

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical
Uses of Isotopes

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Monday, March 1, 2004

Work Order No.: NRC-1327

Pages 1-194

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL

USES OF ISOTOPES (ACMUI)

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MEETING

+ + + + +

MONDAY,

MARCH 1, 2004

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ROCKVILLE, MARYLAND

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The Advisory Committee met in the Auditorium of the Nuclear Regulatory Commission, 11545 Rockville Pike, at 10:00 a.m., Dr. Manuel Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS:

- MANUEL D. CERQUEIRA, M.D., Nuclear Cardiologist,
Chairman
- LEON S. MALMUD, M.D., Health Care Administrator,
Vice Chair

1 COMMITTEE MEMBERS: (cont'd)

2 DOUGLAS F. EGGLI, M.D., Nuclear Medicine

3 Physician

4 NEKITA HOBSON, Patient Advocate

5 RALPH P. LIETO, Medical Physicist, Nuclear

6 Medicine

7 RUTH McBURNEY, State Representative

8 SUBIR NAG, M.D., Radiation Oncologist

9 SALLY WAGNER SCHWARZ, R.Ph., Nuclear Pharmacist

10 ORHAN H. SULEIMAN, Ph.D., Food and Drug

11 Administration Representative

12 RICHARD J. VETTER, Ph.D., Radiation Safety

13 Officer

14 JEFFREY F. WILLIAMSON, Ph.D., Therapy Physicist

15

16 NRC STAFF:

17 ROGER W. BROSEUS, CHP, Ph.D., NMSS/IMNS

18 THOMAS H. ESSIG, Designated Federal Official,

19 NMSS/IMNS/MSIB

20 PATRICIA K. HOLAHAN, Ph.D., NMSS/IMNS

21 DONNA-BETH HOWE, Ph.D., NMSS/IMNS

22 CHARLES L. MILLER, Ph.D., NMSS/IMNS

23 ROBERTO J. TORRES, NMSS/IMNS

24 ANGELA R. WILLIAMSON, NMSS/IMNS/MSIB

25 RONALD E. ZELAC, Ph.D., NMSS/IMNS/MSIB

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

2 (10:22 a.m.)

3 CHAIRMAN CERQUEIRA: This is the open
4 session, and, Tom, if you could begin with your
5 opening remarks.

6 MR. ESSIG: Sure. As the Designated
7 Federal Official for this meeting, I am pleased to
8 welcome you to Rockville for the public meeting of the
9 Advisory Committee for the Medical Uses of Isotopes.

10 My name is Thomas Essig. I am Branch
11 Chief of the Materials Safety Inspection Branch and
12 have been designated as the federal official for this
13 Advisory Committee in accordance with 10 CFR
14 Part 7.11.

15 This is an announced meeting of the
16 committee. It is being held in accordance with the
17 rules and regulations of the Federal Advisory
18 Committee Act and the Nuclear Regulatory Commission.
19 The meeting was announced in the February 18, 2004,
20 edition of the Federal Register.

21 The function of the committee is to advise
22 the NRC staff on issues and questions that arise on
23 the medical use of byproduct material. The committee
24 provides counsel to the staff but does not determine
25 or direct the actual decisions of the staff or the

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1 Commission. The NRC solicits the views of the
2 committee and values them very much.

3 I request that whenever possible we try to
4 reach consensus on various issues that we will discuss
5 today, but I also value minority or dissenting
6 opinions. If you have such opinions, please allow
7 them to be read into the record.

8 As part of the preparation for this
9 meeting, I have reviewed the agenda for members and
10 employment interests based upon the very general
11 nature of the discussion that we're going to have
12 today. I have not identified any items that would
13 pose a conflict. Therefore, I see no need for an
14 individual member of the committee to recuse
15 themselves from the committee's decisionmaking
16 activities.

17 However, if during the course of our
18 business you determine that you have some conflict,
19 please state it for the record and recuse yourself
20 from that particular aspect of the discussion.

21 At this point, I would like to introduce
22 the members that are here today. Dr. Manuel
23 Cerqueira, Chairman, is a Nuclear Cardiologist; Dr.
24 Leon Malmud, Vice Chairman, Health Care Administrator;
25 Ms. Neki -- Nekita Hobson, Patient Advocate; Ms. Ruth

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1 McBurney, State Representative; Dr. Douglas Eggli,
2 Nuclear Medicine Physician; Dr. Subir Nag, Radiation
3 Oncologist; Ms. Sally Schwarz, Nuclear Pharmacist; Dr.
4 Richard Vetter, Radiation Safety Officer; Dr. Jeffrey
5 Williamson, Therapy Physicist; Mr. Ralph Lieto,
6 Nuclear Medicine Physicist; and Dr. Orhan Suleiman
7 from the U.S. Food and Drug Administration.

8 Committee Member Dr. David Diamond, who is
9 a Radiation Oncologist, was unable to attend this
10 meeting due to a conflict in the schedule which he
11 could not resolve.

12 We have three new members of the committee
13 which will officially take office -- two of whom will
14 take office later this year, and another one effective
15 with our 2005 meeting. My understanding is that Dr.
16 Robert Schenter, the new Patient Advocate
17 Representative, will be joining us shortly. He
18 arrived late last evening and will join us during the
19 meeting today. And Dr. Schenter will replace Neki
20 Hobson when her term expires later this year.

21 There are two other ACMUI members, who
22 unfortunately were not able to attend today. They are
23 Dr. William Van Decker, a Nuclear Cardiologist, who
24 will replace Dr. Cerqueira; and Mr. Edgar Bailey, a
25 State Representative, who will replace Ruth McBurney.

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1 Mr. Chairman, that concludes my opening
2 remarks.

3 CHAIRMAN CERQUEIRA: Thank you very much,
4 Mr. Essig.

5 We'll move on to the first agenda item,
6 which is Dose Reconstruction Subcommittee Findings on
7 St. Joseph Mercy Hospital Case. This is an ACMUI
8 subcommittee, and Dr. Jeffrey Williamson will be
9 making a presentation.

10 DR. WILLIAMSON: Okay. All right. How do
11 I connect myself up? I have a --

12 MR. ESSIG: Mr. Chairman?

13 CHAIRMAN CERQUEIRA: Yes.

14 MR. ESSIG: If I may, there was one order
15 of business that I meant to include as part of my
16 opening remarks, and it will just take about one
17 minute.

18 CHAIRMAN CERQUEIRA: Okay. Jeff, if you
19 could begin to hook up.

20 MR. ESSIG: While Dr. Williamson is
21 setting up, I have certificates of appreciation for
22 their tour of duty on the committee to Ms. Ruth
23 McBurney and Neki Hobson that were signed by Chairman
24 Diaz, and I would just like to present them.

25 (Applause.)

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1 DR. WILLIAMSON: All right. Well, thank
2 you very much. Well, you'll notice I have entitled
3 this "Input from Jeff Williamson." Although I have
4 gotten some comments on this from members of the
5 subcommittee, we really haven't had an opportunity to
6 have a telephone conference and really come to an
7 official recommendation or endorsement of this. So I
8 think it's -- it's best that I label these as the
9 result of my independent review.

10 So this is just a review of the major
11 factual findings. Two hundred eighty-five millicuries
12 of I-131 were orally administered to a patient who had
13 impaired kidney function and anomalous clearance of
14 the radioactive material, an apparent three-day half-
15 life rather than the usual 95 percent plus clearance
16 with a half-day effective half-life.

17 The licensee did make daily bedside
18 exposure rate measurements, and the problem, of
19 course, is is over a six-day period the patient's
20 daughter spent anywhere from six to 20.5 hours a day
21 in close proximity to the patient who was her mother.
22 So to quote from the inspection report, "Sat against
23 the bed with her elbows or forearms on the bed."

24 In addition, although no data was
25 presented, time-distance distribution data was

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1 presented. Evidently, of the order of 25 other
2 individuals who were part of the patient's extended
3 family also were in the vicinity and exposed to some
4 level of radiation.

5 The NRC staff concluded that the
6 daughter's total effective dose equivalent was 15 rem.
7 So the regulatory issues are fairly clear and narrowly
8 defined. The regulatory question is whether the
9 daughter's dose exceeded 100 mR, and how we're to
10 calculate it is also clear. The appropriate endpoint
11 is essentially the maximum dose to the body core,
12 including arms and legs proximal to elbows and knees.

13 The Society of Nuclear Medicine and the
14 ACNP have publicly voiced a number of concerns. They
15 argue that the NRC dose reconstruction is too
16 conservative by factors ranging anywhere from 1.6 to
17 17.

18 Some specific comments they make --
19 distance should have been reconstructed from
20 measurements. The bedside distance speculated by Dr.
21 Marcus, or inferred by Dr. Marcus, to be 32 cm is not
22 a realistic estimate of the daughter arm-to-patient
23 center distance, that source was not allowed to decay
24 continuously but was, rather, calculated discretely in
25 24-hour steps.

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1 And, finally, they argue that the TEDE is
2 an inappropriate endpoint for risk assessment, that a
3 whole body average dose would be more relevant for
4 this purpose, and that tissue attenuation in the
5 daughter should have been considered.

6 I did do a few Monte Carlo simulations of
7 this, since I am a Monte Carloist as a --
8 simulationist as a researcher. So I thought this
9 might be interesting for the committee to see. I did
10 very simple geometry. I assumed the patient was a
11 cylinder of water weighing approximately 150 pounds.

12 Since the patient had very low kidney
13 clearance, I presumed shortly after the administration
14 the I-131 became uniformly distributed in the plasma
15 pool. So this could be simply modeled as a uniform
16 volume source. I assumed a three point day effective
17 half-life. I then calculated the point exposure rate
18 as a function of distance in the patient transverse
19 plane.

20 I also looked at the daughter and modeled
21 her also as an elliptical cylinder, but this time as
22 a detector, not a source. I did a couple of
23 calculations, the daughter lying next to the patient
24 in a parallel fashion with a 50 centimeter center-to-
25 center distance, and then the kind of daughter

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1 standing or sitting and the patient in a lying
2 geometry.

3 And this is sort of interesting. What it
4 -- the blue line shows falloff air-Kerma rate per
5 millicurie -- air-Kerma per millicurie hour as a
6 function of distance from the patient's center. The
7 blue line is what you would get with inverse square
8 law from a point source, assuming no attenuation. And
9 the red line is, in fact, what one obtains from the
10 volume cylinder source geometry.

11 And, first of all, you can see tissue
12 attenuation is a fairly large effect. Secondly, you
13 can see that the dose distribution falls off rather
14 more slowly than predicted by inverse square law. In
15 fact, over the distance range in dispute it's
16 essentially one over R falloff, because the patient's
17 cylinder is such a large source relative to the
18 distance that's in question.

19 I guess what my analysis suggests maybe is
20 that the average measurement distance might be
21 inferred to be about 25 cm. You can see the licensee
22 measurements overlaid on my curves for different
23 distances reconstructed from the Monte Carlo
24 calculations with the X-axis being the time and days.

25 So this shows tissue attenuations about 40

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1 percent relative to the point source model, and that
2 to decrease the TEDE by 50 percent essentially the
3 patient-to-daughter distance would have to be doubled,
4 as you can see here. This just shows the sitting --
5 daughter sitting geometry. The top -- the gray box
6 represents the bed, and the white box is the patient
7 lying on it, and the oval is the patient -- the
8 daughter, rather, standing next to the bed.

9 So this shows the -- compares the Monte
10 Carlo point detector dose, also the licensee
11 measurements, the point dose at 31.6 cm, the distance
12 that Dr. Marcus thought best approximated the
13 measurement distance. You can see the green and black
14 curves are the average doses to the patient. So what
15 this shows is that the max dose -- maximum dose, the
16 point dose at 31.6, is about four times larger than
17 the mean dose averaged over the whole volume of the
18 daughter's body.

19 So while it's not of regulatory
20 significance in this question in terms of asking
21 questions, what are the possible medical consequences
22 to the daughter, probably the mean dose is a more
23 relevant quantity for the medical consultant's risk
24 analysis.

25 So it's somewhat presumptuous to label

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1 these as ACMUI comments, so I'll call them kind of
2 suggested discussion points. Overall, when I -- as I
3 looked at this, I thought, well, this does seem to be
4 a fairly conservative calculation. The reconstructed
5 measurement distance seems short for the -- a little
6 short for the patient-daughter distance.

7 It seems somewhat implausible that the
8 daughter didn't move for 21 hours and had exactly the
9 same point on her arm irradiated this whole time. I
10 think the issue of continuous versus sort of step-wise
11 decay is unimportant, with only about a five to 10
12 percent correction. So it's possible. Who knows?

13 We weren't really given any primary data
14 to review, but certainly the actual TEDE could have
15 been a factor of two lower. But that's -- without
16 some more data, it's purely speculative. I don't know
17 what to say.

18 However, I think that, you know, this is
19 really missing the point. There is no doubt that the
20 TEDE was many times higher than the regulatory limit.
21 Even the most liberal analysis, if I can use that
22 word, by the Society of Nuclear Medicine gives a
23 result that's many times in excess of this limit.

24 And so if the question is, "Did this
25 daughter dose exceed -- TEDE exceed 100 mR," I don't

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1 think there is any doubt. We were not, in the
2 subcommittee, provided with any kind of a factual
3 basis that could really lead to an alternative
4 quantitative analysis. I'll comment on that a little
5 bit.

6 I think the mean dose, which is raised by
7 the Society of Nuclear Medicine, is sort of irrelevant
8 to the regulatory question. However, I think, as I
9 say, it is important to assessing -- I think more
10 relevant to assessing possible medical consequences
11 than is TEDE.

12 So given that the regulatory limit is so
13 much lower than any plausible reconstructed dose, I
14 think, you know, the NRC estimate is appropriate for
15 this purpose. But I will say that, you know,
16 acknowledging the uncertainties in this analysis and
17 putting a little bit more in the report to justify
18 some of the assumptions made would have cost little,
19 would not have compromised enforcement actions, and
20 would have prevented what seems largely to be kind of
21 a public relations crisis or, you know, questioning --
22 has led to questions now regarding the scientific
23 credibility of these analyses done by the Commission.

24 So I actually think that is the central
25 question -- how to enhance the scientific credibility

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1 of future dose calculations. What can we learn from
2 this incident?

3 I must say that I found a lot of the
4 licensee actions, at least given the information we
5 were given, to be highly questionable. For example,
6 why was radioiodine therapy administered to a
7 terminally ill patient with compromised kidney
8 function? Why were 20 to 35 members of the public
9 allowed to parade in and out of a high radiation and
10 potentially highly contaminated area? Why wasn't the
11 daughter and other relatives -- why were they not
12 assessed for internal contamination?

13 I mean, I have some experience with these
14 kinds of cases, and, you know, it doesn't take a lot
15 to have a room get terribly contaminated. And why
16 didn't the licensee consider training and monitoring
17 the daughter as a radiation worker exempt from the
18 100 mR limit?

19 DR. NAG: What do you mean by -- what do
20 you mean by "internal contamination"? Can you
21 explain?

22 DR. WILLIAMSON: Yes. I mean, I guess
23 that, you know, this patient was clearing iodine from
24 her body somehow. And it wasn't coming out through
25 the normal route, which is by urinary excretion. So

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1 I think there was probably a lot of iodine on the
2 patient's skin and probably -- potentially, you know,
3 over all surfaces that the patient touched.

4 And to have the daughter in such close
5 contact, presumably touching the patient and sharing
6 the bed, and so forth, I would think that there is a
7 significant probability of ingestion of I-131, I-131
8 getting into the patient's -- or the daughter's blood
9 pool that wouldn't -- there's a reason why there's a
10 10 microcurie limit on I-131 administrations before
11 you have to write a written directive. That is
12 because very small amounts can produce deterministic
13 damage to the thyroid.

14 So all in all, I would say a more
15 sophisticated approach to dose estimation would
16 improve NRC's scientific credibility in the regulated
17 community. I think in this case, like I say, there is
18 no question about this daughter exceeding the
19 regulatory limits. So for that narrow purpose I think
20 what they did was fine.

21 However, one could imagine borderline
22 cases or perhaps whether action would be taken against
23 the licensee based upon whether they thought 200 mR
24 versus 100 mR was given, and I think in those sorts of
25 cases strict attention needs to be paid to the

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1 uncertainty of the calculation, and all of the
2 assumptions scrutinized.

3 Some specific suggestions, you know,
4 implausible scenarios, should be questioned during the
5 interviews. Monte Carlo tools are useful in
6 borderline cases to assess data consistency. I think
7 to enhance the credibility of the report uncertainties
8 should be addressed, and what appear to be peculiar
9 assumptions, such as the daughter not moving for 21
10 hours, you know, something should be put I think in
11 the report to justify this, or at least make it clear
12 to the public that this, you know, really is the -- a
13 reasonable estimate given what could be extracted from
14 interviews from these individuals.

15 For medical risk analysis, alternative
16 non-regulatory endpoints should be used. I must say
17 that my ability to offer advice on this point was
18 really hindered by not having access to any primary
19 data. Essentially, only Dr. Marcus' paper and the
20 final inspection report were available.

21 I understand from NRC staff that many
22 hours of questioning of the relatives and staff did
23 occur, and it would have been helpful to have at least
24 a summary of this information, so that the assumed
25 time-distance distributions -- the reasonableness of

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1 those assumptions could have been evaluated.

2 So it might have been nice, as I say, to
3 have -- if there were no written summaries, at least
4 be able to talk to one of the inspectors who knew the
5 case better. Then these time-distance assumptions
6 could have been more meaningfully evaluated.

7 CHAIRMAN CERQUEIRA: Thank you very much,
8 Jeff.

9 Do we have questions or comments for Jeff?
10 Dr. Nag.

11 DR. NAG: Before you leave, can you
12 summarize, a) what the NRC estimate, what the Society
13 of Nuclear Medicine estimate, and what the ACMUI
14 estimate, all in one slide?

15 DR. WILLIAMSON: Oh, boy.

16 DR. NAG: The three different estimates,
17 so we can have some idea.

18 DR. WILLIAMSON: Okay. The NRC estimate
19 was 15 rem. The Society of Nuclear Medicine estimate
20 was -- it depended what they assumed. The factor of
21 17 lower, or approximately 1 mR, was based on the idea
22 of not using the TEDE but using volume averaging
23 endpoint.

24 DR. NAG: And your estimate --

25 DR. VETTER: Excuse me. May I please

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1 interject? This is not a Society of Nuclear Medicine
2 position. It's two authors who are nuclear -- two
3 authors.

4 DR. NAG: Oh, okay.

5 DR. VETTER: It's not -- but the Society
6 of Nuclear Medicine --

7 DR. NAG: I understand.

8 DR. VETTER: -- has not taken a particular
9 position, to the best of my knowledge.

10 DR. NAG: Okay.

11 DR. WILLIAMSON: I think seven -- and
12 there are other estimates -- 7.1 times smaller. That
13 would have been approximately two rem, I think is
14 based on different distance, time-distance
15 assumptions, and 1.6 occurs -- I believe is based upon
16 largely the sort of issue of continuous versus step-
17 wise decay. You might remember better than I did.

18 What is my estimate? I mean, I -- given
19 what we're told, I mean, I would -- if I use the 31.6,
20 maybe my estimate would be, you know, of the order of
21 10 rem. But I don't have any basis for making an
22 alternative estimate, because no data was provided,
23 and no -- no basis for evaluating the inspection --
24 inspector's assumptions.

25 CHAIRMAN CERQUEIRA: Mr. Lieto, you'd like

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1 to make a comment?

2 MR. LIETO: I guess I'm just -- actually,
3 I have a question. Was the charge to the subcommittee
4 to look at whether regulatory limits were exceeded or
5 what I thought was whether -- or how the region went
6 about calculating the dose estimate provided -- was
7 done in an excessively overconservative manner.

8 VICE CHAIRMAN MALMUD: My understanding of
9 the charge to the committee was to review the NRC
10 calculations and to review the communication from Drs.
11 Marcus and Siegel, and to determine whether the NRC
12 recommendation -- findings were overly conservative --
13 that is, whether the dose estimate was too large --
14 compared to the calculations generated by Drs. Siegel
15 and Marcus.

16 In neither case -- and this is very
17 important -- in neither case, neither that in the
18 letter from Drs. Siegel and Marcus, nor in the NRC
19 calculations, is the hospital involved found to be
20 innocent of allowing an excessive exposure, because
21 even if the individual involved -- the daughter -- had
22 been labeled a radiation worker and been trained, then
23 the cap would have been 500 millirem.

24 Both calculations -- both those from the
25 NRC and from Drs. Siegel and Marcus -- clearly result

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1 in radiation burdens in excess even of that limit.

2 My understanding was that the
3 communication from Dr. Marcus, with calculations by
4 Dr. Siegel, was meant to bring to the attention of the
5 NRC its use of -- its interpretation of the
6 regulations which leads to overly generous dose
7 estimates, and that was the area of concern of Dr.
8 Marcus.

9 The conclusion that Dr. Williamson came to
10 in one of his bullet points was that the credibility
11 of the NRC would be improved if the dose estimates
12 were more liberal, liberal in this case meaning a
13 lower radiation burden than that which was calculated.

14 DR. WILLIAMSON: That's not exactly what
15 I said.

16 VICE CHAIRMAN MALMUD: Oh, all right.
17 Well, then please tell us what you meant by that
18 statement.

19 DR. WILLIAMSON: I think that, you know,
20 paying some attention to the uncertainties, and
21 anticipating assumptions regarding time-distance
22 distributions that outright, when you just see it in
23 this report with no other information, might seem kind
24 of implausible would greatly enhance the scientific
25 credibility of the Commission's future calculations.

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1 And I think that's how we can maybe be
2 helpful by making specific recommendations how they
3 might go about that.

4 VICE CHAIRMAN MALMUD: Thank you. My
5 observation was that the NRC calculations were based
6 upon interviews which required them, under the
7 existing regulations, to make worst-case estimates
8 because the database was not adequate from which to
9 draw conclusions, other than the interviews, the text
10 of which we have not seen, but which gave the NRC
11 investigators the impression that the daughter was at
12 the bedside for what seems to us to be an unreasonably
13 prolonged period of time each day, it being unlikely,
14 but not impossible -- unlikely -- that a relative
15 would sit at the bedside for 20 hours a day without
16 any opportunity for normal bodily functions and food
17 and rest.

18 However, if that's what the daughter said,
19 and we were not privy to the circumstances under which
20 she was interviewed, nor the statements that she made,
21 but if those were the statements that were made then
22 the dose calculation had to be based upon the
23 information available.

24 I think that underlying the communication
25 from Drs. Marcus and Siegel was a concern that, not in

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1 this case specifically perhaps but in general, that
2 the NRC has been overly conservative in calculating
3 radiation burdens. And that seems to be the
4 underlying theme, though it is not specifically
5 expressed. And this is a subjective impression that
6 I get from reading the correspondence.

7 And that the reason for the review of this
8 is to determine if we should request a review of the
9 way in which the radiation burdens are calculated in
10 instances such as this, though neither party, neither
11 the NRC nor Drs. Marcus and Siegel, have any reason to
12 question the fact that the limits were exceeded.

13 DR. NAG: I think there are many
14 uncertainties that do exist, and I think there will be
15 many unknowns, not only on this case but almost any
16 similar cases. Would it perhaps be better for the NRC
17 to give its estimate as a range, that this would be --
18 our best estimate would be that this person would have
19 received somewhere between seven to 18 rems, and that
20 would give some idea of the range would be rather than
21 giving just one figure.

22 CHAIRMAN CERQUEIRA: Neki, and then Tom.

23 MS. HOBSON: Well, from -- I cannot even
24 begin to, you know, address the technical questions of
25 who is right and who is wrong. My concern is that --

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1 is the general principle of whether you're overly
2 conservative or not conservative enough, and how it
3 affects the patient and their family.

4 And I guess it's the borderline cases
5 where you would really see the impact, because if the
6 NRC makes these worst-case assumptions and it comes
7 out that, you know, it was 200 millirem, and someone
8 else would calculate it that it was 98 millirem, there
9 is a different regulatory response.

10 And one of the responses is, you know,
11 that it requires patient notification, and in this
12 case I suppose the family would be notified, which I
13 personally think is a really bad idea.

14 So I would not like to see more and more
15 cases overestimated, have the dose overestimated, not
16 that there should not be regulatory concern and try to
17 keep it as low as possible, but the impact that it
18 would have on the patient and the family by informing
19 them that you have been overexposed, which is going to
20 alarm them, worry them, add concerns to what they're
21 already going through.

22 So, you know, can't we find a realistic
23 way of calculating dose that's -- you know, that meets
24 everybody's requirement without involving the patient
25 and their family in extra worries?

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1 CHAIRMAN CERQUEIRA: That's a good
2 question.

3 Tom?

4 MR. ESSIG: Yes. I just wanted to speak
5 to the comment that both Dr. Williamson and Dr. Nag
6 raised about reporting a range of values. While I
7 agree with that from a scientific perspective, one of
8 the issues we face as a regulator, particularly when
9 we're faced with enforcement action, the -- let's take
10 a different case where maybe the range of the estimate
11 was, say, 50 to 500 millirem -- in other words,
12 bracketing the public dose limit.

13 Then, we'd be asking ourselves, well, did,
14 in fact, an overexposure in excess of the 100 millirem
15 occur, or did it not? You know, what is the most
16 likely situation?

17 So while I think a range is good, and it
18 enhances the credibility because it acknowledges the
19 uncertainty analysis, at some point we would have to
20 come to grips with, what is our best estimate, given
21 all of the facts surrounding the case.

22 So I'm agreeing with your point about the
23 range, but I think we also need to focus on -- not
24 lose sight of what our best estimate might be for a
25 particular evaluation.

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1 CHAIRMAN CERQUEIRA: We have a comment
2 from the back microphone.

3 MS. BHALA: Yes. My name is Neelam Bhala
4 from Office of Enforcement. And in this particular
5 case, going back to your comment about choosing a
6 range, for the -- yes, in the inspection report,
7 15 rem was the estimate.

8 But when we did the final enforcement
9 action we did go with the range in that particular
10 case, only because from patients' interviews it seems
11 like, you know, she was just going back and forth
12 between where she was. And so in that case, because
13 of that, for the final enforcement we used -- I
14 remember it was about from 4.6 to the max of 15.

15 CHAIRMAN CERQUEIRA: Jeff, do you have --

16 DR. WILLIAMSON: Yes. Well, I can see
17 that maybe you have to come up with a number, a single
18 number. But certainly you could acknowledge
19 uncertainty, and maybe even estimate uncertainty
20 limits. And I think that it would be well to
21 calibrate any enforcement action, you know, if it
22 really is a borderline case, taking that into account
23 as well as maybe other factors you observed in the
24 licensee's behavior.

25 I can certainly see, you know, in this

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1 case there was a lot of grounds for concern, it
2 appears based on the written materials we have, for
3 the licensee's behavior. And you definite -- you have
4 a limited number of sort of regulatory hooks that you
5 can use to have some impact, and so certainly the
6 uncertainty of the dose calculation shouldn't be the
7 only factor that informs or influences an enforcement
8 action.

9 But it certainly is one, and I think it --
10 you know, a well-operated facility where, you know,
11 the sort of only issue was, was it 99 or 101 mR, it
12 seems unreasonable to sort of punish a licensee under
13 those conditions. So, you know, I do think it is
14 important that, you know, the integrity and fairness
15 of these calculations be respected by all in the
16 community. And I really think that's the lesson to
17 take home from this.

18 I would say, too, we could do a lot better
19 job for you had we been given some access to primary
20 data. You know, there wasn't really very much to
21 review. I mean, in the end I think that much of Dr.
22 Marcus' letter was very speculative. I mean, how --
23 what basis did they have for assuming that the factor
24 -- that the dose should be a factor of seven lower?
25 That's just sort of an off-the-cuff estimate, no

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1 better than my factor of two it might be lower.

2 And that's because we -- we, you know, had
3 no basis for really assessing that critical
4 assumption, which was how far and how long and for how
5 long of a time was the patient really at a given
6 point. And so I think we could have, within our
7 subcommittee, you know, had a more helpful role had
8 more data been shared with us, whatever form it was.

9 CHAIRMAN CERQUEIRA: Tom, you know, to try
10 to wrap up this discussion, because this was given to
11 the committee relatively late and we formed a
12 subcommittee, and Leon and Jeff especially did a very
13 good job of trying to track this down, but I don't
14 quite see the role that you want us to have in this,
15 because you didn't provide us with enough information
16 based on what your -- the NRC had to make the
17 calculations. And, you know, Jeff has made a very
18 good attempt to model what he perceived was the
19 situation.

20 What do you want from the committee
21 specifically?

22 MR. ESSIG: Well, the -- as part of the
23 tasking of the subcommittee, I had made -- of course,
24 offered the inspection report and the report by Drs.
25 Marcus and Siegel that's been referenced. I also

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1 indicated that because of the shortness of the -- of
2 time that I offered Dr. Sami Sherbini of my staff to
3 engage with any member of the subcommittee who needed
4 additional data.

5 If we didn't have it, we would interface
6 with the -- either the regional inspector or the
7 licensee, as needed. And so that was -- that offer
8 has been on the table since the original tasking.

9 Now, it's not that we had a report that
10 we're withholding from you. We had our own
11 evaluation, but we want to -- because the Commission
12 had directed us to make -- to task the subcommittee or
13 the ACMUI with an independent evaluation, we didn't
14 want to bias that outcome with providing the results
15 of our own evaluation, which, of course, we had at the
16 time of the subcommittee tasking.

17 So we were walking a line between --
18 that's the only thing that we really didn't provide
19 the committee was our own evaluation, because we -- in
20 order to meet that test of independence, we gave you
21 the other reports and the other information to --

22 CHAIRMAN CERQUEIRA: Right. But the
23 timeframe for doing this was relatively short --

24 MR. ESSIG: I understand that.

25 CHAIRMAN CERQUEIRA: -- in that situation.

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1 MR. ESSIG: Yes.

2 CHAIRMAN CERQUEIRA: And I don't think
3 Jeff had enough time to --

4 MR. ESSIG: And, certainly, the committee
5 was -- the subcommittee was challenged in that regard.
6 No question.

7 CHAIRMAN CERQUEIRA: Okay. Charlie -- Dr.
8 Miller would like to make a comment, and then Jeff.

9 DR. MILLER: Let's see if I can either
10 help or make this worse. We all recognize that the
11 timeframe was short. We have a forthcoming Commission
12 meeting.

13 While I know the Commission is anxious to
14 hear the results, I think based upon the discussion
15 that I heard this morning we want to make sure that we
16 give them results that people can -- Jeff has used the
17 word "scientific" information.

18 DR. WILLIAMSON: As much as can be.

19 DR. MILLER: So what I wouldn't want to
20 happen is that we rush to an answer if you feel that
21 more data could help you formulate a better conclusion
22 with regard to the recommendation and the independent
23 assessment that you were asked to do.

24 And I would be prepared -- you know, we're
25 up against having a Commission meeting tomorrow, and

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1 I don't want to let the Commission meeting drive the
2 fact that you've got to get to an absolute answer
3 today if you feel that the benefit of more data and
4 some more time would allow you to get to a better
5 conclusion.

6 I'm prepared to sit before the Commission
7 and take whatever it is that they have to offer in
8 that regard. I think what they asked for in this
9 meeting was a status report on where we are. And I
10 know at least from the staff's perspective the staff
11 is not going to present staff conclusions at the
12 Commission meeting tomorrow, because we were asked to
13 seek independent evaluation by ACMUI, and then take
14 that result and factor that into any assessment that
15 the staff does finally.

16 So that's what I'm prepared to tell the
17 Commission. And I'm prepared to tell the Commission,
18 if you feel you need more time, I mean, you certainly
19 can tell them that at the table.

20 Now, I recognize that certain
21 Commissioners are going to be thirsty and anxious to
22 get an answer. But I think it's important from my
23 perspective that we try to give them the best advice
24 and the best answer that you can give the staff, so
25 that we factor that in as opposed to letting a

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1 schedule of a Commission meeting drive an answer. At
2 least that's my perspective.

3 CHAIRMAN CERQUEIRA: I think the members
4 of the subcommittee would welcome the additional data.
5 There is much data that is missing, and it was my
6 impression, though a subjective one, that part of the
7 reason that the final dose was derived by the NRC was
8 because some of the data simply doesn't exist.

9 It was not -- records were not adequately
10 kept, from what I read between the lines, though I
11 haven't seen the records, to document the actual
12 exposure of the daughter to the mother who was the
13 source. Therefore, we would recommend any additional
14 data that's available.

15 At the same time, this particular case is
16 one in which there doesn't seem to be any question
17 from any of the parties involved that the dose limits
18 were exceeded. That point should be made.

19 CHAIRMAN CERQUEIRA: Jeff, and then Dick.

20 DR. WILLIAMSON: Yes. I guess it would be
21 useful to discuss one comment that I think you made,
22 Leon, and that is, is there anything in Part 20 that
23 basically forces or biases the Commission in one
24 direction or another in terms of making dose
25 estimates? As I read it, I didn't think so.

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1 I think as long as assumptions are
2 reasonable and defensible, they can be used in doing
3 shielding calculations to ensure that the 100 mR
4 annual limit is met. One can make plausible
5 assumptions about how often an individual patient is
6 likely to visit the hospital and be in an exposed
7 area, take into account reasonable occupancy factors,
8 usage factors.

9 So I -- so I guess I'll put my question in
10 the -- or my comment in the form of a question to the
11 staff. Is this not the case, that, you know, the
12 regulation is based upon using all available data to
13 come up with the most reasonable answer, and there
14 isn't a presumption that you should always aim for the
15 highest possible or most conservative estimate.

16 MR. ESSIG: If I may, the requirement to
17 which you refer is in the section of Part 20 that
18 defines what a radiation survey is. And a survey is
19 a combination of measurements and evaluations, and
20 that the survey must be reasonable for the
21 circumstances. I think the word "adequate" is used,
22 and, of course, that isn't defined.

23 But it doesn't mean that we need to take
24 the extreme value on everything and have a worst-case
25 scenario. I believe our experience over time has

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1 shown that -- I mean, certainly, when there is -- when
2 we just don't have factual information, it's lacking
3 and it will never be available, then we are forced to
4 take some rather conservative assumptions.

5 But when we have factual information that
6 we can assess and judge the reasonableness of it, then
7 we -- it's incumbent on us to use it.

8 CHAIRMAN CERQUEIRA: Okay. Dick?

9 DR. VETTER: This case begs a number of
10 issues, but just to clarify what we've actually been
11 asked to address, is it whether or not the dose to the
12 members of the public, or this particular member of
13 the public, was accurately calculated? Was it to
14 determine whether or not the methodology that the NRC
15 used is reasonable? Or is it both?

16 VICE CHAIRMAN MALMUD: It has to be both,
17 because the calculations are based upon the
18 assumptions of the exposure of the daughter to the
19 mother, of the public to the source. And, therefore,
20 one is intimately tied with the other.

21 Parenthetically, the letter from Drs.
22 Marcus and Siegel indicates that using a liberal dose
23 calculation method that the dose might have been as
24 much as 17 times lower than that calculated. I'm not
25 accepting that figure, but I am pointing out to you

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1 that 15 divided by 17 still is in excess of
2 500 millirem, which would be a radiation worker's
3 exposure, which is still far in excess of
4 100 millirem.

5 So I don't believe that any of the parties
6 is challenging the correctness of the conclusion that
7 there was an excessive exposure. I think that it's a
8 matter of how these calculations are made, and it
9 addresses the precise issue that Nekita Hobson raised,
10 which is, if this overlaps the area of acceptable
11 versus unacceptable burden, are we not subjecting
12 possibly the public to unnecessary anxiety? Not in
13 this case, but in other cases.

14 And I would like to raise one other
15 question that I think we should deal with, and that
16 is, when a member of the public -- in this case the
17 daughter -- is warned, as she had been, and given
18 adequate opportunity to protect herself as she had
19 been -- the report says that there was a lead shield
20 moved into the room, which the source would be behind
21 -- and doesn't do that, what -- how do we prevent this
22 from happening in the future?

23 Obviously, there are many issues to be
24 considered here. But I'm not aware that an incident
25 like this has occurred before, and the question is,

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1 how do we prevent it from occurring in the future?
2 Which is my greatest concern, because that which is
3 over is over, but it's the future we want to be
4 concerned about.

5 CHAIRMAN CERQUEIRA: Dick?

6 DR. VETTER: Right. That's one of the
7 other issues that I think this case begs. And I think
8 that what you just said creates an ethical dilemma
9 that needs some exploration. Should the NRC -- here
10 we have a patient who was informed, steps were taken
11 -- we can argue all day about whether they were
12 adequate, but steps were taken. The patient -- the
13 daughter ignored the instructions.

14 Now, should the regulated community --
15 should the regulators -- this is an ethical dilemma --
16 prevent a daughter from spending as much time as she
17 wants to with her dying mother? I think that creates
18 an ethical dilemma. Where is -- you know, what is
19 best for the public here?

20 And I'm assuming that this daughter --
21 this member of the public has been adequately
22 informed, and some steps were taken to reduce the
23 dose.

24 CHAIRMAN CERQUEIRA: Orhan?

25 MR. SULEIMAN: I think you just hit an

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1 important point. I think there are regulatory limits
2 for the -- for the occupational worker. There are
3 regulatory limits under certain constraints for the
4 general public. There are no dose limits for patients
5 medically -- you know, there aren't any.

6 When a family member -- and I believe
7 there are some -- I think there is some guidance out
8 there -- the NCRP, or whatever, regarding maybe family
9 members. But we are transcending an area here where
10 an individual has been informed, is aware, and we're
11 not talking about ignorance. I mean, there is some
12 awareness there. So that's something that maybe
13 should be considered. Obviously, it doesn't affect
14 the discussion right now, though it's important.

15 The other thing -- and I think I mentioned
16 this at the last meeting, and I do agree, and I heard
17 some of the staff say that they did report lower
18 limits and upper limits. I think the worst-case
19 scenario was nice to know. It's also nice to know
20 what the lower limit is, and that is some science.
21 You're not working with no information. You've got
22 some information; it's not the best.

23 So the individual was in the room a
24 certain time. You have to factor in that uncertainty.
25 And as Dr. Malmud has said several times -- I lost

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1 count after two or three -- the lower estimate was
2 still above the action level. And I think most
3 enforcement regulatory agencies also include a factor
4 of tolerance.

5 They know that they're not going to come
6 in and enforce when somebody just meets the 55 miles
7 per hour speed limit. They won't -- you'll get
8 tracked when you're doing 65, maybe 10 percent over.
9 So the point is we may be debating the process, but
10 this is Health Physics 101. Calculating the dose
11 should -- this is not something we're doing 50 years
12 ago. This is something that should be pretty
13 straightforward. I don't think anybody who has done
14 the dose estimates has really been that far off.

15 So I don't know whether we should be
16 continuing to discuss the calculation and really
17 decide is there enough information, and is the
18 uncertainty enough that the NRC decision was
19 appropriate?

20 CHAIRMAN CERQUEIRA: I think we should try
21 to wrap this up. And I think, Leon, I -- you've made
22 several good points. And, you know, there seem to be
23 several issues and agendas here. And I don't think
24 we're really quite prepared to go to the Commissioners
25 tomorrow and tell them, you know, was the NRC

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1 calculation done properly? Was it conservative? But
2 I guess the question is: do we need to go further,
3 let the subcommittee continue and do more work?

4 VICE CHAIRMAN MALMUD: We need more data,
5 and we're appreciative of Dr. Miller's offer to
6 provide us with more data. And that will allow us to
7 make a recommendation to -- that will allow the
8 subcommittee to make a recommendation to the
9 committee.

10 Looking at this as a provider, as well as
11 a member of the public, we must protect the public.
12 And at the same time, there -- we have to be
13 reasonable with the licensee. I believe that the
14 reason for this having been brought to our attention
15 was the concern of some parties about the methodology
16 that the NRC uses in calculating doses such as this in
17 general.

18 This may have been the wrong instance for
19 them to have brought it before our attention, because
20 in any calculation the dose is excessive. However,
21 we've been asked to do that, and we will do that.

22 But there remains the concern that the
23 calculations be based upon reasonable estimates, so
24 that the public is not unduly made anxious, and so
25 that the licensees are not unduly punished.

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1 CHAIRMAN CERQUEIRA: I think, you know, if
2 we're going to just stay on schedule here -- and I
3 gather the feeling is to continue the subcommittee's
4 work with the additional information and to sort of
5 broaden the scope perhaps to deal with some of the
6 issues that I think Neki brought up.

7 And, Neki, I'll allow you one comment.

8 MS. HOBSON: But, you know, in my simple
9 view of the world, it seems to me what we were asked
10 to decide was, are the NRC's way of calculating doses
11 overly conservative? I think Jeff's presentation says
12 yes, at least in this case the NRC was overly
13 conservative, not that it wasn't a -- you know, an
14 infraction, that it is not a regulatory concern.

15 But the fundamental question is: does the
16 NRC make unreasonable, overly conservative assumptions
17 calculating dose? We've concluded that, yes, in this
18 case they did. So what's the benefit of in this case
19 trying to come down to whether it's some point between
20 1.6 and 17? What is the precise point? Do we really
21 want to spend more time on it?

22 You know, we weren't asked to calculate
23 the dose, except in the general sense as to -- to
24 support our position on the question, is NRC overly
25 conservative? We've concluded it is.

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1 CHAIRMAN CERQUEIRA: Leon.

2 VICE CHAIRMAN MALMUD: I think, though,
3 that we do need a little more data. For example, we
4 heard this morning something that I hadn't heard until
5 I attended the session this morning. And that is that
6 the regional office said that the dose range was
7 between four point something rem and 17 rem. I hadn't
8 heard that number until this morning. Obviously,
9 there is some data that we have not -- that has not
10 been shared with us as yet.

11 MR. ESSIG: May I clarify that -- that
12 point?

13 VICE CHAIRMAN MALMUD: Yes, please.

14 MR. ESSIG: I'm reading from the Notice of
15 Violation and Proposed Imposition of Civil Penalty
16 that was sent to the licensee on May 7th of 2003.
17 Part of the citation is that specifically a member of
18 the public received a total effective dose equivalent
19 of between three and 15 rem.

20 If one goes back and looks at the
21 inspection report, you'll find the value of 15, but I
22 don't believe you'll find the value of three. I
23 believe that that was the -- the licensee's estimate
24 of the value, and then we adopted that as a potential
25 lower end of the range. And that's how that -- how

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1 that was included.

2 CHAIRMAN CERQUEIRA: Thank you.

3 VICE CHAIRMAN MALMUD: We clearly are
4 still collecting data for the subcommittee, and that's
5 why I would recommend that we postpone presenting this
6 data to the entire committee and then to the NRC.

7 DR. NAG: Yes. I think that one question
8 that needs to be asked is that you are imposing a
9 penalty on the licensee. The licensee has done its
10 part in warning the member of the public that this
11 potential exists, not to do it, and the member of the
12 public goes ahead and does it anyway. What fault is
13 that of the licensee?

14 For example, we do implants on young
15 children. Now, if you do implants on young children,
16 the mother would want to come in. Now, are we going
17 to force the mother -- no, you cannot come in? If the
18 mother still persists, what do we do? Or are we going
19 to say we are not going to implant your child if you
20 are going to come in, and, therefore, the child will
21 not have an implant?

22 So I think, you know, we need to see --
23 are we going to penalize the licensee for having done
24 it where -- where a member of the public ignores the
25 recommendations of the licensee?

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1 CHAIRMAN CERQUEIRA: I think that's an
2 important point. Unfortunately, I think, though,
3 we're not going to be able to solve this here. I
4 think maybe the subcommittee should kind of redefine
5 its charge a little bit to see exactly what it is,
6 because, I mean, we've identified, you know, the
7 accuracy of the dose calibration, how far off was it,
8 issues of, you know, can you -- if you inform people
9 adequately, can you then prevent them based on having
10 the knowledge to assume the risk. I feel that's a
11 separate issue, and I don't think we're going to solve
12 that here.

13 I really do think we should move on,
14 continue the subcommittee work. I guess the one
15 question is: how much, if anything, do we present to
16 the Commissioners tomorrow?

17 DR. WILLIAMSON: I think that we --

18 CHAIRMAN CERQUEIRA: Jeff?

19 DR. WILLIAMSON: -- need more time and
20 more data.

21 CHAIRMAN CERQUEIRA: Okay.

22 DR. WILLIAMSON: And there wasn't time to
23 get it. And I think rather than -- I think Charles is
24 right. Rather than present something half-baked and
25 speculative, we should, you know, come to the table

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1 with better defined conclusions.

2 I think we might consider broadening the
3 charge of the subcommittee to consider the management
4 or regulatory significance of caregivers and patients'
5 family members, and under what circumstances they
6 might be exempted from the 100 mR limit.

7 It does seem to me unreasonable that in a
8 situation like this family members are prohibited from
9 spending significant time with their loved ones. So
10 I think we could discuss that. We might, you know,
11 also consider, you know, looking more broadly at the
12 methodology of dose calculation, although that would
13 get very involved, rather than just sticking to this
14 one case.

15 VICE CHAIRMAN MALMUD: I agree, and I
16 think that there's another issue we have to deal with,
17 and that's on behalf of the licensee -- licensees in
18 general. And that is, what should the licensee have
19 done, or what should a licensee do in the future, when
20 a member of the public, duly informed, ignores the
21 information, knowingly ignores the information, and
22 exposes himself or herself to a larger radiation
23 burden than is permissible? What's the licensee's
24 responsibility?

25 DR. WILLIAMSON: I'm not sure the 100 mR

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1 was a limit they were obligated to follow. I actually
2 wonder if they couldn't have set things up in a
3 different way for this individual person to get a --
4 have a higher and more generous limit.

5 VICE CHAIRMAN MALMUD: I'm not arguing
6 that, Jeff. What I'm saying is that what should one
7 do in the future to deal with this issue? The limit
8 for a radiation worker would have been 500 millirem --
9 5,000. And in that instance, should this have been a
10 proactive action rather than a retroactive action?
11 Those are the issues we have to discuss in the
12 committee for the future.

13 CHAIRMAN CERQUEIRA: Yes, I think that
14 would be a more important charge. And so maybe if the
15 committee and staff could come up with a new charge
16 and just send it out to the committee so we're aware
17 of what's going on, and then report on this at the
18 next meeting.

19 One final word, and then we'll move on.

20 Roger, if you want to get prepared.

21 DR. MILLER: What occurs to me is where we
22 are. You know, your charge was given to you by the
23 staff at the Commission's direction as to what they
24 wanted you to look at. But like for any case,
25 sometimes when you look at a specific case it causes

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1 you to start thinking about a broader question, and I
2 think that's what we have here.

3 And it certainly seems to me -- and,
4 again, it's up to the committee as to what you want to
5 present to the Commission tomorrow. Far be it from me
6 to tell you what you should be presenting, nor would
7 I even endeavor to try to do so, but I think that --
8 I think that there are some important conclusions, and
9 one is even given your preliminary calculations, there
10 has been a lot of dialogue concerning none of us see
11 that -- I think we're in agreement that at least with
12 what we have out that none of us see that this
13 particular case the enforcement was inappropriate.
14 That much can be said.

15 But I think the second point with regard
16 to some of the dialogue would be worthwhile to discuss
17 with the Commission, because I think together we can
18 tell the Commission we think there are some broader
19 questions here that we can explore from this, and it
20 would be worthwhile to do so.

21 CHAIRMAN CERQUEIRA: So maybe Jeff and
22 Leon could bring this up during the -- and, you know,
23 again, we can -- I think we -- since it's on the
24 agenda, we have to address it. But I think as Charlie
25 has outlined would be the appropriate way to do it.

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1 All right. Well, thank you. This issue
2 will definitely come up again.

3 The next item is -- where are we? Okay.
4 ACMUI review of NRC method -- nope, that was that,
5 wasn't it? Wrong sheet. Status of Rulemaking: Amend
6 10 CFR Part 35/Recognition of Specialty Board
7 Certifications (T&E)/Preceptor Statement/NRC Form
8 313A. Dr. Roger Broseus will be making the
9 presentation.

10 Roger?

11 DR. BROSEUS: Thank you.

12 CHAIRMAN CERQUEIRA: Sorry for the delay.

13 DR. BROSEUS: Excuse my little congestion
14 here.

15 Thank you for the opportunity to address
16 you this morning regarding the status of the proposed
17 rule on training and experience in recognizing
18 specialty board certifications. I'm going to start
19 off by emphasizing that this is a status briefing.

20 It's a presentation giving an overview of
21 comments that we have received to date -- actually,
22 not even to date. The closing date for the comment
23 period was February 23rd, which was last Monday. At
24 that point we received in my office approximately 15
25 letters and e-mails. As of Friday, we were up to 25.

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1 And so my presentation today is meant to be an
2 overview and a summary of some of the comments to give
3 you a feeling for what we've received through last
4 Monday and give you a feeling for where we're at.

5 It's not meant to be an inclusive summary
6 of all of the issues, but I think that this will
7 highlight for you some of the major issues that we
8 see. But before going into discussing the comments,
9 let me indicate where we are in the rulemaking -- just
10 a status report here.

11 The Office of Management and Budget
12 approved the information collection related to the
13 proposed rule on February 2nd of 2004, and that's a
14 nice hurdle to have in our past. I have just
15 mentioned that the public comment period ended on
16 February 23rd, and I'd like to just note for you that
17 you and everybody else can view the public comments on
18 our rule forum website. And sometimes people have
19 trouble finding it, so the URL for the website is
20 included on the slide, so you can find it more easily.

21 As I mentioned, through the beginning of
22 last week we had received e-mails and letters from 15
23 commenters. And you do have before you a copy of the
24 slides, so thank goodness you don't have to be facing
25 away from us and the audience to view what I'm talking

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1 about here.

2 At that point, there were five agreement
3 state representatives and 10 members of the public who
4 had commented. I might mention that I have an
5 arbitrary breakdown between agreement states and the
6 public, just for convenience in presentation.

7 The public commenters included
8 individuals, professional societies, and other groups
9 -- physicians, medical physicists, a whole variety of
10 people. Overall, there was general support expressed
11 for the proposed rule, with five offering what I term
12 "explicit" support like, "We feel this is a good thing
13 to do," just in general terms. And that support came
14 from one agreement state and four of the public
15 commenters.

16 To refresh your memory, and others'
17 memories, we posed three questions in the FRN, the
18 Federal Register announcement, which included our
19 supplementary information explaining the rationale for
20 the rule as well as the proposed rule changes. And
21 these three questions related to: do the proposed
22 changes adequately cover safety? Should agreement
23 states establish requirements in their rules by
24 October 24th of 2005? Or should they be given three
25 full years to develop a compatible rule? And should

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1 the word "attestation" or "attest" be used in place of
2 "certification"?

3 I will deal first with comments on the
4 proposed rule coming from the public. First point
5 that came out in my reading is -- I shouldn't say a
6 first point, but one of the points -- preceptors
7 should not be required to attest to candidates passing
8 board-administered examinations.

9 The way the rule is written it appears
10 that -- the proposed rule -- that in the certification
11 statements or preceptor statements that a preceptor
12 would be attesting to an individual having taken an
13 exam and passed it.

14 Several comments from the public dealt
15 with the timing issue that we mentioned a moment ago,
16 along with pros and cons of the timing of agreement
17 statement adoption. There were comments on -- from
18 the public about using "attest" versus "certify."
19 Generally, the commenters agreed with the ACMUI --
20 excuse my use of the term ACMUI for A-C-M-U-I. It's
21 something I fell into a long time ago. It's just the
22 way it comes out of my mouth. Generally, though, they
23 say use "attest" instead of "certify."

24 One commenter pointed out that in the
25 definition, if you look up the two words, they mean

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1 the same thing. Okay? But another commenter pointed
2 out that to avoid confusion between the use of the
3 word "certification" by a board, and a preceptor
4 certifying or attesting, that they felt "attest" was
5 a better choice of words.

6 Additional comments from the public -- one
7 of the boards indicated they felt that if the rule is
8 put into place immediately after the expiration of
9 Subpart J on October 24th of this year, the boards
10 would not have enough time to submit applications for
11 recognition, and that staff may not have enough time
12 to evaluate them. So they are suggesting that a
13 period of time be allowed to have boards apply and for
14 staff to evaluate.

15 Another comment -- the wording in proposed
16 35.390(c) is unclear. Again, this is an implication
17 that a preceptor must satisfy passing of certification
18 examinations.

19 There was a suggestion that radiation
20 oncologists be proposed from the requirements in 390.
21 These are certain training and experiential
22 requirements.

23 And, finally, coming from the public were
24 many comments that dealt with details such as the one
25 we had talked about and others, as well as details of

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1 implementation of the proposed rule.

2 Let me move on to agreement state comments
3 on the proposed rule, and then we'll go into comments
4 on implementation procedures of the drafts that we
5 sent out a couple of months ago.

6 Agreement states generally are asking for
7 a full three years to develop a compatible rule. One
8 of the themes that came through from several states
9 was that they have to go to the legislatures to change
10 the rules, and they have two-year legislative cycles.
11 And so to be able to phase things and get the rule
12 change into place, they need three years.

13 Another issue that came out in the
14 agreement state comments related to the number of
15 hours of training for various categories of use. They
16 suggested, for example, that there should be explicit
17 requirements in 35.190, 290, and 390, for number of
18 hours of training.

19 One of the arguments that was posed was
20 this would lead to more consistency and ensure that
21 the rules are consistent between states in terms of
22 the way the rule is evaluated and also help ensure
23 compatibility -- adherence to the requirement for
24 compatibility, which means that the state requirements
25 -- agreement state requirements should be essentially

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1 the same as those of the NRC.

2 More agreement state comments -- they'd
3 like a clarification of the definitions in
4 Section 35.2. In particular, they felt that the way
5 the definition is worded in the proposed rule that it
6 wasn't clear that an individual who meets the
7 requirements in the alternate pathway, as opposed to
8 the certification pathway, that they were defined as
9 RSOs or authorized users, or whatever.

10 There was general support for retention of
11 requirements for receptor statements. They like the
12 idea of decoupling of preceptor precertifications from
13 those of the board in some cases. One person termed
14 this change to be unfortunate, but they said it was
15 because it would be confusing for applicants for a
16 while. It would take a while for them to get used to
17 it. Others said they're glad to see the burden shift
18 from boards to -- they characterized it to
19 individuals.

20 Again, as with the public comments,
21 agreement state comments dealt a lot with details of
22 the rule as well as implementation, which we'll talk
23 about in a moment.

24 Now, I want to -- with this slide I just
25 want to draw a distinction between what I've been

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1 talking about to this point and my next topic.

2 We drafted implementation guidance for
3 review concurrently by the Advisory Committee, as well
4 as agreement states. That draft was distributed to
5 this group during the November meeting, and to
6 agreement states on October 23rd. So there was a
7 little bit of overlap, but generally there was a one-
8 month period there where we asked for comments back on
9 the implementation procedures.

10 Dr. Vetter provided a compilation of
11 comments from ACMUI members back to us -- to staff --
12 on December 15th. We also got responses from four
13 agreement states on our draft implementation
14 procedures.

15 Here is what we heard from the Advisory
16 Committee member compilation -- that the NRC doesn't
17 understand the purpose and process clearly of the
18 board certification procedures and requirements. They
19 pointed out that boards do not determine the content
20 of training programs. They determine if a candidate
21 possesses adequate knowledge and understanding of
22 content, and that the draft procedures, as we move
23 forward, should reflect this difference.

24 They indicated they felt that the draft
25 includes redundant requirements, for example, for

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1 boards to declare that candidates must complete T&E to
2 sit for an examination. It felt that it was
3 inappropriate for the NRC to examine board processes
4 -- for example, looking at examinations, passing point
5 workshops, grading procedures.

6 It felt that the NRC should not review
7 specific procedures of boards, and that there was
8 confusion about the role of agreement states in
9 recognizing boards. One of the questions was: can a
10 board recognize a state -- I'm sorry. Can a board
11 apply to a state and be recognized by a state?

12 And if approved, will the certification
13 approved by one state be recognized by all and by the
14 NRC? And there was a question about whether or not
15 states have resources to conduct the recognition
16 program.

17 Continuing on, more comments from the
18 members of the Advisory Board -- Advisory Committee --
19 why should boards be required to renew every five
20 years? In other words, programs are static, they are
21 unchanging; why should the staff keep asking questions
22 of the boards?

23 They indicated that when the NRC invites
24 applications from the boards that the consequences of
25 not applying should be addressed in the invitation to

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1 the board. It said a board should not be delisted,
2 unrecognized, due to non-response to communications
3 from the NRC. That is, if a letter goes out and
4 there's no response coming back, that shouldn't be a
5 sole basis for not recognizing a board, or whatever.

6 They advised the NRC to have interaction
7 with the boards, so they understand the processes --
8 for example, having a public workshop or a
9 teleconference -- to explain procedures as well as
10 announcing in the Federal Register the opportunity, I
11 guess I would say, to apply to the NRC for
12 recognition.

13 I'd like to move on next to agreement
14 state comments on the procedures for implementation.
15 We saw in the comments on implementation procedures an
16 echo. Actually, it wasn't an echo, because we got
17 comments from states on proposed rules after the
18 implementation procedures. But there was crossover,
19 there was a common theme on some issues between
20 comments on implementation and comments on the
21 proposed rule.

22 And one of them was in the area of a need
23 for specification of number of hours, so that hours
24 comment came up both on -- in comments on
25 implementation procedures as well as on proposed

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1 rules.

2 They want guidance for evaluation of
3 training programs for certification, and for alternate
4 pathways. One of the arguments they posed here was
5 they need some common performance indicators for their
6 IMPEP reviews. And IMPEP -- had to go look this up
7 myself -- is Integrated Materials Performance
8 Evaluation Program. This is a program that Office of
9 State and Tribal Programs uses to assess the
10 performance by agreement states.

11 Question?

12 DR. WILLIAMSON: Yes. Before you leave
13 this slide, is the issue of number of hours of
14 didactic training an issue for just the alternative
15 pathway, or the requirements that a board has to meet
16 in order to be recognized?

17 DR. BROSEUS: Both. Both. They'd like to
18 see more specification number of hours as a tool to
19 evaluating how good the certification program is.

20 There was also a comment here on the
21 training area that the states would like to see more
22 specification for T&E, training and experience, for
23 what they termed "modality training" -- that is, what
24 is required in the case of uses that fall under
25 35.1000.

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1 Continuing on with agreement state
2 comments, there was an expression of doubt that boards
3 would allow review of examinations. You might recall
4 that the Commission directed the staff to include
5 procedures for evaluating whether or not agreement --
6 I'm sorry -- certification board requirements were
7 adequate when, for example, there's a trend in medical
8 events.

9 They said that they need more guidance on
10 proposed changes for uses of sealed sources in medical
11 therapy, including the specialty modality such as IVB,
12 intravenous brachytherapy.

13 They indicated states should recognize
14 boards that, for example, might be a state medical
15 physicist licensing board. And if a state were to do
16 this -- I shouldn't say that they should -- but should
17 they recognize state boards, and, if so, were these
18 recognitions to be -- have national applicability.

19 One state indicated they felt there was
20 new process lacking in the procedures, the draft
21 procedures, indicating they would be required to have
22 a hearing should there be a determination to delist a
23 board.

24 I want to move on to where we see
25 ourselves going in the future, but reemphasize that my

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1 presentation today is a first look. You all are the
2 first ones to hear any sort of summary of what
3 comments came in. And the staff will be continuing to
4 compile the comments and put them into a form where we
5 will be organizing them and analyzing and resolving
6 some comments, and so on.

7 After we resolve the comments from the
8 stakeholders, we will prepare a draft final rule. And
9 part of our plan for moving forward is to distribute
10 this to the Advisory Committee and the agreement
11 states for parallel review. We're doing parallel
12 review, because it's necessary to move quickly with
13 this to have a rule published before the expiration of
14 Subpart J on October 24th of this year.

15 So the Advisory Committee will have an
16 opportunity to give us more feedback on the final rule
17 while it's in draft form.

18 After that, we will resolve the comments
19 from the Advisory Committee as well as agreement
20 states and move it on to the Commissioners -- to the
21 Commission for review and approval. We will post --
22 once we've got everything reconciled, we'll publish,
23 of course, the rule in the Federal Register.

24 We hope to do that -- we must do that
25 before the end of October, and our plan is to get it

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1 out in September. We will post revised implementation
2 procedures on the web and contact the boards to invite
3 their application.

4 In closing, I'd just like to -- not only
5 to reemphasize that we're in process here, but also
6 what we will be doing in doing our review, and so on,
7 and that is to make sure that, to the best of our
8 ability, that the rule and the supplementary
9 information explaining the rationale is clear and
10 addresses all of the comments of everybody, there's a
11 clear basis for the rule change, and to have this in
12 place before the expiration of Subpart J.

13 Are there any questions or comments?

14 CHAIRMAN CERQUEIRA: Well, I'd sort of
15 like to make one comment and to acknowledge that I am
16 president of one board that has gone through the
17 application process. It's the Certification Board of
18 Nuclear Cardiology.

19 But, you know, a lot of the -- maybe I've
20 been in the process too long. These were questions
21 that came up at all the various stages, the public
22 forums, and we had a lot of input, and we made some
23 decisions, and now we're going back and we're
24 relooking at it again, which is not necessarily long
25 -- wrong, but it's going to delay the process.

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1 You know, specifically things like hours.
2 We had hours. Well, we got a lot of complaints that
3 we shouldn't have hours, and we ended up taking the
4 hours out. So I think we -- you know, the committee
5 is quite willing to continue to give comment, but at
6 some point we have to ask how often we're going to go
7 back and relook at things that have already been
8 solved.

9 And, Dick, I think you have been working
10 on this more than anyone else. Do you have any
11 comments relative to what Roger has said, or -- you
12 don't have to agree with me necessarily, but --

13 DR. VETTER: And I don't have to agree
14 with Roger either I guess.

15 (Laughter.)

16 No. I don't have any specific comments.
17 He is simply reporting on the feedback.

18 CHAIRMAN CERQUEIRA: Yes.

19 DR. VETTER: And we can argue for or
20 against any of that feedback, but that's not what he's
21 here for. I do appreciate seeing all of this put
22 together in one presentation.

23 CHAIRMAN CERQUEIRA: Good. Okay.

24 Other comments or questions for Roger?
25 Ralph?

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1 MR. LIETO: Roger, when someone posted a
2 response to the proposed rules, how soon after posting
3 does it go up there for review, if they were doing it
4 electronically? The reason I'm asking is because I
5 was looking at this --

6 DR. BROSEUS: Yours weren't there.

7 MR. LIETO: Pardon?

8 DR. BROSEUS: Yours were not up, correct?

9 MR. LIETO: Yes.

10 DR. BROSEUS: The answer is that there is
11 some internal delay. Okay? For example, your
12 comments I believe came in -- they were docketed on
13 the 23rd, which was the deadline, but not posted on
14 the website.

15 Now, I did see your comments, because they
16 were available to staff, but there's a lag time. And
17 one of the things that we say when we're looking at
18 comments is, you know, we will consider comments up to
19 the deadline, which was the 23rd, and others as we
20 can. But part of the process also is to realize that,
21 you know, sometimes there are some time lags. But
22 yours certainly made it in within the docketing
23 period. But the answer is it's about a week.

24 MR. LIETO: Thank you.

25 CHAIRMAN CERQUEIRA: Patricia?

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1 DR. HOLAHAN: And to address your comment
2 fully, we'll accept comments if they're postmarked the
3 day that they're -- postmarked by the 23rd. And that
4 takes time, getting them in, and then it will take
5 even longer to get up on -- them up on the website.

6 DR. BROSEUS: As of Friday -- I'm sorry,
7 Monday, it seems to me -- the 23rd, it seems to me
8 that during the week last week there were on the order
9 of 15 on the website, or maybe 20. But, you know,
10 we're up to 25 as of Friday, comments coming in that
11 will be considered.

12 Another comment or question?

13 CHAIRMAN CERQUEIRA: Yes. Charlie?

14 DR. MILLER: Yes. Will regard, Dr.
15 Cerqueira, to your comment concerning continuing to
16 comment, I think what we need from here on in is not
17 your continued comments that went into the draft rule
18 as it is currently constructed, but, you know, as part
19 of our rulemaking process we're obliged, once we get
20 the public comments, to have to resolve those public
21 comments, and if -- if we see fit based upon those
22 public comments, change the proposed rule in some way,
23 shape, or form.

24 Where we would need your input would be in
25 the final -- once we've done that, in the final

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1 formulation of the rule package, if things are to be
2 changed from what they were proposed based upon public
3 comments, your advice to us would be beneficial. Is
4 that --

5 DR. BROSEUS: I might observe also that,
6 you know, it's typical for people to continue to
7 comment on points they have made before. That's part
8 of the process.

9 CHAIRMAN CERQUEIRA: Right. Okay, good.

10 MR. MOORE: This is Scott Moore. I'm the
11 Chief of the Rulemaking and Guidance Branch. What
12 Charlie said is correct. The next official stage that
13 we would seek ACMUI comments is at the draft final
14 rule stage, and it's the point where we would go to
15 the agreement states also for comment.

16 And if the ACMUI feels that it's commented
17 in your -- and you don't feel inclined to comment
18 again, then that would be fine at that stage, if you
19 don't feel it's a good use of your own resources. But
20 we would come to you to give you the opportunity for
21 comment at that point.

22 And the amount that there are changes in
23 the final rule we don't know yet. As Roger said,
24 we're just getting the comments in now. The comment
25 period closed on the 23rd. Last week the comments

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1 doubled in size. So, you know, as Dr. Vetter pointed
2 out, we haven't analyzed them yet. Roger is just
3 reporting on what they say. We haven't taken a
4 position on any of them yet. We don't know how the
5 final rule will change or not.

6 CHAIRMAN CERQUEIRA: Good.

7 Neki, and then Dr. Miller. Neki? Ruth?

8 MS. MCBURNEY: Yes, I'm Ruth.

9 CHAIRMAN CERQUEIRA: I apologize.

10 MS. MCBURNEY: I think the reason that
11 you're seeing questions about the number of hours is
12 that -- from the agreement state is that you're
13 already getting questions from the training courses
14 that are only like 16 to 40 hours, saying, "Are you
15 going to accept our course?" where the didactic
16 portion -- it doesn't go to the alternate pathway.

17 DR. MILLER: I just wanted to comment that
18 we talked earlier this morning, had a motion passed,
19 to have a conference call for the committee at some
20 point in the mid-term. I'm confident that this will
21 be a topic of discussion for a mid-term kind of phone
22 call, you know, on the final comments for the rule.

23 CHAIRMAN CERQUEIRA: Good. Okay.

24 All right. Are there other questions?

25 Perhaps we could break for lunch, then.

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1 Roger, thank you very much.

2 DR. BROSEUS: Thank you.

3 CHAIRMAN CERQUEIRA: So I think we'll
4 break here for lunch. We'll reconvene at 1:00 and the
5 Emerging Technologies Subcommittee.

6 (Whereupon, at 11:51 a.m., the
7 proceedings in the foregoing matter
8 recessed for lunch.)

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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:06 p.m.)

CHAIRMAN CERQUEIRA: If everybody could please take their seats, we will begin, try to stay on time. This is the post-lunch session of the ACMUI. The first item on the agenda for half an hour is "Emerging Technology Subcommittee Discussion on Mission and Meeting Procedures." Ruth, are you doing that?

MEMBER McBURNEY: Partly. And I think Jeff will have some comment.

EMERGING TECHNOLOGY SUBCOMMITTEE DISCUSSION ON
MISSION AND MEETING PROCEDURES

MEMBER McBURNEY: The draft licensing guidance for the seedSelectron device was sent out in December to the subcommittee for review. Part of the discussion this morning about process and so forth and when a subcommittee could meet and discuss things over the teleconference and discuss matters with staff without that having to be noticed came up.

So in order to save time, I sent out e-mails to the subcommittee members and said, "Do we need to have a teleconference where we are going to have to notice it in the register and so forth or do you just have comments that we can pass on to the

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1 staff?"

2 Basically most everybody just had some
3 minor comments, but I think Dr. Williamson addressed
4 some concerns that were more technical in nature and
5 also in the way the guide was set up.

6 Now that we have gotten information that
7 subcommittees can meet by teleconference and discuss
8 issues with staff without that having to be noticed,
9 I think that in the future, subcommittees can go
10 forward and do the things that we need to do with
11 staff on commenting on documents and get into more
12 detail.

13 Are we talking about the guidance itself?
14 That is basically all I wanted to say about the
15 procedures unless one of the other subcommittee
16 members has some comment about that.

17 CHAIRMAN CERQUEIRA: Jeff, you had some
18 comments?

19 MEMBER WILLIAMSON: Yes, about process.
20 I think we really have been hampered in our
21 activities. We really have only been allowed to meet
22 or have been planned to meet or have had fairly brief
23 meetings at the ACMUI, face-to-face meetings. If the
24 seedSelectron is any good example of what the future
25 holds, these are very detailed technical documents and

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1 take considerable time to go over the technical
2 details.

3 So unless we come up with a methodology by
4 which we can meet for appropriate lengths of time and
5 have the, if necessary, maybe even some outside
6 advice, I don't think we are going to be very useful
7 to the staff on these matters.

8 CHAIRMAN CERQUEIRA: So two items. One is
9 just meetings.

10 MEMBER WILLIAMSON: Yes.

11 CHAIRMAN CERQUEIRA: Do you need
12 face-to-face meetings? Can you do it with the
13 telephone conferences that we have discussed?

14 MEMBER WILLIAMSON: For the most part, my
15 sense is I think we could do it with teleconferences.
16 It may be necessary. For example, with the
17 seedSelectron, there were a number of fairly
18 complicated technical issues that could only be
19 resolved by actually seeing how the device works and
20 having detailed conversations with the vendor's
21 representative.

22 So I undertook that on behalf of the
23 subcommittee. And I think it wouldn't be necessary
24 for the whole group to do that. So for the most part,
25 I think we could have subcommittee meetings by

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1 telephone with perhaps some travel and face-to-face
2 meetings that individual members might have to make.

3 CHAIRMAN CERQUEIRA: You said consultants.
4 Do you think that travel to vendor site would provide
5 adequate information? Do you need additional
6 expertise? I would ask, Tom, is there anything in the
7 budget?

8 MEMBER WILLIAMSON: This is another very
9 interesting aspect of process. I understand there is
10 a more current version of this draft guidance up on
11 the Web site, which I haven't seen certainly. So I
12 base my comments on the one we were given I think in
13 January.

14 This is an incredibly detailed complex
15 document. At least the version I have seen is
16 basically filled with mistakes, misunderstandings.
17 You know, I am not trying to attack anybody. I think
18 that the point I am trying to make is that this is to
19 come up with an effective quality assurance protocol
20 that meets the needs of future regulations for the
21 Commission. You can't do it unless you are an expert.

22 So another aspect of process that the
23 staff might want to consider is in the formulation of
24 these documents forming a working group that has some
25 outside expertise in the form of consultants up front

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1 I think is going to help you get these documents done
2 in a more timely fashion. I think the product would
3 be more appropriate and closer to being finished.

4 So this is really not meant to be a
5 criticism of any specific staff member. I honestly
6 don't think this document or such a document could be
7 crafted without a fair amount of very detailed input.
8 So this device is sufficiently different from manual
9 brachytherapy and sufficiently different from any
10 other type of remote after-loading device that you
11 simply can't take existing 35.600 as a template for
12 this because so much of it doesn't apply.

13 So what essentially Commission staff or
14 NRC staff is faced with is having to go through the
15 same thought process that, for example, the AAPM had
16 to in crafting its task group 56 and 59, which is what
17 the 35.600 is based on.

18 I think to have a better quality product
19 more quickly, it would be better on the front end to
20 try and involve some consultants who have a lot of
21 experience, if not with the specific system in
22 question, with similar systems. That is my other
23 suggestion for process.

24 CHAIRMAN CERQUEIRA: Ruth?

25 MEMBER McBURNEY: Following onto that but

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1 not particularly in comment on this particular
2 guidance document, I am also on the National Materials
3 Program pilot working group dealing with establishment
4 of priorities of regulatory needs. Certainly if NRC
5 is seeing some of these emerging technologies and the
6 need for licensing guidance, the agreement states are
7 as well.

8 In order for the National Materials
9 Program to work under what we call the alliance
10 concept where the states and the NRC are working
11 together to come up with regulatory products, such as
12 rules and guidance and so forth, together, part of our
13 recommendations have been that centers of expertise be
14 identified, that alternative resources be identified,
15 and, as Dr. Williamson suggested, bringing in some
16 expertise from some of the other professional
17 societies to help that have the knowledge of the inner
18 workings of some of these new emerging technologies
19 and the devices.

20 Also, that was the main point. At a
21 recent symposium that we had dealing with like the
22 fusion technologies, the CT PAT, we also had a session
23 dealing with emerging technologies. That was one of
24 the recommendations that came out of that symposium,
25 that there are professional societies that have people

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1 willing to help out.

2 And I realize there might be a little bit
3 of a conflict of interest, but at least give the input
4 onto a more knowledge base on how some of these
5 devices work and what are some of the radiation safety
6 situations that should be taken into account in
7 licensing those devices.

8 CHAIRMAN CERQUEIRA: We have a comment
9 from the back microphone. Can you please state your
10 name?

11 MS. FAIROBENT: Yes. Lynne Fairobent with
12 the American College of Radiology.

13 Listening to this discussion and just
14 suggestions on perhaps bringing in some outside
15 consultants when a subgroup of the entire Committee or
16 even the entire Committee is looking at a new product
17 or a new modality is not inconsistent with how ACRS
18 and ACNW do operate.

19 They quite often have a task force where
20 they look at a special issue, a subset of a global
21 issue they may be analyzing. They do quite often
22 bring in I will use the term "consultants" or
23 temporary federal employees to look and debate or
24 provide added input into that.

25 So I think that this would not be, one,

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1 precedent-setting; and, two, I do think that overall
2 it would give a better start product for NRC and the
3 agreement states but also for the community who is
4 trying to get on licenses and use these modalities as
5 soon as they are approved by FDA for clinical use.

6 CHAIRMAN CERQUEIRA: Those comments are
7 helpful. I guess from staff or from Dr. Miller, I
8 guess you have heard the Committee say that some of
9 these areas are really beyond the expertise of the
10 membership.

11 What is your policy on having outside
12 people? Can we solicit them from the professional
13 medical societies? If they are not special government
14 employees, the process of getting them on board can
15 take forever. Can you use them in other ways?

16 Potential conflicts of interest, we as
17 members of professional medical societies have certain
18 agendas, recommendations. How does that fit into the
19 overall NRC mission?

20 Tom or Charlie, a lot of stuff there, but
21 somebody weigh in.

22 MR. ESSIG: Yes. I believe you did have
23 a lot of stuff there in your question. Certainly, as
24 Lynne Fairbent mentioned, the other two advisory
25 committees have the capability of engaging

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1 consultants, for lack of a better term, as they are
2 needed. Of course, I think this Committee would have
3 that same prerogative subject to budget constraints.

4 The earlier question was, do we have a
5 budget for this kind of thing? I would say my best
6 answer would be the budget is fairly limited. So we
7 would have to choose whoever we needed to engage with
8 in the form of a consultant. We would have to be
9 fairly selective and use it judiciously.

10 But, I mean, we wouldn't, in any event, be
11 talking about a large number of people, perhaps one
12 and maybe two at the outside on any particular topic
13 for a limited amount of time, but we could certainly
14 consider that and review it in light of the budget
15 that we do have for the Committee.

16 CHAIRMAN CERQUEIRA: And do they have to
17 go through all the security checks and all the other
18 things if they have just a very limited role?

19 MR. ESSIG: I don't believe so, but we
20 could certainly look into that.

21 CHAIRMAN CERQUEIRA: Ideally if it is
22 required, it would just be too long a delay.

23 MR. ESSIG: I understand.

24 MEMBER McBURNEY: That's all I had to
25 comment on the --

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1 CHAIRMAN CERQUEIRA: So I guess this
2 Committee --

3 MEMBER McBURNEY: And now that we have
4 heard that we can now actually talk with staff as a
5 subcommittee --

6 CHAIRMAN CERQUEIRA: And have conference
7 calls.

8 MEMBER McBURNEY: -- and have conference
9 calls without having to have all of the Federal
10 Register notices and so forth, that in the future, we
11 can move on and --

12 CHAIRMAN CERQUEIRA: There is no future
13 for you, Ruth.

14 MEMBER McBURNEY: Right. I know there is
15 no future for me here.

16 CHAIRMAN CERQUEIRA: So who is going to
17 take over the committee, then?

18 MEMBER McBURNEY: I don't know.

19 CHAIRMAN CERQUEIRA: Who is currently on
20 your committee?

21 MEMBER McBURNEY: Dr. Vetter, Dr. Diamond,
22 and Dr. Williamson.

23 CHAIRMAN CERQUEIRA: Jeff is on every
24 committee.

25 MEMBER McBURNEY: That's right. Maybe Dr.

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1 Vetter would.

2 CHAIRMAN CERQUEIRA: Dr. Vetter, are you
3 volunteering? Again, you have done a great job within
4 all of the restrictions that have been imposed on you,
5 but in order to keep this moving, we probably should
6 have one of the committee members. Jeff?

7 MEMBER WILLIAMSON: I'll volunteer, yes.

8 CHAIRMAN CERQUEIRA: Great. And so you
9 have got a limited budget that you need to decide what
10 is appropriate in terms of additional people are
11 required and whatever travel.

12 DR. MILLER: Yes. I think what we have to
13 work our way through is bringing in consultants
14 requires a formal arrangement, how we go about doing
15 that. Even if you have the budget to do it, there are
16 contractual ways that we have to do that.

17 MEMBER McBURNEY: It wasn't so much as
18 actually bringing them in for the meeting but to
19 provide information that would help in putting a
20 guidance document together, any technical information
21 needed.

22 MEMBER WILLIAMSON: For example, in the
23 case of this device, there are at least three groups
24 that have had beta versions of this system and have
25 actually had some experience.

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1 At least one of the individuals involved
2 I know has had extensive experience with crafting QA
3 protocols and would have been a very good person to
4 have had the authorization to evolve in this process
5 reviewing this document or even earlier on kind of
6 helping to craft a minimal set of operating standards
7 that would I think be reasonable in clinical practice
8 and satisfy the needs of the staff to be assured that
9 the device would be used safely.

10 DR. MILLER: Help me a little bit with
11 that to be more explicit. The kinds of people you are
12 looking for, are they people that work for the vendors
13 or people who are actually users of the devices?

14 MEMBER WILLIAMSON: Well, this is a
15 difficult situation.

16 DR. MILLER: Yes.

17 MEMBER WILLIAMSON: I mean, at least two
18 of the individuals I know that have used this system
19 have some sort of a consultant relationship with the
20 vendor. And so I think they were, at least in some
21 cases, retained by the vendor to either evaluate the
22 system or help draft QA protocols that could be
23 documented and given to the user to help them figure
24 out how to integrate this into their practice.

25 Nonetheless, they would have a lot of

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1 hands-on experience with this system in thinking about
2 approaches to quality assurance for connecting errors
3 and would understand the weak and strong points of the
4 system, something that is unless you have hands-on
5 experience with the system, it is very difficult to
6 do.

7 MEMBER McBURNEY: Also, the regulatory
8 jurisdiction for the sealed source and device review
9 that's done would provide some valuable input as well.
10 I think in this case, it was Maryland that did the
11 sealed source and device review on this.

12 MEMBER WILLIAMSON: And we had access to
13 that.

14 CHAIRMAN CERQUEIRA: To the State of
15 Maryland?

16 MEMBER McBURNEY: Right.

17 CHAIRMAN CERQUEIRA: Okay.

18 MEMBER WILLIAMSON: Yes. We were given
19 that, too, of the document stream.

20 CHAIRMAN CERQUEIRA: So from what you are
21 telling me, this is a very limited distribution of
22 equipment. It is very cutting-edge. And so the NRC
23 doesn't have expertise, and there are no neutral
24 people out there who aren't consultants or part of the
25 --

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1 DR. MILLER: That's what I am trying to
2 wrestle with. The conflict of interest issues versus
3 some of the things that we move forward on, for
4 example, with the states are that we developed a
5 number of working groups and steering committees with
6 the states on a variety of issues, where the state
7 employees actually come in and work with NRC working
8 groups in trying to move the ball forward.

9 To the extent that these experts would be
10 that kind of an employee, we could develop an
11 arrangement. We wouldn't have to bring them on as a
12 consultant. What we would have to do is we probably
13 would --

14 MEMBER McBURNEY: Because you're probably
15 going to find that some of the states have had to
16 wrestle with this particular device as well in
17 licensing it.

18 DR. MILLER: Right, right.

19 MEMBER McBURNEY: Rather than having about
20 five or six states having to come up with licensing
21 guidance as well as the NRC coming up with a licensing
22 guidance separate from that, if they could work
23 together on some of these issues, it would be a lot
24 more resource-efficient.

25 CHAIRMAN CERQUEIRA: So is the next agenda

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1 item going to address one of these systems?

2 MEMBER WILLIAMSON: I think so, yes.

3 CHAIRMAN CERQUEIRA: So maybe we could
4 have that presented and then come back to the system
5 or the format or the mechanism by which we use these
6 outside people.

7 MEMBER WILLIAMSON: It might help if you
8 give some specific examples of the sorts of things.
9 You know, I found this draft document December 7th,
10 which is the only one until now I have had access to.

11 CHAIRMAN CERQUEIRA: Okay. So the 130, is
12 that the seedSelectron? No. That is the licensing
13 guidance, which is part of the other agenda item.

14 MEMBER McBURNEY: Right.

15 CHAIRMAN CERQUEIRA: Where are we on this
16 agenda? Donna-Beth, are you going to talk about
17 something that would make this more concrete?

18 MEMBER VETTER: We do have a sheet of
19 paper that was submitted from Nucletron.

20 CHAIRMAN CERQUEIRA: Right. And then
21 there is the permanent plant low dose for manual
22 brachytherapy sources and devices. This is what you
23 are talking about, Jeff, as being poor quality?

24 MEMBER WILLIAMSON: An earlier version of
25 this. I have not seen this until today.

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1 CHAIRMAN CERQUEIRA: So you think it has
2 been cleaned up sufficiently?

3 MEMBER WILLIAMSON: I don't know. I have
4 no idea.

5 CHAIRMAN CERQUEIRA: But you are unhappy
6 with the original.

7 MEMBER WILLIAMSON: Certainly I think it
8 would be useful going at least generically through
9 some of the issues raised by this December 7th
10 document.

11 MEMBER VETTER: Who can apprise us of what
12 this issue here with the Nucletron?

13 CHAIRMAN CERQUEIRA: The March 1st, 2004
14 dated letter, Raymond Horn?

15 MEMBER VETTER: Yes. It is addressed to
16 us. It looks like they are looking for a decision.
17 I don't know if we are supposed to.

18 CHAIRMAN CERQUEIRA: Again, I am a little
19 confused as to where we go because we have quite a bit
20 of time here. The Nucletron, is this something we
21 could discuss?

22 DR. HOWE: I was just going to bring you
23 up to date to where we are on the Nucletron
24 seedSelectron and licensing.

25 CHAIRMAN CERQUEIRA: Okay. So maybe we

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1 could have this. And then, Mr. Horn, we will bring
2 you up after we have had your presentation.

3 EMERGING TECHNOLOGY SUBCOMMITTEE DISCUSSION ON
4 SEEDSELECTRON LICENSING GUIDANCE

5 DR. HOWE: We had a TAR from St. Luke's in
6 September. We got it here in headquarters after that.
7 We developed the licensing guidance, which is
8 currently on the Web site. And one should consider
9 that to be a straw man.

10 It is a living document. And Jeff has
11 pointed out that he hasn't had a chance to review
12 that. It will look very similar to what you had in
13 December, but I did incorporate some of your comments
14 into it.

15 We recently completed the TAR. We put the
16 licensing guidance up on the Web site. So St. Luke's
17 should be hearing from the region on what it needs to
18 do to complete its application for use of the
19 seedSelectron. And the guidance is out on the Web
20 site for all new licensees to see what we are looking
21 for.

22 So I think we have addressed some of the
23 issues in Nucletron's memo or letter to you as to what
24 is the status of the St. Luke's application.

25 CHAIRMAN CERQUEIRA: So St. Luke's is the

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1 first application you have received?

2 DR. HOWE: Yes.

3 CHAIRMAN CERQUEIRA: So we really are sort
4 of not prototype, it has been approved, but not really
5 any clinical experience beyond initial testing?

6 DR. HOWE: We have broad scope licensees,
7 which are under a slightly different set of regulatory
8 framework. They can use emerging technologies because
9 their radiation safety committee under 10 CFR Part 33
10 are allowed to do a radiation safety evaluation. So
11 they can use these technologies with a limited
12 specific medical use licensee.

13 So St. Luke's is the first
14 medical-specific licensee. We had to develop a
15 guidance for them to use it.

16 CHAIRMAN CERQUEIRA: Right. How many of
17 these other broad license institutions have had
18 systems in place where they have had experience?

19 DR. HOWE: The manufacturer would have to
20 answer that question because we don't normally get
21 involved in licensing unless they are exceeding a
22 certain limit on the amount of activity they have.

23 CHAIRMAN CERQUEIRA: Okay. Well, when he
24 comes up, we will ask him then.

25 MEMBER NAG: Donna, can we use this system

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1 or have we under the broad license? You have the
2 experience to comment. We can call them. Are we
3 allowed to call them up and ask about the problem and
4 so forth, number one? For that, I don't think it
5 would require any budget. We are just calling them up
6 and asking for their advice.

7 And, number two, maybe we can ask them to
8 be a consultant and give us a brief update in one of
9 the future meetings. Would something like that be
10 allowed?

11 CHAIRMAN CERQUEIRA: Tom?

12 DR. MILLER: I think certainly if it is a
13 vendor, usually my experience has been if vendors are
14 invited to make presentations to the NRC, usually they
15 are more than willing to come in and do that.

16 That wouldn't be a cost to the NRC. They
17 usually do that as an opportunity. If the NRC better
18 understands what it is that they have got, then that
19 is to their benefit.

20 So certainly that is not a problem. In
21 other words, if someone is willing to come in and make
22 a presentation to the Committee on the layers and what
23 they have, we can certainly get that on the agenda
24 provided that the vendor is willing to come in and do
25 that.

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1 MEMBER NAG: But the users who are using
2 under the broad scope license.

3 DR. MILLER: Now, the question there is
4 the same. Are they willing to come in and do that?

5 MEMBER NAG: Who is going to pay them?

6 CHAIRMAN CERQUEIRA: Right. And if they
7 are sponsored by the vendor, would that be acceptable?
8 I am sure the vendors --

9 MEMBER NAG: But then you really want
10 someone neutral. Now, the moment someone sponsors
11 them, they are no longer neutral.

12 DR. MILLER: Right. That is something I
13 would have to look into.

14 MR. ESSIG: Just one point on that. We do
15 have a mechanism called invitational travel, where we
16 could on a limited number of instances invite folks
17 that the Committee felt would make a useful
18 presentation. It is when we start compensating them
19 for their time here.

20 Assuming their employee is willing to pick
21 up the time that they would spend away from the office
22 as part of their normal workday and all we had to do
23 was pick up invitational travel, that would be fairly
24 straightforward. It is when we enter into these
25 agreements to pick up to compensate them for their

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1 time and their travel that it gets a little more
2 complicated and we have to look at these consultant
3 arrangements and that sort of thing.

4 MEMBER NAG: I think most of the time you
5 should be able to invite them to travel. Most
6 scientific people are by the universities. If they
7 have broad scope licensees, it means they are usually
8 at big universities.

9 Part of the responsibility of the
10 university is for their doctors to advise the NRC and
11 other federal agencies. So not only are the
12 compensated for the time, but most universities will
13 let them off.

14 CHAIRMAN CERQUEIRA: Ralph?

15 MEMBER LIETO: I'm a little confused as to
16 what we are supposed to be addressing on this specific
17 agenda item. Are we supposed to be answering a
18 question from the vendor in response to this letter we
19 received this morning or are we supposed to be
20 addressing some specific licensing guidance that
21 addresses this device?

22 CHAIRMAN CERQUEIRA: Well, I think it is
23 the Emerging Technologies Subcommittee. And we have
24 identified some hurdles in the Committee, getting
25 things done that there are some devices emerging that

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1 we don't have expertise within the Committee. And is
2 there some way that we can get it?

3 We are trying to work out a mechanism for
4 doing that. I think as part of that, we are going to
5 get a presentation on this particular device.

6 The letter is brand new. Ruth?

7 MEMBER McBURNEY: The original agenda item
8 was going to be the report of the subcommittee.

9 CHAIRMAN CERQUEIRA: Right.

10 MEMBER McBURNEY: And Donna-Beth is just
11 here to give staff input on what has been done so far.
12 It is not a total presentation.

13 CHAIRMAN CERQUEIRA: Right.

14 MEMBER McBURNEY: Basically the
15 subcommittee has reviewed it. Several of the members
16 had specific comments. And just from initial looking
17 at the new document, -- this is the first time I have
18 seen it -- they have addressed some of the specific
19 comments that some of the subcommittee members had.

20 Dr. Williamson also had some concerns and
21 had some technical questions about the device itself
22 and the appropriateness of some of the licensing
23 requirements. In order to gain information on the
24 device, Dr. Williamson arranged for a demonstration
25 and a discussion with the manufacturer

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1 representatives.

2 I listened in by teleconference to some of
3 that demonstration, although I wasn't there to
4 actually see it. So he can give a summary of what
5 went on at that demonstration and any information that
6 would be useful to the guidance that was gained out of
7 that. And then we can talk about what next steps the
8 subcommittee needs to take.

9 CHAIRMAN CERQUEIRA: Okay. So, Jeff, are
10 you going to do that?

11 MEMBER WILLIAMSON: Yes. I guess I will
12 go over two things, two issues mainly. As Ruth
13 mentioned, we had I think a very productive meeting
14 with the vendor and got a lot more technical detail on
15 how the device operates.

16 I did receive some preprints of papers
17 that are under review by a journal documenting the
18 experience of one of the Nucletron contractors, who
19 did a field evaluation of the device. So there is a
20 lot more information now to sift through.

21 I think based on my interaction, actually
22 seeing the system and talking with the vendor, I do
23 have some detailed proposals for positional accuracy
24 testing that we could either go over as a subcommittee
25 or I could submit directly to Donna-Beth for possible

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1 inclusion.

2 So that was very good. I think it was
3 very difficult to arrange this, and there was a lot of
4 confusion about with whom we could talk and whether we
5 could talk with each other that hindered our
6 operation. I think now that the way is cleared for us
7 to have teleconference meetings as needed and to
8 basically at least talk with outsiders on behalf of
9 the subcommittee to solicit their views.

10 I think we can productively go over the
11 new draft, make detailed comments, I would hope, and
12 have something to Donna-Beth and other interested
13 staff within probably I hope six weeks.

14 I would like to, in addition, go over a
15 few of the general issues raised by the earlier draft.
16 I don't know whether Donna-Beth's current draft has
17 addressed them or not.

18 CHAIRMAN CERQUEIRA: Why don't you go over
19 those items?

20 MEMBER WILLIAMSON: Some of these are
21 somewhat detailed in nature, technical in nature, but
22 I will go through.

23 You know, if one thinks in broad terms
24 about how this device works, it is basically an
25 enhancement of manual brachytherapy. The primary

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1 method by which sources are delivered accurately is
2 the positioning of the needles via the template into
3 the patient. This new device used alone does not
4 change that at all but is the same manual technique
5 for inserting the needles, same kind of template, the
6 same kind of clinician skills.

7 So I think in broad terms, one needs to
8 really ask, what is different, what is added to the
9 procedure by using this new device, and what is the
10 same.

11 A lot of this is still really manual
12 brachytherapy. And I think the rules that currently
13 govern manual brachytherapy should be the ones that
14 are adopted.

15 There are concerns that the rules of
16 manual brachytherapy are inadequate for manual
17 brachytherapy. This is not the place to bring up
18 fixes to those rules. That needs to be done in
19 another discussion and a rulemaking initiative made.

20 So this was one of the problems, that a
21 whole bunch of restrictions were proposed in this
22 licensing guidance that would burden users of this
23 device to basically fix things I think that the staff
24 is concerned about in general with manual
25 brachytherapy.

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1 A good example is a proposal for modifying
2 the written directive. The staff has raised concerns
3 in the past that the written directive as currently
4 defined may not be adequate or permanent seed
5 implants. That may be. That needs to be a separate
6 discussion. There shouldn't be fixes put in this
7 specialized guidance for problems like that.

8 DR. HOWE: Jeff, I took that out because
9 I felt that was better in rulemaking space.

10 MEMBER WILLIAMSON: Right. Okay.

11 CHAIRMAN CERQUEIRA: So your criticism
12 worked.

13 MEMBER WILLIAMSON: Yes. So there were a
14 number of other things. Another cluster of issues had
15 to do with verifying the seed location. Okay? The
16 basic proposal in here was there were a lot of
17 restrictions on testing the ultrasound device to make
18 sure it could see seeds, individualized needle tips,
19 and so forth.

20 Well, taking the two cases separately,
21 since needles are placed manually in this system
22 anyway, why does using the seedSelectron mandate
23 special precautions to verify needle positions than
24 any other manual brachytherapy permanent implant using
25 needles? That part is really the same.

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1 Certainly if you are using the treatment
2 planning system to help guide those needles, special
3 testing might be needed. But this document was to
4 allow for both stand-alone use of the Selectron as
5 well as using it in conjunction with the vendors'
6 FIRST treatment planning system. So that is another
7 example, I think, of trying to impose special
8 requirements.

9 CHAIRMAN CERQUEIRA: So, Donna-Beth, why
10 was that imposed?

11 DR. HOWE: It ends up we put those under
12 the licensee's program for assuring that the written
13 directive is that the administration's in course with
14 the written directive. So this is the old quality
15 management part of the rule.

16 Those procedures are not required.
17 Certain requirements are in the regulations. What I
18 put in here was in the notes to the licensee. It was
19 essentially, we believe, a lot to consider the
20 following things.

21 We tried to make it clear they were not
22 requirements. Nor were they required to submit
23 anything to NRC, but we are just pointing out problems
24 that we have seen in the past with brachytherapy
25 source delivery for this type of use. So it is

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1 voluntary, and it probably needs to be over in the
2 manual brachytherapy consideration.

3 MEMBER WILLIAMSON: Yes, it does. This is
4 sort of what is so confusing is that there is a
5 concern with manual brachytherapy in general. Then
6 maybe an information notice should be sent out or a
7 special rulemaking or guidance initiative started that
8 is broader.

9 But to sort of put all of that stuff in
10 here I think is going to mislead and confuse consumers
11 of this device and I think create at least the
12 impression among Nucletron's customers that they are
13 buying a great big regulatory headache. They get this
14 system. So I truly think this should be very
15 specialized and focused.

16 CHAIRMAN CERQUEIRA: It's not required.
17 It is suggested, which means it has no teeth. Now,
18 Ralph, are you going to clarify this for us?

19 MEMBER LIETO: Well, actually, I am kind
20 of jumping on Jeff's bandwagon here. I think that if
21 you put it in as a quality management requirement, --
22 "requirement" is not the right word here -- every
23 licensee is going to look at that as being every time
24 they do one of these cases, they have got to follow
25 that. And every deviation from that has got to be

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1 documented and followed out.

2 I guess my question was going to go back
3 to Dr. Nag and Jeff. Is that part of the quality
4 management programs for manual brachytherapy seed
5 implants in general that you have all of these
6 requirements for the ultrasound equipment?

7 MEMBER NAG: Right. I mean, we do make
8 sure that the ultrasound is working properly, but we
9 don't have a series of UMP that doubles the
10 ultrasound. We do make sure that however many
11 millimeters off and so on, we catch those.

12 I think I will use this to make a comment.
13 When we had this presentation at the last meeting in
14 November, the licensing document was going to be
15 ordering the 600 rule within the R-1. And I had make
16 it quite clear that this system is a low-dose rate
17 system and that what the guidance should be is mostly
18 ordering the low-dose rate manual brachytherapy with
19 some added provision that this being remotely
20 controlled had the QA part for the remote
21 after-loader.

22 I think that has been done from the very
23 quick look that I have seen of this document. I have
24 not gone into detail. Basically, the low-dost rate
25 manual brachytherapy with the difference being instead

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1 of the person manually pushing the seed in, having a
2 robotic system manually pushing the seed in. So it is
3 not a huge difference.

4 CHAIRMAN CERQUEIRA: What do you say to
5 that, Mary-Beth? I mean, it sounds logical.

6 DR. HOWE: I think that is what I tried to
7 do in this document. I have essentially three parts
8 on where they have to provide additional information.
9 The first is that you will abide by the manual
10 brachytherapy considerations in the following parts
11 because they are a little more appropriate.

12 And then it is an after-loader. So I
13 identified very specific parts of after-loaders that
14 this device needs to follow.

15 And then I had a third category where it
16 really is in between the two. And then in some cases,
17 it was following the after-loader. The after-loader
18 was in such detail for all high-dose after-loaders
19 that you really couldn't say, "I want you to follow
20 A-1 but not C-3." So I just rewrote it to fit this
21 particular device.

22 So I think it fits the device while Jeff
23 is concerned on the voluntary program on how to assure
24 that you are doing what you are doing. We tried to
25 write that so that people understand it is voluntary,

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1 we think you ought to consider these, you do not have
2 to have these procedures, you do not have to submit
3 them to the NRC.

4 MEMBER NAG: I think that portion applies
5 to manual brachytherapy. And that should not be put
6 under this. This is a special requirement for the
7 after-loaded.

8 I mean, there are some problems with
9 permanent seed implant, manual permanent seed implant.
10 You cannot fix those by just writing it in a part of
11 this document. You are confusing the issue.

12 CHAIRMAN CERQUEIRA: So you don't see the
13 automated system being any different than manual
14 brachytherapy. And so you understand what she is
15 saying, but you don't feel that this is the right
16 place for it to be. Is that correct?

17 MEMBER NAG: Right. I do agree with many
18 of the things put in there, but this is not the place
19 to put it in.

20 CHAIRMAN CERQUEIRA: Is this the practice
21 of medicine, rather than radiation safety, though?

22 MEMBER NAG: No. This is how do you
23 prescribe permanent seed implant? Okay? If you take
24 a certain dose, that dose varies by more than 20
25 percent. We all know it.

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1 Now, that will be true for this. It will
2 also be true for the manual brachytherapy. That is an
3 entirely different thing we have to fix but not here.

4 CHAIRMAN CERQUEIRA: So, Donna-Beth, are
5 you willing to take it out?

6 DR. HOWE: I do believe for the first
7 system, since that is directly computer-related from
8 the visual output on the ultrasound into the
9 seedSelectron other part of it, that we think you
10 ought to consider the part on the ultrasound is quite
11 appropriate because there is a direct link in.

12 But we aren't saying what it is you have
13 to have. We are just saying we think you need to
14 think about these things.

15 CHAIRMAN CERQUEIRA: Now, Jeff, what is
16 wrong with asking people to think about things and not
17 have to do it?

18 MEMBER WILLIAMSON: Well, let me defer
19 your question until I can finish my comments on this
20 part.

21 CHAIRMAN CERQUEIRA: Okay. I took a lot
22 of time. I apologize. I am a little confused.

23 MEMBER WILLIAMSON: The SPOT system is a
24 specialized treatment planning system the vendor sells
25 that is much more highly integrated than the range of

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1 other systems, both imaging and treatment planning,
2 that users could use with the seedSelectron in the
3 stand-alone mode.

4 So I think with the fully integrated FIRST
5 system, the SPOT plus seedSelectron, I think many of
6 the suggestions are very good ones. If you use a
7 conventional ultrasound imaging system and a different
8 vendor's treatment planning platform, then, really,
9 this requirement can be met. Okay?

10 There are really standard systems. You
11 can see needle tips and use that in a qualitative way
12 to make sure needles are where they are supposed to
13 be. There is no quantitative way you can measure
14 needle locations.

15 The requirement about visualizing seeds is
16 I think impossible to meet for any currently marketed
17 ultrasound system. Quantitative localization of seeds
18 is an active area of research. And a robust solution
19 has not been advanced to the market to date. So I
20 think it is quite inappropriate to put that in.

21 It may be that fluoroimaging can help you
22 get a quantitative/qualitative feel if you have got
23 the seeds in the correct location, but ultrasound
24 isn't there yet. It is a very difficult research
25 problem.

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1 What I am now to address, your question,
2 why is it bad to put things in here? Like Dr. Nag
3 said, I think it's the wrong vendor. Really, the
4 concern is with all of manual brachytherapy or at
5 least permanent seed, image-guided permanent seed,
6 implants.

7 And so to put this all in here I think
8 certainly gives the impression that because you are
9 buying the seedSelectron, even though it says it is
10 voluntary, I think the community will perceive that
11 they are going to get big regulatory headaches and it
12 might be better to stay with manual brachytherapy and
13 not have to raise the question about following these
14 things.

15 So my advice would be keep it very limited
16 to what this new system does. What is essential for
17 this new system in a stand-alone mode is to make sure
18 that there is a reasonable protocol quarterly and
19 daily QA to make sure that it gets the seeds in the
20 right place in the needle, that when you have the
21 machine automatically retract the needle, you have
22 reasonable expectation that it is accurate. That is
23 what is appropriate I think for you to focus on in
24 this regulatory guidance.

25 If there are broader concerns about how

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1 permanent seed implants are done, I think then a
2 broader communication, an information notice or
3 something, where the domain is less specific and
4 doesn't single out some particular vendor's product,
5 I actually think this is a very nice product and you
6 could inadvertently discourage people from using a
7 system which in the end might actually eliminate some
8 errors and improve radiation safety.

9 A last comment I will make is in high-dose
10 rate brachytherapy, what is contained in AAPM guidance
11 and echoed in 35.600 is a series of up-front tests you
12 do on an annual, quarterly, and daily basis, which
13 give the operator reasonable assurance that the source
14 goals retell it to go.

15 There is no provision in anybody's
16 guidance that says you have to have a dynamic method
17 of verifying that each individual dwell position is
18 actually where it is. You have a reasonable set of
19 quality assurance tests that give you confidence that
20 the source is behaving as you have programmed it.

21 Then you go ahead and treat the patient.
22 And you are making I guess an inductive generalization
23 that if it worked in your QA test setting, it is going
24 to work in the patient. I don't think there is any
25 reason to depart from that paradigm in writing

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1 guidance for this.

2 CHAIRMAN CERQUEIRA: So, Dr. Howe, you
3 have been nodding yes throughout all of this. Does
4 this mean you accept it and you think these are
5 appropriate changes?

6 DR. HOWE: Yes, I think we can work
7 together and make changes to it. I think Jeff
8 commented in the earlier comments that you couldn't
9 see the seeds. So I took out a lot of that and just
10 said, "Visualize the needle in the initial seed
11 position" to make it simpler, but I can go beyond
12 that. So I think I can work with Jeff.

13 CHAIRMAN CERQUEIRA: Again, Jeff has not
14 had a chance to really look at this.

15 MEMBER WILLIAMSON: Yes. I haven't.

16 CHAIRMAN CERQUEIRA: So, again, it would
17 be good if we could get it ahead of time. I realize
18 that these meetings occur very frequently.

19 So where is the disagreement, then? What
20 am I missing here?

21 DR. HOWE: I think our concern is this is
22 a straw man. And I expect comments, and I expect
23 comments back. It is a living document. So we will
24 work on --

25 CHAIRMAN CERQUEIRA: So this is part of

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1 the procedure?

2 DR. HOWE: This is part of the process.

3 CHAIRMAN CERQUEIRA: Dr. Nag, Ralph, and
4 then --

5 MEMBER NAG: Yes. The other thing I
6 suggest is that we have to decouple the seed from the
7 after-loader because everything is put here with this
8 seed with that after-loader. I can very easily
9 visualize that any seed would be used because --

10 MEMBER WILLIAMSON: No. Both the FDA and
11 I think the SSTR guidance are very clear that this
12 system can only be used with that particular seed in
13 pre-loaded cassettes.

14 DR. HOWE: And this seed has only been
15 approved with this device. So it goes both ways.

16 MEMBER NAG: Right. But I am saying when
17 you are making guidance, you should make a guidance
18 for an overall system component, like that with the
19 model. Unless the manufacturer makes similar seed,
20 like the Isotron seed, they make palladium seed using
21 very similar remote after-loading, you don't want to
22 have to make a whole set of rules just because that
23 seed is a different company's seed, though everything
24 else is the same.

25 So I think that whenever you are making

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1 rules like that, make it for the low-dose rate
2 permanent after-loading system, rather than just for
3 that one company's needs. It will save you a lot of
4 headache later on because otherwise the specific
5 radiation safety question would then remain the same.
6 It doesn't matter whether the seed is made by company
7 A, B, or C.

8 CHAIRMAN CERQUEIRA: So saving headaches
9 for the user as well as the NRC would be worthwhile.

10 Ralph, you had a comment?

11 MEMBER LIETO: I guess I wanted to ask a
12 question. If we agreed that this should be placed
13 under the manual brachytherapy rules, what problems,
14 if any, would arise from a radiation standpoint; in
15 other words, if we need to take this out of this 1,000
16 category, where it is being dealt with right now,
17 because it sounds like everything really just applies
18 to manual brachytherapy here.

19 DR. HOWE: No.

20 MEMBER WILLIAMSON: No. I don't think
21 even I agree.

22 DR. HOWE: The remote after-loader
23 component is a very important part of how this device
24 works. You need to address it, but it is nowhere near
25 the restrictions that HDR would have for a

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1 conventional low-dose remote after-loader has. So it
2 doesn't fit in the 600 because you have to grant many,
3 many exemptions to 600.

4 CHAIRMAN CERQUEIRA: So I think everybody
5 wants to keep it in a 1,000 category.

6 MEMBER WILLIAMSON: Maybe it eventually
7 could be incorporated into 35.600, but it would have
8 to be a new section.

9 DR. HOWE: Rulemaking.

10 CHAIRMAN CERQUEIRA: Rulemaking. So you
11 have got the straw man, and you are going to get
12 input. You are getting it from us, and then you will
13 get it from the community. And it will be a process
14 like everything else.

15 DR. HOWE: Yes.

16 CHAIRMAN CERQUEIRA: Yes?

17 MEMBER WILLIAMSON: Well, I would like to
18 understand what our charge is for the next few weeks.
19 Do you want us to undertake the detailed review of the
20 existing version of the document and get back to you
21 with our views?

22 DR. HOWE: I would like that.

23 MEMBER WILLIAMSON: And if that is the
24 desire of the staff, I will make sure we have a
25 meeting and do that.

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1 CHAIRMAN CERQUEIRA: Of your subcommittee
2 of three people now?

3 MEMBER WILLIAMSON: Yes.

4 CHAIRMAN CERQUEIRA: I guess we can keep
5 Ruth on.

6 MEMBER McBURNEY: Yes.

7 CHAIRMAN CERQUEIRA: Right.

8 MEMBER WILLIAMSON: So who are the members
9 now?

10 MEMBER NAG: I would remember assuming I
11 was.

12 CHAIRMAN CERQUEIRA: Does somebody have a
13 list of that subcommittee? Angela?

14 MS. WILLIAMSON: I can find out.

15 CHAIRMAN CERQUEIRA: Maybe what we could
16 do is ask Dr. Malmud to do this. If we could sort of
17 define a charge of these committees? Sometimes we
18 have a general idea, but if we could just have a
19 written charge, it probably would be worthwhile.

20 All right. So I am still a little lost
21 now. We have a letter that is dated March 1st, which
22 was distributed, which none of the Committee members
23 have read.

24 And we have the industry representatives
25 here. Do we need their input in any way or have we --

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1 MEMBER WILLIAMSON: I think we should ask
2 them, in light of these recent deliberations, what
3 concerns they have.

4 CHAIRMAN CERQUEIRA: That sounds
5 appropriate. Raymond Horn, if you could come forward
6 and introduce yourself, your position?

7 MR. HORN: Thank you.

8 I am Raymond Horn from Nucletron
9 Corporation. I am the Director of Clinical Affairs.
10 We are, of course, the manufacturer of the
11 seedSelectron.

12 So with me today is Jack Coats, who is the
13 President of Nucletron Corporation; Lisa Dimmick, the
14 Director of Regulatory Affairs for Nucletron
15 Corporation.

16 I invited and did not pay for Jim Goetz,
17 who is the Director at St. Luke's Cancer Center, who
18 has the pending application, to join us. And also are
19 invited as well Howard Griffith, Ph.D., who is Chief
20 of Radiation Oncology Physics at the George Washington
21 University here in the District and, it should be
22 noted, is operating under a temporary license for the
23 use of this equipment. So there is some precedent in
24 granting a temporary license.

25 In answer to your earlier question, there

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1 are three broad scope licensees that have approval to
2 use the device. There are four agreement state
3 licensees that now have approval to use the device.
4 And there is one large Canadian customer at Tom Baker
5 and another one that is pending, Health Canada,
6 approval as well for this.

7 So there are a number of users that are
8 using this device. This situation with St. Luke's is
9 that they are not a broad scope license and are in an
10 NRC state.

11 CHAIRMAN CERQUEIRA: Can you give me how
12 many patients have been treated at those eight centers
13 that you mentioned in the U.S. and Canada
14 approximately?

15 MR. HORN: About 80.

16 CHAIRMAN CERQUEIRA: Eight?

17 MR. HORN: About 80 so far.

18 CHAIRMAN CERQUEIRA: And how many total
19 done ever with the system? Eighty?

20 MR. HORN: A few hundred, I think,
21 worldwide. It is still --

22 CHAIRMAN CERQUEIRA: So we are really
23 talking about a limited clinical experience?

24 MR. HORN: That's correct. I also would
25 point out there still seems to be some

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1 misunderstanding that this system, as we claim it,
2 offers better tools.

3 But there really is no true feedback
4 integration with the ultrasound. It provides visual
5 QA, and it provides data input for treatment planning.
6 There is no, as Jeff Williamson put it, dynamic
7 feedback that takes place with the ultrasound system.

8 I do want to read a few portions from the
9 letter that I submitted and then make some comment.
10 Certainly Nucletron Corporation, would like to thank
11 the staff of NRC for scheduling the time during this
12 meeting to address the licensing guidance of the
13 seedSelectron.

14 I would say that I certainly am
15 enheartened to hear the discussion about the guidance
16 and how it will shape up. I would say, though, that
17 we feel strongly that the specific guidance for
18 seedSelectron that is pending be considered. I would
19 say even more so after the discussion that we just
20 heard.

21 There is an amendment that was submitted.
22 I know from speaking with Mr. Goetz this morning that
23 they have revised amendment based on the information
24 that they have. It is unclear whether it is the most
25 recently posted guidance that Dr. Howe mentioned.

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1 I think you are well-aware that in the
2 last meeting in November, there was a discussion that
3 there was a pending license amendment. This has been
4 on hold. Dr. Goetz will speak a little bit about the
5 impact to St. Luke's of weighting the process, this
6 amendment. It has really been quite some time.

7 So, really, I think what we are asking is
8 until the guidance is finalized, that you would accept
9 the submittal of this guidance and begin to process it
10 to the best guidance that exists so that it does not
11 wait for finalizations to take quite some time. And
12 I think that they are prepared to modify their
13 amendment in the future should the guidance be
14 different from what the current situation is.

15 I also will point out that the article
16 that has been discussed and submitted to *Medical*
17 *Physics* is under review, but it does try to ascertain
18 that the seedSelectron meets the manufacturer's
19 specifications.

20 It does try to ascertain all of the
21 various AAPM task group recommendations on
22 brachytherapy, how the system can be used to meet
23 those recommendations, and it also includes some QA,
24 both daily and quarterly checks as used at the Tom
25 Baker Cancer Center, where they have done the most

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1 patients in North America and have spent quite some
2 time in evaluating the system.

3 I think the point is also to just follow
4 up on statements made. It would seem to be in the
5 best interest of the community to be able to reference
6 professional society recommendations for QA and
7 safety, rather than to create some kind of new
8 requirements that parallel it.

9 So I guess, once again, we would
10 recommend. And so we would ask the panel the answer
11 to the question, "What are we asking for?" We would
12 ask that the panel recommend to the NRC to process the
13 amendment from St. Luke's and not wait until the
14 guidance is finalized.

15 Again, for the purpose, we are hardened by
16 the discussion that the NRC would limit the scope of
17 the guidance to requirements that are basically found
18 in either the high-dose or low-dose requirements and
19 some combination that is deemed appropriate and to
20 follow recommendations by AAPM and other professional
21 societies.

22 So I hope that that sort of answered the
23 question about what does the manufacturer feel about
24 it. I would ask that you entertain the comment from
25 St. Luke's since they are here as well, perhaps from

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1 George Washington University if it is necessary.

2 CHAIRMAN CERQUEIRA: Jeff?

3 MEMBER WILLIAMSON: Just a comment. I
4 think AAPM guidance is somewhat in the same boat as
5 35.600. It really wasn't written with this particular
6 system and application in mind. It does require a
7 certain amount of thought and consideration, how to
8 best adapt it to cover this device. It is far more
9 restrictive, I think, that it need be for the
10 particular system.

11 MR. HORN: Well, I appreciate it. We had
12 a very good discussion with myself and someone else
13 from Nucletron, a technical expert. I think it is
14 possible to suggest how the system could meet the
15 various task group recommendations. It has a fair
16 number of built-in safety and QA features that I think
17 help it meet these recommendations.

18 CHAIRMAN CERQUEIRA: Other questions? Dr.
19 Goetz?

20 DR. GOETZ: Good afternoon. My name is
21 James Goetz. I am the Director of the Cancer Center
22 in St. Luke's Hospital. Thank you for letting me
23 speak today.

24 First of all, I believe you posted the
25 guidelines on Friday. We did download them. I do

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1 have an amended application for the 35.1000 that I
2 certainly would like to give someone here today. I
3 certainly would like to hand in my amended application
4 if I could.

5 In addition to that, I have letters from
6 the Medical Director, from the Chief of Radiation
7 Oncology stating that there is a demonstrable
8 community need for the prostate seed program.

9 We started this venture well over a year
10 ago. We submitted amendments to our license in June
11 or July of last year and are still awaiting an
12 outcome.

13 Finally, I would like to just read a very
14 brief letter from our urologist. His name is Dr.
15 Mayer, and he came from the University of Pittsburgh,
16 where they have a very large prostate brachytherapy
17 program. He understands the needs, and he states, "I
18 am writing on behalf of all clinically active
19 urologists within the St. Luke's Hospital system. We
20 are seeking your assistance in approving the NRC
21 application for Nucletron, the brachytherapy system at
22 our institution.

23 "We take pride in the fact that the
24 treatment options for prostate cancer offered at our
25 institution rival that of major metropolitan areas and

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1 including modalities such as intensity-modulated
2 radiotherapy and laparoscopic Da Vinci
3 robotic-assisted prostatectomies.

4 "As you are aware, one of the mainstays
5 for prostate cancer treatment in brachytherapy which
6 I have been working aggressively with within the
7 Radiation Oncology Department is to develop a program
8 that will also offer the latest in the technological
9 advances.

10 "Within the last six months, our group has
11 had to refer upwards of 15 individuals to outside
12 locations, sometimes one and a half to two hours away
13 for definitive brachytherapy. This is an
14 inconvenience and potentially affects the quality of
15 our patient care.

16 "We are specifically seeking approval of
17 the Nucletron FIRST system because this represents the
18 next generation in brachytherapy administration. Its
19 unique abilities allow for a lot of time, 3-D
20 dimensional planning, and interoperative adaptations
21 from any changes that may have occurred with no
22 further radiation exposure to the operative staff. We
23 feel also that the longer-term outcomes in terms of
24 prostate cancer controlled with this technique may be
25 superior to those previously in existence."

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1 So, with that, I would like to hand the
2 three letters in also and ask you to please consider
3 our application again. Thank you for your time.

4 CHAIRMAN CERQUEIRA: Thank you very much.
5 Unfortunately, this Committee does not make those
6 kinds of decisions, but I am sure that the NRC staff
7 will be happy to take the material.

8 Dr. Nag?

9 MEMBER NAG: No. I think our role as the
10 ACMUI is to advise the NRC, help the NRC to do what
11 they want. But from my viewpoint as a clinician, I
12 would like to make sure that all of the guidelines for
13 manual low-dose rate brachytherapy seed are followed
14 with the additional proviso that the after-loader
15 array is such that the tip of the after-loader will
16 reach the needle tip.

17 So I think once we have accomplished that,
18 while we are waiting for a permanent guidance document
19 to be made, can we have a temporary licensing done and
20 that can be modified as needed?

21 I think in terms of medical necessity,
22 there are many patients with prostate cancer that need
23 implants. They can be implanted by any system, even
24 the Nucletron system, without the after-loader
25 component. In terms of trying to get temporary

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1 licensing, we want both of these, the safety of the
2 immunity would be maintained.

3 CHAIRMAN CERQUEIRA: Jeff, is that your
4 recommendation? I think it is reasonable that the
5 application of the licensee should be looked at and
6 the major focus should be, do they comply with those
7 restrictions that need to be added to 35.400 relative
8 to reasonably assuring themselves that the remote
9 after-loader is capable of the spatial positioning
10 that they assume?

11 MEMBER NAG: Yes, that's all we need.

12 MEMBER WILLIAMSON: I think it is as Subir
13 mentioned. It is essentially making sure under
14 certain conditions that the layer goes to the tip of
15 the needle when it is supposed to, and it sorts out
16 the program pattern of seeds and spacers that you ask
17 it to.

18 There are I think a number of tests that
19 would be reasonable to expect the licensee to do that
20 go beyond 35.400 to assure that that is the case.
21 Beyond that, I don't think there is much else that is
22 critical in the application.

23 CHAIRMAN CERQUEIRA: Now, Dick, would the
24 Mayo Clinic buy one of these? Would they have like 80
25 patients in the U.S.? And do have you any concerns

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1 about radiation safety issues with using this device?

2 MEMBER VETTER: I don't know whether
3 radiation oncology there is examining. We do not have
4 one of these. Now, I don't know if they are looking
5 at it or not. They do a large number of patients. It
6 is very possible they would in the future. I haven't
7 read anything here that is of a radiation safety
8 concern to me.

9 CHAIRMAN CERQUEIRA: Go ahead.

10 MEMBER NAG: The reason for going into the
11 remote after-loader was to reduce the radiation
12 exposure. Now, that is one of the major reasons.

13 MEMBER WILLIAMSON: One of them.

14 MEMBER NAG: One of the major reasons.
15 Now, we know that or think that iridium and
16 high-energy isotopes because that is a lot of
17 radiation exposure. With iodine, irradiation exposure
18 is low and that high necessity of reducing the
19 radiation exposure is not there.

20 CHAIRMAN CERQUEIRA: Dick?

21 MEMBER VETTER: The radiation exposure is
22 from the fluoroscopy.

23 CHAIRMAN CERQUEIRA: Ralph, would this be
24 a problem at St. John's?

25 MEMBER LIETO: I would say no. It is more

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1 an issue of practice here than --

2 CHAIRMAN CERQUEIRA: Than radiation
3 safety, yes.

4 MEMBER LIETO: Than radiation safety.

5 CHAIRMAN CERQUEIRA: Ruth, do the states
6 have any problems with putting these in?

7 MEMBER McBURNEY: I think that just having
8 some clear-cut guidance would be a little more issue
9 with the states on where it fits in with the rules.
10 And with this being a dynamic document, I think that
11 if one come in out of state, we would look at how it
12 fit in with the regulations and then do guidance on
13 where the differences were.

14 I think that NRC could go ahead and use
15 the guidance that they have developed to process this
16 application and as it is further developed and refined
17 to process any other applications.

18 CHAIRMAN CERQUEIRA: Okay. Ralph, last
19 comment? And then we are going to move on.

20 MEMBER LIETO: I was just going to make
21 sort of maybe, I guess, a summary statement here to be
22 sure I understand things that basically what we are
23 suggesting is that the applicants would have to meet
24 the low-dose rate requirements in addition to certain
25 QA, quality control, steps for positioning of the

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1 sources because I think whatever we decide on
2 obviously is going to be the precedent for any other
3 licensee that is going to be applying to use this
4 also.

5 So I don't think we are just doing it for
6 one. I think there is an urgent, a clinical urgency,
7 being expressed by one specific licensee, but I think
8 we need to understand that what we are doing is also
9 making I think recommendations to the staff that would
10 apply to any of the sites or states.

11 CHAIRMAN CERQUEIRA: Right. And Jeff's
12 committee will continue to work on this to come up
13 with a protocol.

14 MEMBER WILLIAMSON: Is this at the moment
15 Jeff's committee or still Ruth's comment until October
16 1st?

17 CHAIRMAN CERQUEIRA: Well, it's Ruth's
18 committee. This is her last meeting.

19 MEMBER WILLIAMSON: But we could share it
20 through October.

21 MEMBER McBURNEY: Or until the
22 subcommittee's work is done.

23 DR. HOWE: Dr. Cerqueira, I think there is
24 a little bit of confusion. We do have the guidance
25 document up on the Web site.

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1 CHAIRMAN CERQUEIRA: Friday, I guess, it
2 went up.

3 DR. HOWE: So any NRC licensees can use
4 that guidance and submit an application.

5 CHAIRMAN CERQUEIRA: And they have then
6 modified it.

7 DR. HOWE: And they have done that. So it
8 applies to everybody. We do have a provision in there
9 that if we change our guidance and they apply for this
10 authorization, they can make changes to their
11 radiation safety program for this device without
12 coming in to the NRC for an amendment.

13 So I think we have the flexibility when it
14 is issued that if we amend it, we change the
15 requirements so that they are different. Then they
16 can go ahead without having to come in with an
17 amendment.

18 So I think that we are set for licensing
19 any seedSelectron coming in.

20 MEMBER WILLIAMSON: Suppose, based on our
21 deliberations, you decide that in some key respect,
22 that the licensing guidance has to be more restrictive
23 than the one currently on the Web site. Then are our
24 licensees obligated to modify their procedures to
25 follow the more restrictive condition?

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1 DR. HOWE: Generally our process is that
2 you are required to meet what was current at the time.
3 If we get more restrictive and we think that really is
4 important for everybody, we would probably have to use
5 a different mechanism.

6 CHAIRMAN CERQUEIRA: Good. Well, I would
7 like to thank Dr. Goetz and Mr. Horn for bringing us
8 this information. I think the Committee will continue
9 their work and under the new liberalized guidelines
10 for conference calls.

11 I guess the next item before the break is
12 "Removing Modalities Out of Part 35.1000," Dr.
13 Mary-Beth Howe. Dr. Howe?

14 DR. HOWE: Let me see if I can find my
15 slides.

16 REMOVING MODALITIES OUT OF PART 35.1000

17 DR. HOWE: The big question many people
18 have is we have got some devices now over in 35.1000
19 and what has to happen in order for us to move things
20 out of 35.1000. So this talk is going to be global in
21 nature. Basically it is talking about when is it
22 right, when is the time right.

23 The time can't be measured in days,
24 months, or years. You have to measure it in something
25 different. What we are pointing out here is that in

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1 order to move modalities out of 35.1000, you must do
2 rulemaking. There are no other options.

3 There are two methods of getting to
4 rulemaking. One would be the staff initiates
5 rulemaking. And the second would be that stakeholders
6 initiate rulemaking through a 2.802 rulemaking
7 petition.

8 So right now we are wrestling with, "When
9 is it right?" And part of when it is right is the
10 question of when is rulemaking cost-effective. Do we
11 have enough licensees seeking to use the technology
12 that that justifies going into the rulemaking expense?

13 We could have a very elegant emerging
14 technology that only a handful of licensees in the
15 country will need. And once we have licensed those,
16 then the licensing guidance may be sufficient for
17 them. And we would not need to go through the
18 additional expense for doing rulemaking with such a
19 small group of licensees. They would have the ability
20 to use the device.

21 We have other devices which can be used
22 pretty widely. And if they are used widely, then
23 there is a significant need to move those out of
24 35.1000.

25 The other thing is that rulemaking changes

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1 need to be clear and fairly well-established. I can
2 realize the Web site guidance very easily. I can get
3 a consensus from the ACMUI, from the stakeholders,
4 from licensees. They can come up. And we can look
5 into how to modify the guidance. We can take it
6 through our management chain of command, our Office of
7 the General Counsel, and make that revision on the Web
8 site. But if it is in rulemaking space and we need to
9 make a change, we have got to go through rulemaking.
10 So it is a lot more difficult to correct these things,
11 especially on technologies that don't have wide use
12 yet.

13 It also makes a difference on the degree
14 of revision. Some of these technologies almost
15 exactly fit into one of our subsections in part 35.
16 And it would take maybe a little bit of tweaking of
17 the rule to make that technology fit. That would be
18 a good candidate for going into rulemaking.

19 Others, like the seedSelectron, may
20 actually require another set in and of themselves
21 because they are significantly different from both
22 things that they are doing, that you would have to
23 come up with its own set of criteria.

24 So to expand upon the idea that rulemaking
25 changes are clear and established, one is the

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1 technology is not really new anymore. There is enough
2 experience out there. Both stakeholders and the NRC
3 have experience with the technology so that we all
4 understand how to regulate because we are only
5 involved in the regulation of it.

6 The community is involved in its medical
7 use and the practice of medicine issues, which we are
8 not involved with. We are just involved in the
9 regulation.

10 And the guidance is stabilized. It is at
11 the point where we think we know how to regulate it.
12 We aren't going to be making many changes to it. So
13 it makes sense to now codify them in the regulations.

14 So what kind of experience are we looking
15 for? We are looking for licensing experience. We
16 have issued enough of these that we know how to
17 license them. We have inspection experience. We have
18 gone out and inspected facilities that have these new
19 devices and technologies so that we understand how
20 they are being used. We understand the problems that
21 they are dealing with.

22 We have medical use experience. So we
23 have enough physicians out there. And we also have
24 medical event experience because the medical event
25 experience really points out some of the areas that

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1 everybody in their best thinking when they developed
2 the product had no concept this could be a problem
3 area.

4 Sometimes we have one problem area or a
5 one-time event. Sometimes it points out maybe a
6 weakness in the device or a weakness in how the user
7 should use it. So we need experience in all of these
8 categories so that we have confidence that we are
9 ready to go into rulemaking space.

10 In inspection experience, one of the
11 things that we did recently was we developed a new
12 program code. Our program code is tied into
13 inspection frequency. Our program code is for
14 therapy-emerging technologies. And only those devices
15 that we think need to go into that program code will
16 go into the program code. So not all emerging
17 technologies will fit that category.

18 If we think we have got an emerging
19 technology that is in the program code and we have
20 found through our inspection experience that we really
21 don't need to inspect it as frequently, we will pull
22 it out of the program code. Right now we have got the
23 gliocyte. We have got the Yttrium-90 microspheres.
24 We have the IVB devices in that program code.

25 What does it mean when you are in the

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1 program code? It means that it is inspected every 2
2 years and that there is initial inspection within 12
3 months of the license being issued for that device.
4 So we get more feedback early on within the
5 technologies.

6 And, as I said, it is a dynamic program
7 code where if we find that we are not having any
8 problems at all with a certain technology, we may pull
9 it out of that program code and then let the facility
10 be inspected according to its normal facility
11 inspection. So it is a dynamic process.

12 This is kind of a reiteration of what I
13 said earlier, but the guidance is stabilized because
14 it is so much easier for us to modify the Web site
15 guidance. Examples of that are we have two Yttrium-90
16 microsphere devices.

17 One of the device manufacturers uses
18 actually stasis. Actually, it ends up being the most
19 important endpoint for when you deliver all of the
20 microspheres that you are going to deliver. They use
21 fluoroscopy, and they use dyes to monitor whether
22 there is any backflow from the liver.

23 As soon as they start to see the dye not
24 going through the liver, they consider that all of the
25 active sites where the beads could into are filled and

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1 that's at the point at which you should stop the
2 procedure.

3 So we have modified the Yttrium-90
4 microsphere up on the Web site so that you can use
5 stasis in your written directive as an endpoint
6 because there is no desire for anybody to have more
7 microspheres poured in just because a certain dose was
8 supposed to be delivered when stasis essentially says
9 the microspheres are no longer going into the right
10 location. So we were able to make that modification
11 fairly quickly.

12 Rulemaking changes are much slower. Many
13 of you have been involved with rulemaking. It can go
14 on for two to three years, sometimes four to five
15 years depending on how major it is.

16 So we are trying to get as many of these
17 important concepts and ideas into the Web site
18 guidance as we can so that we are really pretty stable
19 before we go forward with the rulemaking. And, as I
20 mentioned earlier, some of these things are going to
21 be minor revisions, some of them being larger
22 revisions. It will take longer.

23 What do we have now for emerging
24 technologies? We have go liquid brachytherapy
25 sources. The liquid brachytherapy source that we have

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1 right now is the gliocyte. That might involve minor
2 changes to manual brachytherapy to be able to
3 incorporate liquid brachytherapy.

4 We have microsphere brachytherapy sources.
5 That one almost fits into manual brachytherapy without
6 a lot of changes. That might be a good candidate.

7 We have beta high-dose remote
8 after-loaders. We actually have two different kinds
9 of beta high-dose remote after-loaders. One is the
10 conventional high-dose remote after-loader, where you
11 have got the beta source on a wire with direct
12 connection to the machine in the distance.

13 The other is a hydraulic one, where you
14 have less of a connection. That is a possibility for
15 looking at rulemaking. And then we have the new one,
16 the permanent implant low-dose remote after-loaders,
17 which may be a more complicated rulemaking just
18 because it fits in between two device categories,
19 where the others may fit closer to one.

20 MEMBER NAG: Donna? In many places, you
21 have low-dose rate after. That is not a low dose.
22 That dose is very high. It is very confusing.

23 DR. HOWE: Point well-taken.

24 CHAIRMAN CERQUEIRA: Dick?

25 MEMBER VETTER: That's a very nice

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1 summary. With all of those advantages of having
2 things in part 1000, why would we want to take
3 anything out of part 1000?

4 DR. HOWE: The question we continually get
5 from stakeholders is, when are you going to move
6 things out of 1000?

7 MEMBER VETTER: Is what? I'm sorry.

8 DR. HOWE: When are you going to move
9 things out of 1000?

10 MEMBER VETTER: Why are they asking that?

11 DR. HOWE: You need to ask the
12 stakeholders.

13 MEMBER WILLIAMSON: I can give you one
14 answer.

15 CHAIRMAN CERQUEIRA: Jeff and then Lynne
16 in the back.

17 MEMBER WILLIAMSON: One answer is that
18 when something moves into regulation space from
19 guidance space, it is subjected to a whole lot more
20 public scrutiny and comment. And in some sense,
21 participatory democracy is working better than if NRC
22 staff just legislates that this is what is going to
23 happen for modality X.

24 CHAIRMAN CERQUEIRA: Lynne?

25 MS. FAIROBENT: Lynne Fairobent with the

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1 ACR again.

2 Richard, I think there are a couple of
3 reasons. One, during the development of part 35, it
4 was clearly stated and understood that part 1000 was
5 never intended to be a permanent licensing home for
6 anything that initially was licensed under it.

7 Secondly, every licensee who wants to use
8 the modality or technology under 1000 has to apply for
9 a license amendment unless they are broad scope. So
10 if we move it into 35 whatever, then they don't have
11 to go through and submit all of the detailed
12 application stuff that is necessary under a 35.1000
13 application.

14 CHAIRMAN CERQUEIRA: Dick, a follow-up?

15 MEMBER VETTER: Thanks. That is helpful.
16 I am still searching, though. I do know we certainly
17 don't want everything in 1000 15 years from now. But
18 I am still searching for the real down side of having
19 to deal with something that is in 1000 now. Even if
20 we didn't have an HDR currently and wanted to get one,
21 we would have to apply for a license amendment.

22 So I am not being critical. I am trying
23 to inform myself. What is driving the urgency to move
24 things out of 1000?

25 MS. FAIROBENT: For example, a lot of it

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1 is that it was intended to be something new or
2 emerged. We get into this whole circular discussion
3 of how do we tell when something has emerged?

4 Well, I would say intravascular
5 brachytherapy is a classic example. It has been in
6 1000 for, what, three years now, three and a half
7 years? I think that it is really time that that one
8 comes out of 1000 and goes into an appropriate home in
9 35.

10 The other issue is some of the stuff --
11 and I agree HDR is one that you would have to apply
12 for a license amendment. But, for example, if the
13 microspheres were initially found to be under a part
14 390 or 300.

15 I don't believe there would have been a
16 license amendment in order to use microspheres. So I
17 think it depends on the individual application as to
18 whether or not there would be an additional license
19 amendment.

20 Also I think you get less of an
21 interpretation difference perhaps between the 17 NRC
22 states and how the agreement states are handling some
23 of the items under 1000.

24 CHAIRMAN CERQUEIRA: Okay. Jeffrey?

25 MEMBER WILLIAMSON: Well, I think several

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1 of the points Donna-Beth made are very good ones.
2 Waiting until the guidance has stabilized, to some
3 extent, that means waiting until the community has had
4 enough experience within their so-called industry
5 guidelines to stabilize and mature as well.

6 So it took how long for HDR to make it
7 into part 35? Probably 12 or 13 years from the time
8 the initial guidance on remote after-loaders was
9 released until it got codified in part 35.

10 So another something to keep in mind maybe
11 or another sign of maturation or emergence from the
12 emerging bin into the accepted bin would be the
13 development of guidance by the AAPM or ACR that NRC
14 could use to inform its formulation of final
15 regulations.

16 DR. HOWE: And I think one of the things
17 we are looking for here are some ideas from you.
18 There are other criteria.

19 CHAIRMAN CERQUEIRA: Ralph, you had your
20 hand up. You've got some good ideas?

21 MEMBER LIETO: I had a question on one of
22 the slides, where it said something about the Web
23 site. I guess that is the sixth slide that you had,
24 "Revising Web Site Guidance is Easy to Do."

25 I guess the question or concern would be

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1 it is much easier to do, but it also doesn't
2 necessarily assure that that information is getting to
3 others that already have the device. In other words,
4 as this is changing, people once they have got it
5 approved may not necessarily be going back to the Web
6 site to see what changes are going into place.

7 It may or may not adversely affect how
8 they are doing things. Imagine if you could take
9 something off, it always makes it that much more
10 attractive. But if you say you are going to do
11 something one way but now you are going to require it
12 to be done another way, there may be more that is
13 involved in that than just simply changing it on a Web
14 site as far as the licensee is concerned.

15 So it makes it easy, but it also makes it
16 very difficult for the licensee to be assured that
17 they are maintaining compliance with what that
18 guidance is and may not be something that they really
19 want to accept.

20 Now, if it is just going to be guidance,
21 then I guess it is sort of like Dick was getting to.
22 Why put anything in regulatory space? Just put it out
23 there on the Web site. Just change things as they
24 come along.

25 DR. HOWE: The licensee has to meet the

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1 commitments they made when they applied for a license
2 amendment. So if the Web site guidance changes, I
3 think Jeff had the question or someone over there. It
4 gets more stringency.

5 What happens? The licensee is still held
6 to what they originally requested. So they aren't
7 held to the new stringency. If they want to take
8 advantage, more flexible, if it grows to be more
9 flexible, then they can do it internally. But your
10 point is also we need to make licensees more aware of
11 when we make changes. That is the point we take.

12 MEMBER LIETO: And also the other point,
13 addressing that point on the Web site, is that one of
14 the concerns with the revision of part 35 originally
15 a few years ago was the fact that a lot of guidance
16 was becoming license conditions basically.

17 And if this is guidance and it's up to the
18 site to accept it or not accept it, that is one thing.
19 But if it is becoming guidance like the Reg Guides of
20 old, I think what we are doing, we are starting back
21 down that slide again, where we are putting things
22 into guidance space, rather than the regulatory space.
23 And you have all of these conditions out there that if
24 it is something that needs to be a requirement, then
25 it should go into regulatory space so everybody know

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1 what is going on.

2 CHAIRMAN CERQUEIRA: From the perspective
3 of the states, is it easier in guidance space or
4 regulatory space?

5 MEMBER McBURNEY: What was your question?

6 CHAIRMAN CERQUEIRA: Regulatory or
7 guidance space. Does it matter to the states when the
8 NRC makes these rule changes?

9 MEMBER McBURNEY: I think for these
10 changing modalities, I agree with Donna-Beth in that
11 there needs to be some time for the requirements to
12 kind of settle in before you actually go through the
13 rulemaking process because, as you well know,
14 rulemaking takes a while. And we are not only flooded
15 with having to do medical rules but all of these
16 others as well.

17 So for these emerging things and the
18 things that are currently in 35.1000, it is easier for
19 us to develop guidance, but we need to assure that
20 there is some level of consistency between the states
21 on the guidance along with that of NRC.

22 Certainly I agree that we need some
23 licensing and inspection experience as well as any
24 experiences to show how the medical use and the
25 outcomes of this are going before we actually put it

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1 into rule space.

2 CHAIRMAN CERQUEIRA: Dick and then Jeff?

3 MEMBER VETTER: Donna-Beth, how will you
4 capture the licensing experience and medical use
5 experience from broad scope licensees? So, for
6 instance, the microsphere, they are allowed to simply
7 do their own evaluation, start doing it, and you will
8 get inspection experience and medical event
9 experience, but there is no licensing there.

10 The medical use experience could be quite
11 vast. I have no idea how many broad scope licensees
12 are using microspheres now, but it is probably
13 becoming fairly common.

14 DR. HOWE: I think you have a good point.
15 We normally think of this in terms of the limited
16 specific licensees. That is where we get our
17 licensing and more of our inspections, but we would be
18 using inspection and medical event experience from the
19 broad scopes.

20 MEMBER VETTER: So there is actually no
21 mechanism unless you went out with a questionnaire or
22 something to capture that experience from broad scope
23 licensees?

24 DR. HOWE: That's correct.

25 CHAIRMAN CERQUEIRA: Jeff, you are next.

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1 MEMBER WILLIAMSON: Well, having heard all
2 of this, I tend to agree with Lynne. I think that
3 once the technology and guidance has stabilized and
4 there is a significant user base in the community, it
5 should move out of 35.1000. It would be in regulatory
6 space, which is I think the best way to assure
7 consistency among broad scope, specific scope
8 licensees, and agreement states.

9 I suspect of all of these indications, the
10 one that probably is most ready to undergo this
11 rulemaking initiative is intervascular brachytherapy.
12 And the ACMUI might consider recommending to the staff
13 to consider working on it.

14 Now that part 35 is over, perhaps they are
15 ready to do the project.

16 CHAIRMAN CERQUEIRA: Part 35 is not over,
17 Jeff.

18 Lynne?

19 MS. FAIROBENT: I just have a question.
20 Maybe I missed it, but I am a little confused as to
21 why NRC is looking for medical use experience. Are
22 you referring to really the radiation safety and
23 protection of using these versus when I think in terms
24 of medical use, I am thinking of clinical applications
25 and clinical findings, --

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1 CHAIRMAN CERQUEIRA: Medical efficacy.

2 MS. FAIROBENT: -- which I don't believe
3 is NRC's jurisdiction. So I am a little confused over
4 what it is you are seeking under your bullet on
5 medical use experience.

6 DR. HOWE: I think in that case, we are
7 looking at the device being out there for a
8 significant number of users. So if there are problems
9 on the radiation safety aspect, there will be enough
10 opportunity for them to come up. We are not looking
11 at practice of medicine issues. But we are just
12 saying everybody has enough experience. We weren't
13 looking at the practice of medicine.

14 MS. FAIROBENT: I think, then, that should
15 be for future discussions perhaps reworded slightly
16 because I think that you could get some reactionary
17 problems that you might not be seeking if it is out in
18 the general medical community from some folks thinking
19 that, in fact, you are crossing over into general
20 practice-of-medicine type experience-based concerns.

21 CHAIRMAN CERQUEIRA: Thank you for those
22 comments.

23 Any additional comments for Dr. Howe?
24 Jeff?

25 MEMBER WILLIAMSON: Well, I would like to

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1 know what the staff's view is on the urgency of
2 intravascular brachytherapy rulemaking, its
3 desirability or lack thereof of pursuing that in the
4 near term.

5 DR. HOWE: I think last year there was
6 quite a bit of question because there were some new
7 stents coming out with drugs in the stents. And so
8 there was a question of whether intravascular
9 brachytherapy would even still be a modality that
10 would be used.

11 I think they have had significant problems
12 with the drug-coated stents. It appears now that one
13 manufacturer has totally ceased making intravascular
14 brachytherapy sources. So out of our three, only two
15 are left.

16 I am guessing that the two will stay. So
17 this year it is different. It is not really in a wait
18 and see will it all go away.

19 CHAIRMAN CERQUEIRA: In the cardiology
20 community, I think the new stents have significantly
21 impacted on the utilization. There probably will
22 still continue to be a few centers that will do it,
23 but the widespread implementation that we had
24 anticipated a few years ago is unlikely to evolve over
25 time.

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1 Now, for peripheral vessels and things
2 perhaps, but I think stents, these treated stents,
3 will have an impact as well.

4 DR. HOWE: So do you see the intravascular
5 brachytherapy staying as a technology that
6 cardiologists use, just not as great as they --

7 CHAIRMAN CERQUEIRA: I think it's going to
8 be localized at a few tertiary centers that are broad
9 scope license to start with. I think the threat of
10 cardiologists using it in their outpatient offices, I
11 don't think that is ever going to happen because of
12 all of the hassles that are involved. I think it
13 probably will continue to be done in conjunction with
14 medical physicists and radiation oncologists.

15 I think, again, we have anticipated what
16 was going to happen. I think it does not appear to be
17 moving in that direction. We probably should wait and
18 see how it eventually ends up.

19 Subir, in terms of non-party applications?

20 MEMBER NAG: What I'm seeing is a change
21 in the lesions. The longer lesions again, again,
22 radiation is still the longer lesions are distant to
23 the drug. So it is not going up astronomically as it
24 was doing before leveling off, but I think that still
25 there will be a need for regulating the ones that we

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1 are doing now. The indications are somewhat different
2 now, slightly.

3 CHAIRMAN CERQUEIRA: Well, if there are no
4 other questions or comments, Dr. Howe, do you have any
5 questions for us?

6 DR. HOWE: No, I don't think so.

7 CHAIRMAN CERQUEIRA: We have answered
8 them. We have had more of your time than you
9 anticipated. So our break isn't supposed to be until
10 3:15, but should we reconvene at 3:15 and get done a
11 little early? That's fine? Okay. Good.

12 (Whereupon, the foregoing matter went off
13 the record at 2:51 p.m. and went back on
14 the record at 3:18 p.m.)

15 CHAIRMAN CERQUEIRA: If everyone will take
16 their seats, we'll reconvene and we have two more
17 presentations today. The first one is "Defining
18 Medical Events Involving Prostate Seed Implants" and
19 Dr. Ronald Zelac will be presenting.

20 DR. ZELAC: Thank you, Chairman. Before
21 I begin, Thomas Essig has an announcement for general
22 interest.

23 MR. ESSIG: It's concerning the handout
24 that was included in the notebooks. There is a
25 memorandum that was not intended to be included at

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1 least in the notebooks that went -- that were on
2 display out on the table in the lobby. So if there
3 are members of the public that received this
4 memorandum, we would ask that you either turn it back
5 in or discard it and some of them may not -- we have
6 removed it from the other notebooks. It's a
7 memorandum dated January 29th from myself to George
8 Panglerner, Region 1. This is typically how we close
9 out a technical assistance request and the region
10 takes the action and then ultimately we make portions
11 of the public, of this technical assistance request
12 publicly available. But the entire contents of the
13 memorandum are not. They're just our input to the
14 requesting regional office. And so it was not
15 intended to include this in there.

16 It may not be -- it was following Dr.
17 Zelac's slides. And if it isn't there, then we may
18 have caught it and removed it. But I know it was in
19 some and it wasn't intended to be. It's about a three
20 and a half page memorandum.

21 And personally, I don't have any problem
22 with members of the Committee having, as long as you
23 understand that it's not a public -- because we often
24 give you documents that are not publicly available.
25 So if you just want to annotate it that it's not

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1 publicly available, I would appreciate that and I
2 would ask any members of the public who picked it up
3 to kindly discard it.

4 Thank you.

5 MS. WILLIAMSON: We've already had one
6 very honest member of the public, Lynne Fairbent that
7 just turned it in.

8 CHAIRMAN CERQUEIRA: Thank you.

9 DR. ZELAC: The other thing worth noting
10 about this is the handouts that were on the table and
11 are on the table don't actually have a copy of the
12 slides, so that was put out afterwards for anyone that
13 picked up before that took place.

14 I've been asked to keep you all awake for
15 a while. I think the discussion that will ensue may
16 accomplish that. This, in fact, is a topic for which
17 we really don't expect a resolution, but it's simply
18 both an update for you and hopefully some additional
19 information for us.

20 We have an issue. It focuses around
21 defining what a medical event is for permanent seed
22 implant, and particularly, in this case, prostate. I
23 had come to you, as you may recall last November when
24 there was a case for which we had had 21 at one
25 facility events that needed to be defined in some way

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1 to determine whether or not they, in fact, were
2 medical events. And we did get guidance from the
3 Committee at that time which was utilized.

4 The regulatory requirement is on the first
5 of the slides. It's a delivery of a dose that differs
6 from the prescribed dose by more than 50 rem to an
7 organ or tissue and a total dose that differs from the
8 prescribed dose by 20 percent or more. These are the
9 requirements that are in 10 CFR 35.3045 that apply to
10 an implant, brachytherapy.

11 Recommendations that we received from the
12 Advisory Committee last November basically said use
13 D90 as the criterion for a medical event. D90, as a
14 reminder, is a dose which is delivered to 90 percent
15 of the target which in this case is the prostate.
16 That's a good criterion for us to use because as you
17 saw in the previous slide, variations from the
18 prescribed dose are, in fact, what's necessary to
19 determine whether or not a medical event occurred.
20 It's a good criterion in comparison to some of the
21 others that could be utilized that are based more on
22 volume than on dose.

23 The criterion that we got, D90, then is
24 perfectly fine and acceptable and can be utilized for
25 under dosing. It basically says that D90 is less than

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1 80 percent. Again, the criteria are 20 percent
2 variation from the prescribed dose. So for a D90
3 that's less than 80 percent, we have a medical event.

4 The problem comes in looking at the other
5 end of the spectrum for over dosing where the dose
6 being delivered differs from the prescribed dose of
7 more than 20 percent, i.e., if we were to apply the
8 D90 criterion, a D90 that was greater than 120
9 percent. The problem is that many standard treatments
10 have D90s that exceed 120 percent of the prescribed
11 dose. And compounding that is the fact that in
12 standard treatments, a significant portion of the
13 target volume receives a dose exceeding 200 percent of
14 the prescribed dose. Now again, this may not have
15 clinical significance in terms of the outcomes, but
16 comparing these kinds of situations to regulatory
17 requirement for medical event, we appear to have a
18 problem if we are going to attempt to utilize D90 both
19 for over dosing, as well as when it is useful, under
20 dosing.

21 So the questions regarding the criterion
22 for over dosing that I have are first, and I solicit
23 your feedback as we go through this, first, are the
24 previous two statements regarding D90s for standard
25 treatments considered correct, i.e., many standard

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1 treatments have D90s exceeding 120 percent of the
2 prescribed dose? And two, in standard treatments, a
3 significant portion of the target volume receives a
4 dose exceeding 200 percent of the prescribed dose.

5 Are these statements correct? I've seen
6 them in the literature. And in fact, Dr. Nag has been
7 one of the people referenced in the particular
8 publications that I have seen these things in, so I
9 can pose the question to you as a Committee, but very
10 specifically to Dr. Nag.

11 DR. NAG: The problem is that there is not
12 a simple answer, okay? First of all, where is the
13 organ? In brachytherapy, everything is in such a
14 small volume that the tolerance of the body is really
15 high. Now when you are treating a big area, if you're
16 giving 20 percent higher dose or 30 percent higher
17 dose, you have problems. When you are treating an
18 extremely small volume, if you are giving that volume
19 even double the dose, you don't have a problem unless
20 you have some normal tissue within that volume.

21 When we talk about prostate, and what we
22 did, what we had was a group of brachytherapists in
23 the country in one room and we asked them to draw
24 where the prostate is on a CT scan on a computer and
25 we put all of those drawings on top of each other.

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1 That's a huge difference in the volumes that a so-
2 called expert do (unintelligible due to strong foreign
3 accent) each other as to what the prostate volume is.

4 Now you take one particular implant and if
5 you have the volume that's drawn differently by the
6 five people, on that same implant you are going to
7 have a D90 that's very high and with the same implant,
8 it depends on how you do the prostate volume, then D90
9 would be very low. So on that same one patient, it
10 depends on who is doing the prostate volume. You
11 could have an over dosing or an under dosing on that
12 same patient. So there is a big problem right there.

13 Secondly, the data about D90 being very
14 important or D90, the dose that correlates with
15 outcome and only in the prostate. The reason why D90
16 is useful in the prostate is that in the prostate and
17 not the whole prostate that has the tumor. Only
18 certain portion called the (unintelligible due to
19 strong foreign accent) that has the tumor. So if the
20 anterior zone of the prostate is even totally under
21 dosed, you are not going to have any problem of
22 recurrence.

23 So with both of these, you are saying that
24 a valuable under dosing of 80 percent of D90
25 automatically is under dosing may not be. I have done

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1 many implants where the D90 is less than 80 percent
2 and the tumors are still controlled. So I don't think
3 we have an answer yet of how low we can go. It's a
4 problem because even if you are given a D90 dose
5 that's 30 percent higher, more than 130 percent, you
6 are still not going to have a problem unless there are
7 normal tissues within the high dose area. There is
8 not so much what the tumor is getting or how high the
9 tumor is getting. It's how high the normal tissue is
10 getting that will be the problem.

11 I know you had some questions and you
12 don't agree with me, right?

13 CHAIRMAN CERQUEIRA: Dr. Williamson?

14 DR. WILLIAMSON: No, I actually agree.

15 (Laughter.)

16 DR. NAG: For once.

17 DR. WILLIAMSON: Essentially, all of what
18 Subir said and I would just like to add to it, you
19 know, there's a significant body of data clearly
20 indicating that CT is an imperfect modality for
21 imaging the prostate and that compared to ultrasound
22 or MR, both of which show the outlines of the prostate
23 more clearly, there can be errors as large as 50
24 percent in the assessment of volume of the prostate.
25 So it's very hard to see parts, certain aspects of the

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1 prostate boundary on CT. It's just part of the turf.

2 A second issue that you should be aware of
3 is that institutions differ in when the post-planning
4 evaluation imaging takes place. Many places do it the
5 day of or day after the prostate implant. At that
6 point, the prostate will have maximum edema. It will
7 be its largest size, and so therefore the dose that
8 you will evaluate will be essentially the minimum
9 dose. This prostate edema resolves with an
10 approximately 10-day half life and so those
11 institutions that do the imaging 30 days down the line
12 which is the other recommended protocol or a protocol
13 a lot of people use will generally show higher doses
14 because the whole volume will have retracted and
15 they'll be calculating dose to a smaller volume with
16 the seeds more concentrated. So this is another
17 issue.

18 I would say the main rationale for using
19 D90 as a parameter for regulatory purposes is the same
20 reason we're interested in it clinically, is that
21 there have been a couple of large retrospective
22 studies which have shown that D90 under doses are
23 correlated with a higher probability of recurrence and
24 that if you can get D90 over 135 or 140 gray, that
25 results in a statistically significant better BNED

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1 outcome. So I think the lower end is justified. I
2 think deciding whether it's 120 or 130 percent, that's
3 really arguable and I don't know that there's a fact
4 of the matter that could be advanced as to which it
5 should be.

6 I would say to err on the side of
7 generosity so that you don't -- you collect gross
8 errors, but don't include a lot of events simply
9 because of these variations in clinical practice as to
10 when you do the imaging and how you outline the target
11 volume and so on. I mean those are events that you
12 probably don't want to see unless you want to be
13 inundated with them. There are a lot of prostate
14 impacts taking place.

15 I would like to point out to you a
16 specific article authored by Gregory Merrick who has
17 analyzed hundreds of patients and gives in table form
18 the values of these indices in the population of
19 patients they treated. I think they're very good and
20 careful clinicians and investigators and this will
21 show you in a really good institution just how much
22 variation there are in these parameters and they show,
23 on average, for some of the cohorts such as more
24 advanced prostate disease treated with a combination
25 of external beam and brachytherapy, their D90s,

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1 average D90s are as much as 113 percent above
2 prescribed.

3 So I think based on Subir's comments, this
4 paper and my own observations, I think 120 percent is
5 probably too narrow an integral for practice.

6 DR. NAG: Not only is it too narrow, but
7 it doesn't matter you are giving the tumor on the
8 higher side. On the lower side, if you're giving too
9 low a dose, the tumor will not be cured. But if you
10 are giving a higher dose, so long as the body is able
11 to tolerate that you are going to cure the tumor. The
12 only problem is if that high dose is in an area of
13 normal tissue, then you may have some normal tissue
14 complications. But if you are able to give a much
15 higher -- even 200 percent of what you are supposed to
16 give, you give it to the tumor without giving a high
17 dose to the normal tissue, you're not going to have a
18 problem.

19 I had a question about the part of how you
20 prescribe in permanent impact. In a way, I think the
21 old method of prescription was better, that is, you
22 had supervision. You give a certain activity, for a
23 permanent implant, you give a certain activity to the
24 tumor and that is how you prescribe rather than by
25 dose. So if you remember the old Part 55, it was the

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1 total dose or number of millicuries that you're
2 giving. So if you're thinking or if your plan was to
3 give 35 millicuries and you gave 35 millicuries plus
4 or minus 20 percent of that volume, then you're okay.

5 I think that in a way solved a lot of
6 problems for prescription of permanent implants,
7 rather than going for the dose.

8 DR. ZELAC: If I recall, that's still
9 available. I don't think it's disappeared. It's
10 total dose for --

11 DR. NAG: Not in the new one. At present,
12 in the new one I think you see the activity and only
13 the dose.

14 DR. WILLIAMSON: I believe Ron -- Dr.
15 Zelac is correct that you can still prescribe.

16 Regarding the 200 percent, I think in any
17 brachytherapy procedure there are going to be small
18 volumes that get incredibly high doses and in the
19 experience of Merrick, his average B150, that is the
20 fraction of the prostate receiving 150 percent or more
21 of the prescribed dose varies, it's about 47 percent.
22 So I'm sure that if I were to extrapolate, my
23 experience is about 20 percent of the volume would
24 have 200 percent or so. That's just a normal implant
25 and there's nothing really to be done about that.

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1 DR. NAG: So long as it's a very small
2 volume and getting a very high dose, the body
3 tolerates that. So you don't want to extrapolate from
4 normal brachytherapy experience when the volume is
5 very large, where if you gave 200 percent to a large
6 volume you are going to have a disaster. When you
7 have an extremely small volume and a small portion of
8 that is 200 percent, it never is a problem.

9 DR. WILLIAMSON: I'm glad that you
10 departed from the idea of D100 or minimum dose because
11 the data Merrick shows that the average coverage or
12 the average D100 is about 67 percent plus or minus as
13 much as 24 percent. So that's really an impossible
14 criteria.

15 DR. NAG: D100 has absolutely no meaning
16 in prostate implant because if 1 percent of that
17 prostate got a very low dose, it will make the D100
18 very low and that does not correlate with anything at
19 all. That is why the ABC came up with the D90
20 recommendations.

21 CHAIRMAN CERQUEIRA: So I'm confused.
22 When do you get too much?

23 DR. NAG: When the normal tissue gets too
24 much, not when the tumor gets too much. If the tumor
25 gets more volume and the tumor got too much, the tumor

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1 is dead, you can't make it any more dead and as long
2 as you're not having a normal tissue complication.
3 Now if the normal tissue is very close to the tumor,
4 then I'm worried about over dosing, but if I don't
5 have any normal tissue very close to the tumor, I
6 think to err on the side of going to a higher dose
7 rather than avoiding and having a failure.

8 DR. ZELAC: You may recall that the issue
9 at hand with the case that we had discussed previously
10 in November was discovered because of recurrence
11 because a significant fraction of the total seeds that
12 were being implanted did not get into the target as
13 intended, but elsewhere. And the result of that was
14 tumor did not get properly dosed and a recurrence and
15 it was after that occurred that it was found that
16 looking at the records of all of the other patients
17 treated by these individuals a significant number of
18 additional cases had been also treated in the same
19 fashion came to light.

20 That was the reason for coming initially
21 here to seek an appropriate criterion and as I
22 mentioned earlier for under dosing it seems to
23 generally be workable. But as you've pointed out,
24 which is something that I recognize and why I came to
25 begin with, we do have a significant problem in trying

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1 to apply it to the high end for overdosing, the
2 delivery of more seeds than had originally been
3 intended which is not very likely or in a smaller --a
4 considerably smaller volume which if it's in the tumor
5 is not going to be an issue anyway. So where do we
6 go? That's what I'm looking for.

7 DR. NAG: I think what we may have to do
8 is have two criteria. One is with the under dosing,
9 the criteria should be to the tumor. Are you under
10 dosing the tumor. When you're over dosing, I think
11 you have to apply the criteria to the normal tissue.
12 Are you over dosing the surrounding normal tissue? If
13 you over dose the tumor, I don't think that's any
14 problem. I do that all the time and I think anything
15 is good, but are you under dosing the tumor and are
16 you over dosing the normal tissue.

17 CHAIRMAN CERQUEIRA: But from your
18 description if you have five people drawing the region
19 you're going to come up with five different regions,
20 what's the measurement technique that you're going to
21 use?

22 DR. NAG: That's the problem.

23 CHAIRMAN CERQUEIRA: Do you routinely
24 measure after you give a dose? Is that part of the --

25 DR. NAG: What we do is we outline what we

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1 think is the prostate and my outlining of the prostate
2 may be quite different from the way Merrick --

3 CHAIRMAN CERQUEIRA: So reproducibility is
4 quite bad.

5 DR. WILLIAMSON: It's not quite so bad.
6 Practitioners differ to some extent on what they
7 define the clinical target to be and this is an issue
8 sometimes of how much margin you add or in dubious
9 areas where it's really -- such as the apex of the
10 prostate where it's very difficult to interpret. It's
11 sort of an issue of what kind of conventions you use.

12 But I do want to -- I think it is
13 important to consider the wrong site issue and this is
14 really a different scenario. And there, I think
15 Subir's suggestion that the written directive perhaps
16 be in terms of number of seeds and total activity,
17 really has merit and perhaps a reasonable criterion
18 might be if more than 20 percent of the seeds wind up
19 in the wrong organ, this is probably a really good
20 indication that maybe somebody doesn't know what
21 they're doing. And make the wrong site criterion be
22 independent of dose and issue of the geometry of the
23 seeds where they have been implanted.

24 So this is I think -- there really have to
25 be three criteria, I think. There's got to be a wrong

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1 site criterion. Did you get the seeds into the right
2 organ and the right number and the right activity?
3 Under dosing, I think is maybe, we all agree is fairly
4 straight forward. Over dosing, normal tissues, this
5 may be something that could be discussed. I don't
6 have a good feel if there are well-defined normal
7 tissue tolerances yet available.

8 DR. NAG: Unfortunately, under dosing is
9 not as simple as you think because again under dosing
10 will depend on under dosing what organ and how you
11 define that organ.

12 If you make your circle two millimeters
13 bigger, you can have a higher under dosing.

14 DR. WILLIAMSON: See, the issue really has
15 always, I think the NRC has always done this and
16 wisely so, is to basically default to the authorized
17 user. How do they draw the target volume and how do
18 they specify the dose themselves and it's relative to
19 their own criterion, but I think the literature would
20 support that if D90 is too low, you know that has
21 clinical significance and therefore it's reasonable
22 that -- more reasonable than if you pursued some
23 arbitrary end point that NRC should have a regulatory
24 interest in that.

25 So I think there's a lot of subtleties to

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1 this as you can tell and I think it would be good if
2 you tried to avoid the subtleties and medical
3 controversies within the field and concentrate on
4 setting limits that really do distinguish bad actors,
5 the really bad actors from the standard of practice.

6 CHAIRMAN CERQUEIRA: But at what point
7 does it become a radiation safety issue versus sort of
8 a practice of medicine issue. I mean do you want
9 these guys involved in every case where the guy is not
10 getting the target correctly? It is a
11 misadministration, but should this be the body, should
12 the NRC be the one that's controlling that?

13 DR. WILLIAMSON: Somebody who impacts 30
14 percent of the seeds in the rectum, yeah, I mean I
15 think that -- we're justified collectively as a
16 society worrying about physicians doing that, given
17 that we do start out with a premise that NRC and other
18 Government bodies have an interest in assuring patient
19 safety or some --

20 CHAIRMAN CERQUEIRA: Patient radiation
21 safety, right.

22 DR. NAG: It depends. If you are having
23 (unintelligible due to strong foreign accent) you
24 know, X millicuries to be given to the organ, he is
25 able to give that X millicuries to the organ, but it

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1 turns out that the dose, if you calculate the dose, it
2 is less than 80 percent of the D90, I don't think
3 that's a problem.

4 On the other hand, if 10 percent or 15
5 percent, not even 20, 15 percent of the seed is ending
6 up in the bladder or the rectum, then it is a problem.
7 So I think you have to add that it's not only going to
8 be a dose issue. I think the percentage of the
9 intended millicurie activity that it was to the right
10 organ is probably a better criteria than the dose.
11 The dose may not be in the hands of the practitioner.
12 It depends on how the seeds were distributed within
13 the volume and many other criteria.

14 To make it a little more complicated there
15 are practitioners who are more advanced and what they
16 are doing is they are -- dose (unintelligible due to
17 strong foreign accent) meaning the areas that have a
18 high risk of tumor, they are purposely giving a higher
19 dose and areas of the prostate that have a very low
20 risk of having tumors, they are purposely giving a
21 lower dose, which by a normal criteria would be called
22 under dosing if you just say less than 80 percent of
23 D90, it will be under dosing, but the purpose of doing
24 that and I think it's a better treatment, not a worse
25 treatment.

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1 So we have to be very careful that we
2 don't penalize the really good -- the ones who are
3 going to be at the cutting edge.

4 DR. WILLIAMSON: But that can be handled
5 by the practitioner appropriately writing the written
6 directive so as to make it clear that they're not
7 trying to deliver 100 percent of the D90.

8 DR. NAG: Yes, but if the practitioner is
9 writing D90 and knows so much and yet the D90 will be
10 much less, so we have to be careful on how we state it
11 because the way it's reported is very simple if it's
12 less than 80 percent of the D90 under dosing it not
13 necessarily shows, that's all I'm pointing out.

14 DR. ZELAC: It's clearly deviation from
15 the prescribed dose which is of concern, so as was
16 pointed out, if the prescribed dose is noted in an
17 appropriate fashion, it's a comparison to that.

18 DR. NAG: But a prescribed dose for what?
19 Are you prescribing it to the prostate or to the
20 tumor?

21 DR. WILLIAMSON: That's up to the
22 practitioner, I would say, and they're going to be
23 judged according to the way they write the written
24 directive.

25 CHAIRMAN CERQUEIRA: We have a comment

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1 from the back microphone. Sorry.

2 MR. WHITE: This is Gerry White from the
3 AAPM. I just wanted to agree with everything
4 everybody said, but the situation may be even more
5 complex than you describe. There's a lot of talk
6 about the prescription and the dose. But in many
7 clinics, not most clinics, there is an arrangement
8 called a pre-plan where a physician does a plan where
9 they anticipate the isotopes curves are going to go
10 and the physician may intend for a certain part of the
11 prostate of significant volume to get 150 percent or
12 200 percent and if you set your criteria for under
13 dose or over dose, based on some percentage of a
14 prescribed dose, a single number. There may be in
15 existence an isodose plan that the physician intends
16 to have applied and it may not meet that criteria and
17 that will be true, that situation may occur no matter
18 where you set the -- no matter where the NRC sets the
19 criteria. You can set a lower and an upper criteria
20 anywhere you like and there may be a physician who has
21 a pre-plan, a prescription in effect, a written
22 directive, that doesn't correspond to that.

23 So the real issue, I think, is the
24 correspondence between the physician's intention and
25 what's actually executed. It's hard to describe that

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1 with just three numbers.

2 DR. ZELAC: Well, that's exactly correct.
3 The problem we're in at the moment clearly is we do
4 have a rule and it does have a stated criterion, less
5 than 80 percent of the prescribed dose is a medical
6 event, greater than 120 percent is a medical event.
7 But the question is how do you compare -- what do you
8 to define the prescribed dose initially. That's where
9 we are.

10 We've got the time, I guess, a little bit,
11 but clearly, we came with the problem at the high over
12 dosing and thinking that the problem at the lower end
13 had been solved. Now we're backing up from that as
14 well. So we're in a little bit more precarious a
15 situation than we were previously, except in the case,
16 I think, where a significant, as Jeff pointed out,
17 significant numbers of the intended seeds were
18 implanted in the wrong place.

19 CHAIRMAN CERQUEIRA: I'm just a simple-
20 minded cardiologist, but I'm getting a little confused
21 because it sounds like you guys are kind of making it
22 up. I mean Ralph and Dick, how do you guys at your
23 institution, how do you decide here?

24 Dick? At the Mayo Clinic, how do you
25 decide the radiation oncologists are doing a good job

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1 or a better job, misadministration or appropriate
2 dosing ?

3 DR. VETTER: Outcome.

4 CHAIRMAN CERQUEIRA: I mean Ron can't deal
5 with outcomes. He's got to deal with --

6 DR. VETTER: I know he can't. This is not
7 a simple issue. We go primarily by seeds, seed count,
8 rather than --

9 CHAIRMAN CERQUEIRA: Seed count in the
10 right location?

11 DR. VETTER: Exactly.

12 DR. NAG: Activity, not seed count,
13 activity.

14 DR. VETTER: Activity, yes.

15 CHAIRMAN CERQUEIRA: Ralph, how do you --

16 DR. LIETO: I would probably agree --

17 CHAIRMAN CERQUEIRA: Seed count. How do
18 the states do it, Ruth?

19 MS. MCBURNEY: I'm not sure.

20 (Laughter.)

21 DR. ZELAC: Just for information, the
22 reference earlier was to what needs to be in the
23 written directive. And of course, for implantations,
24 it's different than all of the others in that you have
25 a before and an after and the after is written in

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1 terms of number of sources and total source strength
2 and exposure time or the total dose. So the option is
3 there. So we could operate with that just the way we
4 are now.

5 CHAIRMAN CERQUEIRA: Dick and then --

6 DR. VETTER: Yes, I think that's an
7 important point to mention that the physician goes
8 into the OR with the plan and sort of a pre-
9 prescription and then they dictate the prescription,
10 the final prescription after the procedure because you
11 might run into something that you did not fully
12 anticipate before you implanted those seeds.

13 Then the final prescription would include
14 all of the documentation to indicate the activity and
15 the distribution within the organ.

16 DR. WILLIAMSON: Well, I think the way the
17 community is approaching this and the inter-
18 institutional trials is they're not requiring, for
19 example, the clinical trials. They're not requiring
20 submission of the pre-plan. What's really important
21 is the post-implant evaluation and so if you -- I
22 think you're on the right track. If you wanted to
23 really do this in a rational way, the answer would be
24 the appropriate written directive would be some
25 statement of the physician's expectations of the post-

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1 implant evaluation and some idea, a time frame, when
2 it's supposed to be done.

3 I guess I have a question for you. The
4 Part 35 is the way it is, so is your question how the
5 current Part 35 within the confines of what's written
6 there can be adapted to best handle this or are you
7 actually contemplating a rule making initiative or
8 some special guidance that would apply just to this
9 class of cases and would attempt to rectify what you
10 see as shortcomings in the current rule.

11 DR. ZELAC: I think you gathered from
12 Donna-Beth's earlier comments that rulemaking is
13 something which first is expensive and time consuming
14 and it has to be justified. Unless there's a real
15 problem, they're not going to move or I would
16 personally not recommend moving to make a change.

17 The question is are there sufficiently
18 well-defined criteria that are used in the community
19 which can be applied to the existing rule in terms of
20 the plus or minus 20 percent? Now if plus or minus 20
21 percent is inappropriate for implants period, then we
22 need to look at a change in the rule on that basis.

23 CHAIRMAN CERQUEIRA: I think Dr. Howe at
24 the back microphone has the answer for us.

25 DR. HOWE: If you remember your last ACMUI

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1 meeting, I talked about proposed changes to Part 35
2 and this one of the issues that we wanted to explore
3 to see if there was a way of making it better, easier
4 to understand for everybody involved. So it is on the
5 agenda for a proposed rulemaking, but we may decide
6 yes, we may decide no.

7 CHAIRMAN CERQUEIRA: Based on the
8 discussion so far, Dr. Howe, I mean what's your
9 interpretation of his?

10 DR. HOWE: It kind of sounds like we need
11 clarification on what everybody means, so at least go
12 through the exercise of can we make the rule language
13 better and maybe we can't.

14 DR. WILLIAMSON: So I'm hearing now maybe
15 that what is desired by the staff is to kind of draft
16 maybe with our input and suggestions what would be
17 sort of an idealized way of writing a written
18 directive and specifying what medical event means that
19 would have some meaning, you know, or it would be
20 reasonable within the regulated community and then go
21 from there to decide whether that could be implemented
22 by interpretation of the existing rule language or
23 whether it's worked well revising the language.

24 DR. WILLIAMSON: What I'm hearing through
25 these discussions is that the expertise which is

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1 available here to us now can't provide anything that's
2 so specific that it can be applied to the existing
3 rule. Now if there's a possibility that as things
4 evolve further that could change, we can kind of
5 muddle our way through for the time being until we can
6 get such a recommendation as to what criterion could
7 be applied to the existing rule, if in fact, the
8 likelihood of there being such a criterion in the
9 future which there doesn't appear to be today,
10 available -- if there's not going to be such a
11 criterion, then we have to think about significant
12 change to the existing rule in that regard.

13 DR. NAG: I think if you are using the
14 activity criteria, you know, you are prescribing a
15 certain millicurie to the target and you have plus or
16 minus 20 percent of that in terms of activity then I
17 think you are okay. But if you are going by what you
18 were saying about the dose, then that's not okay
19 because the dose will depend on where activity went
20 within the volume. If the volume was smaller, with
21 the same activity you are going to get 30 or 40
22 percent or 50 percent higher dose and if you went to
23 a slightly bigger one, you would get much more under
24 dosed. So if you went by millicurie activity you will
25 be okay. But if you are going by a dose criteria, I

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1 have talked with a lot of people and we haven't come
2 up with any solution.

3 CHAIRMAN CERQUEIRA: Do you have a
4 comment?

5 DR. LIETO: Yes. You go to all the
6 separate -- to get qualified, credentialed people to
7 do these procedures. You've addressed, Jack, you've
8 addressed process, you know, double check to make sure
9 that it's been done right at post-implant
10 reassessment. What I hear here is an effort to come
11 up with a quantitative metric, 80 percent, 20 percent
12 for a target that is non-uniform. It is complex that
13 may, in fact, depend on the health of the individuals
14 so you may have the same geometry in a healthier
15 individual versus a sicker individual, how you define
16 healthy and sick are issues too. I hear a lot of
17 concern about coming up with that 80, 20, 90 numbers.
18 That tells me maybe you need to back off, but maybe
19 you need to tighten up the process side and make sure
20 that the qualified experts that are doing this, in
21 fact, do re-evaluate, do make sure that they're doing
22 the quality control checking, that they've done it
23 right. But you really have to defer. The radiation
24 safety in medicine issue, they're overlapping a lot
25 here and I don't think you're going to segregate the

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1 two.

2 CHAIRMAN CERQUEIRA: Yes. I'm mostly
3 having a problem with do you make the prescription
4 before or after? Do you define the target before and
5 after, because if you do this all after, then there
6 will be no misadministrations because you're going to
7 define a dose to the target? No.

8 DR. VETTER: That's not true. After you
9 go back and you look at the film and if 25 percent of
10 your seeds are in the rectum, you have a
11 misadministration.

12 CHAIRMAN CERQUEIRA: Okay, so --

13 DR. WILLIAMSON: No.

14 CHAIRMAN CERQUEIRA: No?

15 DR. WILLIAMSON: That's another issue, but
16 I think Ron's sort of summary of what I thought Sibur
17 and I said was excessively pessimistic. I think we
18 are saying that a reasonable version of the wrong site
19 criterion could be developed in terms of number of
20 seeds/total activity implanted. I actually think
21 under some limited circumstances at least low dose
22 under dosing tightness medical events would be
23 feasible to look at.

24 I think then the next question is whether
25 the criterion or the definition of written directive

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1 as it's now written could accomplish this. I would
2 say probably the answer is no because for one thing I
3 don't think there's a requirement in Part 35 that post
4 implant CT or MR based evaluation be done. There
5 really isn't. So neither of these criteria is
6 implementable or decidable unless you do that kind of
7 image-based evaluation after the implant has been
8 complete.

9 DR. ZELAC: Well, let me say something on
10 a positive note then. Because in 3540 written
11 directives, as I mentioned earlier, the definition of
12 whether or not you did what you had intended is based
13 on number of sources and total source strength or
14 exposure time. That probably -- you would have to
15 talk to our counsel about this, that probably could be
16 turned equivalent to the dose.

17 DR. NAG: Yes.

18 DR. ZELAC: And on that basis you can then
19 look at the criteria for a medical event and rather
20 than talk in dose as the wording said, say use the
21 dose equivalent, if you will, which is again total
22 number of seeds and so forth.

23 So I think the rule is not necessarily
24 fatally flawed in terms of being able to apply what's
25 here already to this particular situation. It's just

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1 a question of what you're going to look at and how
2 you're going to define it.

3 General counsel will have to be consulted
4 on this matter, but I think that would probably work
5 okay.

6 DR. NAG: Ron, I think you are technically
7 correct. If you go by activity, then there's the case
8 of the Guthrie Institution. They had more than 30
9 percent or 40 percent of their seeds outside of the
10 prostate. Now that would then be a misadministration.
11 So I think -- but dosing, again, if I made my prostate
12 very small, I could make the dose very close to the
13 D90 and what the -- for a permanent implant getting
14 away from the dose and going into dose activity to the
15 intended target would be better.

16 DR. WILLIAMSON: I think I would agree
17 with that. It all does depend on the fact though that
18 institutions practice according to the recommendations
19 of the professional, scientific societies which is you
20 do some form of post procedure imaging that's capable
21 of detecting whether the seeds are in the prostate
22 versus somewhere else. And if you don't require that,
23 then you don't require the criterion to be decidable.
24 So I think in that sense, I view the current
25 regulation as being incomplete because a practitioner

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1 could evade the question all together by simply not
2 doing any post implant imaging.

3 DR. ZELAC: You're right. All the
4 practitioner needs to do is to state how many seeds
5 did I implant. He doesn't have to say where they went
6 or know where they went. He just says I implanted so
7 many.

8 CHAIRMAN CERQUEIRA: Dr. Zelac, how would
9 you like us to move forward with this? I think you've
10 gotten some input from the various Committee members
11 who have knowledge. Do you need further
12 clarification?

13 DR. ZELAC: I don't think so at this
14 point. I think we have sufficient information now on
15 the status of the art, so to speak, as well as how it
16 relates to our existing rule, to be able to move ahead
17 to one, as I said, get clarification and an opinion
18 from our general counsel about the issue I mentioned
19 earlier about relating written directive for permanent
20 implant to medical event, the use of equivalent to
21 dose.

22 And the second thing is that it's pretty
23 clear from the discussions as well that we don't
24 really have in the rule as it stands today something
25 sufficient to determine whether or not the seeds went

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1 to the right place and until we do, we will have this
2 problem continue.

3 We do have individual physicians or
4 licensees who will come in, who claim that they after
5 the procedure was completed, they then changed the
6 written directive. It's their prerogative to change
7 the written directive until the procedure is
8 completed. The question is when is the procedure
9 complete? That's another issue that has to be
10 resolved. Is it at the time when the patient leaves
11 the OR? Is it at the time when the evaluation is done
12 30 days post? Those are differing positions.

13 DR. WILLIAMSON: And that's up to the
14 practitioner.

15 DR. MALMUD: As a non-radiation
16 oncologist, I have several questions to ask before I
17 understand this issue. Number one, if a patient is
18 undergoing seed implantation in the prostate for
19 prostate cancer, and a certain percentage of the seeds
20 are not in the prostate, let's say they're in the
21 rectum, there are two problems associated with that
22 from a clinical standpoint. One is that the prostate
23 has not gotten adequate radiation and the second is
24 that the patient may develop a radiation proctitis as
25 a result of the seeds being in the wrong place.

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1 Is it a requirement, is it a clinical
2 requirement, not an NRC requirement, is it a clinical
3 requirement for post implantation x-rays to be taken
4 to determine the location of the seeds?

5 DR. NAG: There is not an NRC requirement,
6 but there is a ABS recommendation, American
7 Brachytherapy Society recommendation, the panel that
8 heads that would say that you should consistently do
9 post-implantation dosimetry. So it is a
10 recommendation, not a requirement.

11 DR. MALMUD: Now it's a recommendation.
12 So the patient really should be the one who's educated
13 to ask his physician if he does routine post-
14 implantation x-rays?

15 DR. NAG: Yes.

16 DR. MALMUD: And if so, let's say that 25
17 percent of the seeds were improperly placed, will they
18 be relocated promptly if they're discovered?

19 DR. NAG: That's a problem. In a
20 permanent implant, you cannot take out seeds. You can
21 put in more seeds, so if, for example, in the post-
22 implantation dosimetry it is found that there is a
23 significant under dose, the physician has the option
24 of going back and putting a few more seeds or doing
25 some external beam radiation to make up the dose.

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1 But if you have extra seeds to certain
2 areas, like if you have extra seed to a normal tissue
3 that does not matter. That's below the prostate.
4 It's not a concern. But if the extra seed has gone
5 into the rectum, you really cannot take them back.

6 DR. MALMUD: Will that patient develop a
7 significant proctitis as a result?

8 DR. NAG: It may with the implants, it
9 may. It does not have to, but he may.

10 DR. MALMUD: What are the complications of
11 the seeds being in the wrong place?

12 DR. NAG: If it went into the bladder
13 cavity, we do a post-implant cystoscopy and we will
14 either take the seed out or the seed will be passed
15 out.

16 If it went right into the urethra or into
17 the urethra wall, then the patient is going to get a
18 lot of urethritis and the patient will be running to
19 the bathroom very, very frequently.

20 If it went into the rectum, then the
21 patient may have rectal bleeding in which case we have
22 to give them still an enema.

23 In the very worse case scenario, the
24 patient can have a fistula in which case there would
25 be a lawsuit.

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1 (Laughter.)

2 DR. MALMUD: So the physician, the
3 radiation oncologist has the option of don't look,
4 don't tell.

5 DR. NAG: Yes, right now, yes.

6 DR. MALMUD: Right now. Now getting back
7 to the NRC issue, the one that Dr. Zelac brings before
8 us which is not a clinical issue, but a radiation
9 dosimetry issue, it sounds to me not having -- not
10 being a radiation oncologist, that the window of the
11 radiation burden needs to be widened a bit, otherwise,
12 under the current regulations a number of routine
13 therapies are outside the limit.

14 Is that a fair understanding for a non-
15 radiation oncologist?

16 DR. NAG: Yes and no. It depends if you
17 are using activity criteria, then it's not a problem.
18 If you are using a dose criteria, then a significant
19 number may be outside the 20 percent issue.

20 DR. MALMUD: The activity criteria means
21 that I am implanting a certain amount of activity and
22 by definition that which I am implanting will always
23 adhere to the criteria because I haven't given more
24 than I had implanted.

25 DR. NAG: No, a certain number of activity

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1 within the volume that you want. So if more than 20
2 percent went outside the prostate, then it's an issue.
3 Or if by mistake you did a miscalculation and you
4 added 30 percent extra seed and all of them went up
5 into the prostate, then you have a problem.

6 DR. ZELAC: Dr. Malmud, we do have
7 something in the regulation that exists under medical
8 events that would cover the kind of concern that you
9 have, if it became known and that medical event is a
10 dose to the skin or an organ or a tissue other than
11 the treatment site that exceeds by 50 rem to an organ
12 or tissue and 50 percent or more of the dose expected
13 from the administration to find in the written
14 directive.

15 So if you have a defined plan and the
16 rectum is to receive, on the basis of this treatment,
17 a particular dose and because of seed misplacement the
18 rectum now receives 50 percent more than was planned,
19 and exceeding 50 rem which it certainly will if there
20 are seeds in it, then that's automatically a medical
21 event. So you essentially have in here already a
22 cover for the over dose to normal tissue, at least
23 part of it.

24 DR. MALMUD: Thank you.

25 DR. NAG: I want to point out there isn't

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1 because what do you mean by more than 50 percent of
2 the expected dose? The rectum is a huge organ. If
3 only a small portion of the rectum, the area near the
4 prostate, that will get a high dose. So now are you
5 talking about the whole rectum in which case which
6 portion of the rectum are you considering and how big
7 is a significant volume?

8 We haven't answered that question yet. If
9 you over dose 1 CM or 1 square CM of the rectum is
10 that a significant volume or if you over dose at 5 CM?
11 The question that we are trying to tackle with 3D
12 dosimetry in which we don't have access. So it is,
13 although you have it in the rule, it's not as simple
14 as the book looks like.

15 DR. WILLIAMSON: My concern is if that
16 were applied literally, again, you might get hundreds
17 of cases that are routine cases because the change in
18 the geometry of the prostate from the position of
19 maximum edemato 30 days later, that alone can change
20 the prostate or the rectal dose by 50 percent. That's
21 been shown in the literature.

22 So one has to be careful. You might use
23 it to catch cases where seeds are implanted in the
24 rectum by mistake, but if you applied the criterion
25 prospectively to all implants, depending on how you

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1 construed it, practically every implant that's ever
2 done might be captured as a medical event criterion
3 and that's my worry.

4 DR. ZELAC: That again gets back to what
5 has been suggested here that we should be using
6 activity and not dose.

7 DR. NAG: Yes.

8 DR. ZELAC: If we can use it across the
9 board, then I think we're in good shape.

10 CHAIRMAN CERQUEIRA: Thank you very much,
11 Ron. It was very enlightening.

12 Okay, then we'll move on to the last and
13 I think brief agenda item and Angela Williamson is
14 going to talk about the update recommendations from
15 the fall 2003 meeting.

16 MS. WILLIAMSON: We only had one, believe
17 it or not, just one recommendation from the last
18 meeting which was two days long, just one formal
19 recommendation that was made to staff. And actually,
20 we sort of initiated the recommendation because I came
21 to you with an issue that we were trying to resolve
22 asking for the Committee's opinion and the
23 recommendation -- the issue was should there be a
24 threshold for the treatment of hyperthyroidism?
25 Should there be a threshold of dose imposed upon

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1 licensees for the treatment of hyperthyroidism. The
2 issue was we had licensees coming in claiming to have
3 experience using levels of iodine for which we had no
4 definitive proof that they really had this experience.

5 So we were trying to determine if it was
6 appropriate for us to grant them this authorization to
7 use activities of iodine for which we didn't have
8 definitive documentation or proof that they had the
9 expertise to handle.

10 And you came back recommending to us that
11 we should have gone ahead and allowed these clinicians
12 to use basically whatever they felt was appropriate
13 for their patients. And this was initiated by
14 technical assistance request from one of the regional
15 offices, Region 1 to be specific.

16 So you came back with that recommendation
17 and we implemented that recommendation and that's
18 basically what happened and that's it. I don't really
19 expect any comments because we agreed. You gave us a
20 recommendation and we agreed with you, so --

21 (Laughter.)

22 CHAIRMAN CERQUEIRA: Dick?

23 DR. VETTER: Was the recommendation for
24 licensees or authorized users?

25 MS. WILLIAMSON: For authorized users.

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1 That's all I have.

2 CHAIRMAN CERQUEIRA: Okay. Well, I guess
3 we're done for the day.

4 Tom, do you have any --

5 MR. ESSIG: Yes, I just wanted to make a
6 clarification. The agenda that we have didn't label
7 tomorrow morning's session from 8 until 9, didn't
8 label it as either open or closed. It is, in fact,
9 open.

10 There's a caption on most of the sessions
11 except that one. It didn't and there may be some
12 confusion. Of course, the Commission briefing is
13 automatically open, but there may be some doubt as to
14 whether or not that is open and when I checked with
15 our Office of General Counsel, they informed me that
16 talking about a presentation alone is not enough to
17 justify closing the meeting to the public. So it will
18 be open. I just wanted to clarify that point for --

19 DR. NAG: Tomorrow's meeting will be here,
20 8 o'clock meeting will be here?

21 MR. ESSIG: Yes, it will. And then we'll
22 adjourn and go up over to the other building for the
23 Commission meeting.

24 CHAIRMAN CERQUEIRA: We have quite a long
25 lunch break there from 11:30 to 1 o'clock. Would

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1 there be any criticism to shortening the lunch a
2 little bit and trying to start earlier so we could end
3 earlier?

4 DR. LIETO: I have an objection.

5 (Laughter.)

6 DR. LIETO: Actually, I have a question
7 regarding the session tomorrow. Will we have the
8 slides so that we can discuss what's going to be
9 presented to the Commission? My PowerPoint
10 presentation and what other --

11 MR. ESSIG: Yes, I think we will.

12 MS. WILLIAMSON: You need a copy of your
13 slides?

14 DR. LIETO: For the whole Committee.

15 MS. WILLIAMSON: For the whole Committee,
16 okay.

17 CHAIRMAN CERQUEIRA: Certainly the first
18 two. Now are we going to see what the first two
19 presenters are going to present?

20 DR. MILLER: We're going to get
21 clarification on the agenda for tomorrow for the staff
22 presentation. There's been some updates. The staff
23 is presenting first to the Commission, as I
24 understand, is that correct, Tom? Yes.

25 MR. ESSIG: Yes.

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1 DR. MILLER: The staff is going to present
2 two items. Dr. Paperiello will represent the
3 Executive Director for Operations as is custom in a
4 Commission meeting. The Executive Director or his
5 designee, one of the Deputy Executive Directors
6 usually opens up the meeting with the Commission and
7 makes opening remarks. The he's going to turn it over
8 to me and I'll introduce the topics that we're going
9 to discuss as a staff.

10 Dr. Sherbini is not going to make a
11 presentation on the dose reconstruction tomorrow. Tom
12 Essig is going to make a presentation on the status of
13 our efforts. We're not going to get in at that time
14 into any technical discussion of the status of the
15 staff efforts. Rather, we're going to -- Tom's going
16 to walk the Commission through where we are in the
17 process which includes the Commission's direction to
18 seek your input before we proceed to finalize any
19 effort that we have.

20 Then Pam Henderson from Region 1 who is in
21 the audience, Pam, maybe you could stand up and take
22 a bow?

23 She's coming -- she's come down from
24 Region 1 and she's going to make a presentation to the
25 Commission with regard to the experiences with regard

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1 to implementation of Part 35. She's interested in how
2 it's going.

3 So there are the basic two topics that we
4 plan on presenting to the Commission. Then we'll turn
5 it over to you and we will leave the Commission table
6 and you'll go to the Commission table and discuss with
7 the Commission your topics.

8 Now along the way, the Commission may ask
9 either of us any question that they so choose at which
10 point we'll be in a question and answer period. I
11 hope that clarification helps for your planning.

12 MR. ESSIG: Yes, Dr. Cerqueira, I think
13 one thing we'll have to decide and maybe we can
14 discuss that at 8 in the morning and that is when as
15 Dr. Miller just noted, we will leave the table and the
16 Committee will sit at the table. You'll have to
17 decide because I don't think there will be room for
18 the entire Committee at the table, so you have to
19 decide some will sit at the table and some will sit in
20 the row behind the table.

21 MS. WILLIAMSON: Just to let everyone
22 know, there are going to be reserved seats, not with
23 specific names, but in the audience for the ACMUI that
24 is not presenting. For those members not presenting,
25 there will be reserved seats. You'll just see some

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1 sort of sign on a row of seats saying ACMUI.

2 CHAIRMAN CERQUEIRA: Well, I think besides
3 myself, I think certainly the two presenters, Ralph
4 and Dr. Malmud who should also be there as the co-
5 chair of the Committee and I think perhaps the dose
6 reconstruction, we should have Jeff at the table
7 because he's actually done most of the work on this.
8 And even though -- now we'll decide tomorrow what
9 we're actually going to say because based on this
10 morning's discussion we're not going to go into much
11 detail because we didn't have enough information
12 available to us to really make any kind of definitive
13 statements, but I think we could certainly have --

14 MR. ESSIG: I think you'll find that Dr.
15 Malmud has already given that considerable thought.

16 CHAIRMAN CERQUEIRA: Okay.

17 MR. MCKINNEY: One of the things I know
18 that the Commission will push both of us on is when
19 are you going to give us an answer. So we probably
20 should think about that overnight for tomorrow
21 morning's discussion as to what we're going to say in
22 that regard.

23 DR. MALMUD: With respect to when we would
24 have an answer ready, we could probably have the
25 review of the NRC data and Jeff's data and have a

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1 report completed between two and four weeks. Which
2 figure are you comfortable with, Jeff?

3 DR. WILLIAMSON: Well, it depends on how
4 narrow or broad we interpret our mandate to be. I
5 think on the narrow issue of this particular incident,
6 two to four weeks is reasonable. I would say four
7 weeks.

8 (Laughter.)

9 DR. MALMUD: Four weeks. Then it will be
10 four weeks.

11 DR. WILLIAMSON: I think I'm echoing a
12 well-established precedent in this Committee,
13 defaulting to the longer time. But I think it's worth
14 bringing up the other issues we'd like to consider,
15 that is, how do manage this small number of members of
16 the general public that have some valid reason for
17 being included in treatment rooms and potentially
18 getting higher doses in the regulatory limit and we
19 may want to offer, I think, we should take advantage
20 of this opportunity to think a little more broadly and
21 deeply about the issue of dose reconstruction and do
22 our best to try to articulate some general guidelines
23 that help avoid a loss of confidence in the staff's
24 calculations.

25 DR. WILLIAMSON: The issue that we're

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1 dealing with though we could complete and have a
2 report to the NRC by -- in four weeks. Let's say four
3 weeks.

4 DR. WILLIAMSON: I think that's reasonable if we
5 get the data promptly. A lot depends on I guess the
6 complexity, but I wouldn't anticipate longer than
7 that.

8 DR. MALMUD: Very good. And the other
9 issue about how we would deal with incidents such as
10 this in the future is an item that we should probably
11 be prepared to deal with by collecting some data and
12 recommendations from a variety of members of the
13 Committee because this is a double-edged sword. On
14 one hand, we don't want the dose estimates to be under
15 -- to be inaccurate in being -- under-measuring the
16 radiation burden. At the same time, in order to
17 reduce public anxiety, we don't want them to be
18 excessively conservative in over-estimating the burden
19 because that subjects members of the public to undue
20 pain and suffering in terms of their own anxiety about
21 what they're experiencing or have experienced.

22 I'd rather deal with the two issues
23 separately, as you suggest. We'll give the first
24 report within four weeks and a number of the issues
25 that we'll be facing, we would not have faced had this

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1 issue been dealt with internally at that licensee, but
2 it's after the fact now. So let's just separate the
3 two and we'll deal with the first issue and then the
4 second.

5 DR. WILLIAMSON: Yes. There's actually
6 three issues, I believe.

7 DR. MALMUD: What's the third?

8 DR. WILLIAMSON: The three issues, the
9 narrow question that we're going to report on in four
10 weeks.

11 DR. MALMUD: Yes.

12 DR. WILLIAMSON: Having to do with the
13 dose calculation for the specific incident.

14 DR. MALMUD: Right.

15 DR. WILLIAMSON: The second issue is the
16 management of patient's relatives who -- where it is
17 warranted, maybe in allowing them to have doses higher
18 than the regulatory limit.

19 DR. MALMUD: Right.

20 DR. WILLIAMSON: The third issue is
21 observations on dose reconstruction, in general, with
22 the ultimate goal to try to enhance the scientific
23 credibility of future dose calculation, avoid such
24 problems in the future.

25 DR. MALMUD: Very good. I'll just ask you

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1 one question so the rest of the Committee can hear it.
2 Would you like the issue of high dose, low dose, most
3 likely dose to be dealt with in answering Question 1
4 or in answering Question 3? The reason that I ask the
5 question is that the deficiency is not in the
6 physicist's calculation of the numbers. It is in
7 getting the data from the licensee upon which the
8 assumptions are made for exposure in terms of time and
9 distance.

10 DR. WILLIAMSON: Well, I think the issues
11 are interconnected.

12 DR. MALMUD: Of course.

13 DR. WILLIAMSON: And it might well be that
14 in four weeks when we make our final report, one of
15 the recommendations might be that the issue should be
16 studied more broadly and hence, we can move forward
17 from there. But I think in the interest of trying to
18 satisfy the Commission's need to have an independent
19 review of this particular incident, I really think it
20 should be issues one, two and three and one needs to
21 be dealt with quickly and two and three can be given
22 a more measured and not leisurely, necessarily, but
23 since they are more general issues I think they have
24 to be deliberated more carefully in that longer length
25 than the four-week period.

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1 DR. MALMUD: Then we will separate the
2 three and just deal with Issue 1 within four weeks.

3 DR. WILLIAMSON: That's correct. That's
4 what I would suggest.

5 DR. MALMUD: Does anyone -- Mr. Chairman?
6 I ask the Chairman of the Subcommittee, does anyone
7 object to that approach?

8 DR. EGGI: No, and I think as we
9 reconstruct the dose for Part 1 that we should take
10 the approach that the regulation suggests which is the
11 most probable dose rather than the worst case
12 scenario.

13 DR. WILLIAMSON: I think that's
14 reasonable.

15 DR. MALMUD: We agree that that's
16 reasonable. The issue is the problem that the NRC
17 faces the problem that Jeff faces, the problem that we
18 face in looking at this is that we don't have the
19 database. We haven't seen the database in adequate
20 detail from the licensee to make a most probable
21 estimate because some of the data isn't there. The
22 measurements were not taken with great frequency and
23 therefore in many instances it might be more
24 acceptable to say worst case/best case/most likely
25 recognizing that there's a range. That would explain

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1 what has happened and what may happen in the future
2 and that's why I, given my preference, would prefer to
3 deal with the first and third issues together. It
4 would explain a lot of the reasoning. It's not the
5 over-aggressivity of some physicists versus others.
6 It's the fact that the data isn't there to have made
7 these precise calculations.

8 DR. EGGLI: It's actually more than that.
9 I think it has to do with the most reasonable
10 assumption to fill in the gap.

11 DR. MALMUD: Agreed.

12 DR. WILLIAMSON: I think it's very
13 abstract. We're wandering off into abstraction and
14 speculation and I think we'll just have to wait until
15 we see the data, until we can make a conclusion about
16 how closely linked 1 and 3 are. You may well be
17 right.

18 DR. NAG: I'm wondering whether we perhaps
19 add a fourth issue under the same thing and that is
20 what if the licensee had issued the proper warnings,
21 but the patient or the patient's relative willfully
22 and knowingly took a dose over the limit and in that
23 case -- right now, we are penalizing the licensee when
24 really the licensee is not at fault.

25 DR. WILLIAMSON: I think that's part of

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1 Issue 2.

2 DR. MALMUD: That is part of Issue 2. You
3 are correct, and we intend to deal with that in Issue
4 2 because the issue may arise again in which any
5 licensee may tell a very intimate relative of someone
6 who is dying that if he or she exposes himself to the
7 patient during this period of time, when there's so
8 much radioactivity within the patient, that they're
9 going to receive a radiation burden which exceeds a
10 level that's permissible. But there are some tactics
11 which could be used other than physically constraining
12 the individual which we're not recommending be done,
13 to alert the individual to the danger that he or she
14 is placing himself in, the potential danger, since
15 even this radiation burden is not carcinogenic, and it
16 would be convenient to have those techniques available
17 to RSOs who are not familiar with them and to
18 licensees who are not familiar with them as a means of
19 encouraging people to be aware of what they're
20 exposing themselves to, other than verbal, putting a
21 radiation monitor on them that beeps, putting a badge
22 on them, etcetera, etcetera, giving them educational
23 material to read while they're there.

24 These things may heighten the individual's
25 concern about his own well-being and thereby lead to

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1 more cooperative behavior. None of these is a
2 guarantee, but they're all techniques which we
3 probably should document in some fashion as means
4 available to inform individuals in a humane way that
5 they are both breaking rules and putting themselves at
6 risk.

7 CHAIRMAN CERQUEIRA: Tom?

8 MR. ESSIG: Just one more comment
9 unrelated to our current discussion. I wanted to pick
10 up on and kind of respond to a couple of comments that
11 were made earlier this morning regarding the interval
12 between the current meeting and the previous one and
13 why it was so short. The reason that we've scheduled
14 this meeting now is because we didn't have any control
15 over the Commission meeting tomorrow. That date was
16 given to us. Our option was to assemble this
17 Committee early and knowing that the interval was much
18 shorter than the nominal six months, and the other
19 option we could have said is well, come in for the
20 Commission meeting and then come back in again maybe
21 two months later. We opted not to do that to save, to
22 combine -- make better use of our travel funds and
23 that sort of thing. So I thought maybe those of you
24 that weren't clear on that -- we didn't -- we do have
25 some flexibility over the Committee meeting itself,

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1 when it's scheduled, but we do not control when the
2 Committee meets with the Commission. And we were
3 given the date of March 2nd and so we lived with that
4 the best we could.

5 CHAIRMAN CERQUEIRA: Last year, we ended
6 up having two separate meetings and we actually met
7 with the Commissioners. A large part of the Committee
8 was not able to make it and that was not desirable.

9 All right, well, I think we'll end it
10 here. Thank you.

11 (Whereupon, at 4:33 p.m., the meeting was
12 concluded.)

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