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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING

OPEN SESSION

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Monday, October 27, 2008

The meeting came to order at 9:00 a.m. in T2B3 of White Flint 2, Leon Malmud, MD, Chairman, presiding.

ACMUI MEMBERS PRESENT:

LEON S. MALMUD, MD, CHAIRMAN

RICHARD J. VETTER, PHD, VICE CHAIRMAN

DOUGLAS F. EGGLE, MD, MEMBER

DARRELL R. FISHER, PHD, MEMBER

DEBBIE B. GILLEY, MEMBER

RALPH P. LIETO, MEMBER

STEVEN R. MATTMULLER, MEMBER

SUBIR NAG, MD, MEMBER

ORHAN H. SULEIMAN, PHD, MEMBER

BRUCE R. THOMADSEN, PHD, MEMBER

WILLIAM A. VAN DECKER, MD, MEMBER

JAMES S. WELSH, MD, MEMBER

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1 PRESENT: (cont.)

2 MICKEY GUIBERTEAU, MD, DIAGNOSTIC RADIOLOGIST

3

4 NRC STAFF PRESENT:

5 STEVE BAGGETT

6 CHRIS EINBERG, DESIGNATED FEDERAL OFFICER

7 CINDY FLANNERY, ALT DESIGNATED FEDERAL OFFICIAL

8 OSSY FONT

9 DONNA-BETH HOWE, PHD

10 ROBERT LEWIS, DIRECTOR

11 JIM LUEHMAN, DEPUTY DIRECTOR

12 ANGELA MCINTOSH

13 GRETCHEN RIVERA-CAPELLA

14 TERRY REIS, DEPUTY DIRECTOR

15 ASHLEY TULL

16 DUANE WHITE

17 RONALD ZELAC, PHD

18

19 MEMBERS OF THE PUBLIC PRESENT:

20 ROBERT ATCHER, SNM

21 ROY BROWN, CORAR

22 TOM BURNETT, MDS NORDION

23 HUGH CANNON, SNM

24 WILL DAVIDSON, UPENN

25 RICHARD EATON, MITA

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1 BRIAN ERASMUS, MDS NORDION

2 LYNNE FAIROBENT, AAPM

3 PRESENT (cont.):

4 EMILY GARDNER, ASNC

5 JIM HAGERMAN, MDS NORDION

6 BONNIE HAMILTON, MDS NORDION

7 MIKE PETERS, ACR

8 DOUG PFEIFFER, AAPM

9 SAM PUTNAM, SIRTEX

10 RICHARD MARTIN, ASTRO

11 JOHN REDDINGTON, SIRTEX

12 WILLIAM RILLING, FROEDTERT MEDICAL CENTER

13 GLORIA ROMANELLI, ACR

14 JOE SALDARINI, SIRTEX

15 REED SELWYN, UNIF SVCS UNIV OF HLTH SCI

16 HARRY SKENE, GEISINGER

17 MICHAEL SOULEN, HOSP OF THE UNIV OF PENN

18 CINDY TOMLINSON, SNM

19 ANN WARBICK-CERONE, MDS NORDION

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Adjourn

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P R O C E E D I N G S

9:02 a.m.

CHAIRMAN MALMUD: It's now 9:02 and if we may we will resume the session, opening the public session. I would invite -- Chris, are you going to -- just give us a minute to sit down.

In addition, I would again remind us that for the court stenographer, it is useful to introduce your statement by giving your name and therefore it will make this daunting task a little easier. Thank you.

We are also welcoming today as a guest, Mickey Guiberteau, welcome. Good to see you again. It's been a number of years.

DR. GUIBERTEAU: Thank you, yes.

CHAIRMAN MALMUD: And with that, I will ask Chris to begin the session.

MR. EINBERG: Thank you. As the Designated Federal Officer for this meeting, I am pleased to welcome you to Rockville for the public meeting of the ACMUI.

My name is Chris Einberg. I am the Chief of the Medical Safety and Events Assessment Branch. And I have been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR part

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1 7.11.

2 Present today as the Alternate Designated
3 Federal Officer is Cindy Flannery, the Team Leader for
4 the Medical Radiation Safety Team. She was here.

5 This is an announced meeting of the
6 Committee. It is being held in accordance with the
7 rules and regulations of the Federal Advisory
8 Committee Act and the Nuclear Regulatory Commission.
9 The meeting was announced in the September 22nd, 2008
10 edition of the Federal Register, Volume 73, page
11 54635.

12 The function of the Committee is to advise
13 the staff on issues and questions that arise on the
14 medical use of byproduct material. The Committee
15 products counsel to the staff, but does not determine
16 or direct the actual decisions of the staff or the
17 Commission.

18 The NRC solicits the views of the
19 Committee and values their opinions.

20 I request that whenever possible, we try
21 to reach consensus on the various issues that we will
22 discuss today, but I also recognize that there may be
23 minority or dissenting opinions. If you have such
24 opinions, please allow them to be read into the
25 record.

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1 Part of the preparation for this meeting,
2 I have reviewed the agenda for members and employment
3 interests and based upon the very general nature of
4 the discussion that we are going to have today. I
5 have not identified any items that would pose a
6 conflict.

7 Therefore, I see no need for an individual
8 member of the Committee to recuse themselves from the
9 Committee's decisionmaking activities. However, if
10 during the course of our business, you determine that
11 you have a conflict, please state it for the record,
12 and recuse yourself from the particular aspect of that
13 discussion.

14 At this point, I would like to introduce
15 the individuals seated at the table today. Dr. Leon
16 Malmud is the Chairman. He's a healthcare
17 administrator. Dr. Richard Vetter, Vice Chairman of
18 this Committee, Radiation Safety Officer. Dr. Subir
19 Nag, Radiation Oncologist. Mr. Ralph Lieto, Nuclear
20 Medicine Physicist. Dr. Douglas Eggli, Nuclear
21 Medicine Physician. Dr. Orhan Suleiman, FDA
22 representative. Dr. William Van Decker, Nuclear
23 Cardiologist. Dr. Jim Welsh, Radiation Oncologist.
24 Dr. Darrell Fisher, Patient Advocate. Dr. Bruce
25 Thomadsen, Medical Physicist Therapy. Mr. Steve

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1 Mattmuller, Nuclear Pharmacist. Ms. Debbie Gilley,
2 State Government Representative.

3 I would like to mention that Dr. Mickey
4 Guiberteau is representing the Diagnostic Radiologist.

5 Dr. Guiberteau does not have voting privileges, but
6 he will listen and speak on behalf of the Diagnostic
7 Radiologists. I would like thank Dr. Guiberteau for
8 acting in this capacity.

9 Dr. Leon Malmud, ACMUI Chairperson, will
10 conduct today's meeting. Following a discussion of
11 each agenda item, the chair at his option may
12 entertain comments or questions for members of the
13 public who are participating with us today.

14 That concludes my opening statement.

15 CHAIRMAN MALMUD: Thank you, Chris. Rob?

16 MR. LEWIS: Well, good morning, everyone.

17 I think Chris covered it very well. I'm Robert
18 Lewis. I'm NRC's Director of the Division of Material
19 Safety and State Agreements. Let me extend NRC's
20 welcome as well to the Members of the Committee and
21 also to Dr. Guiberteau. Thank you for coming and
22 providing your expertise.

23 The work of the Committee is absolutely
24 essential towards our mission regarding safety and
25 security and effectiveness and efficiency of our

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1 regulatory process. And your advice is invaluable in
2 that regard. And I do want to note that since our
3 last meeting we've had several significant
4 accomplishments that are on the agenda for the next
5 two days. Looking forward to on-going discussions on
6 those issues. For example, we had recently a workshop
7 on potential phaseout of cesium chloride as a
8 radioactive material used in a lot of relationship
9 applications as well as a lot of radiation. The
10 Committee supported that workshop in a very superb
11 way. And we thank the Committee for that and we look
12 forward for the Committee's report on their view of
13 the efficacy of cesium chloride versus alternative
14 technologies.

15 We also had made several -- we made a lot
16 of progress on permanent implant brachytherapy
17 rulemaking. The rule is currently out for public
18 comment. Public comments are due on that rulemaking,
19 I think next week and we look forward to continuing to
20 engage the Committee and the members of the public on
21 that rulemaking. We will, as I understand, the
22 Committee intends to comment on the rule. For the
23 public comment process, we will take those comments
24 and respond to them, share the responses with the
25 Committee as we move forward.

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1 Also, fingerprinting. We have issued, as
2 of June of last year, of this year, fingerprinting
3 requirements for all of our increased controls,
4 licensees, and we have thanked the Committee for their
5 input at the Commission meeting on that issue and we
6 have made substantial progress. If there are ongoing
7 issues with fingerprinting that you're experiencing,
8 please let us know. We still have time to work
9 through those before the effective date of December.

10 So thank you very much. We have -- as I
11 said, on the agenda, we have all of those topics, as
12 well as many more and the Committee is certainly very
13 busy and I think I should be quiet and let's get to
14 the agenda.

15 CHAIRMAN MALMUD: Thank you, Rob. We'll
16 move on to the next item on the agenda which is item
17 four, old business, and Ashley Tull will make the
18 presentation.

19 Ashley?

20 MS. TULL: Good morning. If you'll turn
21 to, I believe it's Tab 4, there should be a big list.

22 I have all of the 2007 and 2008 recommendations. I'm
23 going to start with the 2007 ones. I tried to
24 highlight several of them for anything that's changed
25 or has been updated or we've made progress or it's

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1 been closed, things like that. So I'm not going to go
2 through everything, but you have them all. If you
3 have a question on one of them, you can ask me. But
4 I'm going to go through the bolded ones which starts
5 with number two. It should say 2007 at the top.

6 NRC staff should remove the attestation
7 requirement. We found the right page yet?

8 CHAIRMAN MALMUD: It's the second page of
9 Tab 4.

10 MS. TULL: It's the second page behind the
11 tab. Sorry. Okay, NRC staff should remove the
12 attestation requirement for Board-certified
13 individuals and rewrite the attestation requirement
14 for individuals seeking authorization under the
15 alternate pathway. The rewritten attestation should
16 not include the word "competency" but should instead
17 read, "has met the training and experience
18 requirements."

19 Ron Zelac is currently working on a SECY
20 paper for this, and it's agenda item 14, so we will be
21 discussing this later. But this is still an open
22 item.

23 Number three, NRC staff should revise the
24 regulations so that Board-certified individuals who
25 are certified prior to the effective date of

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1 recognition or were certified by previously recognized
2 Board listed in subpart J of the previous editions of
3 part 35 are grandfathered. And again, this is
4 something Ron Zelac is working on and we are currently
5 drafting a letter to the Boards and Ron will talk more
6 about that. It's agenda item 10 today.

7 We're going to jump down item 10. NRC
8 staff should allow more than one RSO on a license with
9 a designation of one RSO as the individual in charge.

10 NRC should create a regulatory issue summary to
11 inform the regulated community of NRC's interpretation
12 and the RIS should be sent to ACMUI and the agreement
13 states for review and comment. The draft RIS was sent
14 to you. Ralph has provided comments and on behalf of
15 the Committee, so we will discuss that. It's agenda
16 item nine.

17 As I'm kind of going through each one of
18 these, these are just to let you know they're still
19 open items. There was an overall recommendation to
20 keep following up on these things, so this is just to
21 let you know that these are still on the front page
22 and still issues that we are dealing with.

23 The next one is item 30, the Electa
24 Perfexion should be regulated under 10 CFR 35.1000
25 until 10 CFR 35.600 is modified to performance based

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1 which would allow the Perfexion to be regulated under
2 10 CFR 35.600. This will be added to the user need
3 memo and will be considered for rulemaking. So we all
4 know rulemaking is a process and takes time, so we'll
5 keep this one open and I'll keep letting you know
6 where it is in the process.

7 If you could turn over to the back, items
8 38, 39, 40, 42, and 43 all have to do with the
9 yttrium-90 microspheres guidance and I'll read through
10 each one of them quickly. NRC staff should revise the
11 microspheres guidance to allow the written directive
12 to include either dose to target tissue in gray or rad
13 or activity administered in millicuries or
14 gigabecquerels.

15 39. NRC staff should revise the
16 microsphere guidance to include a paragraph
17 referencing medical event reporting for microsphere
18 use.

19 40. NRC staff should revise the
20 microsphere guidance to reinsert their proposed
21 paragraph with modification. The paragraph should
22 state procedures for administrations requiring a
23 written directive should for yttrium-90 microsphere
24 administration be performed in accordance with the
25 written directive.

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1 42. NRC should revise the microsphere
2 guidance to add a paragraph which states training in
3 the manufacturer's procedures, commensurate with the
4 individual's duties to be performed must be provided
5 to individuals preparing, measuring, performing
6 dosimetry calculations or implanting microspheres.

7 43. NRC staff should revise the
8 microsphere guidance to read the written directive
9 should include after implantation, but before release
10 of the patient from licensee control. The
11 radionuclide, including the chemical in physical form
12 of yttrium-90 microspheres, the manufacturer, the
13 treatment site, and the total dose or administered
14 activity, all of these changes were approved by the
15 Committee and have been incorporated into the guidance
16 as it is on the web right now. So that was a big task
17 for all of us.

18 45. ACMUI should form a subcommittee to
19 address issues with 35.600 as they relate to the
20 Electa Perfexion. This subcommittee actually already
21 gave us the reports and that is the recommendations
22 from item 30 where we said Electa Perfexion should be
23 regulated under 1000. So those two are tied together.
24 And the subcommittee has done their work on that.

25 Dr. Welsh?

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1 MEMBER WELSH: Ashley, number 43, it says
2 partially accepted, whereas the other is relevant to
3 the yttrium-90 microspheres say accepted. Is there a
4 difference there?

5 MS. TULL: I believe -- I don't have a
6 copy of the guidance in front of me. The intent is
7 the same. It just doesn't read exactly like the
8 Committee had recommended. I don't have a copy of the
9 guidance right in front of me, but what does it
10 actually say? Release of the patient -- I believe
11 it's from the post-operative recovery room. We had
12 that discussion before they are released. I believe
13 that's the wording, from the post-recovery, post-
14 operative --

15 MEMBER NAG: The license control, I think
16 most post-operative recovery area rather than the
17 licensee control.

18 MS. TULL: I'm trying to find the exact
19 wording. It has to do with post-procedural.

20 MEMBER NAG: Right. When we are talking
21 about permanent implant, we had decided when were
22 making a permanent impact rules that the timing would
23 be from the post-operative -- that the post-operative
24 recovery area and -- but they're still under licensing
25 control. Here, in licensing control, it would be before

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1 the needs of the patient from the post-recovery area.

2 CHAIRMAN MALMUD: Perhaps you could get us
3 the wording a little bit later in the meeting?

4 MS. TULL: It is. Is there a microphone
5 over here?

6 MR. BROWN: Do you want a wireless?

7 MS. TULL: How about this. I will print
8 off a copy of the guidance and give it to you. It was
9 something that was discussed and it's not a major
10 change. It goes back to the 2008 recommendations that
11 we're going to cover. And it's the wording from the
12 2008 recommendations that basically replace this.

13 I'll print off copies and give it to you.

14 CHAIRMAN MALMUD: Thank you.

15 MS. TULL: Okay, so jumping to the 2008
16 recommendations --

17 MEMBER EGGLI: Actually, it's in 11.

18 MS. TULL: Yes, it's the post-operative
19 versus post-procedural. We revised that. Yes.

20 CHAIRMAN MALMUD: Back on the -- this is
21 Malmud. We're now back on the other page of 2008
22 recommendations?

23 MS. TULL: Yes.

24 CHAIRMAN MALMUD: Which item are we
25 looking at now, number 11?

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1 MS. TULL: Number 11, NRC staff should
2 make all changes as proposed except on page 2, the
3 word post-operative should be replaced with post-
4 procedural. That's the wording that replaces the 2007
5 wording. Does that answer your question?

6 CHAIRMAN MALMUD: Thank you.

7 MS. TULL: It was an ACMUI approved thing
8 that made this partially accepted. You modified one
9 of your previous recommendations. But I will print
10 copies and give everyone that.

11 CHAIRMAN MALMUD: Thank you.

12 MS. TULL: Okay, so number for the 2008
13 recommendation. NRC staff should provide the basis
14 for the decision to only allow one RSO per license.
15 This was a closed item. We provided emails from the
16 OGC during the last meeting.

17 We will be discussing it though as agenda
18 item nine. So this is an on-going issue.

19 NRC staff should pursue rulemaking to
20 allow more than one RSO on a medical use license with
21 the indication of one RSO as the individual in charge.

22 Again, this is going to be agenda item 9. It's an
23 open item.

24 3. NRC staff should promptly notify ACMUI
25 members in a separate memo when an ACMUI

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1 recommendation is not accepted. I think that this is
2 a practice that we've picked up and we'll continue to
3 do.

4 4. ACMUI should form a subcommittee which
5 includes Dr. Darrell Fisher, Mr. Ralph Lieto, Dr.
6 Bruce Thomadsen, as the chair; and Dr. Richard Vetter.

7 The subcommittee's charge is to evaluate the efficacy
8 and cost of cesium chloride versus current and
9 proposed x-ray technologies and cobalt. And this is a
10 subcommittee report that was actually submitted on
11 October 13th. So if you want to mark this as closed,
12 it is actually a closed item now.

13 5. NRC staff should incorporate the
14 subcommittee's recommendations for the Gamma Knife
15 Electa Perfexion in future rulemaking. Again, we will
16 add this to the user need memo. It is in the process.

17 6. Dr. Subir Nag suggested ACMUI form a
18 subcommittee to discuss the permanent implant
19 brachytherapy rulemaking. The subcommittee would
20 include Dr. Nag, Dr. Bruce Thomadsen, and Dr. James
21 Welsh. The subcommittee would consult with other
22 knowledgeable individuals as necessary. This motion
23 did not pass, but was later, if you look at item 14,
24 there was a subcommittee formed that actually did
25 this. So we'll get to that.

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1 7. Dr. Leon Malmud requested the NRC
2 staff email Dr. Nag separately once the permanent
3 implant brachytherapy proposed rule is published.
4 That was done and the email was sent on August 7th.

5 8. NRC staff should arrange a public full
6 Committee teleconference meeting in July to discuss
7 the permanent implant brachytherapy rulemaking. That
8 did happen. The item is closed as of July 21st.

9 9. NRC staff should revise the abnormal
10 occurrence criteria to read: a medical event that
11 results in (1) death, or (2) a significant impact on
12 patient health that would result in permanent
13 functional damage or a significant adverse health
14 effect that would not have been expected from the
15 treatment regimen as determined by an NRC or agreement
16 states designated consultant physician.

17 This is in progress and actually we talked
18 to the Office of Research. They are the ones who are
19 responsible for revising this abnormal occurrence
20 criteria and they have indicated that in 2009 they
21 will be open to revisions. So our group, our medical
22 group will send our proposed revisions to Research in
23 2009. Until then, we'll keep this item open.

24 10. NRC staff should incorporate the
25 three hands-on, in vitro, simulated cases approach as

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1 proposed during the meeting. Additionally, NRC staff
2 should indicate when it is appropriate for a licensee
3 to submit a license amendment to add the authorized
4 user or yttrium-90 microspheres to the license.

5 Lastly, NRC staff should add a statement
6 to the guidance to require the manufacture to proctor
7 the first three cases performed by an authorized user.

8 This was accepted and it is included in the current
9 guidance.

10 11. NRC staff should make all of the
11 changes as proposed, except on page two, the word
12 post-operative should be replaced with post-
13 procedural. This goes back to the issue that we were
14 just discussing.

15 This has been incorporated and is in the
16 current guidance.

17 12. NRC staff should send an EDO daily
18 note indicating the ACMUI discussed the part 35
19 permanent implant brachytherapy rulemaking at the July
20 21st ACMUI teleconference. We did send that out on
21 July 24th.

22 MEMBER THOMADSEN: Question?

23 MS. TULL: Yes.

24 MEMBER THOMADSEN: What's EDO?

25 MS. TULL: Executive Director of

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1 Operations.

2 MEMBER THOMADSEN: Thank you.

3 MS. TULL: It's us notifying upper
4 management of something that went on at the staff
5 level. So they're aware that you discussed that.

6 13. NRC staff should proceed with -- this
7 is SECY 08-0080. It's just a formal document that
8 staff members sent to the Commission. It was
9 suggested that NRC staff should proceed with this
10 document and publish the proposed rule in the Federal
11 Register as directed by the Commission. That is
12 closed. The SECY paper did go up. The Commission
13 approved it. The proposed rule is published and we
14 have draft comments from the Committee and we will be
15 discussing those comments further later during this
16 meeting.

17 14. ACMUI should form a subcommittee for
18 the permanent implant brachytherapy rulemaking. The
19 subcommittee's charge is to meet within the next two
20 weeks to prepare ACMUI's comments on the proposed
21 rulemaking. The subcommittee includes Dr. Nag as the
22 chair; Mr. Ralph Lieto; Dr. Bruce Thomadsen; Dr.
23 Richard Vetter; and Dr. James Welsh. And this is
24 still on-going and in progress since we will wait for
25 a final report from the subcommittee, once we have a

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1 discussion later today.

2 The proposed comment period is expected to
3 end on November 7th. Now that was extended
4 officially.

5 15. NRC staff should provide a status
6 update on the technical basis for the Rittenour or the
7 AAPM petition at the October 2008 meeting. That is on
8 the agenda, item 10. So we will be discussing that.

9 16. NRC staff should distribute request
10 letters for information on the individuals impacted by
11 the Rittenour or the AAPM petition to the certifying
12 boards as well as the professional societies.

13 I believe there's a draft letter in your
14 binders behind Tab 10 and Dr. Ron Zelac will be
15 covering this in more detail during his presentation.

16 17. NRC staff shall allow the
17 manufacturers to continue to use their current
18 standards for proctoring the first three patient cases
19 for new authorized users for Sirtex. At least the
20 first two cases will be proctored by a physician and
21 from the MDS Nordion, all three cases will be
22 proctored by an MDS Nordion employee.

23 This has required no change to the
24 guidance, so the guidance stood as it was written.

25 Any questions on any of those

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1 recommendations or any others?

2 CHAIRMAN MALMUD: Are there any questions
3 for Ashley Tull?

4 Are none.

5 MS. TULL: Okay, we will keep sending you
6 updated charts.

7 CHAIRMAN MALMUD: Thank you.

8 (Pause.)

9 CHAIRMAN MALMUD: Once again, we are ahead
10 of the agenda. May we move on to the next item which
11 is the Cesium Chloride Subcommittee report. Will that
12 be acceptable?

13 Dr. Thomadsen?

14 MEMBER THOMADSEN: This is great. This as
15 you've heard was the subcommittee that we were
16 directed to form and look at issues regarding
17 replacement of cesium chloride irradiators. And the
18 Committee was set up because of the Report of the
19 National Research Council which suggested that the
20 cesium chloride irradiators be phased out and
21 eliminated.

22 And we were directed by the Commission to
23 address those issues. And the three issues --

24 MS. TULL: Really quickly -- the handout
25 that's in your binder is actually a draft subcommittee

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1 report. It's dated July 22nd, I believe. And I'm
2 passing around the -- it's dated in September. This
3 is the October 13th report, which is the final
4 subcommittee that was approved by the full Committee
5 via email.

6 So please pull out what's in your binder
7 and replace it with the handouts that are coming out.

8 (Pause.)

9 MEMBER THOMADSEN: The three issues that
10 we addressed was the need for cesium-37 chloride
11 irradiators viable alternatives and the current
12 security.

13 Addressing the need for irradiators, there
14 are several uses that they perform. One is the
15 radiation of blood products. The original report that
16 came out assumed that approximately 10 percent of the
17 blood in the U.S. was irradiated and that is the blood
18 used in blood transfusions.

19 Discussions that a subgroup of the
20 subcommittee had with hematologists and oncologists
21 indicated that for these practices the value was
22 somewhere between 15 and 40 percent depending on the
23 particular practice. In patients involved with
24 hematology and oncology with particularly depressed
25 immune systems and that's why the irradiated -- that's

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1 why the blood needs to be irradiated.

2 The lower number in the report probably
3 comes from a higher fraction of trauma cases and that
4 may be a factor of where the survey was done that was
5 included in the original report.

6 So the -- for the trauma cases irradiation
7 of the blood is irrelevant since it's not a matter of
8 immune system response, but just getting blood back
9 into people who are often in accidents.

10 The other uses that these irradiators have
11 is for animal irradiation where a lot of the research
12 is done, particularly for stem cell research and other
13 systemic therapies where you need whole body radiation
14 of the animal, often mice, before infusion, so that
15 you can eliminate the animal's blood marrow before you
16 would be infusing other bone marrow into the patient
17 into the animals rather.

18 The use for animal irradiation is growing
19 as the research on stem cell is growing. And of
20 course, it may soon lead to other treatments for
21 currently untreatable conditions, so the use of the
22 irradiation in animals is very definitely a great
23 benefit to the society.

24 If we just summarize the need for
25 irradiators without the irradiators available,

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1 hematology and oncology patients would suffer
2 potential death from the lack of irradiated blood.
3 Without the irradiators available, much of the stem
4 cell and systemic drug research could not be able to
5 proceed.

6 The Committee then looked at alternatives
7 at cesium 137 chloride irradiators. And the
8 alternatives are conventional x-ray units or linear
9 accelerators. Both have been and are used for blood,
10 animal, and material irradiation. The conventional
11 irradiators, in the report, we go through a number of
12 the models that are available.

13 For blood irradiation, only one of those
14 units is FDA approved. Another one is up before the
15 FDA at the moment, from my understanding. The
16 National Research Council listed the price for these
17 units as \$180,000, with \$10,000 a year for service
18 contracts. We looked at the prices. The current
19 prices seemed to be closer to \$250,000 with around
20 \$33,000 per year for the service contract.

21 Replacement tubes are not counted under
22 that service contract, and would be extra. As is
23 calibration and quality management, which would be
24 required to a much greater extent than with the cesium
25 chloride units. So the expenses are considerable for

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1 replacing a cesium chloride unit with a conventional
2 x-ray unit.

3 Throughput is lower for the x-ray
4 machines, with 48,000 blood product units that have to
5 be irradiated. And x-ray tubes would last about, at
6 the rate of about 50 units per day, would last about
7 3.7 years. So the replacement tubes would have to be
8 replaced about every four years on an average. As we
9 mentioned in the last slide, this adds to the cost of
10 running the machine.

11 For animal irradiation, there are about 10
12 x-ray units available. Most of them are lower energy,
13 around 160 kVp. Very few are above the 200 kVp, and
14 that limits the use to, use in animal irradiation
15 because of the lack of penetration. Most of the
16 prices range between \$146,000 and \$250,000, again,
17 plus the service contracts, all of which run around
18 \$10,000 per year.

19 They do have cheaper units, but they are
20 of the low energy type with short distances, which
21 means that penetration is very small and have small
22 field sizes, again, limiting their use for the animal
23 irradiation.

24 There is also the question of whether the
25 x-ray units can actually replace the cesium chloride

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1 as standards for animal irradiation. The relative
2 biological effectiveness of the irradiation is
3 different, possibly by a factor of two with the lower
4 energy units. That's not a good, hard fixed number.
5 The relative biological effectiveness is not well
6 known, and in addition to that it depends on the
7 species, it depends on the biological endpoint in
8 addition to the energy of the radiation.

9 The dose rates can have an effect on the
10 biological effectiveness as well, which can change how
11 the animal would respond to a given dose, and also if
12 the dose rates are lower, which they usually are in
13 these x-ray machines compared to the cesium, it makes
14 giving anesthesia for the animals more difficult, and
15 you end up having to use drug anesthesia as opposed to
16 gas.

17 The penetration, or the lack thereof,
18 requires irradiating animals from several directions
19 as opposed to the cesium irradiators, where you can
20 just put the animals in and shoot them in one
21 procedure.

22 Use of medical linear accelerators has
23 been used for blood and for animals. We used to use
24 that, must be 25 years ago, for the blood irradiation
25 in the hospital. It was very inconvenient both for us

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1 and for the blood bank before they got their cesium
2 irradiator. It can be done. It presents a challenge,
3 particularly in a busy facility as far as timing and
4 who is going to be doing the irradiation. But it's
5 also a problem when people need the blood after hours,
6 and you have to train the blood bank people in either
7 running the accelerator or you have to have a call
8 schedule for the technicians running the accelerator
9 to come in.

10 If you are not using the radiotherapy
11 department's linear accelerator, but trying to get an
12 accelerator for the blood bank proper, the price
13 becomes quite an impediment at around \$1.5 million as
14 a start.

15 Turning our attention to the security of
16 these devices, because it was the security that was
17 raising the issue for the National Research Council.
18 Since the time that the Council looked at these units,
19 several things have changed.

20 The security of the users has been
21 enhanced through the required background checks and
22 fingerprinting. The security of the facility has been
23 enhanced following the directives of the NRC, and I'll
24 point out such as in our place sometimes at great
25 expenses to the facility.

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1 And finally, there is the security of the
2 units themselves which there is a program with the DOE
3 and DHS to harden the machines themselves, to make it
4 much less likely that somebody who does get passed the
5 facility's security could get into the source proper.

6 So following these three security
7 enhancements, the units present little hazard for
8 unauthorized source removal or disruption. The lack
9 of such security was a major factor in the original
10 report so the current situation doesn't really --
11 doesn't compare with what the original report was
12 looking at.

13 Summarizing all of our results, the
14 irradiation facilities are essential for the
15 irradiation of blood and research. It's -- their loss
16 would be a great detriment to our society, the health
17 and well-being of the people of this country.

18 Forced replacement of 137 cesium chloride
19 based units would force many facilities to stop
20 irradiating because of the great expense to replace
21 the units. Also, to keep them going once you replaced
22 it.

23 A few of the facilities, as most of the
24 facilities are nonprofit and few have resources for
25 funding and new x-ray unit or maintaining the unit and

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1 since the time that we wrote this report and the
2 economy has tanked, there was just an article in
3 today's USA Today about the money that goes into
4 nonprofits which has essentially stopped going into
5 nonprofits. So the likelihood that all of these
6 places could replace their units is dwindling.

7 If not leading to the termination of
8 irradiation, the replacements would place an
9 incredible financial burden on these facilities which
10 have little funding.

11 While the x-ray units have been used for
12 blood, animal, and material irradiation, the
13 difference in the RBE complicates just simple
14 replacement and at the moment just the exchange
15 wouldn't provide the same quality radiation that we
16 are used to.

17 And finally, the enhanced security
18 programs for the 13 cesium chloride units make
19 replacement unnecessary.

20 Thank you.

21 Questions?

22 CHAIRMAN MALMUD: Thank you, Dr.
23 Thomadsen. Are there questions for Dr. Thomadsen?

24 CHAIRMAN MALMUD: Dr. Eggli?

25 MEMBER EGGLI: Not too much as a question,

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1 but a comment on using linear accelerators for
2 radiating research animals. In the Commonwealth of
3 Pennsylvania that violates Department of Health
4 regulation. It requires a special exemption so that
5 would be another additionally limiting factor using
6 linear accelerators for animal research.

7 If a human is used on the machine by DOH
8 regulation you can't do an animal without a special
9 exemption from the state.

10 MEMBER THOMADSEN: Thank you.

11 CHAIRMAN MALMUD: Other comments.

12 MEMBER NAG: I would like to make a
13 comment here that the radiation oncology immunity uses
14 ceramic form of cesium chloride, not cesium chloride,
15 cesium in ceramic for a low dose rate therapy and that
16 should not be confused -- this is going to a public
17 place and the public just sees cesium and cesium and
18 they just confuse one with the other.

19 MEMBER THOMADSEN: I'm sorry?

20 MEMBER NAG: Would you like to amplify on
21 that?

22 MEMBER THOMADSEN: No, you're absolutely
23 correct.

24 MEMBER NAG: The other one is cesium 131
25 which is another new radioactive material that is

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1 being used for therapy again the layperson may confuse
2 that with the cesium 137 chloride.

3 CHAIRMAN MALMUD: Thank you, Dr. Nag, your
4 point being that both the ceramic enclosed cesium and
5 the cesium 131 are not issues of concern in this
6 discussion?

7 MEMBER NAG: right.

8 CHAIRMAN MALMUD: Thank you. Other
9 comments?

10 Rob.

11 MR. LEWIS: Thank you to the subcommittee
12 for this work. I would echo what Dr. Nag said that
13 currently the nonchloride forms of cesium are limited
14 to a matter of tens of curies just from a material
15 science property of production.

16 So the smaller sources of industrial uses
17 and in medical uses tend to be ceramic or glass
18 whereas the chloride form is only used in large
19 sources such as blood irradiation or research
20 irradiation or calibrators.

21 But I would ask the Committee to pull on
22 that issue a little bit. Given the cost you
23 described, if there was a ceramic form at a large
24 curie quantity available, if some fundamental research
25 was done and production was available, that's a big

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1 if, whether that's possible, would replacement of the
2 chloride form be attractive to hospitals?

3 You can speculate a little bit.

4 CHAIRMAN MALMUD: Dr. Vetter?

5 MEMBER VETTER: I'd like the chair to go
6 first.

7 CHAIRMAN MALMUD: I'm sorry, I didn't see
8 your hand. Dr. Thomadsen.

9 MEMBER THOMADSEN: I didn't put it up. I
10 was --

11 CHAIRMAN MALMUD: Region One is on the
12 line. Region One? I beg your pardon? We'll move on
13 if we may with Dr. Thomadsen.

14 MEMBER THOMADSEN: The Committee, in the
15 actual report, it's mentioned that we considered that
16 issue and originally in one of the graphs we had a
17 recommendation that manufacturers --

18 CHAIRMAN MALMUD: Could I ask the people
19 on the telephone to mute your phones please?

20 MS. TULL: It is.

21 CHAIRMAN MALMUD: On VTC as well. Thank
22 you. I see you just did.

23 MEMBER THOMADSEN: But as we discussed
24 this issue, two items came up. One was that the
25 manufacturer, which is not in this country, has

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1 indicated that at the moment, at least, changing the
2 form to something solid would present a hazard to
3 those involved in the manufacturer, and they were not
4 interested in trying to work on that.

5 More importantly, however, the Committee
6 was not convinced that the solid form would actually
7 provide a safer source, and that may not be a
8 justifiable recommendation. The Committee is not
9 convinced that it would make a less safe source. It
10 just didn't feel that there was the research there to
11 make such a recommendation.

12 CHAIRMAN MALMUD: Thank you, Dr.
13 Thomadsen.

14 Dr. Vetter?

15 MEMBER VETTER: Just one further comment,
16 which is more of a question. We did not have the
17 information to tell us whether the activity
18 concentration would be equivalent, and if the ceramic
19 source, it actually occupies larger volume, it is
20 possible that it simply could not be done in our
21 current irradiators. You couldn't simply switch out
22 the sources.

23 MR. LEWIS: It would be a lower specific
24 activity.

25 MEMBER VETTER: Consequently, we may not,

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1 it may not be practical to switch the sources out,
2 which means you would have to trade units in again.
3 We'd be back to the same question of trying, of
4 affordability.

5 CHAIRMAN MALMUD: Dr. Nag?

6 MEMBER NAG: Yes, I'm not sure, but I do
7 know there has been advances in the ceramic industry,
8 so that if this were a high enough priority, the
9 ceramic industry would be able to find some ways of
10 getting enough of the cesium into its ceramic form.
11 So the first thing then becomes, is it more important
12 to release it on an electronic or electrical version
13 that will make the cesium all together, or is it more
14 important for us to find research or to do research to
15 find ways of getting higher quantity of cesium in some
16 safer form. I think that has to be explored.

17 CHAIRMAN MALMUD: Thank you, Dr. Nag. Dr.
18 Suleiman?

19 MEMBER SULEIMAN: I attended the cesium
20 workshop along with Debbie Gilley, and let me share
21 some of my observations.

22 Bottom line, cesium 137 seems to be more
23 reliable, a little bit less expensive, than
24 alternative technologies. The technical differences,
25 notwithstanding, I think the transition to a non-

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1 cesium source would be feasible, but wouldn't be
2 necessarily cheap. It would cause a lot more
3 problems. I think the report also emphasizes the fact
4 that we think with the enhanced security and other
5 aspects, why do you want to eliminate it? There's a
6 comic that somebody made, and I repeat it myself, we
7 did not ban airplanes after 9/11.

8 So I think this is, you know, maybe
9 terminating a technology that is really the best
10 technology out there. I was also surprised at how
11 widespread it was in terms of calibration standards
12 internationally, just not in the country. I knew it
13 was used for calibration purposes, but I didn't
14 realize that it was almost like the de facto standard
15 for radiation metrology.

16 The other thing I think I would like to
17 clarify, which I learned going through this whole
18 process, that the big issue here is really the powder
19 form, and the thing that's been obvious to me is that
20 with all the technology and metallurgy, you know, why
21 isn't there a solid form of it?

22 And what distressed me personally was
23 because we don't manufacture this in this country, we
24 get it from the Russians from their Maya facility and
25 it is part of reprocessing. It's not their reactor

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1 operation, it is their reprocessing of spent fuel.

2 And so, talking with people at the
3 meeting, I'm convinced, I said you ought to make them
4 have a million dollar award, but I'm convinced that a
5 solid form of the cesium source is feasible,
6 notwithstanding some attenuation characteristics or
7 whatever. I think it was a drastic difference, but we
8 get back to the, the Russians seemed to be preoccupied
9 with other, they're the only site in the world that's
10 doing this, and so to start manufacturing from a
11 technical, from a solid form on a large scale would be
12 creating some occupational issues that they were
13 concerned with.

14 Again, I don't think those are insolvable.

15 I think those are all addressable, but you're dealing
16 with one source and so I think the technical problems
17 are resolvable. I think the economic issues are
18 feasible, and I also second, because I raised it also.

19 I question whether the solid form would be any less
20 secure or more secure. You can't predict what a
21 terrorist, I don't have a terrorist manual that tells
22 me how terrorists behave.

23 Even though the powder form is more
24 dispersable, there are hazards associated with the
25 solid bolus of material as well. But I think

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1 everybody is sort of, the consensus I felt was that,
2 don't panic, you know. Come up with some
3 technological solutions to maintain that source.

4 CHAIRMAN MALMUD: Thank you, Dr. Suleiman.

5 Other comments?

6 Dr. Nag?

7 MEMBER NAG: When we had reviewed this
8 last year what I remember the powder form easily put
9 it into a dispersing material and it flows up into the
10 air so although the radiation level is not high it is
11 easily dispersed and is something you cannot clean up.

12 The solid form, even if you do explode it, you can
13 shut down, or gather it up, clean it up a lot faster
14 and therefore that represents less of a problem.

15 MR. LEWIS: We are dancing on some
16 nonpublic information. What you said is okay, but we
17 wouldn't want to go any further about dispersing.

18 MEMBER NAG: That was a public -- it is a
19 public comment.

20 MR. LEWIS: What you said was fine.

21 CHAIRMAN MALMUD: Dr. Fisher?

22 MEMBER FISHER: Darrell Fisher. Having
23 the assignment of reviewing the impact of NRC guidance
24 to licensees on source security especially with
25 respect to blood irradiators, I was impressed with the

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1 degree to which licensees have gone to providing safe
2 and secure facilities.

3 For example, one institution with 4 cesium
4 137 blood irradiators that are used primarily in
5 research had located these irradiators in places in
6 facilities that were highly secure, only accessible
7 through multiple locked entries with coded entry pads
8 with several layers of video monitoring, with limited
9 access to a select group of highly-trained users, with
10 high level of coordination with local law enforcement
11 on both protection of these facilities and local
12 response to a breach of security.

13 It almost seemed as though these
14 facilities were protecting these sources to a degree
15 of overkill. Nonetheless, I found them to be highly
16 safe and secure. In addition, the units themselves
17 had been secured with additional steel locks. It
18 seemed almost incomprehensible that even a
19 knowledgeable person could gain entry to and access
20 and remove a cesium-137 source from these irradiators.

21 And that the impact of improved security as Dr.
22 Thomadsen has mentioned has to a large degree
23 eliminated the need for source replacement to find
24 alternative sources.

25 The other interesting aspect of this

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1 review was the importance of cesium chloride in a
2 research setting, that merely substitution for an x-
3 ray source would provide enormous scientific hardship
4 on institutions that were using cesium chloride in
5 stem cell research to develop new treatments for
6 cancer.

7 From a patient rights perspective, it did
8 not seem that the change out of sources would be
9 beneficial to research and that the forced change in
10 irradiator types would actually be detrimental to on-
11 going research and could cause not only excessive cost
12 to federally-funded medical research, but also
13 significant delays in on-going research without a
14 perceived benefit of any kind.

15 CHAIRMAN MALMUD: Thank you, Dr. Fisher.

16 Do you wish to respond, Rob?

17 MR. LEWIS: Sure. Again, we thank the
18 Committee and the subcommittee for their efforts on
19 cesium chloride.

20 The next step -- I do want to address one
21 point that was made. The National Academies Panel was
22 aware of the enhanced security of facilities of NRC
23 and agreement state licensees. It did occur after
24 they started their report, but they were in place by
25 the time they had finished their report and they were

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1 aware of those -- I don't want to put words in their
2 mouths, certainly, but they made the recommendations
3 in full awareness of those and they thought cesium
4 chloride merited additional security beyond that of
5 all of the nuclides because of its dispersibility and
6 potential attractiveness or criminal acts.

7 The next step will be for the NRC staff to
8 develop a Commission paper which will include an
9 attached ACMUI report and it will also consider the
10 results of the workshop, the National Academies
11 Report, our own visits to each of the vendors for
12 cesium chloride, and additional work we've done with
13 Department of Homeland Security and the Department of
14 Energy on this topic. That Commission paper is due in
15 about a month. And some portion or version of it will
16 be public so that we can provide the Commission all
17 the options they need to make a policy decision on
18 this matter and I think we also are going to be
19 looking at the existing facilities, existing
20 irradiators that have been in place and have paid for
21 themselves at this point long ago, as well as any new
22 licensees that are looking to be an irradiator and
23 whether down the road in the long term we can do some
24 kind of fundamental research that will make an
25 attractive replacement for those new licensees at the

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1 very least, but may be for all licensees.

2 And although the paper will be
3 forthcoming, we need to realize that despite the
4 economic and the scientific arguments, and practice of
5 medicine arguments that are being brought to bear on
6 cesium chloride issue, there is an increasing
7 expectation by Congress and by members of the public
8 that something needs to be done. In fact, legislation
9 was drafted and introduced into both the House and the
10 Senate that would essentially phase out this material.

11 And what you have provided in this report
12 and through your support at the workshop will be our
13 best defense, if you will, against those types of
14 political arguments and provide the Commission the
15 ammunition they need to make a sound policy, public
16 policy. So thank you very much.

17 CHAIRMAN MALMUD: Thank you. Any other
18 comments? I want to thank you all --

19 MEMBER NAG: Not me.

20 MEMBER GILLEY: I just have a procedural
21 question. Now that the ACMUI has given the report to
22 NRC and it will be part of the recommendations that go
23 to the Commission, will this ever be a public document
24 or able to share?

25 MS. TULL: Yes.

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1 MEMBER GILLEY: After the final report is
2 done --

3 MS. TULL: I just distributed it within
4 NRC and kept it there for now. Your report is final,
5 as ACMUI, but I really wanted to kind of hold the
6 report back until the full report went to the
7 Commission with all cesium chloride recommendations.
8 At that point, I'll actually put it as a subcommittee
9 report on the ACMUI website.

10 MEMBER GILLEY: Thank you.

11 MR. LEWIS: And if we are on procedural
12 issues, another one might be did the full Committee
13 want to consider the subcommittees, or do we need to
14 --

15 MS. TULL: It was voted on email.
16 So it is final.

17 MEMBER NAG: Could I have a question? I
18 understand that another cesium chloride, round table
19 meeting or something, that you all went to. What is
20 the relation between the two? Is the ACMUI committee
21 report and round table do they have any relation to
22 each other, they are totally separate or what? Were
23 you referring to some other --

24 CHAIRMAN MALMUD: Are you talking about
25 the workshop?

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1 MEMBER NAG: Workshop. What are the two -
2 - could someone give me a differentiation between the
3 two and --

4 MR. LEWIS: They are unrelated. They are
5 independent data points that will go into the
6 Commission paper.

7 MEMBER NAG: And what was the workshop?
8 What was that?

9 MR. LEWIS: The workshop was a public
10 workshop and it had several roundtable sessions on
11 various topics. We brought in industry, other
12 government agencies, other foreign agencies, to talk
13 about many of the things that are talked about in this
14 paper, but to just give us a separate industry and
15 government and member of the public point of view on
16 moving forward.

17 MEMBER NAG: This one is only a medical
18 use.

19 MS. TULL: Dr. Malmud, this is Ashley, and
20 to answer Dr. Nag's question, ACMUI was formally
21 invited. We asked Dr. Thomadsen as the subcommittee
22 chair to attend. He was unable to attend, but Debbie
23 Gilley and Dr. Suleiman came on behalf on ACMUI and
24 basically just translated what was in the report that
25 was approved by the full Committee.

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1 MR. LEWIS: Your report was not provided
2 at the workshop.

3 MS. TULL: No, but the viewpoints.

4 CHAIRMAN MALMUD: Thank you, Ashley.

5 Does that address your concern, Dr. Nag?
6 Thank you.

7 That ends this discussion. We will now
8 take a break at 10 o'clock to resume at 10:15 with the
9 next item on the agenda, which will be the
10 Fingerprinting Subcommittee report by Dr. Vetter. So
11 thank you. A 15 minute break.

12 (Off the record.)

13 CHAIRMAN MALMUD: As we get together,
14 Ashley Tull has some handouts for us, and we'll --
15 those will be passed out as soon as you all have a
16 chance to get to your seats.

17 MS. TULL: This is Ashley. The first
18 handout is the microspheres guidance that I promised a
19 few minutes ago. And if you look on the second page,
20 there is a number 2 that's kind of highlighted.
21 That's the actual sentence that we were discussing for
22 the recommendations, so if you want to focus on that,
23 that's the final outcome. And the second handout is
24 the fingerprinting report that's in your binder. It's
25 dated July 22nd. This is an August, so this is the

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1 final Subcommittee report that was approved by the
2 Full Committee via email. So if you'll pull out
3 what's in your binder for Tab -

4 CHAIRMAN MALMUD: Six.

5 MS. TULL: Six. This replaces that. And
6 the microspheres guidance that's coming around, if you
7 want to stick it in your binders behind Tab 8, we're
8 going to have a microspheres discussion later today.

9 CHAIRMAN MALMUD: Thank you. If you will
10 turn to Tab 6. Dr. Vetter will introduce the subject.
11 Dr. Vetter.

12 MEMBER VETTER: Thank you, Dr. Malmud.

13 At the last opportunity that we had to
14 address the Commission, we brought up the issue of
15 fingerprints, and that many licensees were having
16 difficulty with the fingerprinting requirements. As a
17 result of that, a Subcommittee was appointed to
18 examine fingerprint options to improve efficiency, and
19 reduce costs for licensees. The team members were
20 Ralph Lieto, Dr. Bruce Thomadsen, and myself.

21 Rather than go through -- I don't have a
22 set of slides, and rather than go through the report
23 line-by-line, I'd just like to focus on the last
24 section of the report, which is basically conclusions,
25 "How to Decrease Costs and Increase Efficiency".

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1 You'll find that on the last page of the report. I'll
2 wait for a moment here as we flip things around. And
3 I apologize, my remarks are based on the report that
4 was provided to us. Let me just quickly review and
5 see if there's -- okay.

6 So how to decrease costs and increase
7 efficiency. First of all, under Item 1, actions that
8 licensees could consider, use fingerprints submitted
9 under other state and federal requirements. For
10 example, if for purposes of using biological
11 materials, if your institution was registered with
12 CDC, and individuals had to have fingerprints, and
13 these individuals also needed to be fingerprinted for
14 purposes of the T&R requirements, you could actually
15 request the NRC to allow you to use those.

16 That requires some -- if you go to
17 Paragraph 3 of the order, which we don't have in front
18 of us, but if you go to those procedures, that
19 requires quite a bit of paperwork, and it's probably
20 easier simply to re-fingerprint. And, to the best of
21 my knowledge, that's what licensees were, in fact,
22 doing.

23 Number 2, reduce the number of people
24 approved for unescorted access. For instance, by
25 pairing up, or designating one person in a laboratory

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1 to do the irradiations, or two or three people, rather
2 than everyone. And, in fact, some licensees, I think,
3 we doing that to a fairly limited extent, however,
4 because schedules and cost schedules depend on who's
5 available, and in order to assure that someone is
6 available to do the irradiation all the time, it gets
7 to be a little bit complicated. And so I think in
8 most cases, the laboratories, blood banks, in
9 particular, simply felt it would be impractical to do
10 that, so they designated a rather large fraction of
11 their people to actually go through the T&R, including
12 the fingerprinting. But that's something in the
13 future that labs, as they get more comfortable with
14 this requirement, could continue to explore.

15 Three, isolate irradiator in a small room
16 to reduce the number of people who need access. Large
17 blood banks actually had the irradiator in a rather
18 central location in the lab, and there were many, many
19 people who could walk by that. They didn't all use
20 it, but they were all in this very large lab where the
21 irradiator was located. And by moving the irradiator
22 to a smaller room and locking that room, as Dr. Fisher
23 mentioned earlier, he observed that some licensees had
24 done that. In fact, that has become a rather common
25 practice.

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1 It's expensive to do that. If you build
2 another room, you build some walls and a door, and you
3 put a security lock of some sort on it, that can be
4 several thousand dollars, so it's expensive for labs
5 to do that. But, in fact, in the long run, it does
6 turn out to be justifiable, even though it is a bit
7 costly, because it does reduce the number of -- it
8 does, number one, increase security. And, number two,
9 it decreases the number of people who have to go
10 through the T&R process.

11 Point Four or D in our report, research
12 facilities could establish a core facility. A core
13 facility is a small laboratory that's been set up to
14 do a very specialized procedure. So, for instance,
15 they might have a core procedure for mass
16 spectroscopy, and if any -- or core procedure for
17 doing PCA analysis. And so, if a laboratory didn't
18 want to set up that particular procedure, but had some
19 research where they needed to utilize that, they could
20 simply pay the core facility do it for them.

21 For irradiator, I talked to several
22 different researchers, the Committee talked to several
23 researchers who didn't think a core facility for
24 irradiation was a good idea. It's setting up a
25 specialized laboratory where you have to hire -- you

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1 probably have to hire someone to be there and operate
2 it. And it gets to be a problem with scheduling, as
3 well. And researchers don't like other people
4 controlling their schedules.

5 In fact, those of you who are familiar
6 with research facilities know that they work 24/7, so
7 the core facility I think is probably not practical
8 for most facilities, but it is an option that larger
9 research facilities could consider.

10 Point F, if employees have to travel some
11 distance -- did I skip one? Yes, okay. E, sorry, I
12 skipped Point E. The order allows relaxing certain
13 requirements for specific individuals, so an example
14 is someone with an active federal security clearance
15 would not have to go through the fingerprinting. So,
16 for instance, in my own case, I could have requested
17 the documentation from the NRC confirming that I have
18 a security clearance. And I could have sent that
19 documentation in for a -- to request a special
20 exemption from the fingerprinting requirements. And
21 we could probably guess how long all of that would
22 take, or when our security unit was in our area doing
23 all of the fingerprinting for all of those individuals
24 in our building, I could have taken the 10 minutes it
25 took me to walk across the hall and get my

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1 fingerprints done. So, obviously, that's what I
2 chose.

3 So even though the order does allow
4 relaxing certain requirements for specific
5 individuals, it does require a fair amount of
6 paperwork, and the paperwork may, in fact, be onerous.

7 It is an option people can consider, and perhaps in
8 some small number of cases it is justifiable to do
9 that. But I think most licensees would find that to
10 be onerous.

11 F, if the employees must travel some
12 distance, like 20 miles for fingerprinting, perhaps
13 they could arrange for their own licensee security, or
14 local law enforcement to do the fingerprinting on
15 site. That is something that I think should be
16 considered. That's not always workable either,
17 though. In fact, a couple of licensees told me that
18 local law enforcement would not do the fingerprinting
19 for them. They simply didn't want to get involved in
20 this NRC business, and so they ended up traveling to
21 another jurisdiction 20 miles away.

22 Well, if you have a large number of people
23 who have to do that, that's considerable amount of
24 time, considerable impact on the time that those
25 people have at work, so what they should explore, if

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1 they haven't already, is setting up a time when that
2 jurisdiction would actually come to their own facility
3 and fingerprint a large number of people at one time.

4 Then under actions that the NRC or others
5 should consider to remove obstacles for licensee, we
6 considered two things. One is that licensees have,
7 and, frankly, they continue to experience
8 unclassifiable fingerprint cards. Some tell me as high
9 as 25 percent. I think a more realistic number, a
10 more typical number is 10 percent or less.
11 Nevertheless, there are some individuals whose
12 fingerprints simply come back unclassifiable. And in
13 my own case, we had 10 individuals that we've gone in
14 six times, and we have now asked -- Minnesota is now
15 an agreement state, so we have asked for an extension
16 of the deadline for those 10 individuals. And,
17 frankly, we're trying to explore options now. We
18 don't know what we're going to do at this point, but
19 the state did give us an extension on the fingerprint
20 deadline for those 10 individuals.

21 What's puzzling about this is I have not,
22 and my experience is very limited, but I or other
23 members of the Committee have not heard about any
24 problems when fingerprinting physicians for licensing
25 purposes. But in those cases, the fingerprints are

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1 done through local law enforcement to the FBI. In the
2 case we're discussing here with T&R, they're first
3 going to the NRC, and then they go to FBI. And we
4 don't understand what all happens in that process,
5 but, apparently, we're just more or less guessing
6 here, the fingerprints -- we think the fingerprints,
7 the images are being degraded somewhere along the way.

8 And so, for a very small number of people, especially
9 those who have skin conditions, the fingerprints
10 simply are coming back unclassifiable.

11 We don't know what the solution to that
12 is. We propose, perhaps, there is a way to look at
13 this in a jurisdictional manner that would allow the
14 licensee to have local law enforcement take the
15 fingerprint and send it directly to FBI, rather than
16 through the NRC. We don't know if that would help or
17 not, but it, perhaps, is an option. But there is a
18 small number of people, real people, real workers for
19 whom we are unable to get classifiable fingerprints.
20 And that issue simply must be addressed, and we don't
21 know -- the licensees are simply sort of stuck. So
22 the NRC, we're asking that the NRC take a look at
23 that, and remove those obstacles.

24 And finally, the Committee recommends that
25 the NRC should address portability of results; that

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1 is, transfer of T&R determinations from one licensee
2 to another so that when an individual who's granted
3 unescorted access at one institution moves to another
4 institution, they could transfer that T&R, or at least
5 the fingerprinting portion of that. Perhaps, in a
6 manner analogous to exposure history requests, where
7 we can simply write to another licensee and get the
8 exposure history of that individual when they come to
9 work for us, or perhaps there's a national registry of
10 some sort that could be set up, or there may be some
11 other process to accomplish portability of results.
12 But we would like to see something done, so that when
13 an individual who's been granted unescorted access at
14 one institution doesn't have to go through the entire
15 process when they transfer employers.

16 And that is our report. Would Mr. Lieto
17 or Dr. Thomadsen like to add anything?

18 CHAIRMAN MALMUD: Additional comments? I
19 want to thank you all for the effort on behalf of this
20 item. As you will recall, we are responding to a
21 request from an authority higher than our own with
22 respect to the need to do the fingerprinting. And,
23 therefore, our response was not an argument for or
24 against the fingerprinting. We understand that it
25 will be done. The question is, how can it be done

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1 most efficiently? And this is the Subcommittee's
2 report with regard to those issues.

3 Did I understand that what you said could
4 be interpreted as when the fingerprints go directly to
5 the FBI, they have a very high rate of acceptability,
6 but when they go through another agency first, that
7 the number of rejects is up to 25 percent?

8 MEMBER VETTER: That's stating it a little
9 bit more confidently than the Subcommittee is. We
10 simply have not heard of any problems associated with
11 physician fingerprints that are sent directly from
12 local law enforcement to the FBI. We've not heard of
13 any problems. We don't know if any exist, but in my
14 own case when I asked about that, physicians said no,
15 we've never heard of any problems in that regard.
16 That doesn't mean some didn't exist. But in this
17 particular case, we are hearing of problems when we
18 talk to RSOs at other institutions, that
19 unclassifiable fingerprints are fairly common. A
20 small number, but -

21 CHAIRMAN MALMUD: Thank you.

22 MEMBER VETTER: We're simply guessing that
23 there is something different about the process that
24 results in degrading the fingerprints when they are
25 going through the NRC first, rather than directly to

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1 the FBI.

2 CHAIRMAN MALMUD: One other item that you
3 mentioned was questioning the need to re-fingerprint
4 when relocating to another institution.

5 MEMBER VETTER: Right.

6 CHAIRMAN MALMUD: But let's say that there
7 is another educated, distinguished, good-looking
8 gentleman, such as yourself, who purports to be
9 yourself as he transfers from the Mayo Clinic to
10 another institution, but is not you, and yet has an
11 I.D. that says he is you. How would that person be
12 confirmed as being you without fingerprints?

13 MEMBER VETTER: I suppose in any other way
14 that an institution who would hire me confirms that
15 it's really me, regardless of the fingerprinting
16 issue. I don't have a good answer for that.

17 CHAIRMAN MALMUD: Is there any other --
18 because it may be that we're raising a question for
19 which there already is an answer, and that is that
20 they either have another way, or there is no other
21 certain way. I don't know the answer. Rob?

22 MR. LEWIS: Well, on that particular
23 point, and there is a question, I believe, in our
24 fingerprinting questions and answers, so it was raised
25 before of, can a doctor who works at many different

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1 hospitals use the first hospital's result at the
2 subsequent hospitals? And the answer is yes and no.
3 I mean, you can use the first fingerprinting result,
4 but each hospital has to have its own T&R
5 determination, because each hospital -- one hospital
6 might say I don't want anybody with unescorted access
7 that has any criminal record. The second hospital
8 might say I don't want anybody with unescorted access
9 without a felony. Since the individual licensees can
10 define their T&R, then you can use the original
11 fingerprinting result, but you put them through your
12 own process at a subsequent facility. And that's the
13 way it's set up. Whether that's the most efficient is
14 something we're interested in feedback in, but that's
15 just the way we've asked people to do it.

16 MEMBER VETTER: If I could just react,
17 just very briefly. The intention of the Subcommittee
18 was to recommend some sort of a process whereby the
19 individual wouldn't have to be re-fingerprinted. We
20 certainly do understand, as Mr. Lewis explained, that
21 each facility has to do its own T&R.

22 CHAIRMAN MALMUD: I wanted to thank you
23 again for a very thorough -- you and the Subcommittee
24 for a very thorough job.

25 I think that Chris wanted to say

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1 something.

2 MR. EINBERG: Yes. Thank you, Dr. Malmud.

3 Thank you, Dr. Vetter, and the Subcommittee for this
4 report. I'll respond to a couple of the points you
5 made, but I just want to let you know what has
6 happened to your Subcommittee report. We've
7 transmitted this to the Commission through a
8 Commission Assistance Note so the Commission has a
9 copy of your Subcommittee report.

10 Additionally, this Subcommittee report has
11 been provided to the Rulemaking Working Group that's
12 dealing with fingerprinting, so they'll be using it
13 for this in their consideration as they move forward
14 in codifying the fingerprinting.

15 To now address some of your points that
16 you raised. You raised some good points, and I want
17 to take time to clarify some of the issues that you
18 did raise. Regarding the rejection rate, you
19 indicated that some licensees, may be as high as 25
20 percent.

21 I did speak to our Office of
22 Administration, who processes the fingerprints for
23 NRC, and handles the submissions of fingerprints, and
24 they confirmed that there are some very high rejection
25 rates with certain licensees. Overall, the rejection

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1 rate is approximately 7 percent, and they attribute
2 the high rejection rate for certain licensees to
3 perhaps the lack of experience in taking fingerprints.

4 And so, licensees that tend to use local law
5 enforcement who are trained to do fingerprints have a
6 lower rejection rate.

7 For those licensees that are experiencing
8 difficulties, they do refer the licensees to the FBI's
9 website, and does give some guidance on taking
10 fingerprints. The FBI and other local law enforcement
11 and professional organizations do offer training in
12 regards to taking fingerprints, so that's available to
13 licensees to decrease the rejection rate, as well.

14 Regarding submittal of fingerprints
15 directly to the FBI by either local law enforcement or
16 by licensees, that's not permitted under the Energy
17 Policy Act. The Energy Policy Act basically states
18 that the fingerprints must be submitted by the NRC to
19 the Department of Justice, which is, in essence, the
20 FBI. And so, under the current law, there is no
21 mechanism for submitting fingerprints directly to the
22 FBI. It has to go through the NRC, and so that's why
23 there's that second step. And that pertains for
24 agreement states, also, so agreement state licensees
25 have to submit their fingerprints to the NRC, and NRC

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1 forwards those fingerprints to the FBI.

2 MR. LUEHMAN: Can I interject there,
3 Chris, for just a second?

4 MR. EINBERG: Sure.

5 MR. LUEHMAN: And one of the reasons for
6 that is that -- well, there's two reasons. One is,
7 that the NRC does -- our Office of Administration does
8 do a quality check, not necessarily just of the
9 fingerprints, but of the cards themselves before they
10 go to the FBI. That's Point A, but then Point B is
11 that if you -- when you go to the FBI directly, if you
12 went to the FBI directly, they have to have, and we
13 have to have verification that your requesting the
14 right kind of check. I mean, the FBI can run checks
15 in all sorts of databases. They can run them on
16 individual databases, they have a number of different
17 databases, and one of the things that sending them --
18 the reason the Policy Act was written the way it was
19 was, the NRC will insure that the right check is being
20 requested. Because, again, the FBI can run through a
21 number of databases, or they can run specifically
22 through one database, depending upon what the check is
23 being done for. So that's an administrative burden
24 that the FBI doesn't want to do. They want to get the
25 Agency to make sure that the checks are classified for

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1 the proper series of checks, or a single check that
2 has to be done. So those are some of the reasons
3 behind, I think, why the Energy Policy Act says what
4 it does.

5 MR. EINBERG: Thank you, Jim.

6 To kind of clarify some of the other
7 points, also, address some of the other
8 recommendations that you made, Dr. Vetter. You had
9 recommended that perhaps there is a master list, or a
10 list of entities that are authorized to approve
11 fingerprints. And the NRC cannot endorse a list of
12 entities who are authorized to perform fingerprinting.

13 We do have a question and answer that's
14 developed, Supplemental Q&A, Number 3. And,
15 basically, that says you can have your local law
16 enforcement agency, or other authorized individuals
17 take fingerprints, but we cannot get into the business
18 of endorsing a list of entities, because, inevitably,
19 there's going to be somebody who's left off that list,
20 and has reason to be dissuaded about that, to put it
21 lightly.

22 And then just to also echo a point that
23 Ron made about the portability of the fingerprint
24 results, or the T&R determinations. Basically, Ron
25 did correctly indicate that each individual licensee

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1 is responsible for making their own trustworthiness,
2 reliability determinations based on their own
3 criteria. Each licensee will have their own criteria
4 for determining who's trustworthy and reliable.

5 For the fingerprinting results to be
6 transferred from one licensee to another, written
7 permission has to be given by the individual
8 requesting that the first agency who requested the
9 original fingerprints release those fingerprints.
10 Now, anecdotally, when we were giving the workshops
11 around the country on this, a lot of licensees said
12 that they would probably be reluctant to provide or
13 release those types of records, because of liability
14 concerns. And so, most likely, the second licensee,
15 or the new licensee would need to request the
16 fingerprints once again.

17 Those are the only points that I wanted to
18 address.

19 CHAIRMAN MALMUD: Thank you. Mr. Lieto.

20 MEMBER LIETO: Well, two points. One, I
21 think I really would challenge your statement that
22 licensees would be reluctant to transfer that
23 information at the request of the individual. You do
24 it all the time for film radiation badge records, and
25 I think the inconvenience of repeat fingerprinting, I

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1 think that you would find that the individual would be
2 more than willing to have that information
3 transferred. So there may be some licensees that are -
4 - may have expressed some reluctance, but there may be
5 questions more to the fact of if the information would
6 violate some confidentiality issues. And I think,
7 again, the NRC could go a long ways to answering those
8 questions by emphasizing the fact that that can be
9 done.

10 The other point that I wanted to make
11 about the unclassifiabes is that it's my
12 understanding that the ink card method of
13 fingerprinting is not the standard practice with most
14 law enforcement, or with law enforcement agencies
15 period. So the high rejection rates -- we're
16 experiencing high rejection rates, and we're using one
17 of the same agencies that's endorsed by our state
18 police. So it may be that what you say is true, that
19 there may be a problem with people's experience in
20 doing this, but it also relates to the fact that the
21 ink card method is a very time consuming, because they
22 have to send it in, it has to be looked at, and then
23 you get the rejection notice. It comes back. We
24 still aren't in compliance with the order, because
25 we're still going through this unclassifiable re-

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1 fingerprinting methodology. And I think the intent
2 was to have everybody done by I think what, June? And
3 so, I think if there would have been some acceptance
4 early on that you could go ink card or electronic, I
5 think there would have been a lot more of the
6 individuals not being rejected than there are. And I
7 think we're still going to have the problems with the
8 ink card methodology.

9 CHAIRMAN MALMUD: Mr. Luehman.

10 MR. LUEHMAN: To respond to that, I agree.

11 I mean, I think that the standard is rapidly becoming
12 the electronic, because, in fact, the electronic --
13 the system can tell you whether you've got -- right
14 away whether you've got an acceptable set of prints.
15 Unfortunately, I don't think -- the availability of
16 that is not uniform across the large numbers and types
17 of licensees that are involved in this. But to the
18 extent that that's accessible to them, I think you're
19 correct, that the electronic is the way to go.

20 That having been said, the FBI does, in
21 fact, our working group that considers this, which is
22 the IICWG, which is the Increased Controls Working
23 Group, has just - we've just approved a supplement to
24 a question and answer on this, because even despite
25 electronic and/or correct ink fingerprinting, the FBI

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1 does experience a certain amount of unclassifiable
2 fingerprints, even with what we consider a valid
3 fingerprint card. And we have recently added to, or
4 we are about to add to our list of questions and
5 answers the procedure that will be followed that after
6 a certain number of attempts to get a set of
7 fingerprints classified, that there are special
8 circumstances where there's a special process that
9 could be followed with the FBI that does not involve
10 fingerprints, does not involve the submission of
11 fingerprints.

12 Again, the criteria under which those can
13 be used, that method can be used is limited. And an
14 inadequate set of fingerprints on the card is not a
15 good reason. But there are -- we have supplemented
16 our questions and answers, or we will shortly be
17 supplementing our questions and answers to address
18 what the FBI says is a valid issue, which is a certain
19 number of people do have unclassifiable fingerprints,
20 regardless of quality of the fingerprints taken.

21 CHAIRMAN MALMUD: Thank you. Chris. I'm
22 sorry, Bill.

23 MEMBER VAN DECKER: As someone who didn't
24 serve on the Subcommittee, I heard more about
25 fingerprinting than I probably want to know right now.

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1 And second, I wanted to thank Chris' little
2 interaction here, because it answered a big part of my
3 question I was going to start with, is where we go
4 with this Subcommittee report, and where things are
5 going.

6 I think there's two pieces to this, as I
7 see. Number one is an informational piece to what all
8 the licensees know, at a time where there's some give
9 and take on codification of what's going on. And I
10 would just say knowing how many small hospitals there
11 are out there, and lots of other stuff, that some way
12 of at least not creating more confusion in all of this
13 will help things down the line, including some of this
14 information that was given as background in the
15 report, which you can't say do this one way, or do
16 this the other way. Some of that information may be
17 helpful to arrive you at places and choosing how
18 they're going to go about doing something like this.
19 So I think that the informational piece of this is
20 important.

21 And I guess the second piece of this is,
22 I'd be interested in what you see as the time line
23 until you have something "codified" in place, that
24 this becomes a more rote issue, and utilizing some of
25 this information. I guess the last piece of that to

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1 Dr. Vetter would then be, looking at your report, are
2 there certain key pieces of it that you would like to
3 see as motions from Full ACMUI to at least give some
4 direct consideration in this process, rather than
5 continuing ongoing discussion. It sounds like it's
6 going to take a while.

7 CHAIRMAN MALMUD: Was that a question to
8 Dr. Vetter?

9 MR. LUEHMAN: The second piece was a -- I
10 guess the first piece was just a reaffirmation from
11 NRC that some type of informational piece is going to
12 be put into place, either through NRC, or through what
13 other groups of interest. And the second piece of the
14 question, NRC's time line to codification. And then
15 the third piece to Dr. Vetter was, what were the key
16 pieces of this report that you see we should have like
17 one or two sentences about that we think are key?
18 That was reasonable.

19 MR. LEWIS: For the first part, could I
20 ask -- could I answer your question with a question?
21 And I had the same thought as you did as we were
22 walking through the presentation. Many of these are
23 things that the Committee or the Subcommittee is
24 advocating that licensees should do. So process-wise,
25 does the Committee have a view on how those things

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1 should be communicated to licensees? And I can offer
2 up some ideas. We could put it on our own
3 fingerprinting toolbox website, or we can do some more
4 formal communications, or we could put it on the
5 Committee's website. There are many options, but I
6 was wondering if the Committee had a particular view,
7 aside from the internal communication, which Chris
8 mentioned, that has been provided to the Commission,
9 and is being considered by the implementation of
10 Increased Control Working Group, and the Rulemaking,
11 which is many -- a couple of years down the road,
12 frankly.

13 The recommendations you have for licensees
14 seem to be more near term recommendations about given
15 the current situation, here's some things you can do.

16 CHAIRMAN MALMUD: Dr. Vetter.

17 MEMBER VETTER: My response to your
18 question would be, what would the Committee -- how
19 would they like to see the information conveyed to
20 licensees? I guess this, just off the top of my head,
21 I wouldn't push, necessarily, that the report itself,
22 as it exists, be put anywhere for licensees. But I
23 think we would appreciate if the information in the
24 report is incorporated into Q&As, or these other
25 websites, web pages you were talking about.

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1 It's the content that might be useful to
2 licensees in one form or another, not necessarily as
3 this particular report. Though I wouldn't object to
4 that if that -- so I think whatever the NRC felt was
5 the most expeditious way to communicate the
6 information to licensees, Q&A or some other way, would
7 be fine.

8 And in response to Dr. Van Decker's
9 question about whether or not the Subcommittee thinks
10 -- requests that any of these points be put in the
11 form of a motion for further support or whatever, the
12 Committee -- the report, itself, was, if I understand
13 correctly, was sent to all of you, and you all
14 approved it. So the report has been approved, so,
15 thus, in terms of being integral part of the report,
16 each of these recommendations has been put forth to
17 the Commission to consider. Notice we use should, we
18 don't have the authority to use shall, anyway. But
19 these are recommendations for them to consider.

20 We would hope that they would have a
21 little more precise view of some of these things, a
22 deeper understanding of some of the issues, such as
23 the unclassifiables, and they would know what's
24 workable, and what isn't. But that they would take
25 the intent of the report, which is supported by the

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1 Committee to heart and do what they can to implement
2 those two particular recommendations.

3 CHAIRMAN MALMUD: Thank you, Dr. Vetter.
4 Is there another comment?

5 MEMBER GILLEY: I have one.

6 CHAIRMAN MALMUD: Please, Debbie.

7 MEMBER GILLEY: Debbie Gilley. In the
8 unclassifiable fingerprints, are you seeing an
9 increase of number of unclassifiables in the medical
10 community versus the industrial community, or is the 7
11 percent across the board?

12 MR. LUEHMAN: I don't have the details of
13 the breakout. I understand it's 7 percent across the
14 board.

15 MEMBER GILLEY: I think it might be the
16 nature of the applicants in the medical community, and
17 some of their hygiene maybe issues that have the
18 sluffing of the skin cells that make it more
19 difficult. I had a lot of trouble getting
20 fingerprints for this particular ACMUI requirement,
21 and that was some of the things that were suggested to
22 me by the fingerprint specialist when I went there.

23 CHAIRMAN MALMUD: I hope that you're
24 suggesting that the health care providers hands are
25 cleaner than most.

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1 MEMBER GILLEY: Absolutely.

2 CHAIRMAN MALMUD: Thank you. I just
3 wanted to clarify that for the record. Any other
4 comments?

5 MR. GUIBERTEAU: I guess I just have --
6 Dr. Malmud, I just have one, clarifying Mr. Lieto's
7 statement about the local law enforcement taking hand-
8 rolled fingerprints. And as you had correctly pointed
9 out, ink is quickly being replaced by electronic
10 fingerprinting.

11 The local law enforcement can take
12 electronic fingerprints, but they have to be reprinted
13 out on the cards and submitted directly to the NRC, so
14 they don't have to necessarily take ink-rolled
15 fingerprints. They could take electronic fingerprints
16 with the machines that they have, and print them out
17 on the NRC cards. And so that may improve, perhaps,
18 the rejection rate, as well.

19 MEMBER VETTER: It was my understanding,
20 though, the order said ink, ink prints on cards. I
21 mean, because we specifically ended up having to go
22 that route when we had the other alternative available
23 to us. So I would -- if that's the case, then there
24 is a huge misconception out there and misinformation.
25 And I think really that needs to be clarified,

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1 because, like I said, it's a route that we would not
2 have gone.

3 MR. EINBERG: I think this is good
4 information, and it could be fed back through the
5 IICWG, and a Q&A could be developed. As you may or
6 may not be aware, electronic fingerprinting submission
7 is allowable to the NRC by licensees, as long as the
8 licensees establish electronic fingerprinting program
9 with the NRC. And this is afforded to any licensee,
10 but it's more cost-effective to large licensees. And
11 that may also cut down on the rejection rate.

12 MEMBER VETTER: Well, I think it goes to
13 the recommendation from the Subcommittee that there is
14 locations where, especially where the electronic is
15 much more available, it facilitates those individuals
16 going to those locations. And, plus, the ready
17 feedback when they do it, that oh, this fingerprint
18 was not acceptable, we need to redo it. And, again,
19 facilitates getting people done, and not having to go
20 through the repetition process.

21 CHAIRMAN MALMUD: Thank you. I think that
22 completes the discussion regarding this item. If we
23 may, we'll move on to the next item, which is under
24 Tab 7, Permanent Implant Brachytherapy Rulemaking
25 Subcommittee report. Dr. Nag. Dr. Nag has a slide

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1 presentation.

2 MEMBER NAG: Yes. Thank you very much.
3 This is the work that has been going on for the last
4 three or four years into forming new rules for
5 permanent brachytherapy because there were some
6 drawbacks to the way the rules were written. They
7 would not apply to permanent brachytherapy, and that
8 was started sometime I believe in 2004. And the
9 report, or the proposed rules were published on August
10 6th, 2008. And the Subcommittee is making comments on
11 that report. I would like to thank the members of the
12 Subcommittee who are up there, Bruce Thomadsen, James
13 Welsh, and Ralph Lieto. We did have teleconference.

14 In addition, we sought input from
15 practicing members of the radiation oncology community
16 as to how it would affect their practice. What we
17 felt was that the proposed rules or written directives
18 for permanent implant is source strength based rather
19 than dose-base was really appropriate. And we,
20 therefore, support this rule, because when you place
21 permanent seed, you know what source strength you're
22 placing in, or what source strength you want to place
23 in. You may or may not know the actual dose that
24 comes out afterwards, because the source is removed,
25 and the organ can expand and so forth.

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1 One little comment, that is in the rule
2 the word "activity" and "source strength" both being
3 used. The correct word is "source Strength", and,
4 therefore, whenever you are having activity in that
5 rule it should be replaced by source strength.

6 Now, when the rules were made, or were
7 formulated, it was developed with the idea of pre-
8 planned permanent brachytherapy, prostate
9 brachytherapy in mind. Now, the rule, however, is
10 going to apply to every kind of brachytherapy.
11 Therefore, you cannot extrapolate from pre-planned
12 prostate brachytherapy to all forms of brachytherapy.

13 And because it was done with a pre-planned prostate
14 brachytherapy in mind, the proposed rule led to some
15 unintended consequences.

16 I'm sure no one thought that these would
17 apply, and it would create some unintended
18 consequences. And I'm going to give some examples of
19 what these unintended consequences are, and what the
20 Subcommittee proposes.

21 One of the unintended consequences would
22 be that very well-performed implant, that's medically
23 acceptable would be classified as medical event, and
24 I'll tell you why. Now, if the source strength
25 administered by more than 20 percent or more from the

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1 total source strength documented in the pre-implant
2 written directive, it will be called a medical event.

3 And the NRC has said that the pre-implant written
4 directive cannot be changed, and the pre-implantation
5 written directive serves as the basis for determining
6 a medical event had occurred.

7 This seemed quite logical. However, it is
8 logical if you are using a pre-planned method.
9 However, there are more than one way of doing a
10 permanent implant. In fact, many times we do
11 permanent implant based on a real time adaptive
12 interactive technique, meaning that the source
13 strength we are putting in is not based on some pre-
14 planned volume, but on the actual volume that we are
15 seeing as we are doing our implant. I'll show you a
16 diagram of that. This is a more accurate method, and
17 we are constantly updating our plan as we are
18 implanting. If we see that the prostate or the organ
19 is expanding, or is getting bigger, or smaller, is
20 moving, we update that. And this to show you an
21 example.

22 On the -- we are having an ultrasound
23 where we are seeing the image of the organ. We are
24 feeding it into a computer, into a treatment planning
25 computer. So what's happening is you are seeing, this

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1 is -- the little one is the preplanned volume, but as
2 we were implanting, on the ultrasound we are seeing
3 that this now the new volume. So if we were going to
4 put the seed according to the old volume, we would be
5 under-dosing this new volume. So, therefore, the more
6 accurate way of doing it is seeing where you are
7 actually implanting, and because you have a computer
8 that is linked to your ultrasound, you can update that
9 dose. And, therefore, doing it this way, we are now
10 putting in the source strength that is required for
11 implanting the organ as it is in the OR. So you
12 cannot base that on a pre-implant volume, or pre-
13 implant written directive.

14 Therefore, the basis for the ME, the
15 recommendation is that the basis for the Medical Event
16 should be the total source strength implanted after
17 administration, but before the patient leaves the
18 post-procedure recovery area. And not to be based on
19 the pre-implantation written directive, and this will
20 allow any intraoperative adaptation, if required, and
21 most of the time it is required. And could then apply
22 to both a pre-planned technique, and a real time
23 adaptive technique. And to add to that, even those who
24 are doing a pre-planned method very often, if they see
25 that the volume is changing on the day of the

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1 implantation, they will modify their written
2 directive, anyway. So this will allow both
3 techniques. And if you are doing that, then the pre-
4 implantation word should, therefore, be deleted from
5 pre-implantation written directive in the other
6 section, as well, to match. So that's our
7 recommendation.

8 The other concern is that it will be
9 considered a medical event if the total source
10 strength implanted outside the treatment site, and
11 within the three centimeter boundary of the treatment
12 site exceeded 20 percent of the total source strength
13 documented in the pre-implant written directive. Now,
14 what do you mean by the treatment site? It's rather
15 simple. Treatment site is the area you treat, but to
16 a radiation oncologist, there are various definitions,
17 and we're going through those definitions.

18 The definition in NRC is anatomical
19 description of tissue intended to receive a radiation
20 dose as described in a written directive. And,
21 therefore, that's somewhat ambiguous. Now, let's see
22 how does the radiation oncologist do a plan, and I
23 think this diagram will help us to understand.

24 The one in the center is the gross tumor
25 volume; that is, if you have a tumor and you can see

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1 it, or you can feel it, that area is the Gross tumor
2 volume. However, we do not just implant -- that is
3 not our only target, because tumor can spread
4 microscopically along that. And, therefore, that
5 microscopic expansion is usually not equal in all
6 directions. Therefore, I have drawn what's called a
7 clinical target volume purposely that it's more in one
8 direction, less in the other direction, because
9 clinically, we see how it the plane spread. If
10 there's a plane where the spread can go more, there
11 will be a bigger margin there; where, for example, if
12 you have a bone or some issue that will prevent the
13 spread, the margin will be less in that direction.

14 But once you have that area where you have
15 the tumor and the microscopic spread, then you have to
16 add the margin in the planning process, because many
17 other things happen in the planning. When you put
18 source in a certain area, there are dips in the
19 isotopes, and there are uncertainty about where
20 exactly the tumor is, and so forth, so we have like a
21 punch for the planning target volume.

22 Again, the margin in the planning target
23 volume is not equal on all sides. In the area where
24 you have a critical structure, for example, you have
25 the spinal cord, you have the bowel, you will have a

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1 less margin in that area, more margin in a place which
2 is like muscle or something that you cannot damage.
3 So that was the area we are really interested in, is
4 the planning target volume, and not necessarily the
5 Gross tumor volume. So the previous definition makes
6 it quite ambiguous. Are you referring to this volume?

7 If you are referring to the Gause target volume,
8 then if you say well, more than 3 cm, you are having a
9 problem, or you are having medical event, then this
10 could be different.

11 So, therefore, what we want to say is that
12 because there are various volumes we have to be more
13 specific of the volume. And the other thing is that
14 the margin, how much to place in the margin, how much
15 to place inside the tumor which is in the margin is a
16 medical decision. That is a clinical judgment. NRC
17 is not supposed to interfere into the medical
18 judgment. And, technically, when you say tumor site,
19 are you meaning the Gross tumor volume, the margin as
20 in the clinical target volume, or the margin as in the
21 planning target volume? This is quite unclear from
22 the definition we have now.

23 So what is the recommendation? We want to
24 clarify that to be considered a medical event, the
25 total source strength implanted outside the treatment

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1 site, and here we want to clarify that the treatment
2 site will include the Gross tumor, the clinical target
3 volume, plus invariable planning margin as defined by
4 the authorized user exceeds 20 percent of the total
5 source strength documented in the written directive.

6 If we are having this definition, then the
7 NRC will not be interfering with the clinical
8 judgment, because you are saying outside the planning
9 target. And the planning target volume is defined by
10 the medical judgment.

11 The other concern is that it will be a
12 medical event, even if a single brachytherapy source
13 were implanted beyond 3 cm outside the boundary of the
14 treatment site. However, what we have seen is that in
15 the normal course of a properly executed implant, few
16 source strength end up beyond the 3 cm outside the
17 boundary. Why? Because seed can be deposited into
18 the periprostatic-like vessels, and then they can
19 migrate to a distant organ, like the lung, but this is
20 correctly recognized by the NRC not to be a medical
21 event, so that's not a problem. However, a few of the
22 deposited seeds can travel to the adjacent pelvic
23 area, maybe 4 cm away, but still in the pelvis, via
24 the pelvic vessel, and then it will be impossible to
25 judge whether it was something that was deposited and

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1 migrated, or whether it was implanted in that area.

2 A few seeds can be implanted into the
3 urethra which is right in the middle of our volume, or
4 into the adjacent bladder. And they're normally
5 excreted in the urine, and you don't see them. But
6 sometimes they may not be totally excreted in the
7 urine, but may be traveling downward, and be somewhere
8 halfway, and then it will be considered a medical
9 event.

10 In the permanent implant of other organs,
11 some seeds can be sucked along the middle plat has
12 been retracted. When you place these seeds, we are
13 placing them one by one. When you're putting them
14 down, if you pull them down, one or two seeds may be
15 pulled down along the middle plat, and may be
16 deposited along the path of the middle plat, but more
17 than 3 cm. And then the patient may accidentally move
18 during the middle of retraction causing some seed to
19 be deposited more than 3 cm.

20 None of these things would be recognized
21 while the implant is going on unless you are doing a
22 pleural continuously doing the implantation of seed,
23 which is not possible.

24 So the other thing is that the permanent
25 implant are done in prostate, but the rule would apply

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1 to permanent implant everywhere, in the liver, in the
2 brain, in the abdominal cavity, and so forth. And in
3 other organs, you may or may not have a strong capsule
4 to define the boundary. And in that case, you may not
5 know exactly where the Gross tumor volume is, and,
6 therefore, you might want to make a volume, and you
7 may not have tissue to anchor the seed. For example,
8 if you are trying to do implant against the bone, what
9 we do is we put this -- or against the surface of the
10 peritoneum, what we do is we place the radioactive
11 seed in gelfoam, and then we plaster the whole gelfoam
12 on top of the area of concern. And sometimes, or in
13 the lung we do the same thing. We place it in a
14 gelfoam, and put it on the surface of the organ, and
15 sometimes the gelfoam will be absorbed, and some of
16 those seeds can then float into the open cavity which
17 will be the thoracic cavity, or the abdominal cavity.

18 And if that happens, then a couple of seeds may be
19 then deposited more than 3 cm away.

20 So all of these would then be considered a
21 medical event, and they are medically not a problem.
22 And we would be spending hours trying to determine
23 whether that was a medical event or not. So our
24 recommendations are medical event would be if the
25 total source strength implanted outside the treatment

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1 site, and now we have accepted that the treatment site
2 should include the planning target volume, exceed 20
3 percent of the total source strength, so this will
4 take care that if you had a few seeds moving, which
5 can happen, we still have that 20 percent. And it
6 will take care of any source migration, any seed that
7 has dislodged, but will still hold accountable some
8 practitioners who have wrongly identified the organ
9 and placed a lot of seed in a different area. And we
10 are still holding accountable people who are making
11 mistakes, but a few seeds being dislodged, et cetera,
12 would not be called a medical event. If you define it
13 this way, then Section 8-2.3 will become superfluous,
14 and, therefore, can be eliminated.

15 An area of concern that the section
16 licensee shall report as a medical event any
17 administration requiring a written directive, if a
18 written directive was not prepared. Not having a
19 written directive prior to the administration is
20 already a violation, so creating that into a medical
21 event, that will -- it will serve only to add to the
22 number of medical events without adding to the safety.

23 The proposed rule change will only add medical events
24 that are rule violation only, but they're not harmful.

25 And administration done without written directive

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1 would, therefore, be cited as a regulation violation,
2 rather than be called a medical event.

3 So, basically, I would like to summarize
4 at this point, that we are concerned that with the
5 proposed rules, the above situations that I have
6 mentioned will inappropriately be deemed to be medical
7 events, when, in reality, they sometimes occur in the
8 course of some normal properly executed brachytherapy
9 implants, and these are beyond the control of the
10 authorized user. We are concerned that this neuro
11 will then simply abandon permanent brachytherapy
12 procedure rather than risking having medical events.

13 In fact, as we know, many people are
14 shying away from doing brachy because the regulations
15 are already so burdensome. And if you are going to
16 now say even good implants will be called medical
17 events, many people will just say I'm going to stop
18 doing it. And this will be then detrimental to
19 patient care, because technically speaking,
20 brachytherapy is still the most conformal form of
21 therapy. It's the best way to put a maximum dose into
22 the tumor compared to any other form of radiation
23 therapy. We, therefore, recommend that in Section
24 (a) (2) (i), (2), (3), and (4), the word "pre-
25 implantation" will be deleted from pre-implantation

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1 written directive. In Section (a)(2)(ii), clarify
2 that the treatment site includes the Gross tumor,
3 clinical target volume, and a variable planning
4 margin, as defined by the AU. And, therefore,
5 (a)(2)(iii) will become superfluous, and, therefore,
6 be deleted. Activity should be made by source
7 strength wherever it applies to permanent
8 brachytherapy, and that administration without the
9 written directive should be cited as regulation
10 violation, and not medical event, per se.

11 The other thing is that some of these
12 things could have been avoided if the NRC had sent the
13 rule back to the ACMUI before sending it out for
14 public comment, because as we have mentioned before,
15 these rules were made on basis of recommendation of
16 the ACMUI several years ago, about five or six years
17 ago. But when those rules were formulated, they never
18 came back to the ACMUI to say is that what you meant,
19 or is that -- because sometimes the changing of one or
20 two words may mean a huge difference. And, therefore,
21 our plea is that if the NRC is going to form some
22 rules based on the recommendation of the ACMUI, they
23 should at least come back to us before they are
24 published. And I think we have to thank members of
25 the Subcommittee. I got a lot of input from members

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1 of ASTRO, ACRO, which is a colleague of radiation
2 oncology, and the Brachytherapy Society. This is the
3 sum total of the opinion of a large number of
4 practicing physicians. Thank you.

5 CHAIRMAN MALMUD: Thank you, Dr. Nag. If
6 I may just ask some brief questions. Was this a
7 consensus report, or was there a minority report, as
8 well?

9 MEMBER NAG: This is -- we did not get any
10 -- when we voted in the Subcommittee, there were no
11 abstentions, and there were no nays. They were all
12 yes.

13 CHAIRMAN MALMUD: Thank you.

14 MEMBER NAG: In the meeting in Ashville in
15 the public radiation oncology forum, again, this is
16 the sum total of their own report. And whatever --
17 there were no minority, they were all addressed.

18 CHAIRMAN MALMUD: So this has the strength
19 of a consensus report.

20 MEMBER NAG: Yes.

21 CHAIRMAN MALMUD: Thank you very much.
22 Other questions for Dr. Nag? Debbie.

23 MEMBER GILLEY: Debbie Gilley. Is there a
24 definition of a gross tumor volume, a clinical target
25 volume, and a planning target volume in the current

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1 regulations? And, if so, does the planning target
2 volume include the pelvis and the urethra?

3 MEMBER NAG: Okay. First of all, in the -
4 - if you are talking about following regulation in the
5 NRC on the Federal Register, that does not have these
6 three volumes. The only volumes they have is the
7 treatment site. And that is why we are saying it's
8 ambiguous, because the word "treatment site", we don't
9 know whether it refers to which of these volumes.
10 These volumes are taken from the ICRU report, the
11 International Commission on Radiation Units, and these
12 are the volumes, these three volumes are used by
13 radiation oncologists universally. So in the
14 radiation oncologist and ICRU report, none of those
15 three volumes are defined in the NRC.

16 MEMBER GILLEY: Currently, we have had
17 medical events that have included implanting seeds in
18 the wrong anatomical position that may have been
19 included in the planning target volume, for instance,
20 for the pelvis, and the rectum. Is this definition
21 going to allow those type of medical events to still
22 be reported, or are we now going to look at the
23 medical community taking the definition of the
24 planning target volume to have it be the practice of
25 medicine?

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1 MEMBER NAG: Can we go into that slide
2 where I had the volume, because I think that is very
3 important, because that will show you -- the reason we
4 cannot give a standard 2 cm or something, the margin
5 cannot be a constant margin. For example, if you are
6 taking a prostate, less than 1 cm from the posterior
7 border of the prostate is the rectum. So, therefore,
8 when we make a planning target volume, the planning
9 volume does not expand posteriorly, because you have
10 the rectum there. The planning volume expands
11 laterally, and anteriorly, but it does not expand
12 superiorly because that will go into the bladder. So
13 that's the reason why we want to use the word planning
14 target volume, because the planning target volume is
15 clinically relevant, because -- for example, here is
16 the gross target volume. So if you were implanting the
17 prostate, you would -- this is the prostate, for
18 example. Then critical spot here would be the rectum,
19 so the planning target volume would not go into the
20 rectum, because you are not going to implant the
21 rectum. So the planning target volume would stop
22 here. On the laterally, where this is no tissue, you
23 expand as much as you want. And I think this is the
24 reason why we have been trying to hammer that it means
25 more clinical -- previously, there were all right, how

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1 many cms do you need to expand? We cannot say it's 2
2 cm, because if you put 2 cm posteriorly, you are going
3 to go into the rectum, and that is absolutely not
4 allowed. But if you go -- and if we take then only
5 half cm, then if you go only half cm laterally, it's
6 not enough. So we have to define the planning target
7 volume for each organ according to the clinical needs,
8 and the clinical should I say risk of harming normal
9 tissue. So the planning target volume includes the
10 risk of spread, and the risk of damaging normal
11 tissue. And it's a balance of normal tissue with the
12 risk of the spread.

13 CHAIRMAN MALMUD: Dr. Vetter.

14 MEMBER VETTER: On one of your slides, Dr.
15 Nag, you were referencing 35.3045 (a), "A licensee
16 shall report as a medical event any administration
17 requiring a written directive if a written directive
18 is not prepared."

19 MEMBER NAG: Yes.

20 MEMBER VETTER: I'd like to ask a
21 question, perhaps of Dr. Howe. I think that
22 particular paragraph was intended to address Iodine
23 131 events, where therapeutic levels were administered
24 when diagnostic were intended.

25 DR. HOWE: This is Dr. Howe. That's not

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1 quite true. In Part 35, we have written directives
2 for unsealed material, and when you have a written
3 directive for unsealed material, that is you go back
4 into the definitions and you have a prescribed dosage.

5 A prescribed dosage includes both diagnostic and
6 therapeutic type of administration, so we have,
7 because we can go back to a procedure for the lower
8 activities of I-131, or maybe I-123, that we have a
9 way of identifying those as medical events.

10 But for the sealed source therapy, the
11 written directive is -- the prescribed dose is the
12 dose in the written directive. So if there is no
13 written directive, there is no prescribed dose, there
14 is no prescribed dose to be out of compliance with.
15 And we ended up with a situation where you could have
16 -- with the sealed sources, you could have a therapy
17 dose given to an individual that would not be
18 considered a medical event. And, therefore, would not
19 be reported to the NRC.

20 Yes, it may be a violation, but it
21 wouldn't be reported to the NRC, and so whether we
22 found it or not would be very arbitrary. And so, the
23 purpose for putting 3045(viii) in was to capture those
24 sealed source events in which there was no written
25 event, no written directive. It wasn't that there

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1 wasn't a complete written directive, it's just there
2 wasn't any written directive at all, because we had no
3 way of getting out of that circular argument that the
4 dose for those sealed sources is what's in the written
5 directive. And if there is no written directive,
6 there is no dose, there is no medical event. So that
7 was the hole that we were trying to fill. With that
8 wording, we will not capture any more I-131s, because
9 we're already capturing those as medical events.

10 MEMBER NAG: Now, if they are ruled
11 violations, but they are not let's say harmful to the
12 patient, is there any way we can say that we can have
13 then a rule violation, because that itself is already
14 -- doesn't that have to be reported?

15 DR. HOWE: No. If you have a rule
16 violation, you do not have to report rule violations.

17 MEMBER NAG: I think this is something
18 Ralph, you had worked on this portion of it. Can you
19 -- do you have any comments?

20 MEMBER LIETO: Well, I think you've
21 summarized it pretty well, Dr. Nag. I see Dr.
22 Vetter's concern that there might be these medical
23 events that are not getting reported. And, to me,
24 again, I guess if a licensee is that unscrupulous that
25 they're not going to do a written directive where it's

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1 required, and then kind of cover it up by not -- upon
2 discovery not doing any type of corrective action, I
3 would think there would be a lot of other issues that
4 you'd need to worry about than not having a written
5 directive. To me, there's just -- I guess I would
6 ask where is the evidence that you're basing this on
7 for the fact that there's a suspicion that medical
8 events are occurring, but they're getting around it
9 because there was no written directive at the time
10 prior to administration.

11 I would think that there would be, one,
12 there would be licensing violations and citations
13 because you violated other parts of Part 35 already.
14 The other thing is that this applies to all
15 applications applying a written directive. The
16 situation you're trying to address is the ones with
17 the sealed sources, but it's going to apply to all the
18 unsealed radiopharmaceutical therapy administrations,
19 as well. And I think in the examples that are given in
20 the Subcommittee report, it actually uses the
21 radiopharmaceutical therapies as a sort of
22 substantiation for that. I really don't think this
23 needs to be made a medical -- this violation needs to
24 be made a medical event.

25 And then I think, also, I think it's a

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1 very slippery slope to start that if you're going to
2 make certain regulation violations relating to written
3 directive compliance a medical event, I just don't see
4 the justification.

5 CHAIRMAN MALMUD: Excuse me. I just
6 wanted to clarify what you were saying, Ralph. So
7 you're saying that you think that currently there is
8 not a need to make this kind of dosimetry a medical
9 event, because it already is being handled otherwise.

10 MEMBER LIETO: Right. It's a regulatory
11 violation already.

12 CHAIRMAN MALMUD: Thank you. Dr. Nag.

13 MEMBER NAG: Yes. The other point I had is
14 that this whole issue is on permanent implant;
15 whereas, the part about having a written directive, or
16 not having a written directive is not specific to
17 permanent implant. This applies to any type of
18 implant, including HDR and so forth. If I do an HDR,
19 and I don't have a written directive, it's not
20 specific to permanent brachytherapy. And my
21 preference would be that since this is a rulemaking on
22 permanent brachytherapy, we restrict it only to
23 permanent brachytherapy, and instead of muddling up
24 the issue somewhat when you're having an overall
25 question, because the written directive -- doing a

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1 procedure without a written directive is the broad
2 base that applies to every form of brachytherapy. And
3 that is separate regulation that says you cannot do
4 brachytherapy without a written directive, because
5 that covers it broadly.

6 CHAIRMAN MALMUD: I think that Rob Lewis
7 is going to make a comment.

8 MR. LEWIS: Well, I guess I do see a
9 circular argument. If we eliminate the word "pre-
10 implantation" from written directive, and we only do
11 the written directive after -- an example of a
12 situation where the new criteria you propose would be
13 tripped to become a medical event. And I think it
14 hinges on the definition of planning target volume,
15 which brings me back to why isn't that defined pre-
16 implementation?

17 MEMBER NAG: Right. Well, I would say that
18 we do this in the operating room all the time. So our
19 planning target would be to say that we are going to
20 implant this organ, and when you do this, you have a
21 diagram that you are planning on the operating room on
22 the computer. And that is printed out, so our plan
23 would be to say implant like I showed you. And at the
24 end, when we do the x-ray, we found half of those
25 seeds were not in the planning target volume, was

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1 below, or on the side, or posterior, or in the rectum,
2 then it will be definitely become a medical event. So
3 you do have a written directive that you can go back
4 to, but that written directive was done when you had
5 just finished doing your implant. Because until such
6 time as you have completed your implant, you can keep
7 on changing as you are seeing change in the shape. So
8 the point where you are completing the implant is when
9 you say well, now I have implanted the target the way
10 I want to, and now we are going to stop.

11 The mistakes are usual -- I mean, I have
12 examined quite a few of the misadministrations. The
13 mistakes were made not because they went outside of
14 what they were planning, but what happened is they
15 misidentified the plan. They thought that the bladder
16 was the prostate, and they put a lot of the seed into
17 the bladder, or they thought that the bladder or the
18 prostate was some other organ, and the sub-urethral
19 area was the prostate, and they put the seed there.
20 So those would be caught because your planning target
21 on your diagram was the prostate with the margin. And
22 when you came back, and all the seeds are outside,
23 that is very easily identifiable as a
24 misadministration.

25 CHAIRMAN MALMUD: Dr. Howe, I think you

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1 wanted to make a comment.

2 DR. HOWE: Yes. This is Dr. Howe. I'd
3 like to clarify two points, and one is that if
4 comments are coming back that not having a written
5 directive is a medical event, will affect in any way
6 the nuclear medicine therapy medical events. That's
7 not true, because the medical event definition for
8 unsealed material is based on dosage.

9 Dosage is defined in Part 35 as, "The
10 activity or range of activity of unsealed byproduct
11 material as documented in a written directive, or in
12 accordance with the directions of the authorized user
13 for procedures performed pursuant to 100 and 200." So
14 if you were -- if you have a procedure manual, and you
15 are intending to give one of the diagnostic
16 procedures, then you have the procedural manual number
17 that gives you the doses. And if you made a mistake
18 and you gave a therapy, something requiring a written
19 directive, we have a means of identifying that as a
20 written directive. So we won't be increasing any
21 written directives for the unsealed material, because
22 we already have a means of determining what the dose
23 is, if there's no written directive.

24 The only one we don't have is the one for
25 the sealed source. Have we had an example of that?

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1 Yes, we have. We had intervascular brachytherapy that
2 was given to a patient that was not -- did not have a
3 written directive provided for them. Are we -

4 MEMBER NAG: Permanent implant?

5 DR. HOWE: In this case, it was not
6 permanent implant, but it could be for other cases,
7 because if there isn't a written directive for that
8 person, then you've got a medical event.

9 The other issue is, we're not -- medical
10 events are not violations, and so a medical event is
11 when -- is an event that NRC wants reported to us.
12 They don't have to injure the patient. That's not our
13 criteria. Our criteria is very, very low. It's
14 almost a precursor type of thing. We get triggered at
15 very low levels, so that we get the precursor events,
16 but we also get the really high events. So we capture
17 both of them. So in this case, the argument that this
18 is already a violation isn't really relevant to the
19 situation, because yes, it's a violation, but NRC
20 wants these things reported to it up front so that if
21 we have trends, we can then take some kind of
22 effective action. And that would be to notify all
23 licensees, not just the violation for the one
24 licensee.

25 CHAIRMAN MALMUD: Thank you, Dr. Howe.

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1 MEMBER NAG: In the old days, there was
2 something called reporting criteria and
3 misadministration or medical event. In that case,
4 there's a difference between the two, and it would
5 probably make sense to make not having a written
6 directive a reportable event, but not a
7 misadministration or medical event.

8 Although you are saying that medical event
9 per se does not have to be harmful to the patient, I
10 agree with that. But the moment you have a medical
11 event in a hospital, it leads to a tremendous amount
12 of paperwork, tremendous amount of anxiety, reporting
13 to the patient where even though you can tell them
14 it's not harmful, the moment you have to report it to
15 the patient separately and to the referring physician
16 separately that there was a medical event, it creates
17 a tremendous amount of anxiety and paperwork for all
18 concerned, the hospital, the NRC, and everyone.
19 Because any of those will then have to be investigated
20 and so forth.

21 CHAIRMAN MALMUD: Dr. Howe.

22 DR. HOWE: I had forgotten, I also had a
23 third point, and that was with regard to the pre-
24 implantation. Okay? And the treatment site. Well,
25 the treatment site right now is written in a very

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1 global manner, in which the authorized user gets to
2 define the treatment site. Whether he uses your terms
3 or uses some other terms, he gets to define it. So
4 the gold standard is the physician sets his own
5 standard.

6 Your description of changing from the pre-
7 implantation, what you're inferring is maybe a week or
8 so before. In this case, pre-implantation is right up
9 to the moment that you implant, so your latest
10 computer diagram the day you're doing the
11 implantation, two minutes before you put the needle
12 in, 30 seconds before you put the needle in, is always
13 pre-implantation, because we don't distinguish it
14 being a week or some other time, just pre-
15 implantation.

16 Have we had medical events where the
17 physician has used our regulations to avoid having to
18 report serious errors? And the answer is yes, and in
19 permanent brachytherapy, and in prostate
20 brachytherapy. We had two cases where the physician
21 was going to implant, and I don't have the numbers in
22 front of me, say 70 seeds. The seeds went into the
23 bladder, the seeds were pulled out of the bladder in a
24 timely manner so there was no dose to the wrong
25 treatment site. The physician rewrote the permanent

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1 prostate brachytherapy to say the first fraction I
2 wanted to give 30 seeds, and I will follow-up with a
3 second fraction. The second fraction was never
4 followed up. There was an error.

5 In another case, the same thing happened,
6 where recognizing that the patient hadn't left the
7 surgery, the physician changed the number of seeds
8 that they were going to give from a reasonable amount
9 of seeds to a very low fraction of that. And neither
10 one of those were medical events, because the
11 physician changed the written directive prior to
12 completion of the procedure. That's what we were
13 trying to go for, the errors.

14 MEMBER NAG: I need to respond to that.
15 This -- what you are referring to is not particularly
16 for permanent brachytherapy only. You can do the same
17 thing in your removable brachytherapy, and in
18 removable brachytherapy you can write your directive
19 and say well, I'm giving four implants instead of
20 three, and so you could do the same thing, as well.
21 And that would not be a medical event in removable
22 brachytherapy, so why would that be a medical event in
23 permanent brachytherapy?

24 But more important than that, whenever the
25 word "pre-implantation" is written in here, the way it

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1 is interpreted by most people, and I would say
2 including many of the NRC officials, the amount you
3 write before you go to the OR. Before you go to the
4 OR, you say certain millicurie. That is the pre-
5 implantation that most people refer to. And then when
6 you went to the OR, you did your ultrasound, and you
7 saw you need 45, that would be then considered a post-
8 implantation, and you are not allowed to change your
9 pre-implantation written directive. And, therefore,
10 would be considered a medical event. So that's what
11 we are trying to prevent, so the actual number that we
12 should go by is the number that we are planning when
13 we are doing the implant. We have put our seeds, we
14 have looked at the dosimetry, because the dosimetry
15 available almost instantaneously within a few seconds.

16 We don't like it, so we need to put a few more seeds
17 here, a few more seeds there, so the written directive
18 from which you have to calculate your deviation is
19 basically the written directive when the whole
20 procedure is done, and the physician has certified
21 that he has done a good implant. So you have to
22 calculate the deviation from that point in time which
23 is basically before the patient is leaving the
24 operating room. This is what our definition is, not
25 leaving the post-procedural area.

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1 I know it's a very fine matter of debate,
2 but it's -- we are trying to prevent frivolous medical
3 events, basically.

4 CHAIRMAN MALMUD: Dr. Zelac has his hand
5 raised, but I have a question for you, Dr. Nag. It
6 wasn't clear to me, how would you deal with the issue
7 that Dr. Howe just described in order to bring
8 attention to the fact that there was a
9 misadministration or a significant problem in treating
10 the patient that she cited? How would you propose
11 dealing with it?

12 MEMBER NAG: Well, in any other treatment,
13 let's even forget permanent implant, in the removable
14 implant, if you haven't given enough, what do you do?
15 You say well, we can -- this is not a
16 misadministration because we can give more. We find
17 that the dose is not enough, so you put your needle
18 in, and you find that with the needle that you have,
19 you cannot give a good enough dose, you say all right,
20 we are going to give a separate dose, and you change
21 your administration to say instead of three plats in,
22 four plats in. So I think this is something being
23 done on-line by the physician as they are seeing it,
24 and I think that is not a misadministration, because
25 they are seeing it as they are going. And if they

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1 feel they cannot give the full dose -- let's say I'm
2 doing an implant. In the middle of the implant, I
3 find the tumor is much bigger, and I don't have enough
4 seeds with me. Then it is up to the judgment of the
5 physician as to whether they should stop the implant
6 at that point, or let implant completed and say needs
7 an additional implant to do the job properly.

8 CHAIRMAN MALMUD: But my understanding,
9 and perhaps I misheard, but I thought I heard Dr. Howe
10 describe a situation in which the physician having
11 made the error, said that the physician was satisfied
12 with giving the smaller number, but would complete the
13 dose with an additional number, which were never
14 administered. Did I hear you correctly, Dr. Howe?

15 DR. HOWE: That's correct.

16 MEMBER NAG: Yes. So in that case -

17 DR. HOWE: And in the second case, they
18 changed the number from a significant number - once
19 again, I may not have the right number - 70 seeds down
20 to 30 seeds, and said that's what I wanted to give.
21 And it was because most of the seeds went into the
22 bladder.

23 CHAIRMAN MALMUD: So how would you propose
24 dealing with that with the proposed -- excuse me, Dr.
25 Nag. How would your recommendation deal with a

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1 situation such as that?

2 MEMBER NAG: Then that situation is
3 something that would be a problem for the hospital
4 administration, because you can rightly -- you can do
5 an incorrect calculation and say I'm going to give 20
6 millicurie, when really I was doing that, I was going
7 to give 40 millicurie, let's say. Some other
8 physician said okay, I'm going to give 20 millicurie.

9 He wrote it in the pre-implantation directive, 20
10 millicurie. He ended up giving 20 millicurie. That
11 patient is not cured. He's going to have a number of
12 those -- there's no regulation from NRC that can catch
13 that. However, over a period of years, he's going to
14 have a lot of recurrences, and he will be caught.

15 On the other hand, another physician is
16 doing wrong planning and putting half the seed in the
17 rectum, he's going to have -- like a fistula. He's
18 going to have lawsuits on their hands, but he's
19 correctly doing what he's saying he's prescribing. So
20 this is not something I think you can solve by
21 changing the way you are writing the prescription,
22 because in the prescription he could put 20
23 millicurie, all the 20 millicurie would be in the
24 prostate, and within the 2 cm of the prostate. Half
25 of them may be in the rectum. They would still not be

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1 considered a medical event. So I think there are some
2 methods that really no matter how you put in the
3 regulation, you cannot rectify.

4 Whereas, the example you mentioned, your
5 objective was to give so many, and your prescription,
6 you said he modified to say two implantations, and a
7 second implantation he's going to do to make up for
8 it. If he didn't do that second implant, well, then
9 it would be a medical event, because he didn't do it,
10 because he had two accidents.

11 CHAIRMAN MALMUD: Perhaps not being a
12 radiation oncologist, I'm asking some very naive
13 questions. Excuse me.

14 MEMBER NAG: No, it's not naive. It's
15 something we deal with every time, too.

16 CHAIRMAN MALMUD: Say that the patient was
17 to have received 60 seeds as the calculated pre-
18 treatment dose. And 30 of those seeds went into the
19 bladder, and, therefore are going to be voided out
20 with urine.

21 MEMBER NAG: Right.

22 CHAIRMAN MALMUD: Therefore, the patient
23 had received 30, which was rewritten to be the correct
24 dose by the physician who administered it in the
25 example that Dr. Howe cited. The 30 that would be

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1 urinated out, what's their fate, how were they
2 accounted for? What happens? Is there a recording of
3 the fact that they were voided?

4 MEMBER NAG: They are recorded in the
5 place where we say -- where we plat the radioactive
6 source. We receive X number of millicurie of
7 radioactive source, then we say Y went into the
8 patient, and number Z was not used or returned back to
9 the manufacturer.

10 CHAIRMAN MALMUD: Will they have been
11 returned? When does the patient void these, the ones
12 that are in the bladder?

13 MEMBER NAG: The ones in the bladder are
14 voided -- there are two ways. One is immediately
15 after the implant before the patient leaves the
16 operating room, we do a cystoscopy, and if we see a
17 lot of seeds in the bladder, usually we do see one or
18 two. In my experience, I have seen one or two. We
19 then pull that one or two seeds out, and then they are
20 stored for decay. And at the end, we would write
21 there are five seeds stored for decay, and 20 seeds or
22 80 seeds placed in the patient.

23 CHAIRMAN MALMUD: So that in the case
24 cited, if 60 were prescribed as the total dose, 30
25 were theoretically in the bladder, and then voided and

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1 retrieved by cystoscopy while the patient was still in
2 the suite, there would be a disconnect; namely, that
3 the dose was to have been X rads, or whatever, and the
4 number of seeds retrieved is one-half of what that
5 would have been.

6 MEMBER NAG: Right.

7 CHAIRMAN MALMUD: But now the dose has
8 been rewritten to be what the patient received
9 retrospectively after having realized that 30 went
10 into the bladder, and no more therapy is being
11 offered. How would that come to the attention of the
12 hospital itself? Is each of these cases reviewed
13 individually?

14 MEMBER NAG: Well, when you do quality
15 assurance, one of the things we do in quality
16 assurance is to say what doses are being given to
17 patients. Same thing in other kinds of implants. I
18 mean, if you -- let's pick out a permanent implant.
19 If we did a removable HDR patient, and you're
20 consistently giving your patient half the dose that
21 the rest of the country is giving, it is not a
22 misadministration, because that's what you wanted to
23 give, but it is below what the recommended, or the
24 standard dose that's been given by the rest of the
25 country. You had something. Right?

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1 CHAIRMAN MALMUD: I understand your
2 explanation. I'm sorry, who was going to raise a
3 question? Please.

4 MEMBER WELSH: I was just going to comment
5 on -- Jim Welsh, commenting on the question, as well.

6 In this particular case Dr. Howe brings up, if a
7 number of seeds were placed into the bladder, by the
8 proposed new definition, these would be outside the
9 PTV. Twenty percent would be outside the PTV, and,
10 therefore, it would be potentially categorizable as a
11 medical event. And the reason why this might be is
12 that the PTV, or the bladder, rather, is a critical
13 organ outside of the expansion that would include the
14 PTV, as Dr. Nag's illustration clearly demonstrated.

15 Therefore, if there's an under-dose to the
16 prostate because X number of seeds have wound up in
17 the bladder, you would recognize that, too, because
18 the normal dose is 145 to 150 gray. If you wind up
19 putting 20 seeds in the bladder, whether they're
20 urinated out, extracted out through cystoscopy, or
21 remain embedded within the bladder wall, it's a
22 medical event because they're outside the PTV. And
23 it's also an under-dosing of the prostate, because
24 instead of the 145 gray, you might be getting half
25 that, and there would be a lot of explaining to do on

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1 that account alone.

2 MEMBER SULEIMAN: So who would pick that
3 up, sir?

4 CHAIRMAN MALMUD: Dr. Suleiman asks who
5 would pick that up.

6 MEMBER SULEIMAN: Yes. Let me regress
7 just a little bit more. You've got a tumor. You want
8 to deliver how many gray, 145 to 150? That's the
9 target calculation. You then back -- then you say I
10 need so many seeds of so much activity to deliver that
11 target -- to deliver the dose there. I mean, that's
12 the thinking that's got to go away before you even
13 start. So then you go in, this is the practice of
14 medicine. You've got a certain uncertainty, you put
15 it in there. And for some reason either the seeds
16 migrate, you don't deliver the -- the tumor is bigger.
17 You finish the procedure. You realize that you're not
18 going to deliver 150 gray. You realize with the
19 amount of seeds you've delivered you've placed, some
20 of whom are now outside the target area, and maybe
21 elsewhere, you really have to go through a
22 recalculation of what the actual absorbed dose is to
23 both the tumor and whatever. At that point, you're
24 just -- the procedure isn't completed as far as I
25 would be concerned, because you do a reassessment, and

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1 then you say we need to go back in and deliver more
2 dose. We need -- you don't just say finished, that's
3 it. This is what we delivered. We gave 100 gray.

4 MEMBER NAG: I wish to correct you there.

5 Actually, that process is going on even before that.
6 When you are putting your needle and you start putting
7 your seeds, you are recalculating as the seeds are
8 going in. You don't wait until you finished
9 everything, and then recalculate.

10 MEMBER SULEIMAN: You can actually do
11 that?

12 MEMBER NAG: Yes. This is what the on-
13 line -

14 MEMBER SULEIMAN: Software.

15 MEMBER NAG: Yes. That is what the real
16 time implantation is, that we are at that thing as we
17 are going, so if we put the needle in and we find it
18 different from the pre-plan, so that's one area where
19 you're adapting. Halfway through the implant, if we
20 see that one area is getting too much, one area is
21 getting too little, we replan -- because all of these
22 are now almost instantaneous.

23 MEMBER SULEIMAN: So you're doing real
24 time dosimetry.

25 MEMBER NAG: This is all real time, yes.

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1 MEMBER SULEIMAN: In a manner of speaking.

2 MEMBER NAG: Right. And as you're putting
3 the seed in, the computer is constantly updating the
4 dosimetry. Actually, I have a paper which is the
5 ABA's recommendation on real time planning. I think I
6 had given it in one of the place here, but I think I
7 have given it in the -- the reference to that is given
8 in the report, not in the slide. But that's the
9 basis, that you're constantly updating your dosimetry
10 as you're placing, and, therefore, correcting.

11 MEMBER SULEIMAN: That's what you do.

12 MEMBER NAG: No. That's what I -- a few
13 of us started doing five to ten years ago. Now, more
14 than half the people are doing it by the real time.
15 So the proportion of people -

16 MEMBER SULEIMAN: Well, then how does Dr.
17 Howe's scenario happen then?

18 MEMBER WELSH: I would find that -- this
19 is Jim Welsh. I'd find it less and less likely to
20 happen. Again, I personally know of no one who is
21 using the old pre-implant dosimetry any more. And in
22 my career, I did it once, and once you have had a
23 taste of real time intraoperative dosimetry, you can't
24 go back to that approach any longer. So I don't think
25 that too many people are going to be using the pre-

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1 planning approach any longer.

2 MEMBER NAG: There's still a lot of people
3 doing pre-plan, but the proportion keeps on changing.

4 And when the rules were promulgated, the basis of
5 that was in 2002, a large proportion was doing it pre-
6 plan, small proportion was doing it real time.
7 Although, the report I was in was 2002. But now, that
8 ratio is changing, more people are doing real time,
9 less people are doing pre-plan.

10 CHAIRMAN MALMUD: I see a hand of NRC
11 staff. Is that right?

12 MS. BHALLA: Yes.

13 CHAIRMAN MALMUD: Could you come to the
14 microphone, please.

15 MS. BHALLA: Sure.

16 CHAIRMAN MALMUD: Thank you.

17 MS. BHALLA: Yes. Dr. Malmud and the
18 Committee, my name is Neelham Bhalla, and I'm in the
19 Rulemaking branch of the Division of Rulemaking and
20 Intergovernmental Liaison. So, anyway, we have done
21 this proposed rule, and it started under my -- as my
22 project. But then with other competing projects going
23 on, my colleague, who is here, Ed Lord, he finished
24 this proposed rule.

25 The whole basis of this proposed rule came

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1 from what ACMUI had given to us maybe about three or
2 four years ago, very nicely written paper titled
3 something like the Guiding Principles for Permanent
4 Brachytherapy Implant, and then we -- Dr. Zelac is
5 here, and this was taken to the Commission, as this is
6 what the ACMUI has been advising us to do. And their
7 problems with the brachy implants specifically, I
8 think the concentration had been for prostate
9 implants, because that has been -- that's where most
10 of these procedures are being done.

11 So we did the proposed rule. Basically,
12 the working group worked very hard, and there were all
13 these parameters given to us in terms of three
14 centimeters from the target volume, in terms of --
15 there were these specifics. And that's what we based
16 -- the whole proposed rule is based on.

17 Two things I would like to go into a
18 detail a little bit about this. So this concept that
19 now Dr. Nag is proposing, and about talking the real
20 time implantation, perhaps it's happening now, but at
21 the same time, there are institutions out there which
22 are still using the old methodology. So when we are
23 doing the regulations, they pretty cover a broader
24 range, so that we are covering people who are on the
25 cutting edge of the practice, as well as those who are

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1 still using the old methodologies. So that would be
2 one of our reasons to really say how we have done it,
3 what we have done it. Okay? So that's one.

4 And two is, I would like to know from Dr.
5 Nag the difference between the source strength, as
6 opposed to activity, because, to me, pretty much
7 activity is a multiplication of source strength times
8 the number of sources. So these are my two questions,
9 and I would like to have an answer.

10 MEMBER NAG: Yes. The first thing, I was
11 a member of that Subcommittee of the ACMUI that had
12 made all the recommendations based on which the NRC
13 recommendation was made. And that is why the first
14 thing I said was had the NRC come back to us first,
15 and said these are the recommendations you made.
16 Based on your recommendations, these are how we are
17 formulating the rules. Some of these things would
18 have been modified at that stage. That's one.

19 Secondly, in terms of the difference
20 between activity and source strength -- we have gone
21 over many times, so I would like Dr. Thomadsen, who is
22 an expert on this, to clarify.

23 CHAIRMAN MALMUD: Please do, Dr.
24 Thomadsen.

25 MEMBER THOMADSEN: The source strength is

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1 a term to express the air kerma strength for the
2 sources. This is a measured quantity for the sources.

3 Activity is ambiguous, first, because it's not clear
4 what is meant by the activity, since it probably is
5 not the activity that's contained in the sources,
6 because there's no way to really know that.

7 MEMBER NAG: Apparent activity.

8 MEMBER THOMADSEN: What's that?

9 MEMBER NAG: Apparent activity. There's a
10 difference between apparent activity and real
11 activity.

12 MEMBER THOMADSEN: Right. The other option
13 is it may be apparent activity, as opposed to what
14 activity is contained in the source. The apparent
15 activity is taking the air kerma strength from the
16 source, which you can measure, dividing it by the
17 exposure rate constant, or air kerma strength's
18 constant for a naked point source of the same
19 radionuclide. And so, the apparent activity is a
20 derivative calculated value that has no real bearing
21 on activity as we think of it, how much activity is in
22 the source. So the air kerma strength, or the source
23 strength as it would be termed, is a much more direct
24 and appropriate quantity for use, if you're trying to
25 be precise about the strength of the source.

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1 CHAIRMAN MALMUD: Thank you, Dr.
2 Thomadsen.

3 MEMBER FISHER: However, when you purchase
4 seeds, you purchase seeds in units of activity,
5 millicurie, becquerel. You don't purchase these seeds
6 in terms of air kerma strength.

7 MEMBER NAG: No, you can do it both ways.
8 You can either specify -

9 MEMBER FISHER: I'm not quite finished.
10 Both units are typically specified. The air kerma
11 strength is the unit used in treatment plan in
12 software, but typically you look at seeds, you
13 purchase seeds in terms of their unit activity in
14 millicurie or becquerel, so I'm not sure that I agree
15 with the statement that you made, that we can only
16 specify this in terms of source strength or source
17 activity. I'm not sure I agree with that yet.

18 I think that the regulations can just as
19 well be written in terms of a seed activity, or a
20 total seed activity for a given patient treatment.

21 CHAIRMAN MALMUD: Thank you, Dr. Fisher.
22 Dr. Thomadsen, you were going to say something.

23 MEMBER THOMADSEN: I was going to say that
24 increasingly, the orders for brachytherapy sources are
25 in terms of source strength, as opposed to activity

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1 because all the treatment planning softwares in terms
2 of that, the base for the dosimetry algorithm, the
3 TG43 is in terms of source strength. The AAPM and the
4 AVS have both recommended that the term activity not
5 be used in brachytherapy, that source strength is
6 used, so the activity designations are decreasing as
7 far as their use in ordering. The companies can
8 handle orders in either. They maintain the ability to
9 do either source strength or activity orders, but
10 increasingly, the source strength is what's being
11 used.

12 Also, the well chambers that are used in
13 assaying the brachytherapy sources come with
14 calibrations in terms of source strength, not in terms
15 of activity, which the calibration labs do not
16 provide.

17 CHAIRMAN MALMUD: Thank you, Dr.
18 Thomadsen.

19 MEMBER NAG: I would like to add to that.
20 From the American Brachytherapy Society, and from
21 ASCO, we have given recommendations to the
22 manufacturers to report and send the sources in source
23 strength in air kerma. Some of them are lagging
24 behind, but it is a tendency, and slowly changeovers
25 have been made. And I think if the NRC also has

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1 source strength, that will push even more
2 manufacturers to go towards source strength reporting,
3 and that is the direction we want to go to, anyway.
4 So I would strongly recommend putting source strength
5 there. If you put activity and source strength
6 interchangeably, this changeover will not happen as
7 quickly.

8 CHAIRMAN MALMUD: Dr. Suleiman.

9 MEMBER SULEIMAN: I have a clarification.
10 Are all of these seeds the same nuclide?

11 MEMBER NAG: No. We are talking about
12 Iodine-125.

13 MEMBER SULEIMAN: That's why you don't
14 want activity, because depending on the nuclide -

15 MEMBER NAG: No.

16 MEMBER FISHER: If you're going to talk --
17 I'm sorry. This is Darrell Fisher. If you're going
18 to speak in terms of units of millicuries, or
19 becquerel, as you did in your discussion, then you're
20 speaking in units of activity.

21 CHAIRMAN MALMUD: Debbie Gilley.

22 MEMBER GILLEY: Yes. I just have some
23 questions about scope of practice. Do you not look at
24 a CT or ultrasound prior to ordering the seeds to
25 determine how many seeds you need, and the activity,

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1 or the source strength?

2 MEMBER WELSH: Sometimes, no. This is Jim
3 Welsh. The answer is no.

4 MEMBER GILLEY: Oh, okay. So that's still
5 - how would you determine what you were going to need
6 prior to the implant? This is a surgical procedure.

7 MEMBER NAG: Okay. Different centers do
8 it a little differently. Most centers do it, do the
9 order by the patient so that they would have more
10 likely than not either a CT or a pre-implantation
11 ultrasound to give some idea, not necessarily to place
12 exactly on that many seeds, and they order a certain
13 percentage more than that. So that is just to have in
14 stock, that is not what they want to implant, so
15 that's a big difference. We have in stock a certain
16 number of seeds more than what we need. Then when we
17 are doing our implant, and you are doing it real time,
18 you have put your probe in, you have determined the
19 volume, then you say well, I'm going to be starting to
20 put X number from that.

21 MEMBER GILLEY: But you're at large
22 medical institutions. What does the surgical centers
23 do that do one or two implants every week? I mean, I
24 have a lot of out-patient surgical centers in my
25 state, so what is the standard of practice?

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1 MEMBER NAG: They usually will order about
2 10, 15 percent more than what they think they will.
3 And then when they are doing the implant, if it is 10
4 percent larger, they have those seeds, because
5 otherwise they will under-dose.

6 MEMBER GILLEY: So I suggest to you that
7 there is already some pretreatment planning as far as
8 a written directive goes at the time you order the
9 seeds.

10 MEMBER NAG: It is not really a pre-
11 implant planning, because what they do is they use a
12 normal gram that X volume will require about Y number,
13 or Y source strength to give approximately so much of
14 dose. It is a very rudimentary planning, it's not
15 really a treatment planning.

16 CHAIRMAN MALMUD: May I just pause for a
17 moment. It seems to me that what we're looking at is
18 a technique which is in transition from a -- you had
19 given us a superb presentation, I believe it was you,
20 several years ago about prostate therapy with photos
21 and so on, which I remember vividly. I think every
22 male in the room remembers it vividly.

23 (Laughter.)

24 CHAIRMAN MALMUD: So we're going through a
25 transition in which the pre-implantation therapy

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1 planning with ultrasound pre-therapy is now fading,
2 and in its place is coming real time CT implantation
3 therapy. Is that correct?

4 MEMBER NAG: The ratio is changing.

5 CHAIRMAN MALMUD: But it is transitioning.

6 MEMBER NAG: It is, yes.

7 CHAIRMAN MALMUD: And so some patients --
8 after all, the patients are not knowledgeable about
9 this, some of us are not knowledgeable, are being
10 treated in departments in which they use ultrasound
11 pre-implantation planning, and others are going to
12 departments where they're using real time CT therapy.

13 MEMBER NAG: No, real time ultrasound
14 planning.

15 CHAIRMAN MALMUD: Real time ultrasound
16 planning.

17 MEMBER NAG: A few centers are doing real
18 time MRI planning.

19 CHAIRMAN MALMUD: All right. So now we
20 have three types of therapy, real time MRI, real time
21 ultrasound, and real time -- and pre-treatment
22 ultrasound.

23 MEMBER NAG: And also a few centers are
24 doing now real time CT. So, basically, real time
25 imaging based planning. That is the whole criteria,

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1 real time imaging based, whatever imaging method you
2 want to use.

3 CHAIRMAN MALMUD: The question arises,
4 this having been brought to our attention by you and
5 by Dr. Howe, how do we, as a responsible consulting
6 committee, protect the patient who is being treated in
7 a therapy unit which uses pre-implantation ultrasound
8 to base the therapy dosimetry, winds up in the hands
9 of a therapist who has accidentally delivered half of
10 the dose into the urinary bladder, which will be
11 excreted promptly, and then does not follow through.
12 Is that simply that would be picked up in the
13 hospital's routine review of radiation oncology, or is
14 this something that the hospital would miss, and the
15 NRC should be concerned about, because this is
16 technically a misadministration, if only half the dose
17 was delivered, and the rest of the dose was not
18 delivered?

19 MEMBER NAG: Well, if he is doing a pre-
20 implantation technique, then he's not using the real
21 time method, then he would have been writing the dose
22 before he went, because he's doing it pre-implant.
23 That would already be in there, how many millicurie he
24 wanted to place.

25 CHAIRMAN MALMUD: But he changed his dose.

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1 In the example cited by Dr. Howe, the therapist, I
2 don't know if it was a male or female, changed the
3 dose. Therefore, how would this be picked up, and how
4 would that patient be protected? Would that patient
5 be protected under the practice of medicine
6 guidelines, with a review within the hospital, or is
7 the only way that that would be flagged, through the
8 NRC mechanism? That's my question.

9 MEMBER NAG: Right. But the problem with
10 trying to flag -- you are trying to use an
11 inappropriate method to do it, because then you are
12 going to be putting -- to try to get that one person
13 who tried to deviate the rule, you are now going to
14 be getting say 100 good implants, because they are now
15 considered a medical event.

16 CHAIRMAN MALMUD: I understand. But if I'm
17 that one patient who naively is in the hands of that
18 one therapist, and has received an inadequate dose for
19 my prostate cancer, it is a critically important issue
20 to me. And having been brought before the NRC, if it
21 hadn't come before the NRC, it wouldn't have been an
22 issue to the NRC, but having been brought to the NRC,
23 can we turn our backs on this for fear of additional
24 paperwork, which we all are generally opposed to,
25 anyway, and abandon that patient? That's the

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1 question. It's a moral question that is raised.
2 We're not a moral group, we're a legal group, but
3 we're still moral human beings. What do we do about
4 that patient, having been brought to our attention?
5 Can it be dealt with? And I ask you, I ask this of
6 the radiation therapists, and the radiation therapy
7 physicists, is there a mechanism already existent in
8 your hospitals, and in out-patient therapy units that
9 will address this issue on behalf of that patient, or
10 is this something that falls to the NRC because there
11 is no current method to deal with that issue? Ralph.

12 MEMBER LIETO: Two points. One, the issue
13 about pre-implantation seems to be driving this, and
14 that's why the Subcommittee recommended that that be
15 dropped. The recommendation that's in the body of the
16 report, and I believe still in the regulation, is that
17 the written -- that the medical event would be based
18 on the source strength in the patient upon release.
19 So that the authorized user would have the ability
20 that after implanting, based on their judgment, if
21 they had to add or subtract number of seeds from their
22 pre-implantation directive, or planning, that that
23 would be the final determination of what the dose was
24 to the patient. Okay? So it's going to be the point
25 upon release from the recovery room, or post-

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1 procedural room, I forget the terms that's used.
2 That's what would be determining whether the written
3 directive was violated or not.

4 The issue about who finds this, the
5 written -- violations or medical events are self-
6 identified events. It's extremely rare, I don't know
7 of any right off the top of my head, but maybe it does
8 occur, where the NRC comes in and looks at the
9 treatment plans, and compares this written directive
10 versus the pre-implantation treatment plan, pulls
11 patient records, and so forth. They may spot check a
12 patient record, but in terms of the medical event
13 reporting, it's a self-identifying process, and so
14 it's really the licensee who goes back, looks at these
15 administrations, and identifies the events. And if
16 they're outside the written -- outside the medical
17 event reporting criteria, reports that to the NRC. So
18 that's, to answer your question, is it the NRC that's
19 identifying this, or is the -- it's the licensee
20 that's actually identifying the events upon review.

21 CHAIRMAN MALMUD: So it is the licensee
22 who identifies it. And, Dr. Howe, was it the licensee
23 who identified this problem to the NRC?

24 DR. HOWE: The physician that changed the
25 written directive identified it but I would also say

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1 that NRC in its inspection program, does identify
2 written medical events that the licensee had not
3 identified in the past.

4 CHAIRMAN MALMUD: So in this case, the
5 physician himself identified the problem.

6 DR. HOWE: And he changed the written
7 directive so he would not have a medical event.

8 MEMBER NAG: But he correct it by doing a
9 second implant.

10 DR. HOWE: But he didn't.

11 CHAIRMAN MALMUD: He didn't.

12 MEMBER NAG: Okay, but that the method --
13 I mean, the community rule for such an implant you
14 need the grade. Now if you have now done your
15 planning and said it's now six for a 30 minute, you
16 are not going to get grade. You are falling below the
17 medical standard, that would be reported by the
18 medical standards.

19 CHAIRMAN MALMUD: So it's a medical
20 practice issue. And this physician identified the
21 fact that he only delivered one-half of the does,
22 let's say that he intended.

23 MEMBER NAG: Right.

24 CHAIRMAN MALMUD: Now, that being the
25 case, was the patient informed that the patient only

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1 received one half a dose? This is really a medical
2 practice issue.

3 MEMBER SULEIMAN: Is it?

4 DR. HOWE: Yes, and no.

5 MEMBER SULEIMAN: Where is it stated in
6 medical practice that the doses got -- well, here's
7 the standard that you flag the person at.

8 MEMBER NAG: Most of the standards that
9 are developed are written by the ABS and most of them
10 were primarily authored either by one of the committee
11 members or one of the principal authors and we do give
12 those guidelines, so those guidelines -- it's like any
13 other medicine, you know, who many milligrams do you
14 take when you have --

15 MEMBER SULEIMAN: You know, I've been
16 bragging on the therapy, on the radiation therapy, the
17 brachytherapy community, big time to my colleagues in
18 FDA, especially, because I think radiation -- radio-
19 therapeutics right now are still in the dark ages
20 relative to that of in terms of dosimetry but if
21 somebody is supposed to get 150 gray and that patient
22 winds up getting 110 or 120, forget the source
23 strength and the activity, you want to know that the
24 dose that was delivered to the tumor was what it
25 should have been. How is that going to get flagged?

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1 CHAIRMAN MALMUD: Dr. Welsh?

2 MEMBER SULEIMAN: How is that going to get
3 flagged?

4 CHAIRMAN MALMUD: How is it going to get
5 flagged?

6 MEMBER WELSH: As I was trying to say
7 earlier, the routine standard recommendation is to do
8 formal post-implant dosimetry and have that documented
9 somewhere in the medical record.

10 MEMBER SULEIMAN: I can't see any
11 physician walking away with an incomplete dose. I
12 mean, that would bother me immensely. I mean, I would
13 think that -- now, maybe the procedure wound up not
14 giving a complete dose, therefore, the procedure --
15 the total treatment is not finished. They've got to
16 go back and do it right.

17 MEMBER WELSH: There are formal
18 recommendations made by our society, the American
19 Brachytherapy Society, for example, that state that
20 post-implant dosimetry should be done and it should be
21 documented in the chart that, for example, if the dose
22 prescribed was 135 gray, what did the prostate
23 actually receive. This way you can get some feedback
24 on what to tell your patient in terms of prognosis,
25 risk of side effects, based on the quality of that

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1 implant using parameters such as the D90 et cetera
2 which are normally used.

3 And this is, in my opinion, standard of
4 care and as mentioned, something that should be done
5 so that an implant can be judged on the quality, how
6 complete was the job really achieved. So, yes, the
7 answer is that there is a procedure that gives post-
8 implant dosimetry to all prostate implants as an
9 example.

10 CHAIRMAN MALMUD: Dr. Eggli?

11 MEMBER EGGLI? I think we're way down in
12 the weeds and we need to bring it up to a higher level
13 for just a second. The regulatory process will never
14 keep pace with changes in medicine. Regulations have
15 to be written thoughtfully to allow changes that occur
16 in the practice of medicine. And we're assessing here
17 harm versus good done. And our goal is to prevent
18 harm, although there are some -- there is no way to
19 prevent all harm, because no regulation can be written
20 such that someone can't sneak by and create harm
21 undetected. But if the community perceives the
22 regulation as oppressive and stays away from a therapy
23 which would benefit patients, then harm has been done
24 and there has to be a balance in the overall risk
25 versus benefit.

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1 If the bad actors are few and far between
2 and thousands and thousands of patients don't get
3 leading edge therapy because the regulation
4 discourages physicians from providing that therapy and
5 I can tell you having to call the patient and tell
6 them that a medical event occurred when a perfectly
7 good therapy happened, will, in fact, discourage
8 physicians from engaging in those therapies because it
9 puts them at medical/legal risk that they are
10 unwilling and rightfully unwilling to endure.

11 So we need to look at the balance of good
12 versus harm and we are concentrating on a few outliers
13 who create harm and potentially throwing out the baby
14 with the bath water and allowing state of the art
15 treatments to be delayed in their adoption simply
16 because we want to catch everyone who does harm, which
17 will never happen.

18 CHAIRMAN MALMUD: Dr. Welsh?

19 MEMBER WELSH: Yes, I would like to
20 reiterate Dr. Eggli's sentiment about our big picture
21 here. The subcommittee, the committee here and the
22 staff should be reminded that the primary purpose of
23 our subcommittee was to focus on the definition of
24 treatment site and what constitutes a medical event.
25 And that is relevant with Dr. Nag's wording and

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1 suggestions. It is relevant and works for whether we
2 use pre-implantation approaches or real time intra-
3 operative methods.

4 The administration of radio-isotope
5 material without a written directive constituting a
6 medical event was considered a less important subject
7 and was thrown in here at the very last slide as a
8 sort of footnote. And it seems like we've focused too
9 much on that aspect and perhaps that is worthy of a
10 complete separate discussion and topic, but I would
11 like to get back to the important point that Dr. Nag
12 brought up, which was the definition of the treatment
13 site and what constitutes a medical event because that
14 was really the core of our subcommittee's goal and
15 this last aspect about whether administration without
16 a written directive would constitute a medical event
17 was really a footnote in all of this.

18 CHAIRMAN MALMUD: Dr. --

19 MEMBER VETTER: I just wanted to point out
20 there are members of the public who have been waiting
21 some time to comment.

22 CHAIRMAN MALMUD: All right. Hello,
23 please introduce yourself.

24 MR. LOHR: Hi, I'm Ed Lohr. I'm with the
25 NRC rulemaking and I have this rulemaking, if you

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1 will, I'm the project manager. What I want to point
2 out is a document that was sent to the NRC by your
3 committee and signed by you, sir, Dr. Malmud, that
4 makes a recommendation to the NRC and I'm quoting
5 here. It says, "Implants in which more than 20
6 percent of the total source strength documented in the
7 pre-implantation written directive is implanted in
8 tissue organs adjacent to the treatment site, should
9 be classified as a medical event".

10 That is the official position from the
11 committee. I just wanted that to be brought out
12 because your subcommittee is now recommending
13 reversing that. My only comment.

14 MEMBER NAG: Yes, and I was one of the
15 principal ones who looked at the subcommittee report.

16 There were two of us, Jeff Williamson and myself were
17 the main ones. But that is why I'm saying some of the
18 unintended consequences that came after we looked at
19 that how exactly we should word it to that unintended
20 consequences do not creep in.

21 CHAIRMAN MALMUD: I saw another hand.
22 Ralph?

23 MEMBER LIETO: I was just going to say,
24 Mr. Lohr's point is well-taken but the suggested
25 change by the current subcommittee is also consistent

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1 with the approach that we've taking regarding the Y 90
2 microsphere brachytherapy device in that the total
3 dose or activity administered is based on the
4 administration before the patient leaves the post-
5 procedural room. So we're just recommending also to
6 be consistent with approach that we've taken more
7 recently.

8 CHAIRMAN MALMUD: Is there another hand?
9 Dr. Zelac?

10 DR. ZELAC: I'm not exactly sure where to
11 jump because there have been a number of things said
12 that I would like to comment on. However, I'll try to
13 keep it as specific as possible to the particular
14 point that's being discussed now. And this is in the
15 form of a question not a statement. As has been made
16 clear, before a procedure is done, seeds have to be
17 ordered and there is some expectation on the part of
18 the therapist as to how many seeds are going to be
19 required to treat this particular case, not the exact
20 number but approximate number.

21 My question is, does the number of seeds
22 which might be implanted differ by more than 20
23 percent from that expected number for implantation
24 very often or not at all?

25 MEMBER NAG: I wouldn't say very often but

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1 I would say often enough. If you want like a
2 percentage, I don't know, maybe 30, 40 percent we do
3 defer quite a lot from what we thought we might need.

4 So I can't give you an exact number but it happens
5 quite a lot, but what I'm saying is that the point
6 from which you should judge the deviation should not
7 be the point from the number of seeds that were
8 ordered but from the number of seeds that we finally
9 plan to put in.

10 If the tumor, for example, happens to be
11 much less then, you know, we might lower the number or
12 might lower source and still be justified. So it does
13 have some relation but you cannot coordinate one with
14 the other.

15 DR. ZELAC: Thank you.

16 CHAIRMAN MALMUD: That was your first
17 question, Dr. Zelac. You said you had others.

18 DR. ZELAC: Not in the way of a question
19 but just a statement I think might have some bearing
20 here. The whole point of having written directives is
21 to provide some reasonable assurance that what a
22 physician intends is in fact, what's carried out.
23 That's the whole point of it, otherwise, we don't need
24 a written directive. And a medical event is supposed
25 to be an indication that what the physician had

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1 planned wasn't carried out. It was outside of the
2 scope of what the original plan had been.

3 And the point about that is that it's
4 important essentially to identify these lapses in
5 procedures where the physician's directions were not
6 carried out. That's the whole point of having medical
7 events.

8 MEMBER NAG: And I agree with you
9 completely, and your second part is also very
10 important that, you know, that there was a deviation.

11 Now, here the point is that my plan is to give --
12 There are two considerations I have. One is what dose
13 I want to give and secondly, what number of source
14 plan we need that it was that dose which is dependent
15 on volume and many other things. So I have a certain
16 plan before but when I go in and I see that it is
17 somewhat different because of the shape and size, then
18 I am, in real time, changing what I'm planning to give
19 because that will -- that actually one is what I'm
20 finally planning on the table based on what I see on
21 the table.

22 So we adjust my deviation based on what
23 I'm seeing on the table, not based on something that I
24 have ordered. And sometimes I'll order 10, 20
25 percent, 30 percent, more if I'm not sure of what I'm

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1 planning to implant.

2 And then the second part of it, and here,
3 and you can go back to the subcommittee report from
4 four or five years ago, that there is a small
5 subparagraph in there that says that the NRC should
6 note that implantation done at other sites, other than
7 prostate, where the boundaries are not so well
8 defined, and there has to be a leeway or words to that
9 effect. So we did recognize even at that time that
10 there are different organs that have to be implanted
11 where the degree of number of seeds placed in the
12 margin are different.

13 CHAIRMAN MALMUD: Dr. Zelac?

14 DR. ZELAC: Let me ask a follow-up
15 question then. If you've made this determination,
16 when you go into the OR based on the treatment
17 planning system and the visualization system is there,
18 that the number of seeds that you anticipate at that
19 point in time needing to implant properly that patient
20 differs significantly from what you had thought
21 before, what would prevent you from simply issuing an
22 oral written directive at that point, before you start
23 the implantation, that says, "I expect to implant so
24 much source strength or so much activity" and then
25 deviations from that would constitute if outside the

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1 boundaries, a medical event?

2 MEMBER NAG: Yes, I think that would be
3 coming a little closer to my actual intent because
4 there are two or three places where I'm changing the
5 plan. One is when I'm in the OR and I'm doing my
6 first planning of the site. Then I have some idea
7 which maybe now quite different from the first, and
8 then as you are doing an implant, remember the dynamic
9 phenomena, the site is changing, where we are planning
10 to put the seeds is changing.

11 So now if I'm seeing that there are areas
12 of under dosage, I am having another one or two doses
13 changes as I'm going. So at the beginning of the
14 implant, the number or the plan that I have would be
15 closer to the truth but still quite far from my
16 initial plan but as I'm going closer and closer to the
17 end of the implant, I'm getting closer to what my
18 actual number should be.

19 CHAIRMAN MALMUD: Thank you, Dr. Nag. Dr.
20 Zelac?

21 DR. ZELAC: I could ask then a follow-up
22 question; if you were making a comparison to what was
23 actually implanted to what you anticipated needing at
24 the beginning of the procedure, not the prior, not a
25 pre-implant, but at the beginning, would you have

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1 variations of more than 20 percent often or not at
2 all?

3 MEMBER NAG: Okay, a very good question.
4 The feeling is that it's going to be less but I would
5 not say it would never happen but I would say it would
6 happen less often.

7 CHAIRMAN MALMUD: We have Dr. Eggli.

8 MEMBER EGGLI: I think an interesting
9 comment is Ron's last one, Dr. Zelac's last comment on
10 the purpose of a written directive. In many cases
11 therapies are provided by a physician other than -- or
12 a person other than the physician actually ordering
13 it. It's true in the nuclear medicine therapies.
14 It's true with a linear accelerator where a therapist
15 delivers the therapy that the physician ordered. The
16 intent of the written directive, you said, and I tried
17 to quote you as close as I can, is to make sure that
18 the patient is given what the physician intended.

19 In the case of brachytherapy, here, it is
20 in fact, that same physician who is administering
21 that dose and their intention is changing dynamically
22 over the course of the procedure are they are more
23 reliably able to determine the volume to be treated.

24 Somehow that concept of the written
25 directive then, needs to encompass the dynamic nature

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1 of treatment planning in brachytherapy so that it
2 accommodates the real time treatment planning that
3 occurs that says that I don't need as many seeds as I
4 thought, and maybe 30 percent less or I'm going to
5 need 40 percent more seeds than I thought because in
6 the real time planning process, as I'm here in the OR,
7 I see that and it turns out I have seeds in stock and
8 I can accommodate it.

9 But there's -- so I see a difference
10 between -- or a subtlety in the concept of the intent
11 of the written directive in a therapy where, in fact,
12 the physician writing the therapy is also
13 administering the therapy. I see the issue. I
14 understand the issue of wanting to make sure that you
15 can't just cover up an error by changing the
16 directive, but you need to be able -- the concept of
17 the written directive has to be dynamic enough to
18 encompass these dynamic changes that occur over the
19 process of treatment.

20 CHAIRMAN MALMUD: Thank you, Dr. Eggli. I
21 think next was, yes, Dr. Suleiman.

22 MEMBER SULEIMAN: I've gone 360 degrees on
23 this. The real true clinical end point or surrogate
24 end point would be the dose in gray and the fact that
25 the activity or source strength or whatever may vary

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1 is -- it's a quality control thing. It's an
2 intermediary thing and trying to lock in on that as a
3 metric is causing problems and it's causing
4 unnecessary, you know, record keeping.

5 Ultimately, you know what the dose should
6 be, what the absorbed dose ought to be and when it's
7 all finished, when it's all finished, you need to come
8 up with a final number and show that to total
9 delivered dose was pretty close to what you had
10 planned in the first place. And you can dispense with
11 all the intermediary stuff because that's up to the
12 skill of the physician and all the support he's
13 getting or she's getting.

14 CHAIRMAN MALMUD: Dr. Nag.

15 MEMBER NAG: The main reason why -- what
16 we are expecting now at the second part but the first
17 part, the main reason why we had to change the way we
18 could have interactive for permanent implants is that
19 as opposed to a removable implant, in a permanent
20 implant you cannot control the dose. You can control
21 the source plant you're putting in but the user cannot
22 control the dose because the dose is the dependent on
23 what happened afterward, the where the seed will end
24 up, where the seed moved afterwards and how the organ,
25 for example, the prostate, expands or contracts after

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1 the implant because you're doing a post-operating
2 implant dosimetry -- that's what the reason --

3 MEMBER SULEIMAN: That is real uncertainty
4 due to --

5 MEMBER NAG: That was the reason why we
6 wanted to change from a dose based prescription to a
7 source like based prescription because that's what the
8 -- one of the major reasons for the change. Now,
9 when we make those change, some of these unintended
10 consequences are creeping up because the major reason
11 of the change was to change from a dose based
12 perception which is controllable to a source plan
13 based prescription which we can control.

14 CHAIRMAN MALMUD: Mr. Lieto and then Dr.
15 Howe.

16 MEMBER LIETO: It seems to me the issue,
17 if I can just attempt to boil this down, is does the
18 committee accept the subcommittee's position that the
19 medical event should be based on the activity
20 implanted --

21 MEMBER NAG: Source strength.

22 MEMBER LIETO: -- source strength
23 implanted at -- when the patient is released from the
24 recovery room or is the medical event going to be
25 based on the pre-implantation activity source

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1 strength? It seems we're going back and forth about
2 this because that's what was currently written in the
3 proposed rules and gets to most of the points, I
4 think, that Dr. Zelac is driving at.

5 And I think we need to, you know, go from
6 there.

7 CHAIRMAN MALMUD: What is your
8 recommendation in this subcommittee report? Just
9 remind the committee what your recommendation is,
10 which of the two options?

11 MEMBER LIETO: The option recommended is
12 that the basis for the medical event should, quote
13 from the report, "The basis of the medical event
14 should be the total source strength implanted after
15 administration but before the patient needs the post-
16 treatment recovery area", end quote.

17 CHAIRMAN MALMUD: And that is the
18 recommendation that this subcommittee of the ACMUI is
19 making now in order to correct the unintended
20 consequence of what a similar subcommittee of this
21 committee made before; is that correct? Do you and
22 Dr. Nag agree with what I just said?

23 MEMBER NAG: Yes, that and the definition
24 of the treatment site because the two are somewhat
25 related.

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1 CHAIRMAN MALMUD: May we take that as a
2 motion?

3 MEMBER LIETO: So moved.

4 MEMBER EGGLI: Second.

5 CHAIRMAN MALMUD: And it's been seconded.
6 All in favor? Oh, discussion? Discussion, sorry.

7 MEMBER LIETO: Can anyone provide, if
8 there is such a thing, a summary of the position of
9 EBS or AAPM on this particular issue?

10 MEMBER NAG: Yes, EBS and AAPM have both
11 made the recommendation in writing to the NRC which is
12 available on the NRC website which AdLaw has which I
13 have seen and they're exactly the same as this.

14 CHAIRMAN MALMUD: I assumed that because
15 you last slide said that your presentation was with
16 the approval of these groups.

17 MEMBER NAG: Right.

18 CHAIRMAN MALMUD: The input of these
19 groups.

20 MEMBER NAG: And the one thing is,
21 basically, the same, and I mean, AdLaw is a public
22 document. If you can, you know -- if you can print
23 out that portion of the letter --

24 MR. LOHR: If you will, sir, what he's
25 referring to is the comments that are received on the

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1 proposed rule, they are public documents. They are
2 available at the NRC website. They're also available
3 at regulations.gov. I only have one hard copy and I
4 have not reviewed them. I simply have them, nor has
5 the working group reviewed them or analyzed them in
6 any manner. So I cannot say anything except that we
7 have them here and they're available publicly.

8 MEMBER NAG: I have reviewed them. I can
9 say that they are exactly the same.

10 CHAIRMAN MALMUD: So the committee, having
11 heard that you have reviewed them, and that from your
12 perspective, they are in agreement, we'll vote based
13 upon your motion and your statement. All in favor.
14 Any opposed? Three opposed, how many in favor again?
15 One, two, three, four, five, six, seven, eight.
16 Eight for, three opposed. Motion carries. Okay, now
17 -- okay, go ahead, Dr. Thomadsen.

18 MEMBER THOMADSEN: I might ask if it might
19 be useful for the NRC staff if there were a
20 subcommittee to look at possible ways to help the
21 staff evaluate whether there have been
22 misadministrations based on this recommendation.

23 CHAIRMAN MALMUD: A retrospective study
24 you mean?

25 MEMBER THOMADSEN: No, no, a prospective

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1 study so to speak based on these guidelines, the
2 problem that you've brought up, how do you record
3 misadministrations in some of these egregious cases?
4 And it sounds like it may be helpful if we were to
5 think about that, too, not that I'm positive that a
6 subcommittee could come up with recommendations, but
7 at least they might be able to contemplate the issue
8 and provide some guidance.

9 CHAIRMAN MALMUD: Someone from NRC wish to
10 respond to Dr. Thomadsen's question?

11 DR. HOWE: Clearly those that people
12 decided weren't medical events because they changed
13 things and it never came to our attention, we're not
14 going to be able to address but we do have a few cases
15 where, two cases in particular where changes were made
16 to avoid a medical event. And using what we consider
17 to be kind of a loophole of before completion of the
18 procedure to rewrite the written directive to
19 something that wasn't intended in any way. It was to
20 cover up -- not to cover up, but to essentially, not
21 to have an error even though the error was there.

22 MR. LEWIS: I would suggest that maybe we
23 have to let the working group on the rulemaking do
24 their work to analyze the comments and we'll be in a
25 more informed position of all the options and part of

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1 looking at the final rule language will be to
2 determine any regulatory impacts that the new language
3 might entail. And so I guess what I'm saying is we're
4 not there yet. Thank you for the offer.

5 CHAIRMAN MALMUD: Dr. Nag?

6 MEMBER NAG: Yes. There are basically
7 three major recommendations. In the last basic
8 recommendation summary there are three major
9 recommendations of the subcommittee and then the
10 fourth one is basically more like a word thing about
11 activity with the source plan and it's a
12 recommendation but, you know, basically more
13 nomenclature.

14 The fifth one about administration without
15 working directive and regulation violation and not a
16 medical event per se, is not a permanent implant
17 specific recommendation. It needs to be something
18 that can be solved for all type of brachytherapy and
19 if that is postponed and not considered as part of
20 this recommendation, that's fine with us. But the
21 first three are specific for permanent brachytherapy
22 and we would like those to be recommendations.

23 Now, if they are going to be delayed or if
24 there are some -- what I would say is we would take a
25 motion of each of these points separately and have a

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1 yes/no vote for each of this rather than a whole vote
2 of the whole document.

3 CHAIRMAN MALMUD: So what you're saying is
4 that what the committee has just voted on --

5 MEMBER NAG: Was the first part.

6 CHAIRMAN MALMUD: I beg your pardon?

7 MEMBER NAG: Was part one.

8 CHAIRMAN MALMUD: Were the three
9 paragraphs that begin -- the three bullet points that
10 begin with Paragraph 35.3045.

11 MEMBER NAG: No, what the committee voted
12 just now was Part One which is that implantation
13 should be deleted with pre-implantation with the new
14 directive. We did not talk about treatment site and
15 so forth. The whole thing was on Part One. What I'm
16 saying is to make it clear, we should vote on each of
17 those sub-parts separately.

18 MEMBER THOMADSEN: Clarification?

19 CHAIRMAN MALMUD: Dr. Thomadsen?

20 MEMBER THOMADSEN: I want to ask Mr.
21 Lieto, I think you made the motion, what his motion
22 actually was.

23 CHAIRMAN MALMUD: Ralph, you're being
24 asked to re --

25 MEMBER LIETO: You mean the one we just

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1 voted on?

2 CHAIRMAN MALMUD: Yes.

3 MEMBER THOMADSEN: What was it that we
4 approved? It would be nice to know.

5 MEMBER LIETO: It was one of the
6 recommendations of the subcommittee was that the pre-
7 implantation piece be -- or excuse me, the medical
8 event should be based on the total source strength
9 implanted after administration but before the patient
10 is released from the post-treatment recovery.

11 MEMBER THOMADSEN: So your motion is --

12 MEMBER LIETO: Basically, it's removing
13 the pre-implantation --

14 MEMBER THOMADSEN: -- you were intending
15 to just move that first.

16 MEMBER NAG: Yes.

17 MEMBER LIETO: I'm sorry, just to move
18 that what?

19 MEMBER THOMADSEN: The first
20 recommendation.

21 CHAIRMAN MALMUD: Take a look at next to
22 the last slide.

23 MEMBER LIETO: It was to get us off what I
24 thought was the sort of the merry-go-round of the
25 issues that we were discussing.

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1 MEMBER NAG: What I'm suggesting are put
2 those up on the board and therefore you can vote each
3 of those -- that is why I had made them in bullet
4 points. The last slide --

5 CHAIRMAN MALMUD: It's the last slide
6 before the roses and it's the first bullet point.

7 MEMBER THOMADSEN: I guess it really gets
8 down to just asking the committee do they accept the
9 subcommittee's report or they don't. I mean, that was
10 what I thought your motion said.

11 CHAIRMAN MALMUD: Well, that's what I
12 thought your motion was, too, that we accepted your
13 report.

14 MEMBER NAG: But the way the motion was
15 made, it was only that first paragraph.

16 MEMBER LIETO: Well, I will so move that
17 the ACMUI accept the subcommittee's report as
18 submitted in the ACMUI's packet.

19 CHAIRMAN MALMUD: That's a motion.

20 MEMBER LIETO: That's a motion.

21 MEMBER THOMADSEN: I second that motion
22 also.

23 CHAIRMAN MALMUD: Seconded again. Is
24 there discussion if this? Yes, Dr. Welsh?

25 MEMBER WELSH: I would be in favor of this

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1 with the exception of the second to last one where
2 administrations without written directive be cited as
3 regulation violation and are not medical events per
4 se. I think that could dilute the overall message and
5 that is such a controversial point which is different
6 in spirit from the first three, which are very clear
7 and fully supported by ASTRO, ABS and ACRO that
8 penultimate one was not discussed by ACRO, ASTRO and
9 ABS and therefore, I would suggest excluding that
10 particular paragraph.

11 CHAIRMAN MALMUD: Dr. Welsh, I will
12 editorialize. I am extremely pleased that you have
13 raised this point because I'm very concerned about the
14 case example cited by Dr. Howe which would have
15 escaped any kind of action by approving the fifth
16 bullet point. Mr. Lieto?

17 MEMBER LIETO: I take exception with that.
18 The example she giving would not be effected by this
19 whatsoever. The issue that Dr. Howe has been raising
20 is the fact that the individual changed the other
21 written directive and then changed it afterwards based
22 on their poor implantation procedure.

23 The point about not having a written
24 directive applies to all written directives, not just
25 brachytherapy, HDR. I mean, it applies to HDR,

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1 brachytherapy, radio-pharmaceutical therapies. And so
2 it also is a part of the proposed rules on permanent
3 implants. This subcommittee was directed to address
4 the proposed rules as they were addressing the
5 permanent implant -- permanent implant medical event
6 definition. That's part of those proposed rules and
7 that's why it was commented on.

8 MEMBER SULEIMAN: So you're saying that
9 that's an absolute violation of the regulation. It
10 shouldn't be factored in as a medical event.

11 MEMBER LIETO: Correct. I don't believe
12 that it should be considered a medical event. It's a
13 violation of the regulations already.

14 CHAIRMAN MALMUD: So they would still be
15 flagged for this.

16 MEMBER LIETO: Absolutely.

17 CHAIRMAN MALMUD: Is that what you were
18 going to say, Dr. Nag?

19 MEMBER NAG: No, what I was going to say
20 is the first four points have been discussed by many
21 scientific organizations including ASTRO, ACRO and ABS
22 and therefore, that -- those four can be taken
23 together. The fourth point about the administration
24 without written directive applies to permanent implant
25 as well as other types of implants. They are -- it's

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1 a slightly different issue, although it is linked to
2 this issue but it's a slightly different issue. It
3 has a much broader implication. It has not been
4 discussed by the other scientific boards like the
5 first four have been and therefore, if we need to make
6 a yes or no vote, it could potentially have some
7 conflicts if you try to make a yes and no vote of all
8 of them together. So I would prefer the first four
9 points to be as block vote and then the fifth point to
10 be a separate vote and, you know, the two can be --
11 both of them may be yes and yes or yes -- or no and
12 no, but they should be voted separately.

13 CHAIRMAN MALMUD: I understand your point.

14 Mr. Lieto?

15 MEMBER LIETO: Well, I've got to voice my
16 strongest objection. This is not an ASTRO report.
17 It's not an ABS report, okay. The fact that they
18 supported it is terrific, but this is a report from
19 the subcommittee of the ACMUI, okay, and if ASTRO has
20 a problem with it, ABS has a problem with it, APM has
21 a problem with it, or Society of Nuclear Medicine has
22 a problem with it, then they can put their comments in
23 and reject to that point if they so believe. I don't
24 think they will but this was a report from the
25 subcommittee of the ACMUI, not ASTRO, ABS or any other

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1 group and I think the fact that it wasn't -- you know,
2 prescreened and approved by the other organizations, I
3 don't think has any bearing on the subcommittee's
4 report.

5 CHAIRMAN MALMUD: Thank you, Mr. Lieto. I
6 interpreted Dr. Nag's comment to clarify his response
7 to my earlier question which was, did it have the
8 approval of all and it turns out that the first bullet
9 -- the first four bullet points had the approval of
10 all but not the entire. That's how I understood your
11 comment. It --

12 MEMBER NAG: Yes, right.

13 CHAIRMAN MALMUD: He was not rejecting his
14 own motion. He was just clarifying his earlier
15 response.

16 MEMBER LIETO: But I think the point that
17 is being made is that that should be pulled off as
18 being a part of where the report is -- the
19 recommendations of the subcommittee is addressed is
20 the fact that these other agencies or other
21 organizations didn't approve it and I have an
22 objection to that.

23 MEMBER NAG: Not didn't approve. They
24 didn't discuss it.

25 CHAIRMAN MALMUD: They didn't discuss it.

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1 MEMBER NAG: They did not discuss that
2 last one.

3 CHAIRMAN MALMUD: They only discussed the
4 first four bullets.

5 MEMBER NAG: Right, because that was not
6 on the agenda.

7 CHAIRMAN MALMUD: Thank you for clarifying
8 that. Dr. Zelac, you had your hand up.

9 MEMBER ZELAC: Just so that perhaps that
10 I'm perfectly clear before a vote is actually taken,
11 with the two events that Dr. Howe described under
12 current regulations the ones that are on the books
13 right now, those were not medical events. Under what
14 is out as the proposed rule, they would be medical
15 events. Under what is being proposed now by the
16 advisory committee's subcommittee, it would not be
17 medical events. Am I correct?

18 MEMBER NAG: I don't --

19 MEMBER LIETO: I don't -- my opinion, they
20 would be because --

21 DR. ZELAC: But if the physician has the
22 opportunity to essentially change the written
23 directive, up until the point where the patient is
24 released, what would preclude exactly what these
25 physicians did?

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1 MEMBER LIETO: It would get right back, I
2 think, to what Dr. Eggli I think stated before, that's
3 the practice of medicine. I mean, if that is his
4 clinical call that he needs to change that --

5 MEMBER SULEIMAN: It's modifying it
6 because of the way the procedure went because of the
7 physiology and whatever. That's just -- I would
8 consider that a modification. If that had lied, if
9 they had adulterated -- if they messed -- if they did
10 something, record something that was not correct,
11 that's -- that crosses over into an ethical situation.

12 I mean, modifying because a car is going off on the
13 shoulder and you bring it on is one thing, but if
14 you've run over somebody, if you change the numbers
15 because you screwed up --

16 CHAIRMAN MALMUD: Well, may I ask a
17 question? In nuclear medicine, if we prescribe 100
18 millicuries of I-131 for thyroid cancer, and it comes
19 in two capsules, and the patients is given the
20 capsules to swallow. Swallows one capsule and then
21 the bottle is put back into the pig and they don't
22 realize the patient didn't get the whole dose. That's
23 considered a misadministration.

24 Why is it not a misadministration if a
25 whole dose of radiation therapy, which was ordered by

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1 the radiation therapist but under the standard
2 practice of his or her therapy, gets into the wrong
3 organ, why is that not administration, particularly
4 when there is mendacity with telling the patient that
5 the patient didn't get what the patient was supposed
6 to get and is not going to get it? Mr. Lieto?

7 MEMBER LIETO: In your example, if the
8 patient had been discharged and left the facility, it
9 would be a medical event. But if the tech went back,
10 assayed the vial, found that the other capsule was
11 still in there, went back and gave the patient that
12 other capsule before they left, it would not be a
13 medical event.

14 CHAIRMAN MALMUD: That's correct.

15 MEMBER LIETO: And that's what we're
16 saying in this example, in this scenario here, with
17 the seeds. It's the same thing. Once they leave the
18 licensee's control from the treatment area, then
19 that's when the medical event is determined.

20 CHAIRMAN MALMUD: That's not the analogous
21 situation. The one that Dr. Howe described was one in
22 which the dose -- I'll give the nuclear medicine. I
23 ordered 100 millicuries. We gave the patient 50 by
24 mistake. The other 50 went back to the pharmacy in a
25 pig because it was thought that the patient had

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1 swallowed both capsules and we changed the order to
2 say 50 millicuries instead of 100. Thank you and
3 goodbye. That's the equivalent of what she described
4 in the patient who was to have gotten seeds into the
5 prostate for cancer.

6 And I wonder why is one situation treated
7 differently from the other? Dr. Nag?

8 MEMBER NAG: The reason for that is for
9 the implantation procedure is a dynamic procedure, so
10 in your case, you are not going to change whether the
11 patient is going to need 50 millicuries or 100
12 millicuries, depending on when he's swallowing and
13 every minute when he's swallowing is it changing
14 something? Well in our case, it means changing minute
15 by minute. So it is a dynamic procedure and we want
16 to be able to be able to have the written directive in
17 such a way that it understands or it takes into
18 account that brachytherapy is a dynamic procedure and
19 not aesthetic procedure.

20 CHAIRMAN MALMUD: Oh, I'm not debating
21 that. I'm not debating that. I'm in favor of what
22 you want. I'm still questioning -- I'm still
23 concerned about this patient who thought he was
24 getting fully treated for his prostate cancer, got a
25 fraction of the dose and then was told everything is

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1 fine, and the doctor changed the dose that he had
2 ordered previously and now there's no follow-up.
3 That's of concern to me and I wonder how will it be
4 picked up?

5 Will it be picked up in a tumor committee,
6 will it be picked up in the ordinary process of
7 medical care and therefore, it's strictly an issue of
8 medical practice or is the fact that the NRC has this
9 oversight ability, the only means that it will be
10 picked up and dealt with? It has to be dealt with.
11 This patient can't be allowed to think that he was
12 adequately treated when the physician himself who
13 planned the therapy knows he didn't treat the patient
14 adequately. That's my concern. Dr. Welsh?

15 MEMBER WELSH: I might argue that in Dr.
16 Howe's presented case that using Dr. Nag's proposed
17 nomenclature this would be classified as a medical
18 event and the reason is that if 20 seeds wound up in
19 the bladder, 20 seeds are outside the PTV, because by
20 Dr. Nag's proposed definitions, critical organs are
21 not part of the PTV. Therefore, if you have a whole
22 slew of seeds in the rectum, a whole slew of seeds in
23 the bladder, regardless of whether they are
24 subsequently removed, urinated out, or remain in
25 place, it is outside of the PTV and potentially an

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1 administration or medical event.

2 So I think that it would satisfy the
3 concern for the patient and when you do the post-
4 implant dosimetry, as a backup check, it would be
5 verified that these seeds are not in the position
6 they're supposed to be.

7 DR. HOWE: Could I make a follow-up --

8 MEMBER WELSH: I do think we need to have
9 some checks and balances though.

10 DR. HOWE: Could I make a follow-up to
11 that comment?

12 CHAIRMAN MALMUD: Dr. Howe?

13 DR. HOWE: If you're permitted to change
14 the written directive before the patient leaves, in
15 this particular case they would have just said, "Oh, I
16 intended to give 30 to the -- put 30 in the bladder
17 and take them out". There's nothing that holds you to
18 the treatment site. You can change the treatment site,
19 too. As long as you can change the written directive,
20 you can change any element of the written directive no
21 matter how strange it appears, because in these cases,
22 we're not really talking about you, Dr. Nag, or you,
23 Dr. Welsh. We're talking about somebody that doesn't
24 want to be held accountable for a medical event and
25 they're using the regulation to not be held

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1 accountable for a medical event.

2 In this particular case, subsequent
3 patients found by NRC had lots of medical events.

4 MEMBER NAG: And let me -- yes, how are
5 you going to write a recommendation for someone who is
6 incompetent? He has determined that he wants to
7 implant again in a prostate and in his calculation,
8 he's totally wrong and he calculated he needs only 10
9 millicuries when you need 100 millicuries. He
10 implants that 10 millicuries, and then he has
11 prescribed 10 millicuries, pre-implantation, post-
12 implantation was 10 millicuries. That patient is
13 bound to fail. That definitely is not a medical event
14 because he said he wanted 10 millicuries.

15 So how is that different from what this
16 unscrupulous physician is to what is an incompetent
17 physician, the other is an unscrupulous physician.
18 How are you going to catch them?

19 CHAIRMAN MALMUD: I would ask you that
20 question since you are the radio-therapist and I am
21 not.

22 MEMBER NAG: And the way we -- the way we
23 catch them is by the medical board. If a patient --
24 if a physician is having a large number of
25 recurrences, we -- you know, we do review the outcome

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1 results. That is an incompetent physician. If the
2 patient is having a rectal morbidity and having a
3 fistula, most likely he will end up with a lawsuit.
4 So you know, I think you know, you cannot catch
5 everything just by the definition of regulation.

6 So the way we are trying to do it is to
7 catch all the usual ones, have a definition that will
8 catch the bad actor, at the same time, it's not going
9 to catch dose-setting post-implant because it's like a
10 sieve, how small do you make the sieve without letting
11 everything out and yet getting the good ones.

12 CHAIRMAN MALMUD: Thank you. So you say
13 that the medical board does review the outcomes of the
14 therapies?

15 MEMBER NAG: Of the patient and also when
16 you're having the dosimetry, it consistently if
17 someone is giving, you know, half of what the ABS has
18 recommended, you know, they are going to be -- they
19 are going to be caught. That's why we have peer
20 reviews and peer reviews, every -- not every implant,
21 every treatment plan is peer reviewed by your peers
22 and --

23 CHAIRMAN MALMUD: No.

24 MEMBER NAG: You're supposed to have a
25 peer review. That's what the charts are meant for.

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1 MEMBER THOMADSEN: But it doesn't have to
2 be every case. This is Thomadsen. There's no
3 specification of a percentage of the cases. So you
4 can't say every implant gets reviewed. They don't.

5 MR. LEWIS: Dr. Malmud, if I could --
6 this, to me brings us back almost full circle, to a
7 point that Dr. Zelac made that what's important to us
8 is at some point in time even in a dynamic procedure,
9 a physician makes a decision that, "This is what I
10 intend to have".

11 MEMBER NAG: Yes.

12 MR. LEWIS: And the medical event then
13 becomes locked in, is contingent upon that decision
14 and if the decision is made after the fact, then what
15 you intend to happen becomes a variable, and you can
16 out of medical events. The current regulation and the
17 as proposed regulation will close that loop but maybe
18 not in a way that appreciates the dynamic procedure.

19 The proposal by the subcommittee, I think
20 you're hearing a lot of concern from the NRC staff,
21 goes too far in the other direction, that you can
22 redefine after the fact and we have a very specific
23 example that's an ongoing event right now, that
24 illustrates that that regulation could be abused. And
25 so maybe I'm stating the obvious but what we need, I

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1 guess, is a consensus point where medical event is
2 locked in, variation from what was intended at some
3 point and as we said, it could be right up until the
4 procedure is being done. It doesn't have to be, you
5 know, days or weeks in advance but we do need a firm
6 decision as regulated.

7 CHAIRMAN MALMUD: Dr. Nag?

8 MEMBER NAG: Yes, we do have our
9 intention. You know, our intention is those in the
10 region of 120 gray, let's say. So that is a dose that
11 is not to be measured by that plus or minus 20 percent
12 but an intention of approximately what we are trying
13 to achieve. And then we have a number of millicuries
14 that we start with to hopefully get that dose and then
15 we are changing from that, so if there's a huge
16 deviation from our initial intended dose in line with
17 -- you know, if you had what is in your case, that
18 patient obviously was less than 50 percent of the
19 intended dose. So maybe we can have both, that you
20 know, that there would be some relation to the dose
21 that was intended and then -- but the 20 percent would
22 be plus, minus, you know, final -- you know final
23 source plan that you wanted to come up with.

24 So, you know, someone -- I'm saying that
25 well, you know, I wanted only you know -- because in

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1 your situation he would end up -- instead of 140, he
2 will end up with 70 gray or somewhere in that range.
3 So we may have to do something like that if you want -
4 - you had some point with that, or --

5 CHAIRMAN MALMUD: Who had a comment, Dr.
6 Welsh?

7 I did. There was -- I don't remember who brought it
8 up here, but there was a suggestion I think, if I
9 recall correctly, or a question about what would we do
10 or what do we think about an oral written directive
11 put down at the time of the real time dosimetry. If
12 we were to accept that proposed solution, whoever, it
13 still could be consistent with Dr. Nag's principles
14 and what he has written down and it might satisfy the
15 concerns of those who are wary of post-procedure
16 written directive changes.

17 So whoever brought that question up, that
18 point up, could you perhaps reiterate what you said
19 before?

20 DR. ZELAC: I did. The current regulation
21 having to do with written directives permits the
22 physician to make changes when it's in the interest of
23 the patient. It's basically a result of changes in
24 the condition of the patient such that there can be a
25 change in the written directive orally as long as it's

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1 put down in writing within 48 hours.

2 Now, if it were possible and I'm not
3 saying it is under the current written directive
4 regulations, to massage that a little bit to
5 accommodate this situation so that you could
6 essentially come up with a pre-implantation written
7 directive, 10 seconds before you start your
8 implantation, and that may solve much of the problem
9 associated with this.

10 MEMBER WELSH: So if I might reply then,
11 it appears that that solution may be a viable solution
12 with the understanding as Dr. Nag has pointed out,
13 that intra-procedure, intra-operatively, there is a
14 dynamic process wherein the volume is changing and you
15 may want to make some subtle changes here and there
16 but it might still be a viable solution that would be
17 acceptable to all.

18 DR. ZELAC: Because again the criteria
19 that we're looking at were changes from what is in the
20 pre-implantation directive by more than 20 percent
21 being a medical event. I mean, that's why I asked the
22 question before if it's just before you start the
23 procedure would you expect variations of more than 20
24 percent from that number in terms of the anticipated
25 source strength to be implanted? And the answer I got

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1 was rarely.

2 CHAIRMAN MALMUD: Dr. Nag?

3 MEMBER NAG: Yes, but the suggestion
4 you're making would not help to catch the really
5 unscrupulous person because after the fact when he
6 implanted and he implanted only 50 percent, he can
7 then make a verbal written directive that I am now
8 giving --

9 MEMBER SULEIMAN: No, the current -- the
10 definition of the written directive is that it must be
11 created before the procedure begins.

12 MEMBER NAG: Right. But then it wouldn't
13 allow intra-operative changes; whereas if you're
14 allowing the written directive to be verbally changed,
15 then you could verbally change it after and say 50
16 percent. So it doesn't solve that problem either.

17 MEMBER FISHER: No, that's not correct.

18 MEMBER NAG: Why?

19 CHAIRMAN MALMUD: Who is speaking? Dr.
20 Fisher.

21 MEMBER FISHER: If you have a written
22 directive that states the physician intent to achieve
23 a certain outcome, and during that procedure you're
24 making those adjustments that you need to make to
25 achieve the original intent, then you're not violating

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1 that written directive.

2 MEMBER NAG: Let me -- with a dynamic
3 procedure, your written directive before what you say
4 you need 15 millicuries or 50 at normal strength.

5 MEMBER SULEIMAN: See, but that's where
6 the problem is because those are variables. The final
7 dose is the one that's the more static, the more
8 finite, the more targeted thing and so that -- you're
9 not going to mess that up often.

10 MEMBER NAG: You will, but that was the
11 reason why we changed from those -- now, we are going
12 back, and saying none of these things will occur.
13 Because now you're going back to the old method of
14 doing it dose-based rather than source-strength based
15 and we said that source-strength based would not work
16 because -- I mean, the dose-based doesn't work in
17 brachytherapy because many of the things are not under
18 the physician's control. So that's why we go back to
19 a dose-based prescription.

20 MEMBER SULEIMAN: I disagree.

21 CHAIRMAN MALMUD: There is disagreement
22 from a number of the members. It's now 1:15. The
23 cafeteria begins closing at 1:30. So in order for us
24 to get some lunch, we'll have to interrupt this
25 discussion if we may and then return to it. So what I

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1 suggest is that we meet back here at 2:00 o'clock. Is
2 that okay? 2:00? And then if we have to we'll adjust
3 the schedule later, because we have some people here
4 for the next presentation who have a return flight and
5 we'll -- so we'll come back to this. I apologize for
6 the interruption but we do not control the cafeteria.

7 (Whereupon at 1:18 p.m. a luncheon recess
8 was taken.)

9 CHAIRMAN MALMUD: Ladies and gentlemen,
10 I'm going to change the order of the presentations
11 today. Because our 2:45 p.m. schedule would delay the
12 departure of those who have flown in just to discuss
13 the Yttrium-90 with your indulgence we'll pick up the
14 topic of Yttrium-90 Microsphere Licensing Guidance now
15 and then come back to the subject we were discussing
16 before.

17 I asked of Dr. Nag and he's agreeable with
18 that. So that we'll move ahead on the next item which
19 will be the Yttrium-90 Microsphere Licensing Guidance.

20 But I think we need an AV person here. Do we have
21 one?

22 He's there. I see him. Okay. Great. I
23 didn't see you back there. Hi. Okay. So Dr. Salem
24 will do the present and we'll skip a minute to get
25 those slides in there because we have changed the

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1 order of things.

2 So the next item on the agenda is Yttrium-
3 90 Microsphere Licensing Guidance. When we have
4 completed that, we will then come back to a discussion
5 of Permanent Implant Brachytherapy Rulemaking and then
6 move on depending upon what the time allows. Dr.
7 Zelac indicates that it may not be necessary for him
8 to use the total time allowed for him. So we may be
9 able to get back on our schedule again.

10 With that, I'll introduce a face familiar
11 to most of you and that's Dr. Salem from Northwestern.
12 Dr. Salem.

13 8. YTTRIUM-90 MICROSPHERE LICENSING GUIDANCE

14 DR. SALEM: Thank you, Mr. Chairman.
15 Thank you for the ability to change the schedule and
16 accommodate some of our earlier flights.

17 MS. TULL: Here are the handouts for Dr.
18 Salem's slides.

19 DR. SALEM: Thank you.

20 MS. TULL: So please take two pages at a
21 time.

22 DR. SALEM: All right. So I'd like to
23 take about ten minutes or so to discuss some ideas we
24 have about the next steps in involving Y-90 therapy
25 at the NRC guidance level. As everybody knows on the

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1 Committee, we've worked with the NRC and the ACMUI and
2 had 490 and 390 now represented for AU eligible for
3 Yttrium microspheres and I'd like to spend a few
4 minutes talking about that and some of the issues that
5 have come up. I'd also like to point out that we do
6 have representation from the Society of Interventional
7 Radiology here and the American Board of Radiology to
8 discuss any issues that NRC or ACMUI might have.

9 As a brief review, this therapy has been
10 around for about eight to ten years or so in this
11 country and I think it's fair to say there is a steady
12 increase in adoption of this therapy as a treatment
13 option for many patients. I think conservatively over
14 5,000 patients have been treated in the U.S. in the
15 last ten years or so. I think that's a conservative
16 estimate.

17 The status for a long time was the 35.490
18 and recently with the September revisions of the NRC
19 document it's now under 390 and some of the work that
20 we did with the NRC on this was for interventional
21 radiologists to fall under 390 or at least meet some
22 of the requirements to become authorized user eligible
23 for Y-90 under 390.

24 In parallel over the last five to ten
25 years or so, I would like to point out there have been

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1 several collaborative efforts between the societies on
2 this therapy. The first one was spearheaded by Dr.
3 Nag. This is the Rebok document published in Rad
4 Journal of 2006 really reviewing this therapy, the
5 status of this therapy. It was very well represented
6 and, in this document, it did recommend that radiation
7 oncology, nuclear medicine and interventional
8 radiologists were all qualified to be authorized
9 users.

10 Also at the American College of Radiology
11 level, another document has been published, the
12 guidance document, practice guidelines in 2008. Also
13 very well represented by several members of ASTRO,
14 ACRO, SIR and the American Board of Radiology and it
15 did go through several committees, the Radiation
16 Oncology Committee, Interventional Committee,
17 obviously the comments reconciliation and again
18 several types of conclusion that specifically to AUs,
19 this document also agreed that all three
20 subspecialties were qualified to be authorized users.

21 So the scope of the issue that we have
22 today that I would like to address is that under 390
23 there are many states and local radiation safety
24 committees or safety officers that are uncertain if
25 interventional radiology fulfill the requirements of

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1 35.390 and the reality of it is that it has created
2 some confusion and certainly an impedance of the
3 ability of interventional radiologists to gain
4 authorized user status and unfortunately this does
5 limit in some cases the ability of patients to
6 therapeutic options.

7 Now ideally, you would want to work
8 collaboratively with nuclear medicine, radiation
9 oncology and IR. Unfortunately, that is not practical
10 or plausible in several centers. Hence some of the
11 confusion that's been created and hence one of the
12 topics of discussion today.

13 I would like to review for the Committee
14 what interventional radiology training is about. It's
15 five years of diagnostic radiology with anywhere from
16 700 to 960 clinical hours in nuclear medicine of which
17 there are 80 hours of classroom and laboratory
18 training. There is a formal written radiation physics
19 examination that reviews safety and biology, etc.
20 There's a formal written radiology examination and a
21 formal oral board examination. Interventional
22 radiologists then complete added fellowships in
23 interventional radiology in catheter-based techniques.

24 Of the 80 hours that interventional
25 radiologists now have, I just sort of underlined some

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1 of the salient features of the training that's
2 included: the radiation biology, radiation
3 protection, safe handling and administration and, of
4 course, quality control of radiopharmaceuticals.

5 If I could have the slides displayed in
6 the front. I apologize. That's been changed.

7 (Off the record comment.)

8 So again also under the 80 hours, other
9 subjects are surveying dose calibration, managing
10 radiation spills and accidents and, of course,
11 prevention and management of medical events.

12 Qualifications for authorized user status
13 by interventional radiologists, I think it is well
14 known and well recognized by most, if not all,
15 knowledgeable of this therapy that Y-90 today is
16 performed safely and effectively at institutions with
17 IRs and non IRs as authorized users. And one of the
18 critical aspects of this therapy does revolve around
19 patient selection criteria for liver-directed therapy
20 and the safety delivery of this therapy using advanced
21 catheterization techniques which is in the realm of
22 interventional radiology.

23 Interventionals have also worked very
24 extensively with Yttrium therapies since the beginning
25 and have organized courses and workshops and symposia.

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1 A lot of the research is being performed by
2 interventional radiology on this therapy. And again,
3 as I described before, there are several consensus
4 documents.

5 One, I think, of the most powerful
6 arguments for interventionalists having a road to
7 authorized users is that authorized users today are
8 being proctored by interventional radiologists. So
9 they are being given their credentials by
10 interventional radiologists.

11 So the proposal to be discussed here
12 today, the above line talks about 35.390 and 490 which
13 is the status today. One of the things I'd like to
14 discuss and proposed for the Committee is to permit
15 interventional radiologists that are under 35.290 with
16 the appropriate examination administered by the
17 American Board of Radiology and this has been approved
18 by the American Board of Radiology to then provide a
19 road or pathway to authorized user status for Y-90.

20 The Society of Interventional Radiology
21 and the American Board would most likely provide a
22 course of CME hours to be determined, taught by
23 experts involved in Y-90 microsphere therapy and the
24 two largest aspects of the course would involve first
25 of all patient selection of preparation at the IR

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1 specific subjects, so therapy planning and dosimetry,
2 techniques of MAA and vascular mapping, the IR-
3 specific portions of the procedure and also the dose
4 selection and preparation of Y-90 and specific
5 radiation physics and dosimetry as it applies to Y-90.

6 This would not prevent people that are going to
7 become authorized user from the vendor-specific
8 training that is already in the NRC guidance
9 documents. So no change in that.

10 So to summarize right now authorized user
11 approach is 35.390 or 490 with vendor training per the
12 guidance document. We would like to propose or at
13 least open up a discussion on the possibility of
14 having 290 plus an ABR primary clinical certificate
15 for Y-90 and, of course, vendor training as a
16 possibility for consideration for IRs as authorized
17 users. The American Board of Radiology has already
18 agreed to this approach to grant this primary AU
19 certificate and, as I mentioned before, would not
20 preclude other recognized and standard vendor training
21 and onsite support from the manufacturers of Y-90
22 microspheres.

23 Open for discussion.

24 MEMBER NAG: One quick question. Who
25 grants the primary AU certificate? I thought it was

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1 not within the jurisdiction of American Board of
2 Radiology. Authorized user is an NRC term and
3 therefore can only be granted by the NRC, not by the
4 ABR. Am I right or am I wrong, someone from NRC?

5 DR. GUIBERTEAU: Mickey Guiberteau. I am
6 the trustee of the American Board of Radiology,
7 primarily for nuclear medicine and other issues.
8 That's the way we perceive it. We give AU eligible
9 certificates. That means that a person who is a
10 diagnostic radiologist, a candidate, who becomes a
11 diplomat by receiving a certificate by going through
12 our exam process that's been approved by the NRC then
13 becomes AU eligible. That is presuming that they have
14 been attested to us that they've completed that
15 training and they've had their examinations. They
16 become -- They basically have achieved deemed status
17 through that certificate for 290 and 392 portions of
18 the rule. But, yes, we don't grant AU.

19 DR. SALEM: I think the correct item would
20 be AU eligibles. Is that it?

21 DR. GUIBERTEAU: That's the term.

22 DR. SALEM: Or AU eligible.

23 CHAIRMAN MALMUD: Dr. Howe.

24 DR. HOWE: Dr. Nag, I think the important
25 thing is we asked the American Board of Radiology to

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1 put some kind of distinguishing mark on their
2 certification that we could tell that these
3 individuals met NRC's requirements versus other
4 individuals that didn't. They happened to select the
5 term "AU eligible." It does not mean they're AUs. It
6 just means that's how we distinguish them.

7 MEMBER NAG: Thanks for that
8 clarification.

9 CHAIRMAN MALMUD: Thank you. Dr. Eggli.

10 MEMBER EGGLI: Could this proposed pathway
11 to be implemented without a rule change?

12 DR. HOWE: No.

13 CHAIRMAN MALMUD: Dr. Eggli.

14 MEMBER EGGLI: If it requires a rule --

15 DR. HOWE: I'm sorry. I'm sorry about
16 that. It's 35.1000. So 35.1000 is not in 35 as one
17 of the regular modalities. So this is guidance on the
18 website. So we would not need a rule change.

19 MEMBER EGGLI: Okay.

20 CHAIRMAN MALMUD: Dr. Welsh.

21 MEMBER WELSH: Jim Welsh. Thanks, Dr.
22 Salem, for that excellent presentation. Right now,
23 390 users are required to have 700 hours of total
24 training, 200 hours of classroom and laboratory
25 training to be AU eligible, documenting that they have

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1 the appropriate safety training. How would you
2 propose that this certification procedure goes? In
3 your presentation, you said a number of hours to be
4 determined. What can you tell us that would assure
5 the Committee that IRs would have the requisite level
6 of training and experience particularly in safety
7 status?

8 DR. SALEM: So I think it's important to
9 recognize that when we talk about AU status here the
10 request is for AU status for Y-90 primarily. And the
11 discussions we've had right now revolve around some
12 type of training course which would be co-sponsored by
13 the SIR and the ABR. And this would be in the
14 vicinity of 20 to 40 additional CME credits where
15 participants would come and attend and really get very
16 in-depth Y-90 only type training.

17 And so this would leave most AU eligible
18 radiologists with their portion that they received in
19 diagnostic radiology to 80 hours plus a number of
20 hours that we deem are acceptable, not too short but
21 also not too long that makes providing this kind of
22 training prohibitive and, in fact, impossible in many
23 ways. From there, the idea is that person might then
24 be able to sit for this examination and from there
25 then become AU eligible for Y-90.

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1 CHAIRMAN MALMUD: Dr. Eggli.

2 MEMBER EGGLI: Most of the therapeutic
3 uses come under part 300 and the training and
4 experience requirements are in 390 with the exception
5 that the use of radioactive iodine has slightly
6 different requirements and is covered in 392 and 394.

7 I guess for some consistency in therapy,
8 although I guess here we would be into rulemaking, I
9 would personally prefer to see something like a 396 or
10 something like that that dealt specifically with a
11 therapeutic application limited to Y-90. If you
12 essentially grant 390 style authorizations to folks
13 trained to 290 I guess the question would be do you
14 open up some kind of a wide range of therapeutic
15 possibilities because actually I actually heard Dr.
16 Salem say it would be predominantly limited to Y-90.
17 So again, I would prefer to see something like a 396
18 limiting the therapeutic use to Y-90.

19 CHAIRMAN MALMUD: Dr. Nag.

20 MEMBER NAG: Yes. Two points. First of
21 all, you can't use 396 because 396 was the pathway for
22 radiation oncologists to be in unsealed sources if
23 they were radiation oncologists and they had to --

24 MEMBER EGGLI: That didn't exist then.

25 MEMBER NAG: But I mean something similar.

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1 MEMBER EGGLI: Something like that.

2 MEMBER NAG: Something similar. But
3 secondly, if we were to have a pathway like that, what
4 would then that interventional radiologist to say,
5 "Now I'm authorized user and now I'm going to use it
6 to do Yttrium-90 or I want -- brachytherapy" or some
7 other thing?

8 MEMBER EGGLI: Again, if you wrote it as a
9 subpart it would be limited to Y-90.

10 MEMBER NAG: That is if it was a subpart.
11 But if it was the way Dr. Salem is requesting that
12 they would therefore gain authorized status with 20
13 hours, wouldn't that prevent that person from now
14 saying, "Well, I am an authorized user. I'm going to
15 put in a catheter and use XYZ isotope"?

16 DR. SALEM: Can I reply to some of that?
17 The intent is certainly not that and, in fact, I
18 specifically stated in the training course that this
19 was specifically for Y-90. The reason I said
20 predominantly Y-90 is because the concept here is
21 transarterial microsphere brachytherapy and there is
22 research being done in P-32 and other types of
23 similarly administered microspheres. This is not a
24 mechanism to have wide scope ability to perform
25 brachytherapy. This is a transvascular micro

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1 brachytherapy. This is what this is. So that's the
2 explanation.

3 CHAIRMAN MALMUD: Dr. Thomadsen.

4 MEMBER THOMADSEN: A precedent for
5 something like that would be 491 which is the
6 strontium 90 ophthalmic applicators which only a user
7 there is only approved for that use.

8 But I would throw a question to my
9 radiation oncologists colleagues here and as well Dr.
10 Salem has pointed out that the interventional
11 radiologists train the radiation oncologists on that.

12 They really don't train the radiation oncologists on
13 that. They train them in the procedure, but the
14 radiation oncologists don't do the procedure. They
15 write a prescription issuably because they are the
16 ones who are familiar with radiation reactions at high
17 doses in various parts of the body and the question to
18 my colleagues would be what would you think would be
19 the minimum requirements necessary for somebody to
20 have enough training and experience in such reactions
21 and expectations and doses necessary for control of
22 tumor in order to qualify as an authorized user.

23 MEMBER NAG: I think for that you would
24 require training on oncology. You would require
25 training on the adverse effects of radiation and how

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1 cancer spreads and how cancer is controlled and
2 basically you would require like a semi-radiation
3 oncology residency. In fact, I don't know how you can
4 learn only about liver cancer oncology without having
5 some general oncology expertise.

6 Now talking about that the report that was
7 sent out says that the radioembolization team requires
8 expertise in medical management, someone who has
9 medical management of the cancer patient, someone who
10 can perform the scan which is an interventional
11 radiologist, someone who can perform a scan with an
12 interventional radiology scan and then assume
13 responsibility for the delivery of the microsphere and
14 be the authorized user and then monitor radiation
15 safety.

16 So that person would therefore have to be
17 a radiologist as well maybe have training in medical
18 management of the cancer patient if they are going to
19 be one and the same. Otherwise this function can be
20 done by two people. So actually we have five
21 functions that are mentioned here probably best
22 managed by at least three or four people. So we have
23 five different individual kinds of management that are
24 needed. Now whether it's performed by -- Can all
25 those five be performed by one person? Almost

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1 impossible. By three or four, definitely. Whether
2 someone has -- whether two people can share and show
3 competency in all those five functions, that's
4 something we have to see.

5 CHAIRMAN MALMUD: Dr. Salem.

6 DR. SALEM: Just a few comments. First, I
7 think interventional radiologists who have been
8 performing and focused on oncologic therapies are
9 extremely well trained and extremely well competent
10 and able to handle and deal with all of the issues
11 that Dr. Nag has mentioned when it comes to diagnosis
12 and management, etc.

13 I think it's also important to recognize
14 that we are not asking to take over the cancer
15 management of the patient. This is an administrative
16 request for authorized user status. Of course, the
17 patient is also managed by his surgeon and his medical
18 oncologist and his radiation oncologist.

19 The request here is for authorized user
20 status without implication that this will be done solo
21 by interventional radiologists without really the
22 multidisciplinary team which is very well laid out in
23 all guidance documents.

24 CHAIRMAN MALMUD: Other comments or
25 questions of Dr. Salem?

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1 MEMBER NAG: I think a similar request --

2 CHAIRMAN MALMUD: I think Mr. Lieto was
3 next.

4 MEMBER LIETO: Along that line of the
5 comment that you just made about the team approach,
6 aren't at least one of those an authorized user to
7 begin with and has been involved either radiation
8 oncology and/or nuclear medicine? So wouldn't one or
9 both of those team members be an authorized user?
10 Because what you're saying is that you would have
11 potentially a team member or a team approach in which
12 none of them have nuclear or say radiopharmaceutical
13 or radioactive material experience and training and
14 it's only going to be the IR that's going to have
15 this. That's why he needs to be the AU. That was a
16 question I guess more.

17 DR. SALEM: Yes. First of all, there are
18 many different models where this therapy is being
19 applied because it depends on local practice patterns,
20 size of the hospital, the referral base, etc. And it
21 is not the norm to have as you stated everybody be an
22 authorized user.

23 However, in some centers, the radiation
24 oncologist is an AU. In some centers, the nuclear
25 medicine and in some centers, the IR. And there are

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1 very successful and well-run practices where in fact
2 only the IR is the authorized user not because of by
3 choice but because of the inability of other
4 disciplines to participate, maybe too clinically busy.

5 It's not often that easy to have everybody join and
6 meet to work with this therapy. But everybody is
7 involved in some way and the interventional
8 radiologist is the common denominator in all
9 practices.

10 MEMBER NAG: Therefore, in these uncommon
11 circumstances where you do not have a radiation
12 oncologist or a nuclear medicine in this modern
13 hospital you are suggesting that the therapy would
14 then be done by interventional radiologists with a
15 surgeon and that's the only involvement that would be
16 there. Is that what you're suggesting?

17 DR. SALEM: I'm suggesting that there are
18 places where this, in fact, happens and has been going
19 on for many, many years.

20 CHAIRMAN MALMUD: Dr. Welsh.

21 MEMBER WELSH: Jim Welsh. I'm not sure I
22 could agree with that because wouldn't -- I understand
23 and agree with the idea that the IR is the common
24 denominator. But isn't nuclear medicine always
25 present, too, if you're doing the imaging? So you

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1 have to have nuclear medicine as well and therefore
2 you would have an AU available in the institution.
3 Correct me if I misinterpret that.

4 DR. SALEM: Yes. So we need to make sure
5 that we're talking about the same thing when we talk
6 about present or the AU or there is some terminology I
7 think that we differ with. At our institution, for
8 example, neither radiation oncologists nor nuclear
9 medicine physicians are authorized users.

10 MEMBER GILLEY: Wait. But you're a broad
11 scope academic.

12 DR. SALEM: Yes.

13 MEMBER GILLEY: Okay. A different set of
14 rules here.

15 DR. SALEM: Well -- What is that?

16 MS. TULL: This is Ashley. I said and
17 agreement states. This is guidance so the agreement
18 states can follow whatever the agreement state feels
19 they need to follow.

20 DR. SALEM: So Dr. Welsh is correct.
21 There is always also nuclear medicine involved in the
22 imaging assessment of lung shunting and extrahepatic
23 flow. That is correct. But that does not necessarily
24 mean that the nuclear medicine physician is an
25 authorized user.

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1 DR. GUIBERTEAU: For Y-90 microspheres.

2 DR. SALEM: For Y-90 microspheres.

3 MS. TULL: Dr. Malmud, this is Ashley.

4 There are interventional radiologists named as
5 authorized users in agreement states.

6 The state can regulate under its own
7 jurisdiction. This is not regulation. There is no
8 level of compatibility with Part 1000. It's
9 Compatibility D. So we write this guidance. We do
10 send this guidance to the agreement states so that the
11 state regulators can look at it. But if they choose
12 to on a case-by-case basis approval an interventional
13 radiologist as an authorized user we found this is I
14 don't want to say a common practice, but it is out
15 there.

16 CHAIRMAN MALMUD: Mr. Lieto.

17 MEMBER LIETO: I have a question for our
18 agreement state member across the table.

19 (Laughter.)

20 MEMBER GILLEY: Not important.

21 MEMBER LIETO: How frequently does or do
22 agreement states not follow NRC guidance? In other
23 words, do they take that as their template and they go
24 from there? Or do they just -- Or is it hit and miss?
25 Some agreement states follow it explicitly or?

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1 MEMBER GILLEY: Some. It depends on the
2 skill level and the number of employees. Some follow
3 NRC agreement guidance documents verbatim. Other
4 states that have larger programs with more people that
5 can do development of regulations and guidance do not.

6 MEMBER LIETO: Thank you.

7 CHAIRMAN MALMUD: Other comments or
8 questions?

9 MEMBER VETTER: Question.

10 CHAIRMAN MALMUD: Please do.

11 MEMBER VETTER: This is Dick Vetter.
12 Could Ashley or someone review for us the
13 qualifications of those authorized users in general?
14 In a state where an IR is an authorized user, what are
15 their qualifications that allow them to be an
16 authorized user?

17 MS. TULL: That is completely up to the
18 state.

19 MEMBER WELSH: Can I ask a follow-up
20 question?

21 CHAIRMAN MALMUD: Dr. Welsh and a member
22 of the public.

23 MEMBER WELSH: Okay. On the same
24 thinking, what would disqualify a radiation oncologist
25 or a nuclear medicine physician who has gone through

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1 all the training and is AU eligible but now is not an
2 authorized user?

3 MEMBER VETTER: Yes, I'm confused about
4 that as well.

5 MS. TULL: I'm sorry. Repeat the
6 question.

7 MEMBER WELSH: So if somebody is a
8 radiation oncologist or nuclear medicine physician and
9 has gone through all the training and has board
10 certification and is AU eligible, a state can say that
11 you're not an authorized user.

12 MS. TULL: They could have more stringent
13 criteria, yes. I can't imagine it being anything more
14 than a radiation oncologist, I mean.

15 MEMBER NAG: The only -- If he wanted to
16 apply and if he could, if he took the training of that
17 three cases, the three cases and the vendor training.
18 So if he doesn't want to do -- If a radiation
19 oncologist doesn't want to do a vendor training and
20 doesn't want to do the three cases then he couldn't
21 apply.

22 MEMBER GILLEY: May I?

23 CHAIRMAN MALMUD: Please.

24 MEMBER GILLEY: I'm Debbie Gilley. Part
25 1000 is a unique animal and because of the way it's

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1 set up it's meant for the innovated new technology to
2 come on board. We would be able to get some
3 experience with that and then the intent I thought was
4 once it became a common practice out there we would
5 roll it out of partner -- and put it into the 200, 300
6 or 400 or 600 or which ever one it best fit and what
7 we have here is a gap.

8 The agreement states, some of them have
9 more experience with this technology than others just
10 by the nature of their size and the number of medical
11 institutions within their state. So they have
12 flexibility to do that and that's part of the reason
13 it's Part 1000 is to give the agreement states some of
14 that flexibility. So you're going to find it to be
15 across the board. There are 35 different agreement
16 states. There are going to be 35 different ways they
17 handle Part 1000.

18 CHAIRMAN MALMUD: Ashley.

19 MS. TULL: Another point to make is for
20 the broad scopes. This is going to be driven by the
21 Radiation Safety Committee. So it's going to be
22 institution by institution. That's how you could very
23 easily have a interventional radiologist as the
24 authorized user.

25 CHAIRMAN MALMUD: Dr. Welsh.

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1 MEMBER WELSH: So then, in summary, Dr.
2 Salem, it sounds like you're proposing that IRs be
3 authorized users because there is a shortage of AUs
4 and because you feel that IRs can be qualified for
5 this type of therapy.

6 DR. SALEM: I mean fundamentally I believe
7 and this has never changed that radiation oncology and
8 nuclear medicine and IRs are qualified and have the
9 qualifications to be authorized users for this very
10 unique technology. This is I think one of the very
11 important aspects. Is there a shortage of AUs? There
12 are at times as I have been told because I'm a
13 representative here of the SIR and the ABR that there
14 are at times a lot of confusion on the qualifications
15 and the ability of IRs to meet the AU standard that
16 the NRC has just put out and so this is why this
17 discussion is being initiated is to find solutions to
18 this. But it is in all honesty part of the problem
19 but certainly not the majority of the problem.

20 CHAIRMAN MALMUD: Member of the Public,
21 would you please introduce yourself?

22 MR. SOULEN: Hi, I'm Dr. Michael Soulen.
23 I'm a Professor of Radiology and Surgery at the
24 University of Pennsylvania and I run the
25 interventional oncology program at the University of

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1 Pennsylvania. I'm using Yttrium before actually it
2 was introduced to the United States. I guess the
3 original TheraSphere trial for HCC almost ten years
4 ago.

5 Just to give you sort of a perspective on
6 the IR as an AU, when we started doing this at Penn
7 one of our nuclear medicine, actually a couple of
8 nuclear medicine attending were the authorized users
9 for Yttrium-90. And the problems that ensued were
10 that although one might conceive that a nuclear
11 medicine physician or a radiation oncologist might be
12 instrumental in the management, diagnosis and
13 prescription for the patient.

14 In fact, the patients are referred to the
15 radiology clinic. They're assessed by us. We make
16 the treatment plan. We review the diagnostic images
17 and analyze them. All the factors that go into the
18 plan, the treatment dose, are actually determined by
19 the interventional radiologist and then we fill out a
20 spreadsheet which we would then hand our authorized
21 user to sign so then the material can be administered.

22 So, in fact, all the treatment planning and the data
23 necessary to do the treatment planning and the image
24 analysis of the treatment planning with the exception
25 of calculation of lung shunts by nuclear medicine on

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1 the diagnostic MAA study was already being done by the
2 image radiologist. He was essentially doing all the
3 work and admitting the patient, treating the patient
4 and doing all the follow-up care of the patient
5 afterward in terms of response evaluation and
6 management of any complications including issues
7 relative with liver function which is something we've
8 been managing frankly for many years. So essentially
9 we're doing almost all the work.

10 Now if we had an AU who was present and
11 active and available to make the patient's access to
12 care smooth and easy that would be fine. But we would
13 be sitting in a room with a catheter in a patient
14 wondering where our nuclear medicine attending was to
15 show up so we could actually administer the dose and
16 sign the treatment plan. Or we would have a nuclear
17 medicine attending come in and inject the dose himself
18 into the wrong catheter because they didn't really
19 understand the mechanics of what was going on in this
20 particular instance.

21 So finally and I think it relates to the
22 comment you just made, our institution came to us.
23 Our radiation safety officers came to us and said, "We
24 want the IR to be the AU for this because you guys
25 really know what's going on and you guys are doing all

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1 the work and trying to get these other people involved
2 is actually inhibiting us, slowing down the process
3 and making it less efficient in our institution."

4 So I think even in major medical centers
5 where there is lots of expertise the care of the
6 patient goes to the people who are willing and able
7 and we do delivery brachytherapy. We work with our
8 radiation oncologists to get the catheters and do the
9 mapping, get the anatomy and get the delivery systems
10 in the right place. But they make the treatment plan
11 to the delivery because that's what they do in taking
12 an active role in the management of the patient.

13 And if you're not therapy, the image
14 radiologists are doing all the work for the treatment
15 planning and the treatment administration and the
16 clinical care and so if you don't have in that
17 institution even though we had a nuclear medicine
18 authorized user they weren't serving a helpful
19 function if, in fact, they were inhibiting access to
20 care by not being an active role in the care of the
21 patient.

22 So I think as we were saying there's
23 really sort of a fairly compelling argument for making
24 possible for image radiologists who are actually
25 providing the care and the treatment of the patients

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1 to have authorized user status in situations where
2 there is not someone else who has authorized user
3 status available to be involved in that care. Again,
4 this is sort of a single institution perspective on --

5 Again I didn't go seeking authorized user
6 status. My physicians came to me and said, "We want
7 you to do this because you do a better job than if we
8 have someone else doing that who is not actively
9 involved in treating liver cancer." Again, I think
10 this applies uniquely to this application of
11 brachytherapy in the liver.

12 CHAIRMAN MALMUD: Thank you. Dr. Nag.

13 MEMBER NAG: Yttrium-90 microsphere is
14 under 1,000. It does not require the physical
15 presence of the authorized user. Am I right? It
16 requires to be involved in the planning. You know,
17 the comment that we are waiting for the authorized
18 user to be able to put it in cannot be true because
19 you don't need the physical presence. Am I right?

20 MS. TULL: This is Ashley. You're
21 correct. There is no physical presence requirement in
22 the guidance right now. However, I believe from
23 talking to the manufacturers the current practice is
24 to wait for the AU to show up.

25 I would ask either one of the

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1 manufacturers to address that. Sam Putnam.

2 MR. PUTNAM: I can speak to that. Sam
3 Putnam from Sirtex, Medical Director. That's true and
4 I think most places across the country when they do
5 have radiation oncologists, nuclear medicine docs, as
6 the authorized user they would appreciate having them
7 actually present in the room. They often and usually
8 do wait for those physicians to show up.

9 So I wouldn't say, Dr. Welsh, that there's
10 a shortage of radiation oncologists or nuclear
11 medicine docs who could be the authorized users. But
12 I think there's a shortage of interest among those
13 doctors to be the AUs and to actually be part of the
14 therapy.

15 MEMBER NAG: Yes, but radiation is not
16 stopping you because it is unique to have user in the
17 planning but the authorized user does not have to be
18 physically present. So it's not hindering the
19 administration of radiation.

20 MR. PUTNAM: Well, it does. At the two
21 institutions I provide this therapy, they don't buy
22 into that and we do have to wait for the authorized
23 users to be present.

24 MEMBER NAG: But that is not a radiati0on
25 issue.

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1 MR. PUTNAM: I understand.

2 MEMBER NAG: That is an institution issue.

3 MR. PUTNAM: It is an institution issue.

4 That's right. But we still wait.

5 CHAIRMAN MALMUD: Dr. Thomadsen.

6 MEMBER THOMADSEN: I think a sampling of
7 the institutions that the AAPM's task group on
8 microspheres would indicate that the authorized user
9 is seldom present for these therapies.

10 CHAIRMAN MALMUD: Thank you. Other
11 comments? Yes, Debbie.

12 MEMBER GILLEY: Just for clarification,
13 there are no regulations on Part 1000. They are
14 guidance documents and you had mentioned the
15 regulations and they simply -- So there's a big
16 difference between guidance documents and regulations
17 when it comes to the agreement states.

18 MEMBER NAG: So in that -- there is
19 nothing like regulation guidance. There's nothing
20 that is stopping the interventional radiologist from
21 going ahead so long as they have an authorized user in
22 their planning committee. Am I right or not?

23 DR. SALEM: I think Dr. Nag is correct. I
24 mean it depends on the location of where you're at,
25 but I think in terms of best medical practice, I think

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1 there are some people that have some inherent
2 resistance to just signing off on written directives
3 that then again in the spirit of medical legal issues
4 that were discussed previously, the previous session,
5 might come into play if a program is run such that an
6 authorized user is never physically present in an area
7 and I would point out that I believe one of the
8 rationales for stating that the authorized user
9 doesn't have to be there was because of the very issue
10 that the interventionalist could not be an authorized
11 user. This was the origin of this. So I think good
12 medical practice if the authorized user can be there
13 whether the radiation oncologist, the nuclear medicine
14 physician or the IR, I think best medical practice
15 would dictate that that would be the best way to do
16 it.

17 CHAIRMAN MALMUD: Other comments? Dr.
18 Vetter.

19 MEMBER VETTER: A question. Maybe I'm
20 just getting foggier. But what problem are we trying
21 to solve?

22 CHAIRMAN MALMUD: I think the issue before
23 us is the request of the interventional radiologists
24 to move ahead with one of two pathways to achieve
25 authorized user status or specifically for the

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1 Yttrium-90. Am I correct?

2 DR. SALEM: Yes.

3 MEMBER VETTER: That's the solution.
4 What's the problem?

5 CHAIRMAN MALMUD: The problem is that they
6 feel that they do not have that process in place
7 currently and they're seeking NRC approval for it.

8 MEMBER WELSH: If I may?

9 CHAIRMAN MALMUD: Yes, Dr. Welsh.

10 MEMBER WELSH: This is Dr. Welsh here.
11 This is why I asked Dr. Salem earlier if you perceive
12 that there's a shortage of AUs. Because if the answer
13 is no, then perhaps there is no reason to change
14 things. But from what I'm hearing where radiation
15 oncologists and nuclear medicine physicians were Board
16 certified are not AUs there very well could be a
17 shortage of AUs for this therapy and therefore there
18 is a problem that needs a solution. So we're hearing
19 the solution. But the question may be is there truly
20 a shortage of AUs to provide this therapy nationwide.

21 CHAIRMAN MALMUD: We have another member
22 of the public.

23 DR. FACCHINI: Good morning. Thank you,
24 Mr. Chairman. My name is Frank Facchini. I'm an
25 interventional radiologist just outside of Chicago.

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1 I'm in an agreement state and a very experienced
2 agreement state due to Dr. Salem's work. Because of
3 my practice, we cover five hospitals. I am an
4 authorized user at only one of those hospitals and our
5 radiation oncologist also covers that said five
6 hospitals.

7 So truly it's very, very difficult for me
8 to have him in the room with me and that is why I
9 sought out AU status personally. I did it post
10 September. I work very closely with our IEMA and I
11 did it by providing my ABR certificate, showing my
12 classroom work and my experience and then under the
13 guidance of our RSO I did the material handling as Dr.
14 Salem has proposed. I provided actually seven
15 patients. I involved all of the planning that went
16 into it, the treatment planning, the receipt of the
17 radionuclide, the disposal and I gained approval that
18 way.

19 But the entire impetus was that it was
20 just near impossible for us to get all of these people
21 in the same room at the same time and it actually
22 compromised in my opinion patient safety because as
23 you have a microcatheter in the artery and you're
24 waiting and waiting that catheter can get clogged.
25 There can be issues. So how efficient we are is

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1 absolutely relevant to patient care. Thank you for
2 your time.

3 CHAIRMAN MALMUD: Thank you. Dr. Nag.

4 MEMBER NAG: Thank you for that statement,
5 but that still the same issue I had before. You don't
6 have to wait for the authorized user to be in the
7 room. Why are you waiting for the authorized user to
8 be in the room if that's not required for their
9 presence? It requires that they be involved in the
10 planning and so forth. So you don't have to wait in
11 the room with the microcatheter in place. So that's
12 an argument that you're bringing in that's not
13 relevant.

14 CHAIRMAN MALMUD: Thank you, Dr. Nag. May
15 I ask a member of the staff? Is it correct that we do
16 not need to have an authorized user in the room at the
17 time of the injection of the radioactive product into
18 the catheterized vessel in the liver?

19 DR. HOWE: This is Dr. Howe. When we were
20 first developing the guidance for the Yttrium
21 microspheres we modeled after the manual brachytherapy
22 and manual brachytherapy did not require the physical
23 presence. The only sections that required the
24 physical presence were HDR and Gamma Knife. So we did
25 not require the physical presence. There was an

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1 understanding that you normally had the manual
2 brachytherapy authorized user there, but that was not
3 a strict requirement.

4 CHAIRMAN MALMUD: Thank you. So your
5 question is answered, Dr. Nag, that it's not required.

6 May I ask a question of the public that's here and
7 also Dr. Salem? Who calculates, who checks, the dose
8 when it's delivered currently?

9 DR. SALEM: Checks the dose or calibrates
10 the dose?

11 CHAIRMAN MALMUD: Yes.

12 DR. SALEM: Pretreatment or post
13 treatment.

14 CHAIRMAN MALMUD: Pretreatment.

15 DR. SALEM: So pretreatment all the doses
16 are calibrated in nuclear medicine.

17 CHAIRMAN MALMUD: By a nuclear physician
18 or a member of the staff.

19 DR. SALEM: Correct.

20 CHAIRMAN MALMUD: Is that true for the
21 other institutions represented here?

22 MEMBER SULEIMAN: What do you mean by
23 dose?

24 (Off the record discussion.)

25 CHAIRMAN MALMUD: The activity in the

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1 product? Who makes sure that what you plan is really
2 what you intend is what you receive?

3 DR. FACCHINI: In my institution, I
4 actually do it personally.

5 CHAIRMAN MALMUD: And you are Dr.?

6 DR. FACCHINI: Facchini.

7 CHAIRMAN MALMUD: Dr. Soulen, how about
8 the University of Pennsylvania?

9 DR. SOULEN: In my institution, a nuclear
10 medicine technologist checks the initial activity in
11 the vial and then they then check the residual
12 activity. So non nuclear medicine physician, but the
13 technologist then brings me the worksheet which I sign
14 off on as the AU.

15 CHAIRMAN MALMUD: Thank you.

16 DR. SOULEN: Prior to that me being the
17 AU, it got signed off by the nuclear medicine AU.

18 CHAIRMAN MALMUD: And is there a third
19 institution represented?

20 DR. VERMEERE: Bill Vermeere from Medical
21 College of Wisconsin. It's the nuclear medicine
22 pharmacist at our institution who calibrates the dose
23 pre and post treatment.

24 CHAIRMAN MALMUD: Thank you.

25 MEMBER NAG: And in the south area --

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1 CHAIRMAN MALMUD: I see a member of the
2 public. Would you go up to the mike? And you are?

3 MR. HAGERMAN: Jim Hagerman from MDS
4 Norran. I'm involved in training many centers through
5 our vendor certification program and very rarely have
6 I seen an instance where a hospital authorized user,
7 be it radiation oncology or nuclear medicine, will not
8 insist on being in the room in the interventional
9 suite. So there are a lot of pragmatic logistical
10 issues with having an authorized user who is not
11 physically infusing the device and I think when you
12 need two people to make that necessary it does impose
13 issues.

14 CHAIRMAN MALMUD: Thank you.

15 MR. SALDARINI: I am Joe Saldarini with
16 Sirtex. Regarding your question about the preparation
17 of dose and certification of the activity, I can speak
18 for 20 institutions and it's all done very carefully
19 and precisely in nuclear medicine.

20 CHAIRMAN MALMUD: By whom in nuclear
21 medicine?

22 MR. SALDARINI: By the hot lab technician
23 under the guidance of the authorized user or the
24 nuclear medicine physician.

25 CHAIRMAN MALMUD: Thank you. Dr.

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1 Suleiman.

2 MEMBER SULEIMAN: I'm just going to reveal
3 my thinking. How accurate are the dose calibrators
4 that you calibrate these with? Or are these just
5 checks for activity? When you say calibrated, it
6 means something very special to me and these are
7 Yttrium sources which are beta emitters. And I hear
8 the term that these are calibrated in the hospital. I
9 think a lot of hospitals don't even have the
10 capability of calibrating Yttrium sources. So I think
11 the very sloppy use of the term "calibration" is
12 misinformative and potentially hazardous to the public
13 safety because it's not an accurate estimate of the
14 activity or the dose.

15 CHAIRMAN MALMUD: Thank you. I'll ask Dr.
16 Zelac to comment on the accuracy of the calculation of
17 an Yttrium dose in a well counter.

18 DR. ZELAC: Pass.

19 (Laughter.)

20 CHAIRMAN MALMUD: Dr. Howe.

21 DR. HOWE: Although we haven't come out
22 with anything addressing Yttrium-90 we have in the
23 past experienced a number of medical events where
24 people have thought they could measure accurately P-
25 32, Samarium and other radionuclides in a dose

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1 calibrator and it wasn't really true. So we've
2 already recommended that you use the manufacturer's
3 number and then extrapolate using a volume type of
4 thing. Although with the microspheres, you have to
5 keep them up in solution. So volume is not
6 necessarily an accurate way of doing things. So we
7 don't depend on the nuclear medicine technologist to
8 be able to accurately measure Yttrium.

9 CHAIRMAN MALMUD: Thank you, Dr. Howe. We
10 have another member of the public.

11 DR. SELWYN: Hi. Dr. Selwyn. My views do
12 not represent the Navy. Let me say that first. All
13 right. They're my views.

14 But in terms of calibration of Yttrium-90
15 in a dose calibrator, they could be upwards of 30
16 percent. This is research that has been conducted.
17 It's in publications as well based on geometry and
18 dependence of the dose calibrator at the facility.
19 So, yes, I would steer away from saying calibration at
20 all with these. All right. It's really just the
21 manufacturer's stated activity and you're injecting
22 that. Okay.

23 CHAIRMAN MALMUD: Thank you.

24 MS. LAIROBENT: Lynn Fairobent with AAPM.
25 Dr. Nag, to your question and the point that NRC may

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1 not require the physical presence, it may be a case
2 that it is required under CMS for reimbursement.
3 However, it may be a procedure done under personal
4 supervision and therefore the individual would have to
5 be physically present.

6 CHAIRMAN MALMUD: Thank you. I see
7 another hand. Dr. Thomadsen.

8 MEMBER THOMADSEN: In answer to that at
9 our institution, we just don't charge for the
10 physician's physical presence and if the radiation
11 oncologist isn't there, we don't charge.

12 But back to your question, I'm not sure
13 that you were getting the answer to the question that
14 you had intended to ask when you were asking about who
15 prepares the dose in that I was interpreting your
16 question earlier how ever it was stated not in who's
17 preparing the dose, but who's preparing the
18 prescription. Was that what you were asking or were
19 you asking the physical handling of the radioactive
20 material?

21 CHAIRMAN MALMUD: I was asking about the
22 handling of the radioactive material because the
23 material comes and it settles. And therefore if
24 you're getting, let's just use a number, 10
25 millicuries and you have to shake it to make sure that

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1 the spheres are evenly distributed and then draw out
2 half of it, you're not really getting 50 percent when
3 you draw out half because the spheres are not
4 uniformly distributed exactly. So you're getting
5 something close to it but not exactly. I was just
6 wondering who was doing that.

7 But your question is one which I think Dr.
8 Salem addressed or one of the members of the public
9 addressed with respect to calculating the dose and
10 that was with the liver geometry and the portion of
11 the liver that needed to be dealt with in terms of
12 calculating the dose. Did you address that or a
13 member of the public?

14 DR. SALEM: No, not really, but I can
15 expand on it a little bit.

16 CHAIRMAN MALMUD: A member of the public
17 addressed that.

18 DR. SALEM: Again it depends.

19 CHAIRMAN MALMUD: Dr. Soulen addressed
20 that.

21 DR. SALEM: So I guess it depends again on
22 who is involved in the team, who the authorized user
23 is. In a radiation oncology authorized users, this is
24 the work of the authorized user and is done by the
25 authorized user. In our institution, this is done by

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1 the interventional radiologist authorized user. So it
2 really is that aspect, a critical aspect, is done by
3 the authorized user. So this does not change
4 irrespective of who it is.

5 CHAIRMAN MALMUD: Thank you. Rob.

6 MR. LEWIS: Getting back to I think to Dr.
7 Vetter's question on what is the problem, if it is not
8 the NRC requirements or even the agreement state
9 requirements that are causing the presence of the AU
10 but rather the vendor recommendations or facility-
11 specific procedures, I guess, is your premise that or
12 thesis that if NRC were to come out and say that the
13 IR can be an AU and therefore have the presence that
14 the vendors and the facilities will be more amenable
15 to changing their procedures? I mean, what are we
16 trying -- What regulatory action are you asking?

17 DR. SALEM: I think that the premise is
18 you've just heard I think several sort of observations
19 about what is working and what is not working and in
20 my opinion unfortunately some solutions are sort of
21 band-aid solutions in terms of this person can be the
22 AU. He doesn't have to be there. And so the request
23 still at its core is irrespective of the practice
24 pattern interventional radiology is requesting and
25 stating that they would like to proceed with a pathway

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1 that will permit them to gain authorized user status
2 just like nuclear medicine or radiation oncology and
3 we'd like to develop a program that is acceptable by
4 the Committee and the NRC to allow this pathway with
5 or without the problems that occur at the institutions
6 and so to leave that as an option. That's really the
7 core of the request for today.

8 CHAIRMAN MALMUD: Thank you. That's clear
9 enough? Yes. Please come up to the microphone.

10 (Off the record comment.)

11 Sorry. Did you want to make --

12 DR. SELWYN: A quick comment again. Dr.
13 Selwyn.

14 CHAIRMAN MALMUD: Dr. Selwyn.

15 DR. SELWYN: On dosimetry versus radiation
16 oncology, dosimetry treatment planning, of
17 brachytherapy treatment planning is much more
18 extensive and we have treatment planning programs that
19 do that. In terms of this treatment, it is very
20 minimum. It is a simple equation. Okay. Technicians
21 can do it. The IR can easily do it. The physicist
22 can easily do it. There's not much to it. It's the
23 liver size. All right. It's the mass of the liver,
24 that's it, versus when you're looking at
25 brachytherapy. So they're not asking the IR to do the

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1 job of the radiation oncologist at this point. In the
2 future, that may change and this may have to be
3 revisited in terms of treatment planning. But
4 currently it's very minimal.

5 CHAIRMAN MALMUD: Excuse me. It's not
6 simply liver size, is it? It's the liver size versus
7 the portion of the liver that's being percused by the
8 vessel that you're injecting and a ratio of that mass
9 over the liver mass and it's calculated by taking
10 slices and then adding them up.

11 DR. SELWYN: No, that is not true. It's
12 an approximation and there are two different
13 modalities. There are two different ways from the two
14 different companies and they can address it if they'd
15 like. But a basic answer to that is that one
16 assumption is that the microspheres go to the entire
17 liver. It's very simple. It's the mass of the liver
18 and the activity is assumed to be distributed
19 homogeneously throughout the entire liver which it's
20 not. But this is the modality that's being used for
21 clinical trials.

22 CHAIRMAN MALMUD: Excuse me. What about
23 shunting? How do you check for shunting?

24 DR. SELWYN: You can subtract the shunting
25 if you have an accurate number on that. But lots of

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1 people don't subtract the shunting at all. But you
2 can and the company does say to do that, one minus F,
3 which is the shunt value. Dr. Salem can also talk
4 very long about this as well. But it is a very simple
5 solution. It is not what I think people think about
6 dosimetry and treatment planning, but it would take
7 longer to go into the details.

8 CHAIRMAN MALMUD: Thank you.

9 MS. BHALLA: This is Neelham Bhalla from
10 NRC Rulemaking. With regard to if I understood what
11 the issue is for the interventional radiologist to be
12 authorized user for the 35.1000 procedures and this
13 one in particular, there is another way and that's how
14 interventional radiologists came to NRC to be the
15 authorized users for perithelial administration of
16 radiopharmaceuticals in terms of Zevalin and two or
17 three other names and they came. They petitioned that
18 these drugs come. They are FDA approved and it's
19 easy. The calibration is easy and therefore they
20 should be allowed to be authorized users.

21 This petition came to us I think about a
22 year ago or so or two years ago and so there is -- A
23 note, the petition was denied. So I just wanted
24 everyone here to know that that is the process for
25 coming to request the NRC to be authorized users for

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1 some things which are not outright in the regulation.

2 DR. SALEM: I'm sorry. This was a request
3 by interventional radiology.

4 MS. BHALLA: That is correct.

5 DR. SALEM: To administer Zevalin.

6 MS. BHALLA: Correct. It's not only
7 Zevalin but there were three Bexxar, Zevalin and --

8 DR. SALEM: By interventional radiology?

9 MS. BHALLA: Yes, the group was the
10 interventional radiologists and it came from -- That
11 is the group that came and it's under Petition No.
12 TRM3519 and you can go into the details of the whole
13 petition in that regard.

14 CHAIRMAN MALMUD: Thank you. Dr. Welsh
15 had a comment before you leave the microphone. What
16 were you going to say, Dr. Welsh?

17 MEMBER WELSH: I think that there might be
18 a misinterpretation here. I think we're alluding to
19 the Stein petition and the Stein petition was
20 hematology/oncology petitioning to administer Zevalin,
21 Bexxar and Quadromed. Is that what we're talking
22 about here or is this something separate?

23 DR. SALEM: That I've heard of. I've not
24 heard of interventional radiology giving Zevalin.

25 MS. BHALLA: Okay. That is correct. It's

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1 the Stein petition, but the issue is very similar.
2 It's --

3 MEMBER NAG: Medical oncology.

4 DR. SALEM: It's medical oncology.

5 MS. BHALLA: It's medical oncologists
6 coming up instead of radiologists. But it's a very
7 similar issue of somebody who wants to be an
8 authorized user which clearly does not meet the
9 requirements spelled out in Part 35.

10 CHAIRMAN MALMUD: Thank you. Dr. Welsh.

11 MEMBER WELSH: A quick reply or comment.
12 There are some superficial analogies, but underlying
13 this are some very significant differences in the meat
14 of the matter and one of the critical differences is
15 that medical oncologists and hematologists have zero
16 training during their residency and fellowship and
17 another critical difference is that there is no
18 shortage of qualified AUs for the administration of
19 Zevalin, Bexxar and Quadromed and that's why I think
20 there are some big differences here where radiologists
21 have some underlying training and there's a discussion
22 about adding some training that would make them
23 qualified to be safe AUs and I still haven't gotten a
24 clear answer about whether there's a shortage or not.

25 CHAIRMAN MALMUD: May I just editorialize

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1 for a moment? When you say that the medical
2 oncologist have no training, you mean they have no
3 training in the handling of radioactive material.

4 MEMBER WELSH: That's correct.

5 CHAIRMAN MALMUD: Thank you. Because we
6 don't --

7 (Laughter.)

8 You would be offending a very large group
9 of people.

10 Dr. Guiberteau.

11 DR. GUIBERTEAU: I think from the
12 perspective of diagnostic radiologists that one of the
13 issues here is the method under which this agent was
14 approved and I think if it was not microbrachytherapy
15 it would clearly be one of the other agents that we
16 have commonly developed and will develop many, many
17 more in molecular medicine in terms of injecting
18 materials that are labeled to peptides for cell
19 surfaces, within the cells, delivered in this case in
20 a mechanical way and I think what the devil is, the
21 radiology community is, the length of time it takes to
22 take a new technology like this from Part 1000 that's
23 clearly being done and integrate it in and making some
24 semblance of fairness to it. That is we have
25 agreement states with apparently a tabula rasa of what

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1 they want to do. We train people in our state to do
2 these and they go to another state and they can get
3 licensed.

4 And so I guess just -- I'm sure you've
5 heard this all before. But the feeling of the
6 community is that we don't know what to do. We're
7 totally confused. IR in terms of the American Board
8 of Radiology is probably in the next five years going
9 to be its own direct pathway and we have to know how
10 to train those people to get this, to get certified,
11 and to get AU status to do these procedures. So I
12 guess my plea is here that it would be very nice if
13 the Committee would consider some way to move this
14 into part of the rules so that we can have some
15 semblance of understanding of what we're supposed to
16 do.

17 CHAIRMAN MALMUD: Thank you. Other
18 comments. Dr. Eggli.

19 MEMBER EGGLI: I think interventional
20 radiologists make perfectly good authorized users. I
21 think my concern here is mixing the part of the
22 regulation that deals with diagnostic applications
23 versus therapeutic applications and I think that what
24 we need to look for is not a way to add it to 290 as a
25 subclass of 290 but as a subclass of 390 setting up

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1 reasonable training and experience requirements that
2 allowed interventional radiologists to do this
3 procedure. But my concern is mixing the definitions
4 of diagnostic applications versus therapeutic
5 applications among sealed sources.

6 CHAIRMAN MALMUD: Thank you. Therefore
7 you would recommend that this be for a very specific
8 application for the therapeutic application.

9 MEMBER EGGLI: Under Part 300.

10 CHAIRMAN MALMUD: Under Part 300. Thank
11 you. We had two hands showing here.

12 MEMBER NAG: I would agree with Dr. Eggli
13 that this is therapeutic and if you want to either
14 have interventional radiologists that will have
15 similar training so that they would qualify either
16 under 300 or under 390 whatever that would be a more
17 logical way that will, too, ensure enough training and
18 yet allow them to do only that portion of 300.

19 CHAIRMAN MALMUD: Thank you and, Mr.
20 Lieto, you had a comment as well.

21 MEMBER LIETO: Yes. Well, I was also
22 going to echo my support for Dr. Eggli's comment about
23 making a specific category under 300 training and
24 experience because I think it's a therapeutic use
25 whether you call it brachytherapy or what it truly is,

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1 a radiopharmaceutical therapy, regardless. It belongs
2 in the therapeutic portion of the regulations.

3 One of the things in talking about the AU
4 and AU being present and why AUs may not be there and
5 so forth, I think you need to understand that and I
6 think, Dr. Malmud, you gave a perfect example to me
7 earlier today in that when you are the AU and you're
8 going to be giving a therapeutic application to a
9 patient just like you said, "I want to be there."
10 That's the patient. I wrote the written direct for I
11 want to be there and know what's going on and I think
12 it's the same way generally speaking in that the AU is
13 not just someone who signs the written directive. He
14 is accountable for supervising in all the aspects that
15 go along with that administration. So it's not just
16 filling out the written directive and that's the end
17 all and be all. They are accountable for the
18 supervision of all the people under that written
19 directive.

20 I'm kind of wondering and they're saying
21 that there's reluctance and some of the colleagues in
22 the back there are saying that getting the multiple
23 parties together may be sometimes problematic. But
24 I'm sure they want to be there because of the fact of
25 their responsibilities that they can't, I shouldn't

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1 say that they can't, but they don't want to delegate
2 to someone else. And I think that's why even though
3 Dr. Nag has said the AU doesn't need to be there the
4 AUs want to be there for these administrations.

5 CHAIRMAN MALMUD: Thank you. I would just
6 comment. We were discussing something different. We
7 were discussing the use of I-131 orally for thyroid
8 disease, either hyperthyroid or cancer. And there
9 it's a simpler process. I see the patient. I make
10 the diagnosis. I calculate the dose. I order the
11 dose. I physically check it in the well counter. I
12 physically hand it to the patient. It's me. It
13 doesn't require a team and what I understand from Dr.
14 Salem is that this is complicated because it requires
15 a team and getting the team together actually makes
16 the process less efficient than more efficient.

17 That's the difference between the two
18 situations. I'm not taking a position either way.

19 MEMBER LIETO: No, actually it wasn't a
20 point. It was actually a point Dr. Nag was making and
21 his point was that the regulations don't require you
22 to be there.

23 CHAIRMAN MALMUD: I know that. I wasn't
24 suggesting that they do. I'm just saying it's a
25 similar process.

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1 MEMBER LIETO: Right and I'm just saying
2 the same thing is that you want to be there because of
3 your responsibilities to the patient having done the
4 written directive and so forth.

5 CHAIRMAN MALMUD: Yes, but I was not --
6 The context of our discussion was not meant to be
7 analogous to this discussion. They were totally
8 unrelated.

9 I'm sorry. Who was next? Someone had a
10 comment. Dr. Suleiman.

11 MEMBER SULEIMAN: I'm going to take a step
12 back. I'm very troubled by these regulations and I'm
13 very troubled by everything that's interdisciplinary
14 and I think the whole purpose of the NRC involvement
15 here is radiation safety clearly from a radiation
16 perspective, not the practice of medicine.

17 I see things very differently from FDA
18 perspective how we approved -- I mean, unfortunately
19 the Yttrium-90 was approved as a medical device. It's
20 a tiny little brachytherapy device. That's because
21 our lawyers got involved and read the laws and said,
22 "This is a brachytherapy source." But the radiation
23 safety characteristic we have, it's more like an
24 unsealed source because there's millions of these
25 little products. Regardless of what people think

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1 about the semantics and the definition, the radiation
2 safety handling of it is as you would an unsealed
3 source.

4 As things get more interdisciplinary and
5 as imaging technologies evolve and they're going to
6 get a whole lot more complicated than we see here, if
7 the NRC is going to try to break these things into
8 more and more subcategories and you have all these
9 evolving, very specialized disciplinary developing for
10 therapy, for diagnostics, for a whole multitude of
11 applications, this approach is going to just get more
12 and more complicated. I think you're seeing that
13 here.

14 I would be more than comfortable with
15 somebody who understands the hazards of radiation
16 involved with thing. I would be more than comfortable
17 with a medical practitioner who understood what it was
18 they were doing and somehow we need to solve that, you
19 know, get that. But to throw all these multitude of
20 regulations and is this person doing this and is this
21 a sealed source, an unsealed source, is it a beta
22 emitter or a gamma emitter which clearly raises
23 different issues, I don't know what the solution is.
24 But I think the problem is that we're trying to
25 microcategorize both the users of these products and

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1 the way we're classifying them.

2 I'm really glad this is under 1000 because
3 when you start to try to break it out and put it
4 someplace else where are you going to put it and
5 wherever you put it you can argue that it belongs
6 probably someplace else.

7 CHAIRMAN MALMUD: Dr. Thomadsen and then
8 Dr. Eggli.

9 MEMBER THOMADSEN: I would like to make a
10 motion at this moment.

11 CHAIRMAN MALMUD: Please.

12 MEMBER THOMADSEN: That there is formed a
13 subcommittee of this group to draft a set of proposed
14 qualifications that if satisfied by an interventional
15 radiologist would qualify them for authorized user
16 status for this application.

17 MEMBER VETTER: Is there a second to that
18 motion?

19 MEMBER VAN DECKER: Second.

20 MEMBER VETTER: Dr. Van Decker seconds.
21 Discussion? You wanted to say something, Dr. Eggli.
22 Is that related to the motion?

23 MEMBER EGGLI: Semi.

24 MEMBER VETTER: Okay.

25 MEMBER EGGLI: I think that as you look at

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1 the way things are broken down if you're authorized
2 for a higher level you're typically authorized for a
3 lower level of functionality and I think from the
4 point of view from safety and training there is a
5 clear break point between diagnostic uses and
6 therapeutic uses of radioactive materials with respect
7 to safety and training.

8 I think that impossible thresholds and the
9 200 hour threshold for Part 390 is something this
10 Committee argued vociferously against. So I think a
11 200 hour threshold for those Part 300 uses may be off
12 the wall, but I think the training requirements are
13 different for diagnostic than for therapeutic uses.

14 And I would agree with Orhan to the extent
15 that I'm a lumpner instead of a splitter. But a
16 mechanism need to be found that allows interventional
17 radiologists to become an authorized user under a
18 portion of the regulation that governs the use of
19 therapeutic radioactive materials. And from that
20 extent I support Dr. Thomadsen's motion that a
21 subcommittee be formed to try to discover this after.

22 But I feel very strongly that it needs to under the
23 regulation that pertains to therapeutic uses not
24 diagnostic uses.

25 MEMBER VETTER: Dr. Malmud, I'll turn the

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1 chair back to you. Just for your information, there's
2 a motion on the floor now by Dr. Thomadsen to form a
3 subcommittee to develop the recommendations for the
4 training requirements as discussed earlier.

5 CHAIRMAN MALMUD: Has it be seconded?

6 MEMBER VETTER: Yes, it has. We are
7 discussing the motion and Dr. Welsh has his hand up
8 next.

9 MEMBER WELSH: So my point is that before
10 we vote on whether there should be a subcommittee to
11 put together some guidelines the question still has to
12 be answered "Do we really need to have interventional
13 radiologists as authorized users?"

14 I've heard some comments from the public
15 that one of the reasons for moving in this direction
16 is that the AU at the institution is dragging his feet
17 and getting to the IR suite. We've learned that the
18 physical presence of an AU is not mandatory. So that
19 argument has to be discarded, although I personally as
20 a radiation oncologist find it embarrassing if a
21 radiation oncologist is not there during the
22 procedure. But nevertheless by the current
23 guidelines, the authorized user does not have to
24 physically be present.

25 Therefore in my mind the only real reason

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1 why we would want to IRs as an authorized user is if
2 there is a shortage of qualified AUs and, if the
3 answer is yes, then I will vote in favor of having
4 such a subcommittee. But if the answer is that there
5 is plenty of AUs already, what's the need?

6 DR. SALEM: I think there is, I mean, as I
7 said before, to a certain extent a shortage. But I
8 also say this sort of representing interventional
9 radiologists that there's a genuine desire to become
10 an authorized user not just to fulfill this shortage
11 but, in fact, out of interest and I think out of best
12 care, out of sort of providing continuity of care. I
13 think there's a genuine desire to do this, not just to
14 plug up holes basically. But there's a genuine
15 request to do this.

16 CHAIRMAN MALMUD: Dr. Nag.

17 MEMBER NAG: Yes. I don't think that
18 there's a shortage per se. But I think that it's lack
19 of interest. I think you would agree with me, but
20 there might be a lack of interest in some of the AUs
21 to be leaving their own area that they are busy at
22 that point to then leave and go to some other area.
23 And then there's a reluctance of the hospital to say,
24 "Well, you can go ahead without the AU." So I think
25 that's what I'm hearing. It's not necessarily a

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1 physical shortage. Am I correct?

2 DR. SALEM: Again, the reality is a
3 mixture of all of these things, a little bit of
4 shortage, a little bit of lack of interest, I think,
5 good clinical care, maybe some medical legal issues
6 and again, like I said, the genuine desire. This is
7 an independent, also, request and desire to become
8 authorized users. I think interventional radiologists
9 believe they have the qualifications and can
10 participate and contribute to this therapy equally.
11 That's really, I guess, at the source of the request.

12 CHAIRMAN MALMUD: Dr. Welsh is next.

13 MEMBER WELSH: My question for you, Riad,
14 is I can't speak for all of radiation oncologists and
15 apparently I don't because I apparently think that
16 there's great enthusiasm in the radiation oncology
17 community and what I'm hearing objectively that maybe
18 there is not and perhaps if it's to the point where
19 it's hard to get a physician out of the oncology
20 center and coming up to the IR to what is his
21 responsibility in my mind, then that represents a
22 problem. It's representative of perhaps a lack of
23 genuine interest.

24 You're telling me that interventionalists
25 in the interest of best patient care and genuine

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1 desire to move this treatment forward and to the
2 forefront interventionalists as a whole are in favor
3 of this. Do you think that perhaps you are
4 representing a small minority yourself?

5 (Laughter.)

6 DR. SALEM: An excellent question. Very,
7 very worded. Again, I used to think that. I'll be
8 honest with you. I used to think that and I am slowly
9 being convinced otherwise. I see more and more
10 genuine interest, investigation, symposia, courses,
11 publications, genuine curiosity than I thought I would
12 ever see. So I used to think that.

13 CHAIRMAN MALMUD: You were next, Dr.
14 Eggli.

15 MEMBER EGGI: I support an
16 interventionalist being able to do that. They're the
17 primary drivers on these patients. If I had to go to
18 somebody else to get them to sign off on my high dose
19 iodine patients that I felt I was responsible for, I
20 would be very unhappy about that.

21 I think the interventional radiologists do
22 take care of patients. I think that's one of the areas
23 where radiation oncology, nuclear medicine and
24 interventional radiology share a common practice
25 pattern in that although for the two interventional

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1 radiologists and the nuclear medicine docs we are
2 imagers. We take care of patients every day and
3 basically this is from my point of view the
4 interventional radiologist's patients and I can
5 understand him not wanting me as an interloper in his
6 case.

7 So I think that the primary driver ought
8 to have a mechanism whereby they can become authorized
9 to do the things that they do. Again, my concern is
10 where we put that authorization. But I firmly believe
11 these guys are taking care of the patients and they
12 ought to be the ones who are driving the bus here.

13 CHAIRMAN MALMUD: If I may, there's a
14 motion on the floor and seconded to set up
15 subcommittee to try to achieve that goal. Is that
16 correct? Is that the motion?

17 MEMBER VETTER: Yes.

18 MEMBER NAG: It's still under discussion.

19 CHAIRMAN MALMUD: You are still discussing
20 the motion.

21 Dr. Fisher.

22 MEMBER FISHER: I would speak against the
23 motion. If this is a workable proposal, then there is
24 no need for this subcommittee to rethink the issue as
25 well as Dr. Salem has presented it here this

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1 afternoon. It looks like he has the, at least from my
2 perspective, two possible answers to the question as
3 long as we understand what the question is. But why
4 form a subcommittee when the work has been done
5 already and you have the American Board of Radiology
6 willing to work it.

7 DR. SALEM: I think 290 is the wrong place
8 for this.

9 MEMBER FISHER: Then let them --

10 DR. SALEM: We could change it to 390 or
11 300 XX or something I guess.

12 CHAIRMAN MALMUD: Dr. Thomadsen.

13 MEMBER THOMADSEN: And that's what I think
14 part of the subcommittee's work would be to craft what
15 that pathway, what we think that pathway should be.
16 Just because the ABR and the Society of Interventional
17 Radiology have defined what they think doesn't mean
18 that we agree anymore than we may think that the
19 pathway to authorized users might be Board
20 certification and the NRC differs with us on that.
21 There are reasons to differ.

22 CHAIRMAN MALMUD: Thank you. Dr.
23 Guiberteau. Then Dr. Vetter.

24 DR. GUIBERTEAU: I just want to say that I
25 have had lengthy discussions with the ABR and we

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1 didn't make a specific proposal about how this should
2 be done. I mean we agree that the NRC is the one who
3 has to set up the training requirements and the safety
4 requirements that they feel are necessary. The ABR is
5 in a position since classically for radiologists and
6 most position users you want training, you want
7 attestation, and you want a test and the ABR has
8 committed if the NRC so agrees to a training pathway,
9 an alternative training pathway, for interventional
10 radiologists that we will provide a test to see that
11 the body of knowledge that has been presented to the
12 candidates will be appropriately confirmed.

13 CHAIRMAN MALMUD: Thank you. And Dr.
14 Vetter.

15 MEMBER VETTER: Yes. Just to clarify as I
16 understood the motion, the motion did not presume that
17 the training requirements would fall under 200, 300,
18 400, 1000, anywhere. That would be all be part of
19 what was developed.

20 CHAIRMAN MALMUD: That's correct. Dr.
21 Nag.

22 MEMBER NAG: I know like Dr. Salem and a
23 few other interventional radiologists who I know
24 really well, they are like a diehard microspheres.
25 They are willing to go through all the training

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1 required to be able to do this successfully and
2 safely. Would other interventional radiologists be
3 equally diehard to be able to pursue the training?
4 Let's say that Dr. Thomadsen's subcommittee would be -
5 - For example, if they say the 700 hours and the 200
6 hours, would they be still having that determination
7 to follow that?

8 CHAIRMAN MALMUD: The only way we'll get
9 an answer to that question is offering the opportunity
10 and seeing how many people avail themselves of it. I
11 think there is no certain way of predicting. Some
12 radiation oncologists practice in freestanding
13 clinics. It would be impractical for them to leave
14 the freestanding clinics and go to an in-patient
15 service, spend the time there and then rush back
16 again.

17 So I don't think we can predict that and
18 given the experience that preceded us with approval of
19 endocrinologists to give I-131 therapy, the majority
20 of them don't do it either. But it's still there for
21 those who wish to. I don't think your question has an
22 answer yet.

23 However, but we will move on this motion.

24 All in favor of the motion?

25 All opposed to the motion?

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1 So it's how many? Four again. It's easy
2 to count the against. How many for?

3 Ten for. One opposed.

4 (Off the record comment.)

5 Is there an abstention?

6 One abstention. So it's 10-1-1.

7 MEMBER GILLEY: May I make a comment?

8 CHAIRMAN MALMUD: Please do.

9 MEMBER GILLEY: Okay. My suggestion as a
10 path forward to go would be encourage NRC to begin the
11 rulemaking process to move microspheres out of Part
12 1000 and move it into regulations and then these
13 issues we have and these gaps with guidelines versus
14 regulations, T&E can all go through the public review
15 process of the rulemaking. It's already in place.

16 CHAIRMAN MALMUD: I think for that you
17 have a second. If that's a motion, Dr. Eggli seconds
18 it.

19 MEMBER EGGLI: Second.

20 CHAIRMAN MALMUD: Is there discussion of
21 that motion? That's in addition to the other motion,
22 not instead of the other motion.

23 MEMBER GILLEY: That's correct.

24 MEMBER LIETO: I just have a question.

25 CHAIRMAN MALMUD: Yes.

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1 MEMBER LIETO: May I ask NRC staff how
2 many items in Part 1000 have ever been moved out?

3 (Off the record comments.)

4 Part 1000 has been there since what?
5 2002?

6 DR. HOWE: This is Dr. Howe. We were
7 going to move intervascular brachytherapy out because
8 we had enough experience with it that we thought we
9 could move it into rulemaking and then it dropped in
10 its use. So it didn't become cost/benefit.

11 Right now, we have a recommendation to
12 move the perfection into 600. We haven't moved any
13 into 1000 yet because there is a tremendous resource
14 that's involved in rulemaking. But that doesn't
15 preclude us from moving it.

16 MEMBER LIETO: Okay. My answer is none.

17 CHAIRMAN MALMUD: The number is quite
18 small in other words.

19 MEMBER LIETO: None.

20 CHAIRMAN MALMUD: That's a small number.

21 (Laughter.)

22 Dr. Suleiman.

23 MEMBER SULEIMAN: I'm going to restate
24 what I said earlier. I think by trying to force these
25 in certain holes and whatever, you're going to cause

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1 problems. The technologies are changing so fast. In
2 this case, they're either going to drop in use by the
3 time you come out with rules. It may not longer be a
4 valid technology. It may have morphed into a hybrid
5 technology with some other imaging modalities. You're
6 seeing some x-ray applications taking over for some
7 radioactive sources like the Gamma Knife or at least
8 competing with them and I think you have -- I think
9 take a step back and think very carefully.

10 I kind of like 1000 because it catches
11 everything. Maybe you eliminate all the others and
12 put them all back under 1000 and just address the
13 users in terms of radiation safety qualifications. I
14 just see this as pretty ugly right now and I don't see
15 it getting cleaner. I see it getting more
16 complicated.

17 CHAIRMAN MALMUD: Thank you. When
18 something is very ugly, the only thing that can happen
19 to it is it begins to look prettier. So the answer to
20 your request, Dr. Salem, is that this subcommittee --

21 MEMBER WELSH: Do we still have a motion?

22 CHAIRMAN MALMUD: I thought we voted on
23 it.

24 MEMBER GILLEY: My motion.

25 CHAIRMAN MALMUD: Your motion.

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1 MEMBER WELSH: To move it out of 1000.

2 MEMBER GILLEY: And may I make another
3 comment. It takes a long time to go through
4 rulemaking. So I suggest if we're going to solve the
5 gaps between the agreement states and the non
6 agreement states and the variabilities that at some
7 point, Tom, we need to start that clock.

8 CHAIRMAN MALMUD: So it's been moved and
9 seconded. All in favor?

10 Any opposed?

11 (No verbal response.)

12 Carries unanimously. So we have two
13 motions.

14 MEMBER SULEIMAN: I am slow.

15 CHAIRMAN MALMUD: Are you abstaining
16 again?

17 MEMBER SULEIMAN: What's the motion that
18 was actually on the floor?

19 MEMBER GILLEY: Encourage NRC to begin the
20 rulemaking process. Move microspheres out of Part
21 1000 and into regulation.

22 MEMBER SULEIMAN: I would vote against
23 that.

24 CHAIRMAN MALMUD: So it's a 10 or 11. How
25 many hands for?

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1 Eleven for. One opposed.

2 MEMBER NAG: Since we made the
3 subcommittee, I would suggest to speed up the
4 procedure, we name members to the subcommittee.

5 CHAIRMAN MALMUD: All right. We will do
6 that. But I wanted just to -- Because we have a guest
7 today.

8 DR. SALEM: Thank you for the time for
9 this, but I must be honest that I find myself
10 confused.

11 (Laughter.)

12 MEMBER EGGLI: At least, there's two of
13 us.

14 DR. SALEM: In terms of -- I understand
15 some of the processes that we may initiate. Is there,
16 I'm going to ask the Committee, a short-term solution
17 to opening a pathway for interventionalists? The
18 reason I say this is with resources that we have in
19 our communities and our societies a program that is
20 numbered to be determined plus a training course that
21 Dr. Welsh was describing with an examination can be
22 accomplished within six to 12 months.

23 But if this is not anything that will
24 accomplish anything substantive for interventional
25 radiologists, then it would be nice to know because

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1 that's certainly much less work for me. But it would
2 be nice to know if this is really not plausible. That
3 really this has to go through the process and this
4 will take some time.

5 CHAIRMAN MALMUD: I understand your
6 concern. What I heard here today is that the spirit
7 of this subcommittee is to find the mechanism to grant
8 you what you're requesting.

9 DR. SALEM: Okay.

10 CHAIRMAN MALMUD: In addition, there's
11 second motion to get things organized with respect to
12 larger issues that are prevalent. That's separate and
13 that will take a long time. The first one should be
14 as rapid as the subcommittee can get together, meet
15 and then report back to the Committee. But the spirit
16 of it was to try to achieve the goal that you're
17 trying to achieve.

18 DR. SALEM: Thank you.

19 CHAIRMAN MALMUD: And you asked me to
20 appoint a subcommittee. Dr. Zelac.

21 DR. ZELAC: It's probably worth noting
22 that guidance is something that is adjustable in a
23 relatively short period of time as opposed to
24 rulemaking. So if a determination is made the
25 Committee that it would be appropriate to move in this

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1 direction and that's the recommendation that comes
2 from the Committee, then the staff is in the position
3 to consider that recommendation and to move
4 accordingly in short notice.

5 CHAIRMAN MALMUD: Dr. Zelac speaks for the
6 NRC. So he suggested to do this as guidance and it
7 would be a relatively short turnaround.

8 DR. SALEM: Thank you.

9 CHAIRMAN MALMUD: I need to appoint a
10 chair of this committee. Who is intensely interested
11 in this subject?

12 (Laughter.)

13 MEMBER NAG: I estimate that Bruce made
14 the recommendation. He would be the chair, but Dr.
15 Thomadsen is the chair but I would help. I'll be
16 willing to help him.

17 CHAIRMAN MALMUD: Dr. Thomadsen, would you
18 please chair?

19 MEMBER THOMADSEN: I would, but this may
20 have ramifications on future motions being made by
21 people on this Committee from now on.

22 CHAIRMAN MALMUD: And I'll ask a nuclear
23 radiologist to be there and that will be Dr. Eggli.

24 MEMBER NAG: I have looked at it for a
25 long time.

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1 CHAIRMAN MALMUD: Dr. Nag certainly. And
2 we need a physicist, don't we? Dr. Welsh.

3 MEMBER WELSH: You need another member on
4 it.

5 CHAIRMAN MALMUD: Yes.

6 MEMBER WELSH: You have a physicist, the
7 chair.

8 CHAIRMAN MALMUD: We have physicist as
9 chair.

10 MEMBER NAG: Yes, I hope so.

11 CHAIRMAN MALMUD: So we have it. Do we
12 need a radio -- We don't need a radiopharmacist for
13 this, do we? No. Okay.

14 MEMBER THOMADSEN: I think it might be
15 very useful.

16 CHAIRMAN MALMUD: You think it would be
17 useful. All right. There we are because the
18 measurements of the Yttrium and the well counter are
19 precise estimates.

20 (Laughter.)

21 CHAIRMAN MALMUD: Very well.

22 MEMBER NAG: I think Jim also that you
23 want to be on the committee.

24 MEMBER WELSH: You're right.

25 MEMBER NAG: Dr. Welsh wanted to be on the

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1 committee.

2 CHAIRMAN MALMUD: They are precise, yes.
3 So we have the committee. You are the chair. Do you
4 approve of your membership?

5 MEMBER THOMADSEN: I think they're
6 delightful.

7 CHAIRMAN MALMUD: Could we have done any
8 better?

9 MEMBER EGGLI: Is there a person NRC staff
10 liaison for us?

11 CHAIRMAN MALMUD: The NRC staff liaison.

12 MEMBER NAG: Not for the subcommittee
13 though.

14 CHAIRMAN MALMUD: Not on the subcommittee.
15 All right. Then we'll go to the person on the NRC
16 staff and sitting over to my left are Dr. Howe and Dr.
17 Zelac, both of whom look intensely interested in the
18 subject. So we'll get it to them and then they will
19 get it to their hierarchy as well.

20 I hope that that shows some progress with
21 this.

22 DR. SALEM: Thank you very much. Thank
23 you for the time.

24 CHAIRMAN MALMUD: Thank you for being here
25 and thank you to the members of the public who spoke

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1 today as well.

2 Do you want to take a short break? Be
3 back at 3:45 p.m. Off the record.

4 (Whereupon, the above-entitled matter went
5 off the record at 3:34 p.m. and resumed at 3:45 p.m.)

6 CHAIRMAN MALMUD: It will be necessary at
7 4:00 o'clock for several members of the Committee to
8 leave so that they can get their badges, which have to
9 be done during this hour. So Ashley will give me a
10 tap on the head to remind me when they have to be
11 taken out.

12 (Laughter.)

13 MS. TULL: I thought you liked me.

14 MEMBER GILLEY: Taken out?

15 MEMBER NAG: What do you mean? You take
16 them out like the mafia?

17 CHAIRMAN MALMUD: All right. Let's see.
18 What are we proceeding with? We're back to Dr. Nag's
19 item. Is that correct?

20 MEMBER NAG: Yes.

21 CHAIRMAN MALMUD: And you will recall
22 there were a number of bullet points. The first four
23 are the ones that you wanted us to hopefully agree
24 with and then --

25 MEMBER NAG: Yes. If I may?

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1 CHAIRMAN MALMUD: You are on. Yes. Go
2 ahead.

3 MEMBER NAG: Okay. I have thought it
4 would be more efficient to make this more into like a
5 line item, make it into part A and part B. So we will
6 work on part A separate from part B.

7 Part A is specific recommendations that
8 are specific for limited brachytherapy. And those are
9 the ones before the line that says permanent
10 implantation should be deleted, treatment sites should
11 be clarified, and then A through B will become
12 superfluous. And that one should be eliminated. And
13 the activities should be replaced by source strength.

14 So my motion is that these are the
15 recommendation of the Subcommittee, and we vote on
16 this. And then I will make a separate recommendation
17 for the next one.

18 MEMBER THOMADSEN: Do we still have the
19 motion, Mr. Lieto's motion, on the floor?

20 CHAIRMAN MALMUD: We do.

21 MEMBER NAG: If we do, I am modifying it
22 to include this all as one.

23 MS. TULL: This is Ashley. You voted on
24 it.

25 MEMBER THOMADSEN: It started as an

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1 amendment to the --

2 CHAIRMAN MALMUD: We voted on it.

3 MEMBER THOMADSEN: Oh, we did vote on it?

4 CHAIRMAN MALMUD: Yes. We passed that
5 one.

6 MEMBER THOMADSEN: Then it was moved
7 again.

8 MS. TULL: The vote was 8:3:0.

9 MEMBER THOMADSEN: I mean, we had passed
10 it. And then we -- what?

11 MS. TULL: This is Ashley. The vote was
12 8:3:0, 8 in favor, 3 opposed, no abstentions.

13 CHAIRMAN MALMUD: We finished.

14 MS. TULL: But that was just for the
15 pre-implantation, which I believe is the first
16 thought.

17 CHAIRMAN MALMUD: That was for the first
18 bullet point.

19 MEMBER NAG: Yes. And then we go to the
20 second bullet point that clarifies that the treatment
21 site include the volume plus a very low treatment
22 margin.

23 CHAIRMAN MALMUD: If that is a motion,
24 will someone second the second bullet point?

25 MEMBER WELSH: I will second it.

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1 CHAIRMAN MALMUD: It has been seconded.
2 Any further discussion of the second bullet, just the
3 second bullet?

4 MEMBER FISHER: I am sorry, but I think
5 that when we took our first vote, we voted on this set
6 of recommendations, not the first bullet.

7 CHAIRMAN MALMUD: Dr. Nag says that his
8 motion was Mr. Lieto, and it was only the first one.

9 MEMBER NAG: Mr. Lieto's motion on the
10 first --

11 CHAIRMAN MALMUD: Ralph, do you recall?
12 Was it one or all four? What had you proposed
13 originally?

14 MEMBER LIETO: Yes.

15 MS. TULL: This is Ashley. I think that
16 there was a second recommendation.

17 MEMBER LIETO: We voted on first one,
18 which was the issue --

19 MEMBER NAG: Pre-implantation.

20 MEMBER LIETO: -- which really addressed
21 the first bullet up there. The second --

22 MEMBER EGGLI: But that wasn't the
23 wording.

24 MEMBER LIETO: Pardon?

25 MEMBER EGGLI: That wasn't the wording of

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1 your motion, though.

2 MEMBER LIETO: No.

3 CHAIRMAN MALMUD: Well, it looks like
4 today is a day of corrections. So do you wish to
5 correct your motion?

6 MEMBER LIETO: No, but it did the same
7 thing.

8 MEMBER EGGLI: Right. Your motion said
9 something to the effect that up until the time the
10 person leaves the procedure area, the written
11 directive could be modified was the essence of your
12 first motion that passed.

13 MEMBER LIETO: Right, that the medical
14 event is based on the written directive at the time
15 the patient leaves the proposed treatment procedure
16 room or whatever the term is used.

17 MEMBER NAG: I would like to now -- it
18 means the same thing, alternative --

19 MEMBER LIETO: It is verbatim out of the
20 report.

21 MEMBER NAG: Yes. The one that was
22 confirmed said it would be a medical event if the
23 total source strength administered occurred by 20
24 percent or more from the source strength documented in
25 the pre-implantation written directive.

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1 Okay. The recommendation was that the
2 administration of byproduct material, all radiation
3 from byproduct material results in total source
4 strength administered deploying by 20 percent or more
5 from the total source strength documented in the
6 written directive, that there is delete
7 "pre-implantation." So basically the same thing is a
8 summarized form of the same.

9 CHAIRMAN MALMUD: Just deleting
10 pre-implantation.

11 MEMBER NAG: Right.

12 CHAIRMAN MALMUD: And that is the motion
13 that we had moved on or that you wish us to move on?
14 That is the motion?

15 MEMBER NAG: That first one was already
16 moved. So I forgot that it had been moved already.
17 So we have to go on to the next two.

18 CHAIRMAN MALMUD: So the proposer's memory
19 of the first motion was limited to the first bullet
20 point. May we move on to the second bullet point?

21 MEMBER THOMADSEN: But I believe that that
22 was the case in retrospect. But then did not Mr.
23 Lieto make a second motion to approve the entire
24 report, the recommendations of the entire report?

25 CHAIRMAN MALMUD: That is correct.

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1 MEMBER THOMADSEN: It was seconded. And
2 in the discussion, it was then --

3 CHAIRMAN MALMUD: Interrupted.

4 MEMBER THOMADSEN: -- interrupted.

5 CHAIRMAN MALMUD: Right.

6 MEMBER THOMADSEN: And now we are resuming
7 that. So I think we have a motion on the floor. The
8 transcriber could --

9 CHAIRMAN MALMUD: You are correct. You
10 are correct.

11 MEMBER THOMADSEN: -- possibly correct me
12 on that.

13 CHAIRMAN MALMUD: Dr. Thomadsen is
14 correct. The motion is on the floor. Perhaps we
15 should just -- do you want to table it or do you want
16 to move it forward? What would you like?

17 MEMBER NAG: What is the motion? I would
18 like to make clear.

19 CHAIRMAN MALMUD: The motion is to approve
20 everything as it stands on that.

21 MEMBER NAG: But the first one has already
22 been approved.

23 MS. TULL: That's okay.

24 CHAIRMAN MALMUD: Yes, we know that. The
25 issue is not the first one any longer. The issue is

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1 what remains on there. You can either table it or you
2 can bring it forward and reject it and then go through
3 each bullet point at a time. Or withdraw it, or you
4 can amend it.

5 Whose motion is it? Ralph, it is your
6 motion. What would you like to do?

7 MEMBER LIETO: To approve. My motion was
8 to approve the report.

9 CHAIRMAN MALMUD: The whole thing?

10 MEMBER LIETO: Yes, all the
11 recommendations in the report.

12 CHAIRMAN MALMUD: All right. Any further
13 discussion of that?

14 MEMBER GILLEY: I would like a definition
15 of what gross tumor, clinical target volume,
16 invariable planning margins are as far as the
17 parameters because that will determine whether or not
18 we have a medical event per se. I don't have
19 definitions for those in the regulations.

20 MEMBER NAG: They are not even in the
21 regs. They are in ICIU-52, I believe.

22 MEMBER THOMADSEN: They updated it to 62.
23 They put some out for the new one, but I'm not sure
24 what that --

25 MEMBER NAG: In the ICIU regs. It

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1 basically says that the gross tumor volume is the
2 volume that contains the tumor. And the minimum
3 target volume is the area of the gross tumor plus the
4 variable margin. That's the margin that contains
5 microscopic tumor. And the planning target volume is
6 the area around that, the area that the radiation
7 oncologists wish to implant. Those are the three
8 volumes.

9 MEMBER THOMADSEN: It is in the slide.

10 CHAIRMAN MALMUD: Mr. Lieto?

11 MEMBER LIETO: Hopefully this will help to
12 answer Debbie's question. The regulation addresses
13 treatment site. And the subcommittee is making a
14 recommendation to clarify that definition so that you
15 can more easily determine medical events. And the
16 treatment site is now being clarified to be named the
17 PTV, the planned tumor volume, which is defined in
18 ICIU. It is an international definition and is
19 clearly understood across the radiological, radiation
20 oncology community.

21 CHAIRMAN MALMUD: Dr. Welsh?

22 MEMBER WELSH: I would like to discuss
23 amending the motion by including the bullet points
24 with the exception of the last one because I think the
25 last one is controversial enough that there could be

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1 enough dissention that the whole package might not
2 pass and could be throwing the baby out with the
3 bathwater by mixing that last item in here.

4 The others are clearly very relevant to
5 prostate brachytherapy and are causing a great deal of
6 consternation to active practitioners.

7 The last issue I think we're going to have
8 a lot different opinions on, but I think the first
9 four items I think we would have a lot of unanimity
10 on. And, therefore, I would propose separating that
11 last one out.

12 CHAIRMAN MALMUD: Dr. Welsh recommends
13 dropping the last bullet point and voting on the
14 bullet points above with the exception of the first
15 one, which has already been approved.

16 VICE CHAIRMAN VETTER: Second.

17 CHAIRMAN MALMUD: It has been seconded by
18 Dr. Vetter. That's an amendment to the motion.

19 MEMBER SULEIMAN: You are saying we are
20 voting on the second, third, and fourth bullet points?

21 CHAIRMAN MALMUD: Second, third, fourth,
22 fifth.

23 MEMBER THOMADSEN: Everything except the
24 last one.

25 CHAIRMAN MALMUD: Two, three, four, five.

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1 MEMBER SULEIMAN: And does that mean we
2 are going to discuss the last one separately?

3 CHAIRMAN MALMUD: That's not being
4 discussed in this motion. The last one is not being
5 addressed in this motion, only the bullet points up to
6 the last one.

7 MEMBER SULEIMAN: Well, if we are going to
8 limit it just to the bullet points up to that and
9 you're not allowing us to decide if we're going to
10 discuss the last one separately --

11 MEMBER NAG: The last one would be a
12 separate motion.

13 CHAIRMAN MALMUD: Dr. Suleiman, I have
14 never disallowed any discussion. No. What I am
15 saying is that the motion that is on the table
16 addresses the bullet points except for the last one.
17 So let's not discuss the last one until we are done
18 with the motion above.

19 MEMBER NAG: Again, I would like to amend
20 the motion since the first one has already passed and
21 --

22 MEMBER THOMADSEN: Don't we have a motion?
23 We have an amended motion on the floor right now.

24 CHAIRMAN MALMUD: Yes, we do.

25 MEMBER FISHER: You can amend an

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1 amendment.

2 CHAIRMAN MALMUD: Sure, you can.

3 MEMBER NAG: I am amending the amendment.

4 MEMBER THOMADSEN: He is not amending the
5 amendment.

6 MEMBER NAG: Yes.

7 MEMBER THOMADSEN: It is a new amendment.

8 MEMBER GILLEY: A new amendment? Until we
9 vote on this amendment.

10 VICE CHAIRMAN VETTER: The amendment is
11 the last item.

12 MEMBER NAG: Right. And I am last. I am
13 eliminating the first and the last. The first has
14 already passed.

15 VICE CHAIRMAN VETTER: Don't worry about
16 it. You succeeded.

17 CHAIRMAN MALMUD: We now understand what's
18 on the table is bullets 2, 3, 4, and 5.

19 MEMBER THOMADSEN: We haven't voted on
20 that amendment yet, have we?

21 CHAIRMAN MALMUD: No. That's the
22 amendment. It would be just those four. So all in
23 favor of this amendment, please raise your hand.

24 Eight.

25 All opposed?

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1 Two opposed. It's -- oh, three. Where is
2 the third? I'm sorry. Okay.

3 MEMBER NAG: Now I would like to make a
4 new motion for the --

5 MEMBER SULEIMAN: Whoa. We haven't
6 finished this one. We just voted on whether we --

7 MEMBER NAG: Yes.

8 CHAIRMAN MALMUD: Do you wish to amend
9 your new --

10 MEMBER NAG: The new motion is now we go
11 to the last bullet point and --

12 MEMBER THOMADSEN: No, no. We have a
13 motion on the floor.

14 MEMBER NAG: No. The motion has already
15 been voted.

16 CHAIRMAN MALMUD: Everyone is going by
17 parliamentary rules now. So we have another amendment
18 on the floor. And that is to vote on items 2, 3, 4,
19 and 5. Am I correct?

20 VICE CHAIRMAN VETTER: That is the motion.
21 That is the new motion.

22 CHAIRMAN MALMUD: That is the new motion.
23 Dr. Vetter says it is so. So it must be so. So it's
24 2, 3, 4, and 5, not 1. It has already been approved,
25 not the last one. It is not on the table. So is that

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1 correct? And it has been moved and seconded. Any
2 further discussion?

3 (No response.)

4 CHAIRMAN MALMUD: All in favor of
5 approving items 2, 3, 4, and 5?

6 Nine.

7 All opposed?

8 Two. Nine to two. Okay. Now we'll move
9 on. So we now have approved 1, bullet 1, bullet 2,
10 bullet 3, bullet 4, bullet 5.

11 Does anyone wish to tackle the last bullet
12 that you wished to be deferred? Dr. --

13 MEMBER NAG: I will make a separate motion
14 for that.

15 CHAIRMAN MALMUD: Okay. Make a separate
16 motion.

17 MEMBER NAG: My motion now is that
18 administration without working with written directive
19 should be cited as regulation violations and are not
20 medical events per se.

21 CHAIRMAN MALMUD: Is there a second to
22 that motion?

23 MEMBER NAG: That was your motion.

24 MEMBER LIETO: That is not exactly what --

25 CHAIRMAN MALMUD: No second to the motion.

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1 I beg your motion?

2 MEMBER WELSH: Second.

3 CHAIRMAN MALMUD: Dr. Welsh seconds the
4 motion. Is there any further discussion of the
5 motion, which has been moved and seconded?

6 MEMBER NAG: I would like Ralph to clarify
7 why that is not what is in the report.

8 MEMBER LIETO: Thank you. The
9 administration without written directive is a
10 violation of regulations already. I mean, it's not
11 that we're adding or changing anything.

12 What the body of the report reflects is a
13 discussion to support the fact that they should not be
14 classified as medical events. And this is part of the
15 proposed rules that the subcommittee was asked to
16 address. It's not something new that was brought up.

17 It's an addition into the definition of
18 the rules that are under the title of permanent
19 brachytherapy. They encompass all written directives,
20 not just permanent brachytherapy. It also includes
21 temporary brachytherapy as well as radiopharmaceutical
22 as well as the part 1000 therapies.

23 So I felt that, for the reasons that are
24 described in the report, that making a violation of
25 the regulations a medical event when there was not --

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1 to me, I guess I am also looking for the support as to
2 why not having a written directive needs to be a
3 medical event. Okay?

4 I'm not saying that it's not a violation
5 that needs to be handled as a violation, but just like
6 any other type of medical event that you find that you
7 self-identify, this would be handled in the same way
8 that you handle any type of self-identified regulation
9 under the licensee's auspices. And that's where I
10 think it should stay. I don't think it needs to be in
11 the medical event reporting.

12 Contrary to what was said earlier, that
13 the reason for this is so that medical events are not
14 necessarily things that indicate harm to the patient,
15 that's true. But these go into the reporting
16 mechanisms for the medical events, which means it
17 automatically within 24 hours goes into the public
18 venue.

19 It's handled just the same way as a
20 reactor event would be in terms of notification to the
21 general public. And I don't think that they warrant
22 that type of reporting.

23 CHAIRMAN MALMUD: Thank you for clarifying
24 that.

25 MEMBER NAG: How would you make a motion

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1 of that, that we should issue an LIS? Can you state
2 how we can make it into a motion?

3 MEMBER LIETO: Just as it states here,
4 that that part should be stricken from the proposed
5 rule.

6 MEMBER NAG: That the LIS be issued
7 emphasizing that administration we thought required
8 written directive of violation of regulation and are
9 not medical events per se, but you must access to
10 identify any deviation from the requirements? That's
11 what mine says.

12 CHAIRMAN MALMUD: May I make a suggestion
13 to you? What would you think of the wording that
14 says, "Administrations without prior written
15 directives are to be cited as regulation violations,"
16 period?

17 MEMBER LIETO: Well, written directives
18 are required prior to the administration.

19 CHAIRMAN MALMUD: Ah, but we heard about
20 written directives that are changed afterwards.

21 MEMBER LIETO: I mean, that's in the
22 regulation right now if I'm not mistaken that a
23 written directive is required to be signed and dated
24 prior to administration. I mean, that's the way the
25 current rule states. I am not recommending changing

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1 that.

2 CHAIRMAN MALMUD: I didn't recommend a
3 change either. I just recommended that it be
4 reiterated.

5 Dr. Suleiman?

6 MEMBER SULEIMAN: If they don't have a
7 written directive, it's a serious violation, correct?
8 Without a written directive, how would you know
9 whether you had a medical event because you wouldn't
10 know whether you have exceeded the area or the
11 quantity or whatever. And it's double jeopardy to
12 both get hit on the lack of written directive
13 violation and then get hit with a medical event when
14 it's an administratively defined medical event.

15 So I think that is consistent. In other
16 words, the lack of a written directive basically just
17 qualifies them from a medical event, but it is a
18 heavier penalty. I mean, it is a heavier --

19 MR. LEWIS: Right. While I agree with
20 what Mr. Lieto said, I think you have to take this
21 slide into context with what it's together with, which
22 is your Committee comments on the proposed rule, not
23 the current rule.

24 MEMBER SULEIMAN: Correct.

25 MR. LEWIS: Among your comments is a

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1 change in when a written directive occurs, whether
2 it's before or after the actual procedure. I think
3 that to properly give context to the last bullet, you
4 have to consider that fact that it's not always ahead
5 of time the way that you proposed that we changed the
6 proposed rule.

7 It's not always a pre-procedural written
8 directive. It can be a post-procedural written
9 directive, as we talked about this morning.

10 MEMBER LIETO: Does that make a
11 difference?

12 MEMBER SULEIMAN: Wait. I want
13 clarification. You can modify it, but you had to have
14 something on the table in the first place. I mean,
15 you are going in with a target dose. And you then
16 modify. And then you make the corrections.

17 But going without any written directive,
18 how do you know if you are on target or not at all?
19 So I think without a written directive to me means no
20 written directive.

21 CHAIRMAN MALMUD: Please, Dr. Welsh?

22 MEMBER WELSH: So this morning we
23 discussed issues relevant to this particular topic
24 One of the issues we discussed was how do you solve
25 the dilemma of real-time interoperative planning,

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1 where the plan is generated in the operating room and
2 then the written directive is put together after the
3 fact?

4 Dr. Zelac put together a suggestion that
5 at the time the plan is finished, that is when an oral
6 written directive might be generated. I kind of like
7 that idea because then you do have something that you
8 use as a template, a guide that serves as your
9 pre-procedural written directive and you could still
10 have an adjustment afterwards based on what happens to
11 volume change, size changes in the procedure.

12 MEMBER SULEIMAN: I would argue that the
13 fact that you are even initiating the software program
14 to start calculating to me is sort of an implicit. I
15 mean, it hasn't been finalized but tells me that there
16 is some planning and thinking going into this process.

17 So I would argue that that doesn't mean it
18 doesn't have a -- it may not have a written,
19 in-writing directive, but I think the initiation of
20 the software to do the treatment planning, do the
21 dosimetry --

22 MEMBER WELSH: In that case, there can
23 never be an administration without a written directive
24 by your definition.

25 MEMBER SULEIMAN: No because you have

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1 said: I want the opportunity to make changes. So you
2 have now committed to having a final directive based
3 on what happened during the procedure.

4 So you cover yourself. You allow yourself
5 that flexibility that when you're finished, you need
6 to document what happened. And then that --

7 MEMBER LIETO: I would agree. I mean, the
8 regulations, the current regulations, in force say you
9 have to have a written directive prior to the
10 administration.

11 What determines the medical event is that
12 written directive that is made before the patient is
13 released. After you have done your changes in your
14 real time and whatever, the medical event is based on
15 the written directive changes before the patient is
16 released.

17 CHAIRMAN MALMUD: I don't think you want
18 that because if you had a sound medical reason for
19 changing the written directive, then you would have a
20 medical event, even though you had a sound reason for
21 it? No. You don't want that.

22 MEMBER LIETO: Why would you have a
23 medical --

24 CHAIRMAN MALMUD: Because you changed your
25 written directive.

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1 MEMBER LIETO: But you did that before the
2 patient was released from your control. During the
3 course of the treatment, you make these --

4 CHAIRMAN MALMUD: You modify it.

5 MEMBER LIETO: -- changes and modify it
6 based on whatever. That then becomes your basis for
7 the medical event determination.

8 CHAIRMAN MALMUD: All right. Now I
9 understand.

10 Dr. Howe?

11 DR. HOWE: This is Dr. Howe. The issue
12 wasn't that you hadn't modified your written
13 directive, and the issue wasn't that you didn't have a
14 complete written directive. The issue was you didn't
15 have a written directive at all.

16 A person receives a treatment that
17 requires a written directive and there is no written
18 directive. And it happens rarely, but we have had
19 patients that have gotten therapeutic procedures in
20 which there was no written directive at all. And we
21 wanted those to be reported to the NRC. And the
22 important concept here is reporting.

23 CHAIRMAN MALMUD: Reported as what, as
24 violations or as medical events?

25 DR. HOWE: No. As a medical event.

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1 CHAIRMAN MALMUD: Oh, okay.

2 DR. HOWE: Because you don't have to
3 report violations, but you do have to report medical
4 events.

5 CHAIRMAN MALMUD: Mr. Lieto?

6 MEMBER LIETO: And I address that in this
7 report. Let's say you have two scenarios, I mean,
8 there are two scenarios. You have a patient. You do
9 not have a written directive, verbal or written. It's
10 the patient you intended to give the therapy to.

11 And you give the patient what you intended
12 to, but there is no written directive. Okay? There
13 are no health and safety issues in terms of harm to
14 the patient in that scenario. That patient hasn't
15 been harmed. Okay. You didn't document what you
16 intended to do. I mean, you did what you intended to
17 do. You just didn't document it.

18 My second scenario is the patient, no
19 written directive or verbal given of what you intended
20 to do. You say you are intended to give a I-123
21 diagnostic administration and, instead of 200 mics,
22 you give 200 millicuries of I-131. Okay? You
23 obviously have exceeded by ten percent and exceeded
24 all the dose criteria for a medical event. And that
25 has to be reported.

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1 CHAIRMAN MALMUD: Okay. May I ask you a
2 question? Why would anyone give a therapeutic dose
3 without a written directive? What would the
4 circumstances be that would excuse the absence of a
5 written directive?

6 MEMBER LIETO: I'm not making any excuses
7 for it. I'm just saying --

8 CHAIRMAN MALMUD: I understand that. That
9 is the first part of my question.

10 MEMBER SULEIMAN: I can see that.

11 CHAIRMAN MALMUD: You can see that. Dr.
12 Suleiman from the FDA?

13 MEMBER SULEIMAN: I would say these are
14 approved for humanitarian use. The patient is not
15 going to live very long. And so you have "Why bother?
16 I'll give this person what I gave the last person"
17 and sort of --

18 CHAIRMAN MALMUD: Well, you still have a
19 written directive. You write out a prescription for
20 what you are going to do.

21 MEMBER SULEIMAN: Well, maybe they felt so
22 casual about the thing they forget to write the
23 written directive. You asked me to come up with a
24 scenario. That's all I did.

25 CHAIRMAN MALMUD: No one on this Committee

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1 will vote for that.

2 Dr. Welsh?

3 MEMBER WELSH: I can't give you an
4 example, but Dr. Howe says it has happened. So maybe
5 we should ask under what circumstances this has
6 happened.

7 DR. HOWE: It happened with intervascular
8 brachytherapy, in which there were patients coming in
9 and the authorized user reviewed cases for -- there
10 were like four potential people. They reviewed the
11 cases for three, never reviewed the case for the
12 fourth one.

13 The first person didn't show up. They
14 gave the intervascular brachytherapy to the remaining
15 three. It was never a written directive for the
16 fourth person. There was never an evaluation for the
17 fourth person. And they received the intervascular
18 brachytherapy.

19 CHAIRMAN MALMUD: We would all agree,
20 having heard this story, that we would object to it.
21 There is no one here who would approve of that I don't
22 think.

23 So, therefore, once again I ask the
24 question, under what circumstances? I mean, after
25 all, this is not emergency room medicine, where quick

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1 decisions have to be made, even then thoughtfully.

2 What would be the reason for giving a
3 patient a therapeutic dose of radioactive material
4 without a written directive?

5 MEMBER NAG: Even in the emergency is
6 obvious because I forget under what part that it is
7 because of the emergency nature of the procedure, you
8 can have a verbal written directive that you can sign
9 within 48 hours or 34 hours. So even that is that. I
10 have used that provision. So I know that.

11 CHAIRMAN MALMUD: This is for radiation
12 therapy?

13 MEMBER NAG: For radiation therapy for
14 brachy dose.

15 CHAIRMAN MALMUD: So you are saying there
16 are valid reasons not to have a written directive?

17 MEMBER NAG: No. But, I mean, the
18 provision is already there for emergency, under
19 emergency conditions, --

20 CHAIRMAN MALMUD: For emergency.

21 MEMBER NAG: -- you have to do that.

22 CHAIRMAN MALMUD: Why would someone be
23 scheduled for -- again I would ask the same question.
24 Can you give me an example?

25 MEMBER THOMADSEN: I am just curious. Why

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1 are you looking for justified examples? I don't think
2 anybody is saying that it is ever justifiable.

3 CHAIRMAN MALMUD: Then we should reaffirm
4 that it's not justifiable. I am puzzled by --

5 MEMBER THOMADSEN: That's fine, too. I
6 mean, it says it's a violation. Nobody is arguing
7 that it is not a violation. It's Hynia's the people
8 are wicked and evil, but it's probably not a medical
9 event. That's the only thing that this is saying.

10 If you wanted to take on an appendix that
11 says, "And we heartily" --

12 CHAIRMAN MALMUD: I said that was the
13 first part of my question. Okay. So now it's okay
14 not to have a written directive. So now I will play
15 the role of the sloppy practitioner. I didn't have a
16 written directive for the last three. I don't need
17 one for this one.

18 Give him 100 millicuries. He only needed
19 ten. Where is the evidence that he only needed ten?
20 Where is the evidence that I gave the wrong dose? It
21 isn't there because there was no written directive.
22 Why wasn't there a written directive? Because I
23 didn't need it the last three times. It doesn't get
24 reported to the NRC. Don't worry about it.

25 Once we go down a slippery slope of not

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1 having written directives, I think we enter a world
2 which none of us lives in but which exists. And that
3 is the world of sloppy medicine.

4 And that's what concerns me. That's why I
5 asked my question in two phases. Once we open the
6 door, who knows what will happen? It's like, you
7 know, look how many prescription errors there are in
8 the United States according to the Institute of
9 Medicine. Why wouldn't the same errors be made with
10 radioactive material?

11 That's what my concern is. My concern is
12 for the patient who will suffer as a result of laxity
13 in requiring us to write a written directive.

14 I don't live in the world of emergency
15 medicine. So, therefore, it's easy for me to write a
16 written directive. And I never have not written one.

17 Dr. Welsh?

18 MEMBER WELSH: I think that we would all
19 agree that there are no circumstances in which you
20 shouldn't have a written directive. Even if it's an
21 emergency and you have to put it together the day
22 after, you should always have a written directive.
23 And I think everyone would agree with that.

24 The question at hand is, if a written
25 directive, for whatever heinous reason, was not put

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1 there, what do you call that? Is it a medical event
2 or is there another category which would be more
3 appropriate? And is there such thing as a reportable
4 regulation violation?

5 CHAIRMAN MALMUD: Is there such a thing as
6 a reportable regulation violation?

7 DR. HOWE: No, there is not. The only
8 thing we have reportable in part 35 is if you have a
9 leak test that exceeds a certain level, if you have a
10 medical event, if you have embryo fetus that receives
11 a dose over a certain level.

12 So there are very few reportable things in
13 part 35.

14 CHAIRMAN MALMUD: Dr. Suleiman?

15 MEMBER SULEIMAN: Yes, a quick question.
16 You are talking about amending the regulations. This
17 is rulemaking. Why can't you have a reportable
18 violation? I mean, I think the resistance against
19 making this a medical event is to make it a medical
20 event so it's reportable.

21 Well, this is where you take the wrong
22 reason, the wrong reg to get a right solution and
23 downstream this is going to cause other complications.
24 Why call it a medical event when, in fact, it is a
25 failure to write the written directive, you know? And

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1 why not make it reportable under the proposed
2 rulemaking?

3 MEMBER NAG: I would agree to that that --

4 MEMBER SULEIMAN: Let's call a spade a
5 space.

6 MEMBER NAG: I mean, having a procedure
7 where a written directive is required, a legal written
8 directive, is a reportable violation. I have no
9 problem with that.

10 MR. LEWIS: Just for the record, we do
11 have other parts that apply to medical licensees. And
12 those have reportable violations of exposures of
13 personnel, releases to environment, failure of --

14 MEMBER SULEIMAN: I mean, this is serious.
15 This is a therapy. And they haven't done a written
16 directive. Yes. As soon as they find out, they
17 should have to report it.

18 CHAIRMAN MALMUD: So there are interim
19 levels between --

20 MR. LEWIS: Well, there are other
21 regulations that have reporting requirements.

22 CHAIRMAN MALMUD: Good. Can you give us
23 one that we could all agree upon that's not as severe
24 as a medical event?

25 MR. LEWIS: Because our system for

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1 reporting for the conditions in part 35, patient dose
2 was off by 20 percent or wasn't what was prescribed,
3 those are defined as medical events. And that is our
4 system for reporting.

5 So, again, I guess one way to look at this
6 is if NRC wants to hear about it, it should be
7 reported as a medical event. Help me out, Donna-Beth,
8 if I am off base, but we don't need another regulatory
9 system of different types of things to report. Let's
10 just have one thing.

11 CHAIRMAN MALMUD: You see, that's where we
12 have a problem. We recognize as physicians that there
13 may be a variation of more than 20 percent in a dose
14 received by the patient, which is not really a medical
15 event. It can occur in the hands of the best
16 physician. That physician and that institution should
17 not be subjected to what you go through when you have
18 a "medical event."

19 We are looking for something in which you
20 will be informed but does not have the course of
21 action following it which actually discourages
22 reporting events.

23 We would like you to know about these
24 events. We would like you to know how many
25 administrations we are given without a written

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1 directive so that you could send somebody in there and
2 say, "Hey, what is going on around this place?" and
3 begin haunting them the way a regulatory agent should
4 haunt a provider that is not adhering to the rules.
5 We are in the spirit of Halloween you raised it. You
6 raised heinous issues before.

7 So the point is we are looking for
8 something. We are not trying to escape it. On the
9 other hand, the punishment does not fit the crime.
10 The punishment is too severe for a legitimate
11 practitioner whose therapy dose is outside the
12 guidelines for a reason which may be very explainable
13 without it being plastered on the internet and causing
14 embarrassment.

15 Is there something between a regulatory
16 violation and a medical event that could be reported
17 to the NRC without the sequelae of a medical event?

18 MR. LEWIS: Not in part 35.

19 CHAIRMAN MALMUD: Then that is something
20 that we would probably want all to work with you to
21 try to develop over the long haul because I think that
22 would improve the safety of patients by making the
23 incidents not so severe that some parties might decide
24 to try and hide them, rather than report them.

25 MR. LEWIS: NRC only wants to hear about

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1 things we need to hear.

2 CHAIRMAN MALMUD: Of course.

3 MR. LEWIS: We are not trying to create
4 something we need to hear about. In the past, we drew
5 the line of things we want to hear about versus things
6 we don't need to hear about at medical event.

7 CHAIRMAN MALMUD: But you realize traffic
8 has three colored lights: --

9 MR. LEWIS: Yes.

10 CHAIRMAN MALMUD: -- a green, an orange,
11 and a red.

12 MR. LEWIS: I appreciate what you said.

13 CHAIRMAN MALMUD: I am trying to get the
14 orange in there.

15 Dr. Zelac?

16 DR. ZELAC: Actually, in thinking about
17 this, we really have kind of a fundamental problem
18 here, which has already been alluded to. The whole
19 concept of medical events was to bring out for
20 consideration facilities where there were lapses in
21 procedures so that there could be attention paid to
22 those lapses.

23 And we have made the point repeatedly that
24 medical events were not violations. Well, here you
25 have got a case where there is something that is being

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1 classified a medical event which, in fact, is a
2 violation. So it doesn't really belong in that
3 category.

4 CHAIRMAN MALMUD: What happens when a
5 medical event is reported to, let's say, district one?
6 What happens?

7 DR. HOWE: For region one?

8 CHAIRMAN MALMUD: Region 1.

9 DR. HOWE: A potential medical event may
10 come into region 1. Region 1 will tell the licensee
11 to report it to the WHO. It becomes an event
12 notification. It can be called a potential medical
13 event if there is still a question or it can become a
14 full medical event.

15 And then region 1 will either evaluate
16 what it was and decide it is really important for us
17 to go out and schedule a reactive inspection or region
18 1 may decide that yes, it was a medical event, but it
19 doesn't appear to be a serious problem with your
20 program. We have an inspection coming up at a certain
21 time. We will go on a routine inspection. This is
22 one of the things that we'll ask about.

23 And so depending on what it is coming in,
24 there will be a value judgment made as to how NRC will
25 react on it.

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1 CHAIRMAN MALMUD: It is not made public,
2 then.

3 DR. HOWE: The event notification is made
4 public. If we think it is a potential medical event,
5 we're not sure, we'll hold it for about five days.
6 And then it becomes public. If we know it is a
7 medical event, we'll make it public.

8 CHAIRMAN MALMUD: Dr. Eggli?

9 MEMBER EGGLI: Well, that's not all.
10 There are other notification requirements, including
11 the patient and referring physician. But the medical
12 event is based on a variance from a planned therapy,
13 which implies it's a variance from the written
14 directive. You're redefining now medical event to
15 include the absence of a written directive.

16 So you are fundamentally changing the
17 definition of the medical event, which is the flip
18 side of what Dr. Zelac just pointed out, which is that
19 medical events are not considered violations, where in
20 this case we have a violation.

21 You are changing the definition of a
22 medical event because you now no longer have anything
23 to benchmark against whether or not this really is a
24 medical event without changing the definition to
25 include absence of a written directive. So you are

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1 now fundamentally changing the definition of medical
2 event across the board.

3 It is sneaking in in a subsection of
4 brachytherapy, but it will apply broadly because it
5 doesn't say brachytherapy administrations without
6 written directive. It says administrations without
7 written directive. So you are fundamentally changing
8 the definition in a place where it probably ought not
9 to be fundamentally changed.

10 MEMBER NAG: And this was another reason
11 why I wanted to separate a discussion of permanent
12 brachytherapy with this because this applies not only
13 to permanent brachytherapy but for other sources, too.

14 I wanted this to be a separate discussion because it
15 implies that there were broad implications.

16 DR. HOWE: It doesn't really deal with the
17 unsealed sources because the way the rules are
18 written, we are able to capture those events in which
19 an unsealed therapy is given but there wasn't a
20 written directive because we can go back to the second
21 part of prescribed dosage and we can see that that
22 prescribed dosage is also based on your procedures.

23 And if your procedure manual includes one
24 of the diagnostic things and you gave a therapeutic,
25 then we say, "This is your diagnostic procedure. You

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1 intended to give whatever this was. You gave this
2 that differs from the dose you would have given in the
3 diagnostic by" such and such.

4 So we have a regulatory basis to get into
5 the unsealed. It's the sealed sources where the dose
6 is dependent on what is in the written directive
7 because no written directive, there's no dose for it
8 to be different from and you weren't supposed to get a
9 dose, but OGC has determined that is not a medical
10 event and it's not reportable.

11 And so someone gets a therapeutic dose
12 without a written directive. It's not reportable to
13 the NRC.

14 MEMBER NAG: Right.

15 DR. HOWE: That's the thing we want to
16 fix.

17 MEMBER NAG: It's more than permanent
18 brachytherapy. It includes removable brachytherapy,
19 HDR, and gamma knife but does not include the unsealed
20 source. Let me correct myself.

21 CHAIRMAN MALMUD: Okay. So where do we
22 stand at the moment?

23 MEMBER SULEIMAN: I would like to amend if
24 there is a motion on the floor. I don't know if there
25 is a motion on the floor.

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1 MEMBER NAG: I have withdrawn it.

2 MEMBER SULEIMAN: I was going to say
3 change the wording on that last thing to say
4 "Administrations without a written directive should be
5 cited as a reportable regulatory violation and are
6 not" --

7 MEMBER NAG: I was going to say the same
8 thing.

9 MEMBER SULEIMAN: And how the NRC does
10 that is up to -- I mean, you have got other
11 reportable.

12 CHAIRMAN MALMUD: Was that a motion you
13 just made?

14 MEMBER SULEIMAN: It was an amendment to a
15 motion I thought was on the floor. Otherwise I will
16 make it a motion.

17 MS. TULL: There is a motion on the floor,
18 yes.

19 CHAIRMAN MALMUD: What is the motion on
20 the floor?

21 MS. TULL: I had NRC staff should accept
22 the sixth recommendation of the Permanent Implant
23 Brachytherapy Subcommittee report, which would just be
24 the last bullet listed on that slide.

25 MEMBER NAG: Yes. I would amend that and

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1 say administration without a written directive should
2 be classified as a reportable regulatory violation.

3 CHAIRMAN MALMUD: That is a motion. Is
4 there a second to that motion?

5 VICE CHAIRMAN VETTER: Second.

6 CHAIRMAN MALMUD: Dr. Vetter seconds it.
7 Is there any further discussion of that motion?

8 MEMBER LIETO: As I understand, there is
9 not any mechanism.

10 VICE CHAIRMAN VETTER: They are writing
11 the rules right now.

12 MEMBER LIETO: Right, but that --

13 VICE CHAIRMAN VETTER: That is
14 nonnegotiable.

15 MEMBER LIETO: That does not get to the
16 gist of the issue in terms of what is being proposed
17 in the current rules. The proposed rule states that
18 any administration without a written directive. And
19 that is what the subcommittee report asks to be
20 withdrawn.

21 CHAIRMAN MALMUD: That can be dealt with
22 as a separate motion. First we move on this motion.

23 MEMBER WELSH: May I ask --

24 MEMBER NAG: I am confused.

25 MEMBER WELSH: Before I make --

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1 CHAIRMAN MALMUD: Dr. Welsh?

2 MEMBER WELSH: I would like to have some
3 clarification from Ralph about that point. I think
4 that the motion is that administrations without
5 written directive should be cited as reportable
6 regulation violations, period.

7 How about if we said "and are not medical
8 events"? Would that satisfy what you just brought up?

9 MR. LEWIS: Or may or may not be medical
10 events because --

11 MEMBER NAG: That is why the "per se" is
12 there.

13 MEMBER WELSH: Yes, per se. Would that
14 satisfy what your thought was?

15 CHAIRMAN MALMUD: You are asking a
16 question of whom, Dr. --

17 MEMBER LIETO: I believe it would, yes.

18 MEMBER WELSH: So, therefore, there is an
19 amendment to the motion.

20 CHAIRMAN MALMUD: The amendment to the
21 motion reads, "Administrations without written
22 directives should be cited as reportable regulation
23 violations and may or may not constitute MEs," period.

24 Is that what you're saying?

25 VICE CHAIRMAN VETTER: Yes.

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1 CHAIRMAN MALMUD: And that has been
2 seconded. And Dr. Zelac has a comment.

3 DR. ZELAC: My suggestion would be to add
4 the words "when a written directive is required"
5 because there are many administrations for which a
6 written directive is not required.

7 CHAIRMAN MALMUD: Thank you.

8 Dr. Zelac makes that suggestion to your
9 motion. Is that acceptable?

10 MEMBER NAG: Yes.

11 CHAIRMAN MALMUD: So that it will read,
12 "When a written directive is required, administrations
13 without written directives should be cited as
14 reportable regulation violations."

15 DR. HOWE: I don't think you want to say
16 "cited." I think you want to say "reported."

17 CHAIRMAN MALMUD: It should be reportable?

18 DR. HOWE: Classified as.

19 CHAIRMAN MALMUD: "Should be reported as
20 regulation violations" -- you can polish up the words
21 -- "and are not necessarily MEs" or "may or may not be
22 MEs." Is that right, "'may or may not be MEs"? Is
23 that acceptable?

24 MEMBER SULEIMAN: I just have a question
25 about the last clause, "may or may not." Why not just

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1 not say anything?

2 CHAIRMAN MALMUD: Well, because a patient
3 can come into the hospital for a bone scan and,
4 instead of getting 20 millicuries of technetium on
5 IMDP, they get 20 millicuries of I-131.

6 MEMBER SULEIMAN: By definition, that
7 would be a medical event you are reporting. Why do
8 you have to have --

9 CHAIRMAN MALMUD: That will be reported.

10 VICE CHAIRMAN VETTER: Because there was
11 no written directive.

12 CHAIRMAN MALMUD: There was no written
13 directive. The patient didn't have a written
14 directive, came in with a referral for a bone scan.

15 DR. HOWE: In that case you would use the
16 procedures for the diagnostic procedures. And there
17 would be something in writing. It wouldn't be a
18 written directive. That's your second alternative.

19 MEMBER SULEIMAN: Standing order dosage
20 activity that they exceeded by --

21 CHAIRMAN MALMUD: How about Mrs. Smith
22 brings her daughter in for I-131 and the daughter sits
23 there and someone says, "Are you Ms. Smith?" and the
24 mother says, "Yes"? They come in. They give the
25 mother the dose. There was no written directive.

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1 I'm trying to bring up absurd situations
2 in which you may want --

3 DR. HOWE: It is more or less someone
4 comes in and gets a therapy dose. And they weren't
5 intending to get anything, and they got it.

6 CHAIRMAN MALMUD: Yes.

7 DR. HOWE: In some cases like the Smiths,
8 you might consider that wrong patient, wrong person.
9 But it's the sealed source one. There wasn't really
10 any written directive there to give anything, but
11 somebody had extra material and they just gave it to
12 you.

13 CHAIRMAN MALMUD: Okay. Dr. Zelac?

14 DR. ZELAC: I think the determination
15 should really be made on the basis of what was
16 delivered. If it was a dose delivered that required a
17 written directive and there wasn't one, that's an
18 issue.

19 CHAIRMAN MALMUD: Yes, I agree.

20 MEMBER SULEIMAN: And the second part of
21 that would be if a dose were given and there wasn't a
22 written directive but it was a dose that was clearly
23 wrong, you know, you were giving them much more than
24 they would have received if you had bothered to write
25 the --

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1 CHAIRMAN MALMUD: Do you want to leave off
2 the last part of that statement, just say that -- it's
3 gone off the board now. We will get it back.

4 MS. TULL: What I am giving you is your
5 actual recommendation.

6 CHAIRMAN MALMUD: Oh, wonderful. Thank
7 you. I hope you have improved it.

8 MS. TULL: So it is this one right here.

9 CHAIRMAN MALMUD: NRC staff should accept
10 the sixth recommendation. NRC staff should accept the
11 sixth recommendation of the Permanent Implant
12 Brachytherapy Subcommittee report, later amended to
13 read "When a WD is required, administrations without a
14 prior WD are to be reported as regulatory violations
15 that may or may not constitute a medical event."

16 Is there agreement on that? Debbie, do
17 you agree?

18 MEMBER GILLEY: I just wanted to know the
19 status of this being a recommendation and the impact
20 on agreement states. Maybe NRC can provide
21 clarification since it is not in regulations and it is
22 not a compatibility issue at this time as a
23 recommendation from ACMUI.

24 MR. LEWIS: This would be a comment on the
25 proposed rule, which we would refer to the working

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1 group. And if the working group for the rulemaking,
2 which would include agreement state people, adopt the
3 final rule, it would be about a year's time. And then
4 the states would have the normal times after that to
5 become compatible.

6 MEMBER GILLEY: So it would be
7 compatibility B.

8 MR. LEWIS: Well, I don't want to say
9 that, but --

10 MEMBER GILLEY: Thank you.

11 CHAIRMAN MALMUD: All in favor of the
12 motion? Do you want to call the motion? All in
13 favor?

14 Any opposed?

15 Two opposed. Any abstentions?

16 (No response.)

17 CHAIRMAN MALMUD: May I see the count
18 again for the number?

19 Ten in favor, two opposed.

20 MEMBER GILLEY: I would like to make a
21 comment. I think this is an implementation issue for
22 agreement states. And that's where I come from voting
23 opposing it. It leaves a lot questionable. And I'm
24 not familiar with what goes on in all the agreement
25 states. So that's why I chose to vote against it.

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1 CHAIRMAN MALMUD: Thank you.

2 Ralph?

3 MEMBER LIETO: So what happens to the
4 subcommittee report? You basically sort of chopped it
5 up into pieces, but the report in its entirety has
6 never been acted on. Will this go to the working
7 group if there is no formal recommendation for that or
8 is it up to the individual members to take this and
9 send it in as individual comments because, as I am
10 viewing right now, this doesn't leave our packets and
11 it doesn't go to to the working group on the proposed
12 rule?

13 Any individual can comment on any proposed
14 rule. So if you feel a certain way as an individual
15 about any rule, I would encourage you to comment.
16 That's what we do that process for.

17 But in terms of this subcommittee report,
18 it is my understanding that the full Committee was
19 going to consider it and submit it as a comment of the
20 Committee to the rulemaking working group.

21 CHAIRMAN MALMUD: That's correct.

22 MEMBER NAG: And based on what I have
23 heard, the way I was planning to modify is to add the
24 way this wording is, that sixth bullet. The way you
25 have that written, that is the way it was supposed to

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1 be on that. That last item I had would be like this
2 wording.

3 CHAIRMAN MALMUD: Yes. That was the sixth
4 bullet. So we passed the first bullet. Then we
5 passed the middle four. Then we passed the sixth. Is
6 that a summary, Dr. Thomadsen?

7 MEMBER THOMADSEN: I think that is a fair
8 summary. And maybe for Mr. Lewis' peace of mind in
9 passing this along, we could just endorse the entire
10 report to be passed on to the group.

11 CHAIRMAN MALMUD: Is that a motion?

12 MEMBER THOMADSEN: That is a motion.

13 CHAIRMAN MALMUD: Would someone care to
14 second Dr. Thomadsen's recommendation? Thank you, Dr.
15 Nag. And any comments?

16 (No response.)

17 CHAIRMAN MALMUD: If not, may I see a show
18 of hands for moving the report forward? All in favor?

19 Let's see. We have ten. And how many
20 abstentions?

21 (Laughter.)

22 CHAIRMAN MALMUD: I fooled you. I asked
23 for abstentions.

24 (No response.)

25 CHAIRMAN MALMUD: How many opposed?

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1 (No response.)

2 CHAIRMAN MALMUD: Two. Okay. Two
3 opposed. All right. Dr. Nag, we thank you for a
4 lively discussion, brief as it was.

5 (Laughter.)

6 MS. TULL: Dr. Malmud, I need to steal the
7 four members to go get badges if you want to take a
8 quick break. And then we'll start right in with the
9 medical isotopes discussion.

10 CHAIRMAN MALMUD: Very good.

11 MEMBER NAG: At 5:00 o'clock or 5:15?

12 MS. TULL: No. Like 4:45-4:50, as soon as
13 we get back.

14 MEMBER NAG: Well, it's 5:00 now.

15 MS. TULL: I'll notify you as soon as we
16 get back.

17 CHAIRMAN MALMUD: And, by the way, we
18 should thank Dr. Zelac for his graciousness in
19 postponing his two presentations until tomorrow.

20 (Laughter.)

21 DR. ZELAC: You are very welcome.

22 (Whereupon, the above-entitled matter went off the
23 record at 4:40 p.m. and resumed at 4:51
24 p.m.)

25 CHAIRMAN MALMUD: I have been asked to

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1 open the topic. The topic is medical isotope
2 shortages, and Chris will do the intro.

3 MR. EINBERG: Very good. Thank you, Dr.
4 Malmud.

5 11. MEDICAL ISOTOPE SHORTAGES

6 MR. EINBERG: Recently there have been
7 some shutdowns and some shortages on medical isotopes.
8 The global production of molybdenum-99 is dependent
9 on a small number of processing facilities and aging
10 reactors around the world.

11 These recent shortages have highlighted
12 this important issue. And we're seeking the ACMUI's
13 input on these shortages, what impact any potential
14 shortages to medical isotopes may have, specifically
15 molybdenum-99.

16 And, as you may know, the Chalk River
17 reactor in Canada is an aging reactor. It's 52 years
18 old. There is a reactor in the Netherlands, the
19 high-flux reactor. That is 47 years old. And
20 recently, as I indicated, these two facilities were
21 shut down at the same time.

22 Combined, these reactors produce 70
23 percent of the world supply for molybdenum-99. And
24 there is an increased attention being paid to the
25 shortages of molybdenum-99 and what the impacts to the

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1 medical community may be.

2 Recently the Chairman of the NRC was at an
3 IAEA meeting approximately two weeks ago. And this
4 was a topic of intense interest at the IAEA meeting.
5 The spring meeting of NEA in Europe will have medical
6 isotopes and the shortages as a key topic on the
7 agenda there.

8 So we have put together a series of
9 questions for the ACMUI to solicit your input on what
10 are the potential impacts to medical shortages of
11 isotopes.

12 Additionally, if there is anything that
13 the ACMUI understands that regulatory relief could be
14 provided or sees that there is regulatory relief
15 needed because of shortages, we would like to
16 understand those issues as well.

17 Currently two entities in the United
18 States have expressed interest in developing
19 facilities to produce medical isotopes, but in the
20 best case, these two facilities will be at least four
21 or five years wait before they were being able to
22 produce any type of medical isotopes.

23 With that, I turn it over to the Committee
24 to address the questions or if you would like, I could
25 read the questions as --

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1 MS. TULL: I'll put the questions on the
2 screen.

3 CHAIRMAN MALMUD: Okay. Dr. Van Decker?

4 MEMBER VAN DECKER: Why don't I open up a
5 piece of this since these jogging questions seem to
6 have the word "cardiac" involved in them quite a bit.
7 I'm sure Dr. Eggli, Ms. Gilley, or I will have much
8 more to say as well because obviously, you know, while
9 we have been talking a lot about therapeutics today,
10 the large volume of what goes on in this country is
11 really diagnostic and where a technician kind of fits
12 into. And so these shortages will have volume-wise
13 quite a bit of impact fairly quickly.

14 You know, we have had two slowdowns
15 already: one in November and December of last year
16 when the Canadian plant had difficulties and was shut
17 down and somehow brought back up relatively quickly.
18 And then we have had another slowdown just a couple of
19 months ago when Europe had a problem.

20 I think you well point out that these are
21 all aging plants. And the reliability I think in the
22 future, how we look at them, we need to be a little
23 bit concerned about.

24 You know, all of the technetium in this
25 country is coming from moly coming in from these

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1 outside countries and are then being made into moly
2 generators by industry here in the U.S. but obviously
3 is getting the raw moly from outside.

4 You know, I don't have the exact numbers
5 to your questions, but I kind of have some sense from
6 some industry surveys and some claims data I have been
7 involved in.

8 I would probably think that on the
9 diagnostic realm in this country, there are probably
10 between 15 and 20 million diagnostic
11 radiopharmaceutical studies performed in the United
12 States. You know, I would think that probably right
13 now almost 50 percent of them are cardiac or close to
14 that.

15 And of that, in the marketplace right now
16 -- and these are just gross numbers -- I would think
17 probably about 70 percent of that is being done with
18 tech radiopharmaceuticals.

19 You know, there is a small percentage of
20 still thallium and some opportunities and some that is
21 obviously some of the PET tracers. But obviously the
22 ability to get to those in a meaningful financial way
23 and for the volumes that we do this for is a hard
24 thing to say.

25 So we're not talking about a small issue

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1 as far as the diagnostic stuff, especially in the
2 realm of cardiology. And I'm sure my two colleagues
3 will talk about the non-cardiology applications quite
4 a bit.

5 You know, in the realm of how soon we need
6 this stuff for diagnostic realm, you know, it is not
7 usually the type of thing that we absolutely need
8 something the next day.

9 I mean, most of that type of stuff if the
10 symptoms are that bad is probably going to cath labs.

11 But, you know, when you are trying to make a
12 relatively straightforward and at least good risk
13 stratification process, I would think that probably
14 the majority of these studies get done, a good chunk,
15 within a week and then another big chunk within two
16 weeks and then only some outliers after that.

17 So you're talking about a relatively short
18 period of time where these become germane to a
19 decision-making process on what is going to be done
20 with the patient as far as further workup goes or
21 further meds or further reassurance.

22 So it's not like we can withstand, you
23 know, several months of slowdowns here and not be in a
24 situations where it will clearly impact care the way
25 patients are used to receiving that care.

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1 You know, obviously at times we have had
2 some slowdown bits. You know, we have had to try to
3 find other ways to kind of make sure that we are
4 taking care of patients the best as possible. I think
5 the fears in people's minds are that, you know,
6 slowdown availability will either lead to some extra
7 people going towards an invasive root to be sure that
8 there is an answer. There might be some people that
9 go to other roots.

10 You know, obviously perfusion pad is a
11 root but not easily available to the volumes we need.

12 There are some other modalities that can be tried in
13 all of this, but depending on a patient-to-patient
14 basis in their patient characteristics, you know some
15 may not fit quite as well for diagnostic reliability.

16 And so you come to a realm where you're
17 trying to say, "Well, am I doing something with
18 slightly less diagnostic possibilities so at least I
19 try to take out the biggest piece of the risk and then
20 retest down the list to look for the intermediate
21 level of risk that I really want to get an answer for.

22 So am I now layering tests because of what
23 I've gotten to plus some degree of exposure to of some
24 of the population to a more invasive approach?

25 And I think that all of that, you know,

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1 hopefully did not go on too much in these two periods
2 of slowdown because they were relatively short, but I
3 can clearly foresee that if this becomes commonplace
4 and unpredictable in how it happens, that certainly
5 we're going to have to re-deal with paradigms of how
6 we deal with all of this.

7 You know, thallium kind of filled the role
8 for some of this in the short term in these places,
9 being cyclotron-produced, but thallium can be a piece
10 of the solution here for short terms. But obviously
11 the radiation dosimetry is not the most perfect for a
12 situation that could deal with some of the tech
13 agents.

14 And I would certainly say that from the
15 world of diagnostic nuclear cardiology anyway, you
16 know, unreliable up and downs when the decision
17 process can have reasonably quick repercussions to it
18 to some degree does create some problems. You know,
19 certainly we would like to see ways that that can kind
20 of be ameliorated.

21 You know, obviously I don't know what this
22 answer could possibly be other than a newer source in
23 a more reliable place. And, as you just pointed out,
24 that likelihood, even at its best, would probably be a
25 few years away. But I think that is something that

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1 the discussion certainly needs to be dealing with.

2 I have to say, looking old but probably
3 being a little bit younger, I'm not quite sure of the
4 outplay of the marketplace and the prior for
5 production of medical isotopes within the U.S.

6 I hear the words Union Carbide sometimes
7 in these discussions, and I picture that on a sign in
8 north Jersey when I was a young kid. I'm not sure
9 what it did back then either.

10 I am not quite sure why that kind of
11 phased out of this country and became more on other
12 soils, whether it was regulatory environment or
13 whether there were marketplace pressures or what
14 really caused this.

15 I guess some understanding of that as we
16 try to figure out what is the best thing for stability
17 in access to patients in the future here would
18 probably be helpful. And I look forward to my other
19 colleagues' comments on that.

20 So I think I would end my piece of it that
21 way. And I will come back in later. I'm looking to
22 hear some of my other colleagues' comments in all of
23 this. But, you know, I think that obviously the high
24 volume issues that are more diagnostic and have
25 turnover time as a piece of workup certainly get

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1 significantly affected by this. And it's something we
2 can handle for short periods of time once in a while,
3 but it's not something I think we want to be at risk
4 for for prolonged periods of time in the future if we
5 could avoid it.

6 CHAIRMAN MALMUD: Thank you.

7 Comment, Dr. Welsh?

8 MEMBER WELSH: Jim Welsh here. I would
9 like to just reiterate a lot of things that we heard
10 from Dr. Van Decker. In my review, I agree with that
11 estimate between 15-20 million cases per year with
12 most of them being cardiology. I've heard estimates
13 of up to 60 percent of the consumption going. We have
14 nuclear cardiology.

15 Also, there are a number of therapeutic
16 uses of radioisotopes that while, representing a
17 minority of the overall uses of byproduct materials,
18 though, nevertheless, quite important, I understand
19 that 80 percent of the world's cobalt-60 comes from
20 one reactor. And that places an exceptional
21 vulnerability for those who own and operate gamma
22 knife units.

23 We had a discussion this afternoon about
24 yttrium-90. There is always discussion about I-131.
25 And new radiopharmaceuticals are going to be using

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1 I-131.

2 Older ones, such as bezar, are perhaps
3 going to have more utility in years to come as data is
4 maturing about the efficacy of these treatments.
5 Therefore, therapeutic uses of byproduct material that
6 is coming from across international boundaries is in
7 the limelight.

8 Then there are these issues about domestic
9 production versus international shipment and the
10 controversy about highly enriched uranium, which we
11 talked about cesium earlier today. That's a
12 relatively smaller security concern compared to the
13 real risk of highly enriched uranium winding up in the
14 wrong hands.

15 And we know that there's a Schumer
16 amendment. The Schumer amendment is being ignored.
17 And there is the Burr amendment that is allowing it.
18 Perhaps by having isotope production in our own
19 country, the Schumer amendment could be abided by. We
20 wouldn't need the Burr amendment, and we would have
21 adequate supply.

22 But, as I said, it's not as simple as just
23 saying, "Yes, let's do it." It's going to take some
24 time. That's my comment.

25 CHAIRMAN MALMUD: Thank you.

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1 Dr. Suleiman?

2 MEMBER SULEIMAN: FDA has a group that
3 actually addresses drug shortages. And with all the
4 press that these supplies have been receiving the last
5 year, we have been in discussions with the
6 manufacturers.

7 Even though there's a heightened concern
8 and awareness, we continued to be assured by the
9 manufacturers that their supplies are okay.

10 The last round when the Canadian reactor
11 was shut down, it turned out that the shipments to the
12 U.S. were not curtailed. They were curtailed to
13 Canada and other places. That's just what I
14 understand right now.

15 CHAIRMAN MALMUD: Steve Mattmuller?

16 MEMBER MATTMULLER: Steve Mattmuller.
17 Just a quick comment that typically have a Covidien
18 generator. And we had a Lantheus generator for a
19 while. And then we were affected by that shortage.

20 But in the interest of time, I would defer
21 my time to the public comments from the SNM, who I
22 know are waiting for us in the audience.

23 CHAIRMAN MALMUD: Dr. Atcher?

24 DR. ATCHER: Robert Atcher,
25 radiopharmaceutical chemist by training. I am here as

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1 the President of the Society of Nuclear Medicine.

2 In response to the four questions that you
3 see, we have responded with answers to all four. In
4 addition, we surveyed our members. So that there is
5 some data -- I don't know if it's in your packages,
6 but there is some data available on the impact.

7 We also have reports that the last outage
8 that Nordion experienced resulted in people not
9 getting generators. So there was some impact in the
10 U.S.

11 Within the answers to our surveys, there
12 is a lot of the questions that I think I have heard so
13 far in the discussion answered in terms of alternative
14 procedures that might be entertained.

15 We are probably closer to 20 million than
16 15 million in terms of the number of procedures done.

17 We are estimating that 90 percent of those procedures
18 are single photon, as opposed to PET imaging. And of
19 those, about 90 percent of the single photon studies
20 are done with technetium.

21 So we are at about 70,000 procedures a day
22 that utilize technetium 99M and, therefore, dependent
23 on the availability of the molybdenum-99.

24 After the outage that occurred about a
25 year ago, we put together a task group in the society

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1 to look at the issues associated with short-term,
2 mid-term, and long-term potential solutions to the
3 issue because having a domestic source of this isotope
4 has become more and more important.

5 And since 9/11 with the potential for the
6 borders to close to shipments of radioisotopes, it has
7 become even more critical over and above the issues
8 associated with the outages that have occurred at the
9 Chalk River facility and the fact that the two new
10 reactors that they assured us were going to be able to
11 supply us in the future have now been canceled.

12 And we still await the ultimate outcome of
13 that since Nordion has now sued AECL. And the result
14 of whatever happens with that particular lawsuit is
15 still up in the air.

16 The bottom line is that our membership
17 and, therefore, the nuclear medicine practitioners in
18 general are significantly impacted by this. The
19 outage that occurred a year ago resulted in some
20 serious scrambling because we were down with the
21 Nordion facility.

22 About 70 percent of the molybdenum-99 that
23 is supplied to the U.S. was not available. And so
24 there was an attempt to up the production at the
25 reactor in the Netherlands, but it was not able to

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1 meet the requirements.

2 Similarly, in my discussions with Nordion,
3 they try to cover any shortages, although, as we
4 describe what happened a few months ago, the perfect
5 storm of having all the reactors go out at the same
6 time, there was really no option there. So we're
7 looking at in the short term those reactors that are
8 currently producing moly-99 to have material that is
9 qualified for use in the United States and which is
10 mostly an FDA issue.

11 In the intermediate term, there is the
12 proposal from the University of Missouri. We recently
13 got one from the reactor at McMaster, which is very
14 similar in terms of its scope of using an existing
15 reactor but building a processing facility to process
16 the material. Again, that is going to be something
17 that is going to take a few years for them to be able
18 to get the licensing and the facility built.

19 And then in the longer term, probably
20 having a facility that would be constructed to current
21 regulatory standards would probably be the optimal
22 solution.

23 I just returned from the European
24 Association of Nuclear Medicine, where this problem is
25 much more critical than it is here right now. And

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1 they are having the same discussions that we are about
2 the potential for a new facility.

3 There is a facility that is under
4 construction now in France which is going to come
5 online, but it will not supply all of the needs of the
6 European community.

7 And so the discussion is, what do we do in
8 the absence of something to replace both the reactor
9 in the Netherlands and the reactor in Belgium that
10 also have been involved in the molybdenum-99
11 production activity?

12 And so this is a worldwide problem right
13 now. And we are kind of at this point where one of
14 the questions that come up is, well, what is the
15 lifetime of technetium 99M as a diagnostic agent?
16 It's probably within a reasonable lifetime in terms of
17 the justification for building a new reactor. So
18 that's one of the things where NRC obviously would be
19 plying a role.

20 The second one -- and we discussed this at
21 the earlier break -- is that there is a proposal that
22 BWXT has been making for an old reactor design but to
23 use it for a current application. And that is a
24 liquid core reactor in which you could just sample the
25 nuclear fuel as the reactor operates to extract the

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1 molybdenum-99, but that is not a research reactor and
2 it's not a power reactor. It's somewhere in the
3 middle. And so there may be some need for some
4 regulatory clarification as far as how that facility
5 would be licensed.

6 I know the hour is late. So barring any
7 questions that you might have for me, I will stop
8 there.

9 CHAIRMAN MALMUD: Thank you.

10 Are there questions? Dr. Eggli?

11 MEMBER EGGLI: Not so much a question as
12 more a comment. In response to question 2, -- and I
13 think the society has answered it in their letter -- a
14 week is by far the outside that most procedures can be
15 delayed. And many of them that are urgent can't be
16 delayed a week.

17 And then what it results in is looking for
18 an alternative diagnostic effort, which is typically
19 either more morbid, higher risk for the patient, or
20 significantly more expensive. So that there is both
21 an economic and a patient care impact.

22 If you look at something like
23 lymphosentigraphy in lymph node evaluation, breast
24 cancer patients, they will simply go without it if the
25 tech is unavailable for the sentinel lymph node

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1 procedure and, as a result, have a high chance of
2 having significant extremity swelling after their more
3 aggressive lymph node dissection than would have
4 otherwise been required.

5 And although the number of nuclear
6 medicine procedures is high, 20 million, it's only
7 about 5 percent of diagnostic imaging procedures in
8 the United States on an annual basis.

9 As a result, in the marketplace, I think
10 there isn't room for a whole lot of competition, that
11 the marketplace supports the vendors that exist and
12 not a whole lot more. So there may be disincentive
13 for vendors to get into the business.

14 We certainly see that on the
15 pharmaceutical side of radiopharmaceuticals, where
16 most radiopharmaceuticals these days have only a
17 single vender. And if the pharmaceutical portion goes
18 away, you simply do without it for extended periods of
19 time.

20 DMSA is a classic example of a
21 radiopharmaceutical that seems to have FDA problems
22 every 18 to 24 months and disappears from the market
23 for 6 months at a time. There is just nobody else in
24 the business.

25 So that even though 20 million seems like

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1 a lot of studies, compared to the cost of providing
2 the service, the market is small. And there has to be
3 some economic incentive for someone to get into the
4 business of building a reactor that is going to be
5 produce molybdenum for medical purposes.

6 If we are going to have one in the United
7 States, it may require some kind of subsidy for the
8 public good to make the technetium
9 radiopharmaceuticals available. Certainly my practice
10 reflects what the society is reporting.

11 The vast majority of all clinical nuclear
12 medicine procedures is, in fact, done with
13 technetium-labeled radiopharmaceuticals. It's safe
14 and effective, and it can be labeled for lots of
15 things. And nothing else really at this point is a
16 viable substitute for a technetium label.

17 And so I think that if we are going to
18 have something in the United States, reactor in the
19 United States, that supplies technetium, there may
20 need to be some form of subsidy, at least on a
21 start-up basis, because the start-up costs are huge
22 and the marketplace is still relatively small.

23 CHAIRMAN MALMUD: Thank you.

24 Mr. Guiberteau?

25 MR. GUIBERTEAU: Well, I think Doug will

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1 be happy to know there is a group that is trying to
2 lobby for decreasing our dependent on foreign
3 molybdenum and allowing for drilling for molybdenum
4 offshore.

5 (Laughter.)

6 MR. GUIBERTEAU: And so far they haven't
7 really come together. I think there are three things
8 in terms of performing nuclear medicine procedures
9 that molybdenum has really, the lack thereof has
10 really, hurt us in the last two times it has occurred.

11 And, of course, it has been brief, as Bill was
12 saying.

13 Most nuclear medicine diagnostic
14 procedures other than cardiac procedures are performed
15 by diagnostic radiologists. And what happens is in
16 the nuclear medicine section, when we are not able to
17 perform these tests reliably, the referral patterns
18 change. And right now it has only been brief.

19 When that happens to us, some of these
20 people eventually if it keeps happening don't come
21 back. And it harms the whole specialty.

22 The other thing that Doug brought up that
23 is very important and what we did in our hospital
24 system when this happened because we are within, our
25 nuclear medicine department is within, the diagnostic

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1 radiology realm, we tracked the names of those
2 patients that we had to cross off our list and find
3 out what other studies they had within our system.

4 Almost all of them went to studies such as
5 CT and MR. The expense increased by two to five
6 percent. And this is not a small amount, even with
7 just five percent of the total diagnostic imaging.

8 So the reliability helps us not only in
9 terms of changing the algorithms for working these
10 patients up. It also makes it much more expensive.
11 And it also can delay the care of patients, which has
12 its own expense.

13 CHAIRMAN MALMUD: Thank you.

14 MEMBER THOMADSEN: This is Thomadsen.
15 Just as a matter of information, for the first
16 question, the report from the NCRP on population
17 exposure, which is now out for comment, has several
18 appendices with fairly good numbers on the number of
19 procedures that are performed each year. The table is
20 for 2005 but probably could just be expanded by about
21 seven percent to get last year.

22 CHAIRMAN MALMUD: Thank you.

23 Other comments? Member of the public?

24 MR. BROWN: Roy Brown with CORAR. In
25 anticipation of this meeting and seeing the questions

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1 that the NRC staff posed, CORAR is the
2 radiopharmaceutical manufactures of North America. We
3 turned to our medical resources about a month ago and
4 asked for their most recent data. It takes quite a
5 while to get this information.

6 I will be passing along -- Dr. Van
7 Decker's numbers were very, very, very accurate. I
8 have 2007 numbers here I will be forwarding on to the
9 Committee, but they go out and sample a few thousand
10 hospitals to get actual numbers of procedures by
11 hospital. And then they expand that out.

12 So all the marketing gurus in the U.S. use
13 AMR data. That's data that I will forward on to the
14 committee for you. But Dr. Van Decker's numbers are
15 very close.

16 CHAIRMAN MALMUD: Thank you.

17 Dr. Welsh?

18 MEMBER WELSH: Just some follow-up
19 comments for discussion. I was disappointed, of
20 course, to hear that the Maple 1 and Maple 2 reactors
21 have been canceled. And in a way, it was a bit of a
22 relief because we know that they were not compliant
23 with the recommendation that they do not use or
24 require HEU.

25 So I have read a number of recent reports

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1 saying that there are solutions that are
2 technologically feasible in which modern reactors if
3 they were built from scratch with modern technology,
4 as opposed to an old reactor that is trying to be
5 adapted to go from HEU to LEU, these modern reactors,
6 like the aqueous homogenous reactors, could use LEU
7 and in principle be much more cost-efficient because
8 of the decrease in the intensity of the security
9 required for HEU.

10 And whether or not that is a reality or is
11 a myth remains to be determined. But it does raise
12 the possibility that there could be considerably less
13 cost associated with a new reactor, with a modern
14 design that doesn't require highly enriched uranium
15 because of the security concern.

16 Also, if we hear that Europe is having
17 this increased need for a radiopharmaceutical and it
18 is not being met by Belgium, France might supply it.
19 If we could supply it here, that also could justify
20 the cost and could perhaps be more profitable than
21 initial predictions, which were that this would not be
22 economically feasible.

23 CHAIRMAN MALMUD: Thank you.

24 Other comments?

25 MR. EINBERG: Do we have any information

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1 on the French reactor or the French initiative to
2 build a new reactor?

3 MEMBER EGGLI: Let me say nothing about
4 the French reactor, but I was involved with a National
5 Academy of Sciences briefing on this issue as well
6 about a year or so ago, I believe.

7 At that time there were other countries,
8 like Argentina, Australia that were saying, "Oh, we
9 can provide all sorts of things." I haven't followed
10 up on this.

11 It was interesting. There were a lot of
12 players who were coming to the table. I had been, I
13 would say, personally a little bit concerned because
14 it seems like it is all foreign reactors.

15 The elimination of highly enriched uranium
16 as a source is basically being dictated by this
17 country. We are not going to provide actors with
18 highly enriched uranium as a target anymore and
19 encouraging the use of low enriched uranium because
20 low enriched uranium poses less of a risk. And so a
21 lot of reactors are having to re-tool. And I think
22 some of the stuff that happened in Canada was actually
23 a direct result of some of that.

24 So I think everything is really in play.
25 I think it's a good effort. It's noble to try to get

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1 an assessment of what is going on right now. I am
2 clueless, I mean, except when I hear somebody tell me
3 that the Australians promise that they can provide
4 everybody with everything, though they are not geared
5 up yet.

6 I haven't heard anything else except for
7 those statements. And there were people from other
8 countries saying, you know, "We are already switched
9 to LEU. And we are already producing."

10 So I am surprised with all of these
11 promises, you know, we haven't seen anything more
12 tangible. There seems to be a lot of lack of
13 information right now.

14 MR. EINBERG: Has the initial Canadian
15 study been finalized on the use of --

16 MEMBER EGGLI: I really don't know.

17 CHAIRMAN MALMUD: Thank you.

18 Other comments?

19 MR. BROWN: Hi. Roy Brown with CORAR
20 again. I can answer some of these questions.

21 The National Academy study is in the final
22 phase right now. We expect it will be out sometime
23 probably in the December time frame.

24 We would be glad to provide, CORAR would
25 be glad to provide, some additional information on

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1 LEU. Just for your information, the IAEA has an
2 effort underway called -- CORAR did a research project
3 called the CRP to help countries develop their own
4 source of moly.

5 That has been the source of a lot of the
6 LEU production. That has been in countries like
7 Argentina, Korea, Indonesia, where it has been very,
8 very, very small-scale.

9 There have been some gel generators in
10 India where they make 50-millicurie generators that
11 really won't do us much good in the U.S. So although
12 there have been some successes with LEU around the
13 world, not only the kind of scale we need in the U.S.

14 CORAR will be glad to come back and
15 provide any information either NRC or ACMUI would like
16 on this at future meetings.

17 CHAIRMAN MALMUD: Other comments? Dr.
18 Fisher?

19 MEMBER FISHER: For the benefit of the
20 Committee, I wondered, Roy, if you would explain what
21 CORAR is, what it stands for, and its purpose?

22 MR. BROWN: Roy Brown with CORAR. CORAR
23 is the Council on Radionuclides and
24 Radiopharmaceuticals. It is the North American trade
25 association for the manufacturers of nuclear medicine

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1 products that includes companies such as Nordion,
2 Lantheus, Covidien, Bracco. All the major
3 radiopharmaceutical producers in North America are
4 members of CORAR. We also represent companies that
5 produce other types of isotopes for medical research.

6 CHAIRMAN MALMUD: Other questions or
7 comments? Dr. Welsh?

8 MEMBER WELSH: Quick comment again about
9 the LEU/HEU issue. The request, the Schumer
10 amendment, came from the United States that around the
11 globe reactors stop using HEU. But since we are by
12 far the largest consumer of radioisotope for medical
13 purposes, there is little financial incentive for
14 Chalk River to switch from HEU to LEU if it is going
15 to come them a lot and there is nothing in it for them
16 other than just being good guys and complying with
17 Americans' request, plus the Burr amendment.

18 And I don't think that we're ever going to
19 get around this unless we take the lead in the United
20 States and make isotope ourselves with LEU and show
21 the world that it can be done. And if Canada,
22 Belgium, France want to be competitive in this market,
23 they would, too, have to follow this lead.

24 But until somebody starts generating
25 isotope en masse, not like Argentina, Australia, with

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1 a lot of promise but nothing being kept, the United
2 States is probably the only country that can do this.

3 And others will then be forced to follow suit if they
4 want to maintain their share of the market.

5 CHAIRMAN MALMUD: Other comments?

6 DR. ZELAC: Dr. Malmud?

7 CHAIRMAN MALMUD: Dr. Zelac?

8 DR. ZELAC: Just for clarification -- and,
9 anyone, please correct me if I am wrong, but when we
10 are talking about HEU versus LEU, we are not except in
11 the case of the homogeneous liquid reactors talking
12 about the fuel itself. We are talking about the
13 targets which are being irradiated and then moly and
14 others stripped off from the fission products. Is
15 that correct? Okay. Thank you.

16 CHAIRMAN MALMUD: No other comments?

17 MEMBER VAN DECKER: Can I ask a question?

18 CHAIRMAN MALMUD: Yes.

19 MEMBER VAN DECKER: Since the NRC put this
20 topic on the table, what were the NRC's thoughts on
21 where it saw itself fitting into this?

22 MR. EINBERG: Well, the NRC would like to
23 have a good assessment as to what the situation is
24 because while we regulate the safe use of medical
25 isotopes, we don't promote the use of isotopes. It's

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1 more of along the lines of Department of Energy and
2 other federal agencies.

3 We want to be fully informed as to what
4 the situation is. We want to be on top of it. And,
5 as such, we're soliciting input. Especially with the
6 medical community, we want to be aware of any
7 shortages and make sure that patient treatment is not
8 adversely impacted.

9 MR. LUEHMAN: The only thing that I would
10 add is that obviously when there is export of HEU to
11 provide targets, you know, the NRC has to approve all
12 of that export.

13 And obviously, as I think Dr. Welsh has
14 summarized, that is a very controversial activity.
15 Every time it comes up that there is going to be
16 export of HEU targets, there are diametrically
17 opposed, probably the correct words, views of that in
18 Congress. And so to the extent that there are other
19 options, that there are other paths that could be
20 explored, I think that the Commission wants to look at
21 those because ultimately the Commission does have to
22 approve exports of high enriched uranium targets for
23 use in this endeavor. And if there were alternatives
24 to that, I think the Commission would like to explore
25 those.

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1 And obviously going to some kind of
2 high-production low enriched scenario would be one of
3 those. I mean, it would probably be preferable even a
4 high enriched as long as it was in the United States
5 and we weren't exporting those targets.

6 So I think that those are the other things
7 that the Commission is looking at, the perception of a
8 proliferation concern.

9 CHAIRMAN MALMUD: Public?

10 MR. BROWN: Roy Brown with CORAR. One
11 more comment on LEU versus HEU. The reactors in
12 Canada and Europe have done a very good job converting
13 the fuel over from HEU to LEU over the last several
14 years.

15 But you are right. The HEU is currently
16 used for targets. To be able to switch to LEU targets
17 is a very long and lengthy and costly process. All
18 the major moly manufacturers now are looking at it.

19 What it requires, it requires a new waste
20 stream. I mean, if you think about it, if you are
21 using less than 20 percent uranium, rather than
22 greater than 80 percent uranium, you produce a lot
23 more mixed fission products.

24 You produce a lot more plutonium. That
25 needs to be taken out of the moly before it is

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1 finished. You need to write new drug master files.
2 You need to go to FDA. The generator manufacturers
3 need to go to FDA with supplements with those new
4 DMFs.

5 So it's a very lengthy and costly process.

6 That's why it will take a long time to convert from
7 HEU targets to LEU targets. So it is not a simple
8 process.

9 This is something the National Academy of
10 Sciences addressed in their report. And hopefully it
11 will have a good write-up in that when that report
12 comes out in December.

13 CHAIRMAN MALMUD: These are informational
14 items only. So there is no action to be taken.

15 MR. EINBERG: I appreciate everyone's
16 input on this issue. And it will help the NRC and the
17 Commission understand this critical shortage if it
18 does appear.

19 CHAIRMAN MALMUD: Thank you.

20 Ashley has several announcements to make
21 now.

22 MS. TULL: I just have three quick things.

23 This is Ashley. For members of the public, if you
24 are not coming back tomorrow, if you would please fill
25 out the public feedback forms? They're right there by

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1 the red and white box. It's four or five questions.
2 Fill it out. Drop it in the box. You're done. If
3 you're staying tomorrow, you can do it tomorrow.

4 For ACMUI members, will you please take
5 off your badges and leave them here so I don't have to
6 reprint them? And you can leave your binders and
7 anything else that you want here because this room
8 will be locked as soon as we all leave.

9 That's it.

10 CHAIRMAN MALMUD: Thank you. So we will
11 all meet here tomorrow morning at 8:00 o'clock.

12 (Whereupon, the above-entitled matter was recessed at
13 5:32 p.m., to be reconvened on Tuesday,
14 October 28, 2008, at 8:00 a.m.)
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