 10 a.m. We don't want to go
13 much earlier.

14 Are there any preferences in December? I
15 talked to Dr. Welsh before he left and he said the
16 first week of December was out for him.

17 MS. GILLEY: The second week is out for
18 me.

19 MS. TULL: Okay. I was actually going to
20 say if we could start with looking at the third week,
21 the 15th, 16th, 17th, and 18th? Dr. Welsh had a
22 preference for the 18th. But that's just a starting
23 place.

24 DR. NAG: I have a preference for the
25 18th as well.

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1 MS. TULL: Okay. Does anyone have a
2 conflict on the 18th? Okay. So we're going to set it
3 for December 18th from 1:00 to 3:00 p.m. east coast
4 time. And we'll be discussing the F-18 presentation
5 --

6 PARTICIPANT: I'm sorry, 1:00 to when?

7 MS. TULL: To 3:00 p.m.

8 PARTICIPANT: 1:00 to 3:00 --

9 MS. TULL: East coast. And we'll be
10 discussing the F-18 infiltration that Cindy was going
11 to talk about.

12 And also for item number 27, which was --
13 actually it is not 27 anymore. I changed them. There
14 was a subcommittee that was going to report back to us
15 -- item number 26. Will this give the subcommittee
16 enough time to get some things together to discuss
17 that issue? I know it's only about six weeks.

18 PARTICIPANT: It's a start.

19 MS. TULL: Okay. Maybe a draft or
20 something?

21 PARTICIPANT: Yes.

22 MS. TULL: Okay. So you guys will be
23 prepared to talk as well during that teleconference?

24 (Laughter.)

25 MS. TULL: It's either that or wait until

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1 after the holidays and then all of a sudden, we're
2 really far out. Okay?

3 All right. So if you will turn the page
4 to April, this is for the spring ACMUI meeting. And
5 this room that we're in right now is not going to be
6 available. It's going to be completely renovated. And
7 we need to find a different room.

8 The best option is the NRC auditorium. And
9 as you can tell by the Xs all over the calendar, we
10 are very, very limited on when the auditorium is
11 available.

12 PARTICIPANT: So the 23rd and the 24th?

13 MS. TULL: Yes.

14 MS. GILLEY: Do you not want to move it
15 into June?

16 MS. TULL: Preferably not.

17 MS. GILLEY: Okay.

18 MS. TULL: We have to coordinate the
19 commission briefing for April or May as well
20 preferably.

21 MS. GILLEY: Okay.

22 MS. TULL: And also if we start pushing to
23 June if we try to keep April and October and all of a
24 sudden we push to June, June-October becomes very
25 close. It's hard to get a teleconference between

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1 those two dates.

2 Is there any opposition to a
3 Thursday/Friday meeting? The auditorium would be
4 available on those days.

5 DR. EGGLI: I'll be out of the country
6 the 23rd -- the week of the 19th.

7 MS. TULL: Okay. Would everyone be
8 available April 30th and May 1st?

9 DR. NAG: No.

10 MS. TULL: No? Okay. The last option --

11 MR. LEWIS: Was that a no or an I don't
12 know?

13 MS. TULL: That was a no from Dr. Nag. The
14 next option is May 7th and 8th.

15 DR. VAN DECKER: I, unfortunately,
16 don't remember when the International Conference in
17 Nuclear Cardiology is but it is one of those two
18 weeks. I'll have to figure out which of those weeks
19 it is.

20 MS. GILLEY: Does it have to be this
21 venue?

22 MR. LEWIS: I think we have to explore our
23 options.

24 DR. NAG: When will this room be
25 available again?

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1 MR. BROWN: It may be available in May. It
2 might -- it might.

3 VICE CHAIRMAN VETTER: That needs to be
4 determined.

5 MS. TULL: It's very difficult to -- a
6 commission meeting needs to be scheduled. And if you
7 would like to meet with the commission and be on their
8 calendar, we really need to pick a date.

9 VICE CHAIRMAN VETTER: That needs to be a
10 high priority for us. If we don't have a meeting with
11 the commission, our visibility goes way down. We need
12 to have a meeting with the commission.

13 DR. SULEIMAN: Which dates in April are
14 the least conflicted?

15 MS. TULL: I had one conflict on the 23rd
16 and 24th from Dr. Eggli and one conflict on the 30th
17 and May 1st from Dr. Nag.

18 DR. SULEIMAN: Can we take a vote on
19 both of them?

20 DR. VAN DECKER: I can do the 7th and
21 8th, I don't know.

22 MS. TULL: Then on the 7th and 8th --

23 PARTICIPANT: There is a computer over
24 here with internet access if you want to check on your
25 meeting for a date.

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1 MS. TULL: Yes, or Gretchen, could you do
2 just a quick Google search on the National Cardiology
3 --

4 DR. VAN DECKER: International -- ICNC.

5 MS. TULL: ICNC. No, that one is not
6 hooked up to the internet. That's my personal.

7 MS. GILLEY: Well, with the
8 Commissioners, if we would meet in their chamber for
9 their actual briefing, would it be possible to meet
10 across the street at the Marriott for the meeting?

11 DR. NAG: No money. Very expensive.

12 MR. LEWIS: Well, with the Marriott, the
13 problem is getting a room that is big enough for a
14 variable public audience. They charge by the person
15 so we can't tell them how many people will show up.

16 MS GILLEY: All right. Okay. I just
17 thought there might be another location.

18 DR. SULEIMAN: We could probably work
19 something out at FDA but you guys have too many people
20 coming in and out. I think you'd probably want it
21 here.

22 MR. LEWIS: Ashley, what is the 22nd? It's
23 not Xed out but it is question marked.

24 MS. TULL: Is it in Spain? The 10th
25 through 13th is your meeting.

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1 MR. LEWIS: Why does the 22nd have a
2 question mark?

3 MS. TULL: The 22nd has a question mark
4 because I called the people who currently have the
5 auditorium reserved and begged and pleaded for them to
6 give me that day so that we could have a
7 Wednesday/Thursday meeting but I do not have
8 confirmation that their meetings would be canceled.
9 And that would have to be something that management
10 would have to --

11 VICE CHAIRMAN VETTER: That wouldn't help
12 us anyway.

13 MS. TULL: And I think there was a
14 preference to not have a Wednesday/Thursday meeting
15 because it is in the middle of week which means you
16 miss two days on either end. And there was a
17 preference to go ahead and have the Friday for the
18 Saturday travel day.

19 VICE CHAIRMAN VETTER: Well, could we work
20 this out -- with your putting a meeting with the
21 commission -- I don't know when you can confirm that
22 meeting with the commission --

23 MS. TULL: I have to give them the date of
24 our meeting. And then hope that they reserve a slot.
25 And then we find out about 30 days before that it is

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1 confirmed. But our dates have to be firm.

2 Just to go back to the 7th and 8th of May,
3 no one actually had a conflict then. Dr. Van Decker's
4 meeting does not conflict.

5 DR. NAG: One question, can we ask the
6 Commissioners if between some of those dates they are
7 not available? Then we can throw away those dates
8 right away.

9 MS. TULL: It doesn't work that way.

10 MR. LEWIS: You can ask them anything.

11 (Laughter.)

12 MS. TULL: Yes. We need to set our
13 meeting date and then I need to contact the commission
14 and say here is our meeting date. Can we please get
15 the commission briefing set up on that date? And
16 that's how we get to talk with the commission.

17 VICE CHAIRMAN VETTER: So you have no
18 information now that would suggest that one date might
19 be better than another for a meeting with the
20 commission?

21 MS. TULL: You can consider them
22 available. We need to pick our meeting based on our
23 dates.

24 VICE CHAIRMAN VETTER: Okay.

25 MS. TULL: So the 7th and 8th there are no

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1 conflicts. Is there any reason not to have the
2 meeting on that day -- those two days? In the NRC
3 auditorium, no traveling.

4 DR. FISHER: Seventh and eighth of May?

5 MS. TULL: Yes.

6 DR. NAG: I would say yes. You all can
7 send an e-mail to Dr. Malmud and Dr. Welsh who are not
8 here.

9 MS. TULL: I'll talk to him. Dr. Welsh,
10 I've already talked to him about these dates. And I
11 will talk to Dr. Malmud after the meeting.

12 DR. SULEIMAN: Okay. It works for me.

13 MS. TULL: Okay. We will tentatively set
14 the next meeting for May 7th and 8th. Please block
15 off your calendars and call the Marriott today.

16 MS. GILLEY: I'll make those
17 reservations today.

18 MS. TULL: If you want to walk back over
19 there and make those reservations, that would be
20 great.

21 MR. MATTMULLER: You know maybe we can
22 have a tent put up in the parking lot and have our
23 meeting there.

24 MS. TULL: Okay, two more quick things.
25 Time for your meeting and time for your travel will be

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1 -- Shayla Glass is our secretary now. She will e-mail
2 you next week. Be sure to turn your time in. I think
3 it will be due on Thursday. You can claim eight hours
4 for travel on Sunday, eight hours for each day. And
5 eight hours again if you are traveling tomorrow. Or
6 up to eight hours I should say.

7 Travel vouchers, I'll do what I did last
8 time. I'll send you examples of if you took the
9 train, here is what your travel voucher should look
10 like.

11 If you took a flight and you paid for it
12 on your own, that's done differently than if the NRC
13 paid for your flight. And also if you took the train.
14 I'll send out four examples. Pick the correct
15 example.

16 And I'm going to have you mail those
17 directly to me so that I can review them because they
18 go to the Department of the Interior now and they are
19 being very heavily scrutinized.

20 So hopefully you'll get you your money as
21 quickly as possible. Payments have been processed
22 much more quickly now that we've gone through DOI. So
23 it's a work in progress.

24 DR. EGGLI: Okay. We've actually had
25 eight hours of meeting today.

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1 MS. TULL: Yes.

2 DR. EGGLI: I will be traveling two-
3 and-a-half hours yet today.

4 MS. TULL: You can claim up to eight
5 hours.

6 DR. EGGLI: So it's just eight?

7 MS. TULL: Yes.

8 MR. LEWIS: For your time. That has
9 nothing to do with your travel voucher.

10 DR. EGGLI: No, I'm driving.

11 MS. TULL: No, he's just asking for time
12 in general. Eight hours max each day.

13 DR. NAG: Now you can sleep here
14 tonight and leave tomorrow. Then you can claim the
15 other two hours.

16 UNKNOWN MEMBER: There is no way he'd get
17 a room at the Marriott.

18 (Laughter.)

19 MS. TULL: Okay. And the very last thing
20 please take off your name tags and set them on the
21 table. Thanks everyone.

22 (Whereupon, the above-entitled meeting was
23 concluded at 4:59 p.m.)

24

25

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