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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
(ACMUI)

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THURSDAY, NOVEMBER 13, 2003

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ROCKVILLE, MARYLAND

The ACMUI met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11545 Rockville Pike, at 8:00 a.m., Manuel Cerqueira, M.D., Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL CERQUEIRA, M.D., Chairman
DAVID A. DIAMOND, M.D., Member
NEKITA HOBSON, Member
RALPH P. LIETO, Member
LEON S. MALMUD, M.D., Member
RUTH McBURNEY, Member
SUBIR NAG, M.D., Member
SALLY WAGNER SCHWARTZ, Member
ORHAN H. SULEIMAN, Ph.D., FDA Representative
RICHARD J. VETTER, Ph.D., Member
JEFFREY F. WILLIAMSON, Ph.D., Member

1 ACMUI STAFF PRESENT:

2 ANGELA WILLIAMSON

3 THOMAS H. ESSIG, Designated Federal Official

4 LINDA M. GERSEY

5 PATRICIA K. HOLAHAN

6 ROBERTO J. TORRES

7

8 ALSO PRESENT:

9 John Szabo NRC/OGC

10 Charles Miller NRC/NMSS

11 Michael Layton NRC/NSIR

12 Lynne Fairobent ACR

13 Nancy R. Daly

14 Angela Lee

15 Bill Uffelman, Esq. SNM General Counsel

16 Gerald A. White AAPM

17 Andrew Kang

18 Donna-Beth Howe NRC/NMSS

19 Ronald Zelac NRC/NMSS

20 Sami Sherbini NRC/NMSS

21 Raymond Horn

22 Kristin Swenson

23 Roshunda Drummond

24 Michele Burgess

25

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I-N-D-E-X

<u>AGENDA</u>	<u>PAGE</u>
SeedSelectron and 35.1000, Donna-Beth Howe,	264
PhD, NRC/NMSS	
Update: Listing Sources by Model/Serial Number	327
on Licenses, Donna-Beth Howe, PhD, NRC/NMSS	
Subcommittee Meeting Information, John Szabo,	374
NRC/OGC	
Radioiodine Activity Threshold for Treatment of	424
Hyperthyroidism, Angela Williamson, NRC/NMSS	
Update: Interpretation of 10 CFR 35.61(b) --	461
Ronald Zelac, PhD, NRC/NMSS	
ACMUI Access to NMED Event Data, Tom Essig,	464
NRC/NMSS	
Discussion of the Draft Information Notice	474
Regarding Issuance of Identification Cards to	
Patients Who are Released After Treatment with	
Radiopharmaceuticals, Roberto Torres, NRC/NMSS	
NMSS Update: Emerging Technologies, Donna-Beth	496
Howe, PhD, NRC/NMSS	
Update: Recommendations from Spring 2003 ACMUI	508
Meeting, Angela Williamson, NRC/NMSS	
Administrative Conclusion	513

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

8:05 a.m.

CHAIRMAN CERQUEIRA: Just a few little administrative things up-front. I have sort of this last minute schedule changes at Georgetown, and since I'm local it's hard for me to miss it. So this afternoon I'm not going to be here, but I spoke to Dr. Malmud yesterday and he will sort of take over as Chair for the afternoon session.

Also, the session this afternoon at 2:15, dose reconstruction and unexplained exposure/extremity monitoring at materials facilities, due to some scheduling conflicts by Dr. Sherbini, that will be given this morning at 10:15, and the update on emerging technologies will be shifted to the afternoon.

We also had a little bit of discussion this morning, Angela had sent out the notices about the Commission briefing, and March 2 seems to be the date that everybody had agreed would work. And to avoid unnecessary travel what I'd like to do is if we could arrange the regular ACMUI meeting on the 1st, which would be a Monday, and then we could meet all day Monday, half a day Tuesday and then meet with the commissioners. That would sort of consolidate the

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1 travel. Is everybody in agreement with that? Okay.
2 So, Angela --

3 DR. WILLIAMSON: What are the dates for
4 this?

5 CHAIRMAN CERQUEIRA: We would meet -- the
6 full Committee would meet on March 1, which is a
7 Monday, and then on March 2, which is a Tuesday, we
8 would have the -- depending on the agenda, either have
9 a half day meeting in the morning and then meet with
10 the commissioners or depending on their time schedule
11 the other way around. Basically, we would consolidate
12 everything into March 1 and 2. Dick?

13 DR. VETTER: Would it be possible to get
14 that nailed down prior to when we try to make airline
15 reservations, because it's very difficult to make
16 airline reservations and then try to adjust things
17 afterwards.

18 CHAIRMAN CERQUEIRA: Yes, especially from
19 Rochester, Minnesota, it's -- yes.

20 MS. SCHWARZ: I do agree with that. Maybe
21 Angela could look into this room availability before
22 we leave, because --

23 CHAIRMAN CERQUEIRA: Right.

24 MS. SCHWARZ: -- that was the problem --

25 CHAIRMAN CERQUEIRA: Last time, right.

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1 MS. SCHWARZ: -- last --

2 CHAIRMAN CERQUEIRA: Now, Angela, is she
3 here?

4 MR. ESSIG: She is here today.

5 CHAIRMAN CERQUEIRA: I did see her this
6 morning, but she's not --

7 MR. ESSIG: She's here. We'll make sure
8 that she does that.

9 CHAIRMAN CERQUEIRA: Okay. Because that
10 would be important. That way we would lock the date
11 in now with enough time, and I think we'd consolidate
12 the meeting.

13 DR. NAG: That would help with hotels,
14 because hotels are hard to get.

15 CHAIRMAN CERQUEIRA: Yes.

16 DR. MILLER: What day of the week are
17 those days? Anybody have a calendar?

18 CHAIRMAN CERQUEIRA: Monday and Tuesday.

19 DR. MILLER: That might work okay. I mean
20 the one -- that was a good suggestion because I know
21 the ACRS meets, I think, with full Committee the first
22 week of the month, if I remember right. Sometimes
23 they'll attach a subcommittee meeting before the full
24 Committee meeting, and the room may or may not be
25 available.

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1 MS. MCBURNEY: So that's a Monday,
2 Tuesday, and so we'd travel on Sunday.

3 DR. NAG: The meeting with the
4 commissioners will be on the second afternoon or on
5 the third?

6 CHAIRMAN CERQUEIRA: Again, it depends on
7 their availability, but I think we could, depending on
8 the agenda items that we have, we could sort of work
9 around the Commission meeting.

10 DR. NAG: But I mean on the 2nd or 3rd?

11 CHAIRMAN CERQUEIRA: On the 2nd.

12 DR. NAG: On the 2nd.

13 CHAIRMAN CERQUEIRA: Yes.

14 DR. NAG: The other possibility you have
15 it on the 3rd.

16 CHAIRMAN CERQUEIRA: That would be the
17 other possibility, although sometimes it's ideal to
18 try to --

19 MS. MCBURNEY: To meet before.

20 CHAIRMAN CERQUEIRA: -- to meet before we
21 actually have the meeting with the commissioners. But
22 I would be in favor or -- if that's the only way we
23 can do it, to do it on the 2nd and 3rd, do it that
24 way rather than do what we did last time which was to
25 have separate meetings.

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1 DR. NAG: The actual meeting, radiation
2 oncologists meeting, is the 26th, 27th, 28th, 29th.

3 CHAIRMAN CERQUEIRA: Is that March or
4 April.

5 DR. DIAMOND: February.

6 CHAIRMAN CERQUEIRA: February.

7 DR. NAG: I guess the day before --

8 CHAIRMAN CERQUEIRA: And see the week
9 after is the cardiology meetings, so I think the other
10 option is the 9th. All right. So maybe if Angela
11 could look into the possibilities of either the 1st or
12 the 3rd for the regular meeting and to finish the
13 business on the 2nd and to meet with the
14 commissioners.

15 The other thing is John Szabo had come up
16 with some -- we had questions yesterday about the
17 subcommittee meetings, and he has come up with some
18 other information that at 10:15 he's going to come
19 down and just take about five minutes to go over
20 those. And then the last item is that Dr. Miller
21 mentioned the fact that the presentation made
22 yesterday on safeguards, training and update, some of
23 that information may have been covered under the
24 Safeguards Act, and we may have to give up our notes
25 and everything. So, Charlie, do you want to --

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1 DR. MILLER: Yes. We got a call from Mike
2 Layton saying some of the information that he
3 presented yesterday may have wandered into safeguards
4 territory. So I think the best thing to do to be safe
5 is they will review the transcripts from the closed
6 meeting, but in the interim if any of you took
7 personal notes on that session, could we just put your
8 name on them and borrow the back -- let us borrow them
9 back and give them to Angela, and then we'll let the
10 Safeguards people look at it. And then if they need
11 to be redacted because of that, they will be, and
12 anything that's not safeguards we'll make sure we get
13 back to you.

14 CHAIRMAN CERQUEIRA: Okay. Good. All
15 right. So we then move on to our regular agenda item,
16 and the first one is SeedSelectron and 35.1000, and
17 Dr. Howe will be --

18 DR. HOWE: Okay. What we're going to talk
19 about this morning is essentially a new device that --
20 well, it's produced by Nucletron, called the
21 SeedSelectron, and, actually, the SeedSelectron can be
22 marketed in a number of different formats. The
23 Nucletron SeedSelectron system itself I'll show you a
24 picture of, and it is a seed delivery system, it is
25 computer driven, and it has cartridges that include

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1 the seeds, which are the isotron brachytherapy
2 sources. And the package can also be expanded to
3 include additional software that puts three-
4 dimensional ultrasound images, real-time into the
5 treatment planning part of the SeedSelectron so that
6 you can do this procedure in the OR at the time of
7 evaluating a patient. And you go directly from the
8 ultrasound through the treatment planning system to
9 the delivery of the seeds, making up the seed matrix
10 and delivering the seeds all at one time.

11 Okay. Well, let's see what the
12 SeedSelectron is. First of all, it's a computer-
13 driven seed assembly and seed delivery system. It has
14 cartridges that are located here that include either
15 the isotron seeds or the spacers. The SeedSelectron
16 drive cable is connected in here to the needles that
17 go into the -- this is used for prostate treatment,
18 and this is a view of the cassettes. One is the seed
19 itself, and the other is the spacer system.

20 And this is a low dose remote-afterloader.
21 It is computer driven, you use the computer to
22 assemble the seeds in the configuration that you want,
23 and you use the computer to deliver the seeds into the
24 patient. You do manually move each time you want to
25 delivery a new seed train, you'll connect it to a

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1 different needle that's already implanted into the
2 patient. So you'll manually reconnect the
3 SeedSelectron to the needle that you're using for
4 delivery. And you can use auxiliary treatment
5 planning systems to do your treatment planning, and
6 then you can manually put the information into the
7 SeedSelectron. Or if you get the complete package of
8 the FIRST system, you will get additional software.

9 Now, this is the same unit that you would
10 see with the SeedSelectron, but there's additional
11 software in here that will connect to the ultrasound
12 probe is right in here so that you have a spiraling,
13 three-dimensional. You get an image of the prostate,
14 you do your mapping and your planning off of the
15 three-dimensional image of the prostate here, and then
16 you use the SeedSelectron software to map out where
17 you want to put the seeds and the spacers, and then
18 you use the SeedSelectron software to deliver the
19 seeds to the prostate. Yes?

20 DR. WILLIAMSON: In the -- so the device
21 actually without -- deposits the seed under motor
22 control.

23 DR. HOWE: Yes.

24 DR. WILLIAMSON: Once the operator
25 connects the meter to the device, there doesn't have

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1 to be a manual intervention to get it to deposit
2 seeds.

3 DR. HOWE: It will assemble the seeds, and
4 it will also deliver the seeds by backing back out of
5 the needles that are already placed in. Dr. Nag?

6 DR. NAG: Yes. I think we have to
7 associate some of the marketing hype from the reality.
8 First of all, isotron does not mean a new seed.
9 Isotron just means I-125c --

10 DR. HOWE: But what it means is this is a
11 specific model of a seed and put into a cassette so
12 that this particular seed is not used independently
13 for brachytherapy. It is put into this cassette and
14 used with the seeds.

15 DR. NAG: But what I'm saying is the same
16 as a regular iodine seed.

17 DR. HOWE: Absolutely.

18 DR. NAG: So there is no stain in the
19 seed. Manually we can always put a seed baser on our
20 own, so although the company hypes it as something
21 new, it's not really something new in terms of
22 radiation safety. That's what I'm trying to point
23 out.

24 DR. HOWE: Well, the device is new then.

25 DR. NAG: Right, the device is new. I

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1 mean you could manually put the needle in and pull it
2 out yourself. And here the motor is doing that for
3 you, so that's -- it's been hyped up, but we have to
4 differentiate the hype from the reality. Otherwise,
5 the way they say it it's like a brand new thing. The
6 online software, I mean for years we have been taking
7 a computer up to the OR, doing the treatment planning
8 in real time. So, again, that is not new.

9 DR. HOWE: It's a package --

10 DR. NAG: Yes.

11 DR. HOWE: -- that comes from one company.

12 DR. NAG: Right.

13 DR. HOWE: And the other point I wanted to
14 make is that this is a remote-afterloader, but it's a
15 low dose remote-afterloader. And most low dose
16 remote-afterloaders have a certain activity source
17 that goes into a dwell time and then comes back out.
18 This is different because it is permanent implant. So
19 if you were to look at the regulations for the remote-
20 afterloader, even the low dose after-loader, you'll
21 find that there are many parts of the regulations in
22 600 that don't apply to this particular device.

23 So then you look at its unique
24 characteristics, and you say, well, the actual
25 delivery of the seeds into the prostate, the permanent

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1 implant aspects are very similar to, as Dr. Nag said,
2 as the manual brachytherapy. But there are the
3 remote-afterloading aspects of the device that don't
4 fit into the manual brachytherapy. So what we've done
5 is we've said, okay. our basic guidelines are if you
6 can fit a device or a drug exactly into a portion of
7 the regulation, that's the portion it goes into. This
8 particular device does not fit exactly into 600 and it
9 does not fit exactly into 400. And if it doesn't fit
10 exactly into one of those categories, it goes into
11 1000.

12 So the next thing you do is you try to
13 figure out what are its unique characteristics and
14 what are its characteristics that are similar to the
15 rest of the regulations? Part 35 has just been
16 revised. It tries to be performance based, risk
17 informed, and so we don't want to reinvent any wheels.
18 So what we do is we sit down with this device and we
19 say, okay, which attributes does it have that can fit
20 under 400, which attributes does it have that will fit
21 under 600? And you start at the beginning of the
22 regulation and you go through and you identify those
23 elements that fit it well and you keep those elements.
24 And then you identify those elements that don't fit it
25 well and you develop guidance for those particular

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1 parts. And we do have a Section 3512.

2 And my next question before I get to you,
3 Dr. Nag, is how many people brought their regulations
4 with them? Okay. If you don't have your regulations,
5 I made copies so that we can follow along. Okay.

6 CHAIRMAN CERQUEIRA: Dr. Vetter and Dr.
7 Williamson got extra credit for bringing the --

8 (Laughter.)

9 MS. MCBURNEY: That's right.

10 CHAIRMAN CERQUEIRA: I have them, I just
11 don't know which version to use.

12 DR. HOWE: Well, hopefully, I've given you
13 the most current version. Dr. Nag?

14 DR. NAG: Yes. Actually, almost
15 everything is the same as any permanent implant. The
16 only difference being that the -- you have everything
17 the same as a permanent implant. Only that last part
18 where instead of manually pushing the needle in, it's
19 a mechanical thing that is pushing the needle in. So
20 all the regulations and all the steps are the same as
21 a permanent implant.

22 DR. HOWE: But there are additional
23 requirements for the 600 that address the device and
24 the functioning of the device and its use that are
25 applicable to this unit too. So what you're saying

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1 about -- is true, but there are also some other
2 aspects on the device that come into play with 600.
3 And one of the first things you do is we use 3512 to
4 provide this information -- to submit an application
5 to use this device. And in 3512, you have to submit
6 a 313, which includes a 313(a), and you have to
7 identify facilities, individuals responsible for the
8 radiation safety program and the radiation safety
9 program.

10 And so the first thing we're going to look
11 at is who can be an authorized user for this? Well,
12 it's both manual brachytherapy and remote-
13 afterloading. So, clearly, the remote-afterloading
14 people understand the computer-driven aspects of it,
15 the manual brachytherapy people understand the
16 permanent implant seed part. So there is no reason to
17 exclude either one of these types of authorized users
18 from using this device, provided that they have --
19 that we ensure they have the training and the other
20 aspect that is not covered under 600 or under 400.

21 DR. NAG: Again, I think I went even
22 further, because all the training you need is the same
23 as the manual brachytherapy because online treatment
24 planning is done in manual systems. The computers are
25 planning where the seeds are going. That is also in

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1 the manual system. Again, I want to point out the
2 only difference is instead of you manually pushing the
3 seeds in, it's the machine pushing the seeds in. So
4 everything is the same as the manual permanent
5 brachytherapy system.

6 DR. HOWE: And I think you're right. It's
7 just that in 35.490 and 35.940 there wasn't a
8 distinction to pull out the interfacing that comes
9 into the 690. So I think what I've essentially said
10 here is that if you're an authorized user with 490 or
11 940, with work experience in remote-afterloading
12 brachytherapy, and in that I just went to the key
13 points of the remote-afterloading work experience
14 criteria that talked about more of the interfacing.

15 DR. WILLIAMSON: What is 960 just for our
16 reference?

17 DR. HOWE: Nine-forty. This is 490, 940.
18 This is the manual brachytherapy.

19 DR. WILLIAMSON: Okay. All right. I see.

20 DR. HOWE: Okay. I may misspeak some
21 digits here.

22 DR. WILLIAMSON: Yes. So you mean for an
23 authorized user either under 400 applications or 600
24 applications would be acceptable is what you mean to
25 say.

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1 DR. HOWE: And what I'm saying is that in
2 this particular case, because I'm -- you use 490, 940,
3 but you want those interfacing experiences, which you
4 may already have because that's how you do manual
5 brachytherapy. But in our regulations it's not in
6 there, okay? So I don't think this is a huge hurdle
7 or a hurdle. I think it just has to be explained.
8 And then the HDR people you meet the criteria of 690,
9 960 with work experience in manual brachytherapy.
10 Now, I think probably if you come through your
11 residency programs, you probably have manual
12 brachytherapy in addition to HDR and --

13 DR. WILLIAMSON: It's a required component
14 of the ACGME approved residency.

15 DR. HOWE: Right. And what our -- I have
16 more detailed guidance that just pulls out -- if you
17 look at 490 and 690, you'll see that there's some
18 elements in the experience part that are just slightly
19 different, because one is more instrument oriented,
20 and the other is more purely treatment oriented.

21 DR. NAG: I agree with Number 2 because
22 even if you have remote-afterloading experience for
23 permanent brachytherapy, you do need the manual
24 brachytherapy. But I don't agree with your Number 1
25 because basically someone who can do a permanent seed

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1 implant can basically do -- you know, use this without
2 knowing what an HDR afterloading is.

3 DR. HOWE: Well, this was not supposed to
4 be HDR experience, it's supposed to be --

5 DR. NAG: Yes, remote-afterloading.

6 DR. WILLIAMSON: She's basically saying it
7 can be either one, Subir, so I don't see why there's
8 a problem.

9 MS. MCBURNEY: Yes. And I think that you
10 do need some experience or the training from the
11 manufacturer, even if --

12 DR. NAG: Yes, always.

13 MS. MCBURNEY: -- all you've been doing is
14 manual, because the nuances of that device.

15 DR. WILLIAMSON: Or even if you have been
16 doing HDR, you still need --

17 MS. MCBURNEY: Sure.

18 DR. WILLIAMSON: -- training on the
19 specific device. So I think the inclusiveness of the
20 order seems quite appropriate.

21 MS. MCBURNEY: Right. That seems
22 reasonable.

23 DR. HOWE: And if you look at the elements
24 for the 490 that I would look for that are not
25 addressed in 490, they will be preparing treatment

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1 plans, calculating doses, using survey meters,
2 selecting the proper dose and how its administered
3 using remote-afterloaders. That's not a high barrier.
4 I think those things are already being done, it's just
5 that they're not in 490 right now. They're over in
6 690. So those are the tasks that you would indicate
7 you have work experience in.

8 DR. NAG: Okay. Now, again, I don't want
9 to belabor the point, but the way you have it someone
10 who has excellent knowledge of permanent
11 brachytherapy, has never done a remote-afterloading
12 brachytherapy will not be able to use this system, and
13 that's what I object to.

14 DR. HOWE: Okay.

15 DR. WILLIAMSON: Well, is that true?

16 DR. NAG: Yes. The way you have it
17 written here it is. The way I read it, that if I came
18 to a permanent implant and I have done that for 20
19 years and I have never done a HDR, I wouldn't be able
20 to use the system, which is wrong.

21 DR. WILLIAMSON: So do you consider
22 acceptable experience to supplement 490
23 qualifications?

24 DR. NAG: Yes.

25 CHAIRMAN CERQUEIRA: Ralph?

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1 MR. LIETO: I guess kind of if we can --
2 I'm trying to understand, and maybe you can refresh my
3 memory, is why does this fit into the 600 also, just
4 simply because it's remote?

5 DR. HOWE: It is a remote-afterloader, so
6 it would go into 600 automatically. But if you try to
7 fit it in 600, you can't fit it into 600 because it is
8 really a cross between the two. It is more like a
9 permanent implant in certain aspects. It is a device
10 with the characteristics of remote-afterloading in
11 another.

12 MR. LIETO: I ask Jeff a question.
13 Remote-afterloaders I always thought you couldn't be
14 in the room --

15 DR. NAG: No, no. That's high-dose rate
16 remote-afterloader.

17 MR. LIETO: Is that just --

18 DR. DIAMOND: The reason this is a hybrid
19 is except for this one device, which is new and I have
20 not used, the purpose of having remote-afterloader is
21 so that you can deliver a high dose rate source remote
22 from the patient and the source protection. In this
23 particular case, the reason they're using a remote-
24 afterloader system is because there's a sense or a
25 claim at least on the basis from the manufacturer that

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1 by having the seeds delivered mechanically as opposed
2 to under manual dexterity, you'll have a more uniform
3 spacing of the seeds and therefore a more perfect
4 implant.

5 So, really, although it is a remote-
6 afterloader, the entire basis, the entire logic of it
7 being a low dose rate system really pushes it much
8 more towards the 400 series with the exception that
9 it's a device delivering it.

10 MS. MCBURNEY: But it's a device.

11 DR. WILLIAMSON: It's an automated seed
12 positioning device, I would say, rather than --

13 DR. HOWE: Well, it's also a seed assembly
14 and positioning.

15 DR. WILLIAMSON: But there are other such
16 systems besides this that assemble seeds.

17 DR. NAG: Yes. Manually you can do that.

18 DR. HOWE: Manually, yes.

19 CHAIRMAN CERQUEIRA: Dick, you've been
20 waiting patiently.

21 DR. VETTER: Well, if a person has -- if
22 an authorized user has experience with manual
23 afterloading and receives training from the
24 manufacturer on this device, wouldn't that satisfy the
25 requirements?

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1 DR. HOWE: Well, I think what I'm hearing
2 you say is that I could probably keep most of my
3 elements except for the one with using remote-
4 afterloaders and make that more -- that can be met by
5 the user training and experience under the vendor.

6 DR. NAG: Yes.

7 DR. HOWE: Not user training but the
8 vendor training.

9 DR. WILLIAMSON: It is really an
10 incremental advance upon an already established
11 clinical art.

12 DR. HOWE: Yes.

13 DR. WILLIAMSON: I agree. If you were
14 going to require some additional kind of remote-
15 afterloading experience beyond normal training and
16 familiarization with this device, I think that would
17 be a mistake.

18 DR. HOWE: Okay. And then when you go to
19 600, you look at the things that are not in 600
20 because of the type of devices you have, and you end
21 up with tasks like ordering, receiving, unpacking
22 radioactive materials safely, performing the related
23 radiation safety surveys, preparing, implanting and
24 removing brachytherapy sources and maintaining running
25 inventories. Because an HDR person doesn't have to do

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1 any of those things. So those are not high barriers
2 to the 690 person either, but those are important
3 elements that they may not do every day.

4 Now, we have not put -- I have not put any
5 hours on this because it's performance based, okay?
6 Different people are at different levels. You may be
7 through a residency program that you've handled manual
8 and remote-afterloading, so you come already prepared,
9 okay? Now, the next one is --

10 CHAIRMAN CERQUEIRA: I guess sort of as
11 somebody who isn't involved in this area for the
12 radiation oncologists in the room, I mean what you're
13 basically doing is you're basically using the
14 ultrasound to define where to put the seeds, and then
15 the computer algorithm will locate the coordinates and
16 do the implants. But how well validated is the
17 algorithm? How consistently does it --

18 DR. NAG: This has been done for many
19 years by --

20 CHAIRMAN CERQUEIRA: Manually, right.

21 DR. NAG: You know, the computer has been
22 through the treatment planning for many, many years,
23 but what we used to do is after the computer gave the
24 coordinates, we were manually pushing and you can
25 assemble the seed and spacer outside manually too.

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1 And then were pushing the needle in and putting the
2 seed in manually. The only difference here -- the
3 computer part is not new, the computer treatment
4 planning is not new, seed and spacer assembly is not
5 new. The only new thing is instead of manually
6 pushing that seed train in, a robotic system is
7 basically pushing it in.

8 CHAIRMAN CERQUEIRA: But I guess the
9 question is how -- I mean with computer algorithms, if
10 you're off by 90 degrees or something, you could
11 basically --

12 DR. NAG: Yes. That has been well
13 regulated with implants for the last ten, 15 years.

14 DR. WILLIAMSON: That's also covered in
15 the provision which replaced the QMP, which outlines
16 a minimal protocol for commissioning radiotherapy
17 planning systems in general.

18 CHAIRMAN CERQUEIRA: Okay.

19 DR. WILLIAMSON: So that would be covered,
20 at least from a regulatory point of view.

21 CHAIRMAN CERQUEIRA: Yes. Dick?

22 DR. VETTER: When placing the seeds
23 manually, the radiation oncologist or urologist is
24 very careful that the seeds don't follow the needle
25 when you withdraw it. What prevents that from

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1 occurring in this case with the remote-afterloader?
2 What prevents the seeds from being drawn out with the
3 needle?

4 DR. NAG: I think the manufacturer can
5 probably tell a little better about mechanism, but I
6 know basically the needle sort of -- you join it and
7 the needle gets pulled out with the seeds remaining
8 there. But if one of the manufacturers wants to tell
9 a little more detail, they can.

10 DR. HOWE: I think the needle stops --

11 DR. WILLIAMSON: If the manufacturer would
12 like to come to the microphone, we'd welcome your
13 input.

14 DR. VETTER: The needle has to be
15 withdrawn, and the seeds will follow that needle --

16 DR. NAG: No, if you have a stylet.

17 DR. VETTER: Oh, the machine has a stylet?

18 MR. HORN: Good morning. My name is
19 Raymond Horn. I'm with Nucletron Corporation, and I
20 have the business responsibility for this product.
21 The SeedSelectron uses a push wire, and that push wire
22 remains in place while the needle is pulled back for
23 the length of the seed spacers. And then the push
24 wire is retracted so the claim of the manufacturer is
25 that this is done in a repeatable way as opposed to a

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1 manual method, which is completely based on the
2 dexterity of the clinician.

3 DR. HOWE: Okay. So the next area is in
4 remote-afterloading you have an authorized medical
5 physicist. And in looking at this the authorized
6 medical physicists, the only ones we list on our
7 license are those that are actively dealing with HDR
8 units, teletherapy units and gamma knife units. Now,
9 if we required an authorized medical physicist, we
10 would be eliminating those medical physicists that are
11 dealing on a daily basis with manual brachytherapy,
12 and so I believe that we want to have a physicist that
13 does not have to meet all the requirements of the
14 authorized medical physicists. So I've given them a
15 name, permanent implant low dose rate remote-
16 afterloader medical physicist.

17 (Laughter.)

18 DR. HOWE: Just to clarify that this is
19 what they're capable of. And who would I put in this
20 category? Clearly, I would put an AMP with work
21 experience in manual brachytherapy. I don't think
22 there's any question about that. The next one is how
23 do I characterize those people that are not qualified
24 to be AMPs because they're not -- and the other thing
25 is this device will go into facilities that don't have

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1 HDRs and teletherapy units and gamma knives, and so
2 there won't be any authorized medical physicists
3 listed on the license. So I can't use an authorized
4 medical physicist listed on the license.

5 DR. WILLIAMSON: Unless they do strontium
6 90 therapy.

7 DR. HOWE: But they won't always be in
8 Puerto Rico and Hawaii.

9 (Laughter.)

10 So this device will go other places. So
11 I said, okay, let's use what we currently have: Board
12 certified with work experience in manual brachytherapy
13 and full calibration measurements and period spot
14 checks for low dose remote-afterloaders. What I did
15 was I picked those elements that I thought were
16 probably more under --

17 DR. WILLIAMSON: Okay. So some questions:
18 Board certified by whom? What would be the criterion?

19 DR. HOWE: The same boards that you see in
20 the --

21 DR. WILLIAMSON: Subpart J?

22 DR. HOWE: In Subpart J.

23 DR. WILLIAMSON: And when Subpart J
24 disappears, then what?

25 DR. HOWE: Then it will be the boards that

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1 are recognized for the 600 authorized medical
2 physicists.

3 DR. WILLIAMSON: Are these seeds when they
4 are supplied by the vendor, do they come in cassettes
5 or does the operator manually load them into
6 cassettes?

7 DR. HOWE: The do come into -- they come
8 in cassettes. You're not supposed to take them out
9 until you get ready to ship them back, but you can
10 also ship them back in the cassettes.

11 DR. WILLIAMSON: And what calibrate --
12 where's the vendor person? What provision is there
13 for the user to calibrate or to verify the calibration
14 for the seeds?

15 MR. HORN: Sure. The seeds arrive pre-
16 sterile and pre-shielded, and I'd point out that we
17 claim higher level of red radiation safety and ease of
18 use with this product than even the manual method.
19 They come with a certificate of calibration. Then the
20 user would excise one of the seeds into -- or multiple
21 seeds into a well chamber. We make an insert that
22 fits PTW or standard imaging chambers that connects
23 directly, so there's no manual handling of the seed,
24 and then the insert is placed in the well chamber and
25 the standard measurements are made the way they are

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1 now. The activity level is entered into the planning
2 system exactly as you would now with the manual
3 system. Does that answer your question, Jeff?

4 DR. HOWE: The part that hasn't been
5 addressed yet is that in Part 35, both for manual
6 brachytherapy and HDR, seeds have to be calibrated in
7 accordance with nationally recognized standards and
8 using instrumentation that meets the qualifications in
9 630. And so if the manufacturer can provide evidence
10 that that's how the seeds are calibrated, then the
11 licensee can use the certifications coming in from the
12 manufacturer that these are the seeds in a certain
13 activity and then do a check. Does that help answer
14 your --

15 DR. WILLIAMSON: I guess. One follow-up
16 question for Mr. --

17 DR. HOWE: Horn.

18 DR. NAG: Horn.

19 DR. WILLIAMSON: -- Horn, Mr. Horn. The
20 APM protocol for doing this is currently specified by
21 Task Group 56, which suggests you should ask, say, ten
22 percent of the seeds. Is there a provision for when
23 you calibrate these seeds not violating their
24 sterility in being able to get them back into the
25 cassette?

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1 MR. HORN: No. You consume the seed when
2 you use it for an external calibration. And I'll
3 point out that the system will also provide 100
4 percent relative check on each seed, and you can
5 generate a report that provides the variance.

6 DR. WILLIAMSON: Is there some sort of
7 detector --

8 MR. HORN: Yes.

9 DR. WILLIAMSON: -- inside the machine?

10 MR. HORN: So there's a detector.

11 DR. WILLIAMSON: What kind?

12 MR. HORN: I don't know the exact diode
13 makeup.

14 DR. HOWE: And so by -- as you'll see
15 later, by using some of the criteria in 35.400, the
16 user and the facility can use the manufactured in
17 place of having to measure each seed individually but
18 then can use the machine to kind of verify a relative
19 precision, not accuracy.

20 DR. WILLIAMSON: One additional question
21 about this. At least some systems that have been
22 proposed and some that have been put together or
23 assembled by individual institutions on an
24 investigational basis actually have feedback between
25 the two parts of the system so that there would be

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1 some mechanism for determining where the seeds were
2 positioned, feeding this information back to treatment
3 planning, and then the computer would churn away and
4 develop a modified treatment plan that would take into
5 account positioning errors. Is there any such
6 feedback loop with this system that you know of? Is
7 there, for example, a seed position detection
8 capability beyond simply positioning the needle in the
9 stylet at a given coordinate?

10 MR. HORN: So the system here that we call
11 the -- has the trade name of SeedSelectron is
12 specifically the automatic delivery mechanism, and
13 that's, I believe, what's at question for licensure.
14 We make treatment planning systems that can be used
15 with this that allow for not an automatic but a manual
16 identification of seed juxtaposition or needle
17 positioning. But that's all composed in the treatment
18 planning system and it's not part of the seed delivery
19 system itself.

20 DR. HOWE: Actually, what --

21 DR. WILLIAMSON: I'll repeat my question
22 because it didn't get answered. So, a --

23 DR. HOWE: But let me just clarify one
24 point first. What I'm providing guidance for is not
25 just the SeedSelectron but also the SeedSelectron and

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1 the FIRST. And it depends on whether they buy the
2 SeedSelectron independently or they get the whole
3 package on the FIRST, because the FIRST does bring in
4 a criteria for 600 on computer program verification.
5 And so if you're getting the FIRST, you've got to go
6 over there and make sure you meet that criteria. If
7 you're just getting the SeedSelectron, then you have
8 to verify your computer treatment planning programs
9 under 400. So this guidance will cover both packages,
10 the SeedSelectron by itself and also the FIRST, which
11 will be your treatment planning program with it.

12 DR. WILLIAMSON: Does the SeedSelectron
13 claim to have the capability either through analysis
14 of the ultrasound images or by fusion of radiographic
15 projections with the ultrasound images, of being able
16 to independently confirm the location of the seeds and
17 the capability of feeding that information back to the
18 treatment planning system?

19 DR. HOWE: I don't know whether the FIRST
20 --

21 MR. HORN: The answer to that is no.

22 DR. WILLIAMSON: Okay. Thank you.

23 DR. HOWE: I thought the FIRST --

24 DR. NAG: There is no system that can
25 identify the seed reliably on ultrasound after the

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1 position. I mean the closest you can do is say this
2 is where it will drop and therefore assume it's there
3 or you can manually locate within one or two
4 millimeters of where you dropped it and say, "I think
5 this spec is the seed."

6 DR. WILLIAMSON: Well, there's actually
7 one commercial product that claims the capability of
8 doing that, so that's not completely true.

9 DR. HOWE: So my question to the
10 manufacturer is what about the FIRST system? Does the
11 FIRST system say it can identify that the seeds are
12 placed?

13 MR. HORN: It does not automatically
14 identify them without manual intervention of the user.

15 DR. HOWE: Okay.

16 MR. HORN: It is possible to identify them
17 in the plan manually.

18 DR. HOWE: So then I have -- getting back
19 to my medical physicist, I have an alternative pathway
20 and that is that you meet -- you have training and
21 experience in the elements that are in manual
22 brachytherapy and those things for low dose remote-
23 afterloaders, so that you can come through by either
24 being an authorized medical physicist, being board
25 certified but having your experience in manual

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1 brachytherapy or being a medical physicist that's not
2 board certified but meets the training and experience
3 criteria that would have made you eligible to be an
4 authorized medical physicist if you had HDRs,
5 teletherapies and other things.

6 CHAIRMAN CERQUEIRA: Dick?

7 DR. VETTER: How many low dose remote-
8 afterloaders are there in the country?

9 DR. NAG: Handful.

10 DR. VETTER: Yes. I just don't think
11 there are many physicists that would fit category 2 or
12 3.

13 DR. HOWE: Okay. Then what I can also do
14 here is I can address the elements I'm looking for and
15 put the low dose remote-afterloading experience into
16 the vendor training part.

17 MS. MCBURNEY: Yes. That would work.

18 DR. WILLIAMSON: That would work better,
19 yes.

20 CHAIRMAN CERQUEIRA: Ralph and then Dr.
21 Nag.

22 MR. LIETO: I really think we're making a
23 mountain out of a molehill here, because if a
24 physicist is qualified to do manual iodine seed
25 brachytherapy, they should be qualified in the

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1 radiation safety aspects in terms of control,
2 accountability and treatment planning. I think we
3 really -- this new definition is really unwarranted,
4 because if you're going to do this for this type of
5 device, then my feeling from a radiation safety
6 standpoint would be, well, why don't you do it for
7 anybody that does iodine seed implants, even if it's
8 manual? Why shouldn't they have those qualifications?
9 And right now you don't.

10 CHAIRMAN CERQUEIRA: Dr. Nag?

11 DR. NAG: Yes. Actually, that was part of
12 my point that, a, are you going to -- because of the
13 remote-afterloader, are you going to have the
14 witnesses that are required to be on-site at all time,
15 because that's not needed. I mean in the same kind of
16 implant where we are using a computer online, you
17 don't have witnesses standing by you at all times; you
18 don't need to. And are you going to be asking
19 witnesses to be on-site. Basically, all you need is
20 same as the authorized user, someone with training and
21 experience in manual brachytherapy with vendor
22 training in the remote-afterloading portion of it.
23 That's all you need.

24 DR. HOWE: The criteria I was going to use
25 for who had to be physically present was going to be

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1 this particular medical physicist --

2 DR. NAG: Why?

3 DR. HOWE: -- or an authorized user.

4 DR. NAG: Okay. Well, authorized user to
5 be there. He's the one pushing it in.

6 DR. HOWE: And then if you had the medical
7 physicist there, you could also have somebody under
8 the supervision of the authorized user.

9 DR. WILLIAMSON: Like a resident, I guess,
10 but that would -- I'm wondering if this couldn't be
11 simplified to put in something that's equivalent to
12 the old alternative, the Subpart J alternative pathway
13 or board certification and the equivalent of vendor
14 supply training in this specific system. I mean I
15 think that would cover it.

16 DR. HOWE: Well, essentially what I have
17 is I have board certification here.

18 DR. WILLIAMSON: Yes.

19 DR. HOWE: And then I have the alternative
20 pathway. And the reason I'm not identifying these as
21 authorized medical physicists is because they may not
22 be at a facility where you would have an authorized
23 medical physicist. So I did not want to exclude --

24 DR. WILLIAMSON: No, I appreciate that.
25 It's just the additional conditions that have been

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1 pointed out that LDR remote-afterloading experience is
2 rather rare.

3 DR. HOWE: Right.

4 DR. WILLIAMSON: Secondly, those remote-
5 afterloading devices are not this device. And,
6 really, what is needed is specific training and
7 practice with this system.

8 DR. HOWE: Okay.

9 DR. WILLIAMSON: I mean that's what we
10 would say. So I would say there's -- it's certainly
11 useful experience to have had either high dose rate or
12 conventional low dose remote-afterloading experience,
13 but it isn't -- it's neither necessary nor sufficient
14 to guarantee somebody can use this device. So I'd say
15 the minimum we want is --

16 DR. HOWE: So essentially take this part
17 out and put it into the vendor training.

18 DR. WILLIAMSON: -- sort of a common core
19 requirements for the alternative pathway or board
20 certification and an appropriate orientation with this
21 specific system.

22 DR. HOWE: Okay. And move the experience
23 part into the vendor training.

24 DR. WILLIAMSON: I'd say that would be
25 reasonable, like you have -- has been proposed --

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1 CHAIRMAN CERQUEIRA: So, Ralph, are you
2 happy with that or do you have --

3 MR. LIETO: No, because -- well, let me
4 ask, do you have requirements for manual brachytherapy
5 for physicist requirements in the regulations?

6 DR. HOWE: For strontium 90.

7 MR. LIETO: For any of the other -- for
8 iodine seeds or anything like that?

9 DR. HOWE: We had one that you had to --
10 the authorized medical physicist had to sign off on
11 something and the rule was changed so that it's now
12 the person that's doing it has to identify, but they
13 don't have to be an authorized medical physicist.

14 MR. LIETO: So, again, I think we're
15 making more regulations, and it's not going to improve
16 anything regarding radiation safety on how things are
17 done in the clinical environment, okay? There's not
18 been anything that's demonstrated a problem with the
19 manual iodine seed brachytherapy, so why are we making
20 it that they have to be an AMP, okay? I mean there
21 are situations where you may not have an AMP there or
22 a board certified physicist.

23 DR. HOWE: That's why I'm saying --

24 DR. WILLIAMSON: Well, I think that's
25 maybe the question.

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1 DR. HOWE: That's what I'm saying is you
2 don't have to be an AMP.

3 MR. LIETO: Then let's not put it in the
4 regulations is my point. Why does it have to go under
5 regulatory space?

6 MS. MCBURNEY: It's not a regulation, is
7 it?

8 MR. LIETO: Well, it's going to be a
9 license condition. So in a sense what you're doing is
10 making a regulation.

11 DR. WILLIAMSON: Ralph, are you arguing
12 that NRC should not require as a condition of
13 licensure of this device that any physicist be
14 involved? Maybe that's what you're saying because
15 right now manual brachytherapy doesn't require a
16 physicist to be involved.

17 MR. LIETO: Right. I mean I guess pretty
18 much that's what I'm saying. In the real sense, in
19 the real world, pretty much there's always a physicist
20 there, pretty much, okay? But I just --

21 DR. WILLIAMSON: I would be uncomfortable.

22 DR. NAG: No. If --

23 DR. HOWE: I know, but even with our worst
24 manual brachytherapy misadministrations, there always
25 seems to be a medical physicist that was present.

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1 CHAIRMAN CERQUEIRA: So it sounds like
2 we're in favor of keeping that in. And, Dr. Howe, I'm
3 looking at the time and the number of slides that you
4 have left. Are we going to be able to cover
5 everything?

6 DR. HOWE: Well, I can do -- the next
7 thing you have to do is you have to do the radiation
8 safety program. In the radiation safety program, I'm
9 saying you use -- you go to the regulations and what
10 the regulations -- the regulations that pertain for
11 permanent implant brachytherapy in Parts A through C,
12 then you follow those. And those parts of the
13 regulation that pertain to low dose remote-
14 afterloaders in A through C you follow those. So
15 you've captured everything and then there are a few
16 things that may not be captured quite right. And this
17 one you may or may not like. We're having problems
18 defining what completion of the procedure means. So
19 I wanted the licensee to define for this particular
20 procedure what do you mean by completion of the
21 procedure in the written directive so that we have a
22 -- everybody has a fair understanding of how you
23 determine that you delivered what you expected to
24 deliver?

25 DR. NAG: But that's the same problem with

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1 any permanent implant, even the manual permanent.

2 DR. HOWE: Absolutely.

3 DR. NAG: I think what I'm trying to say
4 that you are making it unnecessarily complicated.
5 Only thing you need to do with the whole system is
6 make it the same as a permanent implant, requirement
7 for authorized use, requirement for witnesses,
8 requirement for everything else, plus training from
9 the vendor on the use of the equipment. That's the
10 only sentence you need to add. Everything else will
11 follow automatically.

12 DR. WILLIAMSON: Well, in manual
13 brachytherapy there is no requirement for a physicist.

14 DR. NAG: Right. So why do you need it
15 here?

16 DR. WILLIAMSON: Well, I think you do.

17 DR. NAG: Why? I mean then you will need
18 for it a manual one.

19 DR. WILLIAMSON: But I certainly would be
20 very uncomfortable going on record supporting that we
21 don't need a physicist involved.

22 DR. NAG: But then we are seeing a
23 permanent implant in the OR, using computer, using
24 treatment planning, again without any witnesses. What
25 difference is this? There's no difference at all.

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1 The only difference is instead of us putting the seeds
2 in manually we are connecting it and letting the
3 machine push it in.

4 DR. WILLIAMSON: Well, the only difference
5 between remote-afterloading is that a machine is
6 putting the source in place and then automatically
7 retracting it.

8 DR. NAG: Right.

9 DR. WILLIAMSON: And we've come to the
10 conclusion that that device requires some supervision
11 or review, an assessment, commissioning and so on by
12 an authorized medical physicist.

13 DR. NAG: The commissioning of the
14 machine, not placing of the seed.

15 DR. WILLIAMSON: Even something as simple
16 as the Novoste remote-afterloading device also
17 requires an element of physics attention in regulatory
18 space. So why would you think that this element does
19 not?

20 CHAIRMAN CERQUEIRA: So we're getting --
21 Ralph and Dr. Nag feel that you don't need a
22 physicist. Now, Dick, you felt that it was very
23 important to have one.

24 DR. VETTER: Well, I'd be -- since this is
25 a new device, I have no experience with it, perhaps

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1 that's why I'm a little -- I'd be a little
2 uncomfortable without having a physicist involved
3 relative to confirming the treatment, not the actual
4 implant procedure but confirming the treatment plan,
5 making sure things are working out okay, and then if
6 there are problems that develop, having a physicist
7 involved in investigating those.

8 DR. NAG: Right. I mean I'm not against
9 having the physicist as part of the whole plan, on the
10 team, but I don't think you need a physicist to be
11 physically present there for each application.

12 DR. WILLIAMSON: This isn't even being
13 argued. This is not being argued.

14 MS. MCBURNEY: No, that's not being
15 argued.

16 DR. WILLIAMSON: We're talking about
17 quality assurance -- and spot checks and basically
18 having a physicist involved in the assessment and
19 implementation of this device. Donna-Beth has not
20 mentioned physical presence. I would agree with you
21 that we don't need to require physics presence at
22 every single treatment. I think the physicist maybe
23 can substitute for authorized user under some
24 circumstances that's been decided previously, but we
25 haven't discussed that yet.

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1 CHAIRMAN CERQUEIRA: But, Donna-Beth, how
2 do we then make sure that there's a physicist involved
3 at some point during this procedure but make it clear
4 that during the actual procedure itself the physicist
5 doesn't have to physically be there?

6 DR. HOWE: Well, I think you really do
7 that through physical presence, but because you
8 indicate that you have to have one of these physicists
9 or the authorized user physically present, that
10 doesn't mean the physicist has to be physically
11 present every time, but that tells you that there is
12 an authorized medical -- there is a physicist that's
13 involved in this procedure, that's going to be listed
14 on the license, and he's going to do what he's
15 supposed to be doing. And then the licensee has the
16 option of having either the physicist or the
17 authorized user or someone under the supervision of
18 the authorized user present during treatment. But you
19 get at it, I think, through physical presence, because
20 that's where you say I need a medical physicist
21 associated with this device.

22 DR. WILLIAMSON: The implementation of a
23 system in clinical practice through the full and spot
24 check calibrations. Really, that's all that's being
25 discussed here.

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1 DR. VETTER: I think I like that, because
2 then it allows the licensee to have the urologist
3 actually present rather than the authorized user, but
4 the physicist would have to be there. So one or
5 other. The authorized user, the physicist, urologist
6 can work on a team and decide which of the two, the
7 authorized user or the physicist, would be present
8 during the actual procedure. I like that. That gives
9 some flexibility.

10 MS. MCBURNEY: I do too.

11 CHAIRMAN CERQUEIRA: Ralph, do you want to
12 make a comment?

13 MR. LIETO: This is where we're getting --
14 like here, they're talking about the physical
15 presence.

16 DR. NAG: Yes.

17 MR. LIETO: And 615 requires --

18 DR. HOWE: And this is a conforming
19 change. In other words, 615 doesn't fit exactly. So
20 there's a conforming change for physical presence, and
21 that would be either/or.

22 DR. WILLIAMSON: It's either/or.

23 DR. HOWE: Not both; either/or. But that
24 does say that there's a physicist with the right level
25 of training and experience associated with this device

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1 somewhere in the process, and securing the room. This
2 is a conforming change to 610. Six-ten says you've
3 got to have the room locked whenever the device is
4 there. This thing has cartridges. When you finish a
5 procedure the cartridges are taken out and the device
6 has no radioactive material. So they're conforming
7 changes. You only have to have it secured when the
8 sources are there. So there are conforming changes to
9 address this device and the fact it does not need all
10 of the bells and whistles that you see in the regular
11 part of the regulations.

12 CHAIRMAN CERQUEIRA: So it seems like we
13 have agreement on what we want to do, and I guess I
14 would ask the people the way it's written would it
15 basically assure that a physicist is involved at some
16 point, yet allow the flexibility at the time of the
17 actual implantation you're not going to put undue
18 burden on the team?

19 DR. WILLIAMSON: I think it hangs on how
20 exactly we define the minimum requirements for full
21 calibration measurements.

22 DR. HOWE: In the full calibration
23 measurements, what I did was I looked and I said,
24 well, most of these things really don't pertain to
25 this device.

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1 MS. MCBURNEY: Right.

2 DR. HOWE: So I went through and I said do
3 you have to calibrate it every time you change the
4 source? No, because this gets new sources every time
5 it's used. So, first use, annually you need to check
6 the device to make sure it's working, and I went
7 through and just fit it for this device. And I think
8 you'll see I have extra slides that -- well, I guess
9 they don't go into too much detail, but --

10 DR. WILLIAMSON: I'm curious to know what
11 you came up with as the sort of required elements.

12 DR. HOWE: Okay. So for radiation safety
13 --

14 DR. WILLIAMSON: You could make it either
15 very reasonable --

16 CHAIRMAN CERQUEIRA: Let's just try to
17 keep one conversation going here. Go ahead.

18 DR. HOWE: And so this is just kind of a
19 quick outline. The next slides go into more detail.
20 I think these are in A, and we can skip through a lot
21 of these. So these are the parts of manual
22 brachytherapy that I think pertain to this device.
23 Four-ten is except a(1), and a(1) I've modified to
24 address -- where is 410? No, not 410. Sorry, that
25 was 610. These are the manual brachytherapy things

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1 that address permanent implant. These are the low
2 dose remote-afterloader elements that I think fit.
3 And 610 is except a(1), because a(1) says you've got
4 to lock the room for the device and the sources aren't
5 there most of the time, so I'm saying, hey, you may
6 want to lock it to keep the device from walking away,
7 but it's not a radiation safety problem, so you only
8 have to keep the device secure when the sources are
9 there.

10 CHAIRMAN CERQUEIRA: Ralph?

11 MR. LIETO: This isn't an operating room.
12 Most of these are done in an operating theater, okay?
13 You can't just -- I mean securing the room isn't going
14 to happen. You're going to have people coming in and
15 out.

16 DR. HOWE: And that's what I said. The
17 only time you have to have it under surveillance is a
18 conforming change to 610, and that's only when the
19 sources are there, and then the people are there.

20 MR. LIETO: But this is always done when
21 you have the seeds in the room. It's not anything
22 different than what's always done when you seed
23 implants in this type of situation. Why are we making
24 it --

25 DR. WILLIAMSON: I don't know that we are,

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1 but, Donna-Beth, may I make a suggestion?

2 DR. HOWE: Yes.

3 DR. WILLIAMSON: I think by putting up the
4 numbers here and not telling us the substance in words
5 of what you're recommending is leading to a lot of --

6 DR. HOWE: Confusion.

7 DR. WILLIAMSON: -- hypothesizing and
8 misunderstanding on the part of the Committee members.
9 So could you like make a brief verbal description of
10 each one of the requirements and explain in a positive
11 way what your bottom line is for --

12 DR. HOWE: Now, I think I'll probably run
13 out of time here.

14 CHAIRMAN CERQUEIRA: Yes.

15 DR. HOLAHAN: I think your later slides do
16 that. I was going to suggest that when we get an
17 application in --

18 DR. HOWE: We have an application.

19 DR. HOLAHAN: We have an application in.
20 We'll send you out the draft conditions that we're
21 putting on the license to review. Would that work?

22 CHAIRMAN CERQUEIRA: It would be ideal to
23 standardize it so you wouldn't have to review each
24 application individually.

25 DR. HOLAHAN: Yes. Well, that's what I

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1 was saying, that we could do a sample of what we're
2 planning on putting in the license and send it over to
3 the ACMUI for review.

4 DR. HOWE: But I've got it now in
5 concurrence. I can make modifications based on what
6 I'm hearing, and depending on how quickly the ACMUI
7 can get back to me, the licensee is not going to want
8 to wait another six months. So we may go ahead with
9 licensing guidance that will get modified based on
10 your comments later, and you will see that I -- I
11 might talk this afternoon about emerging technologies.
12 I've got a provision that we're putting up on the web
13 site that allows people to change their program to
14 match whatever is current in the web site without
15 having to come in for an amendment. So it will give
16 the licensees the flexibility to revise their program.

17 And the assumption is that when we revise
18 the web site as we gain more experience, we're going
19 to be reducing some of these things that we've put on
20 them earlier. So that would kind of meet our criteria
21 to get our licensee up and running and allow them the
22 flexibility. As you come out with maybe a release of
23 an easier system and we change that on the web site,
24 the licensees can take advantage of that. So I think
25 that's probably our compromise.

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1 CHAIRMAN CERQUEIRA: That would be a
2 preferable system, but, Patricia?

3 DR. HOLAHAN: Well, I was going to suggest
4 if the ACMUI could look at it quickly, we could do it
5 before -- we could do the first license.

6 DR. WILLIAMSON: How quickly is quickly?

7 DR. NAG: One week?

8 DR. HOLAHAN: One week.

9 DR. WILLIAMSON: One week? Two weeks?

10 CHAIRMAN CERQUEIRA: How many of these are
11 we anticipating?

12 DR. HOLAHAN: Well, we'd like to
13 standardize it.

14 DR. NAG: The first one.

15 DR. HOLAHAN: The first one, and then we
16 could send --

17 DR. MILLER: I'd like to keep ACMUI out of
18 the licensing business.

19 MS. MCBURNEY: Right.

20 DR. MILLER: Because John Szabo told me
21 that if you get into that, that puts different ethics
22 restrictions on you than you currently have as a
23 committee. But if you were to look at a sample of
24 standards that we could use, and we get buy-in on
25 that, well, then I think that gives us a path forward

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1 that we're all comfortable with.

2 MS. MCBURNEY: Would you want our
3 individual comments or have the Emerging Technology
4 Subcommittee send in that way.

5 MR. LIETO: Probably quicker individually.

6 DR. NAG: Individually.

7 CHAIRMAN CERQUEIRA: I think so too
8 because some of us won't have any real expertise in
9 these areas and be able to give you much insight. I
10 think just going to the Committee members where they
11 have the expertise in that area would be the
12 appropriate way of doing it.

13 DR. MILLER: I'm comfortable with that if
14 the Committee's comfortable with if those members that
15 are expert in this area make the comments that the
16 Committee -- they're speaking for the Committee.

17 DR. WILLIAMSON: I will be happy to
18 volunteer. I think it would be good for my esteemed
19 physics colleague, Ralph, to also participate.

20 (Laughter.)

21 DR. HOWE: Well, how timely that you
22 volunteered him.

23 DR. WILLIAMSON: Well, I think the two of us
24 will look carefully and see. I think that the way
25 we're conducting this, because we're not really

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1 understanding what Donna-Beth is exactly requiring,
2 it's difficult to give you the feedback.

3 DR. MILLER: You're struggling with it,
4 and you need a way to get past that.

5 CHAIRMAN CERQUEIRA: But I guess we have
6 to make it clear that even though the initial
7 recommendations that go on the web site are published
8 and available, that they will be modified depending on
9 the initial application and the recommendations of
10 this Committee. I think most people feel that once
11 it's on the web site and it's -- you know, it may not
12 be regulation but it's guidance and it's difficult to
13 change.

14 DR. HOWE: Well, one of the reasons our
15 35.1000 guidance is on the web site is that it is much
16 easier to change it and bring it up to date as we gain
17 additional experience. And I'll be talking to you
18 this afternoon about just one such case and what we've
19 done, and I think we've done it in a global manner to
20 make it more flexible for everybody.

21 DR. NAG: Basically, Donna-Beth, what I'd
22 like to say is that whenever you're making any
23 regulation on this, instead of trying to -- just
24 because the word, "remote," is there in all the 600,
25 basically this is nothing but a 400. All the

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1 regulation of 400 has to be in there rather than the
2 600.

3 DR. HOWE: Subir, if you look at the parts
4 of the regulation that I've referenced, you'll see
5 that if I had an option between a 400 and a 600 and
6 the 400 addressed everything I needed, I left the 600
7 out. I only brought the 600 in when it addressed
8 instrument calibration, instrument QA and the types of
9 things you want to do to make sure the system is doing
10 what it's supposed to do. So I've done that balance.
11 And that's one reason that even though I'm saying this
12 is a remote-afterloader, you're seeing an awful lot of
13 references to 400, because this is also a permanent
14 implant which is much more closely covered on the
15 actual implantation part by the 400 system.

16 DR. WILLIAMSON: May I make a suggestion
17 to our Chairman? I think since there is the
18 possibility that there could be some disagreement
19 between the three of us individuals who seem to be
20 really interested and with some experience in related
21 applications, maybe the three of us should be
22 delegated as like a --

23 DR. NAG: Subcommittee.

24 DR. WILLIAMSON: -- little subcommittee,
25 working group of the Emerging Technology Subcommittee

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1 to get together and try to achieve consensus so that
2 we don't present the staff with a divergent body of
3 opinion.

4 MS. MCBURNEY: That was what I was trying
5 to get at.

6 DR. WILLIAMSON: So we have a conference
7 call if this is allowed to sort of go over it and iron
8 out differences if we have differences in our
9 individual views.

10 DR. HOWE: I think I'd also like to see at
11 least one conference call where you could include me
12 and Ruth, because --

13 DR. WILLIAMSON: Sure.

14 DR. HOWE: -- that way you get the
15 regulator viewpoint also.

16 DR. NAG: And I think we should combine
17 that with the first application. Send the first
18 application in --

19 DR. HOWE: No.

20 DR. WILLIAMSON: No.

21 DR. NAG: -- we will look in, and then --

22 DR. WILLIAMSON: We shouldn't look at the
23 application.

24 DR. HOWE: No, no.

25 DR. WILLIAMSON: We should just look at

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1 the criteria.

2 DR. HOLAHAN: The criteria. Right.

3 CHAIRMAN CERQUEIRA: That's the only thing
4 that we should review.

5 DR. WILLIAMSON: Yes. Let's just look at
6 the licensing guidance.

7 CHAIRMAN CERQUEIRA: Charlie?

8 DR. MILLER: I don't want to get ahead of
9 ourselves today. I think we need to listen to what
10 John Szabo's going to tell you a little bit later with
11 regard to some FACA changes. I think the idea of
12 having a small subcommittee look at this is a great
13 idea, but John's going to give you some information
14 concerning when it has to be public, when it doesn't
15 and what the responsibilities of the subcommittee are
16 in reporting out to the full Committee in a public
17 forum. So I think that will help better frame how we
18 proceed on this if we could just --

19 DR. HOWE: Okay.

20 CHAIRMAN CERQUEIRA: Now, who were the
21 three that -- Williamson and Subir, okay. Right. I
22 think -- okay, that's fine. And then we'll talk to
23 John.

24 MS. MCBURNEY: And Ruth.

25 CHAIRMAN CERQUEIRA: And Ruth is --

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1 MS. MCBURNEY: Or was.

2 CHAIRMAN CERQUEIRA: Is Emerging
3 Technology.

4 DR. HOWE: Ruth, is this pretty much your
5 whole subcommittee?

6 MS. MCBURNEY: Yes.

7 DR. HOWE: Who else is on the
8 Subcommittee?

9 MS. MCBURNEY: Who was on that
10 Subcommittee?

11 DR. HOWE: Jeff, you had a question about
12 what was going to be the full calibration and the spot
13 checking. And if you look into your slides in the
14 eight series, you'll see that I did bring forth what
15 I thought was going to be part of the full
16 calibration. First one says when it has to be
17 calibrated before first medical use, and then
18 following reinstallation of the unit in a new location
19 or facility, repair of the unit that includes repair
20 components associated with source exposure assemblies.
21 So I deleted a lot of the things that were in the 600
22 series because it just doesn't pertain to this. And
23 I thought B was in intervals not to exceed a year.

24 DR. WILLIAMSON: Well, some of this we'll
25 have to look at, because I'm not sure whether --

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1 DR. HOWE: That's where it is.

2 DR. WILLIAMSON: -- guide tubes and so on
3 is relevant to the accuracy.

4 CHAIRMAN CERQUEIRA: Charlie?

5 DR. MILLER: I think it's critical that
6 Ruth be involved in this effort from the perspective
7 of the states.

8 DR. HOWE: I do too.

9 DR. MILLER: Since we have agreement
10 states that you're licensing and getting the states'
11 participation.

12 MS. MCBURNEY: And several of those states
13 are going to be among the first to get applications
14 for this type of application.

15 CHAIRMAN CERQUEIRA: Yes. No, you clearly
16 should be in it. So you've got four members that --
17 okay.

18 DR. HOWE: So if you look at those slides,
19 you'll see what I've put in and I deleted a lot of
20 stuff under 600 because I just didn't think it
21 pertained. And as a group, you can discuss that more.

22 MR. LIETO: So, Donna-Beth, in your slide
23 these are your recommendations of what should be the
24 spot check content and what should be the full
25 calibration content.

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1 DR. HOWE: Yes. And you'll see some of
2 these things like when you do source calibration you
3 go further down, maybe not in this one but you go
4 further down and you'll see that there is an option
5 for using the manufacturer's calibration. So that
6 deletes some of the things up above it. And that's
7 the way 610 is written also, once the manufacturer
8 confirms that they're meeting our requirements and
9 their initial source calibration.

10 DR. WILLIAMSON: And there is no reason we
11 couldn't -- if we had wanted some detailed information
12 about the system operation, we couldn't have a vendor
13 contact and ask them some questions.

14 DR. HOWE: I don't think so.

15 DR. WILLIAMSON: Okay.

16 MR. HORN: Thank you. I'd be delighted to
17 also provide you with --

18 CHAIRMAN CERQUEIRA: If you could use the
19 mic just for the record, please.

20 MR. HORN: I'm sorry. Thank you. I would
21 also be delighted to provide you with one or two
22 medical physicists that are using the system at
23 academic institutions that -- I think they're people
24 you know.

25 DR. WILLIAMSON: That would even be

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1 better.

2 CHAIRMAN CERQUEIRA: Could you please
3 identify yourself for the record.

4 MR. HORN: I'm sorry. I'm Raymond Horn.
5 I'm Nucletron Corporation. And there are -- for the
6 record, there are several systems in operation already
7 in North America. So it's not a question of the first
8 one to go into operation. It is the question of
9 approval or guidance for additional systems that are
10 not in broad scope license locations.

11 DR. NAG: How are these, the ones that you
12 have, how are they being licensed? Are any of them in
13 a non-broad scope area?

14 MR. HORN: No.

15 DR. HOWE: And that's what we're dealing
16 with now is the first application for the non-broad
17 scope and developing the guidance for the limited
18 specific, because we in our regulations require the
19 broad scope licensee to do a safety evaluation before
20 first use and have the Radiation Safety Committee
21 review and approve that safety evaluation. So we're
22 comfortable with the broad scopes and figuring out
23 what they need.

24 MS. MCBURNEY: Where is your company
25 located, and where will the device evaluation be done

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1 or has --

2 DR. HOWE: It's been done in Maryland.

3 MR. HORN: Nucletron Corporation is based
4 in Columbia, Maryland, so we're local. The company is
5 a Dutch-based firm.

6 MS. MCBURNEY: So Maryland has done the --

7 DR. HOWE: Maryland has done the sealed
8 source and device registration already, so that's part
9 of it is done.

10 Now, this may be controversial. This is
11 part of procedures for administrations requiring a
12 written directive. So I'm expecting that you guys
13 will have a lot of comments about this. We're finding
14 most of our -- this is computer driven. If you get
15 the FIRST system, then you're really tied into the
16 treatment planning and the three-dimensional
17 ultrasound. It's all tied together. And we're having
18 a lot of misadministrations with prostate
19 brachytherapy, and most of the root causes are
20 ultrasound imaging related, not being able to identify
21 where the prostate is, getting the wrong
22 identification, putting the seeds in the wrong place.

23 So I'm proposing that within your program
24 to assure that you're delivering what you have written
25 in the written directive, that you include procedures

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1 that assure the specifications for your ultrasound
2 unit are compatible with the SeedSelectron so that you
3 really can see them if you're supposed to be seeing
4 them and that the probe is properly positioned and
5 assure that the image system is properly functioning.
6 Now, those would be part of what in the old days was
7 a QM program. Those are noticed by licensing
8 conditions, those are internal procedures that are not
9 required on the license. So we're just suggesting
10 that you consider addressing these issues to try to
11 assure that you're delivering what you're expecting to
12 deliver.

13 DR. NAG: Again, I'm sorry. How can the
14 manufacturer confirm -- this is something an operator
15 who's putting the system in has to look and see where
16 the prostate is. I mean you cannot have --

17 DR. HOWE: This is the licensee's program.
18 This would be how the licensee ensures that what
19 they're using is fully functional and is compatible
20 and can see what it's supposed to be seeing.

21 DR. NAG: Again, to assure the ultrasound
22 will be properly positioned. Now --

23 DR. HOWE: That's the position, the
24 physicist, whatever the licensee is.

25 DR. DIAMOND: Donna-Beth?

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1 DR. NAG: And how is that different from
2 a permanent --

3 DR. DIAMOND: This is ridiculous. I mean
4 I don't mean to be too difficult here but just when I
5 read a sentence like that or a phrase like that, it's
6 ridiculous. I mean you're doing a prostate implant.
7 Who the heck is going to do a prostate implant if they
8 can't reasonably visualize the prostate gland? That's
9 like telling me that I should go and make sure the
10 patient's alive before I treat the patient with
11 radiotherapy, I mean it's just ridiculous.

12 DR. NAG: Except that I know that there
13 have been cases where the person who's doing an
14 implant for the first time is putting seeds in the
15 bladder. But you cannot -- I mean in a permanent
16 implant the same things happens.

17 DR. HOWE: Within the last year we've had
18 prostate implants where they haven't gone in the
19 prostate; they've gone into a different area that's
20 centimeters away. We've had -- a little bit further
21 back, we've had users that used an ultrasound unit
22 because they believed ultrasound was ultrasound that
23 couldn't even image the prostate. Now, what they saw
24 we have no idea, but we do get those dramatic events.

25 DR. WILLIAMSON: Remember the tale of the

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1 distribution of practitioners that these regulations
2 are targeting. I mean there are some people who are
3 so many standard deviations out of what you'd consider
4 acceptable practice. What this is trying -- this is
5 what this is targeted to, not --

6 DR. DIAMOND: I'm not going to be reading
7 this, I assure you.

8 CHAIRMAN CERQUEIRA: The problem we're
9 having here it sort of goes into this -- I mean these
10 are issues that the local Privileging Committee at the
11 hospital needs to address in terms of who should be
12 qualified to do that. This really goes beyond the
13 issue of radiation safety.

14 DR. NAG: Question.

15 DR. DIAMOND: This goes far beyond
16 radiation -- the purview of this Committee. This is
17 practice of medicine, and we've had this discussion
18 whether we are talking about this in many different
19 context before, but this is really why any time a
20 physician, for example, applies to perform a given
21 privilege, let's say an individual wanted to
22 electrophysiology or an individual wanted to do
23 interventional cardiology, that's why the Credential
24 Committees exist. They wanted to know about your
25 training, the number of cases you've done. This is

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1 what they do.

2 CHAIRMAN CERQUEIRA: There are mechanisms
3 in place for doing these things, and there is QA that
4 goes on with this, and if people have problems such as
5 this, it is reviewed by the hospitals. I understand
6 what you're getting at here, it's obviously very
7 important, but I'm not sure that it's the role of the
8 NRC to set regulations or guidance that would deal
9 with this.

10 DR. HOWE: The other thing you need to
11 understand is that this won't be used exclusively in
12 hospitals, so you're not going to have that safety net
13 for all of our users. And this is more QA than
14 getting into --

15 DR. NAG: But this is exactly the same as
16 the permanent manual implant. I mean if you were are
17 going to have this requirement for the SeedSelectron,
18 I mean you have to have it for the permanent implant.
19 I mean if the person is going to make a mistake
20 putting the probe in the wrong place here, that person
21 is going to make the same mistake pushing the wrong
22 probe and manually putting the seed in. There is
23 absolutely no difference. That's all I'm trying to
24 tell you.

25 DR. HOWE: I think in some respects when

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1 you get these computer interfaces where you're not
2 doing those manual moving data from one point to the
3 other, it does become a bigger part of the problem of
4 ensuring the whole package.

5 DR. NAG: You still have to know where the
6 prostate is.

7 DR. WILLIAMSON: Yes. I think Subir's
8 point is right on. The misadministrations have been
9 reported, not for the SeedSelectron but for manual
10 brachytherapy with prostate implants. This is a
11 really important point I think you bring up. I would
12 like to say in response to David mainly I think that
13 NRC has no choice but to get involved in this in some
14 respect, because misadministrations are being
15 reported. They have to do something if only as
16 information notices and guidance where they can. I
17 think the legal problem is is there is a basis for
18 requiring something additional beyond 35.400 as a 1000
19 device because this device, this Nucletron system has
20 some additional novelty and engineering involved in
21 it. I don't know that you -- other than putting the
22 same thing in an information notice saying, "We advise
23 you do this," you can require people to do this as a
24 license condition. It doesn't seem that 400 gives you
25 that authority the way it's written.

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1 CHAIRMAN CERQUEIRA: Will these systems be
2 used in office settings independent of hospitals.

3 DR. HOWE: Yes.

4 DR. NAG: Yes.

5 DR. WILLIAMSON: Yes.

6 MS. MCBURNEY: Yes, absolutely.

7 MR. LIETO: I think we're getting ahead of
8 ourselves. I mean I don't know all the details of the
9 incident regarding the ultrasound and the manual
10 brachytherapy misadministrations, and maybe the issue
11 is not the ultrasound but the training of the
12 individual that's doing it. I think before -- and I
13 think this gets back to maybe one of the things that
14 the commissioners brought up at the meeting when we
15 met with them in the spring was that maybe we need the
16 details of these events, because I think maybe we're
17 discussing and trying to come up with administrative
18 procedures to address a problem that it's not really
19 the ultrasound equipment but who's operating it, okay?
20 And that's two different things. What you're
21 addressing here is something entirely different than
22 what I'm suggesting. And so I'm not really sure if
23 this is a really an appropriate thing for that right
24 now.

25 DR. WILLIAMSON: I think this is a good

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1 point if you want some meaningful feedback on this
2 from us. And, clearly, since the basis of this is
3 some experiences you've had with manual brachytherapy,
4 perhaps it would be very prudent for you to release
5 the details of some of these events to us much as you
6 did with the Novoste brachytherapy, and then we can
7 give you much better advice, I think, with a full
8 understanding of what's going on.

9 CHAIRMAN CERQUEIRA: Yes. This is getting
10 into sort of a real complicated area. I mean I think
11 that the views that David and I have expressed are
12 still appropriate, and I'm not sure that it's the NRC
13 role to regulate the practice of medicine. But yet at
14 the same time there are mechanisms in hospitals, but
15 once you get out of the hospital environment there is
16 no oversight, and so I think we do have to worry about
17 it, but I'm still not certain that it's the NRC that
18 has that role. But trying to think who does regulate
19 what happens in an office and you do have minimal
20 regulation. So it gets to be a difficult situation,
21 and I --

22 DR. HOWE: And the other thing you really
23 need to keep in mind is that these programs under --
24 are totally the option of a licensee. It's what do
25 you as a licensee think you need to assure you're

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1 giving what you have in the written directive? And I
2 caveated with consider and none of this is tied to
3 your license. You won't be cited against this
4 program. You will be recognized if you have medical
5 events. And what I did was I used our experience with
6 manual brachytherapy to say there is a root cause out
7 there and it is normal.

8 CHAIRMAN CERQUEIRA: I think getting back
9 to the point that's been made that if we knew the
10 specifics, and, clearly, there are people who are
11 probably not fully trained, and my question originally
12 about how well this algorithm works sort of gets at
13 this issue, that if you're doing it manually, at least
14 you've got some idea. You can still make the same
15 mistakes but it's not going to be systematic. But if
16 somebody is doing this totally wrong, using the wrong
17 ultrasound system or having the thing rotated to some
18 extent, then you can make fairly major systematic
19 errors. But I still -- again, I'm not sure that this
20 is an area that the NRC wants to get into.

21 DR. WILLIAMSON: Well, I think you could
22 argue that you're not going to have much choice. I
23 mean welcome to the brave new world of image-guided
24 therapy. This is refining and changing our definition
25 of what the target site is. So I think that the

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1 agency needs to confront the issue and at least decide
2 at some point what their boundaries are, and I think
3 it sounds like these cases in permanent brachytherapy
4 and prostate therapy provide a really sort of good
5 basis for defining a policy.

6 CHAIRMAN CERQUEIRA: It's a little bit
7 more complicated than that, because it's a site of
8 service issue, and there are safeguards within
9 hospitals, and when you get out of the hospital
10 environment, it doesn't exist there.

11 DR. WILLIAMSON: I'm not arguing you're
12 wrong. I'm just saying --

13 CHAIRMAN CERQUEIRA: Yes. No, no. Right.

14 DR. WILLIAMSON: -- I think it needs to be
15 considered and confronted as a problem and a change in
16 technology that invalidates an older regulatory
17 paradigm. And maybe the limits will be as you
18 suggest, and maybe they won't. That's the issue, and
19 we can probably offer a lot of advice if we're given
20 more information.

21 CHAIRMAN CERQUEIRA: Right. Yes, please.

22 DR. SULEIMAN: My experience is that, as
23 Dr. Williamson had mentioned, you've got a tail and
24 writing regulations is an art. But you're not writing
25 it for the people that are doing it right; you're

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1 writing it for the people that are going to be on the
2 fringes or that are maybe even doing it wrong without
3 any concern. But I think with multiple imaging and
4 ultrasound and MR, you have a whole multitude of
5 imaging modalities out there. Sometimes you say,
6 well, isn't that obvious, verification beforehand, but
7 sometimes if you don't write the very obvious in a
8 non-prescriptive manner, then say, well, why do you
9 write it since it's not very detailed, but sometimes
10 asking for the obvious it's not for you, it's for the
11 fringe operator so that they may do something that
12 they wouldn't have done otherwise.

13 CHAIRMAN CERQUEIRA: But we have to be
14 careful that we don't penalize all the people that are
15 doing it right. You know, maybe there's other
16 mechanisms by which to eliminate the tail, the people
17 that aren't -- don't even know where to start. Again,
18 I'm looking at the time and we're about half an hour
19 --

20 DR. HOWE: I think I'm done.

21 CHAIRMAN CERQUEIRA: What have we
22 concluded, though?

23 DR. HOWE: I think we've concluded that
24 the Emerging Technology Subcommittee will -- I'll give
25 them my guidance that's more fleshed out into words

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1 and sentences, but I'm going to take back what I've
2 heard from the ACMUI and bring it into what I think I
3 heard the ACMUI say before I pass it on to them, and
4 I should be passing that on probably next week.

5 CHAIRMAN CERQUEIRA: Okay. Good. Okay.

6 DR. NAG: What about some timelines? When
7 are you going to be sending it to the Subcommittee?

8 DR. HOWE: I'm going to try to send it to
9 the Subcommittee next week. I'll be sending it --
10 emailing it to Rick.

11 DR. WILLIAMSON: What about the other
12 proposal for reviewing these events you've made
13 illusion to?

14 DR. HOWE: Let me get this done before I
15 start going into NMED, and I'll try to get you those
16 events.

17 DR. HOLAHAN: Tom will address that this
18 afternoon.

19 DR. WILLIAMSON: Okay.

20 CHAIRMAN CERQUEIRA: Okay. Then we have
21 you again for listing sources on -- yes, it does list
22 you -- listing sources by model/serial number on
23 licensees.

24 DR. HOWE: Okay. Fine.

25 CHAIRMAN CERQUEIRA: Can we do that in

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1 half an hour? It seems like it's straightforward.

2 (Laughter.)

3 It never is.

4 DR. HOWE: Yes, right. Where's my
5 computer help? How do I get back to the regular
6 screen? It's probably not going to be that non-
7 controversial.

8 CHAIRMAN CERQUEIRA: Of course.

9 DR. HOWE: But part of it I think will
10 just be starting dialogue and will involve the ACMUI's
11 work for a very long time.

12 CHAIRMAN CERQUEIRA: Job security.

13 DR. HOWE: Okay. I've termed this
14 potential Part 35 rulemaking, because the first thing
15 was the ACMUI feels very strongly that it is an undue
16 burden to have to amend licenses to provide
17 information for new manufacturers, new sources from
18 the same manufacturers or certain device use,
19 primarily the manual brachytherapy. And the
20 requirements are in 10 CFR 30.32 and I've written the
21 requirements here.

22 Now, the last time we met we had to bring
23 you the sad news that you wanted an exemption for the
24 medical use people from this requirement, and we
25 brought you the sad news that NRC did not believe we

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1 could give you an exemption because of what was going
2 on and after 9-11 the importance of security, the
3 importance of knowing where sources are and who has
4 different kinds of sources. And what I'm bringing you
5 today is that same message, we're not going to give
6 you an exemption but we think we've come up with a way
7 that will satisfy your major problem and also satisfy
8 our major concern. And that is to go into Part 35 and
9 recommend revising the requirements for a license
10 amendment and the requirements for notification.

11 And by revising those two things, we could
12 move -- we still want the information. We want to
13 know when you use new sources and new devices, but if
14 you're already authorized for, say, manual
15 brachytherapy and a given manufacturer but not this
16 source and we think we could write a new regulation in
17 such a way that you could notify us that you're going
18 to be using a new source, we would have the
19 information, you would be able to use it without
20 seeking an amendment, and we think this would be a
21 good compromise.

22 And we would -- that would give you
23 flexibility in obtaining sealed sources from new
24 manufacturers or new models of sealed sources from
25 manufacturers that you already have listed. We'd have

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1 to write it tightly enough so that it fits your
2 license and you're just adding something you're
3 already authorized for globally, like you're already
4 authorized for 400 or for 600 and there's a new device
5 coming in.

6 So that's going to be our -- what we're
7 bringing to you is not giving you an exemption but
8 going an alternative pathway and that's the
9 notification pathway. Any comments?

10 DR. VETTER: Question.

11 DR. HOWE: Questions, yes.

12 DR. VETTER: It's still acceptable for a
13 licensee to ask for -- to submit a license application
14 that says either/or; is that correct? So they could
15 -- in their original application, they could say, "We
16 want to use any one of the following sources, and you
17 wouldn't know which one they are actually using but
18 they would be allowed to use any one of the -- let's
19 say they ask for three.

20 MS. MCBURNEY: Several models.

21 DR. HOWE: Yes. Yes. That's acceptable.

22 DR. VETTER: And then if a fourth one
23 became available on the market, they would simply have
24 to inform you. That wouldn't show up on their
25 license, but they would simply inform you that they

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1 are going to be using this fourth --

2 DR. HOWE: I see it being similar in how
3 it functions to authorized users, medical physicists
4 and nuclear pharmacists. We would not amend your
5 license at that point, but the next time we amend your
6 license we'll put it on your license.

7 DR. VETTER: Okay.

8 DR. HOWE: It's in your folder that you
9 have authorization for it, but the next time we amend
10 the license we'll add it to the license. Now, we'll
11 have to figure out exactly how to work this for
12 ensuring that you can receive it from your suppliers,
13 and that may be a little trickier, but I think we can
14 work those things out.

15 DR. VETTER: I personally like that
16 flexibility. I'm just a little concerned that, again,
17 for the fringe they'll lose -- as long as you keep
18 track, as long as the agency keeps track of what
19 they're doing in terms of what they've submitted and
20 updates the license periodically, that should help.
21 I'm just worried about the fringe people losing track
22 of what they're authorized to use and what they
23 aren't.

24 One subsequent question is if they decide
25 they want to order the fourth source and the vendor

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1 says, "Show me a license that says you're authorized,"
2 how will that be handled?

3 DR. HOWE: Well, that was what I was just
4 alluding to. We have to figure out how to have a
5 document that allows them to get that fourth source
6 because they've notified NRC that they have it.

7 DR. WILLIAMSON: So you'd write them a
8 letter back and say they're allowed to have this
9 source or what?

10 DR. HOWE: Normally what we do in
11 notification we review the information that comes in
12 and if it is acceptable for the notification, the
13 licensee gets nothing back. If it's not acceptable,
14 we send back a letter and say, "What you've submitted
15 to us is not acceptable under the notification. You
16 need to amend your license." So that's how we handle
17 it now. We'll have to figure out something to keep
18 you in conformance with your manufacturers.

19 CHAIRMAN CERQUEIRA: Subir?

20 DR. NAG: There are about 15 or 16 of
21 these different kinds of iodine sources, essentially,
22 very similar. Is it possible when we are making the
23 initial license application we just list all the 16?

24 DR. HOWE: You can list all 16.

25 DR. NAG: I mean that would solve the

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1 problem.

2 DR. HOWE: That will solve the problem for
3 you today. You can list all 16. Tomorrow --

4 DR. NAG: Yes.

5 DR. HOWE: -- the 17th comes out and the
6 18th and the 19th. So this would give you the
7 flexibility --

8 DR. WILLIAMSON: Sometimes they change the
9 names and model numbers of these things too, so there
10 are --

11 DR. HOWE: Do I hear that the ACMUI likes
12 this proposal?

13 CHAIRMAN CERQUEIRA: Ralph?

14 MR. LIETO: Yes. I don't have an
15 objection to the general process. I think it's that
16 end piece of how does the licensee notify the vendor.
17 Maybe a couple things to consider -- or is that coming
18 up?

19 DR. HOWE: No. We haven't figured out --
20 I mean I'll be doing a --

21 MR. LIETO: I mean anybody that's done
22 interactions with the --

23 DR. HOWE: -- what do you call it, a user
24 need memo up to the RGB Group, so I haven't really
25 outlined anything in detail how we would solve it.

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1 MR. LIETO: I would suggest one of two
2 things. Maybe simply an email from the reviewer who
3 gets it and says everything's there, it's okay, or
4 just some type of stamp, and Nicki suggested just a
5 stamp on there and fax it back to the licensee.

6 DR. WILLIAMSON: Well, I think there may
7 be even some easier way. I mean I think if the Part
8 35 is amended and they then send to the vendor their
9 existing license plus evidence that they've sent this
10 notification to NRC, that would be an obvious
11 compliance with Part 35, and it's simply a matter of
12 an information notice to inform the vendors that this
13 is the new process. Because they're anxious to sell
14 seeds. I'm sure they're not going to subvert it. As
15 long as they know they're not going to get into
16 trouble, that would be the solution.

17 MS. MCBURNEY: That was going to be my
18 comment, that if the procedure changes, that the
19 licensee can do it by notification by sending a copy
20 of that notification to the vendor that would indicate
21 that they're meeting the regulation.

22 DR. HOWE: And then the implementation
23 time is going to be dependent on whether we -- and
24 I'll go through some other changes that we'd like to
25 see -- whether we think we could go direct final rule

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1 or we think we have to go just regular rulemaking. So
2 that's still up in the air.

3 Okay. I have some other what I think are
4 fairly insignificant but important changes to Part 35.
5 In 35.49, it permits a licensee to use sealed sources
6 that are non-commercially transferred from a Part 35
7 licensee. And the question isn't what's in here, the
8 question is what's missing? And what's missing is
9 that this did not permit an NRC licensee to receive
10 sealed sources and devices non-commercially
11 transferred from an agreement state medical state
12 licensee, and so we're proposing that --

13 MS. MCBURNEY: Especially a renegade one.

14 DR. HOWE: Yes, especially a renegade one.

15 DR. DIAMOND: In terms of the ACMUI --

16 DR. WILLIAMSON: Could you define non-
17 commercially transferred and explain to us what the
18 sort of typical clinical application would be so we
19 understand better the --

20 DR. HOWE: Actually, you guys discussed
21 this for a long period of time during the Part 35
22 development, and this was that instead of -- you've
23 got a hospital or a clinic and they want to transfer
24 their device to another facility, not a manufacturer
25 but transfer the device over. Now the new facility

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1 takes it. So in the past, the new facility could only
2 get it from someone authorized under 3274. So this
3 allows that transfer between --

4 DR. WILLIAMSON: So this would be for
5 mobile remote-afterloading, it would be an
6 application?

7 DR. HOWE: No, it's for any device.

8 DR. NAG: I have 100 iodine seeds left
9 over and you need 100 iodine seeds. I give it to you.

10 DR. WILLIAMSON: All right.

11 DR. HOWE: He has an HDR. He wants a new
12 HDR and maybe he wants to transfer it to someone else
13 that for them that would be a great advantage. So
14 this allows the non-commercial transfer, so he's not
15 in the business of transferring his seeds. If he
16 wants, he'd be under 3274. So I'm going to recommend
17 that we add, "or equivalent agreement state medical
18 use licensee."

19 DR. WILLIAMSON: Excellent.

20 DR. HOWE: Thirty-five.sixty-five(b),
21 we've had a number of questions coming through for the
22 implementation of the new Part 35, and this appears to
23 be a little confusing, and we think there are at least
24 two places that need to be fixed and possibly break
25 this into simpler sentences might help. This permits

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1 the redistribution of sealed sources that don't exceed
2 30 millicuries provided you -- the person you're
3 getting it from is authorized to redistribute it and
4 the sources were originally authorized for
5 manufacturing distribution under 3274. And it's
6 confusing when people read this to understand who
7 needs to be authorized under 3274. Is it the sources
8 or is it the person redistributing? It's both.

9 And the other thing that you'll see is
10 also there's something missing here. This says that
11 the sealed sources had to be manufactured and
12 distributed by a person licensed under 3274. And what
13 are you missing? "Or equivalent agreement state
14 regulation." So we're proposing to revise it and add,
15 "equivalent agreement state authorization," and also
16 to revise it to make it clear that the person
17 redistributing it needs 3274 authorization or
18 equivalent agreement state and that the sources
19 themselves needed to come through that route.

20 DR. WILLIAMSON: Notwithstanding that we
21 may have extensively discussed it in the past, can you
22 again explain a typical scenario where this might be
23 used, what the intended application is?

24 DR. HOWE: All right. This one is to
25 permit for the most part commercial nuclear pharmacies

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1 to redistribute brachytherapy sources that are not
2 their brachytherapy sources but were originally
3 manufactured and distributed by a brachytherapy source
4 manufactured under 3274. The commercial nuclear
5 pharmacy comes under 3272, and they must have an
6 authorization under 3274 in order to do this. So this
7 is to clarify that they are not transferring under
8 3272; they're transferring under 3274. Okay? So
9 that's the main thing. And then we want to the
10 equivalent agreement state so that there is this
11 additional flexibility.

12 And I think this is -- we had an inquiry.
13 Thirty-five.six-fifty-five requires the licensee to
14 have each teletherapy unit and gamma stereotactic
15 radiosurgical unit fully inspected and serviced during
16 source replacement or at intervals not to exceed five
17 years, whichever comes first. That makes sense for a
18 teletherapy unit, but what we found is that the fully
19 inspected and serviced for a gamma stereotactic unit
20 can only happen when we do source exchange, because
21 there are parts of this device that you cannot get to
22 when you have the sources in. And we have a licensee
23 that will not exactly make the five-year period. The
24 manufacturer can come in --

25 DR. NAG: Five and a half years.

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1 DR. HOWE: Well, December is when their
2 five years is up. The manufacturer can come in
3 February. So we don't want to shut them down from
4 December to February because they can't do it in five
5 years, which is first, and there isn't anything that
6 can be done until they replace the sources. So we're
7 recommending that we decouple the five-year
8 requirement from the gamma knife for inspection and
9 servicing.

10 DR. NAG: One question. That this will be
11 only to cobalt because if it's a gamma stereotactic
12 and if it's a cobalt, yes, the five years applies, but
13 if someone makes up a new one with a new material that
14 has different half-life, then the five years is not
15 applicable. So this has to be only referenced to a
16 cobalt system.

17 DR. HOWE: Give me an example of a
18 different source and what you think --

19 DR. NAG: No, but I'm asking.

20 DR. HOWE: -- and what you think that
21 source exchange would be.

22 DR. NAG: I mean if it is a different
23 radioactive material, then if it's a shorter half-
24 life, five years is obviously far too long and if it's
25 a longer half-life, then it could go on for more than

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1 five years.

2 DR. HOWE: Okay.

3 DR. NAG: So if you want the flexibility
4 of -- I mean right now I agree cobalt is the one that
5 we use, but if we are using any other radioactive
6 material --

7 DR. HOWE: What we're recommending is
8 taking us five years out.

9 DR. DIAMOND: I don't think we need to
10 spend too much time on this.

11 MS. MCBURNEY: No. No, I don't think so.

12 DR. HOWE: Okay. What we're recommending
13 is we're taking the five years out of the gamma
14 stereotactic and whenever the sources are exchanged
15 that's when you do the full inspection. So if for
16 some reason you end up with an isotope with a short --

17 DR. DIAMOND: Subirium.

18 DR. WILLIAMSON: Subirium.

19 DR. HOWE: Subirium. It will be done
20 whenever it's exchanged. If that's three years or if
21 it's 20 years, it will be done in 20 years, okay?

22 DR. MILLER: I guess what I would propose
23 is if that happens we visit it at the time.

24 MS. MCBURNEY: That's right.

25 DR. HOWE: No. Actually, if we make the

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1 change that we're expecting for this gamma knife, it
2 will automatically be covered.

3 DR. NAG: Yes.

4 DR. MILLER: I don't think you're
5 understanding what I'm saying.

6 (Laughter.)

7 DR. NAG: I withdraw my question.

8 DR. MILLER: All I'm saying is if we ever
9 have Subirium, then we can visit what the servicing
10 and inspection period should be.

11 MS. MCBURNEY: Right.

12 DR. HOWE: Now, up to this point, I think
13 the --

14 MR. LIETO: I had a quick question just on
15 the gamma knife in general in terms of the servicing
16 and source exchange. Is it normally a five-year
17 period?

18 DR. DIAMOND: Yes. Most institutions five
19 years. Sometimes we do it a little more frequently if
20 we want to have quicker treatment times, obviously.
21 So, for example, our center would usually do it at
22 closer to four years than five years, but five years
23 would be a standard.

24 MR. LIETO: Okay.

25 DR. HOWE: Right. And it's just the

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1 question of --

2 MR. LIETO: Because I was just thinking
3 this might be just sort of a one-time only thing and
4 maybe it could just be handled as a one-time only
5 exemption. But if it's something that is going to be
6 coming up more often, then I guess probably it would
7 be --

8 DR. HOWE: We routinely -- well, we don't
9 get them as much now because we don't have as many,
10 but there are -- routinely, there are scheduling
11 difficulties even with the teletherapy units, and
12 we've granted our regions the option of granting
13 short-term exemptions for it. So I think this would
14 come up more frequently than you think.

15 MR. LIETO: Should this then be for not
16 just gamma knives but teletherapies also?

17 DR. HOWE: No. The teletherapy can have
18 a full servicing with the source exchange, but the
19 gamma knife cannot.

20 MR. LIETO: Okay.

21 DR. HOWE: Okay. Up to this point, I
22 think most of the changes -- I think the wording for
23 the notification process might be a little
24 complicated. We have to figure all of that, but these
25 other changes have been pretty minor and might

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1 possibly subject -- maybe if we could go direct final
2 rule would be a good candidate. So the ones I'm going
3 to be talking about now may be more controversial and
4 you may want to discuss them in more depth. So having
5 said that, I will continue.

6 In 35.4(b)(6), and this is the issue that
7 you guys have really wanted to get to all along, is
8 manual brachytherapy, the written directive. Before
9 implementation you have the treatment site, the
10 radionuclide and the dose. After, you've got the --
11 after implantation but before completion of the
12 procedure, you've got the radionuclide, the treatment
13 site, the number of sources and the total source
14 strength and exposure time. We have problems with
15 what do you mean in a permanent implant as what is
16 after implantation and before completion of the
17 procedure? What is completion of the procedure?

18 DR. WILLIAMSON: Forever.

19 DR. HOWE: Yes. And so we'd like to
20 decouple the permanent implant from this and have you
21 help us develop what should really be in the written
22 directive for the permanent implant and it also opens
23 up the issue of -- and I have another one I think
24 later on about what's a medical event for a permanent
25 implant, and so I think this is a much longer term, a

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1 lot more discussion. I don't think this is an easy
2 fix, but we're seeing a number of cases that we
3 believe are clear medical events. Most of them are in
4 the prostate. Thirty seeds go to the bladder. OGC
5 says it's not a medical event because the authorized
6 user changed the written directive before completion
7 to only require 40 out of the 80 seeds to go into the
8 prostate. Now, that's an error. That's something
9 that the whole misadministration medical event was
10 designed to have reported so that we could go back
11 with information notices or other things. It's not
12 punitive to the licensee but those are the kinds of
13 errors we want to hear about.

14 We had an agreement state licensee that
15 was doing a prostate implant. They had two patients,
16 one with I-125, one with palladium. They realized
17 after they had given a few of the palladium seeds to
18 the I-125 patient that they had given the wrong seeds.
19 So they revised the written directive for the
20 palladium. Now, should that have been reported as a
21 medical event? It was a misadministration for them
22 under the old rule but not for the new rule. So
23 you'll see something else on that.

24 So what is this -- how much change can you
25 get between prior to implantation and this second

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1 part? Our understanding originally was that you,
2 especially for the prostate, you don't know exactly
3 what size it's going to be when you get ready to put
4 the seeds in, so you need some flexibility to take it
5 into effect that it's grown and modify your written
6 directive at treatment time. But does that allow you
7 to modify your written directive six months later? It
8 doesn't quite seem like it should, especially if it
9 was an error that you're modifying it to correct.

10 And this is 40(c). This is existing
11 written directive can be made if the revision is dated
12 and signed. And it also includes an extraction dose.
13 Well, our -- this is also -- what do you do about a
14 procedure that's supposed to be given in only one
15 procedure, and the authorized user realizes they put
16 30 seeds in the bladder and they decide, "I'll switch
17 it to fractionalization now."

18 DR. WILLIAMSON: What do you mean
19 fractionalization?

20 DR. HOWE: The writing of the written
21 directive for the second fraction.

22 DR. WILLIAMSON: You mean do two permanent
23 seed implants?

24 DR. HOWE: Yes.

25 DR. WILLIAMSON: All right. That's what

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1 I'm asking to clarify the sequence of events.

2 DR. HOWE: Yes. And this is not a
3 procedure that you would normally have
4 fractionalization. So in our mind, with the old
5 misadministration rules and things, you would have
6 identified this as a medical event and reportable
7 because it should only be given once.

8 DR. SULEIMAN: So they calculate the dose
9 from the first -- what does get to the prostate and
10 then they recalculate what they need from the second?

11 DR. HOWE: That's what he was going to do,
12 and then eventually he decided that he wasn't going to
13 go back and treat at all.

14 DR. NAG: Yes. Just add 30 more seeds.
15 I mean that's --

16 DR. HOWE: But he wasn't adding them in;
17 he was going to have the patient come back at some
18 later time.

19 DR. NAG: Right. Yes. Next week or
20 whatever. I mean that's the reason why you do the
21 dosimetry so that in case you are under dose you can
22 reimplant. And I think that's been done -- this is
23 not an exceptional case. That's been done routinely
24 -- I mean not routinely, but that's been done quite
25 often.

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1 DR. HOWE: I think there's -- what you're
2 doing in the normal practice in medicine when you're
3 saying it's bigger, it's smaller, you have to go back
4 and put more in, that's -- we don't -- but when you
5 make a significant error, a human error, and it
6 clearly is a mistake in what's administered, can you
7 use these what we consider to kind of be loopholes?
8 So this is going to be much more controversial --

9 DR. NAG: But that is what medicine is.

10 DR. HOWE: -- and you guys are going to
11 want to discuss this forever.

12 DR. VETTER: Yes. We could discuss it
13 forever, but just one point I'd like to make. The
14 ultimate outcome is what's important.

15 DR. NAG: Yes.

16 DR. VETTER: Treatment could be
17 interrupted for a variety of reasons, one of which
18 could include a mental error on the part of the
19 radiation oncologist. But he catches it, it's a close
20 call, but he catches it and he corrects it, and the
21 outcome is just fine. So those -- I know, where do
22 you draw the line at? I think it's too difficult to
23 draw that upstream anywhere. You really have to look
24 at the ultimate outcome. What's the outcome?

25 DR. HOWE: And I think what you look at is

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1 in our regulatory space we hope the physician makes
2 the right medical decision and does what is right for
3 the patient. And we don't get into that aspect. But
4 we do have a requirement that what the physician
5 directs is delivered, and that if there is a
6 significant departure because there are some -- there
7 is wobble room here in the difference between what
8 they are projecting to give and what they give. But
9 if there is a significant departure, then there is
10 some kind of error in the administration, and those --
11 and they fit the criteria of the medical event, and we
12 those medical events reported to the NRC. In many
13 cases, we'll send out an information notice, we'll
14 make other licensees aware of common factors. It's
15 not a punitive type of thing. The Commission has a
16 long history of wanting to be informed when there are
17 significant errors to what was supposed to be given.
18 We don't get into whether they asked for the right
19 thing to start out with, we don't get into that. We
20 don't get into whether it would have been acceptable
21 over here and it wasn't acceptable. We just want to
22 know if it wasn't administered. Trish, you look like
23 you want to say something here.

24 CHAIRMAN CERQUEIRA: David?

25 DR. DIAMOND: Donna-Beth, just speaking to

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1 this one particular point, this is probably the one
2 point that you've made that I don't agree with in that
3 I'll give you a real-life example that you could get
4 into a little bit of trouble in a good medical center
5 with good physicians. Let's assume that you have a
6 patient with prostate cancer with a lot of disease at
7 the base of the bladder -- at the base of the
8 prostate, excuse me. The bladder is large in this
9 particular case, there's a big bladder diverticulum.
10 You go ahead and you do your prostate implant, and at
11 the conclusion of it you find there's a couple seeds
12 in the bladder, which is not to be unexpected because
13 the urologist does cystoscopy, he removes the seeds --
14 he or she removes the seeds. There's no harm done to
15 the patient.

16 Now, in the past we would always go and
17 order extra seeds so that at the time of fluoroscopy
18 at the conclusion of the implant you could go back and
19 add a couple more seeds. But because of changes in
20 reimbursement and costs, we don't do that anymore,
21 because the hospital loses a lot of money if you order
22 five or six extra iodine seeds. That would be a case
23 where that patient may have to come back the next day
24 or two days later when you've acquired some more seeds
25 to go and have a few more seeds placed to go and

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1 optimize room plant. And that would be an example, a
2 real life example that you would have to go ahead and
3 report that under your revision in which there has
4 been no harm or no foul, to use the lingo. Do you
5 understand what I'm saying?

6 DR. HOWE: I understand what you're
7 saying, and I don't think we're going after --

8 DR. DIAMOND: Yes, but you just -- I
9 understand what you're trying to do, but I'm just
10 saying it's all in the wording. And this would be an
11 example -- you know, you're spending a lot of time
12 talking about this one horrendous anecdote and I
13 appreciate that. I don't know how often this occurs,
14 but I'm just a little concerned, as Subir was also
15 mentioning in his examples of how we sometimes do
16 repeat a procedure. I wouldn't use the term,
17 "fractionation," really, but that we go back -- you
18 know, if a woman has a very big cervix cancer and you
19 have to a big sidewall implant, oftentimes you really
20 don't know how many seeds to order up-front, and there
21 are instances where you may have to go back a second
22 time, and I wouldn't want those situations to somehow
23 cause a problem.

24 DR. HOWE: We wouldn't want those either.

25 DR. WILLIAMSON: But then the law allows

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1 you this wiggle room from time zero. At the moment
2 when you insert the sources to the time you remove the
3 sources, that's the allowed period where you can --

4 DR. NAG: Removal for implant doesn't
5 create the problem.

6 DR. WILLIAMSON: That's sort of off the
7 table. So the issue is that you don't have that kind
8 of control over a permanent implant. You know, Dr.
9 Diamond is absolutely right there. There are inherent
10 limitations to the physician's control over these
11 seeds, and even a well-experienced investigator due to
12 some anatomical oddity or challenge that some
13 particular patient may present, we'll find that maybe
14 the D-90 falls short occasionally of the target dose.
15 And one has to supplement with external beam or
16 additional seeds, and somehow you don't want to
17 capture those events.

18 It all goes back to the philosophy of what
19 a medical event is, and you may remember when we were
20 negotiating this some years ago, a group of us
21 recommended that a medical event be identified as a
22 wrongfully delivered dose due to a technically
23 avoidable error on the part of the caregiver and then
24 list the specific criteria. And that somehow you've
25 got to sort of have that qualification in here, I

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1 think, when you revise this to sort of exclude the
2 many legitimate circumstances that may require a
3 revision. And you probably want to avoid
4 philosophical difficulties such as trying to define
5 the end of treatment for a prostate for a permanent
6 implant by probably completing rewriting in a separate
7 written directive section what are the rules for
8 writing a written directive for prostate implant that
9 don't refer to that concept. That would solve it.

10 And if you think there needs to be some
11 sort of a legitimate deadline for the physician being
12 able to say what are the number of seeds he or she
13 prescribed to the prostate 24 hours or something, you
14 say that. And don't argue about is the treatment
15 complete at time infinity or 30 days or 14 days,
16 because that's very arbitrary and different
17 practitioners will do the definitive imaging at
18 different time intervals and you simply can't
19 prescribe a standard. That is the practice of
20 medicine.

21 DR. HOWE: Right. And I think if we could
22 decouple the permanent implant and get the discussion
23 as to what is it really that you guys do and how to
24 characterize it.

25 DR. WILLIAMSON: Just a practical

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1 suggestion. You're obviously being motivated in your
2 thinking by a number of incidents that have been
3 reported. And maybe, again, if you bring us up to
4 speed on the database that conditioned your
5 experience, maybe then we can be more helpful.

6 DR. HOWE: Okay, I can do that. And
7 35.3045, which is the number of reporting, it requires
8 you to report a medical event for a dose that exceeds
9 a certain level for the equivalent dose equivalent or
10 to an organ tissue for the wrong radioactive drug
11 containing byproduct material. Now, in the old
12 misadministration rule, we also identified that you
13 had to report if you used the wrong radioisotope in
14 brachytherapy, and so we're recommending that you'd
15 have to report if you used the wrong radioisotope for
16 a brachytherapy procedure, and this goes back to your
17 palladium/I-125 mixup.

18 DR. NAG: I mean palladium and iodine we
19 use fairly interchangeably. If the -- not the number
20 of --

21 DR. HOWE: You use them interchangeably
22 but in this case you've got a -- you have two patients
23 coming in. One is in I-125 treatment, the next one's
24 a palladium. You start treating the I-125 patient.
25 They don't put I-125 in; they put palladium in.

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1 DR. NAG: Right. But if the equivalent
2 number of molecular, not the exact number of
3 millicurie, I think it's about a ratio of -- but the
4 equivalent number of millicurie the same, the end
5 result is going to be exactly the same, and therefore
6 if -- let's say I wanted to have 30 millicurie of
7 iodine, which would be equivalent to about 90
8 millicurie of palladium, if I put 90 millicurie of
9 palladium instead of 30 millicurie of iodine, my dose
10 distribution, et cetera, is going to be exactly the
11 same. And not the second dose but the equivalent dose
12 would be the same.

13 DR. HOWE: Ruth?

14 MS. McBURNEY: That may be true in iodine
15 and palladium, but there may be cases where a really
16 wrong isotope is used in brachytherapy, and that's not
17 in the rule. So that probably needs to be addressed.

18 DR. WILLIAMSON: I think it's reasonable
19 to address it. I think that while the medical event
20 sort of is designed to capture events that are
21 clinically significant in terms of hurting patients,
22 that's not a necessary or even sufficient condition
23 for something to be a medical event. It's kind of a
24 surrogate for there's questions about the underlying
25 quality of this technical program if they do this

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1 thing. Even if it doesn't hurt a patient, the fact
2 that the controls are so loose that one winds up
3 putting palladium instead of iodine when that was the
4 intent, I mean I think that in a performance-based
5 system that's a reasonable endpoint to have as a
6 regulatory endpoint, that you get the right
7 radionuclide in the intended patient and to have a
8 mechanism for capturing those events. Regardless of
9 whether the operator compensated for it properly upon
10 detecting the error, it's a useful bit of information
11 that I don't see any problem collecting.

12 CHAIRMAN CERQUEIRA: Ralph?

13 MR. LIETO: I was going to say kind of
14 actually -- I can't believe I'm going to say this --
15 but expand it and just to say wrong radioisotope for
16 a therapy procedure, period. Whether it's a
17 brachytherapy sealed source or a non-sealed source, I
18 think that that based on even using just reasoning
19 would be justified as being reportable.

20 CHAIRMAN CERQUEIRA: And usually if you
21 know ahead of time that one is available and not the
22 other, you can change the directive to reflect that.
23 But if you unknowingly administer the wrong one even
24 though the medical event is going to be -- the outcome
25 will not be any different, I think it still needs to

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1 be reported. So I think you have pretty good
2 agreement on this.

3 DR. HOWE: And then I guess I should be --
4 you guys need to mentally back up to the written
5 directive and the medical event part. And we have a
6 case now with a licensee that has multiple
7 brachytherapy medical events, and this particular --
8 and we've included some of the information that was
9 submitted by the region in your packet, I don't have
10 a slide for it, and it gets to the issue you guys have
11 really wanted to talk about for a very long time, and
12 that is how do we define a medical event for permanent
13 implant brachytherapy? And the licensee wants to use
14 -- I'm not sure I can get all the --

15 DR. NAG: D-100.

16 DR. HOWE: D-100 that's 80 percent -- and
17 then there's the D-90 and then there's all kinds of
18 permutations combinations in here. Generally, when we
19 do wrong site, it's a real clear-cut case. Here's the
20 prostate, here's where all the seeds went. We aren't
21 quibbling.

22 DR. WILLIAMSON: So where were -- you
23 know, I can't believe these were 12 percent of the D-
24 90 and ten to D-90. So why was that, I might ask?

25 DR. HOWE: I don't have the root cause for

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1 this particular case.

2 DR. HOLAHAN: The issue was it was a
3 previous licensee there before and a current licensee
4 -- well --

5 DR. HOWE: Previous group.

6 DR. HOLAHAN: -- a previous group was
7 there before, and they used AP films to localize the
8 prostate. And then the current group has come in and
9 done MRIs on all the prostates that have been -- MRIs
10 or CTs?

11 DR. HOWE: CTs.

12 DR. HOLAHAN: CTs. CTs on all the
13 previously treated prostates and they found this out
14 recently, but they were treated in 2000 and --

15 DR. HOWE: I think they also had films
16 that were never read, and they went back and started
17 reading the films and realized that most of the seeds
18 did not get into the prostate.

19 DR. NAG: One thing, you gave us the
20 numerator. What was the denominator during that
21 period of time? I think you had about, what, 16 or so
22 --

23 DR. HOWE: I think there are 21 of them.

24 DR. NAG: Yes, 21, but how many implants
25 was that? One thousand, 20, 21 or -- that is an

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1 important factor.

2 DR. HOWE: I don't know that right now,
3 but there were a number of problems with this
4 particular licensee. They were taking the films after
5 the fact but they weren't reading them. They were not
6 checking to see where the seeds were going. They were
7 just putting the implants in and then they got a new
8 contractor. The new contractor came in and started
9 reviewing and -- well, the reason the new contractor
10 started reviewing was they had a patient that came
11 back after brachytherapy treatment that had --

12 DR. NAG: A recurrence.

13 DR. HOWE: -- recurrent cancer, and they
14 looked at the images and they found out that -- I may
15 have the numbers wrong -- maybe only 30 percent of the
16 seeds went into the prostate. And so they said, well,
17 okay, is this generic to the practice that was here
18 before or is this an isolated case? And they went
19 back and found 21 cases.

20 CHAIRMAN CERQUEIRA: Now, is this health
21 care -- is this a hospital base or is this an out-
22 patient facility?

23 DR. HOWE: It's a hospital.

24 DR. DIAMOND: Where is it?

25 DR. HOWE: It's in Pennsylvania.

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1 DR. NAG: Pennsylvania.

2 CHAIRMAN CERQUEIRA: But, again, there
3 should be mechanisms in place. I mean, clearly, if
4 people aren't reading x-rays and are going back, I
5 mean that's a standard of care that's certainly not up
6 to standard, and so the hospital needs to take some
7 action on this. But, again, from our perspective,
8 it's clearly --

9 DR. HOWE: But from our perspective, it is
10 you have always had the issue, how do I define a
11 medical event for the prostate which is hard to image?
12 I don't think these are -- most of these are
13 borderline. I think they're way off for the prostate,
14 but the issue is here, you guys get a chance to
15 address it.

16 DR. MILLER: There were two aspects to
17 this that we looked at -- are looking at through our
18 regional office, and that is the former group who was
19 performing this is no longer at the hospital, so the
20 hospital did take some action. Our concern is also
21 what happened to that former group? Are they all --

22 (Laughter.)

23 DR. DIAMOND: That's the main concern,
24 because if they're still doing this with these
25 protocols, that cannot be allowed to continue.

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1 CHAIRMAN CERQUEIRA: But it's beyond the
2 NRC's purview --

3 DR. DIAMOND: Correct.

4 CHAIRMAN CERQUEIRA: -- to control that.
5 But, obviously, notification of some sort for these
6 events needs to be made.

7 MR. LIETO: Mr. Chair, I would disagree.
8 I mean if they know that these guys are out there and
9 may be potentially providing medical events for other
10 individuals or patients, I think there is a patient or
11 member of the public concerning it.

12 DR. WILLIAMSON: And there is a mechanism
13 for saying these individuals have to be barred from
14 handling licensee --

15 MS. MCBURNEY: From being an AU.

16 DR. WILLIAMSON: -- licensed byproduct
17 material for --

18 CHAIRMAN CERQUEIRA: Concerning for the
19 licensee, yes. We agree this needs to be done. Both
20 from radiation safety but then also from the practice
21 of medicine, this is clearly not appropriate.

22 DR. NAG: Yes. I think we have to
23 recognize that historically before the day of the CP
24 people were implanting and we were all implanting seed
25 into the prostate and taking AP and lateral films

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1 only. So you would get the dosimetry in relation, in
2 this case, you know, your dosimetry would be quite
3 good. It was only after the days of CP-based planning
4 and CP-based dosimetry that we found out that even
5 though you may have a very good dose distribution in
6 your relation to the seed, the dose distribution may
7 not be that good in relation to the prostate. So
8 these physicians may have been doing it the old way
9 rather than the new way.

10 DR. WILLIAMSON: But there was a
11 difference, though. In the pre-CT era, they were
12 doing open surgical procedures, and they were using
13 the traditional surgical palpation and visualization
14 technique. Now this is done in a more indirect way
15 with ultrasound guidance. So you can argue that the
16 ancillary 3-D imaging procedure is more essential in
17 some ways for perineal trans-rectal ultrasound-guided
18 implants maybe than it was in the old surgical open
19 procedure.

20 CHAIRMAN CERQUEIRA: Leon?

21 DR. MALMUD: Dr. Miller took the words
22 right out of my mouth, and I fully agree with Dr.
23 Miller and of course with Dr. Howe's concern. A
24 practical question of interest: Does the hospital
25 administration know that there were these, for lack of

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1 a better term, misadministrations, and is there any
2 way that the hospital or organization to which this
3 group went knowing of their past experience currently?

4 DR. MILLER: Our region was trying to
5 investigate that, and I don't know if we got the
6 results of that or not. The last that I checked with
7 them they had not located this new medical -- this
8 former medical group and if they were still a group if
9 they had split up and gone their various ways. And we
10 got into a debate with regard to where does our
11 jurisdiction end and what should be done, but I'd have
12 to -- I think we need to follow up on that to get --

13 CHAIRMAN CERQUEIRA: But your license must
14 have individual names, so you should be able to track
15 down the physicians.

16 DR. MILLER: Right. There ought to be
17 some way to track that, yes.

18 DR. MALMUD: But, again, is the -- you
19 said those occurred at a hospital.

20 DR. HOLAHAN: Yes.

21 DR. MALMUD: Is the hospital aware of what
22 had happened?

23 DR. HOLAHAN: They are now.

24 DR. MILLER: They obviously are because
25 they reported it.

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1 DR. MALMUD: The hospital reported it to
2 you. So the hospital is aware of it.

3 DR. MILLER: Yes. So as the licensee they
4 reported it to the NRC that this had happened, yes.

5 DR. MALMUD: Okay. Fine.

6 DR. HOLAHAN: And the offered to go out
7 and do 100 percent review of patients that have been
8 treated by the former group during those two years.

9 DR. MALMUD: That hospital has a
10 significant risk management issue.

11 (Laughter.)

12 PARTICIPANT: They should move to Philly.

13 DR. MALMUD: I hope it's not one with
14 which I'm familiar. My concern is our role on this
15 Committee and our not allowing something to slip
16 through the cracks simply because we believe it is not
17 our responsibility and it has not been our
18 responsibility because this is an issue of significant
19 clinical concern that this could have happened and may
20 still be happening elsewhere and may happen again if
21 this particular group fractionates and then practices
22 that way in two different places. Then we have a
23 metastasis of this kind of practice.

24 So I think this is an issue where if there
25 is ambiguity in this instance, that we take the

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1 aggressive position and try to pursue it until someone
2 assumes responsibility for this. If it is not going
3 to be this Committee then some other body but not
4 allow the public to be subjected to this from this
5 moment forward. This is a very serious issue for
6 patients who have presumed that he was treated
7 adequately, and for some body of knowledgeable
8 individuals to know that that patient was not treated
9 adequately is a significant issue, we would all agree.

10 DR. DIAMOND: Do we know if these patients
11 are aware, the individual patients are aware of this?

12 DR. NAG: They have to be.

13 DR. MILLER: What the NRC elected to do,
14 what the regional office elected to do is the hospital
15 itself was performing an investigation, and what we
16 will do with any licensee sometimes is to allow them
17 to perform their investigation and then we evaluate
18 the investigation that they've done. And then if it's
19 insufficient, then we would step in and take further
20 action. So that was an ongoing process I underwent
21 weeks ago.

22 DR. DIAMOND: I understand.

23 DR. HOLAHAN: But the patients were all
24 called back and to have CTs done.

25 DR. DIAMOND: They were.

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1 DR. HOLAHAN: So I don't know if they know
2 specifically what was going on.

3 DR. DIAMOND: And they were told the
4 results of the dosimetric analysis?

5 DR. HOLAHAN: I don't know that.

6 DR. HOWE: Now, clearly, if they're
7 identified as medical events --

8 DR. NAG: They have to be.

9 DR. HOWE: -- they have to be notified.
10 But part of what we have to do is whether we agree
11 with how the licensee identified their medical events
12 or not. That's part of what we're asking.

13 DR. DIAMOND: I understand -- I mean we
14 all understand that, and the point is well taken. If
15 we cannot agree a unified or a meaningful definition
16 of the event, then how do we go in pursuit from here?
17 What is our jurisdiction? What's our purview? And we
18 have a legal question and an ethical question.

19 DR. MILLER: What I'd like to propose to
20 do is let us follow up with the region to see what the
21 status of the investigation is. I will pass on to our
22 regional staff that there's a lot of concern on the
23 part of this Committee and the staff with regard to
24 this, and we'd like to get some follow-up activities
25 and we'll get back to you.

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1 CHAIRMAN CERQUEIRA: And the concerns are
2 for specifically what happened but also the fact that
3 these individuals, especially since this was probably
4 an institutional license, their names should have been
5 on it, but we're concerned that this group in whatever
6 form, or these individuals, are now allowed to
7 continue to practice. And so if they're going to
8 practice, they could go to an agreement state in which
9 case it would not come to you, but some effort should
10 be made to try to track them down and identify which
11 ones are responsible to make certain that they aren't
12 allowed to be on a license again to do this without
13 further investigation. Is that the sense of the
14 Committee?

15 DR. WILLIAMSON: Yes. I mean I think this
16 motivates --

17 CHAIRMAN CERQUEIRA: Ruth has been waiting
18 patiently.

19 MS. MCBURNEY: My point was that if you
20 are able to find out or if the hospital is able to
21 find out where these individuals have gone, I think it
22 would behoove you to contact the regulatory
23 jurisdiction in that area where they have moved.
24 Because I know we can take compliance history into
25 account when licensing folks or not.

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1 CHAIRMAN CERQUEIRA: Subir and then Dr.
2 Miller.

3 DR. NAG: Yes. A couple of things.
4 Number one, obviously, this does represent a
5 substantial deviation from normal practice, but I
6 would still like to know the denominator of this, and
7 I'm sure they are investigating how many.

8 DR. MILLER: I think that's what they're
9 looking into.

10 DR. NAG: But that number I would like to
11 have, the 21 out of how many. Secondly, the 80
12 percent of the D-100 that is a wrong criteria to use,
13 but even if you use the other one, the ABS, the
14 American Brachytherapy Society, and also AAPM, they
15 prefer the D-90 dose, even if you use that, it's still
16 a substantial deviation. But I would suggest using
17 the D-90 rather than the V-100. Those are the two
18 things.

19 CHAIRMAN CERQUEIRA: Leon and then Nicki.

20 DR. MALMUD: I would just like to
21 reiterate that this is really an ethical concern, and
22 if we are aware that, as you reported, there were
23 unread films, meaning that the group never really
24 intended to check on their work, that it would seem to
25 me that it's the responsibility of the NRC, which is

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1 aware of the issue, to site visit these individuals
2 where they are practicing now, wherever they are
3 practicing now, if they are in the United States, and
4 just do routine checks on them, because we now know
5 that they were guilty of not reading films that they
6 should have read. And, therefore, we have an ethical
7 concern, if not a legal concern, with regard to the
8 way they're practicing radiotherapy currently. Is
9 there anyone who disagrees with me?

10 CHAIRMAN CERQUEIRA: Wait. Nicki next and
11 then -- if you want to go, go ahead.

12 MS. HOBSON: Well, I just wondered what
13 happened to the patients and what would be a normal
14 procedure if you find out that you didn't give the
15 full dose or is the patient called in and given an
16 option to go through the procedure again? Were these
17 patients actually informed that, "Oh, you only got 11
18 percent or something."

19 DR. HOLAHAN: Well, that's what the
20 investigation is doing and they've called in 100
21 percent of the patients that they think are involved,
22 and I don't know --

23 MS. HOBSON: But I thought you said that
24 you weren't really sure that if the patients
25 understood why they were being called in.

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1 DR. HOLAHAN: Yes. And we'll have to find
2 out from the region.

3 DR. MALMUD: If I may, you are -- Dr.
4 Holahan's correct, the hospital, knowing what happened
5 at that institution, is responsible for the follow-
6 through, and the hospital's own risk management
7 department and lawyers will make certain that the
8 hospital follows through with a high degree of
9 certainty.

10 My concern is from this point forward the
11 hospital at which these incidents occurred is aware of
12 their problem. We are aware of the error of the way
13 in which these patients were treated. We now have the
14 ability to know where these physicians have moved.
15 All we need to do is monitor them under the existing
16 regs, not excuse them, just casually monitor them. Do
17 we not do that? Does the NRC not do that, have that
18 ability?

19 DR. HOLAHAN: Yes, but if, as Donna-Beth
20 says, they didn't read some x-rays or things like
21 that, would we know of another event?

22 DR. WILLIAMSON: I think that one --

23 CHAIRMAN CERQUEIRA: Let's -- Bill?

24 MR. UFFELMAN: I just wanted to comment,
25 as former council to the Medical Malpractice Study

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1 Commission, it strikes me that this is an event that
2 is reportable to the Pennsylvania -- the Medical Board
3 of Pennsylvania, this over and above NRC-related
4 issues. I mean the fact that these gentlemen -- or
5 these people have done films that they haven't read,
6 that they haven't done these other things, I mean
7 they, in my mind, it's a very clear allegation of
8 malpractice that is now known to physicians who
9 practice in Pennsylvania, and I believe you have an
10 obligation once the folks are identified to in fact
11 report them to the Pennsylvania Medical Board.

12 CHAIRMAN CERQUEIRA: Jeff and then Subir,
13 and then we should end.

14 DR. WILLIAMSON: I think this -- I just
15 want to point out that I think this does underscore
16 that we really need to revisit the definition of
17 medical event and written directive for prostate
18 brachytherapy because in principle the way, as I
19 understand the rule, there is a big loophole in it
20 now, and these physicians, had they read their films,
21 could have come back and revised the prescription to
22 say 11 percent of the initial dose. And I think that
23 is wrong for such a big loophole to be left that
24 really gross mistakes can be concealed. And even
25 though coming up with a clear criteria is going to be

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1 a very difficult and probably not totally successful
2 undertaking, it's something I think we definitely
3 should work on.

4 CHAIRMAN CERQUEIRA: Subir?

5 DR. NAG: If the films were taken and if
6 the films were billed for and the dosimetry was billed
7 for and the dosimetry and the films were not read,
8 that becomes a fraud and anyone who has found that --
9 who has discovered that fraud has to report it. Now,
10 I don't think we have an option. We have to report it
11 to Medicare or whatever organization.

12 CHAIRMAN CERQUEIRA: Well, it's fraud or
13 malpractice. And I hate to -- we don't know all the
14 facts. I mean --

15 DR. MILLER: Let us get that.

16 CHAIRMAN CERQUEIRA: Yes. But I think
17 that if the concerns are if these facts as presented
18 are indeed true, that films were not read and
19 decisions were made and especially if they were billed
20 for, then if that's true, then the NRC does have some
21 obligation to --

22 DR. NAG: And we get ten percent.

23 (Laughter.)

24 CHAIRMAN CERQUEIRA: -- to report that.

25 DR. SULEIMAN: The entire issue of medical

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1 error and reporting there's a whole initiative in
2 Health and Human Services on that very issue. And I
3 think the fact that the NRC even picked up on this
4 obviously somebody came forward and reported it. So
5 I would assume I think what you want is just
6 validation that the appropriate authorities are taking
7 action. Otherwise you're going to have everybody
8 running around like a three-ring circus trying to get
9 involved here. I think it's important to make sure
10 the right groups are aware.

11 CHAIRMAN CERQUEIRA: Leon, one last
12 comment and then we'll --

13 DR. MALMUD: My last comment will be my
14 first comment. This is an ethical -- this is a basic
15 ethical breach. We are aware of it. Being aware of
16 it we have a responsibility to pursue it. To know
17 about something like this, to have the thought that it
18 could be happening to other, in this case it's men,
19 male patients, while we are talking if this group has
20 not changed its mode of practice becomes our
21 responsibility as well by simply knowing about it.
22 And, therefore, though it may not be a legal
23 responsibility, it is, I believe, an ethical
24 responsibility to make certain that those individual
25 are located and that someone's monitoring their

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1 practice so they don't continue to make the same
2 errors that they made in the past.

3 CHAIRMAN CERQUEIRA: I think that really
4 expresses the sentiment of the Committee. All right.

5 MR. LIETO: There was a question I think
6 that Donna-Beth asked, and I don't know if we got to
7 what was the criteria for classifying -- classifying
8 may not be the right term -- but determining whether
9 an individual falls into a medical event or not.

10 DR. HOWE: I think Subir said that he
11 would go with the D-90.

12 MR. LIETO: I think that would be at least
13 some justification is, is that is certainly a
14 parameter that retrospective studies --

15 DR. NAG: Right.

16 MR. LIETO: -- have been shown to be
17 correlated with --

18 DR. NAG: And also that it's advised by
19 both AAPM and ABS.

20 DR. WILLIAMSON: So all 21 events fall
21 into that.

22 CHAIRMAN CERQUEIRA: It looks it uses the
23 D-90. All right. So why don't we take a ten-minute
24 break.

25 MR. ESSIG: Mr. Chairman, John Szabo

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1 showed up at 10:15, as he was --

2 CHAIRMAN CERQUEIRA: Okay.

3 MR. ESSIG: We did take our break between
4 ten and 10:15; we didn't realize it.

5 (Laughter.)

6 PARTICIPANT: You just didn't notice it.

7 CHAIRMAN CERQUEIRA: Okay. All right.

8 MR. ESSIG: So if we could have John come
9 on since he's been waiting for the last ten minutes or
10 so.

11 MR. SZABO: You can't get rid of me. But
12 I got a question regarding subcommittees this morning,
13 and some of the things we also work on is the Federal
14 Advisory Committee Act. And for those of you who
15 aren't familiar, that's the law that back in 1971 that
16 sort of tried to get some control over the kinds of
17 advice that the government was receiving from outside
18 the federal government. And it established a whole
19 bunch of regulations. We have regulations for our
20 advisory committees that are published in the Code of
21 Federal Regulations, and Tom Essig is for the ACMUI
22 what is known as the designated federal official,
23 which is brought over here.

24 If you have -- basically, the law requires
25 that when you get a group of people who are not

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1 permanent federal employees together to provide some
2 advice to the federal government, you have to follow
3 some requirements, including the ACMUI and ACRS.
4 There has to be a charter filed and every meeting has
5 to be open and notice for it happens. Detailed
6 minutes have to be kept, and there are procedures for
7 closing parts of the meeting, very specific rules such
8 as we had yesterday personnel issues, proprietary
9 information, classified information, security
10 information.

11 The Federal Advisory Committee Act was
12 remanded a number of times and recently new
13 regulations came out and then, in our regulations,
14 updated ours. The most important one is mentioned
15 about subcommittees. The old rule until actually
16 earlier this year was that if you had a subcommittee
17 of a FACA committee, you had to go through all the
18 requirements of openness and notice and et cetera.
19 Under our new regulations, you do not have to follow
20 those rules. You can have a closed subcommittee
21 meeting. The only requirement is that if the
22 subcommittee makes a report or some recommendations,
23 it must go to the parent committee, and the parent
24 committee has to review those recommendations under
25 the regulations.

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1 A couple other things that we have that
2 are different is that if there is a meeting between
3 full-time employees with state and local government
4 officials, those meetings are not subject to these
5 requirements as well. Those are some --

6 DR. NAG: What does that mean, I'm sorry.

7 MR. SZABO: If you had a federal employees
8 meeting with state employees or local employees or
9 members of Indian tribes, for example, just those
10 people, that's not a FACA committee. It wouldn't have
11 to go through those requirements. They've made an
12 exception for state, local and tribal governments with
13 federal employees. So if that ever happened, you
14 wouldn't have to go through those requirements.

15 There are some other things, but I don't
16 think they're really too relevant to the ACMUI. But
17 if there's anything else on FACA, you can always
18 contact me about it.

19 DR. NAG: Ruth is a state employee.

20 MR. SZABO: Right. So if the meeting were
21 between her and Tom, then -- or a group of other NRC
22 employees, you wouldn't have to have the openness
23 requirement for meetings or something like that.

24 DR. NAG: Now, the subcommittee -- I mean
25 it would be between her and three or four of us.

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1 MR. SZABO: That's right, but if it was
2 strictly under those --

3 DR. DIAMOND: John, how large can it be?
4 In other words, could it be eight members of this
5 committee, ten members of this committee and still be
6 defined as a subcommittee?

7 MR. SZABO: You could define a
8 subcommittee any way you want to define it, but,
9 again, if you had most of your committee members as a
10 subcommittee, still whatever you did had to be --

11 MS. MCBURNEY: Reported.

12 DR. DIAMOND: Back to the main committee.

13 MR. SZABO: -- reported to the full
14 committee, and the full committee would have to review
15 it, just like a FACA group.

16 CHAIRMAN CERQUEIRA: John, with regard to
17 the full committee reviewing it, then their obligation
18 would be to do that in a public forum.

19 MR. SZABO: Oh, yes. Oh, yes.

20 DR. HOLAHAN: They can't email it to the
21 full committee and get reviewed and comments.

22 MR. SZABO: No. That action has to be
23 kept in a public forum other than for those topics
24 that --

25 DR. DIAMOND: But also the key is whether

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1 it's three of us or six of us or eight of us working
2 on a particular topic, we can go and schedule phone
3 conferences without doing notice, without the Federal
4 Register and get some business done.

5 MR. SZABO: Absolutely. There's no
6 minimum number. You can define the subcommittee any
7 way you want to.

8 MS. MCBURNEY: So what we do as a
9 subcommittee and feed that comment back to the NRC
10 staff then as long as we report it out and have it
11 reviewed by the full Advisory Committee at the next
12 meeting --

13 MR. SZABO: That's correct.

14 MS. MCBURNEY: -- the noticed meeting,
15 that would meet the --

16 MR. SZABO: That would meet the
17 requirements.

18 MS. MCBURNEY: Okay.

19 CHAIRMAN CERQUEIRA: Does it have to be
20 posted anywhere? Does their report have to be made
21 available to the public or can it just be reviewed
22 orally at the next committee meeting?

23 MR. SZABO: Well, if you have the meeting
24 and you're reviewing the report, the report should be
25 available just like any other document.

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1 MS. MCBURNEY: Right.

2 CHAIRMAN CERQUEIRA: So it should be part
3 of the material.

4 MS. MCBURNEY: The agenda packet.

5 CHAIRMAN CERQUEIRA: Right. Right.

6 DR. MILLER: Ruth has brought a key
7 statement to make sure we get things in the right
8 order. The full committee only meets twice a year.
9 The subcommittees will meet as needed. If a
10 subcommittee does some work for us in a closed forum,
11 develops a report, the requirement is that they report
12 that out to the full committee. But the NRC, if
13 they're going to take an action based upon that
14 report, would have to have the full committee's
15 endorsement in a public forum before we take the
16 action or we're violating FOIA. So that's a key
17 innuendo.

18 DR. WILLIAMSON: But couldn't the --

19 DR. HOWE: John, why can't we --

20 DR. NAG: Mic.

21 MS. MCBURNEY: State your name for the
22 record, please.

23 DR. HOWE: Donna-Beth Howe. Why can't we
24 take information that we collect from the subcommittee
25 and take some kind of action which is not a final

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1 action? I'm thinking specifically of my emerging
2 technology. I can put guidance up on the web site, I
3 can revise the guidance at any point. Can I take
4 information I get from them, put it up on my web site
5 and then when the full committee meets and talks about
6 their report and finalizes what they want to
7 recommend, I can go back and modify the web site.

8 MR. SZABO: You can use individual
9 comments, remarks, recommendations made by members,
10 but if it's the subcommittee itself making a report,
11 an agreement of some sort, recommendations, then it
12 has to have the sanction of the full committee. Now,
13 maybe you don't have to have a -- bring everybody
14 here.

15 DR. WILLIAMSON: It could be done by a
16 telephone call.

17 MR. SZABO: It could be done by
18 chronicling, yes.

19 CHAIRMAN CERQUEIRA: Oh, okay.

20 MR. SZABO: But still there would have to
21 be some openness to this.

22 CHAIRMAN CERQUEIRA: All right. So if
23 it's sent out to the Committee members, do we need to
24 take a vote on it? Can we just --

25 MS. MCBURNEY: Just an open meeting.

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1 DR. NAG: Has to be open.

2 DR. WILLIAMSON: Well, since you're
3 planning to institutionalize the sort of mid-meeting
4 phone conference, couldn't that be noticed in advance
5 and then you could --

6 MR. SZABO: Yes, absolutely. Sure.

7 DR. HOWE: That could, but I don't think
8 our licensing actions want to wait for you to have
9 quarterly meetings.

10 DR. MILLER: I mean what it would require
11 if we had a subcommittee, given what you all have
12 said, is that the subcommittee would have to report
13 out in some way to the full committee before the full
14 committee to tell the NRC, "This is our recommendation
15 for you to proceed."

16 DR. HOWE: But also it sounds like I could
17 take information during the discussion and incorporate
18 it.

19 MR. SZABO: Absolutely.

20 DR. HOWE: As long as I'm not depending on
21 their recommendation.

22 MS. MCBURNEY: Right.

23 MR. SZABO: That's right.

24 MS. MCBURNEY: As long as we didn't make
25 a formal recommendation that we involve the staff with

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1 our discussions on the subcommittee and she could use
2 that information --

3 MR. SZABO: That's right. If you made a
4 -- and these are my views.

5 MS. MCBURNEY: Right.

6 MR. SZABO: That can be used --

7 MS. MCBURNEY: And these are Dr. Vettters'
8 views, and these are Dr. Williamson --

9 MR. SZABO: Not the so-called
10 subcommittee's views.

11 MS. MCBURNEY: Right.

12 DR. HOWE: So I can use the information
13 before they put it into a report.

14 MR. SZABO: Yes.

15 DR. HOWE: But once it's in a report, I
16 have to wait for the full committee.

17 MR. SZABO: Yes. Before you can say this
18 is the subcommittee's views.

19 DR. HOWE: Right. Okay.

20 MR. SZABO: Individual views are always
21 not subject to these requirements. And you can even
22 take the comments, informational questions that are
23 asked, let's say they're talking and asking questions
24 and what not, that's still not a problem either.

25 DR. NAG: So like two levels. One is the

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1 discussion that we had among the subcommittee members,
2 that would be our individual thoughts.

3 MR. SZABO: That's right.

4 DR. NAG: And then at the end of that we
5 could make a combined subcommittee recommendation that
6 would go to the full committee and be acted on at a
7 later date.

8 MR. SZABO: That's right. The full
9 committee would have to act on that subcommittee's --

10 MS. MCBURNEY: But in the meantime she
11 could take what information and advice that individual
12 members of the subcommittee present to use to do the
13 licensing.

14 MR. SZABO: Right. As long as it's
15 considered to be the views of that particular member.

16 CHAIRMAN CERQUEIRA: The individuals,
17 okay.

18 MS. MCBURNEY: Sounds good.

19 MR. ESSIG: And I would offer, I think if
20 we had a particularly important recommendation at this
21 pace, the subcommittee was going to make to the full
22 committee and we needed to act on that recommendation,
23 we could go ahead and schedule a noticed conference
24 call of the full committee, discuss that and then use
25 it. That's what I think I hear.

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1 MR. SZABO: That's absolutely correct,
2 yes.

3 CHAIRMAN CERQUEIRA: Just a residual
4 question. For that kind of confirming conference
5 call, how long in advance do you need to post it? I
6 mean how long would it take to do that if --

7 DR. HOLAHAN: Ten days.

8 CHAIRMAN CERQUEIRA: Ten days. Okay. All
9 right.

10 MR. LIETO: I have a question. For the
11 teleconferences of the full committee, do minutes have
12 to be maintained of those also?

13 MR. SZABO: Yes. Yes. They're subject to
14 the Act.

15 DR. NAG: And they're open. Anyone can
16 call in and --

17 MR. SZABO: You have to call in, yes.
18 Because we said reasonable access for the public.

19 CHAIRMAN CERQUEIRA: That's great. Any
20 other questions for Mr. Szabo? Well, I thank you for
21 coming and we'll take a break. We'll reconvene at
22 quarter to 11.

23 (Whereupon, the foregoing matter went off
24 the record at 10:37 a.m. and went back on
25 the record at 10:53 a.m.)

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1 CHAIRMAN CERQUEIRA: All right. This
2 session we've changed the schedule a little bit. It's
3 going to be dose reconstruction in unplanned
4 exposure/extremity monitoring materials facilities.
5 And Dr. Sami Sherbini will be making the presentation.

6 MR. ESSIG: If I might just add, I think
7 Dr. Sherbini is new to the Committee. I don't know
8 that you've made a -- he's made a presentation before.
9 Dr. Sherbini is on my staff. He's a senior level
10 health physicist, and he is the person that we go to
11 for most of our modeling work. And so we felt it
12 appropriate that he lead this particular discussion.

13 DR. SHERBINI: Okay. Thank you. There
14 are actually two topics that I'm going to talk about
15 today, and they're not really related except that both
16 deal with dose assessment of some kind.

17 Okay. The purpose of the first item or
18 topic, dose modeling, is for those concerns that were
19 raised that NRC tends to be excessively conservative
20 in its dose rate construction to come up with
21 excessively high dose assessments and unrealistically
22 conservative assumptions when it does these things.
23 And what I'm going to try to do is show you very
24 briefly how we do these dose reconstructions and maybe
25 illustrate how some of these conservatisms tend to

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1 creep them and what causes them to creep in to this.

2 The other topic is monitoring of the hands
3 of workers, especially workers in the radiopharmacy
4 industry who handle high specific activity, vials or
5 syringes containing these materials and the
6 difficulties we've encountered in getting a good
7 assessment of the dose of their hands when they do
8 these things.

9 I thought in the dose modeling discussion
10 I would present this in the form of three cases that
11 we've dealt with, and I think through the presentation
12 of the cases we can identify the places where
13 conservatisms enter and how they might be avoided in
14 the future. And those are to show that really what
15 NRC tries to do is to try whenever possible to use
16 data rather than make assumptions. And we try to
17 reconstruct events based on firsthand accounts. In
18 other words, we interview the workers, we interview
19 their supervisors and so forth to get the story
20 directly from the people who are affected. And when
21 it is necessary to make assumptions, we try to make
22 them as realistic as possible.

23 Again, when we're uncertain, we tend to
24 slightly overestimate or make slight conservative
25 assumptions with the idea that it is better to

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1 slightly overestimate the dose than underestimate it.
2 We do not want to underestimate doses for a variety of
3 valid reasons, I think. We also use a graded approach
4 in dose reconstruction for cases that involve very low
5 doses. We do approximate calculations. It's not
6 worth the effort to do very exotic and very detailed
7 calculations. Of course, as the dose or as the dose
8 we think may have been received goes up, then we spend
9 more time and we use more elaborate modeling to
10 reconstruct the case.

11 The first case we have to talk about is
12 interesting case that happened in 1995 at MIT that
13 involved a post-doc research worker, research student
14 who was working one of the cancer labs there. And one
15 day when he was frisking out of his lab, as is
16 required when he works with radioactive material, he
17 found that he was radioactive, and it turns out that
18 the radioactivity was internal, it wasn't surface
19 contamination. And further assessment showed that it
20 was caused by P-32 antibody.

21 The licensee did their own immediate
22 investigations and they notified the NRC, and the NRC
23 did special inspections. And based on the data
24 collected, we did those assessments. Fortunately, the
25 licensee had collected a large quantity of urine

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1 samples and had also done whole body counting, and so
2 we had a lot of data to work with. We used what was
3 then the industry standard for internal dosimetry,
4 CINDY, which is a code that uses -- that we use to
5 calculate internal dose. We also did some hard
6 calculations. And these are the results.

7 We had a consultant also working for us
8 who did independent assessments. We got 600
9 microcuries, the licensee got 560, and the consultant
10 got 580. The limits, the dose limit for occupational
11 exposure for intake of P-32 is 600 microcuries intake
12 limit. So our assessment was right at the limit. The
13 licensee's was lower.

14 We decided to accept the licensee's
15 assessment because they had done all the right things.
16 They had done pretty good job in doing the
17 assessments, and we decided that even though the
18 number came up lower than ours and below the dose
19 limits, we decided that it should be accepted and
20 that's what we went with.

21 And the conclusions for this case is that
22 if the licensee does a good job, we will accept their
23 assessment without any further question, even though
24 ours might be higher. I think in this case there are
25 several important things that should be pointed out to

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1 show how this case could have -- had it not been for
2 the licensee's quick response to the situation, it
3 could have ended up being a very conservative dose
4 estimate and could have probably put them well above
5 the dose limit, even though the assessment here showed
6 it below the dose limit.

7 When the licensee first became aware of
8 the contamination, they tried to pinpoint when the
9 intake might have occurred. Incidentally, we never
10 did find out how the P-32 was ingested. We
11 investigated all kinds of possibilities but we never
12 did find out how this person ingested P-32.

13 The point is the licensee tried to narrow
14 down the point at which the P-32 might have been
15 ingested. The student is required to frisk when he
16 leaves the lab, so we know when he left the lab on
17 that day when he was contaminated obviously the intake
18 must have occurred before then. Unfortunately, the
19 student hadn't worked with radioactive material for
20 quite a few days before that, and so the other data
21 point we had was about a week earlier. And so there
22 was a time span of about a week or so within which the
23 intake could have occurred. Given that P-32 is
24 excreted fairly rapidly from the body, it's important
25 to know very closely when the intake occurred. A span

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1 of uncertainty of a week, especially if you have to
2 make the assumption that the intake occurred at the
3 beginning of that time span, which we would have done
4 without any additional data, could have easily put the
5 licensee over the limit.

6 What the licensee did, which is very
7 interesting and very smart, I think, was realizing
8 that P-32 appears in there almost immediately after
9 the ingestion -- not immediately but within hours --
10 they went to the person's home and they went through
11 the laundry hamper of the person's house with a
12 frisker, and they peeled off layers of laundry and
13 frisked the underwear, basically. And each layer was
14 radioactive until they reached a layer that was not,
15 and so they were able to -- and I think that was very
16 clever -- they were able to -- this guy was very
17 methodical and so he changed his underwear once a day
18 at the same time every day. And so by finding the
19 dividing line between the contaminated and not
20 contaminated underwear, they were able to narrow down
21 the intake interval to within 24 hours, which was a
22 considerable improvement. And I think this was an
23 illustration of where the licensee I think bears some
24 of the responsibility for the conservatism that you
25 might see in some of NRC's assessments.

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1 If the licensee had not done that, we
2 would have had to assume that the intake occurred may
3 be four or five days before it had actually occurred.
4 That makes a big difference in the intake assessments,
5 especially for cases like P-32. And so by the time
6 the NRC got to the site, it would have been too late
7 to do the standard activity. We got there a week or
8 two after the incident, and so most of that data would
9 have been gone, and so we would not have had the
10 benefit of this kind of reconstruction. So quick
11 thinking on the part of the licensee to get data as
12 quickly as possible is very important for dose
13 reconstruction.

14 The other factor I think that the licensee
15 was smart in doing was that one of the important
16 factors in assessing intake is -- based on data is how
17 much P-32 is excreted in a 24-hour period in the
18 urine. Now, a lot of licensees would collect one
19 voiding of urine, okay? But that leaves the assessor
20 with the task of having to guess based on the
21 consideration in this one voiding how much might have
22 been voided during a 24-hour period. That introduces
23 a great deal of uncertainty. The licensee instead
24 made sure that they collected 24-hour urine samples
25 every day for two or three weeks after the suspected

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1 intake.

2 So we have 24-hour urine samples. We did
3 not have to guess how much was the 24-hour excretion
4 for each day. It was there in the data. There was no
5 need to make any kind of assumptions. And so this is
6 the kind of thing that makes dose assessor's job much
7 easier, it makes assumptions unnecessary, and it
8 eliminates guesswork. It eliminates the conservatisms
9 that would have had to be introduced if this data was
10 not available. And I think I would like to highlight
11 the fact that, yes, we do bare some responsibility for
12 conservatisms, but I think the licensee is in an
13 excellent position because of proximity the incident
14 to collect data as quickly as possible and as
15 completely as possible to as to make it unnecessary
16 for us to make any guesses or assumptions. And that,
17 I think, is a very important point, as illustrated by
18 this case. This case could have easily been -- could
19 have easily ended up in a citation for overexposure
20 had the licensee not acted the way they have done.

21 The second case involves a 1 curie cesium
22 source that was left sitting on an oil rig in Montana
23 for a period of about 12 hours. During that period,
24 workers were working around the source. Nobody
25 realized that the source was sitting out there, and

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1 they continued working. Some of the people were
2 exposed for the entire 12 hours, some for less time.
3 The number of people involved was 31. These are all
4 members of the public. They are not radiation
5 workers, and so they were subject to the 100 millirem
6 limit.

7 The licensee did an initial quick
8 assessment, and they came up with a maximum dose of
9 about 6 rem. They also had one of the people give
10 blood and they did a cytogenetics analysis to
11 determine chromosome aberrations and then estimate the
12 dose. And the result came back at a dose of 200 rads.
13 Now, this is something of great concern because that
14 starts to border on a lethal dose. Some people die
15 from 200 rads of radiation. And so we were very
16 concerned; so was the licensee.

17 We quickly did just a very quick
18 calculation. We assumed the bare 1 curie cesium
19 source. We assumed the distance that the people were
20 standing at, and we did a rough calculation. And our
21 calculation showed that there was no way these people
22 could have received 200 rads. It's just not possible.
23 We refined the calculations, we used Microshield,
24 which is another industry standard for external
25 exposures, and, again, the calculations showed there

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1 was no way the dose could approach 200 rads.

2 We had a special inspection go out and
3 interview the workers, inspect the site. We also --
4 because we did the dose assessments based on a 1 curie
5 cesium source, we thought, well, maybe the cesium
6 source was mislabeled. Maybe it's not a 1 curie
7 source. Maybe it was just mislabeled. And so we did
8 measurements on the actual source that was on the ring
9 to make sure that it was really 1 curie. And in fact
10 it turns out to be it was 1 curie, and so that gave us
11 some confidence.

12 We decided to repeat the blood testing, so
13 we had ten workers volunteer for the tests, and we
14 sent the blood out to two labs. One was in the UK,
15 which was a well-known lab in this area. And the
16 reason we used two labs was to eliminate the
17 possibility that maybe the technique used by the lab
18 that did the initial test was not correct, that they
19 were doing some kind of systematic error that produced
20 the wrong dose. We also got detailed drawings of the
21 source and the reg, and we modeled it using Monte
22 Carlo computer codes and the merge phantom to do the
23 dose calculations.

24 The results of all this effort was that
25 the calculations showed that the maximum dose could

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1 not have exceeded 300 millirems for the most highly
2 exposed worker. All the bloods tests that were done
3 the second time came back negative, at least within
4 the sensitivity of the members.

5 DR. NAG: Does that include the oil worker
6 who had the high dose or not?

7 DR. SHERBINI: He was negative also.

8 DR. NAG: Okay.

9 DR. SHERBINI: Yes. Yes. So at least the
10 tentative conclusion is that the first cytogenetics
11 tests was probably an error, although we're still
12 discussing that. But, clearly, this incident did not
13 -- if the person had received 200 rads, he did not get
14 it from that incident.

15 DR. DIAMOND: Sami, did this individual
16 have an acute radiation syndrome?

17 DR. SHERBINI: No, he didn't.

18 DR. DIAMOND: Just from basic common
19 sense, if you receive 200 CUI whole body over a
20 limited number of hours, essentially a pseudo
21 fraction, if you will, I don't know if it was two
22 hours or six hours, you would expect very substantial
23 acute radiation toxicities, the classic manifestations
24 you'd expect, very typical platelet drops, and I don't
25 know, did the patient have any of those laboratory

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1 manifestations?

2 DR. SHERBINI: No. The patient did not --
3 luckily, it was. Luckily, it was. The patients was
4 kind of a hypochondriac.

5 (Laughter.)

6 He was very concerned about his exposure,
7 and so what he did was he had blood drawn every week
8 after the exposure for a period of about three months.
9 So we had weekly blood samples for a three-month
10 period. And the blood samples, of course, count the
11 lymphocytes and so forth, and we had the plot and
12 there was no indication of any kind of radiation
13 exposure.

14 DR. WILLIAMSON: So where did the 200 rem
15 cytogenetic estimate come from?

16 DR. SHERBINI: It came from the first
17 blood test that was done on this person, and we think
18 -- it's not clear what went wrong in this test, but --

19 DR. SULEIMAN: Could they have radiated
20 the blood?

21 DR. SHERBINI: No. We checked on that.
22 We checked with Fed Ex, we checked with everybody but
23 there was -- no, no, the blood was not irradiated.
24 There was also shipping dosimeters that accompanied
25 the blood, and these did not show any exposure.

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1 DR. DIAMOND: I think that's an
2 interesting question. Since I don't know how these
3 systems work, let's say a blood sample was taken and
4 let's say that luggage or that cargo, if you will, was
5 irradiated in the search for explosives or whatever we
6 look for. Could that have possibly --

7 DR. SULEIMAN: Not 200 rems worth.

8 DR. DIAMOND: I'm just asking. I mean if
9 there's such a difference between -- there's such a
10 disparity between the critical syndrome that this
11 patient did not have on basic laboratory parameters
12 and the calculations. I'm just trying to think of
13 anything --

14 MS. McBURNEY: There was an error made at
15 the lab. And it was dosimeters with the blood sample.

16 DR. SHERBINI: There is potential for
17 error in cytogenetics testing. I don't know if you
18 know the details of the process but what you have to
19 do is look at the cells after culture and identify
20 cells that two centimeters dicentric.

21 DR. DIAMOND: Hopefully he doesn't have
22 acute leukemia.

23 DR. DIAMOND: Seriously. That's a degree
24 of cytogenetic anomalies.

25 DR. SHERBINI: No. Actually, there are

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1 several conditions that can mimic dicentrics, and
2 that's one possibility, the lab might have mistaken
3 these conditions for true dicentrics. And what they
4 do is they count dicentrics and then go to calibration
5 curve and read off the dose from these curves. And so
6 it's easy to make mistakes.

7 But the other piece of data is the repeat
8 test on that person showed that the dose was negative,
9 that's all.

10 The net result of this was that the NRC
11 rejected the initial cytogenetic test, and they also
12 rejected the licensee's dose assessments as being too
13 conservative. We felt that the licensee made
14 assumptions that were completely unwarranted. For
15 example, they neglected all the shielding around the
16 source, which of course raised the dose. They also --
17 they had estimated how far the people were standing
18 from the source, let's say three feet. They used that
19 three feet as the distance to the body, which is of
20 course not correct, because you'd be calculating the
21 dose to the feet, basically, which is not what you
22 want. You want the dose to the vital organs, and so
23 the distance up from the source is much greater than
24 three feet. And so putting all these things together
25 makes a big difference in the dose you assess. And

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1 when all these assumptions were removed, we were able
2 to drop the dose from 6 rem to 0.3 rem quite easily,
3 and these are the numbers we finally accepted for this
4 assessment.

5 I think this clearly demonstrates that NRC
6 will go to great lengths to try and get the most
7 reasonable assessment of the dose to the people. But,
8 again, the fundamental underlying thing is that the
9 data has got to be there. We don't like to make
10 assumptions, but we will if we have to, and avoiding
11 having to do that means that the data must be
12 available. And usually the best person to provide it
13 is the licensee. Yes?

14 MS. MCBURNEY: If this is the case I'm
15 thinking of, this was a Texas licensee and he was
16 working in Montana.

17 DR. MILLER: You're right.

18 MS. MCBURNEY: And one of the lessons that
19 we learned from this and several other instances in
20 which we want to get good data on cytogenetics is that
21 the program that we had depended on for many years at
22 Oak Ridge had lost its funding. And so we're trying
23 to work with NRC and perhaps COE and try to get that
24 reinstated.

25 DR. MILLER: Yes. What Ruth's identified

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1 is this particular case identified a dilemma, I guess,
2 for lack of a better word for us in getting good
3 cytogenetic test results domestically. Sami touched
4 on the fact that we had separate blood tests
5 evaluated, but we had to go overseas to get that done.
6 And getting it done in a timely manner and getting it
7 done economically, as economically as we could, so
8 it's Sami's currently working on an effort trying to
9 see other -- what other capabilities are, and are
10 there indeed other capabilities in the United States
11 that we haven't identified?

12 And part of the reason that he's doing a
13 presentation this morning and not this afternoon is
14 he's traveling this afternoon to the University of
15 Pittsburgh to do some further evaluation of their
16 capabilities there. But it's identified a dilemma for
17 us. It's rare that we or maybe the states would have
18 the need for this, but when we do have the need for
19 it, as Sami's pointed out, we had the need for it in
20 a fairly timely manner. And I guess, Sami, you
21 haven't talked about it but we made a third attempt,
22 I guess, to go to South America to try to get some
23 results --

24 DR. SHERBINI: Oh, yes.

25 DR. MILLER: -- and it does add to the

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1 dilemma of having to go overseas, and because of the
2 time delays of the samples reaching the laboratory in
3 South America, the samples end up being, I guess,
4 voided because of time delays.

5 DR. SHERBINI: Yes. They degrade it. As
6 Charlie indicated, the problem with using overseas
7 facilities is that we tried to send a sample to Brazil
8 because they were the people who did the Guyana
9 incident so they had a great deal of experience. But
10 the difficulty we encountered was the Brazilian
11 government does not permit blood samples into the
12 country. And so we could not get the blood into the
13 country to get it to the lab. Fortunately, the UK
14 does allow this kind of shipment as we were able to do
15 that, but this varies from country to country and of
16 course it can change over time. And so we might lose
17 our UK capability any time if we change their laws in
18 that area. So it's very important to have a U.S.
19 based facility, and that's what we're working on.

20 DR. MILLER: It's a challenge.

21 CHAIRMAN CERQUEIRA: It is, definitely.
22 Subir, you had a comment, question?

23 DR. NAG: Yes. I think this also
24 underscores that when you are making an estimate, a
25 dose estimate, there are so many factors that you are

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1 presuming or assuming that the dose difference can be
2 not just a matter of two, three, four times but as
3 much as 20 to 100 times depending on the assumptions
4 we are making, inverse square law, biological half-
5 life of the radioactive material and so on.

6 I mean just because you're getting an
7 estimate of, say, 100 millirems may mean you went from
8 one milligram to as much as ten grams.

9 DR. SHERBINI: Well, yes and no. I agree
10 with you that this is the case, but what I'm trying to
11 say is that, for example, in the MIT case it's true
12 the biological half-life can vary from person to
13 person, but there was enough data in that case for us
14 to actually determine the biological half-life for
15 this particular person. And so that allowed us to
16 eliminate this source of uncertainty. And if you go
17 -- for each factor that goes into the calculation,
18 then they can add up, and if you have the actual data,
19 then you can eliminate the sources.

20 The third case, it's a controversial one,
21 St. Joseph's Mercy Hospital, it had to do with a
22 patient was administered I-131.

23 DR. NAG: The famous one.

24 DR. SHERBINI: Yes. And the daughter of
25 that patient was sitting next to her. The patient was

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1 dying and the daughter, presumably, sat next to her
2 bed on and off during the period July 1 to 7, 2002.
3 When doing the dose reconstruction we found that it
4 was not necessary to do those calculations, because
5 the licensee had actually measured the dose every day
6 at the place where the daughter was sitting, and so
7 there was no need to do dose rate calculations. What
8 was necessary was to estimate the time, the duration
9 of exposure for each day that the daughter was sitting
10 next to her mother.

11 The total dose assessed by the NRC for
12 that period and by the licensee, unfortunately, were
13 at variance with each other. They did not agree by a
14 large margin. And although there was no disagreement
15 regarding the dose rates on which the calculations
16 were based, the disagreement centered on the estimates
17 of stay times, how long the daughter stayed next to
18 her mother during that period. And the licensee and
19 the NRC disagreed quite significantly in that
20 parameter, and so what we are doing now is we're going
21 back to the region to ask for details and maybe even
22 to the licensee to find out what the story is and what
23 really is the most appropriate time to reconstruct
24 that dose situation.

25 DR. SULEIMAN: Do you need to come up with

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1 a single number? Why don't you put an upper or lower
2 estimate?

3 DR. SHERBINI: We can do that. It would
4 be nice to narrow down the range because the range is
5 quite wide. I don't want to say what the range is
6 because it's still -- we're still discussing it, but
7 it is quite wide, and it would be nice to narrow it
8 down.

9 DR. SULEIMAN: Let the facts speak for
10 themselves. I mean that always fascinates me. If
11 it's an order of magnitude, then you should --
12 obviously, you want to tighten that up, but --

13 DR. SHERBINI: Yes. Well, obviously, if
14 we can't tighten it, then that's how it would have to
15 stay. But you would think that, well, the stay times
16 are basically just talking to the daughter and asking,
17 "What did he do?" And so it's interesting that even
18 there there is disagreements between the two groups.

19 DR. DIAMOND: Sami, just out of curiosity,
20 was this woman truly ill when the 300 millicurie were
21 delivered or did the patient have an intercurrent
22 illness after administration of high-dose iodine in
23 which she became extremely ill, had a massive heart
24 attack the day after administration?

25 DR. SHERBINI: No, no. She was certainly

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1 ill. I mean in fact she died on July 7. That's when
2 the --

3 DR. DIAMOND: Just for the sake of this
4 committee, nothing to do with what you're talking
5 about, it raises a very interesting aspect of medical
6 judgement on why in the world a physician would give
7 high-dose I-131 to a person of this life expectancy,
8 not only from an ethical point of view but also any
9 time you give a radionuclide you have to consider that
10 patient's ability to comply with regulations. Is this
11 patient going to be able to be helpful with the
12 nursing care? There are a whole sort of issues with
13 this, and at first glance, not knowing the case, there
14 are some important clinical issues at hand.

15 DR. MILLER: The other issue that we face,
16 which I'm sure you would be concerned with is that
17 human nature issue of a loved one who is next to a
18 dying parent or a dying relative who's received that
19 dose and the exposure of that loved one, and you --
20 where do you strike the balance with regard to their
21 ability to be with their loved one in their dying days
22 versus the radiation concerns? It strikes a balance
23 -- it's a moral dilemma as well as --

24 DR. DIAMOND: But there are very, very few
25 circumstances in which you can justify with a person

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1 with -- let's assume, since we don't have the facts,
2 she's dying of complications of widely metastatic
3 thyroid cancer, differentiated thyroid cancer.
4 Administration of 300 millicurie in this setting will
5 have no absolutely no bearing on that person's life
6 expectancy and only impair that final relationship,
7 the quality of it and so forth.

8 CHAIRMAN CERQUEIRA: Sami, I wonder if
9 you'd care to comment on the letter that was received
10 from the Carol Marcus and several letters are going
11 back and forth. This was given out to the Committee,
12 and the Committee members got letters from -- emails
13 from Carol and the other people.

14 DR. SHERBINI: I take the Fifth. First of
15 all, I think there are things that are not clear in
16 the letter. For example, she mentions dose
17 calculations whereas in fact there were no dose
18 calculations. There were measurements and so those
19 calculations were not necessary. And the only thing
20 that had to be estimated in fact was time, and so --

21 DR. NAG: And distance?

22 DR. SHERBINI: Pardon?

23 DR. NAG: Distance and time.

24 DR. SHERBINI: Well, even distance is not
25 really --

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1 DR. NAG: Because you can't be right on
2 top of the basin 24 hours a day for so many days.

3 DR. SHERBINI: True, but the dose gradient
4 close to the patient's bed was not very short. And so
5 even if the daughter moved back and forth a little
6 bit, it really wouldn't have such a great impact. And
7 I don't think there is much controversy or
8 disagreement regarding the dose rate in which the
9 daughter was sitting. I think the disagreement was
10 how long she sat there. And that's really it.

11 DR. SULEIMAN: There wasn't an issue where
12 she embraced her mother and hugged her?

13 DR. SHERBINI: No. The times involved are
14 very large. We're talking tens of hours. And so it's
15 not a two second thing. She sat there for what some
16 claim is the entire day, and so we're talking long
17 time periods, and so it's --

18 MR. LIETO: And there's also a discrepancy
19 as to when it started.

20 DR. SHERBINI: Yes.

21 MR. LIETO: As Sami pointed out, the NRC
22 calculation began with the day of administration. And
23 to answer one of Dr. Diamond's questions, the patient
24 when administered, had renal function and was
25 conscious and the expectation was that she was going

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1 to be discharged. So it wasn't that she was in -- she
2 didn't go into renal function until two or three days
3 after, and that's when things went sour.

4 DR. SHERBINI: I guess the --

5 MR. UFFELMAN: Bill Uffelman, Society of
6 Medicine. And not to defend Dr. Marcus but there are
7 additional documents in the pile that you have by Dr.
8 Royal as the President of the Society of Medicine. We
9 had a couple meetings with at least commissioners,
10 Commissioners McGaffigan and Merrifield, and then
11 there are some letters relative to that. And one of
12 the topics was not so much the specifics of this but
13 the reality that there is expertise out in the
14 community, sitting around this table that we as a
15 society felt that the NRC could benefit from bringing
16 in additional experts or calling on that expertise.
17 And at the end of September your charter was amended,
18 and I presume you've all seen that, to indicate that
19 you in fact can all now be experts. And we have since
20 written a letter to the commissioners commending them
21 for doing that because we felt it was consistent with
22 the discussion that was kind of summarized in the
23 letter there.

24 And then Dr. Seigel and Dr. Marcus have
25 written a monograph that at some point will be

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1 published in the Journal of Nuclear Medicine soon.
2 You may have all or some of you may have benefited
3 from the emails to that effect, but I didn't feel that
4 I could distribute that until it got published. Then
5 I guess when you have your future meeting, that
6 probably will be included with it.

7 DR. SHERBINI: Well, if I might comment on
8 that. I think this mischaracterizes the problem and
9 the issues really. The problem, as I see it, is not
10 one of expertise. I think we have plenty of high-
11 quality expertise in the agency. I think, as these
12 cases should have illustrated, and there are a lot of
13 other cases similar to that, is that the outcome is
14 dependent on the quality of the data that we use to do
15 the assessments. The expertise in terms of actually
16 doing the calculations, running the codes and so forth
17 is there. But as the famous computer "garbage in,
18 garbage out" kind of thing, you have bad data in,
19 you're going to get bad assessments out. It has
20 nothing to do really with the expertise. It has to do
21 with how much later do we have the quality of the data
22 and how many assumptions we are forced to make because
23 the data is not there.

24 DR. WILLIAMSON: Well, I think there is a
25 legitimate issue that's being raised by these letters.

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1 I certainly agree the industry standard is when you
2 don't have the data, you make the worst possible
3 assumption to get the highest number. But I guess
4 maybe in these scenarios one can question whether
5 that's really a good idea, that perhaps you should
6 provide a range of numbers based upon different
7 scenarios and site uncertainty and that this should
8 probably be taken into account in the severity of the
9 regulatory response, that if indeed the people were
10 making reasonable efforts to protect this grieving
11 person and someone comes along later and comes up with
12 some different estimate, I mean this should all be
13 considered, and maybe the individuals shouldn't have
14 been cited.

15 I think this is really the issue of
16 philosophically when there is a large amount of
17 uncertainty in the data, this should be acknowledged,
18 and it doesn't seem appropriate, especially when
19 there's no issue of medical harm to anybody, this is
20 all sort of a -- at the sort of epidemiological level
21 we're considering even 2 rem exposure. Why do you
22 necessarily hit the licensee with a regulatory
23 response as if with certainty they delivered this high
24 limit?

25 CHAIRMAN CERQUEIRA: Although, again, it

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1 looks like there are several issues here. One is just
2 a conservative approach to the dose calculations, and
3 I think in this particular case that you had all the
4 data, it's just a matter of the time, and that seems
5 to be a very subjective variable that went into the
6 calculation. And in the other cases, I think, again,
7 the differences in that initial one between their
8 estimate of 600 -- I mean those numbers are relatively
9 small. So I think one thing is just the overall
10 approach, and certainly from the three cases presented
11 here, it seems to be a realistic approach.

12 DR. WILLIAMSON: I think that -- well --

13 CHAIRMAN CERQUEIRA: David?

14 DR. DIAMOND: Yes. We all understand that
15 there are inherent difficulties in the calculations
16 based upon those variables. I think the more
17 important point is, Sami, in your opinion, are there
18 truly differences between how the staff, NRC staff
19 calculates these doses, what algorithms they use and
20 perhaps the methodology and the algorithms that would
21 be used by outside individuals? In your opinion, is
22 there a difference?

23 DR. SHERBINI: No, there is no difference.

24 DR. DIAMOND: So if there's no difference,
25 I don't understand the substance of these letters

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1 then. If the methodology is the same, there's no
2 difference. If there truly is a difference in
3 methodology, then there needs to be discussion on the
4 topic.

5 DR. NAG: There's not a difference in
6 methodology of calculation, it's the difference in
7 your estimation. For example, are one foot away or
8 one and a half foot away. Although it doesn't sound
9 like a big difference --

10 DR. DIAMOND: I understand that.

11 DR. NAG: -- it makes a huge difference.

12 DR. DIAMOND: But that's not what the
13 letters are saying.

14 DR. NAG: If you add a lot of assumptions,
15 when you add four or five different assumptions, they
16 all add up. Two times, that's a two-fold difference
17 with one assumption. Another two-fold difference --
18 and all of them are on directive sides. When you
19 multiply them then it becomes, in a sense --

20 DR. DIAMOND: Right. That I agree with.
21 It would be more useful to have ranges, as was pointed
22 out, but as far as the actual methodologies, I mean
23 it's radiation -- it's basic radiation calculation.

24 DR. SHERBINI: Yes. There's no
25 difference. I think the point raised here was well

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1 taken in that the most fruitful area to discuss and to
2 consider I think is the kinds of assumptions that
3 would be reasonable to make in each given case.

4 DR. SULEIMAN: Did you do any chromosome
5 testing for the --

6 DR. SHERBINI: Pardon?

7 DR. SULEIMAN: Did they do the blood
8 testing on the woman, on the daughter?

9 DR. SHERBINI: No, they did not.

10 DR. SULEIMAN: Because that would validate
11 if you're -- that would clearly come in -- that would
12 support one or the other set of --

13 DR. SHERBINI: The doses even with the
14 high estimates are below the sensitivity limits. So
15 they wouldn't really help very much.

16 MS. SCHWARZ: I have a question.

17 CHAIRMAN CERQUEIRA: Yes.

18 MS. SCHWARZ: Is the NRC planning to at
19 some time in the future look into the idea of
20 collaborating with members in the community in terms
21 of doing these types of calculations?

22 DR. SHERBINI: I think what we're trying
23 to do is to absorb the information that we've received
24 and try to decide where to go from here. The NRC is
25 going --has been going through what I would call a

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1 paradigm shift. Traditionally, when we did dose
2 calculations --

3 DR. NAG: Most conservative.

4 DR. SHERBINI: -- we always used
5 conservative analysis, because that way if things are
6 okay based upon conservative analysis, you had nothing
7 to worry about; it was easy to defend. We're moving
8 towards a realm of trying to risk inform our
9 operations and our way of doing business. That's not
10 a step change in the way that we do things and the way
11 we do business. It requires what I would call a shift
12 in the way that we think. And that shift doesn't come
13 overnight because you're taking people who have been
14 working in the field, in many cases, for many, many
15 years and you're asking them to change the way that
16 they're doing business. That takes, in some respects,
17 a cultural change. That's the challenge, but
18 nevertheless our challenge and what the Commission
19 wants us to do is move towards a more risk-informed
20 approach. To that extent I think trying to build the
21 various thoughts that we get from groups into that
22 helps, and to the sense that the Committee can give
23 us counsel in that area, that also helps.

24 But I think what Sami's tried to point out
25 are two things. One, to the extent that the licensee

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1 can take immediate action to try to gather
2 information, that goes a long way from not having to
3 apply conservatisms where you don't need to. To the
4 extent that that doesn't happen, well, then we're left
5 with how do we use a risk-informed approach to try to
6 analyze the situation.

7 And it's very interesting from our
8 approach because going back to the second case that he
9 talked about, the well logging case, I had an
10 opportunity to go out to Montana and meet a number of
11 people who were involved in this case. And these are
12 plain people who work -- they're not -- and I don't
13 mean this in any derogatory manner, for the most part
14 they're not college-educated people, they work out in
15 the field, they're oil rig workers. It's a community
16 who doesn't understand medical science in any way,
17 shape or form, and they really are looking to the NRC
18 to try to make sense of this for them. Because
19 they're worried about what kind of health effects,
20 what did they read in the newspapers, what did they
21 see on TV. Radiation is harmful, so they get very
22 concerned about that. So we have to take our duties
23 seriously to decide where do we draw the line. I
24 guess that's kind of a long-winded answer, but we are
25 trying to move towards a more risk-informed approach.

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1 To be quite blunt, Same's too much of a
2 gentleman to say this, but some of the letters we
3 received were pretty, I would call, violent kinds of
4 letters. And they go back d-- they don't go back just
5 because of this one case, it goes back to a number of
6 years, I think, of frustration on the part of the
7 letter writers with regard to how they view the
8 conservatism that's put into the NRC's calculations.

9 So we're trying to move towards trying to
10 get enough information as we can so that we can move
11 not only to a risk-informed approach but to try to get
12 as realistic of results as we possibly can. And
13 that's the challenge that I have, that's the challenge
14 that I've given my staff.

15 DR. WILLIAMSON: Well, I mean, I guess --
16 I think that, you know, what a good scientist does is
17 not just think in terms of an answer that you get with
18 a computational methodology. You think in terms of
19 uncertainty, there are established rules for
20 estimating uncertainty and principles, and I think
21 this is sort of one way to inform your regulatory
22 responses to take into account not only that magnitude
23 of the estimate but the uncertainty thereof.

24 DR. WILLIAMSON: And I think we do
25 sometimes. I mean if you're looking at that second

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1 case, we could have taken the first results we got
2 with regard to the cytogenetic testing and came out
3 with a complete overreaction.

4 MS. MCBURNEY: Right.

5 DR. WILLIAMSON: But it didn't make sense
6 to Sami, as the expert on the case. It just didn't
7 make any sense, given there were no health effects
8 noticed, something just -- the reconstruction given
9 the size of the source didn't seem to make any sense.
10 So that's where you've got to take a step back and
11 start trying to use other logical uniques to say
12 something's not right here.

13 CHAIRMAN CERQUEIRA: All right. I think
14 we should try to wrap up the discussion. Bill, one
15 last comment.

16 MR. UFFELMAN: The comment I wanted to
17 make was one of the frustrations that Dr. Royal and
18 others had voiced was the lack of availability of the
19 information that you all have used so that you could
20 independently sit down with the back of an envelope
21 and make a calculation, that the information was not
22 available at the time and became available after the
23 meeting with the commissioners.

24 DR. MILLER: Yes. And to a certain degree
25 we have to protect that information because of the

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1 rights of the individuals who have been affected by
2 this. So there's certain privacy rights that they
3 have, and the way that we have to roll out the
4 information has to continue to protect those privacy
5 rights.

6 MR. UFFELMAN: But the results were
7 announced but not the arithmetic -- not what went into
8 the --

9 DR. MILLER: The numerology that was used
10 to do that?

11 MR. UFFELMAN: Right. That was the
12 difficulty, the lack of data.

13 CHAIRMAN CERQUEIRA: Sami, thank you very
14 much.

15 DR. SHERBINI: There's a second part.

16 CHAIRMAN CERQUEIRA: Oh.

17 DR. SHERBINI: I'll try to go through this
18 very quickly.

19 MR. ESSIG: Angela does not need 45
20 minutes.

21 CHAIRMAN CERQUEIRA: Okay. Well, she's
22 going to have about ten. Okay. Nicki, go ahead.

23 MS. HOBSON: Well, you know from listening
24 to me five and a half years that access to quality
25 medical care delivered by competent physicians in a

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1 safe environment is a major issue for patients. And
2 to the extent that the application of the regulations
3 interferes with that process, that's also a concern to
4 patients. We want good health care to be available
5 easily, and if the regulations drive providers out of
6 the business of giving these treatments or diagnostic
7 tests of whatever, then that's bad for patients.

8 Now, I don't have any opinion on who's
9 right and who's wrong on this particular issue, but it
10 looks to me in my simple way of looking at things that
11 you have two groups of very highly qualified people
12 who are disagreeing over something. Maybe it's the
13 methodology or I don't know what it is. But what harm
14 would come from getting those groups together to see
15 where are the differences, where are the points of
16 disagreement, who could we resolve that? Seems to me
17 that some benefit would come out of a process like
18 that, informal or formal, however you would structure
19 it. I would encourage you to do it.

20 MS. SCHWARZ: It seems to me also that
21 actual collaboration with individuals in the community
22 certainly would be a positive thing to pursue, because
23 there is expertise in the agency as well as certainly
24 in the community. And it wouldn't have to be that it
25 would be a violation of the individual's trust either.

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1 I mean this doesn't have to be announced in the
2 newspaper, but it could be certainly calculations
3 performed to assure both sides of this issue that the
4 right approach is being taken and that the ranges are
5 being looked at, not just the actual number.

6 DR. SHERBINI: Okay. I'll whiz through
7 this second one in five minutes, hopefully, because
8 we're running short of time. What I'll do is just
9 present the problem just to make you aware of what's
10 going on.

11 This has to do with monitoring of the
12 hands of people working with radiopharmaceuticals.
13 The problem is this: People usually monitor the dose
14 to the hand using finger badges, which are worn like
15 a ring on the base of the finger, and people are
16 handing things with the tips of the fingers in many
17 cases. Our regulation requires that the dose be
18 monitored at the location that receives the highest
19 dose. Now, the place where the dosimeter is located
20 and the place where the dose is being received are not
21 the same. And the question is should there be some
22 kind of correction factor that is added to the
23 dosimeter reading to get a dose that would be used to
24 show compliance? And that is really the issue that we
25 are struggling with.

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1 To complicate this is the fact that the
2 dose limit to the skin or the extremities has been
3 changed recently. The previous dose was -- the
4 previous limit was 50 rems to the most highly exposed
5 one square centimeter of skin. The new limit is 50
6 rems to the most highly exposed ten square centimeters
7 of skin. Now, that represents a relaxation of the
8 dose limits, in some cases quite considerably, but it
9 makes monitoring a bit more difficult or at least it
10 makes deciding whether a correction factor is needed
11 or not is more difficult.

12 So if you're doing -- there's a two-
13 pronged approach going on right now. Industry is
14 making some measurements of dose placement and dose
15 received using multiple dosimetry and so forth to try
16 and figure out what kind of correction factor would be
17 appropriate in that case.

18 And the other effort is theoretical. We
19 don't need -- the other effort we're working with Oak
20 Ridge to try and do this by calculation. We are
21 trying to calculate when somebody handles various
22 types of geometries with various 3-D nuclides in these
23 containers, what kind of dose would be received by
24 fingering and what kind of dose would be received to
25 show regulatory compliance?

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1 And the end result we're hoping to get
2 from this is to decide whether it is appropriate to
3 use the fingering reading directly without any
4 corrections or whether a correction factor is needed
5 in order to show compliance with our dose limit. So
6 that's where we are right now. We don't know the
7 answer yet, but that's where we are.

8 MS. SCHWARZ: And you're collaborating
9 that with Oak Ridge?

10 DR. SHERBINI: Yes. At least that's one
11 part. Corrar is the industry arm that's doing the
12 measurements of -- or supervising the measurements.

13 MR. LIETO: Sami, is the, I won't say the
14 intent, but what you're thinking is that the
15 correction factor would be a number greater than one
16 and that would have to be applied to
17 radiopharmaceutical handling?

18 DR. SHERBINI: Well, we're hoping that
19 with the change in the dose limit to -- ten square
20 centimeters is basically the area of the entire
21 finger, and so we're hoping that with this change the
22 appropriate correction factor might be so close to one
23 that we don't need a correction factor. This would be
24 the best outcome really to make things a lot simpler
25 than having to use a correction factor. Especially,

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1 if you have to use a correction factor, it will
2 probably be different depending on the kinds of
3 manipulations that you are doing, and so it kind of
4 complicates things a little bit. So, yes, we're
5 hoping that the correction factor would come out to be
6 nearly one, but we don't know yet.

7 MS. SCHWARZ: And I have one other
8 question. When do you anticipate this work would be
9 completed?

10 DR. SHERBINI: It will probably take close
11 to a year, I would think. It's a complex set of
12 calculations, and so it will take some time.

13 DR. WILLIAMSON: Do you plan to publish
14 this as a technical report or NUREG or something?
15 That sounds like it would be a very interesting study
16 to summarize in some detail, in writing for the
17 benefit of the community.

18 DR. SHERBINI: We're hoping to publish
19 this in the open literature once we get all the data,
20 yes. Thank you.

21 CHAIRMAN CERQUEIRA: Thank you, Sami.
22 While Angela's coming up, she's just informed that
23 after lunch the Ron Zelac update on interpretation of
24 10 CFR 35.61 will be given first, and then the other
25 things will follow after that. And now Angela is

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1 going to be talking about radioiodine activity
2 threshold for treatment of hyperthyroidism.

3 MS. WILLIAMSON: Good afternoon. I'll try
4 to make this very quick. I probably never really
5 needed the 45 minutes. It kind of depends on how many
6 questions this issue raises, but we actually might be
7 in good shape despite how things look right now.

8 I know that the ACMUI, that everyone
9 sitting around the table this morning knows who I am,
10 but for the benefit of the audience my name is Angela
11 Williamson, and I work in NMSS, the Office of Nuclear
12 Material Safety and Safeguards. And one of my primary
13 functions is coordinator for this Advisory Committee,
14 and I'm here today to bring an issue to the ACMUI to
15 get their input on an issue that the regions have
16 recently identified. And that issue, as the title
17 states, is should there be an activity, a radioiodine
18 activity threshold for the treatment of
19 hyperthyroidism. So let's go on ahead and get
20 started.

21 What brought this issue -- let me give you
22 a little bit of background to put this all into
23 context. Under the previous regulation, the previous
24 medical regulation, 10 CFR 35, the regions were not
25 listing an iodine activity limit on the licenses of

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1 licensees for the treatment of hyperthyroidism, and
2 the reason why they didn't is because it was assumed
3 that no one would use more than 33 millicuries. Well,
4 now we're operating under the new Part 35, which was
5 effective as of October 2002 and there are limits that
6 are in the new regulation. For less than or equal to
7 33 millicuries there are training and experience
8 requirements, and for greater than 33 millicuries,
9 under 35.394, there are training and experience
10 requirements.

11 This has now brought up an issue within
12 the regions because the regions are now renewing
13 licenses for people who previously were authorized
14 users under the new regulation but they're renewing
15 the licenses -- they have to renew the licenses under
16 the revised regulation now. And these very same
17 licensees they're claiming that they have experience
18 using greater than 33 millicuries, but we don't have
19 any documentation because we didn't -- it was not
20 being listed in previous licenses.

21 In addition, these same licensees are
22 stating, "Not only should I be able to use greater
23 than 33 millicuries, no documentation
24 notwithstanding," they're also saying, "I should be
25 able to use whatever activity I want to use." So for

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1 I think a now obvious reason, this has become
2 problematic in the regions. They want to accommodate
3 the licensees but they don't quite know how to do it
4 because they never had the initial proof in the first
5 place that demonstrates that these people are indeed
6 qualified.

7 So that brings us to the question that
8 needs to be answered: For these particular groups of
9 licensees, should NRC, regardless of what they claim,
10 should we restrict their activity or restrict the
11 activity that they are using for the treatment of
12 hyperthyroidism or is this a practice of medicine
13 issue and we shouldn't Get involved with restricting
14 the activity? That's the first question. And the
15 second question is if the activity should be
16 restricted, then what's the upper limit?

17 Now, let me throw in one more qualifier as
18 we're debating these questions. The reason why the
19 licensees believe that they should be able to use
20 however much activity that they feel is necessary is
21 because they're saying for certain cases of patients
22 they have to superdose them because of the low uptake
23 within the thyroid. The uptake is somewhere between
24 five and seven percent, so they have to compensate for
25 that, and that's the general reason that they're

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1 giving people -- the general reason why they feel they
2 should be able to give them whatever they feel is
3 necessary to give them. So that's the question.

4 CHAIRMAN CERQUEIRA: Dick?

5 DR. VETTER: Yes. It appears to me that
6 within the regulation hyperthyroidism is not even
7 mentioned and it shouldn't be, because we're not
8 trying to tell doctors what they would prescribe the
9 iodine for. We simply more or less, arbitrarily,
10 based on experience, drew a line at 33 millicuries
11 saying below this number you need a certain amount of
12 training, above it you need additional training. And
13 it's not referring to any medical condition at all.
14 We're not telling a doctor he can't give 50
15 millicuries for hyperthyroidism, but if he wants to
16 give 50, he's got to have more experience in handling
17 radioactivity.

18 DR. WILLIAMSON: To follow, my point was
19 the same thing. I don't see where hyperthyroidism or
20 thyroid cancer are mentioned as the two clinical
21 indications in this regulation. Very quickly reading
22 35.392 and 394, the only difference in the training
23 and experience is that they have to show three cases
24 of experience greater than 33 millicuries in one and
25 three cases less than 33 millicuries in the other. So

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1 what is wrong with applying that criterion and asking
2 them to basically fill out a Form 313A that documents
3 experience with three cases less than, three cases
4 more than and license them for both?

5 CHAIRMAN CERQUEIRA: Ralph?

6 MR. LIETO: Angela, were these individuals
7 licensed under the old Part 300?

8 MS. WILLIAMSON: Yes.

9 MR. LIETO: Well, then I would think that
10 they would be grandfathered in.

11 MS. WILLIAMSON: Yes.

12 MR. LIETO: Okay? And so it wouldn't be
13 an issue from that standpoint. If it's an issue of
14 possession limit in terms of how much they could have,
15 again, I think it would be a matter of what they felt
16 was appropriate for their practice of medicine. The
17 issue of being above 33 millicuries would be if the
18 patient follow directions or comply with the
19 restrictions for release into the general public, then
20 they have to be hospitalized and if they're
21 hospitalized, then you've got all those things. And
22 that's where that 33 millicuries came in. But I think
23 the question about whether having the authority would
24 again I think under this renewal process would be a
25 matter of if they were authorized for 300.

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1 Now, the question that's come up actually
2 is the reverse in that under 200, old 200 physicians
3 were allowed to administer millicurie amounts of I-131
4 for diagnostic studies, whole body retention studies
5 and so forth. The problem has occurred that under the
6 new Part 35 that with the Section 392, okay, there's
7 this gap or gray zone where they're not allowed to use
8 the I-131 because it requires a written directive and
9 they have no necessarily documented training that they
10 did this. And I have questions about relating to
11 Dick's question about preceptor. Well, how do we
12 document this as we move into the new Part 35 for
13 renewal? We're documenting for these physicians to
14 allow them to continue to do the diagnostic studies
15 with I-131, which required maybe more than 30
16 microcuries.

17 MS. WILLIAMSON: The grandfathering -- we
18 know that these people are qualified. They were
19 qualified under the old regulation to be AU so we know
20 that they continue to retain that qualification, but
21 the issue with grandfathering -- the issue with it is
22 that they are -- we have no documentation that they
23 have actually -- no proof that they have actually
24 handled what they said they handled. And so we're
25 trying to get a grasp on how we can ascertain whether

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1 or not they really have this experience.

2 MR. LIETO: Well, if they were authorized,
3 say Dr. X --

4 MS. WILLIAMSON: Right.

5 MR. LIETO: -- was approved for 35.300.
6 Well, the training and experience had to have been
7 there for him to get authorized under the license. So
8 you --

9 MS. WILLIAMSON: True, but we assume that
10 he was using no more than 33 millicuries, and now
11 they're coming in --

12 MR. LIETO: No. No. Three hundred was
13 any radiopharmaceutical therapy, period.

14 CHAIRMAN CERQUEIRA: Yes. Dick and then
15 David.

16 DR. VETTER: If it's a matter of
17 documentation, then these physicians simply need to
18 fill out a new 313A and whoever they were working with
19 or under sign it as the preceptor, and now they have
20 the documentation.

21 CHAIRMAN CERQUEIRA: David?

22 DR. DIAMOND: Yes. I think that issue can
23 be easily resolved as well. I would like just to
24 point out that these requirements are not to my
25 thinking in any fashion, and in fact this is exactly

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1 the language that the endocrinologists wanted a couple
2 years ago. I see absolutely no reason to modify this
3 language. I don't feel there's any burden whatsoever,
4 and I think that the grandfathering issue is easily
5 overcomable to me. So I don't think any additional
6 action needs to be taken on these regs.

7 MS. WILLIAMSON: So I think what I'm
8 hearing is that -- for any licensee that fits into
9 this category ask them to fill out a new 313A, get a
10 preceptor's statement that the person is experienced
11 handling greater than 33 millicuries, and don't be
12 worried about restricting activity, don't worry about
13 an upper threshold for these folks.

14 DR. WILLIAMSON: I think that's right,
15 just qualify them as 94 or 92, as appropriate, for
16 what they've asked and plan to do.

17 CHAIRMAN CERQUEIRA: Leon?

18 DR. MALMUD: There is an underlying
19 question. Currently, radiologists are not required to
20 have more than three months of nuclear medicine
21 experience in the course of their residency. I think
22 it had been six months and in the course of either
23 three or six months they may not have had the
24 opportunity to provide to provide radioiodine therapy
25 in a dose greater than 30 millicuries. It may be that

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1 during that period of time no patient was treated with
2 over that dose of radioiodine. The question,
3 therefore, is not having had that experience is that
4 of concern to us for a board certified radiologist who
5 does have the experience and who has had the
6 experience in providing doses of less than 33
7 millicuries. Is that of concern to anyone here?

8 DR. VETTER: If I understand this
9 correctly, the current regulations someone ABR-
10 certified in diagnostic radiology is not automatically
11 qualified to administer radioiodine. They must see
12 these -- they must have additional training and
13 additional patients even if they are board certified,
14 because ABR in diagnostic radiology does not include
15 this qualification.

16 DR. MALMUD: So that currently, from your
17 understanding of the regs, and I'm not on top of the
18 regs currently on this issue, a radiologist is not
19 authorized to give I-131 therapy unless he or she has
20 had experience, documented case -- on a case-by-case
21 basis?

22 DR. VETTER: I'll clarify. A radiologist
23 certified by ABR and diagnostic radiology is not
24 qualified. If that person is certified by the
25 American Board of Nuclear Medicine, then they are

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1 qualified.

2 DR. MALMUD: I wasn't referring to the
3 nuclear physician. I was referring to the
4 radiologist. Many hospitals don't have nuclear
5 physicians.

6 DR. VETTER: Well, a radiologist could be
7 certified by American Board of Nuclear Medicine.

8 DR. MALMUD: Many hospitals do not have
9 radiologists that are certified by the American Board
10 of Nuclear Medicine. So that the question is, and I
11 don't know the answer, but the question is a board
12 certified radiologist who has had a rotation or
13 rotations in nuclear medicine as part of his or her
14 residency currently qualified to provide I-131
15 therapy?

16 DR. WILLIAMSON: Well, I think it's a
17 complicated question. If you look at the current
18 training and experience regulation, I believe that the
19 ABR diagnostic radiology qualification does not
20 conform to the requirements as currently stated for a
21 recognized credential. So anybody in radiology
22 through the regulations in the main part of the
23 document would have to qualify under the alternative
24 pathway. If you look in Subpart J, 35.92 and 94, it
25 doesn't actually mention any residency.

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1 MR. LIETO: Well, Dr. Malmud, to answer
2 your question, if a physician is ABR certified in
3 radiology, can he be authorized to administer
4 radiopharmaceutical therapy, and the answer is, yes,
5 providing he applies and is approved before October of
6 2004.

7 MS. McBURNEY: Right.

8 DR. VETTER: Excuse me?

9 MS. McBURNEY: Because they can use
10 Subpart J.

11 DR. VETTER: You need be careful about
12 radiology versus diagnostic radiology. Radiology is
13 an old board that included training in therapy, but
14 ABR and diagnostic radiology does not include that.

15 DR. MALMUD: I'll rephrase my question.
16 A radiologist finishing his or her training in the
17 year 2003 does not require much by way of nuclear
18 medicine training in the course of the radiology
19 residency. Currently, those individuals can be in
20 practice or enter practice and provide I-131 therapy.
21 Is the question on the table --

22 DR. DIAMOND: No. The answer is no.

23 DR. MALMUD: The answer to what question
24 is no?

25 DR. DIAMOND: The answer is there's a

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1 diagnostic radiologist coming out of training today
2 who by virtue of his training -- his or her training
3 experience has not, for whatever reason, satisfied
4 these additional requirements. Is that individual
5 able to go and give I-131? I believe from my
6 understanding of the regulations the answer is no.

7 DR. MALMUD: Including less than 33
8 millicuries.

9 DR. VETTER: That's correct.

10 DR. DIAMOND: That's correct.

11 DR. MALMUD: Okay. So you've answered the
12 question for me.

13 DR. DIAMOND: May I ask you why you were
14 asking the question in the first place?

15 DR. MALMUD: Because I don't see the great
16 significance and difference between giving 33
17 millicuries and giving 50 millicuries for precisely
18 the reason that Angela raised, and that is that are
19 some patients who may be coming back for a second
20 treatment of I-131 whose uptake is low because the
21 first dose reduced the uptake and yet they have still
22 have a larger goiter, are still hyperthyroid and
23 require a dose greater than 33 millicuries.

24 DR. DIAMOND: And that's precisely why two
25 years ago, I guess, we substantially relaxed the

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1 requirements for 35.394 at the request of the Society
2 of Endocrinology because they made exactly that point.

3 DR. MALMUD: And how does that affect the
4 answer to your question, Angela? Does that satisfy in
5 any way the answer to -- does that satisfy you? Or
6 the issue. It's not you we're trying to satisfy, it's
7 the issue you're trying to help us satisfy.

8 MS. WILLIAMSON: Well, I think I have the
9 answer I need for now to go forward to answer the
10 region's questions. The question was pretty
11 straightforward, but I guess ultimately it depends on
12 what kind of feedback we get back from the regions.

13 CHAIRMAN CERQUEIRA: Then I guess if it's
14 a question of licensing, clearly, if they had a
15 license previously, they should be grandfathered in.
16 And the feeling of the Committee is that 33, greater
17 than or less than, should still be considered in the
18 same category and not require any additional training
19 or restrictions.

20 MS. WILLIAMSON: Right. It's just that
21 newer people they have to be able to meet one or the
22 other, so we didn't really want people sort or sliding
23 in and giving them authority to handle a level of
24 activity that we can't even prove that they've ever
25 really handled.

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1 DR. MALMUD: It is a matter of certainty
2 that if a resident currently in training is required
3 to take as little nuclear medicine as he or she is to
4 satisfy the current American Board of Radiology,
5 Diagnostic Radiology, then that individual will most
6 likely not have had any experience in providing doses
7 equal to or greater than 33 millicuries. Then the
8 question arises does it matter? In other words, does
9 it matter -- are you concerned about someone providing
10 the dose of 50 or 60 millicuries?

11 DR. VETTER: Yes, it does matter. Less
12 than 33 -- the regulations clearly spell out that
13 relative to 35.75, and you can go to the reg guide to
14 do all the calculations or whatever, less than 33 the
15 patient can be treated as an out-patient. Above 33
16 you need to determine whether they can be treated as
17 an out-patient or whether they have to be kept in the
18 hospital for radiation protection purposes. So you're
19 really in a new ball game above 33.

20 DR. MALMUD: Thank you. You clarified
21 that for me, and I am reassured by your answer.

22 DR. NAG: The other -- usually more than
23 33 for thyroid cancer and not for hyperthyroidism.
24 That's another reason why I think there was a
25 differentiation. The major reason whether it's in-

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1 patient or out-patient.

2 CHAIRMAN CERQUEIRA: Okay. Leon?

3 DR. MALMUD: But the issue that Angela
4 raised was specifically for hyperthyroidism, not for
5 cancer, and the issue is correctly raised. There are
6 patients who are being treated for hyperthyroidism who
7 need more than 33 millicuries, and it's not the usual
8 but it's not uncommon either, and it's a reasonable
9 question to have raised.

10 DR. SULEIMAN: I think the answer to your
11 question is it is a practice of medicine issue. I
12 mean regardless of what -- but I think the second part
13 is it's a radiation safety issue. At what point do
14 you release them outside? So I think you've got to
15 keep those two issues segregated.

16 CHAIRMAN CERQUEIRA: Dick?

17 DR. VETTER: Just to underscore what Dr.
18 Suleiman just said, but I would reverse those. The
19 primary issue is a radiation safety issue, and we are
20 not in the business of determining, of telling doctors
21 whether they are administering the iodine for
22 hyperthyroidism or cancer or how much to give for
23 either of those. So it's just a radiation safety
24 issue above and below 33 millicuries.

25 DR. WILLIAMSON: Yes. And the question is

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1 do they want to be licensed for 920, 940 or both? And
2 you have an established pathway for forms and so on
3 that have to be filled out to establish the
4 credentials for each.

5 CHAIRMAN CERQUEIRA: Okay. Does that --

6 MS. WILLIAMSON: I'm going to go forward
7 with a recommendation for when the regions get this
8 type of -- when they encounter this type of situation
9 to request the training and experience on Form 313A
10 and to get a preceptor's attestation that the person
11 is capable of handling greater than 33 millicuries.
12 And I'll also underscore the fact that we should not
13 be concerned about an upper threshold limit of what
14 they should be -- what is appropriate for prescribing.

15 CHAIRMAN CERQUEIRA: And I guess in terms
16 of the preceptor, as we discussed yesterday, it
17 doesn't have to be the person who originally did the
18 training, because some of these people might be
19 difficult to do, but somebody who is currently in the
20 state of -- you know, in practice and understands what
21 they're capable or not capable of doing. Leon?

22 DR. MALMUD: What about the situation in
23 which the radiologist did not have experience with
24 doses over 30 millicuries, is practicing in an area
25 where he or she is the only person available to treat

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1 the person with hyperthyroidism and there's a
2 physicist in the department who can deal with the
3 issue of the radiation exposure and wants to treat the
4 patient with 40 millicuries. Should not that person
5 be able to treat, given the current advice and counsel
6 of a competent physicist? Dr. Vetter?

7 CHAIRMAN CERQUEIRA: Dr. Vetter says no.

8 DR. VETTER: Well, no simply because the
9 regulations don't allow it. Now, if we think that
10 that person -- that the threshold for 33 millicuries
11 should be changed, then we'd have to make a case for
12 that. But it really has nothing -- the regulations
13 have nothing to do, and shouldn't have anything to do,
14 with whether this is -- we're treating hyperthyroidism
15 or cancer. It has to do with the radiation safety of
16 the amount being given. And this doctor has no
17 experience dealing with patients who have received 40
18 millicuries, above the 33, then based on our
19 experience and the wisdom behind the regulations, that
20 person should not be allowed to prescribe more than
21 33.

22 CHAIRMAN CERQUEIRA: Ralph?

23 MS. MCBURNEY: You can go ahead, Ralph,
24 first.

25 MR. LIETO: I may burn for this for

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1 disagreeing with Dick, but I would say that if the
2 radiologist had experience in the administration in
3 hyperthyroids, the issue mainly becomes can by their
4 assessment the patient follow the directions for
5 release? And if it's basically -- the only reason is
6 the hyperthyroidism, they're coherent, family member
7 situations, all those factors come into play that this
8 can be administered as an out-patient. I think in
9 consultation and with the appropriate documentation
10 that it would be appropriate for them to administer
11 that 40 millicuries in that situation.

12 DR. VETTER: That would be in violation of
13 the regulations.

14 MR. LIETO: Why would it be a violation?

15 DR. WILLIAMSON: Because the regulation
16 says that they're authorized only for less than 33
17 millicuries and if they're not authorized --

18 DR. VETTER: It doesn't have to do with
19 hyperthyroidism.

20 DR. WILLIAMSON: Yes.

21 CHAIRMAN CERQUEIRA: Comment from the back
22 and then Ruth and then we'll come back here.

23 MS. FAIROBENT: Lynne Fairobent, American
24 College of Radiology. From sitting and listening to
25 this discussion, I think you're confusing two

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1 different points. One of the issues, and I think the
2 primary issue Angela was trying to deal with, is how
3 do we deal with those individuals who are currently on
4 a license where we did not have the separation of less
5 than and equal to 33 and greater than 33? I think
6 that we have a problem if we now require and to
7 backfit the grandfathering provision -- sorry, my
8 reactor background comes out with backfit analysis --
9 but under the grandfathering provision, I don't see
10 how we can now add under that for this situation a
11 requirement for the preceptor statement. If an
12 individual is currently on a license to do iodine
13 therapies and we did not in the past under the old
14 regulations specify any limit for the amount of
15 activity delivered in that, I think those individuals
16 need to be or considered to be grandfathered under
17 both 392 and 394. For anybody in the future who will
18 be a new user under the new regulation, the
19 regulations, I agree, are clear. The three case
20 studies are different, the preceptor requirements are
21 different, and I think that has to be looked at as we
22 go forward.

23 Dr. Malmud, I will get an answer to your
24 question over lunch about the Diagnostic Radiology
25 Board, because in any case if they have a diagnostic

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1 radiology certification, if they're certified by ABR
2 in that, in order to do the iodines they still have to
3 have three case studies that are done under the
4 supervision of an authorized user. And so I believe
5 that if they've already -- going forward in 2003 they
6 may not have gotten it in their residency, but if they
7 then practice at an institution and they do the three
8 case studies under the supervision, that should be
9 sufficient, at least the way I read the regulations
10 from 92 and 94.

11 The issue during the promulgation of the
12 draft rule was the difference between the
13 endocrinologists who only have the 80 hours of
14 radiation safety training versus diagnostic radiology
15 residents who have a three-month or a four-month
16 residency in which their radiation safety training is
17 greater than the 80 hours. And I think that's why we
18 had the differentiation in the ultimate final rule for
19 both 392 and 394 and not just the caveat of everything
20 being in 390.

21 CHAIRMAN CERQUEIRA: Ruth, did you want to

22 --

23 MS. McBURNEY: I was just going to agree
24 with Dick Vetter's assessment that the way the rules
25 are written it's based on the limits and radiation

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1 safety concerns dealing with those limits rather than
2 what the material is going to be used for.

3 MS. WILLIAMSON: So the issue of the
4 preceptor that Lynne brought up, do you still agree
5 that it's appropriate for us to go back and ask for a
6 preceptor statement?

7 CHAIRMAN CERQUEIRA: Dick?

8 DR. VETTER: I think Lynne brings up a
9 good point, and, actually, I think it really clouds
10 the issue, because in the new Part 35 it's strictly
11 radiation safety -- it's strictly based on safety.
12 And in Subpart J, it differentiates between
13 hyperthyroidism and cancer and does not refer to
14 activity.

15 MS. MCBURNEY: Right.

16 DR. VETTER: So someone who has been --
17 perhaps someone has been treating patients with
18 hyperthyroidism but if it's always been below 33
19 millicuries, now when Subpart J expires, will you be
20 able to treat someone with more than 33 millicuries?
21 think maybe counsel needs to look at that.

22 CHAIRMAN CERQUEIRA: Jeffrey?

23 DR. WILLIAMSON: Well, would it be
24 acceptable to request from these individuals who want
25 under the grandfathering provision to have both 394

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1 and 392 to provide a filled out 313A form to document
2 that they have been doing this under their old license
3 minus the preceptor statement since they may indeed by
4 a solo authorized user with no other authorized user
5 that could sign on their behalf? It would seem to me
6 reasonable evidence or you could ask even a radiation
7 safety officer to sign as a witness to these records.

8 MS. WILLIAMSON: What's the difference
9 between a witness and a preceptor.

10 DR. WILLIAMSON: Well, the preceptor is
11 legally defined as somebody who has to be an
12 authorized user for that category on an agreement
13 state or NRC license --

14 MS. WILLIAMSON: But I mean in the mind of
15 the licensee what would be the difference.

16 DR. WILLIAMSON: You could ask for a
17 reasonable level of evidence that that's been their
18 proactive pattern that they could comply with but
19 falls short of -- it may be very difficult to satisfy
20 legal requirement that this person have the status of
21 being an authorized user. It seems that's the issue,
22 but it seems a very reasonable request to document
23 that you have this experience in your past practice
24 pattern under the old whatever the number was, I can't
25 remember it, the single indication use for

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1 hyperthyroidism. That seems a reasonable request for
2 a regulatory body as long as you don't make the
3 standard for who can validate that impossible for
4 these individual to meet, which I think may be
5 underlying Lynne's point.

6 CHAIRMAN CERQUEIRA: Leon?

7 DR. MALMUD: In a practical sense, the
8 issue is radiation safety, and I believe that as the
9 rules are currently written, and as Angela points out,
10 there seems to be a disconnect. If the patient has
11 thyroid cancer, I may treat the patient for thyroid
12 cancer with 100 millicuries. If the patient has
13 hyperthyroidism, I may not treat the patient with 40
14 millicuries. Both of whom are on an out-patient
15 basis, by the way -- unless I've proven that I had
16 experience in treating patients with over 33
17 millicuries. There's a certain lack of logic to this
18 because the issue is radiation safety, and my
19 radiation safety standards for the population
20 surrounding that patient are the same, whether the
21 patient had thyroid cancer or hyperthyroidism.

22 DR. WILLIAMSON: Not necessarily.

23 DR. MALMUD: Really?

24 DR. WILLIAMSON: Yes. Because at 33
25 millicuries or less, basically the issue of whether

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1 you can release the patient is answered with 100
2 percent uncertainty. And if it's over 33 millicuries,
3 you have to go through this sort of more complex
4 procedure of determining whether the patient is going
5 to meet the half rem limit to members of the general
6 public, and I think that is a safety issue. But I
7 think that's probably the basis for why they
8 distinguish between the two categories.

9 DR. MALMUD: Being back in practice, I
10 inform every patient -- I may be exceeding the
11 requirements, but every patient that I treat as an
12 out-patient with radioiodine for hyperthyroidism gets
13 the same forms from me indicating are they going to be
14 exposed to any pregnant women, any infants? Are they
15 are any young children living in the home? If they're
16 going to work, will they be close to any pregnant
17 women or any infants? And if so, I recommend they
18 take two or three days off since my belief is the best
19 exposure for someone who doesn't need radiation is
20 zero, and that's regardless of whether I'm treating
21 them with ten millicuries or with 30 or 50
22 millicuries. Now that may be a peculiarity of my
23 practice rather than requirements, but whether the
24 patient's getting five millicuries or 100 millicuries,
25 I want to know who they're going to be exposed to.

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1 CHAIRMAN CERQUEIRA: Right. We're going
2 to have to wrap this up soon. We've got two comments.

3 DR. ZELAC: Ronald Zelac, NRC. I simply
4 wanted to point out that the basis for the release is
5 not any more on activity. It's based on meeting the
6 dosage limits to those who are in the now to be
7 exposed population. So it's not automatic that 33
8 means that you are okay. It means you still have to
9 consider where that patient is going and where they're
10 going to reside. So you could say the release
11 criteria even applies to those patients that are
12 receiving diagnostic amounts of materia. You know
13 basically with certainty in almost all circumstances
14 that you will satisfy the criteria for those people to
15 be released, but certainly for a 33 millicurie, 35
16 millicurie iodine case, you can't with certainty, you
17 still have to consider where they're going and what
18 they're doing.

19 CHAIRMAN CERQUEIRA: Okay. Lynne, did you
20 want to make a --

21 MS. FAIROBENT: Yes. Angela, to your
22 question of the difference between what Jeff was
23 proposing from a preceptor to somebody else, right now
24 by definition of the preceptor and all the coupling to
25 the various subsections under T&E that we're looking

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1 at, for example it would have to be a preceptor
2 authorized user in order to sign that. I think what
3 Jeff was trying to get to is part of the discussion we
4 had yesterday on whether or not a preceptor can be in
5 a broader sense. So, for example, if it is small
6 practice hospital where you have say a diagnostic
7 radiologist who is the only one in town doing this,
8 there may not be a preceptor or authorized user
9 available to sign for him, but there -- and there may
10 or may not be a separate RSO, but chances are there
11 would be a consulting physicist in fact the physician
12 was serving as the RSO.

13 I'll throw out that Bill Uffelman and I
14 will go back and look in the nuclear medicine
15 community with this question, and we'll provide
16 something back to staff and the ACMUI as to what we
17 think the extent of the problem is.

18 CHAIRMAN CERQUEIRA: David?

19 DR. DIAMOND: I've enjoyed the discussion.
20 I don't see any problem. What are we talking about?
21 What's the problem?

22 DR. MALMUD: The problem, as I understand
23 it, and I may have a misunderstanding but I don't
24 think that I do, as I understand it, currently a
25 radiologist -- a licensee who has not proven

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1 experience with a greater than 33 millicuries of I-131
2 for hyperthyroidism is not approved to treat a patient
3 with 40 millicuries of I-131 on an out-patient basis;
4 is that correct?

5 MR. LIETO: No. That's not my
6 understanding.

7 DR. MALMUD: Oh. What's your
8 understanding.

9 MR. LIETO: What we have is our physicians
10 who have been approved under 300, which is approval
11 for radiopharmaceutical therapies -- all. They are
12 now renewing their license. There's no -- they are
13 now applying for either 392 and/or 394. And the
14 answer is does that previous training and experience
15 and approval process authorize them to be approved
16 under those two categories? And --

17 MS. WILLIAMSON: Well, particularly the
18 higher one.

19 MR. LIETO: And my answer --

20 MS. WILLIAMSON: Because we don't have any
21 proof.

22 MR. LIETO: My answer would be, yes, and
23 that --

CHAIRMAN CERQUEIRA:

24 DR. MALMUD: Yes.

25 DR. WILLIAMSON: Yes.

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1 DR. DIAMOND: There's the answer; we're
2 done. I don't think there is a big problem.

3 MS. WILLIAMSON: Okay.

4 MR. LIETO: The thing is is that -- the
5 other question that she had was should there be some
6 documentation, and my answer is no, because the
7 assumption that they have been ongoing --

8 DR. DIAMOND: A de facto assumption.

9 MS. WILLIAMSON: Okay.

10 MR. LIETO: Otherwise every license
11 renewal is going to require that approved physicians
12 are going to have to submit preceptors, and it's not
13 going to just be for radiopharmaceutical therapy, it's
14 going to be for radiation oncologists who want to get
15 approved for HDR, I mean because of the different
16 categories. So that would be my recommendation.

17 MS. WILLIAMSON: So am I hearing now that
18 we don't need the 313A? They just come in, they say,
19 "Look, I was approved previously."

20 CHAIRMAN CERQUEIRA: "You had approved me
21 before."

22 MS. WILLIAMSON: "I want to use whatever
23 activity I feel is necessary," and we just say,
24 "Okay." Is that what I'm hearing?

25 MS. SCHWARZ: I have a question. In terms

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1 of grandfathering, does that expire when Subpart J
2 expires?

3 DR. VETTER: No.

4 MS. SCHWARZ: So then it will continue to
5 be grandfathered. So it seems to me that it should be
6 acceptable.

7 DR. WILLIAMSON: I guess I would say I
8 generally agree with this. I think the grandfathering
9 has -- there's no talk of having to have preceptors
10 and so on to demonstrate that you've actually been
11 doing this. And while it might be reasonable to ask
12 for some kind of evidence that you indeed had this
13 practice pattern, I think that the standard should be
14 much lower than for somebody that's trying to
15 establish -- let me finish -- that's trying to
16 establish qualifications for a practice de novo as a
17 new practitioner. There the law is clear, you have to
18 have a preceptor statement. But for this the standard
19 should be greatly relaxed.

20 MS. WILLIAMSON: Well, I'm not sure I have
21 a grasp on what the Committee is recommending.

22 CHAIRMAN CERQUEIRA: I think the Committee
23 -- well, the defray was -- you want to make a motion?

24 MR. LIETO: Yes, make a motion. That will
25 force the issue.

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1 CHAIRMAN CERQUEIRA: I hope I make it
2 right. My motion is that physicians currently
3 authorized under 35.300 --

4 MS. MCBURNEY: Which is?

5 CHAIRMAN CERQUEIRA: Radiopharmaceutical
6 therapy -- are authorized for 35.392 and 35.394.

7 DR. WILLIAMSON: But that's not the issue.
8 The issue is practitioners who were qualified to
9 practice hyperthyroid therapy, single indication
10 therapy --

11 MS. MCBURNEY: Like endocrinologists.

12 DR. WILLIAMSON: -- can they be authorized
13 automatically?

14 MR. LIETO: Excuse me. Thirty-five.three
15 hundred addresses if you're approved under that,
16 you're approved for all the radiopharmaceutical
17 therapies that are FDA approved.

18 DR. WILLIAMSON: That's right, but that's
19 not the issue we're discussing.

20 MS. FAIROBENT: Just for clarification,
21 Ralph, I think that what the party of people that
22 we're trying to assist are those physicians who are
23 only approved under what is now 932, Subpart J 932,
24 which was hyperthyroidism, are those who are currently
25 on a license under 934 for therapy -- thyroid therapy.

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1 And because those were written as disease-specific, if
2 I may use that term, in the new Part 392 and 394 is
3 not written disease-specific but activity-limited.
4 Someone under 932 currently had no upper bound or
5 lower bound limit on how much iodine he or she could
6 administer for hyperthyroidism. So should they be
7 grandfathered now and able to practice under both 392
8 and 394? And if not, then what other additional
9 documentation therefore you have no grandfathering of
10 these folks because we changed the structure of the
11 regulation for these individuals. And if routine
12 doses of hyperthyroidism today can go 30, 40 or even
13 higher, as Dr. Malmud was stating, they probably don't
14 have much documentation to show what they had been
15 routinely delivered. And under the new regulation now
16 we have the split for the added requirements. It's
17 that body of authorized users.

18 MR. LIETO: I guess I'm thoroughly
19 confused because I guess the basic premise under which
20 this is coming in is changing. Let me re-ask the
21 question again. Were they approved under 35.300,
22 period?

23 MS. WILLIAMSON: No.

24 MR. LIETO: Or was it 35.300 with license
25 condition disease-specific?

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1 MS. WILLIAMSON: Yes. Yes.

2 MR. LIETO: Okay.

3 CHAIRMAN CERQUEIRA: Some are saying no
4 and some --

5 MR. LIETO: Angela, please.

6 MS. WILLIAMSON: The license is written as
7 disease-specific. Training and experience is 35.300
8 with limitation of what they can do.

9 CHAIRMAN CERQUEIRA: So that's why the
10 thyroid comes into the -- Dr. Howe?

11 DR. HOWE: I think Trish answered it. And
12 the problem is that the licenses for the
13 endocrinologists were written very specifically. It
14 was for hyperthyroidism only, and there is not a one-
15 to-one correlation between the old 932 and the new 392
16 and the old 934 and the new 394, and so we cannot make
17 a direct assumption that someone that was authorized
18 under 392 now can get both. We have the same problem
19 with diagnostic nuclear medicine because diagnostic
20 nuclear medicine in the old Part 35 included the
21 diagnostic treatment for people that had cancer, had
22 already had their thyroid removed. And so we're
23 having to write specific license conditions in order
24 to grandfather these people that already had
25 experience with that, because the new regulation is

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1 not one to one with the old regulation.

2 CHAIRMAN CERQUEIRA: David and then --

3 DR. DIAMOND: Given that the whole
4 rationale for making these regulatory changes was to
5 accommodate the wishes of the endocrinology community
6 to make sure they had maximum flexibility in the
7 administration of I-131, in this spirit I would like
8 to make a motion: Individuals authorized to use --
9 authorization to use I-131 under the extant
10 regulations, those individuals also be considered to
11 be authorized to delivery I-131 under the new 35.392
12 and 35.394 without a specific requirement for a
13 preceptor statement nor for requirement to have a
14 documentation of cases, period. That's what the
15 endocrinologists wanted; that's what we gave them.

16 CHAIRMAN CERQUEIRA: Do we have a second
17 on that?

18 DR. MALMUD: Second.

19 CHAIRMAN CERQUEIRA: Okay. Now, we've had
20 a lot of discussion. Do we need any more discussion
21 or should we just take a vote?

22 DR. WILLIAMSON: I would speak against the
23 motion because the current Part 35 the reason -- I
24 agree we wanted to take into account the needs of the
25 endocrinology community, but the current Part 35 is

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1 constructed around radiation safety, not disease.
2 And, therefore, I think this particular solution --
3 the solution to this particular problem is simply to
4 ask them to provide documentation that they have in
5 fact treated patients above 33. That would eliminate
6 them the problem of all endocrinologists perhaps who
7 had only prescribed ten millicuries in the past from
8 being able to suddenly administer 100 millicuries.

9 DR. DIAMOND: I have no problem with the
10 basic premise of your point. I would like to remind
11 the Committee that if you are a physician who would
12 like to go and use these higher activities, that you
13 also -- that every credentialing committee that I
14 think of will ask you to document a number of cases so
15 that you can go and provide that service at a
16 hospital. So from my personal viewpoint where I still
17 feel that credentialing committees do have some value,
18 I think that your concern would be addressed. If the
19 Committee, however, feels that it is useful or
20 important to have these endocrinologists go back and
21 just write down the name of three patients they've
22 done, that will not be a major problem to me.

23 DR. WILLIAMSON: I would support it with
24 that addition.

25 CHAIRMAN CERQUEIRA: So how do you want to

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1 modify your motion so we can move forward?

2 DR. DIAMOND: Any other strong feelings on
3 either side regarding the documentation of the three
4 cases under, what is it, 313?

5 MS. MCBURNEY: I think that since we've
6 switched to a more radiation safety based rule, that
7 allowing them to do that would open the door for them
8 to go ahead and treat for carcinoma and so forth,
9 because it's not specified in the rule what they're
10 going to use that material for.

11 DR. DIAMOND: But you're missing my point
12 that if you wanted to treat for thyroid cancer at my
13 institution, at Manny's and Subir's, you need to also
14 be credentialed to do that. And if you've never done
15 that before, I would assume your credentialing
16 committee would not approve you to do that.

17 MS. MCBURNEY: Unless you're wanting to do
18 it in a freestanding --

19 CHAIRMAN CERQUEIRA: In a facility, in an
20 office.

21 MS. MCBURNEY: And we have had those
22 situations where someone --

23 DR. DIAMOND: You need to have it approved
24 in an office?

25 MS. MCBURNEY: We have had requests for

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1 that. I mean we denied it, but --

2 CHAIRMAN CERQUEIRA: What do you think
3 about the amendment for the endocrinologists to
4 require the three cases?

5 DR. MALMUD: I would agree with it.

6 CHAIRMAN CERQUEIRA: All right.

7 DR. DIAMOND: Then I would like to amend
8 my motion that those individuals who are applying,
9 those individuals who were authorized solely to use I-
10 131 for hyperthyroidism under the new 35.392 and the
11 new 35.394 that those individuals do not require a
12 preceptor statement but they must submit at least
13 three cases documenting that they have used greater
14 than 33 millicurie of I-131 in the past.

15 CHAIRMAN CERQUEIRA: Okay. Do we have a
16 second on the --

17 DR. MALMUD: Second.

18 DR. WILLIAMSON: Second.

19 CHAIRMAN CERQUEIRA: Could we call the
20 question? Okay.

21 All those in favor? Opposed?

22 (Committee votes.)

23 CHAIRMAN CERQUEIRA: Okay. So the motion
24 is carried, and I think that deals with it. If we're
25 going to have lunch, we should break now. And then we

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1 should come back at 1:15 at which point Dr. Malmud
2 will be running the meeting, so thank you.

3 (Whereupon, the foregoing matter went off
4 the record at 12:36 p.m. and went back on
5 the record at 1:19 p.m.)

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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:19 p.m.

DR. MALMUD: Do you have slides?

DR. ZELAC: No. Good afternoon. I've gotten the call. Apparently we are resuming to try to stay on schedule. I'm speaking briefly, presumably briefly, simply to close a loop. At the last meeting of the Advisory Committee in May, I gave a presentation called, "Interpretation of 10 CFR 35.61(b): Conditions for Use of Survey Instruments." That particular section of the rule reads as follows: "A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent."

There was good advice given from the Advisory Committee at the last meeting as to where those particular words applied. Did they apply strictly and only to the calibration procedure or did they actually apply to the usage of the instrument in the field? We, I have to say, from an appropriate, perhaps, healths physics, point of view, we're looking at it based on usage of the instrument in the field. However, on reconsideration, looking at the rule, it appeared that in fact the appropriate interpretation was that these words applied to the calibration

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1 procedure alone, and on that basis if the licensee
2 calibrated an instrument using, as is typically done,
3 a high energy source and the response to the
4 instrument was within the plus or minus 20 percent
5 range, then that instrument was good to go for field
6 use.

7 It would be expected that if an individual
8 licensee was going to be using an instrument in a low
9 energy field, that they might choose to calibrate the
10 instrument as well using a low energy source, such as
11 the brachytherapy sources that they received for
12 clinical use. However, this is not part of the
13 requirement, although the ANSI standard, which is the
14 basis for survey instrument calibrations, speaks to
15 using a low energy source if you are going to be
16 measuring low energy fields. That is not part of the
17 regulatory requirement.

18 So on that basis, the practice, the common
19 practice of calibrating with high energy sources and
20 using energy correction factors when appropriate and
21 necessary is acceptable, reasonable and will be the
22 position that the agency takes with respect to
23 enforcement.

24 Ralph Lieto had been charged, I believe,
25 or volunteered, perhaps, at the last meeting to be the

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1 official conduit of opinion, although we had
2 discussion at the meeting there needed to be an
3 official transmission, if you will, of the combined
4 views or the considered views of the Committee. He
5 sent me a letter last July and response was provided
6 to him in October. We, of course, had to be sure that
7 what we said was acceptable to our legal counsel, and
8 it was. And it basically says the following, "That
9 the correct interpretation of the requirement of
10 35.61(b) is that this section applies to the outcome
11 of the calibration process, not to the use of survey
12 instruments after acceptable calibration." And, two,
13 "The use of energy correction charts or graphs after
14 acceptable calibration is permissible." And I would
15 hope, unless there are other points of view, that that
16 should conclude this issue.

17 DR. MALMUD: Are there any questions of
18 Dr. Zelac? Shall I assume that the silence is
19 agreement with both Dr. Zelac's statement and Dr.
20 Lieto's comment?

21 DR. ZELAC: The last thing I will mention
22 is that there is currently a Q&A on the Part 35 web
23 site dealing with survey instrument calibration. The
24 information there is not incorrect; however, based on
25 this interpretation of the rule, we are revising the

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1 wording of that Q&A. It is now in the review process
2 now and will be put up on the web as a revision as
3 soon as it's completed that process and whatever
4 adjustments are required.

5 DR. MALMUD: Thank you, Dr. Zelac --

6 DR. ZELAC: Thank you.

7 DR. MALMUD: -- and thank you for bringing
8 us back to our agenda and the next item, which is to
9 begin at 1:30. May we begin the 1:30 item early or is
10 that in violation of the rules? Didn't you switch,
11 Dr. Zelac with someone else or is Dr. Essig next?

12 MS. WILLIAMSON: Tom Essig is next.

13 DR. ZELAC: I simply moved up in the
14 schedule.

15 DR. MALMUD: Oh, okay.

16 MS. MCBURNEY: Right. So it's Tom.

17 MR. ESSIG: I'll be short too.

18 DR. MALMUD: Thank you.

19 MR. ESSIG: There should be a one-page
20 addition to your notebooks under the tab, "Access to
21 -- ACMUI Access to NMED." Oh, it hasn't been added
22 then. Angela, is that handout --

23 MS. WILLIAMSON: Oh, I guess I forgot to
24 pass it by --

25 MR. ESSIG: Oh. The public has it but you

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1 don't have it. Sorry about that.

2 MS. MCBURNEY: The last to know.

3 MS. WILLIAMSON: I put it out but I forgot
4 to give it to the Committee.

5 MR. ESSIG: Okay. The issue was because
6 of the fact that we're asking the Committee to be more
7 involved in evaluation of medical events, it's
8 incumbent on us to then provide the Committee members
9 with the appropriate data. We looked at two options
10 to do this. One is to provide the Committee on some
11 periodic basis, maybe quarterly or so, a download of
12 medical events from NMED on the CD, this would be sent
13 out by our contractor to each of you, and then the
14 user, each of you, would sort the data via the Access
15 software.

16 We felt the advantage to that would be
17 that it would be -- you would be sent only the data
18 that had been reviewed by the staff and determined to
19 meet the criteria for medical events, and so in that
20 way it would be a focused data set, and the extraneous
21 information would be excluded. The downside of that,
22 of course, is that the data may not be totally
23 current. It's a function of when the latest batch was
24 processed, the quarterly batch, and the search engine
25 to sort the data was not available. That is, you'd

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1 have to rely on an Access database to sort the data or
2 process the data.

3 The other option that we looked at was to
4 provide what amounts to real-time access to NMED
5 database for each member. And the advantages of that,
6 of course, more flexible unfettered access to the data
7 by all members. The NMED has a search engine that can
8 sort the data. The downside is that for some of you
9 that may be somewhat daunting because it includes all
10 events. I mean medical events are only a subset of
11 the database. And it also includes those events which
12 have not been reviewed by the staff, some of which
13 fall by the wayside because they don't meet the --
14 they later prove to be non-reportable. And
15 considering those two options, we feel it's -- that
16 our proposed approach is going to be to select Option
17 2, that is to provide each of you access to NMED.

18 We can do this as early as next week. We
19 have all of your email addresses, and so it's just a
20 question of our notifying our contract at the Idaho
21 National Environmental Engineering Lab to add you to
22 the -- provide you that access. Your access will be
23 limited to your term on the Committee, and that of
24 course it's to be accessed and used only really in the
25 performance of your duties on the Committee, and we of

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1 course are available to provide initial orientation
2 and handle any technical questions that you may have
3 in going into the database. That's pretty much my
4 spiel.

5 I have our NMED Project Manager, Michele
6 Burgess, available in the audience here to help field
7 any questions that you might have. But I thought
8 given the two options that we have of providing you
9 either direct access to it or providing you with
10 digests of the data through a CD, we felt that access
11 to the NMED database, which has records dating back to
12 about 1990 or so, that's when it was first
13 constituted. Of course it's read-only access. That's
14 all anybody has.

15 DR. MALMUD: Thank you. Jeff?

16 DR. WILLIAMSON: I think that's a great
17 idea. With regard to Option 1, I found the Access
18 database not just daunting but totally impenetrable
19 without some fairly thorough orientation to how you
20 had created the data structure. So I suspect with an
21 automated search engine it will be easier on
22 everybody.

23 MR. ESSIG: Okay.

24 MR. ESSIG: Subir?

25 DR. NAG: With the second method, will

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1 there be an easy method just to pull up the medical
2 event or do we have to go through a lot of hoops to
3 get to the medical events?

4 MR. ESSIG: I would ask Michele if you
5 could come to a microphone and if you could help with
6 that. This is Michele Burgess who's the Project
7 Manager for NMED. And just address the question about
8 the ease of searching through. And Michele herself is
9 fairly new to this. We had Sam Pettijohn who had been
10 the Project Manager forever retired last May or June
11 -- was it August? Okay. And Michele has been taking
12 his place since that time.

13 MS. BURGESS: Well, to answer the question
14 about using the web site, it's very easy to use. The
15 front end let's you choose what criteria you want to
16 sort the data by, and it can pull up all the medical
17 events. There's a lot of push buttons you can use,
18 icons you can choose from. It leads you through
19 pretty well. You can always call either me or INEEL
20 directly if you're looking for a certain piece and
21 you're not sure how to get that piece out of what you
22 see on the screen. We're also upgrading the web site
23 and we hope next spring a new one will be coming out
24 that will have even a more user-friendly interface
25 with more choices.

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1 DR. MALMUD: And how may you be reached if
2 there are calls for you?

3 MS. BURGESS: You can reach me -- here at
4 the NRC it's 301-415-5868. Also, on the front page of
5 the NMED web site, it gives contact information for
6 both me and for the contractor. If that's what the
7 decision is and we're going to give you access, then
8 someone will be contacting you directly to establish
9 your contact and at that point can give you some
10 basics on logging in and starting to use the system.

11 DR. MALMUD: Thank you. Other questions?
12 Comments? Thank you very much. Oh, I'm sorry.

13 DR. WILLIAMSON: I'm sorry. Not to
14 belabor this but how narrowly is performance of
15 official ACMUI duties to be defined? Is it like only
16 we're to use it when we're given a specific request to
17 evaluate something like the Novoste event or can we
18 have more latitude as to when we think it might be
19 useful? I just ask you to explain what you mean so we
20 don't transgress any boundaries and all wind up in
21 jail or something.

22 MR. ESSIG: Well, let me give you a for
23 instance. I could probably -- no, it's not -- I don't
24 believe it's a jailable offense. The for instance
25 would be to cover two extremes. Obviously, the

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1 Novoste would be -- or something similar, which would
2 have been a tasking from us, would clearly fit that
3 description. Something that might not fit the
4 description is if you're wanting to research events to
5 write a REFRI journal article that has really no
6 connection to your ACMUI duties at all. That would
7 probably be the other extreme. And that we would
8 probably say would not fit that definition of access.
9 And, obviously, there are a lot of things in between,
10 but if those examples help illustrate the thing. We
11 don't have any real hard and fast rules here, but
12 encourage or I should say discourage the use of it for
13 those tasks which a reasonable person would come to
14 the conclusion this isn't really related to my ACMUI
15 duties.

16 DR. MALMUD: Thank you. Any other
17 questions? Ralph?

18 MR. LIETO: When we met with the
19 commissioners, one of the things that they mentioned
20 that they wanted the Committee to look at were events
21 that occurred -- medical events that occurred for
22 review and comment. Will this now become sort of
23 standing agenda item with the Committee that we'll
24 review medical events since the last meeting or
25 something like that? I'm trying to look at where

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1 we'll have access to this but if it's just sort of
2 like you sit down with your morning coffee and bagel
3 and look at what's happened over the last couple weeks
4 in the medical use, I'm kind of trying to get a handle
5 on what we need to do with this access.

6 MR. ESSIG: We're in the process of giving
7 that further thought, and so we'll have to share that
8 with you at the time. But, basically, what we're
9 trying to -- what I see the Committee can fill an
10 important niche is we used to have in a previous NRC
11 organization it was an office for the analysis of
12 operational events. It was AEOD was the acronym. And
13 there was a small medical subset of that -- or
14 materials subset of that with this Sam Pettijohn that
15 I mentioned who was the Project Manager. He and one
16 other staff person did perform those long-term trends
17 and tried to glean from that lessons learned, what did
18 we learn from these events and how do we feedback that
19 back into the regulatory process? Well, when that
20 office was dissolved we lost that capability.

21 Now, granted, the charter here is for
22 medical events, which are a subset of the materials
23 events, and so we're in the process currently of
24 reevaluating how we want to approach the events, but
25 we thought it would be very appropriate to use this

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1 committee as a source of expertise that would help us
2 dissect, diagnose what happened in those events and to
3 help us with root cause analysis and that sort of
4 thing.

5 DR. MILLER: Remind me of the exact words,
6 Tom, if you can remember them, if anybody can remember
7 them, but the Commission gave us guidance back after
8 your meeting with them and the staff requirements
9 memorandum and it encouraged the staff to use the
10 Committee to help us analyze events. What they said
11 after that was when there is a regulatory need. Okay.
12 What's a regulatory need? I think there's a fair
13 amount of latitude in that, but I think, as Tom
14 pointed out, I think that if it's aimed at official
15 duties and if it's helping frame Committee
16 recommendations with regard to where we go in the
17 future or helping us to determine do we have a problem
18 in any specific area based upon the events that had
19 been reported, clearly, I think there's a regulatory
20 need.

21 What would not be a regulatory need, my
22 personal opinion is I think a lot of us are
23 professional enough that we know what we're doing in
24 this area, and I didn't look at that as a particular
25 constraint. But I guess it was to prevent -- I guess

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1 it was to prevent any abuses of using the Committee
2 for other purposes or personal purposes.

3 DR. MALMUD: So you're asking us basically
4 to exercise our judgment with regard to the need to
5 know with respect to the responsibilities that we have
6 with the ACMUI.

7 DR. MILLER: Yes. And I guess let's use
8 common sense. If you have a question and you're not
9 sure --

10 DR. MALMUD: Thank you.

11 DR. MILLER: -- just call and we'll --

12 DR. WILLIAMSON: I think one thing that's
13 a burning issue on -- or a current issue is prostate
14 brachytherapy and that would certainly be a good first
15 thing for those of us that are interested to use the
16 event database to get that information and think about
17 events that have led you to the quandary where you
18 are.

19 DR. MALMUD: Thank you. Any other
20 questions for either Tom or --

21 DR. MILLER: I guess the only thing I
22 would say in closing is based upon the discussion I
23 would assume this is a desirable thing --

24 DR. MALMUD: Yes.

25 DR. MILLER: -- for the Committee to have

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1 access.

2 DR. MALMUD: There's full agreement.

3 DR. MILLER: Okay.

4 DR. MALMUD: Thank you. And thank you for
5 the brevity of the presentation. This brings us back
6 to pretty much the schedule. And the next item is the
7 discussion of the draft information notice regarding
8 issuance of identification cards to patients who are
9 released after treatment with radiopharmaceuticals.
10 Roberto Torres.

11 MR. ESSIG: Yes. Roberto Torres is
12 recently, because I think this is his first appearance
13 in front of the Committee as well, he's one of my --
14 I'm sorry? The third? Okay.

15 DR. NAG: I've seen him before.

16 MR. ESSIG: But his first in his new
17 capacity as he is one of my two section chiefs. He's
18 responsible for Part 35 implementation, among other
19 things.

20 DR. MALMUD: Welcome in your new first
21 presentation in your new capacity.

22 MR. ESSIG: Yes.

23 MR. TORRES: Thank you.

24 MR. ESSIG: Since August.

25 MR. TORRES: Good afternoon. As it was

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1 mentioned before, the Commission has directed us
2 through an SRM to become more engaged with the members
3 of the ACMUI, and this is an example of engaging you.

4 We developed an information notice, which
5 it's title is, "Heightened Awareness for Patients
6 Administered Unsealed Byproduct Material or Permanent
7 Implants." And I will go in some history what
8 prompted the information notice.

9 Around March 2003 a boat load of
10 passengers was traveling from New York to New Jersey,
11 across the Lincoln Tunnel and there was a radiation
12 detector at that tunnel and the alarm was triggered.
13 There was some commotion, law enforcement responded to
14 the event, and it was found after some time that there
15 was a passenger who has been given ten millicuries of
16 Iodine-131 that morning. The patient was discharged,
17 was given written instructions, and one of the
18 instructions in the written instructions said that the
19 patient need not to use public transportation for at
20 least two days.

21 What happened afterward was that the head
22 of the New Jersey Radiation Control Program sent a
23 letter to the NRC and basically was telling NRC,
24 "Please, NRC, emphasize to your licensees the
25 importance of patient instructions." But she also

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1 suggested that the NRC considered issuing -- the
2 licensee considering issuing identification cards to
3 the patient with some sort of information like type of
4 treatment, type of isotope that the patient received.

5 Dr. Lipoti's letter received media
6 attention, it got the attention from the Commission
7 also. There were discussions between commissioners'
8 technical assistance and the Region 1 office, and it
9 was agreed by the NRC that we were going to issue an
10 information notice to address Dr. Lipoti's concerns.

11 The first board shows the title of the
12 information notice, which you have a copy of it in
13 your booklet. There were some discussions initially
14 whether we should write this information notice to
15 therapy patients versus diagnostic, but we are using
16 the new terms under the revised Part 35, which is
17 unsealed byproduct material. We don't want to use
18 language that will reflect the old philosophy,
19 philosophy of the old regulation which is diagnostic
20 and therapeutic.

21 So we came up with this title, "Sealed
22 Byproduct Material or Permanent Implants," meaning and
23 that's the next bullet, the second one, there is
24 language in the information notice that will reflect
25 there's a high probability that therapeutic patients

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1 will trigger an alarm, but we also have to consider
2 that patients who receive lower dosages will also
3 trigger an alarm. The third bullet reflects that the
4 IN, information notice, is reminding licensees of
5 their regulatory requirements: Sit down with the
6 patient, discuss and go over the written instructions.

7 Also, the information notice is
8 recommending two voluntary actions. The Action Number
9 1 is provide an explanation to all released patients
10 that they can trigger radiation monitoring equipment,
11 so that they'll be aware of it. And the intent of
12 this is if they know that there's a possibility for
13 them to trigger an alarm, that they can step forward
14 to law authority officials and find the cause of it.

15 The second action is generic post-study or
16 post-treatment part, and, initially, these are the
17 recommended information that we wrote down in the
18 information notice: Patient's name, date of the
19 procedure, isotope and activity, expiration date, some
20 language there indicating that the patient poses no
21 danger to the public and was released under current
22 regulations, and the physician's telephone number.

23 The draft IN was sent to the Advisory
24 Committee for medical uses of isotope, all of you, for
25 comment. It was also sent to the NSIR, our new Office

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1 of Nuclear Security on Incidence Response for comments
2 also.

3 And we received a comment mainly from Dr.
4 Vetter and basically he agreed on the Voluntary Action
5 Number 1, so did NSIR. And he disagreed with
6 Voluntary Action Number 2 mainly because it looks like
7 it is an undue burden to medical licensee, and several
8 of the issues are will the hospital be expected to
9 provide this card? Another issue is the
10 implementation issue. Different hospitals will come
11 up with different type of cards. Another issue is
12 what's the validity of that card when a law
13 enforcement official looks at it. And there are also
14 concerns about HIPAA regulations which prevents
15 decision from releasing information to third parties.
16 You can imagine a local federal law enforcement
17 official calling the hospital and then asking the
18 licensee, "Did this patient receive ten millicuries of
19 Iodine-131 this morning?" That's the issue.

20 If there is a need to issue a card, Dr.
21 Vetter agreed that it should be very, very generic and
22 that it should basically say that this patient poses
23 no danger to the public. NSIR's comments is that they
24 agree in Voluntary Action Number 1. They disagree in
25 Voluntary Action Number 2 basically this is not the

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1 right time. The Department of Homeland Security is
2 considering implementation of a nationwide system of
3 radiological detection, and if they're considering
4 that system, they will also have to consider
5 operational procedures, protocols for alarm response
6 and determining a threshold level to screen out all
7 those patients that are medical patients.

8 Also, NSIR agreed that instead of issuing
9 a generic card with all that information that you have
10 seen in the two or three previous slides before to
11 issue or give the licensees a business card or the
12 physician's business card. NSIR also recognizes the
13 fact that the card will not be a carte blanche that
14 will allow the patient or the local authority to tell
15 the individual, "Go ahead and we will not search you."
16 The card it's just some sort of information that
17 enforcement authority will look at the patient and
18 will try to screen out the patient and put that
19 patient through a different search criteria.

20 And the example I am trying to bring here
21 is there's an NRC employee who has a metal implant and
22 he carries a card that says that he has a metal
23 implant. Every time he goes to an airport he shows
24 the card, but that card does not allow him to go
25 through. He will undergo a different type of search

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1 to screen out other possibilities and to verify what
2 he is saying, what he is claiming.

3 So what is NRC intent for this Voluntary
4 Action Number 1? What law enforcement officials need
5 to hear from this patient they have in front of them
6 that it's emitting radiation is that that radiation is
7 safe and that it is allowed by law. Those are the key
8 points that we want that patient to communicate to law
9 enforcement.

10 This leads us to a revised Voluntary
11 Action Number 1, which is give the patient the
12 licensee's business card and provide written
13 information for law enforcement use stating that the
14 radiation that this patient is carrying is safe it is
15 allowed by law. In other words, the second point is
16 that a business card licensee can write behind the
17 business card two words, "safe" and "allowed by law,"
18 for the patient to convey that information to various
19 law enforcement authorities. And this is our proposal
20 that we are putting here in front of the Committee.
21 Do you agree with this revised Voluntary Action Number
22 1 with that language or should it be modified to
23 reflect our intention, which is radiation is safe and
24 it is allowed by law?

25 DR. MALMUD: Dr. Nag?

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1 DR. NAG: Yes. I'm not sure what is being
2 done at other hospitals, but I know that in our
3 hospital any patient that has a permanent radioactive
4 implant has two things. They have, one, a bracelet
5 that says -- on the bracelet they've imprinted the
6 date of the implant, the radioactive material and what
7 the half-life date is. And we also provide them with
8 one page that has instructions about the implant and
9 when it is implanted and what the radioactive material
10 was. So either of those two I'm sure would be useful
11 in lieu of your Action Number 2. I wonder how many
12 hospitals provide that routinely on all implant
13 patients. Do you have a requirement for permanent
14 implants?

15 DR. VETTER: They provide written
16 instructions to the patient or written instructions
17 and to radiopharmaceutical therapy patients as well.
18 They do not provide written instructions to diagnostic
19 patients, but in fact someone who just got 30
20 millicuries of sestimebe could set off an alarm as
21 well. So I think there is some wisdom in this in the
22 sense that a diagnostic patient could set off an alarm
23 as well.

24 One of the things I like about this
25 proposed change is it's still -- it's information

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1 notice only, and it allows a hospital to provide this
2 information to patients in any way they wish with an
3 armband or whatever, but it does provide guidance in
4 a rather generic sense that offers consistency. So if
5 hospitals decided to follow this, then Homeland
6 Security people would get used to that sort of a
7 thing, and it might be a little bit easier for them.

8 DR. MALMUD: Other comments?

9 MS. MCBURNEY: I agree with the change and
10 this would also not violate HIPAA regulations. It's
11 generic enough that it gives the information to the
12 law enforcement people that they need but not so much
13 that it would violate HIPAA probably.

14 DR. VETTER: Could I make one comment in
15 HIPAA? Actually, that was a concern for me too. When
16 law enforcement calls, if they have a legitimate need,
17 then HIPAA doesn't really matter.

18 MS. MCBURNEY: Right.

19 DR. VETTER: But if law enforcement calls,
20 gets the Secretary of Nuclear Medicine, says, "I need
21 to know this information and I'm in law enforcement,
22 you've got to give it to me," the Secretary's been
23 trained by the Compliance Officer at the hospital to
24 not share any of that.

25 MS. MCBURNEY: Right.

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1 DR. VETTER: So it's going to take hours,
2 perhaps, to sort all that out. So I think HIPAA is a
3 valid concern. But simply for writing a business card
4 without a lot of other information law enforcement can
5 follow up on that if they need to. They need to
6 recognize they might not get an immediate answer.

7 DR. WILLIAMSON: Well, the information is
8 under the voluntary control of the patient. It's not
9 like the stamped on the patient's forehead against the
10 patient's will. The patient has the right to withhold
11 the information from whomever they want. So how can
12 that be a violation of HIPAA to provide the patient
13 with some documentation? They can share?

14 MS. MCBURNEY: That wasn't the concern.
15 It was the way the first Action 2 is written.

16 DR. WILLIAMSON: Yes.

17 DR. MALMUD: Other comments from the
18 table?

19 MR. LIETO: It relates to the licensee's
20 business card. The expectation then is that the law
21 enforcement officer can call that number and get an
22 answer to his questions or is it just simply that's
23 where the patient came from? It's just letting him
24 know where the patient came from.

25 MR. TORRES: That's where the patient came

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1 from, and I have already samples which customer
2 official has been given the information where this
3 patient has came from, and it's up to them whether to
4 pursue that phone call or they just isolate and search
5 the individual or the vehicle. So they have other
6 means of verifying the information without the need of
7 calling the licensee.

8 DR. HOLAHAN: I have a question. Do all
9 doctors carry a business card? I'm thinking more of
10 private practice.

11 DR. NAG: I think a business card wouldn't
12 be a problem, but what may be a problem is getting a
13 hold of that person on the weekend and after hours.
14 That's almost very difficult at times.

15 DR. MALMUD: The answer to your question
16 is that most physicians have business cards but all
17 have prescription blanks, and either means is adequate
18 for putting a short note. The method that I've been
19 using with my patients is to on the back of the
20 xeroxed sheet, which talks about the treatment of
21 hyperthyroidism, I have a copy of my business card and
22 then the dose of radioiodine that they received and
23 the date. And I tell them to use that if they need
24 it, but I also tell them that they will avoid a lot of
25 embarrassment for themselves by no crossing a bridge

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1 or taking a tunnel unless they have to and not
2 entering a federal building where they know that
3 they'll be monitored. That they're not breaking the
4 law by doing either of these two things but they will
5 be possibly picked up as being temporarily
6 radioactive. And I cite the example of the amusing
7 case that's amusing to patients about the patient who
8 was treated in New York and took the bus to New
9 Jersey.

10 There will be situations in which patients
11 will of necessity have to cross a bridge or go through
12 a tunnel which is monitored. The patient from New
13 Jersey comes to New York for I-135 therapy and goes
14 back home to New Jersey after the getting dose he or
15 she will have to have gone either over bridge or
16 through a tunnel and they may be picked up.

17 The other thing is that the cards that we
18 give them are not proof of anything except that
19 someone has that card. But it is a means of reducing
20 embarrassment. I think that if we're looking for a
21 discussion about the intent of the revised Voluntary
22 Action 2, we can move on that as soon as we hear a
23 comment from the floor which I think has been standing
24 here patiently.

25 MR. WHITE: Gerry White from AAPM. I just

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1 wanted to comment I agree with much of what's been
2 said except I'd like to point out that it's really not
3 the patient's responsibility to educate law
4 enforcement personnel, which is what this does, by and
5 large, nor is it the licensee's responsibility to
6 train patients so that they can educate law
7 enforcement personnel. I think conceptually this
8 project is flawed.

9 I'd also like to follow up on the remarks
10 we just heard that the card really cannot possibly
11 provide additional security. It may avoid
12 embarrassment to a patient, but an evildoer who had
13 bad intentions with radioactive material would simply
14 need to make a trip to Kinko's to make this all better
15 for him, and it's really not worth that to make this
16 a nationwide policy for all our patients.

17 Lastly, I'd like to say it's very poor law
18 enforcement policy. It takes a normal activity,
19 something that millions of Americans undergo every
20 year, some sort of radionuclide procedure, and places
21 it into sort of a potentially suspicious activity.
22 It's much like vetting people for bank fraud who
23 happen to have a checkbook in their purse. It just is
24 wrong. And there's a much better way to do this if
25 education is going to be had, if recommendations or

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1 voluntary actions are going to happen, and that is to
2 insist that law enforcement agencies that have these
3 radiation detectors have proper radiation detectors.

4 One can purchase for not much money a
5 radiation detector that has a pulsite analysis device
6 that prints out the isotope and could be programmed in
7 the simplest case to flash medical or non-medical
8 after examining the patient with the device. They're
9 not expensive, they're available, and I think that if
10 there's going to be a burden for this, it shouldn't be
11 on the licensees. It certainly shouldn't be on the
12 patients. It should be on the law enforcement
13 personnel whose job it is to make this right for us.

14 DR. MALMUD: Thank you for your comments.
15 I would just point out that everything that you've
16 said is true. Our goal is to relieve pain and -- as
17 physicians is to relieve pain and suffering. The note
18 in the patient's hands will reduce the embarrassment
19 that will come to the patient since the patient will
20 not have broken any law, and that's my only purpose in
21 giving my patients those notes at this time.

22 I agree with your observations and
23 recommendations, and they probably should go to the
24 new Department of Homeland Security rather than to us
25 as clinicians. And we all agree that the notes are

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1 not proof positive. The goal is to try and make the
2 patient as comfortable as possible.

3 And, lastly, as anyone who has a handicap
4 knows, it is for the handicapped to try to educate
5 those who should have been wiser in dealing with the
6 handicapped, and unfortunately the burden falls to the
7 person who's carrying the disability. In this case,
8 the disability is decaying rapidly but it nevertheless
9 it is a disability which is on board for a short
10 period of time. Dr. Vetter?

11 DR. VETTER: Yes. I think the real value
12 in this is the same value as Mr. Torres mentioned
13 relative to a card that's given to a patient with a
14 metal implant. It simply calls out to security that
15 they can be checked in a little different manner and
16 probably cleared quite quickly, in particular if they
17 get a spectrometer, but that's, again, beyond our
18 control.

19 DR. MALMUD: Yes, Dr. Suleiman.

20 DR. SULEIMAN: Yes. We have -- I mean the
21 whole medical alert cards and everything else the
22 patients carry, the issue came up with security
23 screening devices at one of the FDA advisory
24 committees. People with implants or muscle
25 stimulators, a whole sort of electronic devices that

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1 could be interfered with with magnetic fields and so
2 on. So this is just one more thing that probably the
3 patient needs to be aware of, but how many cards is a
4 patient going to carry around?

5 DR. MALMUD: The other question that I had
6 is how many incidents have there been? I'm only aware
7 of one that's come to my attention. That that's
8 incident in New York. Are there many more?

9 PARTICIPANT: There's been a number of
10 them.

11 DR. MALMUD: There have been? Ruth, I
12 think you --

13 MS. MCBURNEY: Just coming from a
14 regulator standpoint, it's really noble to try to
15 require a certain type of monitor for law enforcement.
16 But as radiation regulators, we can't do that because
17 they're not possessing radioactive material except
18 maybe some exempt sources or so forth. And also some
19 of the states are providing the training for the first
20 responders, and we're finding just a wide assortment
21 of -- you know, they get Homeland Security money and
22 they just go out and buy whatever type of instrument
23 they can. And so we also provide some calibration
24 services for them. But to require them to have a
25 certain type of monitor I think would be under the

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1 purview of some other agency. And what we're dealing
2 with is the reality of there are patients being
3 released and picked up by these monitors.

4 DR. MALMUD: So the question before us is
5 do we agree with Voluntary Action Number 2? It is a
6 voluntary action, it's not required, and it would
7 simply be to give the patient a note with the
8 physician's name and address and phone number
9 indicating that they've been treated and that it's
10 safe and allowed by law. That would be for the
11 patient to carry. If the patient wishes to share that
12 information with whoever stops them, he can, and if he
13 doesn't wish to, he doesn't have to under the law.
14 Dr. Nag?

15 DR. NAG: Yes. I'm wondering whether it
16 should be the physician who may not be easily
17 contacted or the person in charge of radiation safety,
18 because there's always somebody who is approachable in
19 case of radiation accident, and we provide the name of
20 the radiation safety person.

21 MS. MCBURNEY: Yes. It's the licensee's
22 business card rather than the physician's.

23 DR. MALMUD: It's the physician who always
24 sees the patient because it's the physician who
25 personally oversees the administration of the

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1 therapeutic dose for I-131. If an individual
2 physician works out an arrangement with his or her
3 radiation safety officer and that individual is
4 willing to have their number, so be it. This is a
5 voluntary system. Our main goal, I believe, is to
6 reduce the embarrassment of being stopped for the
7 patient, and any constructive suggestion is welcome,
8 as is yours. Dr. Vetter?

9 DR. VETTER: Yes. I like the new revised
10 statement, and I also like the use of the word,
11 "licensee's business card," because it allows us to do
12 -- it could be the physician, it could be radiation
13 safety, it could be the President, whomever the
14 licensee decides is the best contact.

15 DR. MALMUD: It appears that you have
16 reached a consensus among this table.

17 DR. NAG: One of the few times.

18 (Laughter.)

19 DR. MALMUD: So your first motion in your
20 role and your third time here has brought you a
21 consensus, and we thank you for bringing it to our --
22 oh, is there another? I'm sorry, excuse me.

23 MR. LIETO: Yes. I'm a little concerned
24 about Voluntary Action 1. I guess it's maybe some of
25 the language. It says, "ensure that all patients."

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1 It's almost like you're -- it's not a recommendation
2 and when you say, "ensure all patients," it kind of
3 takes, to me, that voluntariness, if there's such a
4 word, out of this action.

5 DR. NAG: Where?

6 DR. HOWE: Where does it say, "ensure."

7 MR. LIETO: This was the draft that was
8 distributed in our packet.

9 DR. NAG: Oh, not on this, right?

10 MS. McBURNEY: No. On the handout it just
11 says, "provide."

12 MR. LIETO: This is the draft as of just
13 a week ago -- or a month ago, last month.

14 DR. HOLAHAN: In your package.

15 MR. LIETO: It's in our packet. It has a
16 strikeout of Voluntary Action 2 and a replacement,
17 okay? And I guess I would like to know if we're going
18 to talk about this or maybe there's going to be
19 another version of this and we can maybe respond to
20 that at that time, I don't know.

21 MR. TORRES: Our intent is once we make
22 the changes we're going to resubmit the IN to the
23 ACMUI for a final go ahead.

24 MR. LIETO: I would like to not have the
25 "ensure" because it takes, as I mentioned, that

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1 voluntariness out of it, and it says, "all diagnostic
2 and therapeutic." I mean we're saying every patient's
3 going to have to have -- be instructed and have a card
4 when they leave, and I think that's a greater burden
5 than is being recognized here in terms of commitment
6 of time and resources in the Nuclear Medicine
7 Department.

8 I guess I'd like the institution or the
9 licensee to be left to their decision as to what
10 groups or, I don't know, maybe we might want to just
11 say some likely groups that might be -- I mean I can
12 understand for therapy. Obviously, that might be
13 appropriate. And I guess, as Dick said, maybe stress
14 technetium studies. But I think the majority would
15 not need this to be -- need this card or instruction
16 when they leave.

17 DR. MALMUD: Dr. Vetter?

18 DR. VETTER: Yes. I'm not too concerned
19 about it because of the preceding paragraph that says,
20 "Licensees should consider the following voluntary
21 action." So in Rochester, Minnesota where they all go
22 back to their farm, it's not a big deal. At Sloan-
23 Kettering, it's a little different. So I think each
24 hospital's going to have to treat these a little
25 differently. They will have to decide for themselves

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1 whether or not, but it is very voluntary, so it
2 doesn't concern me.

3 DR. MALMUD: Other comments? We note your
4 concern, Ralph.

5 MR. LIETO: Thank you.

6 DR. MALMUD: I would just comment once
7 again that I think the goal is to reduce the
8 discomfort for the patient, and if the patient is
9 aware that he or she may trigger a radiation
10 monitoring device, it's to our advantage to let the
11 patient know that, either through the technologist for
12 diagnostic procedure or through the physician through
13 a therapeutic procedure. Whether or not it's in
14 writing is less important as long as the patient knows
15 that he or she may be in an embarrassing situation if
16 they enter a federal building or cross a bridge or
17 tunnel that's being monitored.

18 DR. NAG: One question. Where are these
19 radiation detectors? I mean are they in airports
20 also? Because most patients will be flying in and out
21 for the treatment.

22 MR. LIETO: I can tell you that they're on
23 the borders, okay. Being from Detroit, the bridges
24 and the tunnels from Canada to Detroit and they do --
25 each one of the stations have detectors, each one of

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1 the personnel that inspect vehicles.

2 DR. NAG: But my question was what about
3 airports? Do they have it all the airports or not?

4 MS. MCBURNEY: No.

5 DR. MALMUD: I have no idea. I know that
6 we had an amusing situation about 15 years ago or so
7 in which I treated a policeman who was to be assigned
8 as a civilian group surrounding the Secret Service who
9 was accompanying the President. And I told him that
10 he was temporarily radioactive, he should let his
11 commanding officer know, perhaps they wanted to
12 reassign him, and instead they told him to stay home
13 for a day or two because they didn't want to trigger
14 off any of the monitors and have trouble with the
15 federal agency. And that was before the era of our
16 concern about terrorism. So these things can pop up
17 anywhere depending upon who's visiting town. So I
18 would assume that once again my goal is to reduce the
19 anxiety for the patient, give the patient the card or
20 the note and from that point on it's simply a matter
21 of fate. Until Homeland Security develops standards.
22 That's a different department.

23 Once again, have we reached consensus? Is
24 everyone --

25 MR. TORRES: So my action item will be I

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1 will incorporate -- use the revised Voluntary Action
2 Number 1. We'll take out the "ensure all language,"
3 and we'll resubmit to the ACMUI. Thank you very much.

4 DR. MALMUD: Thank you. Now back to the
5 revised agenda, and the next item on the agenda is Dr.
6 Howe. You're back on.

7 DR. HOWE: I'm back.

8 DR. MALMUD: And the subject is emerging
9 technologies.

10 (Pause.)

11 DR. MALMUD: There are only three slides.

12 DR. HOWE: Yes. Yes.

13 DR. HOWE: We have a group that's working
14 on implementation questions for Part 35, and we're
15 fielding a lot of questions from a lot of different
16 places -- stakeholders, people -- et cetera. And we
17 got a request from the Department of Veterans' Affairs
18 and we looked at it, and it really was kind of an
19 interesting question we hadn't thought about.

20 They wanted to use a 35.1000 device. They
21 wanted to follow the web site guidance, but they had
22 earlier been authorized to use this device before the
23 new 35 came into place. And the license condition
24 that they had on their license said that intervascular
25 brachytherapy that you had to have the authorized

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1 user, the medical physicist and the cardiologist
2 present for all procedures. Well, when we went to the
3 new 35 we went to more performance base. The new 35
4 did not include, say, for the gamma-knife was kind of
5 the model that we used, the gamma-knife no longer
6 required the neurosurgeon. The old licensing guidance
7 required the authorized user, the neurosurgeon and the
8 physicist. The new guidance didn't. So we thought,
9 well, the intervascular brachytherapy is pretty
10 similar to the gamma-knife in that we've got this
11 individual that's probably on the team -- really a
12 radiation user and so if you didn't need the
13 neurosurgeon to be there, he probably is there but
14 it's not required, then in intervascular brachytherapy
15 we should not require the cardiologist to be there,
16 although he probably is there.

17 So when we developed the web site guidance
18 we included only the authorized user and the medical
19 physicist. But we had licensees out there that were
20 using these devices that are now 1000 that were
21 conditioned by license conditions before the new 35.
22 So they had a license condition that said, "I've got
23 to have an authorized user, I have to have a
24 cardiologist, and I have to have an authorized medical
25 physicist physically present."

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1 And when we looked at the new rule, we
2 said, okay, 35.26 allows you to change your radiation
3 safety program with certain criteria. The change has
4 to be in accordance with your license. Well, in this
5 case, the change would not be in accordance with the
6 license. They had a license condition that said three
7 people had to be there. So they wouldn't be able to
8 make the change at the facility. They'd have to come
9 in with an amendment request to drop this person.
10 Now, will we grant the amendment request? Of course.

11 So our answer to the question was, no, you
12 cannot make this change under 35.26. There may be
13 other things that you are doing if you use this device
14 that are not tied down by license condition. In that
15 case, it would be in agreement with your license if
16 you made those changes, and you'd just follow the
17 other conditions in 35.26. So the answer had to be
18 no.

19 And then we thought, well, yes, the
20 answer's no but is that really what we want to do? As
21 we get additional experience with 35.1000 uses,
22 they're not going to be so exotic and new. They'll
23 become more routine. Chances are we're going to be
24 decreasing some of the guidance that we have up on the
25 web site today, and when we do revise that guidance,

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1 it's going to show NRC's current philosophy on what is
2 needed to license that particular device. And I say
3 device because all of our 35.1000 uses are devices
4 right now.

5 So we said how do we get around this
6 problem that 35.1000 requires a licensee to submit
7 information that's going to be tied down by license
8 conditions so they have to be in a higher standard
9 than other uses that are already in the regulation.
10 The answer was to give licensees authority in their
11 license that allowed them to make certain changes. I
12 don't think this is it -- oh, yes, it is. Okay. I
13 just have three of these, so they all look the same.
14 So this was the problem. As our web site guidance
15 gets revised, in many cases you can't use 35.26 to
16 change your radiation safety program because you're
17 tied down by license condition.

18 So our solution was to preauthorize
19 licensees to be able to make the kind of changes that
20 would keep them in conformance with changing web site
21 guidance for 35.1000 uses. And that would give them
22 the kind of flexibility they have for 35.26 for other
23 uses. So I developed essentially a system. It's
24 modeled after 35.26 but it is specifically for 35.1000
25 uses.

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1 Now, a licensee or someone coming in and
2 asking for one of these uses is going to have to
3 request it because they have to be -- this particular
4 set of criteria to the program will be tied down by
5 license condition. So it will already be in the
6 license. They'll essentially have a preauthorization
7 as long as their changes to the radiation safety
8 program meet these criteria. And the biggest criteria
9 is instead of being based on the license it will say
10 the revision based on NRC's current guidance for
11 gliacyte, microspheres, intervascular brachytherapy,
12 SeedSelectron posted on the web site. As in 35.26,
13 the revision has to be approved by the radiation
14 safety officer and the license management. All
15 affected individuals have to be instructed in the
16 change so they can all report to that program and that
17 you retain a record for three years and then what this
18 record is going to contain. So it will be the change
19 that you made, the web site guidance, the signature of
20 the licensee. So it's essentially modeled exactly
21 after 35.26.

22 And OGC has blessed this, and this is
23 currently up on the web site as like a conforming
24 change to 36.26 for 1000 uses. It comes at the end of
25 the licensing guidance for the gliacyte, the

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1 microspheres, each one of the intervascular
2 brachytherapy units, and when we do the SeedSelectron
3 it will be up there also. So you can either -- for
4 the SeedSelectron when they're asking for the initial
5 use, they'll ask you this right away. Other licensees
6 that are using intervascular brachytherapy come in and
7 ask for an amendment for this. It will be granted and
8 then you can follow whatever revisions we make to the
9 web site.

10 And that's why I was saying this morning
11 for the SeedSelectron you can go ahead with -- we'll
12 get your comments back again, but before the ACMUI
13 really takes its final stand on the SeedSelectron, we
14 can put our licensing guidance up there and our
15 licensees will have this flexibility to revise their
16 program without getting an amendment if we modify the
17 web site guidance to reduce any of the restrictions or
18 change any of the restrictions. Yes, Jeff?

19 DR. WILLIAMSON: Thanks. Sounds pretty
20 good. I guess I would suggest in Bullet Point Number
21 2 the revision is consistent with rather than based
22 upon.

23 DR. HOWE: Okay.

24 DR. MALMUD: Any other comments?

25 DR. HOWE: Yes, Ralph?

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1 MR. LIETO: I have I guess maybe a more
2 fundamental is that this seems like things will never
3 leave 1000. The intent is that 1000 would sort of be
4 sort of this temporary holding area where things would
5 be for maybe a year or two before they decided where
6 they needed to go or NUREGs needed to be formulated or
7 whatever. And there are things that are in 1000 that
8 are -- that I believe have approached several years
9 now, and I guess I see this as being just another
10 mechanism that once they're put in 1000 they're going
11 to be there until the technology or the USCA
12 terminates or whatever, and that will always be in
13 this guidance licensed condition type mechanism. And
14 I can see this for new, for new things, especially as
15 -- well, like for example, Novoste has made
16 engineering changes and stuff come on board to maybe
17 improve it. But I don't know.

18 DR. HOWE: There are some devices in the
19 emerging technology that will never get enough use to
20 warrant their own regulatory place. There are other
21 devices that may be overtaken by time, and there are
22 other devices that need to come into the regulation.
23 But we haven't -- we don't have a schedule for when to
24 bring those devices into the regulations. And that
25 would be probably a fairly good size commitment on

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1 rulemaking's part, and so this is an attempt that
2 while things are still over there -- so far the 1000
3 uses that we have don't fit into any one category. So
4 it would require a rulemaking to bring them out of
5 1000.

6 MR. LIETO: I recognize that. I guess
7 what also is the other concern is NRC will be making
8 changes to the guidance. Your example was in cases
9 where it would be loosened and certain restrictions
10 might be taken out. But I could see it going the
11 other way is that there might be increased
12 restrictions or added requirements that would not have
13 the opportunity for input by the users and the
14 licensees.

15 DR. HOWE: And I thought about that aspect
16 too, and this is licensing guidance. This is the
17 information that you would provide when you're getting
18 authorization to use that particular device. So if
19 the web site guidance when you're applying says A, B,
20 C and you're given authorization for it because you
21 met those criteria in A, B, C or alternative criteria
22 that we felt were acceptable and then we added a D, we
23 won't go back and unlicense you for it. It's kind of
24 a grandfathering type of thing unless we issued
25 something that made things applicable to everybody

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1 like bulletins that try to get people to commit things
2 on orders. So I think you would not be necessary hit
3 by --

4 DR. HOLAHAN: Well, I'm sorry, I agree
5 with your comment, and we need to form a process
6 whereby we recognize certain things that are licensed
7 under 35.1000 get into the regulations, and we'll work
8 on that.

9 MR. LIETO: One other point --

10 DR. HOWE: But his point was backfit. In
11 other words, if we tighten up on the licensing
12 criteria at some later date, but you got through
13 earlier when we didn't have those tighter
14 restrictions, and I'm saying that I think that is the
15 same as any other licensing action we take. Unless
16 NRC takes some across-the-board action, like an order
17 or a bulletin or something, then you are licensed
18 under what you came in on.

19 DR. HOLAHAN: Yes, because --

20 DR. HOWE: And you're not backfitted.

21 DR. HOLAHAN: Because that's only in
22 guidance space, and we can't put requirements --
23 backfit requirements. When they come in for license
24 renewal, we'd look at the whole thing.

25 MR. LIETO: The correlate is that would be

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1 an absolute nightmare for the regional inspection
2 enforcement people, because they're going to come in
3 and they're going to look this is what the current
4 criteria is on the web site, and that's how they're
5 going to be inspecting.

6 DR. HOWE: They have the license and they
7 inspect against the license. They do not inspect
8 against the web site guidance.

9 MR. LIETO: But the license just has
10 references. Those tie-down conditions are referenced
11 by the date of the application. The license itself
12 does not have the tie-down condition specifically
13 listed.

14 DR. HOWE: But our inspectors are trained
15 that the license is the license, and the license
16 includes all of those documents that are tied down,
17 and they are supposed to know or have access to those
18 documents. Because that's what tell us what the
19 license is committed to. Otherwise we would have
20 documents about yea thick.

21 DR. MALMUD: Dr. Williamson?

22 DR. WILLIAMSON: Yes. I want to, I guess,
23 underscore my support for Ralph's first point and what
24 Patricia said as well. It's not fair to the user
25 community to allow something to sort of sit in

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1 guidance space forever as a substitute for rulemaking
2 and the opportunity for public comment and
3 participation in the process that it allows. So I
4 think a first step would be to have some kind of
5 reasonable criteria for when something moves out of
6 the guidance space and begins to move into the
7 regulated/rulemaking space and kind of have a process
8 set up for that.

9 DR. HOWE: Yes.

10 DR. WILLIAMSON: I really think it is
11 incumbent upon you not to just sort of let this sit
12 forever.

13 DR. MALMUD: Dr. Vetter?

14 DR. VETTER: Notwithstanding these
15 previous comments -- the NRC likes us to use
16 notwithstanding.

17 (Laughter.)

18 I think this is a very positive, proactive
19 step that makes it easier for licensees to make
20 changes in their program.

21 DR. MALMUD: I agree with Dr. Vetter's
22 comment. Any other comments? Are you looking for any
23 kind of statement or action from this Committee?

24 DR. HOWE: No. I just wanted to make you
25 aware of what we've done, what's up on the web site

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1 and the flexibility we think we've given the licensees
2 on this particular thing.

3 DR. MALMUD: Thank you. I think this does
4 add flexibility. It may create an opportunity for
5 clarification later on with respect to how things move
6 out of this, but, certainly, they're moving into this
7 stratus, so we'll speed up some issues for those who
8 may be concerned about them. And we thank you for
9 your effort in drafting this.

10 MR. LIETO: Is this going to be
11 communicated to the licensees in like an information
12 notice or is it just going to be visit the web site if
13 you've got this type of technology?

14 DR. HOWE: Yes. I think our management
15 will tell me whether I can or not, but I do think it
16 needs to probably go out as an information notice so
17 that people are aware of it. We've made -- we have
18 master materials licensees, and the master materials
19 licensees have to issue licenses in the same manner
20 that we do, so we put the notice out to them already,
21 but we haven't done the message to go out to all the
22 licensees.

23 MR. LIETO: Thank you.

24 DR. MALMUD: Next item on the agenda is
25 Angela Williamson.

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1 MS. WILLIAMSON: This is sort of a routine
2 administrative exercise that we perform at every
3 meeting. I'd briefly go over the recommendations from
4 the last meeting and the staff's response and
5 disposition of the recommendations. Although the last
6 meeting was crammed full of agenda topics, only two
7 recommendations actually came out of the meeting. And
8 the other actions were action items that NRC
9 management promised to follow through on.

10 But I'm not going to go over the
11 recommendations in too much detail because, actually,
12 the first one has already been addressed by Dr. Howe
13 during her presentation, the generic listing of
14 sources and model numbers on licenses. And everyone
15 has -- the Committee as a whole agreed to the staff's
16 plan to modify the notifications and the amendment
17 section of the regulation. So I don't think we really
18 need to go over that one in too much detail.

19 The next recommendation, continuous
20 tracking of items generated during ACMUI public
21 meetings, is a non-controversial issue as well --
22 well, not as well -- a non-controversial issue in and
23 of itself. And what the staff -- well, to briefly
24 read the recommendation, at the last meeting, the May
25 20 through 21 meeting, the ACMUI made a recommendation

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1 that about two weeks after distribution of the staff's
2 response to any recommendations that came out of ACMUI
3 public meetings, that we will hold a conference call
4 with the ACMUI, a public teleconference call, to
5 review and prioritize items so that the various items,
6 the numerous items that are generated during public
7 meetings are not inadvertently forgotten about and not
8 followed through.

9 And staff's response to this
10 recommendation is that, well, we agree in principle
11 that in between the bigger meetings where ACMUI
12 assembles here at NRC headquarters, that we can meet
13 or we should meet again with the ACMUI, but we don't
14 want to hold to the two-week deadline. We just would
15 like for it to be approximately midpoint between the
16 two main public meetings. And we've already done
17 that, as you already know, with the July 17 meeting.
18 So that's kind of a done deal as well.

19 There are only about two action items that
20 were generated from the last meeting. The first one
21 had to -- it came out of the ACMUI's reaction to Dr.
22 Robert Ayrs' presentation on exemption requests that
23 were granted for those licensees who wanted to use
24 gamma stereotactic radiosurgery. And after he gave
25 the staff's rationale for accepting or rejecting the

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1 exemption request, ACMUI felt pretty strongly that
2 they should be contacted to assist with these
3 exemption requests or at the very least staff should
4 make a little more effort to engage the licensees to
5 see if additional information can be brought to the
6 surface that will enable staff to approve most of the
7 requests.

8 And so the action item that was generated
9 as a result of that discussion was that staff would
10 explore ways to improve the application process, as I
11 mentioned. Well, if the application process is
12 improved, then maybe you can approve more exemption
13 requests. What we decided to do is to -- well, we
14 felt the best way to improve the applications is to
15 also do another thing that ACMUI recommended which was
16 require licensees to use NRC Form 313A. But before we
17 can do that, we have -- the NRC Form 313A does have to
18 be amended.

19 And once it is amended, we plan on to get
20 the word out to licensees that, okay, we need you to
21 forward these requests on this form. Please do it.
22 We really can't process your request otherwise. So
23 before -- well, I should after Form 313A is amended,
24 then we plan to get the message out by preparing an
25 article in the NMSS newsletter as one vehicle for

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1 informing them, and then also issue a document called
2 a regulatory issue summary and send that out to the
3 licensees and just try to get the widest dissemination
4 possible so that people understand that you just can't
5 grab a piece of paper anymore and just kind of
6 scribble a request on it and send it to the NRC
7 offices. So that's in the works.

8 And the last and final action item that
9 was generated is also a done -- it's a done deal like
10 the recommendations are. The ACMUI -- or, excuse me,
11 the NRC management agreed that we would explore ways
12 to engage ACMUI more effectively or more actively, and
13 that was done at the Commission meeting, basically.
14 We seek approval to utilize ACMUI as more than
15 advisors but also as consultants when necessary and
16 appropriate, and we've already change the charter to
17 reflect that new capacity. So, again, that's pretty
18 much a done deal.

19 Also included, and I'm sure everyone has
20 figured this out by now, but I'm reading from the
21 table of recommendations tasks and action items, we've
22 also engaged the two medical physicists fairly heavily
23 during the last six months in having them assist us
24 with approving requests from licensees for those folks
25 that are seeking authorized medical physicist status

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1 but they don't quite meet the training and experience
2 requirements. And we've been successful in approving
3 those applications using the expertise on the ACMUI.

4 And that's basically all that I have.

5 DR. MALMUD: Thank you. Are there
6 questions for -- yes?

7 DR. NAG: Well, a comment. Basically, I
8 think I want to amend the NRC officials and staff
9 authorizing the feedback. This is something we've
10 been looking for year after year, and now we are being
11 provided this loop, so thank you very much.

12 MS. WILLIAMSON: Okay.

13 DR. MALMUD: Dr. Williamson?

14 DR. WILLIAMSON: I don't know if this is
15 the point to bring it up but I thought the draft
16 summary minutes were very well written and complete.
17 And I thought this was really good.

18 MS. WILLIAMSON: Thank you.

19 DR. WILLIAMSON: This is a very nice
20 readable summary of the meeting and obviously
21 reflected a lot of work on the part of someone that
22 should be commended, I think.

23 DR. MALMUD: I think that's a consensus
24 from this committee.

25 MS. WILLIAMSON: I'll take credit.

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1 DR. MALMUD: So you have another consensus
2 today from the Committee and praise over the work of
3 your offices.

4 MR. ESSIG: Just one question I need to --
5 because I was asked earlier, Angela, on the July
6 conference call summary minutes, have those been made
7 available to the Committee? There's was at least one
8 member that expressed -- that thought that they had
9 not received them.

10 MS. WILLIAMSON: I will have to check into
11 that. It was my understanding that it had been made
12 available.

13 DR. HOLAHAN: They're not available in the
14 book.

15 MS. WILLIAMSON: Well, no, they wouldn't
16 be available in this book, because --

17 DR. HOLAHAN: Oh, it was a closed meeting.

18 MS. WILLIAMSON: Right. Okay.

19 DR. MALMUD: Thank you.

20 MS. WILLIAMSON: Actually, that's not why,
21 the fact that they were closed. That isn't really
22 why. It's just that it was a time issue.

23 DR. MALMUD: Then we move on to the
24 administrative conclusion.

25 MS. WILLIAMSON: I do have an update

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1 there. I found out that this room will not be
2 available around the March 2 time frame. In fact, it
3 won't be available for that entire week. So what
4 we're trying to do is to see if we can get the
5 auditorium either March 1 and 2 or 2 or 3, so that
6 another trip is not necessary for the Committee to
7 make another trip here.

8 DR. MALMUD: So you'll let us know whether
9 the two days are going to be 1 and 2 or 2 and 3.

10 MS. WILLIAMSON: Well -- right, right.

11 DR. MALMUD: We'll look forward to hearing
12 from you about that so those who will require them can
13 make airline reservations in advance.

14 MS. WILLIAMSON: I might already have an
15 answer waiting on me. I just need to check my
16 messages. So by the time you get back to your --

17 DR. MALMUD: We'll check our emails.

18 MS. WILLIAMSON: Yes, you might already
19 have an answer.

20 DR. MALMUD: Any other issues to be
21 covered in the administrative conclusion? Next
22 meeting date? Agenda topics? Meeting summary? If
23 not, may we entertain a motion for adjournment?

24 DR. VETTER: So moved.

25 MS. SCHWARZ: Second.

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1 DR. MALMUD: Thank you all. Thank the
2 staff for an excellent meeting. I've been asked to
3 hit the gavel. Meeting adjourned. Thank you all.

4 (Whereupon, at 2:41 p.m., the ACMUI
5 meeting was concluded.)
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