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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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6 THURSDAY, MAY 7, 2009

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8 The meeting was convened in the auditorium of
9 Two White Flint North, 11545 Rockville Pike,
10 Rockville, Maryland, at 8:00 a.m., Leon S. Malmud,
11 M.D., ACMUI Chairman, presiding.

12 MEMBERS PRESENT:

13 LEON S. MALMUD, M.D. Chairman
14 DOUGLAS F. EGGLI, M.D. Member
15 DARRELL FISHER, PhD Member
16 DEBBIE GILLEY Member
17 MILTON GUIBERTEAU, M.D. Representative
18 RALPH P. LIETO Member
19 STEVE MATTMULLER Member
20 SUBIR NAG, M.D. Member
21 ORHAN SULEIMAN, PhD Member
22 BRUCE THOMADSEN, PhD Member
23 WILLIAM VAN DECKER, M.D. Member
24 RICHARD J. VETTER, PhD Member
25 JAMES S. WELSH, M.D. Member

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1 NRC STAFF PRESENT:

2 ROB LEWIS Director, MSSA

3 CHRIS EINBERG Branch Chief, RMSB

4 CINDY FLANNERY

5 STEVEN BAGGETT

6 NEELAM BHALLA

7 ASHLEY COCKERHAM

8 DONALD COOL, PhD

9 LEIRA CUADRADO

10 CASSANDRA FRAZIER

11 SANDY GABRIEL

12 DONNA-BETH HOWE, PhD

13 DORIS LEWIS

14 ED LOHR

15 PATRICIA PELKE

16 GRETCHEN RIVERA-CAPELLA

17 MARK SCHAFFER

18 MARK THAGGARD

19 GLENDA VILLAMAR

20 DARREL WIEDEMAN

21 DUANE WHITE

22 RON ZELAC, PhD

23

24 MEMBERS OF THE PUBLIC PRESENT:

25 GARY BECKER, ABR (PHONE)

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1 KEVIN CROWLEY, NAS

2 MEMBERS OF THE PUBLIC PRESENT CONT.

3 MELISSA CACIA, AACE (PHONE)

4 ROBERT DANSEREAU, NY (PHONE)

5 WILLIAM DAVIDSON, U OF PENN (PHONE)

6 RICHARD EATON, MITA

7 LYNNE FAIROBENT, AAPM

8 BONNIE HAMILTON, MDS NORDION

9 KAREN LANGLEY, UT (PHONE)

10 MATTHEW MAURO, SIR

11 KATRINA MILLER, AACE (PHONE)

12 MIKE PETERS, ACR

13 DOUG PFEIFFER, AAPM

14 GLORIA ROMANELLI, ACR

15 JOE RODGERS, THERAGENICS (PHONE)

16 RIAD SALEM, SIR

17 REED SELWYN, UNIF. SVCS. UNIV. OF HLTH. SCI.

18 BRIAN STAINKEN, SIR

19 STEPHEN THOMAS (PHONE)

20 KEN THURSTON, SIRTEX

21 CINDY TOMLINSON, SNM (PHONE)

22 ANN WARBICK CERONE, MDS NORDION

23 EMILY WILSON, ASTRO

24 JENNIFER YOUNG, AACE (PHONE)

25

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19 Adjourn

20

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

8:00 a.m.

MR. EINBERG: Good morning. As the Designated Federal Officer for this meeting, I am pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Chris Einberg. I'm the Chief of the Radioactive Material Safety Branch and I have been designated as the Federal Officer for this Advisory Committee, in accordance with 10 CFR, Part 7.11.

Present today as the Alternate Designated Federal Officer is Cindy Flannery, Team Leader for the Medical Radiation Safety Team.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

The meeting was announced in the April 2, 2009 edition of the Federal Register, Volume 74, page 15313.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The Committee

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1 provides counsel to the staff, but does not determine
2 or direct the actual decisions of the staff or the
3 Commission.
4 The NRC solicits the views of the
5 Committee and values their opinions. I request that
6 whenever possible, we try to reach a consensus on the
7 various issues that we will discuss today, but I also
8 recognize that there may be a minority or dissenting
9 opinions. If you have such opinions, please allow
10 them to be read into the record.
11 As part of the preparation for this
12 meeting, I have reviewed the agenda for members and
13 interests based on the very general nature of the
14 discussions that we are going to have today and
15 tomorrow.
16 During this meeting, the Committee will
17 discuss the National Council on Radiation Protection
18 and Measurements Report 160, ionizing radiation
19 exposure of the population of the United States.
20 Three members of the Committee were
21 identified as contributing to certain sections of this
22 report. The identified contributors are Dr. Bruce
23 Thomadsen, Ms. Debbie Gilley and Dr. Orhan Suleiman.
24 These individuals can provide factual
25 information and answer questions on these sections of

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1 the report that they worked on. However, they should
2 not make any recommendations to the Committee or staff
3 on these specific sections.
4 Additionally, these members may advise the
5 Committee or staff on those sections of the report
6 which they had no involvement.
7 I have not identified any additional items
8 that would pose a conflict. Therefore, I see no need
9 for an individual member or -- of the Committee to
10 recuse themselves from the Committee's decision making
11 activities, other than those just discussed.
12 However, if during the course of our
13 business, you determine that you have a conflict,
14 please state it for the record and recuse yourself
15 from that particular aspect of the discussion.
16 At this point, I would like to introduce
17 the individuals seated at the table today. Dr. Leon
18 Malmud, Chairman, Health Care Administrator; Dr.
19 Richard Vetter, Vice Chairman, Radiation Safety
20 Officer; Dr. Subir Nag, Radiation Oncologist; Mr.
21 Ralph Lieto, Nuclear Medicine Physicist; Dr. Douglas
22 -- can you hear us? Pause just for a moment.
23 (Off the record comments.)
24 MR. EINBERG: I'll continue. Dr. Douglas
25 Eggli, Nuclear Medicine Physician; Dr. Orhan Suleiman,

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1 FDA Representative; Dr. William Van Decker, Nuclear
2 Cardiologist; Dr. James Welsh, Radiation Oncologist;
3 Dr. Darrell Fisher, Patient Advocate; Dr. Bruce
4 Thomadsen, Medical Physicist, Therapy; Mr. Steve
5 Mattmuller, Nuclear Pharmacist; Ms. Debbie Gilley,
6 State Government Representative.
7 I would like to mention that Dr. Milton
8 Guiberteau is representing the Diagnostic Radiologist.
9 Dr. Guiberteau does not have voting privileges, but
10 he will listen and speak on behalf of the diagnostic
11 radiologist. I would like to thank Dr. Guiberteau for
12 acting in this capacity.
13 Dr. Leon Malmud, ACMUI Chairperson, will
14 conduct today's meeting. Following a discussion of
15 each agenda item, the Chair, at his option, may
16 entertain the comments or questions from the members
17 of the public who are participating with us today.
18 Regretfully, as Dr. Malmud pointed out,
19 Rob Lewis will not be joining us until after lunch
20 today, and so, I have a few opening remarks to add to
21 the comments that I just made.
22 The pre-publication copy of the NCRP
23 Report 160, that was just provided to you for your
24 review, it's anticipated that that final copy will be
25 published this month.

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1 Rob also previously provided updates on
2 the National Source Tracking System. The system is
3 now up and running, and licensees are required to
4 report category one and two material, transfers to the
5 system.
6 Regarding the status of hiring for the
7 three positions on the Committee, the RSO, the
8 Radiation Safety Officer selection is currently with
9 management for final approval. A recommendation for
10 the nuclear medicine physicist position is being sent
11 to management and the radiation oncologist call for
12 nominations closed on April 21st. Nominees will be
13 reviewed in the next few months.
14 Also, we wanted to note that there have
15 been changes to the agenda, to accommodate some of the
16 speakers who need to attend the funeral of an NRC
17 staff member on Friday. So, that's why we have
18 rearranged it a little bit.
19 So, with that, I'll turn over to Dr.
20 Malmud.
21 CHAIRMAN MALMUD: Thank you, Mr. Einberg.
22 We'll move directly on to the item of old business,
23 for which Ashley Cockerham will make the presentation.
24 MS. COCKERHAM: All right, I have two,
25 actually. I have two charts that I'm going to pass

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1 around. One is from 2007, the next one is from 2008.
2 We're going to go through the 2008 recommendations
3 first, and they are displayed up on the screen.
4 Gretchen, if you could scroll down to them.
5 Okay. So, everyone has a copy. We're
6 going to start with 2008. This is item number two.
7 It says, "NRC staff should pursue rulemaking to allow
8 more than RSO on a medical use license with the
9 indication of one RSO as the individual in charge,"
10 and this is scheduled as a part of the next Part 35
11 rulemaking, which will begin later this year. So,
12 that item should be accepted.
13 Item number five, "NRC staff should
14 incorporate the subcommittee's recommendations for the
15 Gamma Knife Elekta Perfexion in future rulemaking."
16 This is in the user need memo for the 2009 rulemaking
17 and this is something that's moving from guidance
18 space to regulations. So, I know that's always been a
19 concern of the Committee's. This will be the first
20 item to do that.
21 Item number nine, "NRC staff should revise
22 the AO criteria to read, `a medical event that results
23 in one, death or two, a significant impact on patient
24 health that would result in permanent functional
25 damage or a significant adverse health effect that

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1 would not have been expected from the treatment
2 regiment, as determined by an NRC Agreement State
3 designated consultant position."
4 This item is still pending and the last
5 time we talked to you, we said that AO revisions would
6 be sent to research in early 2009. We have submitted
7 this request to research.
8 I do know that both -- the two reactor
9 offices also have pending commission action items that
10 may require them to revise their AO criteria as well,
11 and so, research is waiting to see if NRR, NRO and
12 FSME, which is our office, will have changes, and they
13 would like to make all of those changes at once.
14 There's a working group within research
15 that will be meeting this summer, and they will make
16 that determination then. So, we should have another
17 update at the next meeting.
18 So, item number 14, "ACMUI should form a
19 subcommittee for the permanent implant brachytherapy
20 rulemaking." The subcommittee's charge is to meet
21 within the next two weeks to prepare ACMUI's comments
22 on the proposed rulemaking.
23 The subcommittee includes Dr. Nag as the
24 Chair, Mr. Lieto, Dr. Thomadsen, Dr. Vetter and Dr.
25 Welsh. There is no NRC action on this, and the

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1 subcommittee did provide their final report in
2 November 2008.
3 DR. NAG: Ashley?
4 MS. COCKERHAM: Yes.
5 DR. NAG: Can I ask you a question? What
6 do you mean by no NRC action? This is something
7 that's still ongoing, and I know that the NRC is still
8 in the middle of this passing. What do you mean by no
9 NRC action?
10 MS. COCKERHAM: The recommendation
11 pertains just to the creation of the subcommittee,
12 there's nothing that NRC needs to do.
13 You created the subcommittee, you reported
14 and so, when I received the report for the
15 subcommittee, I close out your subcommittee. The
16 recommendations related to that, do come later.
17 Okay, so, we're going to move to item 15,
18 "NRC staff should provide a status update on the
19 technical basis for the Rittenour or AAPM petition at
20 the October 2008 ACMUI meeting."
21 We did provide this status update at the
22 October meeting on the 28th. So, that item is now
23 closed.
24 Item 18, "NRC staff agreed to consider
25 incorporating the subcommittee's recommendations from

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1 the August 1, 2008 fingerprinting subcommittee report
2 and the NRC's questions and answers, with regards to
3 fingerprinting and criminal history records, records
4 checks or use another appropriate method of
5 communication to transmit the information to
6 licensees."
7 The medical team has passed along the
8 ACMUI's recommendations to the working group, and we
9 will let you know what action they take.
10 Item 19, "NRC staff should accept the six
11 recommendations of the current implant brachytherapy
12 subcommittee report with one modification."
13 Recommendation six should be modified to
14 read, "When a written directive is required,
15 administrations without a prior written directive are
16 to be reported as regulatory violations and may or may
17 not constitute a medical event."
18 This item is pending, and ACMUI's
19 recommendations are being considered and acted upon
20 with other comments on the proposed rule by the Part
21 35 revision working group.
22 This is --
23 MS. GILLEY: Debbie Gilley. Is this the
24 2009 rulemaking activity or later?
25 MS. COCKERHAM: This is -- I will ask Ron

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1 Zelac, but this is the rulemaking that already
2 started, not the 2009 rulemaking that will start.
3 This was one that they had already started
4 and then, we stopped it to do a direct final rule and
5 some other rulemakings, but it was already in the
6 process and had already gone out for public comment.
7 Cindy, is that correct? The permanent --
8 MS. FLANNERY: Yes, that's correct.
9 MS. COCKERHAM: Okay, so, this rulemaking
10 had already started. Okay, so, we're on to item 20.
11 "The ACMUI endorsed the permanent implant
12 brachytherapy subcommittee report." There was no NRC
13 action on this, so, the item was closed.
14 Item 21, "The ACMUI formed a subcommittee
15 to draft a set of proposed qualifications, that
16 interventional radiologists must satisfy to become
17 Authorized Users for yttrium-90 (Y-90) microspheres."
18 The subcommittee includes Dr. Bruce Thomadsen as the
19 Chair, Dr. Douglas Eggli, Dr. Subir Nag, Dr. James
20 Welsh and Mr. Steve Mattmuller.
21 There is no NRC action, and I have left
22 this item open until the subcommittee reports back to
23 the NRC, and this is an item on the agenda for today.
24 Item 22, "ACMUI encouraged NRC staff to
25 begin the rulemaking process, to move the medical use

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1 of Y-90 microspheres from 10 CFR 35.1000 to another
2 section of the regulations, so that the training and
3 experience requirements for Authorized Users can be
4 vetted through the public review process, instead of
5 residing in guidance space.
6 This item was partially accepted. We do
7 intend, as we have done with the Gamma Knife
8 Perfexion, to move Y-90 microspheres from guidance to
9 regulations. However, we made two revisions in 2007,
10 two revisions in 2008 and there's a possibility that
11 we'll make another revision in 2009.
12 So, we would look to put this in the next
13 rulemaking, and when I say next, I don't mean the 2009
14 rulemaking that will start next, but when that 2009
15 rulemaking closes, we would look to put Y-90
16 microspheres into rulemaking space.
17 MR. EINBERG: Ashley, before you proceed,
18 Dr. Malmud, with your permission, Dr. Miller is here,
19 and he'd like to make a few statements and remarks.
20 CHAIRMAN MALMUD: By all means, thank you.
21 MR. EINBERG: Okay, Dr. Miller.
22 DR. MILLER: Good morning. Thanks for
23 letting me crash in on your agenda. Today's the day
24 that is one of those days that's kind of melancholy
25 for me because some of the members are here for the

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1 last time and I wanted to take a few minutes to come
2 down and present them a certificate of appreciation
3 for their service.
4 So, with your indulgence, Dr. Malmud, I'll
5 do that.
6 CHAIRMAN MALMUD: Thank you.
7 DR. MILLER: What I'd like to do, is to
8 bring them up, just read a little bit for the benefit
9 of everyone, some of the highlights of their service
10 while they've been on the Committee.
11 First, I'd like to acknowledge Ralph
12 Lieto. Ralph's a nuclear medicine physicist. He's
13 been on ACMUI since 2001. He's chaired the medical
14 radioactive material event subcommittee. He's been a
15 consultant to the NRC staff on the review of training
16 and experience of medical physicists, and he's served
17 on numerous subcommittees, which include the iodine-
18 131 therapy incidents review subcommittee, Part 35
19 training and experience and the medical event
20 revision. Ralph.
21 Dr. Subir Nag. Dr. Nag is a radiation
22 oncologist and he's been with ACMUI since 2000. He's
23 aided the NRC by reviewing and commenting on
24 rulemaking and guidance documents for brachytherapy.
25 He's served on numerous ACMUI subcommittees, including

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1 Part 35 training and experience, new modalities,
2 medical radioactive material events subcommittee,
3 permanent brachytherapy subcommittee, Perfexion Gamma
4 Knife subcommittee. Dr. Nag.
5 Dr. Richard Vetter, the first Radiation
6 Safety Officer representative on ACMUI. So, we think
7 that that's been a great addition, with regard to that
8 specialty.
9 He's been a Radiation Safety Officer
10 representative since 2000, the Vice Chair of ACMUI
11 since 2006 and he's served on numerous subcommittees,
12 including Part 35 training and experience, new
13 modalities, subcommittee on sodium iodide-131
14 incidents, dose evaluation subcommittee,
15 fingerprinting quarters, working group, fingerprinting
16 subcommittee, medical physicist subcommittee. Dr.
17 Vetter.
18 Just maybe a couple other words. I think
19 the service that each of your provide to the Committee
20 is extremely valuable. I'd like to thank each of you
21 because I think the nature of the Committee and the
22 challenges that are before you and the challenging of
23 the staff and each other in areas is very healthy for
24 the regulatory process.
25 So, again, thank you very much for your

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1 service and I wish you well in the rest of your
2 careers. Thank you.
3 CHAIRMAN MALMUD: Thank you, Dr. Miller.
4 As Chairman of the Committee, I'm certain that I speak
5 for the current members of the Committee, as well as
6 those members of the Committee who rotated off prior
7 to your leaving the Committee, in expressing our
8 thanks for you collegiality, your wisdom, your advice
9 and it's been extraordinarily productive and helpful
10 to all of us, to learn from you and to gather your
11 advice and then use it in a constructive fashion on
12 behalf of the mission of the ACMUI.
13 So, it's as the Chair for the Committee
14 that I also wish to second the thanks of Dr. Miller on
15 behalf of all of us who have enjoyed working with you
16 as colleagues.
17 CHAIRMAN MALMUD: Thank you, Dr. Miller,
18 and we'll return to the agenda with Ashley.
19 MS. COCKERHAM: All right, I believe we're
20 still on the 2008 recommendations. We're going to
21 turn to page two and start with item number 23.
22 Item 23 reads, "The ACMUI strongly
23 encourages NRC to continue supporting the exportation
24 of highly enriched uranium materials for Moly-99
25 targets used by international producers and provide

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1 all possible help towards the development of U.S.
2 producers of moly-99."
3 In response to this, NRC has acknowledged
4 this recommendation and adds that, "NRC's role in the
5 exporting of highly enriched uranium for the
6 production of medical isotopes is to issue export
7 licenses to the U.S. Department of Energy."
8 In 2008, NRC's Office of International
9 Programs issued DOE a license to export HEU target
10 materials to Atomic Energy of Canada for medical
11 isotope production in 2009 and as far as the second
12 item, to provide all possible help towards the
13 development of producers, NRC does not have a role in
14 promoting a domestic supply of moly-99.
15 NRC's role is to provide stable regulatory
16 basis -- provide a stable regulatory basis for
17 evaluating any application and regulating any domestic
18 supplier.
19 In fiscal year 2009, NRC received two
20 letters of intent from Babcock & Wilcox and the
21 University of Missouri, to develop domestic
22 molybdenum-99 production facilities in the U.S.
23 The Office of Federal and State Materials
24 and Environmental Program staff will work with NRC's
25 Office of Reactor Regulation to review and resolve

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1 policy issues associated with the new licensing
2 request.
3 Item number 24, "ACMUI formed a
4 subcommittee to develop a solution that satisfies both
5 the training needs of residency program and the NRC
6 requirements for achieving Authorized User status,
7 using board certification pathway. The subcommittee
8 should create a recommendation to be discussed at a
9 future teleconference prior to the spring 2008 ACMUI
10 meeting."
11 The subcommittee includes Dr. Douglas
12 Eggli as the Chair, Dr. Subir Nag, Dr. William Van
13 Decker and Dr. Milton Guiberteau, as the technical
14 consultant.
15 There is no NRC action this, and the item
16 is still open, and we will be discussing this on
17 Friday.
18 Item number 25, "NRC staff should revise
19 10 CFR 30.35(b) to allow licensees to exceed the
20 limits short term, for example, 60 days, during source
21 exchange." This item is accepted, and it was included
22 in the user need memo for the 2009 rulemaking.
23 For item number 26 -- actually, for items
24 26, 27, 28, 29 and 30, all of these are to be
25 included. The items are accepted, and they are

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1 included in the user need memo, which means they'll be
2 looked at in the 2009 rulemaking. So, I'm just going
3 to read the recommendations.
4 "NRC staff should revise 10 CFR 35.40 to
5 clarify that the Authorized User should sign and date
6 the pre-implantation and post-implantation portions of
7 the written directive for all modalities with two-part
8 written directives."
9 Item 27, "NRC staff should revise 10 CFR
10 35.40, to clarify that an Authorized User, not the
11 Authorized User, should sign and date both the pre-
12 implantation and post-implantation portions of the
13 written directive for all modalities with two-part
14 written directives," and there is a note that this
15 allows for one AU to sign the pre-implantation portion
16 of the written directive and another AU to sign the
17 post-implantation portion of the written directive.
18 Item 28, "NRC staff should revise 10 CFR
19 35.65 to clarify it does not apply to sources for the
20 medical use. However, NRC staff should not require
21 licensees to list the transmission sources as line
22 items on their license."
23 "NRC staff should also revise 10 CFR
24 35.590 to permit the use of transmission sources under
25 10 CFR 35.500 by Authorized Users meeting the training

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1 and experience requirements of 10 CFR 35.590 or
2 35.290."
3 Item 29, "NRC staff should revise 10 CFR
4 35.204(b) to require a licensee that uses moly-
5 99/tech-99m generators of preparation of tech-99m
6 radiopharmaceuticals to measure the moly-99
7 concentration after the receipt of a generator to
8 demonstrate compliance with not administering to
9 humans more that .15 microcuries of moly-99 per milli-
10 curie of tech-99m."
11 Number 30, "NRC staff should require
12 licensees to report to NRC, events in which licensees
13 measure moly-breakthrough that exceeds the regulatory
14 limits."
15 Number 31, "NRC staff should pursue a
16 change to allow grandfathered AU's to be supervisors
17 and preceptors," and this item is accepted and is
18 being addressed in the current rulemaking.
19 Number 32, "The ACMUI medical nuclear
20 materials event subcommittee should review events and
21 provide analysis to the full committee annually in the
22 spring, instead of the fall." There's no NRC action
23 on this, and it is an item on this spring agenda.
24 Item 33, "ACMUI believes that 10 CFR
25 35.491 provides adequate training and experience for

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1 the use of NeoVista's EpiRad 90 device, if the
2 training under 10 CFR 35.491 is accompanied by
3 appropriate device specific training."
4 This item is accepted. The guidance was
5 revised recently and was sent out on the medical list
6 server on May 5th. So, this item is now closed.
7 Item 35, "NRC staff should notify ACMUI
8 when the NRC Office of General Counsel makes a
9 determination on the regulations regarding
10 grandfathered Authorized Users as supervisor and
11 preceptors for the purposes of training and
12 experience." This was completed. We provided the
13 response on January 9th.
14 At this time, NRC -- item number 36, "At
15 this time, NRC should continue its policy of not
16 requiring infiltrations of diagnostic dosages to be
17 reported as medical events." There is no action on
18 this, since this is our current policy, and this item
19 was closed.
20 Item 37, "As recommended at the October
21 ACMUI meeting, NRC staff should revise the guidance to
22 allow individuals qualified under 10 CFR 35.491 with
23 device specific training to be Authorized Users for
24 the NeoVista EpiRad device."
25 This authorization only applies for the

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1 use of the device under the current standard protocol
2 used in clinical trials. Furthermore, any off-label
3 use of the device should require the Authorized User
4 to meet the current guidance which states Authorized
5 Users must meet the T&E requirements of 10 CFR 35.490
6 or 35.690.
7 ACMUI added that there should be no
8 physical presence requirement for individuals
9 qualified under 10 CFR 35.490 or 35.690. This item
10 was accepted. The guidance was revised and was sent
11 out on the medical list server on May 5th.
12 CHAIRMAN MALMUD: Thank you. Are there
13 questions? Debbie Gilley?
14 MS. GILLEY: Yes, item number 31, which was
15 the grandfathering AUs to be supervisors and
16 preceptors, I thought you all were going to do a
17 direct final rule for that activity.
18 MS. COCKERHAM: Ron, I would ask you, are
19 we doing the direct final rule on that right now?
20 MR. ZELAC: Yes, we are.
21 MS. GILLEY: Thank you.
22 CHAIRMAN MALMUD: Dr. Nag?
23 DR. NAG: Item number 33 and 37, is 37
24 going to be an explanation on top of the 33, because
25 33, on its own, can be misleading. It says 491

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1 bringing in experience for the EpiRad 90 device, but
2 then it's only true if it's accompanied by 37, not as
3 it stands alone.
4 CHAIRMAN MALMUD: Is that a question?
5 DR. NAG: Yes, I mean, the 33 will make
6 sense only if it is accompanied by 37. But 33 on its
7 own can be misleading, because 33 on its own looks
8 like if you have 491, you can use the EpiRad 90
9 device. That's true, only if you are doing under
10 protocol.
11 Your 33 and 37 should be linked somehow,
12 and not be a stand-alone.
13 CHAIRMAN MALMUD: Thank you, Dr. Nag. I'll
14 ask Dr. Howe to comment on that.
15 DR. HOWE: Dr. Nag, if we -- we just
16 published new guidance for the NeoVista and if you
17 look at the guidance, you're required to have -- meet
18 the same kind of hours and topics in 491, but everyone
19 that's an Authorized User needs the specific NeoVista
20 training.
21 So, they are linked together. They are
22 not independent. So, we used 37, where you have both
23 491 and NeoVista specific training.
24 MS. COCKERHAM: Dr. Nag, I think this will
25 clarify. If you look at the dates of when these

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1 recommendations were made, the Committee was moving
2 towards what you're seeing in 37.
3 I think that 33 was a step towards that.
4 That's where the Committee started in October and we
5 realized we needed more information and we held a
6 teleconference in December. We discussed it more
7 thoroughly and then 37 was the final recommendation we
8 got out of it.
9 So, when Cindy revised the guidance, she
10 was looking at both, but obviously, at 37, with 33.
11 Does that help?
12 DR. NAG: Yes.
13 MS. COCKERHAM: Okay.
14 CHAIRMAN MALMUD: Thank you.
15 MS. COCKERHAM: All right. Now, we're
16 going to switch over to the 2007 recommendations. For
17 item number one, "NRC staff should issue an
18 information notice which describes errors previously
19 made and provides examples of best practices with
20 regards to units of Air Kerma Strength (AKS) versus
21 apparent activity in milli-curies for brachytherapy
22 sources."
23 "The IN should be done in collaboration
24 with the American Association of Physicists and
25 Medicine and coordinated with the Agreement States."

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1 This recommendation was accepted and we're
2 still working to incorporate comments and get a final
3 draft.
4 Item number two, "NRC staff should remove
5 the attestation requirement for board certified
6 individuals and rewrite the attestation requirement
7 for individuals seeking authorization under the
8 alternate pathway. The rewritten attestation should
9 not include the word 'competency', but should instead
10 read, `has met the training and experience
11 requirements'."
12 This item is accepted, and it is included
13 in the User Need Memo for the 2009 rulemaking.
14 Additionally, I have here the paper that went to the
15 Commission providing these recommendations and the
16 Commission came back and said, "Yes, please pursue
17 this." So, if anyone wants to see a copy of the
18 actual recommendations and the Commission instructions
19 they sent back, I have it here.
20 For item number three, "NRC staff should
21 revise the regulations so that board certified
22 individuals who are certified prior to the effective
23 date of recognition were certified by previously
24 recognized boards listed at subpart J of the previous
25 editions of Part 35 are grandfathered."

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1 This item is pending. We will need to
2 develop a technical basis, and the decision of whether
3 or not to pursue a technical basis has not yet been
4 determined. Ron Zelac is working on this now. We
5 sent letters to the boards, and Ron is working to
6 incorporate those comments, to determine if a
7 technical basis is justified.
8 For item number six, "NRC staff should add
9 the words `or equivalent', so it is clear that
10 information included in the letter is the same as that
11 which would have been submitted in NRC Form 313A."
12 This item is accepted and is in the User Need Memo for
13 the 2009 rulemaking.
14 Item number seven, "NRC staff should
15 revise 10 CFR 35.50(c)2) to include Authorized Users,
16 Authorized Medical physicists or Authorized Nuclear
17 Pharmacists identified on any license or permit that
18 authorizes similar types of use of byproduct
19 material."
20 Additionally, the authorized, Authorized
21 Medical Physicist or Authorized Nuclear Pharmacist
22 must have experience with the radiation safety aspects
23 of similar types of use of byproduct material for
24 which the individual is seeking Radiation Safety
25 Officer authorization.

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1 This item is accepted and is in the User
2 Need Memofor the 2009 rulemaking.
3 Item number eight, "NRC staff should
4 remove the attestation requirement from 10 CFR
5 35.50(d) for Authorized Users, Authorized Medical
6 Physicists and Authorized Nuclear Pharmacists seeking
7 Radiation Safety Officer status. If the AU, AMP or --
8 or ANP seeking RSO status will have responsibilities
9 for similar types of uses, for which the individuals
10 authorized."
11 This item is accepted and it's in the User
12 Need Memo for the 2009 rulemaking.
13 Item 10, "NRC staff should allow more than
14 one RSO on a license with the designation of one RSO
15 as the individual in charge. NRC should create a
16 Regulatory Issue Summary (RIS) to inform the regulated
17 community of NRC's interpretation. The RIS should be
18 sent to ACMUI and the Agreement States for review and
19 comment."
20 This draft RIS was sent to ACMUI in
21 September of last year, and it is scheduled as part of
22 the next Part 35 rulemaking to begin this year.
23 Item 16, "NRC staff should revise the
24 current guidance to conclude that the surgical removal
25 of the sentinel lymph node is an independent procedure

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1 and should not be regulated by NRC."

2 This item was accepted. The guidance was

3 revised and this item was closed -- I'm sorry, the IN

4 was sent out in January of this year.

5 Number 25, "NRC staff should revise the

6 current regulations to include Canadian trained

7 individuals who have passed the American Board of

8 Nuclear Medicine certification exam."

9 This item is accepted and it's in the User

10 Need Memo for the 2009 rulemaking.

11 For item 30, "The Elekta Perfexion should

12 be regulated under 10 CFR 35.1000 until 10 CFR 35.600

13 is modified to be performance based, which would allow

14 the Perfexion to be regulated under 35.600."

15 This item is accepted and it's in the User

16 Need Memo for the 2009 rulemaking.

17 Item 31, "NRC staff should require

18 experienced RSO's and AMP's to receive additional

19 training if the individual is seeking authorization or

20 responsibility for new uses." This item is accepted

21 and it's in the User Need Memo for the 2009

22 rulemaking.

23 Item 32, "NRC staff should not require

24 experienced RSO's to attain written attestation to

25 become authorized or have responsibility for new

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uses." This item is accepted and it is in the User Need Memo for the 2009 rulemaking.

Item 34, "NRC staff should modify 10 CFR 35.491(b)(2) to specify superficial ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify superficial ophthalmic treatments."

This item is accepted and it's in the User Need Memo for the 2009 rulemaking.

Item 35, "NRC staff should not revise 10 CFR 35.491 to include training and experience for the new intra-ocular device. Instead, NRC staff should regulate the new intra-ocular device under 10 CFR 35.490."

This item is partially accepted. Staff expects to include in future rulemaking.

Item number 36, "NRC staff should not require medical licensees regulated under 10 CFR 35.400, 500 or 600, as applicable, to only use the sealed source and devices for the principle use as approved in the Sealed Source and Device Registry."

This item is accepted in the User Need Memo for the 2009 rulemaking.

Item 37, "NRC staff should revise 10 CFR 35.290 to allow physicians to receive training and

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1 experience in the elution of generators and
2 preparation of kits under the supervision of an
3 Authorized Nuclear Pharmacist."
4 This item is accepted and is in the User
5 Need Memofor the 2009 rulemaking. Any questions?
6 CHAIRMAN MALMUD: Thank you. Are there any
7 questions?
8 MS. COCKERHAM: I think overall, we're
9 making progress. We have many, many items that have
10 been on the back0-burner since 2007, but they are
11 moving into rulemaking and we are starting the
12 rulemaking, which is good news.
13 CHAIRMAN MALMUD: Thank you very much.
14 MS. GILLEY: I have a question.
15 CHAIRMAN MALMUD: There is a question.
16 Debbie Gilley?
17 MS. GILLEY: The IN from June 2007,
18 concerning Air Kerma Strength vs. apparent activity.
19 Two years? We've had quite a few medical events.
20 MS. COCKERHAM: It's being drafted.
21 MS. GILLEY: Thank you.
22 CHAIRMAN MALMUD: Any other questions? If
23 not, thank you for a very thorough presentation, and
24 we'll move on to Ms. Burgess, who is going to present
25 item number three, which is medical event reporting to

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1 the International Nuclear Event Scale.

2 MS. BURGESS: Hi, I'm Michelle Burgess. I

3 am one of the regional coordinators in Chris's branch

4 and I wanted to use this as an opportunity, this

5 meeting, as an opportunity to bring an issue to your

6 attention.

7 About three years ago, France forwarded a

8 proposal to the IAEA, to start including medical

9 events in INES, and that's the international database

10 that collects the high end events.

11 At this point, all of the medical events

12 are excluded from that, and France would like to start

13 including them in there.

14 INES is the database that's primary

15 function is a communication tool to the public. The

16 NMED database, which a lot of you are familiar with,

17 is a tool that we use here nationally, to collect all

18 of our events. We to trending on it. It's sharing

19 amongst more regulators than a public-type information

20 tool.

21 But the gist of the IAEA database is a

22 public communication tool. So, there's a little bit

23 of a different approach to and are some sensitivities

24 that might be there.

25 In your binders, there is the background

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1 information from the last meeting that we had, to
2 discuss the proposal to IAEA and some background
3 information on INES, as well as the summary of the
4 scale that France is proposing that we use for medical
5 events.
6 I've given that information to you. We're
7 not going to -- I wasn't going to go through it today
8 in detail, because our primary purpose here is to make
9 you aware of this proposal and to begin soliciting
10 some feedback from you guys.
11 We see this as somewhat different than
12 some of the other issues that we've addressed with
13 INES. Most of the other proposals for changing the
14 scale or including events haven't had quite the
15 sensitivity that we've had with the medical industry
16 and we would -- one of our primary goals is not just
17 alignment of the scale with the agency position and
18 our goals here, but this has that extra component of
19 making sure that we understand the impact and the
20 effect from the medical industry, because of the
21 publicity of the events that are going on here. For
22 most of the other licensees, there isn't that same
23 sensitivity.
24 I'm not sure if we have -- have had a
25 lot of chance to look through the presentation

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1 materials and if you guys have any specific feedback
2 for me here, now, or if this is a thing that we need
3 to stage out for you providing some input to us at a
4 further -- at a future date, because of the timing for
5 the next meeting, they want to have that in November.
6 We're looking to see if we can any input
7 that you may have for us, any thoughts or feedback or
8 insights, by the end of June, so that we can
9 incorporate anything we have in any response, in
10 preparation for that November meeting.
11 Was there any specific input that you had
12 now for us?
13 CHAIRMAN MALMUD: Does any member of the
14 committee any comments? Yes, Dr. Vetter?
15 VICE CHAIRMAN VETTER: More of a question.
16 Is the intent to actually add medical events to the
17 database or is it -- or is the intent to use the INES
18 scale to measure the significance of medical events?
19 MS. BURGESS: To add them to the database.
20 To create a scale and the scale that we have from
21 France now, is not quite in alignment with the IN --
22 the current INES scale, with respect to relative
23 significance.
24 It's one of the things we'd like to hear
25 back from you on. We have to set the scale. That's

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one step of it. But then the end point is an intent to actually include all of these events in INES, which would then put them out there in that public communication tool.

That's one of the reasons that we think it's important to make sure we have the scale set correctly. Right now, the scale is set in the French proposal -- is off-set from the INES scale, where it's going to put an apparently higher significance level for any kind of event.

For example, a death call by a medical event is going to look like it has more significance than the death calls by any other kind of event and there are some proponents in the international arena that think that that's appropriate, and other thinks that we need to kind of base line it, so that we're not calling medical events out as somehow more egregious than any other kind of radiation exposure, for example.

So, it's two parts. It's to set that scale and then eventually, to be able to include those in INES.

CHAIRMAN MALMUD: Dr. Nag?

DR. NAG: On the INES scale, that would -- that calls for people where any regulation exposure

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1 would face the accidental -- not normal. Whereas, in
2 a medical implant, you as using radiation to treat and
3 therefore, those scales are much higher and when ever
4 you're trying to reach one side on medical event on
5 INES scale, you have to keep that in mind, that the
6 medical event or medical therapy, you are giving the
7 therapy to that patient that would be quite -- there
8 would be some amount of radiation exposure already
9 expected on that patient.
10 So, for other devices, yes, you can use
11 the INES scale, but for the patient himself or
12 herself, the amount of radiation that you're giving
13 them might be quite high, you know. That has to be
14 kept in mind when ever you're trying to match the two
15 scales.
16 MS. BURGESS: And that's correct, and one
17 of the things that we're doing is the idea of -- what
18 would be included in there would be things defined as
19 a medical event, which also -- which already tries to
20 take that into consideration because it has to be an
21 unexpected dose in the -- to a wrong area or higher
22 than expected to the correct area.
23 So, we try to take that into consideration
24 in that aspect. But there is also the idea that some
25 of the effects, you may get a measurable effect from

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1 another radiation event that is totally unexpected.

2 But when you're dealing with a medical

3 event, sometimes some of those results -- the

4 unwanted, but expected results, is that a matter of,

5 it would happened anyway, or is that a matter of, it

6 happened because there was a medical event?

7 Those are some of the issues that we're

8 trying to bring forward, raise those, the points that

9 we need we need to make sure that we cover, if we're

10 going to include these, that even in the definition,

11 how we define the event or what we're going to put in

12 the threshold that we use for events, that we make

13 sure we take all those things into consideration, that

14 we're not giving the wrong message to the public, with

15 respect to the significance of the medical events.

16 CHAIRMAN MALMUD: Dr. Van Decker?

17 DR. VAN DECKER: Yes, I just want to raise

18 some concerns in the process here, that this gets done

19 with a lot of thought.

20 I think that we're all very cognizant, as

21 you're trying to gently point out, that there is

22 emotional overlay to medical events, who is the

23 adjudicator of what's a medical events, whether there

24 was real harm done or not.

25 We know we deal with this all the time in

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1 the definition of what's a medical event and public
2 disclosure and Congressional disclosure and everything
3 else.
4 I think this discussion would probably
5 have been a little bit more helpful to some degree, if
6 could bring like concrete examples of what we think
7 are -- or what really -- real life events would have
8 fit into this scaling system, who would have
9 adjudicated it in the scaling system and how it would
10 really play out, as far as where it's going, where the
11 information is going.
12 I think we're all for transparency and we
13 want to see good be done, but I think that I'm a
14 little bit nervous, without seeing some concrete
15 pieces to this, as to exactly how this is going to
16 play out, and I think that since the process is moving
17 along quickly until November, somebody along the way
18 has to think about each of those different stops.
19 MS. BURGESS: And that's one thing that
20 we're doing. In the meetings, we've started some
21 preliminary checks against, here is real events, here
22 is the scale. Where would they fall out?
23 November is not when they're going to put
24 it into place. November is simply the next meeting
25 where the working group needs to come together and

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1 bring all of the issues and start discussing where we
2 need to go, the things we need to resolve.
3 So, the timing is just for getting all the
4 information together, to get to that next step for
5 discussion, and we do have examples that we've started
6 to work through. The purpose of bringing it to this
7 meeting today was to start dialog with ACMUI, to see
8 if you wanted to engage in this and then, we can move
9 forward through Ashley, to figure out what the best
10 mechanism is, to continue the discussions that we
11 start today.
12 But this was to raise the issue to your
13 attention and get it started, but I'm looking forward
14 to whatever interactions we can have between now and
15 November.
16 CHAIRMAN MALMUD: I think Dr. Suleiman has
17 a question and Mr. Mattmuller, then Dr. Vetter.
18 DR. SULEIMAN: I don't care much for
19 conceptual concepts, but this is nice in this case. I
20 think you have to be very, very careful. I think
21 other people expressed that. We're talking about
22 patients, you know, the dose that's being delivered to
23 them, whether it's a therapeutic, whether it's a
24 diagnostic.
25 You're talking about the occupational

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1 workers. You're talking about the public, and how you
2 blend them into a broader scheme that the IAEA has
3 developed that may cover things that are clearly
4 outside the purview and trying to lump them in there,
5 strictly based on some technical radiation metrics,
6 could be, if not clearly planned out and thought out
7 ahead of time, could be problematic.
8 I think we had some of that issue earlier
9 with defining the border of a tumor, you know, where
10 practice of medicine is not very, very black and white
11 and there's a lot of grey in there and that grey is
12 allowable., and so, you don't want that to trigger a
13 number.
14 I know with FDA, you know, we have a very
15 -- we require -- we ask, we beg people to report
16 information. The intent is to identify if there's a
17 recurrent emerging problem associated with a certain
18 technology, with a certain drug and so on.
19 So, we classify it -- things as either
20 adverse events, which could be nothing more than a
21 slight rash on the skin to serious adverse events,
22 which basically has the term `life threatening' and
23 that still is pretty broad.
24 But the intent, and I think your intent is
25 to identify emerging problems with a certain product

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1 that all users are doing wrong or maybe a certain, you
2 know, source that is having a problem. I think that's
3 really what the mechanism is intended to identify.
4 So, I think how you parse that off from
5 the very beginning would be critical. If we get
6 blended in with everything else, you're going to have
7 problems down-stream.
8 CHAIRMAN MALMUD: Thank you, Dr. Suleiman.
9 I believe that you were next, Steve.
10 MR. MATTMULLER: My one concern with
11 reporting this and using it as a tool for the public
12 is that there's -- it's just a number of incidents.
13 There is not -- I didn't see any temporary expression,
14 medical cases, having a denominator, so they could get
15 a feel for the rate of how often this happens, because
16 if it's one event with the total number of say, a
17 Gamma Knife exam or a procedure versus a much more --
18 you know, one event there is much more significant
19 than one event, say, with a therapy for the item at
20 issue.
21 So, I think it would very important to
22 make at attempt, at least, to estimate the total
23 number of procedures that that event derived from,
24 which I realize is a huge issue, but I think it's
25 important to the public to see that because I think it

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1 takes much imagination for them to see one event this
2 year and next year, there's two in there and they say,
3 "Oh my gosh, the medical community is out of control,"
4 because there's 100 percent increase in events, and
5 without the other information, I'm afraid our media
6 might make those conclusions.
7 MS. BURGESS: And I have that down here as
8 a note with an asterisk to see if there's a way to
9 address the denominator issue at large because in
10 INES, there is no denominator addressed for anything.
11 If somebody does output from the data,
12 then you'd try to put the denominator in. For
13 example, NMED, we do the same thing here. There is no
14 denominator in NMED, but then when we do the annual
15 report that comes out of NMED, there is where we try
16 to apply the denominator.
17 So, it's a difficult subject in any of
18 these data collection systems, to figure out what that
19 denominator is and any information that you might be
20 able to offer us, ACMUI might be able to offer us,
21 with respect to denominators or where we can get that
22 information, we're always open to that.
23 We've gone to different sources when we do
24 our annual reports that we do out of NMED. So, we're
25 always looking for a better, more up to date, more

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1 accurate source or two sources to compare, so that we
2 can have some sort of range and validation.
3 But I'll put that down as a general issue,
4 not just for medical, but for everything and I will
5 make sure that it's clear that part of our concern is
6 that it's not just the data that's going in, but
7 making sure that we understand how any trending or
8 analysis will be characterized. That was raised on
9 this side of the room as well.
10 We need to make sure that denominator is
11 in there. That's part of any trending. So, I have
12 there here as well.
13 CHAIRMAN MALMUD: I believe that Dr. Vetter
14 was next.
15 VICE CHAIRMAN VETTER: Many hospitals and
16 clinics are accredited by The Joint Commission and
17 they have a term called sentinel event that describes
18 various bad things that can happen and have to be
19 reported, investigated and so forth, and I just wanted
20 to point out that as you proceed forward here in
21 defining what these events are and where they fit on
22 the scale, it might be good to be sure you're not --
23 that any of these definitions are not inconsistent
24 with The Joint Commission's definitions of sentinel
25 events.

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1 CHAIRMAN MALMUD: I believe --

2 MS. BURGESS: You said that's a Joint

3 Commission?

4 VICE CHAIRMAN VETTER: The Joint

5 Commission.

6 CHAIRMAN MALMUD: That's JCAHO.

7 VICE CHAIRMAN VETTER: No, I'm sorry.

8 CHAIRMAN MALMUD: Just The JC? Started out

9 as JCIH and then became JCAHO and now they're JC?

10 VICE CHAIRMAN VETTER: Yes, now, they're

11 TJC.

12 MR. MATTMULLER: Now, they're The Joint

13 Commission, TJC.

14 CHAIRMAN MALMUD: What's in a name?

15 VICE CHAIRMAN VETTER: The is capitalized.

16 They probably learned that from The Ohio State

17 University.

18 MS. BURGESS: And the point you raise ties

19 into a lot of what we're trying to do, as far as

20 definitions. Right now, the definitions that are in

21 the French proposal, are not very clear.

22 Significant effect or less significant

23 effect, that's not helping us. We wanted one, to make

24 sure that the rankings are clear, so that everybody is

25 ranking things the same way.

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1 If the whole purpose of INES is to give a
2 relative significance, we want to know -- we want to
3 make sure everything is pretty fairly being
4 consistently characterized and the other piece is with
5 this interaction with the industry, is the impact on
6 it, but also trying to use things that are
7 understandable by the community, that fit in with --
8 or at any rate, aren't inconsistent with the
9 definitions that already exist, since there's so many
10 out there already, in the medical arena versus others.
11 VICE CHAIRMAN VETTER: Just as one example,
12 probably the most specific example that's pertinent to
13 this discussion is a skin dose that exceeds 15 Gray
14 (Gy) is a sentinel event, period, and the hospital
15 must investigate that as a sentinel event.
16 CHAIRMAN MALMUD: I believe the Chris had a
17 statement.
18 MR. EINBERG: Yes, Michelle, I guess what
19 you're seeking right now, and let me know if I'm
20 wrong, you're seeking the recommendation as to what
21 the threshold for a medical event should be, to report
22 it to the INES and also, you're seeking what the
23 definition for a medical event that's reportable to
24 INES should be, is that correct?
25 MS. BURGESS: We're looking for several

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1 things here, open dialog to start and then to build
2 upon. We're not going to accomplish everything today.
3 So, opening some dialog, getting some
4 thoughts and then either here or working with Ashley
5 to figure out a way we can continue to work.
6 The content that we're looking for is any
7 input on the definition of what events should be
8 included in here versus not included, making sure that
9 we're consistent with the medical community, the words
10 and the definitions that are used there, looking for
11 any feedback that you can give us, with respect to
12 should we try to engage with industry itself?
13 We want to measure -- we want to know that
14 what we're going to do here isn't going to have some
15 adverse effect and the medical community is going to
16 have difficulties or sensitivities in what we're
17 trying to do here.
18 If we could accomplish that here, that's
19 fine, but if not, and you recommend that somehow, we
20 reach out to the medical community itself, any input
21 that you can have that way, with how to do that, the
22 timing for doing it, how best to accomplish it, so
23 that we -- if we're going to put it out there, we put
24 it back out with our best foot, so that we can engage
25 productively with them, as opposed to triggering

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1 sensitivities and it becoming an upsetting situation.

2 All of this is -- again, we're just trying

3 to pull as much as we can together in preparation for

4 that November meeting.

5 The U.S.'s position at this point is to

6 move forward slowly, so, we're well aware of what we

7 do because the problem with one of these databases is,

8 once you get it started, it's hard to stop.

9 So, we want to make sure all the pieces

10 are in place before we start and that we're fully

11 aware of where we're going and the impacts that we're

12 going to have.

13 CHAIRMAN MALMUD: Dr. Suleiman?

14 DR. SULEIMAN: One more clarification.

15 Looking at the schema, it appears this is more

16 accident or major failure type of reporting. It's not

17 necessarily what happens during routine practice of

18 medicine.

19 MS. BURGESS: Correct, it would be --

20 DR. SULEIMAN: So, maybe it would be good

21 to steer clear of that and just allow catastrophic

22 elements to --

23 MS. BURGESS: To drive it.

24 DR. SULEIMAN: Yes, to drive it.

25 MS. BURGESS: Yes, the minimum threshold

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1 that we would have here would be reportable events,
2 events that are reportable to the NRC, because that
3 would be the sub-set that we would pool from and for
4 the most part, it should be immediately reportable
5 events, not the 30 days reportable, but anything --
6 most of the medical ones trigger to the tie-in's
7 anyway.
8 So, that's what we're looking for as a
9 minimum threshold. For IAEA though, for other events,
10 we don't send everything that gets sent to us.
11 There's a higher threshold. It's sort of like where
12 we do the AO's, there's that higher level. It's a
13 higher level that we send to INES as well.
14 So, we would be looking for, is there a
15 way of those things that are immediately reportable,
16 to cut some other threshold in there, to say these are
17 the things that we're going to communicate to INES and
18 it's the things that are going to be out that -- that
19 the public has a right to know about. It's that
20 communication tool, the same way we're putting out for
21 other events.
22 CHAIRMAN MALMUD: Dr. Eggli?
23 DR. EGGLI: Who do you propose will
24 actually do the categorization of the severity? Will
25 that be done at NRC before it's -- before it's

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1 submitted? Are you expecting the end-user to
2 categorize, because looking for uniformity, even if
3 you say the scale is one to five, plus the zero,
4 that's six categories and expecting the end-user to
5 have any kind of uniformity in that kind of a rating
6 system is very difficult.
7 I think Orhan referred to a two grade
8 system at FDA, so that you would assume you would need
9 a very small group of experienced folk to assign the
10 category before that information would be submitted
11 forward, to try to maintain some form of uniformity
12 and grading.
13 MS. BURGESS: The grading is done here at
14 the NRC, the same way that we do for the IN - - all
15 the rest of the INES events that are already going in.
16 There is a guidance document that's put
17 out, but then it's staff here in our branch here, we
18 would be doing it and then it's double checked some
19 individuals that are down in our incident response
20 branch, NSIR-- the operations side of that and then it
21 gets submitted over.
22 So, it's done here by a small group, so
23 you do have that consistency.
24 CHAIRMAN MALMUD: Mr. Lieto?
25 MR. LIETO: I have a few questions,

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1 actually, a follow up to Dr. Eggli's question. I
2 think there's a real concern with the fact one, that
3 this is going to be a public reporting and then you
4 want this immediate -- you know, as soon as it's
5 reported by the licensee or where ever the event
6 occurs, to get transferred into this international
7 reporting mechanism, and I think there needs to be --
8 I guess to use medical terminology, a time-out where
9 you really investigate this one, to determine is it a
10 medical event that needs to go into this international
11 reporting mechanism.
12 And I guess I have a question, and I don't
13 know if you have an answer for this now, but is, what
14 is the purpose of this immediate reporting of these
15 medical events in one country, into an international
16 mechanism and I'm still a little confused as to, you
17 know, what's going to be the value of that?
18 I could see if there was some type of a
19 process of being sure that this is an actual medical
20 event. What is the lesson learned? In other words,
21 some follow up investigation, because right now,
22 medical events have to be reported within 24 hours of
23 discovery, and I would really hate to see that being
24 sort of escalated and then it's, "Oh, nevermind," you
25 know, after a month later.

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1 Another point that I'd like to make is
2 that these would be only radioactive material events.
3 The international, shall I say practice of radiation
4 medicine, if you will, encompasses all uses, which
5 basically are the machines, and that's where you're --
6 where I'm going to say your largest use of radiation
7 occurs and maybe events are likely to be reported.
8 I'm assuming, this is just my personal
9 opinion, I'm assuming that because this is largely
10 coming out and driven by the French, it's a follow up
11 to the events that occurred in their country, I think
12 a year or two ago, where they had just a major issue
13 with improper, I think, calibrations of the machines
14 and so forth, and I can understand that process.
15 But there is no mechanism in the United
16 States where there is reporting of medical events into
17 a national database regarding machines, and so, I
18 think that's a major discrepancy between what you're
19 going to be trying to compare on an international
20 scale versus what's happening in this country.
21 So, I think that's an issue that needs to
22 be addressed before we, shall we say, join this.
23 Also, looking at your information, I think
24 that if this is going to be an internationally
25 reporting mechanism, I think you need to include more

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1 of the international community.

2 I notice that there's no representatives

3 from Canada or the UK on this, at least in the

4 descriptions that I read, and I think that you really

5 need to, as you go forward -- and this warrants -- you

6 want buy-in by, I think the United States. I think

7 that you need to be sure that there is going to be a

8 buy-in by other countries, and this isn't just sort of

9 a U.S/French type thing.

10 So, that was another point I wanted to

11 make and again, you know, I think how are the

12 differences in the practice of medicine in from one

13 country to another, going to be incorporated into this

14 reporting mechanism?

15 MS. BURGESS: To hit your point, the

16 concern about the immediately -- immediate release to

17 the public, the timing for that would be the same as

18 the timing that we have for release of reportable

19 events to the NRC's website. I think there's a three

20 day hold on it.

21 A five day hold on it. So, it -- the

22 timing for what would be no sooner than that. We

23 would have to arrange -- although the reporting for

24 INES right now, for other types of events, is 48

25 hours. We would need to tie that timing to, at the

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1 minimum, at least not -- before we would be putting it
2 out on a public website.
3 But I have the note here with, do we want
4 to have an even longer wait, because of the fact that
5 we're dealing with patients and medical issues, to
6 make sure that we're not a potential event, but we
7 really are certain that this is an event and we have
8 our facts straight.
9 Your second point was about needing more
10 -- why do you need international reporting? The whole
11 concept with INES for reporting all types of events is
12 participating in this national effort to ensure that
13 the public as a whole, not just the U.S., but across
14 the board, are aware of the types of things that are
15 happening. It's the disclosure, the transparency
16 part. So that's what's been driving the whole thing
17 for all of INES, including this proposal to include
18 medical events. They're just trying to roll a subset
19 of events that have always been excluded into the
20 general rule.
21 On the other radioactive only versus
22 machines, you're right. And that is one of the issues
23 we're trying to address. The NRC can easily address
24 the radioactive material part.
25 On the table is one of the questions. And

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1 you're bringing one that we have raised ourselves,
2 what about all the machine events? And that's going
3 to be something we're going to have to tackle.
4 We're going to have to figure out, what do
5 we do? If that's the intent and we're supposed to be
6 including those events in here, there is no easy
7 mechanism, like there is to pull it out of NRC's
8 events. And so we have to figure out how to address
9 that. And we don't have an answer that. So we'll
10 need to work through that.
11 And your last one about the international
12 representation, the people who were at this particular
13 working group were just those entities, those
14 representatives from the member states, IAEA, that
15 could participate.
16 There's a larger putting a contacts group
17 that anything this working group comes up with goes to
18 that larger group and all the member states, where all
19 their representatives vote on it.
20 So there is larger participation. This
21 isn't just France and the U.S. and the couple of
22 countries that happened to be there. It is a larger
23 group. Unfortunately, the working group couldn't draw
24 the people together.
25 I know I am running out of my time.

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1 CHAIRMAN MALMUD: No, you're not.
2 Actually, is there another question for you from Dr.
3 Thomadsen?
4 MEMBER THOMADSEN: Further on that last
5 point, there is a large European database for
6 radiation --
7 MS. BURGESS: Machines?
8 MEMBER THOMADSEN: -- medical events, for
9 Rosis. Do you know, are they in discussion with this
10 group, this IM permit?
11 MS. BURGESS: I don't know. I haven't
12 heard that name brought up. Will you tell me that
13 name one more time?
14 MEMBER THOMADSEN: R-o-s-i-s.
15 MS. BURGESS: Okay. Is that materials
16 only or machine?
17 MEMBER THOMADSEN: It's medical radiation.
18 MS. BURGESS: So it's everything. Okay.
19 I'll double check of that, but that would be one thing
20 that we would make sure we would need to bring into
21 this as far as the mechanism and agree to discuss it.
22 I mean, I know they wanted to talk with
23 the World Health Organization to bring it under
24 discussion. It happened the same way we're engaging
25 with you to engage with them to get the perspective

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1 that we might not be seeing from the regulators and
2 just looking at it from an event point of view but
3 bringing these extra things in it that we're not aware
4 of.
5 MEMBER THOMADSEN: That is not in
6 regulatory space. That is in medical space.
7 MS. BURGESS: No. But that's what I mean.
8 These things that we're not aware of that can help
9 bring those pieces to us that might change where we
10 want to go or improve where we're going.
11 CHAIRMAN MALMUD: Dr. Guiberteau?
12 MEMBER GUIBERTEAU: I would like to focus
13 a comment on your comments regarding whether or not to
14 consult and/or interface with the medical community
15 and if so, how to do that.
16 I would hope that you move beyond the
17 first and are focusing on how to do that. I believe
18 not only with respect to acceptance of this in the
19 future, but in many cases, it is the medical
20 organizations and the physicians who will have to
21 explain these things to their patients.
22 And I would implore you to use what we
23 already have in place in the United States. And that
24 is numerous medical representative organizations who
25 deal with these issues because I think, as Ralph said,

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1 the practice of medicine does have different
2 sensitivities in the United States than it may have in
3 other countries. And so I think it would be
4 exceedingly important to get this on the right footing
5 to begin with.
6 MS. BURGESS: Do you think that as an
7 active participation in development or for awareness
8 and information?
9 MEMBER GUIBERTEAU: Well, I think either
10 or both. I do think the broader spectrum of input you
11 can get at this stage would be great guidance in terms
12 of any trends that you see and concerns from the
13 medical community.
14 Participation might be a little more
15 difficult because obviously these things are perhaps
16 better done in smaller groups. But some participation
17 would likely be a good thing.
18 CHAIRMAN MALMUD: Thank you, Dr.
19 Guiberteau. I believe that Debbie Gilley had her hand
20 up next.
21 MEMBER GILLEY: Just a clarification.
22 There are states out there that do also monitor
23 medical events with machines and do keep registries of
24 that, just as we do with radioactive materials. Thank
25 you.

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1 CHAIRMAN MALMUD: Thank you.

2 And Dr. Van Decker?

3 MEMBER VAN DECKER: I was just going to

4 ask a question. Beyond the international public

5 transparency of this, do you see an additive

6 regulatory advantage to this? Because most registries

7 are done not just to let people know what is going on

8 in the community but also some sense for rulemaking or

9 regulation in the future. Where do we see the

10 regulatory advantage of this for U.S.?

11 MS. BURGESS: The IAEA standpoint on this

12 is it's from their viewpoint only a public

13 communication tool. That said, I do see a regulatory

14 benefit for those member states that want to use it.

15 I, for example, go in. I am one of the

16 events coordinators. I go in. And I do watch the

17 events that are on there to see if there are any

18 lessons I can learn from those materials events that

19 are being posted on the site that we can then drop in.

20 In fact, I dropped them, was dropping them in, and

21 Duane is dropping them in now, into NMED so that we

22 can see them with the lessons learned concept.

23 Is it something only here? Is it

24 something that happened there that we can learn from

25 their event before it happens here for the device

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1 failures or a new mode of failure?

2 Somebody did something wrong and it's not

3 been seen, that mode, here before. So yes, I do see

4 that regulatory benefit for those member states that

5 want to go out and use it.

6 CHAIRMAN MALMUD: Thank you.

7 Dr. Suleiman?

8 MEMBER SULEIMAN: I am confused when you

9 say "machine events." FDA requires industry to report

10 to us all problems with their equipment analysis,

11 causing radiation-related issues with mechanical

12 problems or whatever.

13 Then, of course, we're cast with the

14 problem of trying to differentiate whether it was, in

15 fact, a machine problem or it was a user problem using

16 the equipment inappropriately. But that's required.

17 And I know that NRC is aware of this.

18 Donna-Beth Howe I know is aware of this. This has

19 been going on for decades.

20 MS. BURGESS: Right. There is reporting.

21 I don't think FDA has the kind of centralized

22 repository that we have like for NMED. And so far we

23 have never had the opportunity, the need to tap into

24 that concept with respect to drawing that information

25 together to report to IAEA at any rate.

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1 Since NRC's mission doesn't include that,
2 we haven't spent the resources to find out if anybody
3 is taking that data, doing anything with it, doing the
4 trending or the analysis that we're doing in the
5 materials events. So it's one thing that we're
6 starting to look into in all of these data points.
7 Donna-Beth has some points for us that we
8 can use to go in and see what is happening as we try
9 to answer that question. Do we send the machine
10 events over? And if we do, where do we get that data?
11 Who puts it together? Where can we pull the source?
12 And how do you get it over there?
13 And then right now we're trying to make
14 sure that the definitions, the international community
15 is trying to make sure that the definitions, fit, not
16 just for materials events but for machine events as
17 well, that the scale fits everything.
18 And we're also looking at the difference
19 between therapeutic and diagnostic. There are some
20 that think it ought to be limited to the therapeutic
21 only because there is where you get your more
22 significant issues.
23 But there are some that are curious
24 whether or not there is a way or a need to put the
25 therapeutic in there as well.

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1 CHAIRMAN MALMUD: Dr. Thomadsen?

2 MEMBER THOMADSEN: Not wanting to put

3 words into --

4 THE REPORTER: Could you speak into the

5 microphone, please?

6 MEMBER THOMADSEN: Not meaning to put

7 words into Ms. Gilley's mouth, I think when she said

8 "machine event," she just meant events using

9 accelerators, as opposed to radioactive materials, not

10 implying that there was a problem with the machine

11 that would be reported to the FDA.

12 MEMBER GILLEY: It could be both. We

13 haven't found the FDA reporting requirements to be

14 significant as far as us communicating with our

15 licensees or registrants with linear accelerators.

16 Your reporting requirements are much more delayed than

17 our reporting requirements for a medical event.

18 MEMBER SULEIMAN: Well, most of the

19 accelerator events I would suspect would fall under a

20 user issue, rather than equipment problems.

21 CHAIRMAN MALMUD: Mr. Lieto?

22 MS. BURGESS: For this database, we're

23 looking for human error issues as well as device

24 failure issues because the modes of failure, of human

25 failure, sometimes can be something we can learn from

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1 as well.

2 MEMBER SULEIMAN: I mean, manufacturers

3 are required by law to report to us. So I know that

4 information is collected. But, as I said, radiation

5 is just one subset of many.

6 CHAIRMAN MALMUD: Mr. Lieto?

7 MEMBER LIETO: Yes. Just one final I

8 guess maybe suggestion for improvement is that if you

9 are going to be using the NMED reporting mechanism as

10 the principal route and having chaired the committee

11 that has reviewed these and reports to this group, I

12 think there need to be some real improvements in what

13 the reporting mechanism is in format because if you're

14 going to learn anything from this by reporting it on

15 an initial level, there needs to be I think much more

16 details of the event than currently are provided by

17 those reports.

18 And I am sure as you go forward, there is

19 going to be some type of established standard

20 reporting format, as opposed to every country just

21 kind of like taking their piece and throwing it into

22 this international mechanism.

23 But I think there needs to be some

24 improvement there in order to follow up with what Dr.

25 Van Decker said, that if you're going to learn

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1 anything from reporting in this, you need to be sure
2 you're getting the information that is going to
3 provide you a mechanism to find where those areas of
4 source or problems occur.
5 MS. BURGESS: To characterize it
6 correctly, to make sure there is sufficient detail in
7 there to characterize what went wrong and where it
8 might have been able to be either mitigate it or avoid
9 it.
10 MR. LIETO: Right.
11 MS. BURGESS: Okay.
12 CHAIRMAN MALMUD: If I may summarize,
13 therefore, it sounds as if the Committee feels that
14 the exercise of investigating this opportunity is
15 worthwhile, number one; number two, that our databases
16 are not coordinated perhaps in the same fashion in
17 which European or French method is coordinated or in a
18 way in which they are seeking the data.
19 In addition, in the United States, there
20 are certain cultural differences in the way that we
21 deal with these issues and the way that we investigate
22 these issues and upon whom we rely for our database.
23 So that perhaps the advice that you
24 mentioned earlier that we go slowly is good advice,
25 not in the sense of creating friction but in the sense

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1 of collecting appropriate data so that we understand
2 what we are doing ourselves before we share the data
3 with an international body that might interpret the
4 data in a way that we had not intended or in a way
5 that is not in the best interest of the public, which
6 is essentially our concern.
7 Does that summarize that which has been
8 said thus far?
9 (No response.)
10 CHAIRMAN MALMUD: I assume the silence is
11 agreement and, therefore, you have our opinion at the
12 moment. So that we should pursue this, but our first
13 goal should be to refine our own database and
14 understand how we achieve it and whether or not we are
15 prepared to evaluate it in a fashion in which it has
16 been suggested that we do this.
17 MS. BURGESS: And as far as further
18 communications, work that through --
19 CHAIRMAN MALMUD: We welcome further
20 communication on a regular basis from your efforts.
21 We are intensely interested in it. It would affect
22 the practice of medicine, which is our concern, not as
23 members of the ACMUI but in our professional lives
24 and, therefore, are very concerned about the risk of
25 unintended consequences coming from an intellectual

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effort, which may not have a sound database at the moment.

MS. BURGESS: I greatly appreciate all of the input here. I have been taking notes throughout. Some of them are echoing things that we brought up in our committee, which is reassuring me because at least we were on track for a good bit of it. We're having apparently some of the same thoughts that you guys were. But there are a lot of details that you have added to this.

So I thank you very much for the immediate input and will work with Ashley to continue this dialogue. And hopefully we'll be in a better place for November and what we want to tell IAEA then.

CHAIRMAN MALMUD: Thank you.

From the discourse that just occurred, it's obvious to me that the Committee is very interested in what you are doing. And if we can be of any assistance in the future, we are here and ready to do so.

MS. BURGESS: Thank you.

CHAIRMAN MALMUD: Thank you.

CHAIRMAN MALMUD: We will, therefore, move on to the next item on the agenda, which is Dr. Thomadsen, who will be discussing training and

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1 experience, T&E, a subcommittee report on
2 interventional radiologists as Authorized Users for
3 yttrium-90 microspheres.
4 MEMBER THOMADSEN: I have some slides to
5 know where we are on this.
6 MS. COCKERHAM: This is Ashley. If you
7 are looking for slides, they were provided today. So
8 we don't have any hard copies.
9 MEMBER THOMADSEN: Right. I apologize for
10 that, but maybe people will pay attention to the
11 screen.
12 The goal of the subcommittee was to
13 develop training and experience requirements for
14 interventional radiologists, who become Authorized
15 Users for radiolabeled microspheres.
16 In general, for whatever medical use, the
17 Authorized Users have three sections, two or three
18 depending what they are, as far as requirements,
19 training in basic radiological sciences, the training
20 specific to the modality sort of, and experience under
21 supervision.
22 The basic radiological science was fairly
23 standard between all of the modalities. I won't put
24 the list up. The duration is different for the
25 different uses. Ophthalmic applicators was between 24

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1 and 80 hours of these didactic trainings. And they go
2 up for different types of modalities depending on how
3 complicated they may be as far as the radiological
4 sciences.
5 The subcommittee took a vote on this.
6 There was sort of consensus around 80 hours. It was
7 not uniform. There were some who felt that it was too
8 much, some who felt it was too little. But there
9 seemed to be a number of hours that people could agree
10 on.
11 Here are the topics. And the list, as I
12 said, is very standard across the board. The 80 hours
13 is towards the low side. It's higher than the
14 ophthalmic applicators but at the bottom of everything
15 else.
16 And we get the specific modality
17 trainings. And I have lists here of what is specified
18 for some of the similar types of therapies. Here is
19 I-131, greater than 33 millicuries.
20 And you have experience in -- and then
21 there is the lowercase Roman numerals: ordering,
22 receiving, and packing, performing quality control,
23 calculating measuring safety, preparing patients,
24 using administrative controls to prevent medical
25 events, using procedures to contain spilled byproduct

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1 material, and administering doses to patients.

2 One through 5 are sort of under the

3 misconception that the Authorized User would ever do

4 those things. Number 6 is actually the part here that

5 they have to have experience administering doses to

6 patients or human research subjects and include three

7 cases.

8 Manual brachytherapy, 500 hours work

9 experience ordering, receiving, et cetera, checking

10 survey meters, preparing implants. C is certainly

11 relevant -- it's not clear that most Authorized Users

12 do that, as opposed to their staff --

13 maintaining/running inventories, using administrative

14 controls, et cetera, using emergency procedures.

15 And this is the third part of the training

16 and experience that I had on that second slide.

17 Manual brachytherapy, as opposed to the I-131

18 therapies, has the additional requirement to have

19 three years supervised clinical experience in

20 radiation oncology.

21 Ophthalmic applicators, you need the

22 supervised training, of course. I, examining each

23 individual to be treated, calculation of the dose to

24 be administered, administration of the dose, and

25 follow-up and review of each individual case history.

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1 This list actually deals with stuff that
2 the Authorized User has to do. I and IV deal with the
3 practice of the individual, but it's not dictating
4 medical practice. It's just dictating what sort of
5 experience the person has to have in order to do this,
6 just like requiring a medical license would be.
7 Dose rate brachytherapy, we have similar
8 lists of items that the Authorized User has to be
9 trained in: 500 hours work experience, including
10 those things it does not have a list of practice
11 things, but it does have a three-year requirement in
12 that potential third part of the training and
13 experience.
14 The subcommittee at this point had a
15 little problem. Here is one proposed list of training
16 that the Authorized Users for microspheres should
17 have. Taken as a hybrid from some of the other lists,
18 you'll see a lot of the same things there. The
19 suggestion does not have anything like a three-year
20 residency following it as a third part to this
21 proposal.
22 In discussion of the proposed training,
23 there was concern by one of the people looking at the
24 list that the red were comments that we should change
25 some of the wording there, "performing quality control

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1 procedures and instruments." That's fine.

2 Number 3 was commented as vague and

3 dealing with practice of medicine. Three was

4 examining each individual patient to be treated. And

5 down in number 7, some words again. That's not a big

6 problem.

7 In number 8, we have the follow-up and

8 review of each individual treatment case treatment,

9 where another individual had some similar comments in

10 number 3, that this dealt with the practice of

11 medicine and should be stricken. And number 5 also

12 was practice of medicine and should be stricken.

13 So one of the questions that's coming up

14 and I wish to discuss with the whole ACMUI right now

15 so that we can get past the training and experience is

16 whether or not these do dictate medical practice or if

17 they do just relate to the medical training and

18 experience of the Authorized Users for this procedure.

19 So what I would like to do, Mr. Chairman,

20 is that this is the report of the subcommittee that we

21 have not come to a consensus on this. I would like to

22 discuss with the whole Committee proposed specific

23 training and experience for the interventional

24 radiologists.

25 CHAIRMAN MALMUD: Thank you.

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1 You are opening this for discussion now?
2 MEMBER THOMADSEN: If I may.
3 CHAIRMAN MALMUD: Thank you.
4 Dr. Eggli?
5 MEMBER EGGLI: In response to Dr.
6 Thomadsen's comment, I think that the -- what is it?
7 -- 3 and 8 are sort of practice of medicine, but when
8 you look at the issue of risk, they're sort of more
9 interference in the practice of medicine as the risk
10 gets greater.
11 On every therapy I do in part 390, I do a
12 focused examination of the patient. And, likewise, I
13 don't think you will find a single interventional
14 radiologist who doesn't do extensive follow-up on
15 their interventional patients. I don't see that as
16 imposing a good to the practitioner to do those things
17 because I think they're part of our practice anyway.
18 CHAIRMAN MALMUD: Thank you.
19 Dr. Nag?
20 MEMBER NAG: I agree wholeheartedly that 3
21 and 8 are not really the practice of medicine. They
22 are necessary to effectively treat this patient. And
23 if you are going to give them Authorized User status,
24 they necessarily have to evaluate. Otherwise you are
25 giving X number of millicuries without knowing why you

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1 are giving that number of millicuries. So you
2 graduate to medicine.
3 So 3 and 8 are necessary to be in there.
4 If it's under 390 or 490 by 3 years experience, we
5 don't have 3 years experience here. So we hare not
6 giving medicine, but we are making sure that the
7 individual who is becoming an Authorized User might
8 have the training to be able to use it properly.
9 CHAIRMAN MALMUD: Thank you.
10 Dr. Welsh?
11 MEMBER WELSH: I would concur that item 3,
12 examination of the patient, and 8, follow-up and
13 review of each individual case, is imperative as a
14 component of this treatment modality for an Authorized
15 User.
16 It, of course, is medically related and
17 relevant, but it is also very essential for the
18 radiation safety aspects. There are nuances about
19 radiation safety in medicine that are sometimes
20 under-appreciated, specifically regarding the organ to
21 be irradiated and the isotope that is being used.
22 For example, the radiation of the sclera,
23 which is very, very radiation-resistant, might not
24 require the same degree of intensive understanding and
25 training that somebody who is going to treat the

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1 retina would have to experience.

2 For example, in this particular case, I'm

3 talking about that there might be a difference in the

4 level of training and expectations for somebody who is

5 using an ophthalmic applicator versus the NeoVista.

6 Similarly for thyroid treatments with

7 iodine-131, the risk of injury to this person and the

8 organ that is being targeted is very different from

9 injury to the liver or to the lung, which possibly

10 could be a fatal event.

11 And, therefore, there are differences in

12 training and expectations between thyroid treatment

13 with I-131 and Y-90 microsphere therapy of the liver.

14 These radiation safety aspects are often

15 under-appreciated and are really involved with

16 radiation safety as well as medicine.

17 Therefore, items 3 and 5 are truly

18 relevant to this group here when we talk about

19 radiation safety, although they superficially could be

20 more medical-related, rather than safety-related.

21 They are truly safety-related.

22 CHAIRMAN MALMUD: Thank you. Dr. Welsh.

23 Are there other comments? Dr. Guiberteau?

24 MEMBER GUIBERTEAU: As a diagnostic

25 radiologist representative, I don't think there is any

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1 real issue with either of these because it is the
2 standard of practice for interventional radiologists
3 for all of their procedures, a pre-qualification
4 examination of the patients in a follow-up for
5 expected or unexpected complications. I mean, this is
6 really the standard of practice.
7 Second of all, I would just like to remind
8 those of you here that interventional radiologists are
9 also board-certified diagnostic radiologists, many of
10 whom are qualified to get if they have not already
11 Authorized User status in 290, 392, and many in 394.
12 So there is experience in their diagnostic
13 radiology training that they get. So that they do
14 have experience with unsealed radioisotopic sources.
15 CHAIRMAN MALMUD: Thank you.
16 I believe we have a comment form a member
17 of the public.
18 DR. STAINKEN: Thank you very much.
19 CHAIRMAN MALMUD: Introduce yourself.
20 DR. STAINKEN: Certainly. My name is
21 Brian Stainken. I'm here as a representative of the
22 Society of International Radiology. I serve the
23 society as its president currently. We represent
24 4,300 interventional radiologists practicing across
25 the country.

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1 With regard to the specific issues, we
2 agree wholeheartedly. We strongly emphasize and
3 endorse that all of our members should see patients
4 prior to treatment and follow the patients
5 longitudinally for the treatment that they provide
6 that's also endorsed by the American College of
7 Radiology as a resolution ten years ago.
8 CHAIRMAN MALMUD: Thank you.
9 Dr. Van Decker?
10 MEMBER VAN DECKER: Yes. You know, it
11 would be different if it said that this category
12 should be applied only to the following types of
13 patients or it made specific clinical scenarios here.
14 That would certainly be interfering with medicine.
15 But the question I guess I wanted to put
16 on the table just to raise a ball of wax is it says,
17 "each patient to be treated," and it doesn't really
18 give a number, which right now I guess is a guidance
19 space to some degree.
20 You know, I have no horse in this race,
21 but I was just wondering what the thoughts of that
22 were as far as keeping things in guidance and to dah
23 dah dah dah dah and where we thought that was going
24 because iodine is not necessarily the same.
25 CHAIRMAN MALMUD: Thank you.

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1 Dr. Thomadsen?

2 MEMBER THOMADSEN: May I address that?

3 CHAIRMAN MALMUD: Please.

4 MEMBER THOMADSEN: In the third part of
5 this, there is a requirement to participate in three
6 cases for the type of microsphere that is being used.
7 This list doesn't give a number of cases for that
8 because it is training in the follow-up and review of
9 teach individual's case; that is, making sure people
10 know for these types of cases how they should be
11 reviewed and followed up. So that's why there's no
12 number of cases listed for that.

13 CHAIRMAN MALMUD: Thank you.

14 And I believe that Dr. Suleiman was next.

15 MEMBER SULEIMAN: I want to remind people
16 that the indications for which the microsphere
17 products were approved by FDA were for humanitarian
18 use for non-resectable hepatocarcinoma.

19 And I wanted to be very clear that when
20 you hear the term "dose" here, it doesn't mean
21 anything near the level of precision or accuracy when
22 you're dealing with external beam or brachytherapy.

23 There have been some interesting
24 investigations, but you probably cannot accurately
25 estimate to within an order of magnitude what the

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1 actual dose is being delivered.

2 A certain amount of radioactivity is

3 administered. And so you don't have the benefit yet.

4 It's something to be developed of scientifically

5 determining how much activity has been delivered to

6 the tumor.

7 So be careful about comparing this

8 specific application to a lot of other traditional

9 therapeutic applications.

10 CHAIRMAN MALMUD: Thank you.

11 I think there is another comment from a

12 member of the public.

13 DR. STAINKEN: Thank you. Brian Stainken

14 again.

15 With regard to that, I appreciate what you

16 are saying. I think that a lot of the competency with

17 regard to these therapies relates to the knowledge and

18 skill and catheter placement, catheterization, and

19 microcatheterization in the label, which also

20 certainly influences the dose delivered on the per cc

21 basis.

22 In terms of determining a threshold number

23 of cases for the purpose of experience, I would

24 support the three-case observation threshold with the

25 experience of getting through residency and fellowship

DRAFT

1 and interventional radiologists, which addresses the
2 catheterization experience. And most programs also
3 experience observing Y-90 procedures.
4 CHAIRMAN MALMUD: Thank you.
5 It sounds as if, Dr. Thomadsen, that there
6 is unanimity of agreement with regard to the eight
7 items on the slide entitled "Proposed Specific
8 Modality Training."
9 MEMBER THOMADSEN: Excellent. We have one
10 more order of business here, then. If I go backward
11 through here, high dose rate brachytherapy requires
12 500 hours of those items; that is, in addition to the
13 three years supervised training. Actually, it's
14 concurrent with.
15 Ophthalmic applicator does not really
16 specify the duration of the training for those four
17 items. Manual brachytherapy has the 3-year residency
18 and the 500-hour again requirement for those items.
19 I-131 treatments greater than 33 millicuries does not
20 specify the number of hours.
21 So the next and the last question that I
22 think we need to address is for the eight items, do we
23 feel we need to put a time for the training on these
24 items or not?
25 In argument against a time, all except

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1 possibly 3 and 8 would be included during the
2 residency for a radiologist in their training. And,
3 as a result, the residents would receive all of these
4 trainings normally. The argument for putting a thumb
5 limit on these is for completeness, just so that we
6 specify that.
7 I would entertain suggestions from the
8 Committee.
9 CHAIRMAN MALMUD: Dr. Eggli?
10 MEMBER EGGLI: I think as a general
11 pattern, when a training requirement is specific and
12 limited to a single application, the time required has
13 been less than when you can broadly practice in a
14 category. I'll take the areas that I'm familiar with,
15 which are the part 300 uses.
16 If I am going to treat broadly and my
17 training requirement comes under 390 and I have to
18 have 200 hours and training but if I have a narrow
19 focus, such as the radioiodine training -- and I
20 actually think that both 392 and 394 do require 80
21 hours of training -- then a lesser number of hours is
22 required.
23 Part of the reason for putting the hours
24 in there I think is to support the alternate pathway
25 for people who don't always achieve board

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1 certification but, yet, qualify as Authorized Users.

2 And I think given the pattern that we have

3 seen over many applications, that it is reasonable to

4 have the 80-hour T&E requirement for this application

5 as well.

6 And, as you have already mentioned, Dr.

7 Thomadsen, that 80 hours is typically covered in most

8 training programs because ABR requires that the

9 trainees meet requirements currently, at least for

10 392, which does have an 80-hour requirement in it, so

11 we don't produce a hardship for the diagnostic

12 radiologist requiring 80 hours of basic education in

13 radiologic sciences. But we do set a recommendation

14 for the individuals, who would train via an alternate

15 pathway.

16 So I agree with you that it is important

17 to set a limit. And, again, I would use the pattern

18 that has been used for regulation in this arena. When

19 you train broadly, you have a greater requirement than

20 when you train specifically. And I would support an

21 80-hour training requirement for this application.

22 CHAIRMAN MALMUD: Thank you, Dr. Eggli.

23 Dr. Welsh?

24 MEMBER WELSH: I was one of the

25 individuals who did support an hour, number of hours,

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1 in this particular proposal. And this is why I
2 brought up my points earlier about radiation safety
3 being organ-specific. And there are some nuances that
4 are sometimes or not infrequently overlooked.
5 And with iodine-131 therapy as an example,
6 the potential risks associated with this type of
7 treatment are such that perhaps 80 hours is
8 sufficient. But when you are talking about treatment
9 to the liver, to the lung, other treatments that might
10 have potentially fatal consequences if not
11 administered properly, I do think that it is very
12 prudent to have a set number of hours as a minimum
13 level of training. And that's why I would propose in
14 favor of having hours stated.
15 CHAIRMAN MALMUD: Dr. Nag?
16 MEMBER NAG: Dr. Thomadsen, I thought in
17 your second or third slide, it had shown you had
18 already said that the members of the subcommittee had
19 agreed on 80 hours. So why is the number of hours
20 coming up again if the subcommittee members had agreed
21 on 80 hours?
22 MEMBER THOMADSEN: These are again the
23 three areas of training. The first is basic
24 radiological sciences. That's mostly didactic
25 training. And that is where we have the 80 hours for

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1 this curricula.

2 The next is specific for the modality.

3 And that's where we have these lists of these types of

4 training, which would be didactic and laboratory,

5 which we have not set the hours for yet. The 80 hours

6 was for the basic radiological sciences.

7 We now have the specific modality

8 treatment that we have not set hours for. The

9 subcommittee did not either. We were divided on that

10 issue.

11 CHAIRMAN MALMUD: Thank you.

12 Does that answer your question, Dr. Nag?

13 MEMBER NAG: Yes.

14 CHAIRMAN MALMUD: I think we have a member

15 of the public, then Dr. Eggli.

16 MR. STAINKEN: Thank you very much. Brian

17 Stainken for SIR.

18 As far as modality-specific training, I

19 would submit to the Committee that the critical

20 training relates to the understanding of

21 catheterization, the technical experience, and

22 microcatheterization, understanding of the flow

23 dynamics, particularly in the liver collateral

24 circulation particle flow and distribution, and a

25 fairly sophisticated understanding of the dynamics of

DRAFT

1 the bed in which one is working.

2 This is gained through both a diagnostic

3 residency and certification there as well as the

4 fellowship in interventional radiology and the second

5 step of certificate-added qualification after a year

6 of fellowship. Those aspects, unlike a radioisotope

7 that might be orally, are critical to the effective

8 performance of the procedure.

9 Thank you.

10 CHAIRMAN MALMUD: Thank you.

11 Dr. Eggli?

12 MEMBER EGGLI: I think I have to do it in

13 hoops. I was supporting the general 80 hours, not an

14 additional 80 hours, of modality-specific training.

15 When I treat a patient with radioactive

16 iodine who has lung metastases, I can cause pulmonary

17 fibrosis and kill the patient. If I treat a patient

18 with limited bone marrow reserve with radioactive

19 iodine, I can kill the bone marrow and subsequently

20 kill the patient.

21 The patient complaint that I have had most

22 commonly that caused patients to refuse further

23 treatment is the management of the possible risk of

24 zero stoma.

25 So I would argue that there are both

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1 life-threatening and disabling consequences of
2 treatments that fall in the part 300 range that I
3 think are of similar magnitude to the microsphere
4 treatment of the liver.
5 So I will say I misunderstood the
6 question. I would not support any additional
7 modality-specific training. I think that the risks of
8 this treatment are quite comparable to a part 394
9 treatment. And I would not support any additional
10 training requirement beyond the 80 hours of basic
11 radiologic science.
12 CHAIRMAN MALMUD: Thank you for clarifying
13 your position, Dr. Eggli.
14 Dr. Howe?
15 DR. HOWE: I wanted to kind of expand upon
16 something Dr. Eggli said earlier and also to clarify.
17 When NRC revised 35-300 area and added 396, 396 can't
18 really be equated to 392 or 394. Three ninety-two and
19 394 were meant primarily for endocrinologists that
20 were treating a single organ. And so those 80 hours
21 pretty much stand alone.
22 If you look at 396, that was an expansion
23 upon an ability for a group that already had three
24 years of residency training or three years of clinical
25 experience in 400 uses or 600 uses.

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1 So the radiation safety basis for the 396
2 people is much more extensive than for the 392 and 394
3 for a reason. And that's why we accepted 80 hours
4 with the 396 people, because they had much more
5 extensive radiation safety patient training.
6 CHAIRMAN MALMUD: Thank you, Dr. Howe.
7 Dr. Thomadsen? Are the questions that you
8 raised resolved in your mind with respect to the
9 Committee's opinion?
10 MEMBER THOMADSEN: No. Before we get out
11 of here for the break, I think we need to have a time
12 set on this. As far as a lot of the radiation safety
13 problems with this, the modality is a
14 multidisciplinary treatment, where there is either a
15 medical physicist or a radiation oncologist present.
16 So addressing many of the radiation safety
17 problems would probably fall to those people. And the
18 interventional radiologists, who may not have as much
19 experience with preventing spills and addressing
20 contamination due to the spills, would have the backup
21 of people who are trained and certified in that, those
22 types of issues.
23 So I would suggest that the duration here
24 of 80 hours would also be sufficient. And I would put
25 that forth as a proposal for this list of training.

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1 CHAIRMAN MALMUD: You are proposing that
2 80 hours would be sufficient for the use of yttrium
3 microspheres in the liver?
4 MEMBER THOMADSEN: For the interventional
5 radiologists in this listing. That's assuming that
6 they have gone through a residency. We could specify
7 that in the part 3, like this, the interventional
8 radiologist, who is applying for Authorized User
9 status for the microspheres has completed a three-year
10 residency in radiology. We could do that also.
11 CHAIRMAN MALMUD: Other comments? Dr.
12 Stainken?
13 MR. STAINKEN: I believe I was after Dr.
14 Guiberteau, but I would be glad to proceed if you
15 choose. Several quick comments.
16 The radiology residency is four years
17 after a one-year clinical internship. Subsequent to
18 that, interventional radiologists complete a one-year
19 fellowship, all of which go through the American Board
20 of Radiology certification process.
21 The issue specific to Y-90, we believe
22 that are unique aspects to the arterial delivery of
23 these radioisotopes. Technically it's performed in a
24 fairly well-controlled sterile environment, with a
25 sterile operator being the interventional radiologist.

DRAFT

1 We believe in many centers across the
2 country, teams have been formed with IRs, radiation
3 safety, radiation oncology, which are working well.
4 And we endorse that. Likewise, there were teams that
5 had been formed with nuclear medicine and radiation
6 safety and interventional radiology.
7 What we are seeing in the community,
8 however, is that there appears to be a greater need
9 for these procedures than capacity to form these sorts
10 of teams can provide for.
11 What we're seeing is upwards of 170,000
12 new patients a year presenting with colorectal
13 liver-dominant disease and hepatocellular carcinoma,
14 the majority of which are unresectable, and can
15 potentially profit personally from this sort of
16 treatment.
17 We see this as an access issue. We
18 believe that the combination of residency training,
19 fellowship training, observed experience, and a
20 focused course specific to the delivery of Y-90 will
21 provide a pool of safe operators and give more
22 patients access to this important therapy.
23 Thank you.
24 CHAIRMAN MALMUD: Thank you for your
25 comments. I have only observed two of these

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1 procedures and don't pretend to be an expert in them.
2 Clearly, the skill of the interventional
3 radiologist is an essential component to delivering
4 the microspheres. And that skill resides from my
5 observation only with the interventional radiologist.
6 There's no one else on the team who has the ability
7 to provide that service.
8 With respect to the radiation issues,
9 however, the interventional radiologist is not the
10 individual who traditionally, at least in our
11 environment -- and I admit to very limited experience
12 with this -- has the routine ability to identify the
13 dose to be administered and who has the experience in
14 handling the radioactive material. There is always
15 some other person there, whether that is a physicist,
16 a nuclear physician, or a radiation oncologist.
17 Would you agree or is my perception from
18 my limited experience not valid?
19 MR. STAINKEN: Well, certainly from the
20 perspective of the regulations as they currently
21 stand, that would be accurate because that is a
22 requirement of the regulations that the Authorized
23 User be present.
24 As an interventional radiologist
25 Authorized User personally, I can speak to those

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1 issues. I think that it is an issue of focused
2 competency.
3 I think that this therapy, in particular,
4 has been addressed earlier, the whole issue of
5 dosimetry, how the dose is delivered, flow dynamics in
6 the area of the presence or absence of collaterals in
7 terms of determining target or this is off-target
8 delivery are critical. It's a lot of expertise, a lot
9 of unique and unusual perhaps expertise that's
10 required toward accurate dosimetry.
11 We are certainly moving into a phase where
12 it also may be driven to some degree by the type of
13 histology or in the nature of the tumor in terms of
14 how dosimetries performed.
15 I would submit to you that what is
16 required is focus and expertise. I believe that that
17 can be obtained through a team of radiation oncology
18 in IR with radiation safety nuclear medicine, IR with
19 radiation safety as well, as IR plus radiation safety
20 presence as long as that IR is sufficiently expert.
21 What we are proposing is a process to
22 document and validate that, in point of fact, they can
23 meet that standard.
24 CHAIRMAN MALMUD: I'm not sure that I
25 understand. And you'll pardon my confusion.

DRAFT

1 To me it is axiomatic that the key person
2 here is the interventional radiologist. Now, who
3 calculates the dose? That's my question. Are you
4 suggesting that a interventional radiologist himself
5 or herself be the individual who does the initial
6 calculation of what percentage of the liver is
7 involved and the dose to be administered, not under
8 the current regulation but under the theory that in
9 order to provide this therapy to the latest number of
10 patients possible, that the interventional radiologist
11 have this responsibility? Is that what --
12 MR. STAINKEN: In centers where the
13 interventional radiologist is the Authorized User, the
14 expectation would be that the interventional
15 radiologist will perform the dose calculation and sign
16 off on the prescription.
17 In institutions where the Authorized User
18 is someone other than the interventional radiologist,
19 that responsibility would go to that individual.
20 CHAIRMAN MALMUD: Well, in a situation in
21 which the interventional radiologist is an Authorized
22 User, that interventional radiologist would be sole a
23 practitioner who is doing the catheterization and also
24 calculating the shunting, if you will, calculating the
25 dose to the liver without any other necessary skills

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1 from radiation oncology or physics or nuclear
2 medicine?
3 MR. STAINKEN: That's correct. And that's
4 currently my practice. And, actually, other people
5 around the country are interventional radiologists,
6 Authorized Users.
7 CHAIRMAN MALMUD: I just want to make sure
8 that the Committee understands what the proposal is.
9 Dr. Suleiman?
10 MEMBER SULEIMAN: All right. With a
11 little prodding from Dr. Eggli, this is an area that
12 when I started to look into it, I was very surprised.
13 Dosimetry in the classical sense is not conducted
14 here.
15 The imaging is done to make sure that
16 there is no contraindication that most of the
17 particles are going to the liver. The distribution in
18 the liver is not uniform or homogenous.
19 They're not calculating dose per for the
20 target organ. These are refractory patients,
21 humanitarian use label. It is not dosimetry at all in
22 the classical sense.
23 Maybe somewhere down the line people will
24 image, determine the volume of the tumor, somehow
25 deliver an accurate within maybe 100 or 200 percent

DRAFT

1 absorbed dose. It's not being done here. This is not
2 X-ray beam therapy, external beam therapy, or
3 brachytherapy.
4 So the skill here is in the delivery of
5 the radioactivity to the patient and hopefully that
6 it's going primarily to the liver and not getting
7 sidetracked through the vascular system elsewhere.
8 CHAIRMAN MALMUD: If I may, Dr. Suleiman,
9 but the issue is not hopefully because there has to be
10 someone with the skill -- and that could be the
11 interventional radiologist if the interventional
12 radiologist has a skill to make certain that the
13 shunting is not excessive because then the injected
14 material will not go solely to the liver.
15 MEMBER SULEIMAN: Oh, absolutely. I agree
16 with that.
17 CHAIRMAN MALMUD: So it is an issue of
18 concern about delivery of radiation to a portion of
19 the body that was not intended to receive it? That's
20 the issue. I agree that it's not an issue of
21 dosimetry in the classical sense. I just want the
22 Committee to understand it. That's all I'm trying to
23 do.
24 Dr. Eggli?
25 MEMBER EGGLI: But that estimate of the

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1 shunting to other critical organs is really done by a
2 fairly standard nuclear medicine procedure with
3 regions of interest and percent activity shunted.
4 And regardless of whether or not the
5 interventional radiologist is the AU, odds are some
6 nuc med doc or radiologist with a region of interest
7 program in standard clinical nuclear medicine software
8 will contribute that part of the determination as
9 typically MAA has shut down the catheter and the
10 distribution as a percent of activity in the field of
11 view in the lung or in the stomach is reported.
12 And, again, the other second thing is we
13 don't prescribe a dose. We prescribe an activity to
14 be administered. And to me the key thing is knowing
15 when to turn off the pump because you are seeing
16 reflux of activity outside of that distribution.
17 And I think that the interventional
18 radiologist is well-qualified to do these things with
19 the proper software support. I see the interventional
20 radiologist as well-qualified to determine the percent
21 of activity administered that resides outside the
22 liver in either the lung or the stomach.
23 CHAIRMAN MALMUD: Thank you.
24 I am not sure that I heard you say that he
25 is or is not qualified to determine.

DRAFT

1 MEMBER EGGLI: Is well-qualified.

2 CHAIRMAN MALMUD: Well-qualified. Good.

3 Okay. Thank you.

4 Dr. Nag?

5 MEMBER NAG: Thank you. At one point Dr.

6 Suleiman's statement about users, but there is only

7 one TheraSphere. What it says here, it is

8 FDA-approved for use for the past uses for colon

9 cancer. So that does seek clarification.

10 I think in our previous ACMUI meetings, we

11 have already, the ACMUI had already, solved the

12 problem. We have said that interventional

13 radiologists could be Authorized Users.

14 I think the only work at hand now is what

15 are the additional qualification and additional

16 experience that are needed by an interventional

17 radiologist to become qualified as an AU.

18 So we have already agreed that we are the

19 best person to know where to place the catheter, how

20 to place the catheter. All of that has already been

21 solved. Therefore, I don't see a need to discuss

22 whether interventional can be Authorized User or not.

23 We have already voted on that, and we had said yes.

24 So the additional thing that they need to

25 know is how to help make how many millicuries to be

DRAFT

1 placed in, who are the proper candidates to be done
2 because if you are not having a nuclear medicine
3 person or a radiation oncology person involved, they
4 need to do that. You just have to add those persons
5 in.
6 So I think we have only a limited amount
7 of work left to solve this problem.
8 CHAIRMAN MALMUD: Exactly. Now, from the
9 prior meetings of the ACMUI, did we not agree that
10 three cases would be sufficient, the experience of
11 three cases would be sufficient?
12 MEMBER NAG: Yes.
13 CHAIRMAN MALMUD: So that if the
14 interventional radiologist is the Authorized User and
15 has experience with three cases supervised, he or she
16 is now qualified to do this procedure in his or her
17 institution.
18 MEMBER NAG: Right. And having these 80
19 hours, we have agreed on 80 hours also, right?
20 MEMBER THOMADSEN: The 80 hours at the
21 basic radiological sciences. We have not agreed on,
22 first, whether we want to place a number of hours on
23 this list or just use this list as a check sheet of
24 what things they have to have had. And if we want a
25 number of hours, how many hours would be covered by

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1 it.

2 CHAIRMAN MALMUD: That's why I asked my

3 question. I wanted the Committee to understand what

4 we are discussing so that when the Committee makes a

5 recommendation, it will be on the basis of your

6 summary.

7 Dr. Guiberteau?

8 MEMBER GUIBERTEAU: I think it might be

9 informative to learn or be reminded by one of our

10 interventional radiologists what sort of training is

11 provided since this was originally coming to us as a

12 device, what sort of training for interventional

13 radiologists is provided by the manufacturer.

14 CHAIRMAN MALMUD: Thank you, Dr.

15 Guiberteau. We have actually had that review at prior

16 meetings.

17 MEMBER GUIBERTEAU: I understand. I know

18 we are --

19 CHAIRMAN MALMUD: You are reminded of it?

20 MEMBER GUIBERTEAU: Well, I think just in

21 terms of -- we're talking about three cases, but I

22 think it wouldn't be a bad idea to have at least two

23 minutes to hear again so that the Committee can be

24 reminded that there is some additional training

25 involved because we have heard about reflux through

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1 the catheters, et cetera.

2 But these were major concerns because

3 these are the things that lead to what you have been

4 talking about. And that is the appearance of Y-90

5 microspheres in places where it was not intended to

6 be.

7 CHAIRMAN MALMUD: I am happy to have it

8 reviewed. Though the Committee has already approved

9 it, I am happy to have it reviewed for historical

10 purposes. Who would care to review that?

11 MR. SALEM: I guess I can do that.

12 CHAIRMAN MALMUD: Please introduce

13 yourself again.

14 MR. SALEM: Riad Salem, interventional

15 radiologist.

16 So just to go over what we had discussed

17 last time for the training, there are two

18 manufacturers of the microspheres: Sirtex Medical and

19 MDS Nordion.

20 Sirtex Medical provides on-site support

21 and proctoring by physicians that are Authorized Users

22 for three infusions. And I think Dr. Malmud mentioned

23 that he was -- that's the treatment that he underwent

24 for MDS Nordion and TheraSpheres. They actually put

25 on a course that actually we administer at

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1 Northwestern for all sites that are starting. And I
2 believe Mr. Lieto and Dr. Thomadsen, in fact, have
3 been to that course.
4 So there are two different mechanisms.
5 And, in fact, the Committee has reviewed them last
6 time and has approved that either mechanism is
7 appropriate.
8 CHAIRMAN MALMUD: Thank you.
9 Dr. Guiberteau, is that sufficient for
10 your suggestion?
11 MEMBER GUIBERTEAU: Yes, it is.
12 CHAIRMAN MALMUD: Thank you.
13 Dr. Welsh?
14 MEMBER WELSH: Well, I have a question
15 that may be relevant to this matter at hand. And the
16 question is, during diagnostic radiology residency
17 training, do all of the residents receive the 80 hours
18 that we're talking about here?
19 The question, of course, is relevant
20 because if they do, that would mean they aren't
21 qualified to do SIR-Spheres and TheraSpheres because
22 of their residency training and not necessarily have
23 to have additional hours and training during their
24 interventional radiology fellowship.
25 I might have some comments and questions

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about that depending on your answer. Can anybody answer that question?

CHAIRMAN MALMUD: Dr. Guiberteau?

MEMBER GUIBERTEAU: Under the current residency programs, our residents in diagnostic radiology, which would include budding interventional radiologists, does include 80 hours. That 80 hours falls under 392 at the moment -- we are in the process of requesting an expansion of that -- plus 700 hours of training and experience under 390.

MEMBER WELSH: Thank you.

If I may continue with that?

CHAIRMAN MALMUD: Please do.

MEMBER WELSH: So then I would ask this Committee as well as our interventional radiologists who are in the public audience today if we are all in agreement that the 80 hours that are obtained during diagnostic radiology training are truly sufficient for microsphere brachytherapy.

I can tell you in my opinion additional training specifically in radiation safety, radiation biology, and the medical aspects of this particular procedure may be appropriate.

But I just raised the question because the question I had about the number of hours doing

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1 radiology training.

2 CHAIRMAN MALMUD: Dr. Eggli?

3 MEMBER EGGLI: I would agree with one of

4 the three issues that Dr. Welsh raises on the specific

5 radiation safety of handling microspheres for therapy.

6 But that's provided in the additional training that

7 one has to receive to become certified.

8 Again, I think anyone who has met the

9 threshold and, again, as ABR goes back and I believe

10 upgrades for 394, then I believe that they have had

11 sufficient radiation biology for this purpose, again

12 given the very primitive state of dosimetry that Dr.

13 Suleiman has already described.

14 So I would agree that any end user needs

15 specific training in the handling of particulate

16 unsealed source, which is effectively at, behaves as

17 therapeutic agents. But that is provided in the

18 specific training that's required.

19 CHAIRMAN MALMUD: Thank you, Dr. Eggli.

20 Dr. Nag?

21 MEMBER NAG: I would like to make sure

22 that we do not leave any unintended consequence. We

23 are now dispensing how and in terms of interventional

24 radiologists who could become an Authorized User. So

25 we are starting with the assumption based on

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1 assumptions that these are going to be for diagnostic
2 radiologists who have then also undergone
3 interventional training because they have already had
4 quite a lot of training in radiation.
5 What I do not want to happen is that
6 sometimes the way it is written, that portion is
7 missed. And someone from a different specialty, maybe
8 medicine or someone, a medical oncologist, for
9 example, can say, "Well, I'm only going to do this 80
10 hours." And they are not fully qualified because they
11 would not have had many of the other general radiology
12 training.
13 Dr. Thomadsen, could you make sure that we
14 do not create a report like that?
15 MEMBER THOMADSEN: After we finish with
16 the discussion of the eight, we will terminate with
17 discussion of a similar requirement to this specifying
18 that they have completed three years supervised
19 clinical experience in diagnostic radiology with
20 particular emphasis on interventional.
21 MEMBER NAG: Yes. I think that will help
22 to put that in.
23 CHAIRMAN MALMUD: Thank you, Dr. Nag.
24 Dr. Thomadsen? The ball is back in your
25 court, Dr. Thomadsen. What are you seeking from the

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1 Committee at this point?

2 MEMBER THOMADSEN: Well, I would hear Mr.

3 Lieto's comments since he has I think been waiting.

4 CHAIRMAN MALMUD: Oh, I am sorry. I

5 didn't see you raise your hand, Ralph.

6 MEMBER LIETO: Just regarding the list

7 here, I had just a question on clarification. It's

8 not really clear to me where the specific training

9 requirements for dose calibrators or devices used to

10 measure dosages is in that list. And I am wondering

11 if we should maybe add a specific line item to that

12 effect. That was one question.

13 And just a comment regarding the training.

14 I think we need to be careful because if we're

15 looking at using the diagnostic radiology residency

16 training as documentation of adequate training and

17 experience, we need to be careful because there is

18 also a requirement that when they apply to become an

19 Authorized User, that has been completed within a

20 seven-year period.

21 So if you have somebody doing a residency

22 and completing their training and they don't apply for

23 this Authorized User application until beyond that

24 time period, they're still going to have to go through

25 this 80-hour requirement again anyhow.

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1 CHAIRMAN MALMUD: Thank you, Mr. Lieto.
2 Dr. Guiberteau?
3 MEMBER GUIBERTEAU: Well, I want to point
4 out several things in terms of the diagnostic
5 radiology certification process. There is a portion
6 of the examination dedicated only to radiation biology
7 that must be passed by all of the diagnostic
8 radiologists.
9 I think in section 392, which is also part
10 of the certification process, there are a number of
11 items here, in fact, many items, that overlap with the
12 390 and with the items up here, including calculating,
13 measuring, and safely preparing patient and human
14 research subject dosages.
15 And in this case, as we have pointed out,
16 the administered activity is the most important aspect
17 of this therapy. So that this training is what is
18 included in the current process.
19 CHAIRMAN MALMUD: Thank you, Dr.
20 Guiberteau.
21 So, if I may, Dr. Thomadsen, it seems to
22 me that what the Committee is saying is that we
23 recognize that an interventional radiologist is, first
24 of all, a radiologist who has received the requisite
25 number of hours of training, that the interventional

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1 radiologist, in addition, has the skills of the
2 interventional radiologist which are necessary,
3 essential for the performance of the actual delivery
4 of the material into the blood vessel and that if the
5 interventional radiologist is an Authorized User, that
6 that individual is the captain of the ship for this
7 procedure and assumes the responsibility for the
8 procedure having been done correctly, whether or not
9 the interventional radiologist has working with him a
10 radiation oncologist, a nuclear physician, or a
11 radiation physicist. Is that a fair summary of what
12 the Committee has said?
13 MEMBER GUIBERTEAU: Yes.
14 CHAIRMAN MALMUD: Hearing no comment --
15 MEMBER NAG: Yes.
16 CHAIRMAN MALMUD: Oh. Dr. Nag?
17 MEMBER NAG: I would agree with your
18 comments except for one part, which is that even when
19 a radiation oncologist, like me, is involved, I still
20 have a radiation physicist who is helping in many of
21 the calculations. So I would not be very open to
22 excluding a radiation physicist from that group.
23 CHAIRMAN MALMUD: Well, I would ask you a
24 question, then. Do your requirements in providing
25 radiation oncology require that you have a radiation

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1 physicist backing you up or may you practice without
2 the physicist if you wish?
3 MEMBER NAG: We basically supervise the
4 physicists, but I need detailed calculations through
5 the physicists. And I think, Dr. Thomadsen, if you
6 would like to make some comment? We depend for many
7 of our calculations on our physicist.
8 CHAIRMAN MALMUD: Dr. Eggli?
9 MEMBER EGGLI: I think generally that's
10 true. But, again, to come back to Dr. Suleiman's
11 point, there are no detailed calculations occurring in
12 this procedure.
13 CHAIRMAN MALMUD: We agree. We agree. My
14 question to Dr. Nag was of a different nature. And
15 that is that in order for you to provide radiation
16 oncology, is it a requirement in writing that you must
17 have a physicist participate in the case with you.
18 MEMBER NAG: In many of the subparts; for
19 example, in HDR brachytherapy, you use an Authorized
20 User and a physicist, too. There is at least a
21 subpart of radiation oncology where we need the
22 critical calculations.
23 CHAIRMAN MALMUD: The reason I am asking
24 the question is that if that applies to radiation
25 oncology, then there would be a logical extension for

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1 that to apply here with regard to radiation safety.
2 But if it's not a requirement, then you as the captain
3 of your ship in providing radiation oncology can
4 provide a therapeutic program without the
5 participation of the physicist if you choose to do the
6 calculations yourself.
7 MEMBER THOMADSEN: Can I? Just a point of
8 order.
9 CHAIRMAN MALMUD: Dr. Thomadsen?
10 MEMBER THOMADSEN: I don't think that this
11 is really germane to this discussion.
12 CHAIRMAN MALMUD: Okay.
13 MEMBER THOMADSEN: We're only talking
14 about whether the interventional radiologist can serve
15 the function of the Authorized User. And it's not
16 dealing with anything different about how the
17 procedure is being done.
18 CHAIRMAN MALMUD: Of course, you're
19 correct, but the purpose of my question was to avoid
20 putting into a regulation or a standard of practice
21 something that would constrain the interventional
22 radiologist from performing the procedure in an
23 institution that is not a large institution that
24 doesn't have a large staff in order to provide the
25 service to the patient.

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1 Not all of us are large university
2 hospitals or very large institutions. And the
3 incidence of the potential application of this therapy
4 we have heard might be as great as 170,000 cases a
5 year.
6 I doubt that they are all going to get it,
7 get that therapy, but the point is that that is the
8 incidence of the disease, metastases to the liver.
9 DR. STAINKEN: That's correct.
10 CHAIRMAN MALMUD: So I am just trying to
11 make sure that all of us understand what we are voting
12 for and about. Now, what is the question remaining on
13 the table?
14 MEMBER THOMADSEN: Mr. Lieto still has a
15 --
16 MEMBER LIETO: No. I was just going to
17 answer the Chairman's question in that my
18 understanding is that what we're voting on is the
19 training and experience requirements to authorize IRs
20 to function independently as Authorized Users without
21 necessarily the presence of medical physics, radiation
22 oncology, or nuclear medicine involvement.
23 CHAIRMAN MALMUD: And we know that they
24 have the 80-hour requirement because they are
25 board-certified and they received it in the course of

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1 their residency. So now that we know that they have
2 that 80 hours and we also know that from our previous
3 discussions we are requiring participation in three
4 cases or attendance of that course depending upon the
5 product, the question is, do we want to require
6 anything more by virtue of number of hours? Isn't
7 that your question on the table?
8 MEMBER THOMADSEN: I will make a motion
9 right now --
10 CHAIRMAN MALMUD: Please do.
11 MEMBER THOMADSEN: -- that the training
12 and experience for interventional radiologists would
13 include: one, the list that we have already used;
14 two, is this list with the addition of another Roman
15 numeral dealing with the operation and quality
16 management or operation of dose calibrators without
17 specification of hours; and a third part specifying
18 completion of three years supervised clinical
19 experience in radiology with particular concentration
20 in interventional radiology.
21 CHAIRMAN MALMUD: That's a motion. Is
22 there a second to the motion?
23 MEMBER NAG: I will second to the motion.
24 I was going to make a similar motion anyway. So I
25 will second it.

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1 CHAIRMAN MALMUD: Thank you.

2 Discussion of the motion? Dr. Eggli?

3 MEMBER EGGLI: My only concern is the
4 question of the dose calibration because it is very
5 difficult with the standard dose calibrator to
6 calibrate a Y-90 dose. And typically you rely on the
7 statement of activity provided by the provider of the
8 dose, who has better capability of measuring the
9 actual activity. And then you apply an NEK
10 correction, which may be necessary based on time of
11 administration.

12 So I'm not sure that we need a specific
13 statement about calibrating doses in a dose calibrator
14 because, again, betas are notoriously difficult to
15 calibrate in a dose calibrator.

16 CHAIRMAN MALMUD: Thank you, Dr. Eggli,
17 for reminding us of that. You're correct, of course.

18 Dr. Howe?

19 DR. HOWE: I was just asking for a
20 clarification. In the discussion ACMUI is having
21 right now, the proposal that Dr. Thomadsen has put up
22 does not require board certification. And when you
23 are discussing it, you keep saying that because they
24 have board certification, we know they have this. But
25 that is not in the criteria.

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1 CHAIRMAN MALMUD: Thank you for bringing
2 that to our attention. Dr. Thomadsen, did your
3 recommendation include board certification?
4 MEMBER THOMADSEN: Well, it did not
5 because I was mostly thinking of this as how we can
6 specify for the alternate way. And I take that as
7 almost a friendly amendment that we should specify
8 board certification as we normally would, however we
9 normally would do that nowadays for these people.
10 But that would be covered by the three
11 years supervised clinical experience.
12 CHAIRMAN MALMUD: Are you suggesting that
13 the three years of supervised clinical experience
14 would be instead of board certification?
15 MEMBER THOMADSEN: As the alternate
16 pathway.
17 CHAIRMAN MALMUD: So either board
18 certification and/or three years of supervised
19 clinical experience?
20 MEMBER THOMADSEN: Yes.
21 CHAIRMAN MALMUD: Is that acceptable? Can
22 we have a discussion? Mr. Lieto first.
23 MEMBER LIETO: Well, I would ask our
24 visitors in terms of becoming an interventional
25 radiologist, are there interventional radiologists who

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1 are not board-certified?

2 CHAIRMAN MALMUD: Please?

3 MEMBER LIETO: I would be real reluctant

4 to have such an alternate pathway required.

5 CHAIRMAN MALMUD: Okay. Let's get the

6 question answered.

7 MR. MAURO: Thank you, Mr. Chairman. My

8 name is Matt Mauro. I am actually chairman of the

9 Interventional Radiology Commission and one of the

10 Board of Chancellors of the American College of

11 Radiology.

12 My answer is that currently everyone who

13 is practicing this level of therapy are subspecialty

14 trained and board-certified interventional

15 radiologists. And from our perspective, we will

16 support the notion of requiring board certification.

17 And, in addition, we support Dr. Thomadsen's notion of

18 requiring added training in interventional radiology

19 for this type of experience.

20 CHAIRMAN MALMUD: Therefore, there is

21 enthusiastic support from the representation of

22 interventional radiologists that board certification

23 be included in diagnostic radiology.

24 Dr. Eggli?

25 MEMBER EGGLI: This may be a regulatory

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1 question. I realize that most regulations have
2 definitions up front, but maybe as a portion of the
3 credentialing for this, we could describe the
4 qualification, the base qualifications, of what it is
5 to be an interventional radiologist.
6 CHAIRMAN MALMUD: I can't answer that
7 without asking an interventional radiologist to
8 comment. Dr. Thomadsen, do you want to say something?
9 MEMBER THOMADSEN: Yes. Just to question,
10 a legal question, is there a problem with that with
11 restraint of trade? I mean, I think the reason why
12 there are alternative pathways is to avoid that
13 problem. I don't think this is any different from
14 anything else.
15 CHAIRMAN MALMUD: Dr. Howe?
16 DR. HOWE: I don't know if I can answer
17 that, but I will tell you that we call the alternate
18 pathway the alternate pathway. The alternate pathway
19 historically has been the primary pathway because it
20 was the first pathway. And then board certifications
21 came later.
22 I think NRC might have difficulty figuring
23 out what interventional radiology boards because there
24 may be more, there may be more groups that want -- if
25 you put criteria in there, there may be more groups

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1 that want to come under that that you may not have
2 considered. You just have to be very careful. And
3 that's probably something that OGC has to answer.
4 CHAIRMAN MALMUD: Then would your motion
5 be amended acceptably if it said either satisfying the
6 alternate pathway for radiologists or a board
7 certification in radiology plus the training in
8 interventional radiology? Would that be acceptable?
9 MEMBER THOMADSEN: Almost, with the
10 wording that I had used before, with the supervised
11 training in radiology plus a -- I think it was a
12 concentrated training in interventional. Then it
13 would be acceptable.
14 I think the task of the subcommittee was
15 essentially to define the alternate pathway, what
16 would be the acceptable training and experience other
17 than just saying board-certified radiologist?
18 CHAIRMAN MALMUD: Dr. Eggli?
19 MEMBER EGGLI: What if you were to take
20 this statement and add to that "which includes at
21 least one year of training in interventional
22 radiology"?
23 MEMBER THOMADSEN: I would like that
24 myself if that would be acceptable. I would consider
25 that a very friendly amendment.

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1 CHAIRMAN MALMUD: May I ask the
2 interventional radiologist who was our guest today to
3 comment on that?
4 MR. SALEM: We would enthusiastically
5 support that.
6 CHAIRMAN MALMUD: It has enthusiastic
7 support of interventional radiology. May we move on
8 with the motion then? Another comment? Steve?
9 MEMBER MATTMULLER: Yes. Another friendly
10 amendment. I'm not sure whether it belongs on this
11 page or the previous page. I know we have discussed
12 this in past discussions, and I haven't seen it quite
13 yet, the requirement that -- I'm trying not to say
14 interventional radiologist, IR, but the individual
15 would also complete specific training from the
16 specific manufacturer of the product that they are
17 going to use.
18 MEMBER THOMADSEN: That's already --
19 MEMBER MATTMULLER: Is that?
20 MEMBER THOMADSEN: Yes.
21 MEMBER NAG: I think it's in there.
22 CHAIRMAN MALMUD: We've done that
23 previously.
24 MEMBER THOMADSEN: That's not in here.
25 That's already in the requirement for performing the

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1 procedures. They cannot perform the procedure without
2 specific training for participation in three cases.
3 That's outside of this scope. It's already in
4 authorization to do the procedure.
5 Whether you are an interventional
6 radiologist Authorized User or radiation oncology
7 Authorized User, that requirement stays.
8 CHAIRMAN MALMUD: Thank you.
9 Ashley, you had your hand up.
10 MS. COCKERHAM: Actually, I just would
11 like you to come back to me before you vote so I can
12 clarify exactly what I have written down is going to
13 be your actual recommendation.
14 CHAIRMAN MALMUD: We will do that before
15 we vote.
16 MS. COCKERHAM: Thank you.
17 CHAIRMAN MALMUD: We have two more
18 comments, I believe. Dr. Van Decker?
19 MEMBER VAN DECKER: The dumb guy from
20 north Jersey still needs a clarification, I guess. So
21 this magic three patients, that's then going to be in
22 guidance for the procedure? And does it need to be in
23 rulemaking space that will be considered a requirement
24 of any of the people being involved in the procedure?
25 Is that the way we envision this? What

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1 space does that sit in? This is going to go in some
2 category of point whatever, right? And so the
3 question is, where does this other requirement go?
4 How does it get linked?
5 CHAIRMAN MALMUD: The space experts are
6 here. Dr. Howe? Dr. Zelac?
7 MEMBER SULEIMAN: If you will recall, when
8 we first started on microspheres, it was only
9 specifically the radiation oncologists that were the
10 Authorized Users, acceptable Authorized Users. And it
11 was easy in the guidance to indicate who those persons
12 were because we have a category in the regulations
13 already under 490.
14 So simply saying under 490 or 690, I think
15 it says, the person could be an Authorized User, then
16 subsequently be considered nuclear medicine
17 physicians. And who from that group could have
18 appropriately also be considered as an Authorized
19 User? And, again, it was easy to do because it was
20 simply a reference to 390.
21 Here for interventional radiologists,
22 however, we have a difficulty because there is no
23 section in the regulations who can easily be
24 referenced by a number when stating who the Authorized
25 User should be.

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1 So that's why we're getting more specific
2 here as to exactly what the qualifications should be
3 for an individual whom I'll call the interventional
4 radiologist to be named as the Authorized User.
5 DR. HOWE: Dr. Malmud, also to clarify in
6 space, microspheres are in 35-1000. So the
7 requirements for using the microspheres are currently
8 posted on the Web site and can be revised in a much
9 easier manner than if they were in the regulations.
10 And, as Ashley said earlier today, we are
11 still seeing evolution of the microsphere use. So we
12 are not putting it into rulemaking space until the one
13 after the 2009. We're hoping it's stabilized by then.
14 So it's in 1000 space.
15 CHAIRMAN MALMUD: Thank you.
16 Does that answer your question, Dr. Van
17 Decker?
18 MEMBER VAN DECKER: Yes and no. It
19 answers my question that the 3 is in 1000 space right
20 now, which is what I would have assumed. And then
21 when it comes out, then it would have to go in here
22 somewhere I would assume.
23 DR. HOWE: And the decision of where it
24 goes hasn't even been started to be made.
25 CHAIRMAN MALMUD: Thank you, Dr. Howe.

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1 Dr. Nag?

2 MEMBER NAG: Two friendly amendments. One
3 would be taking it out of calibration and putting it
4 as someone should have experience and training in the
5 three calculations, instead of calibrator, since
6 calibrator is probably not appropriate or not needed
7 in this case.

8 And the second amendment would be that we
9 put the three cases -- we bring the training here
10 because for diagnostic radiologists, they do not have
11 three cases or they do not have the space, like we do
12 for 490, 690, or 390. So that's the three cases
13 through the training requirements right here.

14 MEMBER THOMADSEN: I don't consider either
15 of those friendly. The last, I think since we have
16 not put three cases in anywhere for the radiation
17 oncologists or the nuclear medicine physicians, I
18 don't think this is the appropriate place to put this
19 at this given time.

20 And if it moves out of part 1000 and we
21 will have to do that for the others, other Authorized
22 Users, that would be the time to figure out where
23 we're going to be putting them. So I would rather
24 wait and be consistent with all the Authorized Users
25 for this procedure at that time.

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1 As far as this calibrator, I disagree
2 heartily with Dr. Eggli as far as the appropriateness
3 of a dose calibrator. I think you do have to know
4 what you are doing if there are peculiarities with
5 dealing with the beta emitter. That's why the
6 training in the dose calibrator is so important.
7 It is also important to check the
8 radionuclide's activity when you receive it. There
9 have been cases where it has not been correct.
10 CHAIRMAN MALMUD: Dr. Eggli, do you wish
11 to respond?
12 MEMBER EGGLI: I understand Dr.
13 Thomadsen's point. And I don't disagree with it.
14 However, currently I guess, then, requiring the use of
15 a dose calibrator to measure this dose on the site is
16 currently not in regulation.
17 I realize it's in the revisions proposed
18 for radioactive iodine, but I don't believe there is a
19 current requirement to actually measure a dose on site
20 that has been precalibrated by a supplier. Am I wrong
21 on that?
22 CHAIRMAN MALMUD: Dr. Howe?
23 DR. HOWE: The microspheres are currently
24 considered as manual brachytherapy. And so I believe
25 in the guidance you're supposed to be following the

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1 criteria in the 35-1000 series. And there you have to
2 either calibrate it or use the manufacturers' numbers.
3 MEMBER EGGLI: But that's either/or.
4 CHAIRMAN MALMUD: That's either/or. Thank
5 you, Dr. Howe.
6 So Dr. Thomadsen would prefer that the
7 motion stand as it is if that is acceptable to you.
8 MEMBER NAG: I am okay with that.
9 CHAIRMAN MALMUD: Thank you.
10 Any more comments before we move on the
11 motion? Dr. Suleiman?
12 MEMBER SULEIMAN: Yes. I would first like
13 to get clarification myself. I am confused about what
14 is exactly on the table. I also want to share my
15 feelings just for the record.
16 As a scientist, when I first got involved
17 with some of these radiotherapeutics, I was basically
18 in shock at the lack of dosimetry. But then I started
19 to realize that these are competing not only with
20 radiation therapy procedures. They're also competing
21 with conventional oncology drugs.
22 And when FDA approves a product, we pretty
23 much defer to the medical community and the practice
24 of medicine and the self-standardization and
25 certification and qualification. So we really don't

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1 get into that level of detail. Maybe sometimes we
2 should, but we don't.
3 And something that still burns in my ear
4 from one of our physicians because we have all sorts
5 of specialists back at the agency and I was arguing
6 with them about the dosimetry and they said, "We have
7 to get these products out because if we make them so
8 restrictive, they may never see the daylight."
9 And these are not necessarily competing
10 with radiation therapy. They're competing with
11 chemotherapy drugs. And there are some inherent
12 advantages.
13 So I am wondering, are we, speaking on the
14 Nuclear Regulatory Commission, the ACMUI, so muddling
15 this? Are we going to handicap the users to such a
16 degree?
17 And I really defer to the medical doctors
18 on the Committee for their opinions on this. But can
19 the profession self-regulate itself sufficiently or
20 does everything have to be specified within 10 CFR?
21 So I am just laying it out there. I think
22 you are going to need a lawyer to figure out what you
23 are supposed to do. And is this going to so inhibit
24 the adoption of some of these therapies that they just
25 won't be used? They'll defer to the alternative

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1 chemotherapy drugs or some other alternative.

2 CHAIRMAN MALMUD: Well, thank you for

3 bringing that concern to us. That was my concern in

4 trying to allow the interventional radiologists to

5 perform this technique because it's the interventional

6 radiologist's skill, the catheterization that is

7 lacking in all the other specialties.

8 So if we don't encumber him or her with

9 unnecessarily regulation, we can move forward. And it

10 seemed to me that Dr. Thomadsen's subcommittee's

11 recommendations fulfilled that need to get the therapy

12 to the patient in the hands of a highly recognized,

13 highly trained group of individuals, meaning the

14 interventional radiologists in this case.

15 So if we may with the motion on the table

16 vote for it, recognizing your concern, our concerns, I

17 think we could achieve some guidance for the use of

18 the therapy.

19 Dr. Nag?

20 MEMBER NAG: I would appreciate Ms.

21 Cockerham and with the Committee, Dr. Thomadsen,

22 review what the motion is after all the amendments

23 have been made to everyone? Because we made some

24 amendments after the initial statement.

25 CHAIRMAN MALMUD: Thank you.

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1 I will ask Dr. Thomadsen to do that since
2 it's his motion.
3 MEMBER THOMADSEN: I would be happy to,
4 and I never thought I would say this. But Mr. Lieto
5 is very shy and has not made himself obvious as he
6 wants to make comments today. But it looks like he
7 has one more comment before we summarize.
8 MEMBER LIETO: Well, I just wanted to
9 clarify the three-case training and experience. It is
10 my assumption that this here is in addition to the
11 three-case training and experience that must be a part
12 of this training and experience to become an
13 Authorized User because it's ubiquitous whether you're
14 a rad onc or a nuc med or an IR. Is that correct?
15 MEMBER THOMADSEN: That is correct, yes.
16 MR. LIETO: Okay.
17 MEMBER THOMADSEN: The proposal on the
18 table, are we ready over there?
19 MS. COCKERHAM: Yes.
20 MEMBER THOMADSEN: And please correct me
21 if you have something I don't have.
22 MS. COCKERHAM: I am going to type it
23 twice.
24 MEMBER THOMADSEN: Training and experience
25 for interventional radiologists desiring Authorized

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1 User status for radioactive microspheres would include
2 80 hours training in this list.
3 I won't read the list because you can
4 capture it from the slides and training that includes
5 these eight items plus a ninth item, which would be
6 the operation and quality management for dose
7 calibrators and --
8 MS. COCKERHAM: Can you repeat that part
9 at the end?
10 MEMBER THOMADSEN: Yes. The operation of
11 and the quality management for dose calibrators and
12 has completed three years of supervised clinical
13 experience in radiology and one year in interventional
14 radiology. Has that captured the amendments that you
15 guys made?
16 CHAIRMAN MALMUD: Yes, I believe that it
17 does.
18 MEMBER THOMADSEN: I think that's it.
19 CHAIRMAN MALMUD: We'll move the motion.
20 All in favor?
21 (Chorus of "Ayes.")
22 CHAIRMAN MALMUD: Any opposed?
23 (No response.)
24 CHAIRMAN MALMUD: Any abstentions?
25 (No response.)

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1 CHAIRMAN MALMUD: Let the record show that
2 the motion moved unanimously.
3 First of all, thank you, Dr. Thomadsen,
4 for a yeoman's job. And congratulations.
5 (Applause.)
6 CHAIRMAN MALMUD: May we take a break now?
7 Thank you. No more than 15 minutes.
8 (Whereupon, the foregoing matter went off
9 the record at 11:00 a.m. and resumed at 11:21 a.m.)
10 CHAIRMAN MALMUD: Dr. Howe will make the
11 next presentation, which is the topic of potential
12 changes to 10 CFR Part 35. Dr. Howe?
13 DR. HOWE: Thank you, Dr. Malmud. I
14 really only have two issues that I am going to be
15 presenting today. The first one is that, as we have
16 been implementing Part 35, we have looked at 390.
17 Yes, Ashley?
18 MS. COCKERHAM: Can everyone turn to
19 Tab 12 in their binders to find these slides?
20 DR. HOWE: Yes. I was going to give this
21 presentation tomorrow, and we changed it to today. So
22 -- okay?
23 MS. COCKERHAM: Tab 12.
24 DR. HOWE: And as we looked at 35.390, and
25 the clinical experience, we looked more carefully at

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1 the definition of what we had for Category 3, and it
2 says it is parenteral administrations of any beta
3 emitter or photon-emitting radionuclide with a photon
4 energy less than 150 keV.
5 And as we looked at the reading that we
6 had, and of course it is one that requires a Written
7 Directive, we realized that you don't have -- as we
8 implemented the NARM rule, we are starting to see
9 alpha emitters. And the question is: where did the
10 alpha emitters go?
11 And we found out that there are very few
12 -- there are no pure alpha emitters. They have a beta
13 associated with them, or they have a gamma associated
14 with them. And, therefore, they don't go into
15 Category 4; they come into this Category 3.
16 So we took a more extensive look and we
17 said, "Do we have anything that fits into Category 4?"
18 Because originally we did the reading, that -- we
19 thought that was going to pick up the alphas if we
20 ever got them, and that they would be anything other
21 than what was in 3.
22 And the conclusion we came to is there is
23 nothing in Category 4. And we are looking, and we are
24 saying, "Well, that is not really what we intended to
25 do." And so now that we have alphas and we have now

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1 radionuclides that are being used therapeutically for
2 their alpha component, even though they may have
3 incidental betas or gammas.
4 So what we are proposing is that we revise
5 35.390(G)(3) and (G)(4), so that 3 becomes the betas
6 and the low energy emission photons, and that is your
7 primary -- that is the component of the radionuclide
8 that you are really using on a therapeutic basis.
9 And then, for 4, that it is requiring a
10 written directive for any radionuclide that is being
11 used, because of its alpha particle emission. So what
12 we changed is the words "because of its beta emission
13 or low photon emission."
14 So we are looking now at different
15 radionuclides fitting into Category 3 because they
16 have a radioactive modality as -- because of their
17 alpha emission and their photon emission is what is
18 being used. And then, in 4 we want to put the alphas
19 that are being used primarily for the alpha emissions.
20 So that is our recommended way of solving
21 the problem that everything was going into 3, and we
22 weren't really distinguishing between differences of
23 experience that you needed.
24 CHAIRMAN MALMUD: Thank you, Dr. Howe.
25 Are you looking for comments from the Committee?

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1 DR. HOWE: I certainly am looking for
2 whether you agree with the issue and our potential
3 resolution.
4 CHAIRMAN MALMUD: Perhaps one of our
5 physicists has a comment. Mr. Lieto?
6 MEMBER LIETO: I guess if you are looking
7 for agreement or disagreement, I disagree. My
8 recollection is to the contrary, that when we proposed
9 this rule, number 4 was intended to capture anything
10 other than what was up there. And I guess I would ask
11 you, what would ever go into 4 if it wouldn't be an
12 alpha emitter, or a combination alpha/beta emitter?
13 DR. HOWE: The way 3 is written nothing
14 ever goes into 4. And the intent -- and I believe you
15 are right, we were thinking that the intent was that
16 it would go -- the alphas would go into 4. But the
17 way the rule is written, because it says "any beta,"
18 not that it is being used for its beta, but if there
19 is any beta associated in the radionuclide, it
20 automatically fits into 3.
21 So we are changing the focus in 3 and 4 to
22 what component of the radioactive decay scheme is
23 being used.
24 MEMBER LIETO: Well, I --
25 DR. HOWE: Yes, keep going.

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1 MEMBER LIETO: Then, what I would suggest
2 is that you delete 4 and just put -- and add "beta
3 emission, low photon emission, or alpha emission," and
4 just make it -- and just add that one -- those two
5 words on to that, and just delete 4 all together, if
6 there is never going to be anything to go into it.
7 DR. HOWE: We managed to separate them,
8 because we believe that with the three clinical cases
9 that there is a difference in using the alphas for
10 radionuclide therapy, but you mainly have -- may want
11 different experience than just using P-32 or I-125.
12 MEMBER LIETO: Well, it was my impression
13 that for number 3 -- would be something like samarium-
14 153, which is both a beta and a gamma emitter. And
15 that would fall into number 3, which is a combination
16 of the two. I think by -- again, my suggestion of
17 just adding "or alpha emission" would -- into number 3
18 would cover anything or any combination of the three
19 emissions.
20 CHAIRMAN MALMUD: So Mr. Lieto is
21 suggesting that 3 and 4 be combined, because the
22 wording is essentially the same for the first two
23 lines, and just add "alpha particle" under 3. But
24 that doesn't separate the two, as you are suggesting.
25 Are you opposed to their separation, Ralph?

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1 MEMBER LIETO: I just am thinking that
2 this would be more flexible in terms of any future
3 radionuclides that might come down the pike, because
4 something that is both a gamma and an alpha emitter, I
5 mean, would that then have to have a number 5?
6 I think, again, just -- my suggestion of
7 having the "or beta or low photon or alpha" would be
8 -- would cover any combinations and be more flexible
9 and not have to revisit this rule again.
10 CHAIRMAN MALMUD: Are there other
11 comments? I think somebody had his hand up. Dr.
12 Vetter?
13 VICE CHAIRMAN VETTER: Well, I think what
14 Dr. Howe -- I think Dr. Howe's point, one that I
15 picked up on anyway, was the issue of, when do you
16 need to have another three patients as part of your
17 training? And alpha therapy would certainly be quite
18 different from beta/gamma therapy, and that would be
19 the reason for separating it out, so that when a new
20 monoclonal antibody with alpha emitter attached to it
21 is developed and needs to be marketed, you wouldn't be
22 able to use the training under number 3 -- that is,
23 the three patients, satisfy the three-patient rule --
24 under 3. You would have to have a new three patients
25 for that alpha particle if you have -- if the alpha is

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1 under 4. That is the way I understood your comment.

2 DR. HOWE: And that is --

3 CHAIRMAN MALMUD: Was that your point?

4 DR. HOWE: That is our point.

5 CHAIRMAN MALMUD: That was Dr. Howe's

6 point. Dr. Suleiman?

7 MEMBER SULEIMAN: I tend to lean toward

8 Ralph's concepts more so, because I think by trying to

9 differentiate between the actual -- we are thinking

10 physics here -- alpha, beta, gamma, whatever -- most

11 of the emissions give off -- most of the decay schema

12 give off everything. It is just that some are more

13 predominant than others.

14 So I don't know -- most any decay has some

15 very low energy gammas coming off of it, and the alpha

16 and the beta are more particulate. They are more

17 local. They have more in common than you may

18 appreciate. I think the key thing is the ultimate

19 indication for which the drug has been developed.

20 And so by trying to segregate, that is

21 going to dictate how it is used more so than the

22 radiation safety aspects. I think alpha and beta

23 therapeutics are probably going to behave similarly

24 and be treated similarly than a gamma emitter.

25 So I think you are going to fall into this

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1 problem of trying to micro-define the different types
2 of emissions.
3 CHAIRMAN MALMUD: Dr. Thomadsen?
4 MEMBER THOMADSEN: Well, I would tend to
5 disagree with that. I think the alphas themselves
6 make a big difference. And I don't think that we want
7 to be using -- or that there are applications where we
8 are using a radionuclide that has incidental alpha
9 emissions other than maybe two or three parts per
10 million, or something where it is very low, because
11 the biological effect of those alphas are very high.
12 And I can see why they should fit in a
13 separate category from the others, although I think
14 you do raise a very good point. And I think that the
15 -- some of the radioimmune drugs are very different
16 from just labeled molecules that aren't mediated in
17 the same way, and they might form their own category.
18 CHAIRMAN MALMUD: Dr. Thomadsen, can you
19 clarify for me, please, are you in favor of Dr. Howe's
20 motion or Mr. Lieto's recommendation?
21 MEMBER THOMADSEN: I am in favor of Dr.
22 Howe's recommendation. I am suggesting it may not go
23 far enough in dividing classifications. But at the
24 moment, just narrowly looking at the proposal, I would
25 support the proposal.

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1 CHAIRMAN MALMUD: Thank you. Dr. Fisher?

2 MEMBER FISHER: Darrell Fisher. I support

3 the potential changes that Dr. Howe has presented. I

4 think I like this because of the -- it recognizes the

5 functionality of the isotope, rather than just its

6 emissions, radiation emission quality.

7 There will be drugs in the future that are

8 cocktails of both alphas and betas and gammas, and

9 this recognizes the therapeutic benefit of the alpha

10 emitter.

11 CHAIRMAN MALMUD: Thank you. Dr. Nag was

12 next.

13 MEMBER NAG: Yes. I would support

14 separating the alpha with -- the penetration is not

15 the same. Alpha has very limited penetration. It was

16 more in line with the beta. Plus, the effects at the

17 molecular level are much higher. So I would favor the

18 separation. You know, I would go along with Dr. Howe.

19 CHAIRMAN MALMUD: And Dr. Welsh?

20 MEMBER WELSH: So I generally support the

21 concept of the separation. However, with the new

22 wording, two points. One is, do we mean to say "low

23 energy" rather than "low photon emission"? Maybe that

24 is just semantics. But the more important question

25 is: where would something that is primarily being

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1 used because of its Auger electron emission now fall?
2 With the old wording, it would fall into 3. With the
3 new wording, it becomes a question.
4 CHAIRMAN MALMUD: I will address that
5 question to Dr. Howe. The question relates to
6 something that is an Auger electron.
7 DR. HOWE: Ron, would you like to jump in
8 here?
9 DR. ZELAC: The Auger electron clearly is
10 not going to fall into category 4 as alpha. I think
11 it belongs in 3, but the wording I think in 3 needs to
12 be polished a bit before it would be proposed.
13 MEMBER WELSH: That was my point. Maybe
14 we should add another line there.
15 CHAIRMAN MALMUD: A line to which? I am
16 sorry.
17 MEMBER WELSH: To 3, as it is currently
18 written. "That is being used because of its beta
19 emission or low photon energy emission or Auger
20 electron emission."
21 CHAIRMAN MALMUD: So Dr. Welsh is
22 suggesting that the line of subparagraph 3 have
23 "and/or Auger electron emission," and that 4 remain as
24 it is. Is that what your suggestion is?
25 MEMBER WELSH: Yes.

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1 CHAIRMAN MALMUD: All right. Is that
2 acceptable to you, Dr. Howe?
3 DR. HOWE: That certainly is acceptable,
4 because what you are saying is it is being used
5 because of that.
6 CHAIRMAN MALMUD: We will accept Dr.
7 Welsh's recommendation as the second.
8 Any more discussion of this motion? Dr.
9 Suleiman?
10 MEMBER SULEIMAN: I still disagree. Each
11 drug is going to be based on its characteristics. And
12 the physician that is using it is going to know that
13 if it is an alpha emitter it is going to be prescribed
14 for a certain indication. If it is a beta emitter,
15 whatever. I think you should look at it from the
16 radiation safety profile.
17 And if you look into your decay scheme,
18 which I have had the misfortune of having to do
19 lately, you get lots of -- go back to physics. You
20 know, these things are not pure emitters. They all
21 give off all sorts of other emissions. So I think by
22 trying to come up with specific definitions for all of
23 these things, you are going to cause more problems
24 downstream.
25 CHAIRMAN MALMUD: I will ask a question if

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1 I may. Would it be acceptable to both parties if
2 paragraph 3 read that, "The parenteral administration
3 requiring a written directive for any radionuclide
4 that is being used primarily because of its beta
5 emission or low photon emission and/or Auger," and
6 that number 4 be written, "That is primarily being
7 used because of its alpha particle." Would that be
8 acceptable?
9 MEMBER SULEIMAN: Not to me.
10 CHAIRMAN MALMUD: Not to Dr. Suleiman.
11 How about to Dr. Fisher?
12 MEMBER SULEIMAN: Just combine them.
13 MEMBER FISHER: Yes, that would be
14 acceptable I think.
15 CHAIRMAN MALMUD: And Dr. Welsh?
16 MEMBER WELSH: I was going to ask a
17 separate question.
18 CHAIRMAN MALMUD: Okay. Dr. Thomadsen?
19 MEMBER THOMADSEN: Yes.
20 CHAIRMAN MALMUD: It is acceptable to him.
21 MEMBER THOMADSEN: With the correction
22 of --
23 CHAIRMAN MALMUD: Yes.
24 MEMBER THOMADSEN: -- low energy photon
25 emissions.

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1 CHAIRMAN MALMUD: Right. Dr. Howe, is
2 that acceptable?
3 DR. HOWE: That is acceptable to us.
4 CHAIRMAN MALMUD: Primarily --
5 DR. HOWE: Yes.
6 CHAIRMAN MALMUD: Now, Dr. Welsh did have
7 a question.
8 MEMBER WELSH: My question is for Dr.
9 Howe. I understand Dr. Suleiman's points, but, Dr.
10 Howe, you said you wanted to have separate category
11 number 4 for alpha. Can you please explain why you
12 feel that way, and why it should not be lumped into 3,
13 as some of us have suggested?
14 DR. HOWE: Well, we think as the
15 radiopharmaceuticals that are being developed with the
16 accelerator produce materials that now have -- are
17 being used primarily for the alpha. Because you have
18 a different factor of four in their ability to kill
19 cells, there are a lot of different things that you
20 are going to want to know about in order to make the
21 right judgment on why you are using it.
22 And we believe that judgment is different
23 for alphas than it would be for the existing
24 pharmaceuticals we have now, like P-32 and samarium
25 and the other ones that are being used, and I-125.

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1 MEMBER WELSH: My question -- my followup
2 question might be that, isn't that for a medical
3 decision that --
4 DR. HOWE: But we are distinguishing based
5 on what your primary radiation function is. And we do
6 for therapy address radiation safety, the patient for
7 therapy. And so we are saying that we think you need
8 to know more about how an alpha is measured, how it
9 functions, how you are using it, than you might for
10 something else. So we are basing it on its radiation
11 properties.
12 CHAIRMAN MALMUD: Mr. Lieto?
13 MEMBER LIETO: Based on what you just
14 said, Dr. Howe, then you should have different
15 requirements for P-32 colloidal chromate phosphate,
16 different requirement for P-32 phosphate, and then
17 something else for Y-90, because they are all
18 different beta emitters, have all entirely different
19 clinical applications and uses.
20 And I think the distinction was intended
21 to be made originally, because 1 and 2, which aren't
22 shown here, are oral administrations, and these are
23 parenteral administrations. And that was I think the
24 difference in the separation originally for the
25 classifications for the different uses of

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1 radionuclides.

2 CHAIRMAN MALMUD: Dr. Eggli?

3 MEMBER EGGLI: Yes. There are sort of two

4 questions here. One is the scientific question, which

5 I have heard debated, and the next one is, what is the

6 practical impact for end users? The reality is, I

7 think as a new therapeutic comes out, the chance that

8 the vendor will let you have that without some

9 specific vendor training, because they don't want

10 someone to mess up shortly after a product's

11 introduction, is pretty remote.

12 So whether you tell me I have -- you know,

13 that I am covered or I am not covered by my prior

14 training, odds are the vendor is not going to let me

15 have it without specific training. We even see that

16 in diagnostic radiopharmaceuticals, you know, and I

17 can't see a new class of therapeutics coming out,

18 regardless of the regulation, without the vendor

19 requiring vendor-specific training.

20 So I think the impact on the regulated

21 community would be small. The scientific discussion

22 is a legitimate one, but I think the impact doesn't

23 matter, because you are going to be required by the

24 vendor to train.

25 CHAIRMAN MALMUD: Thank you.

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1 We have a motion, Dr. Howe's motion,
2 seconded by Dr. Welsh I believe. Further discussion?
3 Dr. Thomadsen.
4 MEMBER THOMADSEN: Yes. A question to Mr.
5 Lieto. I am very sympathetic with the points you were
6 just making, and they were similar to the points --
7 Dr. Suleiman's points that I also was sympathetic
8 with, that in addition to the physical differences
9 between the emissions, probably a greater difference
10 in their use as far as their application to humans, is
11 the vehicle.
12 Do you have a suggestion for what should
13 happen to this part? And should you maybe -- are you
14 recommending getting rid of the four parts all
15 together, and just making some general statement as
16 far as training relevant to the nature of the emission
17 and the carrier?
18 MEMBER LIETO: I guess I am trying to look
19 at a less prescriptive regulation. I mean, I
20 recognize their concern about the alpha emitters.
21 Okay? But I think I would rather have a regulation
22 that is less prescriptive, more flexible. I mean, can
23 you say that somebody who has been doing beta emitter
24 radiotherapy for years, a new alpha emitter comes
25 along, and their training and experience is not

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appropriate?

I mean, just as Dr. Eggli said, you are going to get the clinical training for that specific modality anyhow. But is the radiation safety training and background that you have done already, say for -- if you had training and experience in just beta emitters, now going to have to be duplicated because you haven't used an alpha emitter before?

MEMBER THOMADSEN: It is only the three cases, not the training.

MEMBER LIETO: Well --

CHAIRMAN MALMUD: I am sorry. I didn't hear the last comment.

MEMBER THOMADSEN: It is only the three cases we are talking about, not the -- all of the other training.

CHAIRMAN MALMUD: Thank you.

Was there another comment? Dr. Welsh?

MEMBER WELSH: Maybe a quick comment is that for somebody who has had seven hundred hours of residency training and experience, 200 hours of classroom training, do you really need three cases for learning how to use an alpha emitter, if you have done hundreds or thousands of beta emitters over your career? It is a question of -- it is a rhetorical

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1 question, but I think that this concept of three cases
2 might need to be revisited.
3 CHAIRMAN MALMUD: Dr. Suleiman?
4 MEMBER SULEIMAN: I think it would have to
5 be for the specific product. I think if -- even betas
6 have different energies. So one radio-labeled beta
7 emitter may not perform the same way as another radio-
8 labeled beta emitter. But they probably have more
9 similarities with an alpha emitter.
10 I think you should look at the safety
11 profile back again. How is it being delivered? Is it
12 a generator? Is it pre-packaged? And how is it going
13 to be handled from that point to when it is
14 administered to the patient? And then, when it is
15 administered to the patient, again -- I assume we are
16 dealing with therapeutics here, but you administer to
17 the patient after that.
18 You are not going to worry about the range
19 of the beta or the alpha or whatever. That has
20 already been thought out ahead of time. That is why
21 you are using that specific radio-labeled drug. So
22 trying to define a regulation that is going to kind of
23 second-guess that after the fact, the physician is
24 going to make the choice of the appropriate radio-
25 labeled drug based on its characteristics, be it

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1 radiation, be it anything else, be it that it is
2 labeled to a monoclonal or it is being physically, you
3 know, stopped by the liver.
4 That decision has already been factored
5 in. And so if it is a therapeutic where you are
6 dealing with large quantities, and whether it is a
7 gamma emitter or a particulate emitter, it is going to
8 have a very different radiation safety profile, and
9 you are going to handle it based on two or three
10 general classifications.
11 You are micro-regulating here in terms of
12 trying to define alphas and betas and gammas and Auger
13 electrons, and we can think of some other emissions in
14 there, too. I think ultimately the product has been
15 approved based on evidence-based science. It works or
16 it doesn't work. And that has all been factored in
17 during the trial.
18 So I think trying to micro-regulate based
19 on different energies -- you might as well, if you are
20 going to go with the alpha definition, you might as
21 well define "beta" by energy range and get more
22 specific. I mean, you either take that argument to
23 its full degree or back off and keep it simpler.
24 CHAIRMAN MALMUD: I think Mr. Lieto was
25 next.

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1 MEMBER LIETO: I just wanted to follow up
2 on a question that Dr. Welsh posed. Has this come
3 from, like, the Agreement States? Has this been an
4 inquiry from the Agreement States? Or are you guys
5 kind of like looking into your crystal ball and trying
6 to predict what might be coming down the pipe and cut
7 it off at the pass?
8 CHAIRMAN MALMUD: Your question is
9 addressed to Dr. Howe.
10 MEMBER LIETO: Yes, I am sorry.
11 DR. HOWE: Yes. I think we are looking at
12 it. It hasn't come from the Agreement States. It has
13 come from thinking about the new radionuclides that we
14 have now, thinking that this is where they were going
15 to go, and then reading the regulation carefully and
16 realizing that they, as currently written, don't go
17 there. And that is where we had expected them to be.
18 CHAIRMAN MALMUD: Okay. Dr. Thomadsen?
19 MEMBER THOMADSEN: Well, I actually, after
20 having spoken towards the motion, will speak against
21 it.
22 (Laughter.)
23 And suggest that there either be a
24 subcommittee of ACMUI established to work with Dr.
25 Howe to look at what might be the most effective and

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1 efficacious way of addressing the problem and
2 potential problem, although I can't make that motion
3 now because we have a motion on the floor.
4 CHAIRMAN MALMUD: Dr. Eggli?
5 MEMBER EGGLI: As a Part 300 practitioner,
6 and just to sort of -- I would like to sort of talk a
7 little bit about how I think about Part 300 therapies.
8 In general I think, is the radiation gamma or not? I
9 think, is the thing I am administering soluble or not?
10 And then, how do I administer it? Intravenous,
11 intra-arterial, orally, intracavitary, or intra-
12 articularly? And all of those things are important in
13 a therapy.
14 The reason I spoke before that it probably
15 -- that 3 or 4 probably doesn't matter is because,
16 again, I still think within a new -- with a new agent
17 you are going to get vendor training. But,
18 truthfully, I am not sure how an alpha particle, other
19 than its range and tissue and its appropriateness for
20 some therapies, versus a beta particle, will change my
21 thinking on, you know, is it radiation gamma or not?
22 Is the physical form soluble or not? And how do I
23 administer it?
24 Those are the things I think about when I
25 do a Part 300 therapy. And I would ask that since Jim

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1 does Part 300 therapies, I would ask if he thinks
2 differently about the therapeutic agents.
3 MEMBER WELSH: I would say I agree 100
4 percent with your thinking, which is why I asked Dr.
5 Howe the question initially about why he would want to
6 have category 4 with alpha being separated from the
7 others, when clinically we think of unsealed isotope
8 therapy just as Dr. Eggli has outlined.
9 So, in my mind, I am still not fully clear
10 why the alpha is being treated separately, other than
11 the idea that this is a new category of agents that
12 may have widespread applications in the next couple of
13 years. So, therefore, for the time being, if NRC
14 still feels that it is appropriate to take alpha out
15 as a separate category, I would say that I agree with
16 3 and 4.
17 But, conceptually, I think that ultimately
18 we will just have category 3, as Ralph Lieto has
19 stated, and some day just add, "In addition to beta
20 emission, low energy photon emission, Auger electron,
21 and alpha emission." Instead of having category 4
22 separate. But for the time being, I guess the idea is
23 that alpha is going to want to be separated, but I
24 agree 100 percent with the clinical thinking of Dr.
25 Eggli.

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1 CHAIRMAN MALMUD: Mr. Lieto?

2 MEMBER LIETO: I would like to suggest
3 that -- I don't know if there is a proposal on the
4 floor already, but I would like to suggest that this
5 be tabled, because there is not any urgency to it. I
6 think we are trying to solve a problem that doesn't
7 exist yet.

8 I think there are additional questions
9 being raised, because if you look at this it says --
10 you know, was it A, B -- 1, 2, 3, and 4. One and 2
11 address oral, 3 and 4 address parenteral. Are there
12 other ways to administer radionuclides that may not be
13 listed here, in terms of the clinical --

14 CHAIRMAN MALMUD: How are you defining
15 "parenteral"? Does that cover all of the categories
16 of intravenous, intra-arterial, intracavitary,
17 interstitial, and intra-articular? Are those all
18 broadly covered under the term "parenteral"?

19 DR. HOWE: That was our concept. The
20 original one was the oral I-131, and then you went
21 into parenteral.

22 MEMBER LIETO: To me, the treatment
23 implications of those five routes are very different.
24 And it is interesting that you would separate "oral"
25 off when an intracavitary treatment or an interstitial

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1 treatment or an intra-articular treatment are very
2 different than an intravenous or an intra-arterial
3 treatment.
4 DR. HOWE: I believe the oral was
5 separated out, because it is not just oral, it is oral
6 I-131. And that treatment can be done by physicians
7 that don't necessarily need all of the training and
8 experience for 300.
9 MEMBER LIETO: I can buy that.
10 CHAIRMAN MALMUD: So we have a motion on
11 the floor, which is Dr. Howe's motion with the
12 addition under paragraph 3 of Auger electron, and
13 paragraph 4 in the initial motion stands as it is. Is
14 that the motion? No.
15 MEMBER WELSH: And the inclusion of the
16 word "primarily."
17 CHAIRMAN MALMUD: Right, and the word
18 "primarily."
19 MEMBER LIETO: And low energy. Did you
20 get that? Low energy photons.
21 CHAIRMAN MALMUD: Low energy? Inserted
22 where?
23 MEMBER LIETO: Between "low" and "photon."
24 DR. HOWE: I think there is --
25 MEMBER LIETO: As opposed to "low photo

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emission," which would mean few. Unless that is the intent.

DR. HOWE: I think it is a typo, because I think that is in the regs right now as low energy. Ashley is looking.

CHAIRMAN MALMUD: Then, that should be "low energy emissions."

DR. HOWE: Yes.

CHAIRMAN MALMUD: Low energy photon. The word "energy" is missing.

MEMBER LIETO: It says "photon-emitting radionuclide with a photon energy less than 150 keV."

CHAIRMAN MALMUD: Yes. So it is "low energy" in the regulation currently.

DR. HOWE: It is what -- it is "low energy," yes.

CHAIRMAN MALMUD: Okay. So we have those three corrections to the motion, which were moved and seconded. Should we call the motion?

All in favor? Would you keep your hands up, please? Three, four, five.

Opposed? Three opposed, four opposed. Five-four. Motion carries.

DR. HOWE: Thank you.

The next topic is --

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1 CHAIRMAN MALMUD: Excuse me.

2 MEMBER WELSH: Dr. Thomadsen had proposed
3 that we create a working group to get back with you.
4 Dr. Thomadsen, would you like to expound on that or
5 discuss it any further?

6 MEMBER THOMADSEN: It seems that the
7 Committee has made a decision on this. So there is
8 not much point to that.

9 CHAIRMAN MALMUD: Well, Ashley has her
10 hand up. Has the Committee made a decision?

11 MS. COCKERHAM: I am not sure if the
12 Committee has -- no. I have five votes in favor, four
13 opposed. That is nine. I need 11 votes.

14 MEMBER EGGLI: We have got an abstention
15 here.

16 MS. COCKERHAM: Two abstentions?

17 CHAIRMAN MALMUD: Two abstentions.

18 MS. COCKERHAM: Thank you.

19 CHAIRMAN MALMUD: Drs. Eggli and Van
20 Decker.

21 DR. HOWE: Now, I want to remind you that
22 if you have agreed that we could go put this into our
23 user need memo, you will see this again. This is not
24 the last time you will see it, and there are still
25 other barriers it has to get over in order to get into

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1 rulemaking. So -- okay?

2 Can I move on to the next issue?

3 CHAIRMAN MALMUD: Please do.

4 DR. HOWE: Okay. We actually had a

5 question come in on this one, and the question was

6 whether an Authorized User for 400 uses, and then we

7 extended it to 600 uses, could get their 500 hours of

8 supervised work experience at some place other than a

9 medical institution, in a private practice, a limited

10 clinic, where you did not meet the criteria of being a

11 medical institution.

12 And I believe the criteria for being a

13 medical institution is that you practice two or more

14 specialties. It doesn't say, "Did you practice two or

15 more radiation specialties?" It just says, "Did you

16 have two or more specialties?"

17 So part of the concept is that medical

18 practice has changed over the ages, and now we do have

19 more procedures being done at stand-alone units, and

20 especially like for manual brachytherapy, but it may

21 also apply to those 600 uses of remote afterloaders,

22 teletherapy, or gamma stereotactic. And so the

23 question is whether we would want to change from

24 medical institution to something else.

25 Keep in mind that both of the requirements

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1 in 490 and 690 do require three years of radiation
2 oncology, radiation training. And in that part, you
3 probably would get a diversity of exposure. So the
4 question we have, because we don't really have a --
5 that proposal is whether a stand-alone clinic would be
6 an appropriate place to receive the 500 hours of
7 training.
8 CHAIRMAN MALMUD: Well, it looks as if Dr.
9 Nag wants to be the first one to tackle this issue.
10 MEMBER NAG: Thank you. Whether we bring
11 in a given, you know, university medical institution,
12 or part of that is given in a non-medical institution,
13 really should not matter. It is still training. So
14 if the less than -- or part of the time with a smaller
15 entity, that is still included in the training.
16 And, you know, even for board
17 certification, the training at whatever level is all
18 included. I have no problem of the training being in
19 any institution, not necessarily in a non-institution.
20 DR. HOWE: Okay. Just let me clarify.
21 When we say "medical institution," we don't
22 necessarily -- certainly a university medical
23 institution meets the criteria, but there are also
24 smaller entities that meet the institution, smaller
25 hospitals. Actually, some multiple group practices

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1 with two or more specialties could also meet the
2 definition of "medical institution."
3 So I just wanted to clarify we are not
4 talking about the difference between a university
5 medical institution and some other place. Just to
6 make it clear.
7 CHAIRMAN MALMUD: Dr. Howe, does "other
8 institution" include those that are not reviewed by
9 the JC?
10 DR. HOWE: Yes.
11 CHAIRMAN MALMUD: Well, I certainly have
12 feelings about it, but I will let the other members of
13 the Committee speak first. You realize that this is
14 almost anti-Flexnerian. Flexner was the man who
15 reviewed American medical institutions in the second
16 decade of this 20th century and found that people were
17 getting certified as physicians by simply paying a
18 subscription to a doctor and then getting certified,
19 and they had no training.
20 And he recommended the closure of a number
21 of American medical schools based upon the fact that
22 there was not adequate supervision of the training of
23 medical students. His impact was felt immediately and
24 led to the closure of a number of American medical
25 schools, the conversion of others into first-quality

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1 schools.

2 We do need supervision, and allowing for
3 supervision to occur without oversight by anybody
4 other than an individual can lead to -- can lead to,
5 would not lead to in most circumstances, but can lead
6 to, in a minority of circumstances, inadequate
7 supervision without any oversight.

8 So it concerns me, but that is just a -- I
9 am just speaking as a citizen. It concerns me. And
10 it is almost anti-Flexnerian in its aura.

11 So I will allow my colleagues to comment
12 on this. Dr. Eggli?

13 MEMBER EGGLI: One is a question. The way
14 this is written, I assume that no one could vouch for
15 training for a modality that they weren't authorized.
16 For instance, say, 400 practitioners certainly
17 shouldn't be able to vouch for 600 training. And
18 then, secondly, I am inclined to agree with Dr. Malmud
19 generically when training programs aren't answerable
20 to some authority that maintains and validates the
21 quality of that training.

22 There is a tendency toward crawling under
23 rather than jumping over the bar, and I think that I
24 have no problem with free-standing clinics being able
25 to provide training, but it needs to be in a framework

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where the quality of that training is validated by some validating authority.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: Just a quick clarification, because we deal with this in a vague way ourselves. How do you actually define "medical institution"?

MS. FLANNERY: I can read it for you. It is in 35.2. "Medical institution" means an organization in which more than one medical discipline is practiced."

MEMBER SULEIMAN: Period.

MS. FLANNERY: Period.

MEMBER SULEIMAN: Okay. Interesting.

DR. HOWE: Very open.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: I can see a problem. For example, some radiation oncologists, as part of their board certification, have to spend a short time in getting experience in a modality -- for example, high dose radiation brachytherapy.

So that their primary institution has good training in everything else, but had only limited HDR experience, so they are sent out to a clinic that does nothing but HDR brachytherapy. And if you are going

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1 to discount that part of their experience, this
2 individual, although he is now board certified, would
3 have a problem meeting that requirement.
4 DR. HOWE: Dr. Nag, there is still a
5 requirement for a three-year residency program, and
6 there is no restriction in the three-year residency
7 program as to where the training is obtained in that
8 residency program.
9 So if the residency program has an
10 arrangement with other facilities to pick up that
11 training, that is under the three-year residency part.
12 MEMBER NAG: Under what circumstance do
13 you think someone would get board certified, would
14 have training but have training only in a private
15 practice institution? I fail to see how that would
16 be --
17 DR. HOWE: We are not necessarily talking
18 about the board certification process, because in the
19 board certification process you successfully complete
20 three years of residency -- I am looking at 490 --
21 three years of residency program and radiation
22 oncology that is approved by the Residency Review
23 Committee. And then, you pass the examination.
24 What we are looking at is the alternate
25 pathway where you have 200 hours of classroom

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1 laboratory training, you have 500 hours of work
2 experience in these things, and then you also have
3 completed three years of supervised clinical
4 experience in radiation oncology under an Authorized
5 User who meets the requirements of 35.490 as part of a
6 formal training program approved by the Residency
7 Review Committee. So the 500 hours is outside of that
8 three-year residency.
9 MEMBER NAG: So if someone has not had
10 enough experience and is more experienced in, let's
11 say, HDR brachytherapy, and went outside that to have
12 extra experience, I think that -- you know, that is --
13 that should be counted and be used. Otherwise, this
14 person would have no way of getting Authorized User
15 qualification for that subspecialty. I mean, this
16 person would already have three years of training in a
17 broad specialty, and is going outside that to get
18 extra training in a subspecialty.
19 DR. HOWE: Now, the 500 hours is -- if you
20 look at 35.490 is specific to the basic radiation
21 safety issues -- ordering, receiving, unpacking,
22 checking survey meters, preparing, implanting, and
23 removing brachytherapy sources, maintaining running
24 inventories, and using administrative controls, and
25 then using emergency procedures. And they are all

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1 under the supervision of someone that meets -- that is
2 already an Authorized User for 35.490.
3 But this is -- so this is not your three
4 years of clinical residency, but it is more focused on
5 the radiation safety.
6 CHAIRMAN MALMUD: Dr. Zelac?
7 DR. ZELAC: And because it is focused on
8 radiation safety, I believe that that was the reason
9 for having it at a medical institution, as defined,
10 meaning there was more than one discipline being
11 practiced, so that the breadth that one would receive
12 during this 500 hours would be sufficient, and not
13 focused on one particular type of usage, to cover the
14 subjects that Dr. Howe just enumerated.
15 CHAIRMAN MALMUD: Thank you. Mr. Lieto?
16 MEMBER LIETO: I am very sympathetic to
17 what Dr. Zelac just pointed out, but what we are
18 looking at is a specific use training, which is manual
19 brachytherapy. So I guess the question would be --
20 DR. HOWE: We raised the question also for
21 35.690.
22 MEMBER LIETO: Well --
23 DR. HOWE: So you may want to address just
24 one of them, or you may want to address both of them.
25 MEMBER LIETO: Well, okay. I guess the

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1 question would go to both modalities. The question
2 is, if someone wants to get just manual brachytherapy
3 or teletherapy training in authorized use, is it a
4 requirement that they have to be in a medical
5 institution? And if they weren't, would they still
6 end up getting inadequate training and experience?
7 CHAIRMAN MALMUD: That is the question you
8 are raising.
9 MEMBER LIETO: That is the question I
10 have.
11 CHAIRMAN MALMUD: Yes. And that is the
12 question we are discussing. We agree the question is
13 good. Do you have any feelings about it?
14 MEMBER LIETO: Well, I would feel that,
15 yes, they could. I mean, if a physician wishing to
16 become just -- becoming an Authorized User, say, in
17 manual brachytherapy, could he get the appropriate
18 training and experience in a free-standing clinic that
19 specializes in that modality? I think, yes, he could.
20 CHAIRMAN MALMUD: Thank you.
21 Dr. Nag?
22 MEMBER NAG: There have been regulations
23 made that they may not have had the broad training,
24 but that portion of it would be met by the three
25 years' training in radiation oncology, because it is

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1 not a stand-alone. They must also have had three
2 years of training in radiation oncology, and that
3 would give them the broad basis, and, you know, this
4 is only for the -- specifically for that -- either 690
5 or the 490 use.
6 CHAIRMAN MALMUD: Dr. Vetter?
7 DR. HOWE: I think Debbie Gilley has been
8 over here --
9 (Laughter.)
10 CHAIRMAN MALMUD: I am sorry, Debbie. My
11 head was turned. Debbie Gilley was next. All right.
12 MS. GILLEY: Debbie Gilley. I would just
13 add a little clarification on this. Manual
14 brachytherapy happens in outpatient surgical centers.
15 They are one use. All they have is a license to do
16 seed implants. This is a group that if you do any of
17 your training, your 500 hours, at an outpatient
18 surgical center, currently it cannot count towards
19 those 500 hours with the way this is written.
20 Thank you.
21 CHAIRMAN MALMUD: Dr. Vetter?
22 VICE CHAIRMAN VETTER: So I guess I -- I
23 am not sure if I was going to make a comment or ask a
24 question. I just want to be sure that we are talking
25 about one modality here, the 500 hours is for a single

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1 modality, not for --

2 DR. HOWE: No. The 500 hours is to get

3 authorization under -- and it ends up that the

4 regulations are identically worded for 490 and for

5 690. So if you are looking at 490, the 500 hours

6 would cover anything that would be under -- when you

7 got the authorization, you would have the

8 authorization for anything under 490, and the same

9 would hold for the 690.

10 CHAIRMAN MALMUD: Dr. Thomadsen?

11 MEMBER THOMADSEN: A question for --

12 DR. HOWE: Can you please speak into the

13 microphone?

14 MEMBER THOMADSEN: I am sorry, a question.

15 For those stand-alone centers that do implants, they

16 would be practicing radiation oncology, and,

17 assumably, anesthesiology, would they not? So would

18 they not qualify as a medical institution?

19 DR. HOWE: I know our license reviewers

20 have essentially taken a pretty broad view of this.

21 Are you practicing more than one specialty? And in

22 most cases they come out with yes, but they are not --

23 so they are not -- the definition doesn't limit it to

24 more than one specialty we regulate. It just says

25 "more than one specialty."

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1 MS. GILLEY: My interpretation is it is
2 more than one specialty we regulate. If they did
3 diagnostic nuclear medicine and seed implants, then
4 they would be classified as a medical institution. We
5 didn't look at it at the broader scope -- broader
6 scope as if they do anesthesiology or orthopedic and
7 seeds, then it would be multi-specialty.
8 MEMBER WELSH: "Medical discipline"
9 doesn't seem to be defined in Section 2.
10 MS. GILLEY: So it opens itself up for
11 interpretation.
12 DR. HOWE: That is correct.
13 MEMBER WELSH: So it would have to be
14 clarified.
15 CHAIRMAN MALMUD: May I ask Debbie a
16 question?
17 MS. GILLEY: Sure.
18 CHAIRMAN MALMUD: So in Texas it is okay
19 to get the training.
20 MS. GILLEY: Florida.
21 CHAIRMAN MALMUD: In Florida, sorry. In
22 Florida, it is okay to get the training in a free-
23 standing clinic?
24 MS. GILLEY: Not at this state. We only
25 allow the training to be done at medical institutions,

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1 and it has been a problem in our state with people
2 meeting the 500-hour requirement, both for HDR, gamma
3 knife, and for low dose permanent implants. We are
4 looking at changing that within the state of Florida
5 to allow the 500 hours to also be included as part of
6 those facilities that only have one discipline.
7 Most of our gamma knives we -- our gamma
8 knives, only two are associated with a broad scope
9 medical. There are other -- the remaining ones are
10 privately owned gamma knives. HDR devices, over half
11 of them are in clinics, and then maybe the other half
12 are in a medical institution.
13 CHAIRMAN MALMUD: So that in the state of
14 Florida you don't have enough gamma knives to train
15 all of the potential users.
16 MS. GILLEY: Not affiliated with our
17 definition of a medical institution.
18 DR. HOWE: Debbie, isn't your definition
19 of a medical institution the same definition as our
20 definition of "medical institution"? It is a
21 compatibility E.
22 MS. GILLEY: No.
23 DR. HOWE: Definitions?
24 MS. GILLEY: A medical institution is a
25 compatibility D, I believe, for that particular one.

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1 And ours is --

2 DR. HOWE: Some definitions are --

3 MS. GILLEY: -- of what our state of

4 Florida defines as a medical institution under the

5 Medical Quality Assurance Act.

6 DR. HOWE: So what you are looking at is

7 to loosen up on your definition of "medical

8 institution"?

9 MS. GILLEY: Yes. For the purposes of

10 meeting the 500 hours of training requirement, to

11 allow them to get it at more than medical institution

12 locations, since the nature of health care has moved

13 somewhat away from the hospital-based to a more clinic

14 or outpatient-related facility.

15 DR. HOWE: If I understand your position,

16 you are essentially moving to where some of our

17 licensed reviewers are looking, and they say two

18 medical specialties. They don't restrict it to

19 medical specialties we regulate. And then, you may go

20 one step further and just say, "Okay. Only one

21 medical specialty there," and that is brachytherapy.

22 MS. GILLEY: Well --

23 DR. HOWE: Or gamma knife.

24 MS. GILLEY: -- one medical radiation-

25 related specialty there. It is the termination -- the

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1 definition of "medical specialty" that is also at
2 issue in how we interpret it versus how NRC interprets
3 it.
4 DR. HOWE: And that is --
5 MS. GILLEY: I suggest that there are 35
6 other states that have their own interpretation of
7 this, too, not just Florida.
8 CHAIRMAN MALMUD: Dr. Suleiman?
9 MEMBER SULEIMAN: A quick question. How
10 do you differentiate between a free-standing clinic
11 and an outpatient clinic that is associated with an
12 institution, but they are physically the same type of
13 structure?
14 DR. HOWE: We would do it by license. In
15 other words, if they are free-standing and had their
16 own license, then they are not part of an outpatient
17 that is associated with the hospital.
18 MEMBER SULEIMAN: But the two physical
19 structures could have the same exact environment.
20 MS. GILLEY: But it also depends on who
21 owns it. It becomes a legal entity issue that we are
22 dealing with. I have broad scope medical facilities
23 that have 14 different locations. They are all under
24 one licensing authority because of their corporate
25 structure. I have affiliates of other medical

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1 institutions that have a stand-alone license.

2 CHAIRMAN MALMUD: I am still not clear on

3 this. Let me give you a concrete example, maybe a

4 little absurd, but a concrete example. If I were a

5 physician entrepreneur who controlled a particular

6 technique in a private office, and recognized that I

7 could augment my income by charging other physicians

8 to rotate with me and get the training required,

9 without any oversight of any educational institution

10 or board or licensure organization, I could do that

11 under the proposal. Is that correct?

12 DR. HOWE: I think under our broad -- or

13 original broad interpretation of "medical institution"

14 you may be able to do that now. The criteria we would

15 look at is whether you had an Authorized User that was

16 doing the supervision that was the required Authorized

17 User and was actually supervising the right topics.

18 CHAIRMAN MALMUD: Does the Authorized User

19 at the private for-profit institution have to be -- he

20 or she be monitored by anyone in his supervision of

21 the trainees?

22 MS. GILLEY: Not as we do with medical

23 institutions and radiation safety committees that

24 would approve a preceptor activity.

25 CHAIRMAN MALMUD: By anyone? Would anyone

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1 be monitoring the effort put forth in training
2 individuals? Anyone other than the Authorized User
3 himself or herself?
4 DR. HOWE: I think for that one you have
5 to look at what we have accepted under supervision in
6 Part 35, and we have accepted a very broad description
7 of "supervision." So it is only in a few special
8 cases where we require the physical presence that you
9 would have someone that would be physically there
10 supervising by requirement.
11 Now, so that is the only answer I can give
12 you.
13 MS. GILLEY: May I suggest that the
14 definition of "medical specialty" includes
15 anesthesiologists and seed implants. We already have
16 that going on.
17 CHAIRMAN MALMUD: I didn't gather -- I
18 didn't understand the last thing you said.
19 MS. GILLEY: I suggest that if we are
20 looking at the definition of a medical institution
21 being more than one medical specialty, that we may
22 already have that particular activity going on.
23 CHAIRMAN MALMUD: With more than one
24 specialty.
25 MS. GILLEY: If you look at the medical

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1 specialty being something other than the two that we
2 would regulate -- or more than one medical specialty
3 that we regulate, as NRC regulates.
4 DR. HOWE: And, Debbie, do you have in
5 your definitions of medical specialty -- is something
6 that you regulate? You have narrowly defined it?
7 MS. GILLEY: Ours is you have to have more
8 than one radioactive material activity going on. And
9 we also require you to offer 24-hour services, and a
10 lot of other things, because we have to use the state
11 of Florida's definition of what a medical institution
12 is.
13 DR. HOWE: Okay.
14 CHAIRMAN MALMUD: Excuse me. That wasn't
15 my concern. My concern was not the issue of medical
16 institution. In training medical students or
17 residents, we are required to have any rotation that
18 they go through monitored for the quality of the
19 education that they are receiving, either by the LCME
20 or by the Residency Review Board.
21 We can't send a resident to a private
22 doctor's office because he has a piece of equipment
23 that we don't have without supervision, without his
24 being a member of our faculty, and use that as
25 training experience for one of our residents. And it

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1 seems to me that those rules make sense, because we do
2 have to protect the public from people who are not
3 really trained.
4 And we know from history that there is a
5 temptation, not amongst the majority of physicians but
6 certainly among a very small minority, to augment
7 income by "training," but not delivering the training.
8 There has to be some monitoring of the
9 educational process, and this proposal, as I interpret
10 it -- and I may be misinterpreting it -- would allow
11 for an individual to provide training with our
12 approval without oversight. That concerns me.
13 DR. HOWE: I believe your interpretation
14 is correct. We --
15 CHAIRMAN MALMUD: That concerns me.
16 DR. HOWE: We still have the requirement
17 for three years of residency, and the three years of
18 residency does have the more -- I don't want to use
19 the word "institution," because then it could be
20 confusing. But you have oversight from groups that
21 are saying the residency program is adequate, not the
22 NRC, but you have already residency review groups, but
23 this is the 500 hours, and that is separate.
24 CHAIRMAN MALMUD: Please, Dr. Welsh.
25 MEMBER WELSH: It is not uncommon for a

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1 medical institution, as defined here, which has a
2 residency training program in radiation oncology and
3 came to provide the board certification requirement
4 and the 500 hours, it is not unusual for those
5 institutions to not provide the full breadth of
6 brachytherapy experiences.
7 Therefore, they occasionally will have
8 their residents go to an institution which may not
9 meet the definition of "medical institution" as here
10 defined. It may be a facility that does only
11 brachytherapy, but why not tap into the resource and
12 allow the residents to get that training? And,
13 therefore, meet the 500 hours of work experience.
14 To answer Dr. Malmud's point, these
15 individuals who the residents are training with are
16 typically adjunct faculty, they are always Authorized
17 Users, and they happen to have a great deal of
18 expertise in a specific area of specialization. And
19 this I think is a very good solution to the problem of
20 institutions -- medical institutions who do not have
21 the full breadth of brachytherapy experience to allow
22 the individual to get that 500 hours of required work
23 experience.
24 So I am in agreement with the expanded
25 definition here.

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1 CHAIRMAN MALMUD: If I may, you just
2 included adjunct facility as part of the requirement.
3 MEMBER WELSH: Yes.
4 CHAIRMAN MALMUD: And our adjunct faculty
5 must meet certain standards to be adjunct faculty.
6 This does not address -- this motion does not address
7 faculty appointments or any oversight at all.
8 DR. HOWE: And I think that what we are
9 looking for is for you to separate out the residency
10 aspects of it, because we only cover the residency
11 aspects where I think -- you know, I don't know in
12 every case, but I am assuming in the residency aspect,
13 if you don't have the modalities, there is an
14 agreement between whoever offers the residency and
15 this other location.
16 So they come under the umbrella of the
17 group offering the residency, and we would consider
18 them to be part of this institutional training under
19 the residency program. But this is separate from
20 that, unless you are saying it is part of that.
21 CHAIRMAN MALMUD: Dr. Nag?
22 MEMBER NAG: Yes. I would support
23 expanding the private practice limits. And the reason
24 I submit is that the specialty clinics who do, let's
25 say, only seed implants or only HDR, are even more

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1 specialized. They do a higher volume. If anything,
2 they will probably provide a higher degree of training
3 than other institutions which only does it part-time.
4 It may be an institution, but they do a smaller
5 volume.
6 And the safety of the public would be
7 safeguarded, because these individuals would also have
8 to qualify and have done a residency training anyway.
9 So the broad experience would have been qualified,
10 and they are going to a center of excellence where
11 they can learn some of this specific training. I
12 would support it.
13 CHAIRMAN MALMUD: The concern that I have
14 is as follows. When we approved, for example, three
15 cases to get approved for the microspheres or the
16 course, we recognized, whether we said it explicitly
17 or not, that the manufacturer was at risk for not
18 assuring that this process was a real process, because
19 the manufacturer has the deep pocket, if there is to
20 be an adverse event on the part of the trainee at his
21 own institution, and then proof that he wasn't really
22 trained.
23 I don't see that protection built into
24 this motion. This is a motion which says it is up to
25 an individual who owns a piece of equipment. Yes, we

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1 know that 99.5 percent of the time it will all go
2 according to the way that we propose. There is no
3 oversight.
4 Everything that we do in education
5 requires not only the teaching but the documentation
6 that the teaching really occurred with some oversight
7 bodies, someone monitoring it. I don't see the
8 monitor here, and it may be my deficiency in not
9 seeing it.
10 Dr. Eggli?
11 MEMBER EGGLI: Let me paint a generic
12 situation that describes what Dr. Malmud is talking
13 about. Again, this would be I think a rare situation.
14 But I am a radiation -- I am a radiation worker
15 physician who has been in practice for many years. I
16 now take a new job at a practice where a modality is
17 practiced that I have never been trained in.
18 My partner really wants me to share the
19 call responsibility. My partner is trained in that.
20 So my partner just writes a preceptor for -- statement
21 for me, even though I have really never had a whole
22 lot of training. Who guarantees in a situation like
23 that that the training is actually occurring and is
24 quality training?
25 And that is whether it be, you know, a

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1 390, a 490, a 690, type of use, because if you change
2 this, you allow that. And maybe you allow it anyway
3 right now.
4 DR. HOWE: I would suggest that that does
5 occur even in medical institutions, from my
6 inspection.
7 MEMBER EGGLI: I understand that it does
8 occur.
9 MEMBER NAG: Again, whether a medical
10 institution or non-medical institution, the same thing
11 would occur. That is number 1. Number 2, in private
12 practice, the liability even more on that private --
13 if the partner is sued, he is also involved in that
14 lawsuit. So for his own protection, he will make sure
15 that he has been properly trained before allowing his
16 partner to take care, because in private practice the
17 liability is even higher.
18 DR. HOWE: I will say that probably 20, 30
19 years ago we did not allow a private practice
20 physician to train someone else just for Dr. Eggli's
21 reasons. We felt that the -- the NRC felt that the
22 pressure to say this person had the training was too
23 great to really give them the training. But we have
24 moved on from there.
25 CHAIRMAN MALMUD: If I may digress, that

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1 is 20 or 30 years out of date. The NRC has moved on.
2 Dr. Guiberteau?
3 MEMBER GUIBERTEAU: I just have a comment
4 that the word "private practice," having just been on
5 a task force for the American College of Radiology,
6 trying to determine what that means, is that actually
7 it is an economic determination. The Mayo Clinic is a
8 private practice of physicians. So many institutions
9 under this definition, many clinics, are also private
10 practices.
11 I think that is a very difficult word to
12 define, and I suggest that whatever happens here that
13 we do not use that one. There is solo practice, there
14 is community practice. There are non-academic
15 practices, but private practice is an all-encompassing
16 term.
17 CHAIRMAN MALMUD: Thank you. I believe
18 the term that Dr. Howe used was "stand-alone clinic."
19 DR. HOWE: Well, I used "clinic" or
20 "private practice," meaning I guess in our mind, since
21 we are not involved with the definition of it the way
22 he is, is it is essentially a very narrow practice.
23 They do one thing. They may have one person; they may
24 have two people. But there are not a whole bunch of
25 people there.

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1 MEMBER NAG: Then, we call it a single
2 specialty practice.
3 CHAIRMAN MALMUD: Mr. Lieto?
4 MEMBER LIETO: I don't think we need to
5 even go here. I am looking at this b1, the 500 hours
6 in b1. It says you have to complete that, and then it
7 says "and." And then, there is two, "has completed
8 three years of supervised clinical experience," dah,
9 dah, dah, dah, dah, dah, dah. "This experience can be
10 obtained concurrently" -- no, "as part of a formal
11 training program approved by a Residency Review
12 Committee."
13 So I don't see how they are going to get
14 -- if 1 and 2 are linked, 2 requires that you are part
15 of a three years' supervised residency program. You
16 have got to be at a medical institution. So I think
17 that Part b1 is already going to have to occur at an
18 institution regardless. Otherwise, you -- I mean,
19 because you are not going to have a residency program
20 approved at something that is not a medical
21 institution.
22 Is my logic making sense here? I just
23 don't think we -- I don't think we even need to change
24 this.
25 DR. HOWE: Your logic is not there,

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1 because what you are doing is you have b1, and it is a
2 structured educational program. It doesn't say where
3 it is. And then, b2 -- well, and part of that goes
4 into your 500 hours. Then, you get to the next one,
5 and the next one stands alone. You have to have all
6 of them, but the next one stands alone.
7 The next one does not -- the residency
8 program is the residency program, and it has nothing
9 to do with the medical institution out there. It
10 could have something to do, but it doesn't have to.
11 You have to meet the requirements of b1
12 and b2. You have to meet the requirements of b1 and
13 b2. b1(ii), is the one that says it is at a medical
14 institution, and specifically says that. b2 doesn't
15 say that, because there is an assumption that if you
16 are in a -- as part of a formal training program
17 approved by a Residency Review Committee, there is no
18 issue here as to whether you are at a medical
19 institution or not. There is that oversight doctor I
20 was looking for.
21 CHAIRMAN MALMUD: Dr. Eggli?
22 MEMBER EGGLI: I think I have to agree
23 with Ralph on this, because Part b1 is connected to
24 Part b2 by an "and" not an "or." So --
25 DR. HOWE: Which means you have to have

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1 the -- you have to meet the criteria in b1, and you
2 have to meet the criteria in b2. That does not say
3 the medical institution -- that the residency program
4 is where you get the D(ii). The D(ii) doesn't have to
5 be in the residency program. That is just at a
6 medical institution.
7 You don't go back up. You say, okay, I
8 have got to meet the training and experience
9 requirements, the formal training and experience and
10 work experience requirements of b1. Then, you go to
11 b2, and you say, I have got to have three years of
12 residency program. You have got to do both of those
13 things. But it doesn't take the residency program up
14 into b1.
15 Ralph, do you want to jump in?
16 MEMBER LIETO: I would agree with Dr.
17 Eggli. It fits in linked by an "and." They both have
18 to occur. And they are under -- and they are both
19 under the 500 -- has completed a structured program.
20 CHAIRMAN MALMUD: Dr. Zelac?
21 DR. ZELAC: I have been wanting to say
22 this for a while, and this seems to be the appropriate
23 place. I don't understand why there is an issue here
24 with regard to either the 490 requirements or the 690
25 requirements, because both of those, for these

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1 alternate pathways, require a three-year residency in
2 radiation oncology.
3 And it is inconceivable to me that an
4 individual going through a three-year residency
5 program in radiation oncology would not cover --
6 include in that three months covering these specific
7 topics in each of 490 or 690.
8 DR. HOWE: It could be, but it doesn't
9 have to be.
10 DR. ZELAC: It could be, but it doesn't --
11 well, I am not so sure about that. I think it really
12 depends on what the requirements of the residency
13 program are. And I can't imagine in either case that
14 the residency program wouldn't include these subjects.
15 CHAIRMAN MALMUD: Dr. Welsh?
16 MEMBER WELSH: Perhaps I could bring up a
17 specific example to illustrate one area that I think
18 might be of concern. I was trained at the Johns
19 Hopkins Hospital. The residency program was
20 considered an outstanding program in general, but we
21 did not have any prostate brachytherapy at all.
22 So, to me, it seems like it would be a
23 deficiency in residency training to allow our
24 residents to graduate without any experience in
25 prostate brachytherapy. And, therefore, since the

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1 institution does not perform or did not perform
2 prostate brachytherapy in the '90s, it would be a
3 great idea to allow the residents to get training in
4 this modality at a clinic or private practice, which
5 is exactly what the residents wound up doing.
6 But I guess because of the definition it
7 couldn't count towards the 500 hours, which seems a
8 little bit absurd. Therefore, I think that the
9 training at the clinic, or private practice, as herein
10 defined, should be considered part of the 500 hours of
11 work experience, because the residents going there
12 were being trained under Authorized Users with years
13 and years of experience, and who happen to be adjunct
14 faculty and were approved by the residency program in
15 general.
16 Therefore, I like this proposal.
17 CHAIRMAN MALMUD: Dr. Nag?
18 MEMBER NAG: I would like to add to Dr.
19 Welsh's argument that they really do not even need to
20 be adjunct faculty. You could have a, you know,
21 world-famous brachytherapist next to you and that
22 person may not be an adjunct faculty of Johns Hopkins,
23 but would be very well qualified to provide that
24 practical training.
25 So even adjunct faculty are not needed, as

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1 long as that person is an Authorized User and is
2 prepared to sign that they have, you know, provided
3 that training, because when that private practitioner
4 signs that, you know, "I have provided that training,"
5 he carries certain obligations with him or her.
6 CHAIRMAN MALMUD: So it would appear from
7 the discussion that the Committee feels that the
8 training, as part of a residency, even though it is
9 not in the NRC-reviewed component of the residency, if
10 it is in association with the residency, is
11 acceptable.
12 DR. HOWE: It doesn't even have to be part
13 of the residency in our regulations. It can be
14 outside of the residency.
15 CHAIRMAN MALMUD: This would change the
16 regulation?
17 DR. HOWE: No. Our regulation does not
18 have it inside the residency. It is not required to
19 be inside the residency. It can be outside.
20 CHAIRMAN MALMUD: So, then, we are okay
21 with approving this. So we will take this as a
22 motion? With --
23 DR. HOWE: I can't make a motion.
24 CHAIRMAN MALMUD: No. We still have to
25 make a motion.

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1 MS. GILLEY: I can make the motion.
2 CHAIRMAN MALMUD: Please do. Debbie?
3 MS. GILLEY: I make the motion that we
4 accept the proposed changes to 10 CFR 35.490 as
5 described.
6 CHAIRMAN MALMUD: Is there a second to the
7 motion?
8 MEMBER NAG: I would like to offer a
9 friendly amendment.
10 MS. GILLEY: Sure.
11 MEMBER NAG: Instead of having the words
12 "private practice" there, that be taken out, at a
13 medical institution or --
14 MS. GILLEY: Clinic?
15 MEMBER NAG: -- or private clinic. But
16 not private practice, because most practices now, even
17 if they are multiple specialty, are private practice.
18 MS. GILLEY: Friendly amendment accepted.
19 DR. HOWE: Debbie, does your amendment
20 include 690? You just said 490.
21 MS. GILLEY: Oh. We will do both 490 and
22 690, two birds with one stone. Yes.
23 CHAIRMAN MALMUD: It has been amended to
24 include 490, 690, drop the term "private practice,"
25 just say "medical institution or clinic."

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1 MEMBER FISHER: Second.

2 CHAIRMAN MALMUD: And, Dr. Fisher, you

3 were seconding it as well?

4 MEMBER FISHER: Yes.

5 CHAIRMAN MALMUD: All in favor? Any

6 opposed? Any abstentions? Mr. Lieto abstains. All

7 of us voted for it.

8 DR. HOWE: Thank you.

9 CHAIRMAN MALMUD: Thank you, Dr. Howe.

10 Now, we are running a little behind in our

11 agenda, so what we are going to do now is, if it is

12 okay with you, take the lunch break, come back

13 promptly. Let's see what time we should come back.

14 Any suggestions? 1:15?

15 All right. We will come back at 1:15, and

16 then there will be some slight adjustments in the

17 agenda in order to accommodate some of our speakers

18 whose times are limited. Is that okay, Chris?

19 MR. EINBERG: That is fine.

20 CHAIRMAN MALMUD: 1:15 return. Thank you,

21 all.

22 (Whereupon, at 12:38 p.m., the proceedings in the

23 foregoing matter went off the record for a

24 lunch break.)

25

DRAFT

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

(1:28 p.m.)

CHAIRMAN MALMUD: There is a change in the program for this afternoon. Patricia Pelke has offered to give the next presentation, because our other speaker has been held up.

So as soon as the substitute is ready, we will begin. But I gather that that is going to take a few minutes to get ready.

MS. PELKE: Oh, no. I think we are all set up.

Ron, did you have some comments before we get started?

DR. ZELAC: No. If you just want to get started, that is fine for us.

CHAIRMAN MALMUD: In that case, I will introduce our next speaker, who is Patricia Pelke, the Chief of the Materials Licensing Branch for Region III. I am familiar with Region III.

MS. PELKE: First of all, I would just like to clarify that I will not be the speaker. Sandy Frazier actually, one of the inspectors, is going to be doing the presentation this afternoon.

Sandy, if you are ready.

MS. FRAZIER: Yes.

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1 MS. PELKE: Just another last minute. We
2 also had another co-presenter, Darrell Wiedeman, who
3 is frantically back at the hotel picking up his
4 baggage. And he is en route to leave later on this
5 afternoon, but he should be back momentarily.
6 CHAIRMAN MALMUD: So our speaker will be
7 Cassandra Frazier, Senior Health Physicist for
8 Region III. Welcome.
9 MS. FRAZIER: Thank you. Good afternoon.
10 I am going to try to -- attempt to work this.
11 I am going to have a presentation on the
12 Department of Veterans Affairs Medical Center and the
13 multiple medical events involving the prostate
14 brachytherapy treatments.
15 Go to the first slide.
16 We thought before we start with the
17 specific details that we would talk a little bit about
18 the Master Materials License. The VA Philadelphia,
19 which is the facility that had the medical events, is
20 under a Master Materials License. So I am going to
21 give you just a little bit of background.
22 The Department of Veterans Affairs, the
23 DVA, they hold a Master Materials License. And a
24 Master Materials License is a license that is issued
25 to a federal facility, organization, and it authorizes

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1 the use of material at multiple sites.

2 The DVA has a National Radiation Safety

3 Committee, and that Committee has the responsibility

4 to provide oversight of the implementation of the

5 Master Materials License.

6 Just to give you an idea of the National

7 Radiation Safety Committee, it has several members on

8 the Committee, and it is made up of different areas,

9 including research. It includes the medical field, it

10 includes the radiation safety area. And that

11 Committee has delegated the authority to actually

12 manage the radiation safety program to its National

13 Health Physics Program, and we call that the NHPP.

14 The NHPP, they are responsible for issuing

15 licensing permits to the individual VA facilities.

16 They also have the authority to conduct inspections.

17 They perform event followup. They investigate

18 incidents. They also process allegations. And they

19 do enforcement.

20 As you can tell, the MML is a unique

21 license of ours in that they remain an NRC licensee,

22 but they also have the authority to perform certain

23 functions and activities as regulators. So that makes

24 them very unique.

25 And the VA Philadelphia, they are a

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1 permittee that is issued under the Department of
2 Veterans Affairs' Master Materials License.
3 I wanted to give you an idea of how VA
4 Philadelphia's brachytherapy prostate program is set
5 up. They maintain -- retain the services of
6 consulting radiation oncology physicians, and they
7 also have the medical physicists and the dosimetrists.
8 They are all contractors.
9 And the rest of the program, the health
10 physics staff, as well as the nursing staff, is part
11 of the VA. And their consulting services include --
12 they do the pre-treatment planning, they do the
13 implant preparations, they do implant treatments, and
14 they do the post-treatment planning.
15 And what we find is that a lot of the VAs
16 are set up this way, in that most of the brachytherapy
17 program is set up by contractors.
18 Now, I will start with the sequence of
19 events. The VA Philadelphia, they initiated their
20 brachytherapy program, and they implanted their first
21 patient on February 25, 2002.
22 On February 3, 2003, as well as October 3,
23 2005, they had two adverse events involving their
24 prostate brachytherapy program, and both of the events
25 involved seeds being mistakenly implanted into the

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1 patient's bladder instead of into the prostate.

2 In the first case from February 2003 -- we

3 are going to provide some details on both of these two

4 cases. As Patty said earlier, Darrell Wiedeman will

5 be coming in, and he is going to actually provide the

6 specific details on these two procedures.

7 So what I am going to do is I am going to

8 keep going, and when Darrell comes in he can come up

9 and do his talk on that.

10 I am going to skip down to May of 2008.

11 The National Health Physics Program notified NRC on

12 May 16, 2008, of a possible medical event involving a

13 patient that received a dose to the prostate that was

14 less than 80 percent of the prescribed dose. Once --

15 MS. PELKE: Darrell is here now.

16 MS. FRAZIER: Oh.

17 MS. PELKE: That way we can maintain our

18 order of presentation.

19 MS. FRAZIER: Okay. Darrell will come up,

20 and he will speak on the February 2008 and October --

21 I mean, sorry, 2003 and October 2003 events.

22 MR. WIEDEMAN: Back in October 2005,

23 during a seed implant, 45 out of 90 seeds were

24 implanted mistakenly into the patient's bladder. At

25 that time, a urologist was able to take a cystoscope

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1 and remove the seeds from the bladder. And the
2 physician, he revised the written directive.
3 So, therefore, it was determined that this
4 did not meet the criteria for a medical event.
5 Then, later on, in 2005 -- I am sorry,
6 this happened also in 2003, and then also in 2005.
7 The sequence of events in May of 2008,
8 NHPP initiated an onsite reactive inspection in
9 response to reported medical events. Based on the
10 number of discovered medical events, in June of 2008
11 they suspended the prostate brachytherapy program.
12 The program, when it was suspended, NHPP
13 expanded the scope of their inspection and review and
14 looked at an additional 19 prostate implants. And the
15 NHPP reported four additional possible medical events,
16 and, again, expanded -- on 6/11 of '08, they reported
17 four to five possible medical events.
18 Out of the 92 medical events, 57 were
19 considered underdoses of less than 80 percent of the
20 prescribed dose. An additional 35 were considered
21 overdoses to organs or tissues that were unintended.
22 Out of the 35, there were 25 of them that met the
23 current AO criteria.
24 Can we go to -- let's see. It is not
25 working.

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1 Once again, we have the 92 medical events.
2 Fifty-seven were due to low doses, and 35 to higher
3 than what was expected.
4 Here is a case that we looked in
5 Minneapolis VA. The prescribed dose was 144 Gray, and
6 the dose that they actually administered was 148. You
7 can see that the seeds are pretty well distributed
8 throughout the prostate.
9 Now, for those that are unfamiliar with
10 this particular computer program, this came from the
11 VariSeed program. This is essentially a sagittal
12 slice. You can look at the little man over here on
13 the far left, and that shows you the orientation.
14 Head is to your left, and the rectum would be to the
15 right.
16 They used the color isodose curves, and,
17 once again, you will see 140 Gray. And that was the
18 prescribed dose. And, as you can see, the prostate is
19 pretty well distributed around 140.
20 Here is Cincinnati VA, and you can see
21 that the seeds are pretty well distributed throughout
22 the entire prostate. This was considered an
23 acceptable and a very good implant.
24 Now we go over to the Philadelphia VA.
25 Prescribed dose was 160 Gray. But the dose that was

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1 administered was actually 43 Gray.

2 Now, an interesting thing about this was

3 that for about a one-year time period they were unable

4 to do post implants, because the CTs would not talk to

5 the VariSeed program. There was an interface problem.

6 But that didn't stop them from doing the implants.

7 So, basically, for about a year, a lot of

8 their patients they didn't even know what the actual

9 dose was. And as you can see, there are quite a few

10 seeds on the outside of the prostate. Here is one

11 where they just about missed the prostate completely.

12 In this case, 160 Gray was prescribed.

13 However, only 24 Gray was administered. The physician

14 that did this particular implant, once again, he felt

15 that the 24 Gray was clinically acceptable.

16 And, once again, we don't prescribe what

17 the dose is for the patient. That is a medical

18 decision. And if he felt that 24 Gray was

19 satisfactory, that is the way it was.

20 Okay. Anything else, Sandy?

21 (No response.)

22 Any questions? Yes, sir.

23 MEMBER NAG: Yes. There will be plenty of

24 questions, and I will just go one by one. What was

25 the numerator? You have said there are 92 medical

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1 implants. Out of how many total that were examined?
2 And how many total implants were there at the VA?
3 MR. WIEDEMAN: One hundred fourteen
4 treatments.
5 MEMBER NAG: Okay. So out of 114, 92 were
6 medical events. That is about 80 percent or so. Now,
7 out of these 92, how many were medical events because
8 of something like this, where half the seeds are
9 outside the prostate?
10 MR. WIEDEMAN: 57.
11 MEMBER NAG: Versus how many were medical
12 events, because they just met the criteria of medical
13 event as it was defined in 2005/2006? Because I am
14 sure you realize that the ACMUI -- and we have
15 documentation that many of the criteria for medical
16 events that were there are not really appropriate to
17 define medical event for permanent brachytherapy.
18 So that separation is very, very
19 important. Otherwise, you create fear in the public.
20 MR. WIEDEMAN: There are -- 57 of those
21 implants were considered underdoses. One of them was
22 considered 20 percent above the prescribed dose. The
23 other --
24 MEMBER NAG: My question is different.
25 How many were underdosed because of something like

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1 this, where most, if not all, of the seeds were
2 outside the prostate versus how many of those 57 were
3 underdosed? Because when you implant the prostate,
4 the prostate can expand. It depends on how you -- on
5 the contour, and you may get 72 percent, and that is
6 still an underdosing but not necessarily an underdose
7 based on the current definition that we are
8 recommending.
9 So there are two different -- one is
10 something like you show it here, which is an obvious
11 underdose. And the other would be all or most of the
12 seeds are put -- or have been placed within the
13 prostate volume, but because the prostate has expanded
14 in between, the final dose after one month -- a CT
15 done after one month, and during that time the
16 prostate has either grown bigger or smaller.
17 And, therefore, when you finally do the
18 dosimetry, you find the number is now 72 percent of
19 what you expect. And that difference is something
20 that is very, very important, at least to me, because
21 I am going to make a comment about the two
22 differences.
23 MS. FRAZIER: Dr. Nag, let me make sure I
24 understand. Are you saying that maybe if they were
25 recontoured that a number would have been different?

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1 MEMBER NAG: No. What I am saying is that
2 even if you do a proper medical implant of a prostate,
3 and an implant -- you had thought you needed 30
4 millicuries, you give 145 Gray. Even if you execute
5 it properly, there will be certain cases where it will
6 not meet the dose criteria.
7 We recognized that in 2003 we had -- the
8 ACMUI had said that it is not appropriate. There was
9 a subcommittee meeting to come up with new ways to
10 examine prostate -- oh, not prostate, permanent
11 brachytherapy. We came up with those recommendations.
12 We know very well that the prostate,
13 especially prostate, for any permanent brachytherapy,
14 you cannot really examine it those ways. You have to
15 examine it based on the activity that has been
16 prescribed. Was it the activity that had ended up in
17 the treatment area? And that is all the discussion
18 that has been going on in the last two or three years.
19 I know you have been reacting by going --
20 by what is on the criteria in the books, but I want to
21 make that differentiation, because what is happening
22 is that you may have five cases where the seed is
23 completely outside the prostate. That is a bad
24 medical practice.
25 And another 20 or 30 where the seed

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1 already implanted itself, but it also, for various
2 reasons, like prostate shrinking or prostate
3 expanding, and so forth, it became a medical implant
4 based on the criteria that are in the books.
5 So that differentiation is very important
6 to make the differentiation for the public. I mean,
7 from a purely medical -- based on what we have in the
8 book, you may be correct. But then, if you go and
9 examine the entire county based on the method that you
10 have done on this book, you are going to find about
11 maybe 20 percent or so that will not meet the
12 criteria.
13 And so of the 100,000 of them that have
14 been done in the country that became a permanent
15 implant, you are going to have 20,000 cases which will
16 meet the current definition of "medical implant." And
17 that is the reason why we changed the definition of
18 "medical implant" from being a dose-based to being
19 activity-based or source-based.
20 MR. WIEDEMAN: Dr. Nag, I think I
21 understand your question. It is a good question. I
22 will say this is not the only view that looks like
23 this. There are several that I have seen. I can't
24 tell you there was 45 out of the 57. Maybe the region
25 knows that.

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1 What we are asking the regional inspection
2 team to do is verify compliance with the current
3 regulation, though.
4 MEMBER NAG: Sure. I understand.
5 MR. WIEDEMAN: We have an action from the
6 results of this study, which we have actually delayed
7 the "medical events" definition rule to make sure that
8 the things that we learn from this inspection are
9 factored into that rule and how we ultimately redefine
10 "medical events."
11 MEMBER NAG: Right. Are you going to see
12 -- you are going to have 20,000 medical events at
13 least in the country, if you examine everyone.
14 MR. WIEDEMAN: We have --
15 MEMBER NAG: If you use the same rule that
16 you are applying now.
17 MR. WIEDEMAN: We have done a lot of
18 inspections of brachytherapy, and we don't see a lot
19 of inspections that have results like we saw at the
20 VA.
21 MS. PELKE: If I can just carry on to
22 Rob's comment, and also, Dr. Nag, your comments. We
23 are assessing these treatments in accordance with
24 current rules and current requirements. So we were
25 looking at the plus or minus 80 percent of the D-90.

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1 We did determine that we could go with D-90, and there
2 was a consensus, and we have documentation that that
3 was an appropriate measure for prescribed dose.
4 What we had here -- and we had to make an
5 assessment based on what we saw at this particular VA
6 facility in Philadelphia, and assess, well, could this
7 possibly -- could we have the situation at other VA
8 permittees that were doing prostate brachytherapy?
9 And so we went out and did an extended
10 condition inspection. That inspection activity is
11 still open, but what we have found at the other
12 facilities conducting permanent prostate brachytherapy
13 is dramatically different than what was going on at VA
14 Philadelphia.
15 There were some situations or some
16 scenarios that aren't necessarily unique to a
17 Veterans' Affairs hospital. They employ contractors
18 they -- going on good faith that the contractors that
19 they had retained were experts in the field, they
20 believe.
21 And we have not only seen this at the VA,
22 but we have seen this at other medical institutions
23 that have actually had medical events identified with
24 the modalities that were practiced by that contracted
25 group, is that when a contractor comes on board, and

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1 they are experts in the field, that there is some
2 assumption that they are experts, they should be
3 running the shop, and that we should be getting, you
4 know, a high standard of care. And that is not
5 necessarily so.
6 So we do believe, once we have wrapped up
7 all of our inspection activities, and we have
8 completed the extent of condition, that we will
9 hopefully be coming out with some type of generic
10 communication, just on the contracted services, and
11 reminding licensees of their responsibility going
12 forward.
13 And I will say that the events and the
14 treatments that were done at Philadelphia, there are
15 -- you know, there were two precursor events, in 2002
16 and 2005. And as a result of those precursor events,
17 there was a concern by the physician about putting
18 seeds into the bladder. And as a result of that, the
19 physician, in their technique, tended to back off, but
20 without any quantitative measurement of how far they
21 were backing off. And as a result of that, you see an
22 example of the quality of the implants.
23 And then, they also had an extenuating
24 circumstance in that the treatment planning system
25 they were using, the VariSeed, they had done some

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1 upgrades on security. And as a result of some of the
2 upgrades that they did, they had experienced problems
3 with transmission of the images they were using of the
4 prostate into the VariSeed treatment planning system.
5 They had been working on resolving those
6 issues, but in the meantime approximately one year
7 went by where they continued to treat patients. That
8 kind of never crossed their mind, that maybe we should
9 suspend the program until we get this treatment
10 planning system up and running, and our images or
11 input, so we are getting accurate results. They
12 didn't do that.
13 So, you know, there is a number of issues
14 relative to some of the decisionmaking. And we did
15 have a team there. We didn't have necessarily an
16 Authorized Medical Physicist, because that is not
17 required, as you know, for permanent prostate
18 brachytherapy. But we certainly had medical
19 physicists involved, as well as qualified Authorized
20 Users.
21 So, really, I think that there is a
22 benefit coming out of this in that, you know, the
23 timing is right. We have proposed rulemaking on the
24 table. We are going to be able to better inform that
25 process, so that we will get a rule moving forward

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1 that includes all of the parameters that we may want
2 to consider moving forward. But right now we are
3 still with a dose-based requirement.
4 MEMBER NAG: May I -- I agree with all of
5 the points you made. What I am trying to say is that
6 you will probably make this a better report if you did
7 write those two kinds of medical implants separately,
8 one where there was a definite case where the seeds
9 are either well below or well above the prostate
10 versus what you have done at -- you have two different
11 kinds of problems, one a problem with a definite seed
12 outside the prostate, and that is called a medical
13 event, and I agree wholeheartedly with that.
14 But, at the same time, you have quite a
15 few -- I don't know how many -- that have opened up a
16 full medical event, just because it meets the
17 definition of "medical event," although from a -- if
18 you are using activity-based it would not be called a
19 medical event. And if you lump the two together, you
20 are going to create a fear throughout the community,
21 because people are going to say, "I am doing the right
22 thing. I have put all my seeds into the prostate,"
23 but it is still called a medical implant, because you
24 are going by dose-based.
25 If you separate the two issues, you will

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1 be more believable, because then you are going to
2 hear, "Well, out of the 92, 80 or 60 were really
3 medical events, because seeds were outside the
4 prostate." But my -- although in part the definition
5 of "medical implant" is the -- you know, if you are
6 applying the new definition, it will not be.
7 I am just asking you to separate those two
8 separately.
9 MS. PELKE: And, Dr. Nag, I will -- I can
10 let you know that part of the charter for the
11 inspection activity was not to compare the results of
12 the implants that we assessed at Philadelphia against
13 proposed language in a rule. And we also understand
14 that that rulemaking language will be changing as we
15 move forward, so we assessed those under a current set
16 of criteria.
17 Now, I would also like to offer that
18 certainly 92 identified medical events out of just
19 maybe less than 120 treatments totally performed
20 between 2002 and 2008 as a regulatory agency is very
21 troubling to us.
22 So of course we wanted to get a better
23 assessment on, you know, do we have certain
24 circumstances at one facility that were precursors to
25 this? And to not use this as an example of where we

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1 want to go in regulatory space going forward.

2 MEMBER NAG: It may be possible that one

3 or two of the practitioners were bad practitioners or

4 they didn't know how to use the ultrasound.

5 And then, you got quite a few that were

6 really bad implants, and the others may be reasonably

7 good brachytherapists, but because of the definition

8 got caught in the net, and I want you to -- if you

9 don't, you are going to make everyone afraid to do any

10 permanent brachytherapy because of fear they might do

11 it wrong, but yet it may be called, you know,

12 misadministration.

13 MS. PELKE: And I will offer that those

14 that were identified as underdoses, we are not talking

15 at 79 percent of what was delivered, or close to 80

16 percent. We are talking about percentages

17 dramatically lower than that.

18 CHAIRMAN MALMUD: I think that Dr. Fisher

19 has a question.

20 MEMBER FISHER: This is an interesting

21 case. Obviously, the problem is, as you show on the

22 slide, incorrect placement of seeds. Was this

23 transrectal-guided ultrasound-administered seed

24 implant?

25 MR. WIEDEMAN: Yes.

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1 MEMBER FISHER: Have you identified what
2 the root cause is of the incorrect placement of seeds
3 over a series of patients? You have listed corrective
4 actions that include going back and reviewing the
5 treatment planning relationship. But what was going
6 on that the seeds were consistently placed
7 incorrectly? What was the root cause of that?
8 MR. WIEDEMAN: Well, one of the things
9 that we noticed was that the physician that was
10 primarily involved in the brachytherapy program, he
11 consistently did this. They didn't use fluoroscopy
12 during seed placement. He refused to use fluoroscopy,
13 said he didn't need it.
14 And also, their computer program, they
15 couldn't do a final treatment plan, so, therefore,
16 they weren't sure of where the seeds were once they
17 implanted them into a patient.
18 We also have a situation where we had a
19 medical physicist, Authorized Medical Physicist, back
20 in 2002 realize that, in his words, the placement of
21 seeds were not appropriate. And he had talked to the
22 Authorized User about it, and I asked, "Well, what did
23 the Authorized User do about it?" and he said, "He
24 just said he would try to improve his technique."
25 And so they realized -- the physicist

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1 realized back in 2002 that there was a problem, and
2 then just recently, in 2007, another physicist said
3 the same thing, that he felt that the seeds were
4 improperly implanted. And he was concerned about
5 it, but unfortunately he didn't take it to the
6 licensee and discuss it with them. He discussed it
7 with people across the street, the university
8 hospital.
9 And the one thing -- we found that there
10 was poor management oversight, or there was none, of
11 the contractors. The training, when we interviewed
12 various different people, they indicated they have
13 never been trained on the definition of a medical
14 event, who to report a medical event to if they did
15 discover one, and the typical things that you would
16 expect a medical physicist to know. But in this case
17 they claimed that they were not very knowledgeable
18 about that.
19 And then, we found that the contractors,
20 both the physicist and the physician contractors, no
21 one was looking over their work. The radiation safety
22 staff, they did quarterly audits, but their audits
23 didn't pick up any of these problems. So we also have
24 another problem.
25 CHAIRMAN MALMUD: Mr. Lieto, you had a

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1 question?

2 MEMBER LIETO: Two questions. Is it

3 correct that they use the standard to bring the

4 patient back after so many weeks and do some type of

5 an image to evaluate seed location and migration,

6 after edema settles out and so forth? Are you saying

7 that they did not bring any of these patients back at

8 some time period afterward and do, say, a CT imaging

9 or whatever the standard might be?

10 MR. WIEDEMAN: They brought the patient

11 back in 30 days, and they did a CT. But the CT, at

12 that time, couldn't -- they couldn't interface it with

13 the VariSeed program.

14 MEMBER NAG: If I may clarify. That means

15 that they did the CT, but they did not do the

16 dosimetry. So they did the CT, but they never looked

17 at it. In fact, if you do the CT, you don't even do a

18 dosimetry, you just look at the CT and you see both of

19 the seeds are outside the prostate, even without any

20 dosimetry you would know that it is a mistake or an

21 error.

22 So not having the dosimetry or the

23 VariSeed program working is really not an excuse,

24 because if you can see half of your seeds are outside,

25 there is no way you will meet the definition anyway.

DRAFT

1 MS. PELKE: I might offer that the
2 Authorized User stood by all of these implants and
3 believed in some cases if you intended to give
4 160 Gray and you only delivered 23 Gray that you were
5 still delivering some dose to the treatment site.
6 So there was -- I mean, that is a practice
7 of medicine issue, and -- but I will tell you that we
8 were confounded by some of the information that we
9 obtained.
10 CHAIRMAN MALMUD: Are there questions?
11 Dr. Welsh?
12 MEMBER WELSH: You mentioned that
13 fluoroscopy was not used intra-operatively. And I am
14 not so sure that fluoroscopy really is essential or is
15 necessary for this type of procedure. But it seems
16 from the two examples that you did provide the seeds
17 were grossly outside the prostate volume suggesting
18 that the clinician was not fluent with prostate
19 anatomy on ultrasound. That is what I would guess is
20 the root cause of this particular problem.
21 But that raises the question about these
22 images here. Who contoured the prostate on these CT
23 images? And do we have confidence that those seeds
24 are not truly within the prostate? And that that
25 volume of prostate is accurate?

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1 MR. WIEDEMAN: The prostate was contoured
2 by a combination of two people. One was the
3 Authorized User, and the other was a urologist.
4 MS. FRAZIER: Well, let me just explain.
5 What they did is they had an independent organization
6 come in. They had an independent radiation
7 oncologist, expert in the field, and they had an
8 independent medical physicist. And so they did a new
9 CT on every single patient, and they had that
10 independent radiation oncologist recontour the
11 prostate, and then they had the dose calculations
12 completed by the medical physicist.
13 So they had outside independent experts
14 come in. And after they had that done, then they made
15 the call of medical event or not.
16 MR. WIEDEMAN: I might add that this
17 particular VariSeed picture, it was taken over a year,
18 year and a half later after they finished the implant.
19 MEMBER NAG: May I offer up an impression?
20 One is that if you are taking a CT one year later,
21 the prostate shrinks remarkably, so you have to take
22 that into account. I am not saying it totally negates
23 your report, but you have to take that into account.
24 Number 1.
25 Number 2, I have investigated quite a

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1 number of medical events in prostate brachytherapy.
2 The most common reason I have found is
3 misidentification of the prostate on ultrasound,
4 because -- usually because of inadequate training on
5 ultrasound, whether it is by the urologist or whether
6 it is by the radiation oncologist. Urologists are
7 good at surgery. Radiation oncologists are good at
8 developing radiation. Some of them may not have had
9 training -- either the urologist or the radiation
10 oncologist may not have training in the ultrasound.
11 So that is the major reason I have found
12 for these medical events. The other thing is that
13 when you are contouring the prostate independently,
14 even though it is kind of like an independent third
15 person doing it, there is a huge variation on how
16 someone contours the prostate post-implant.
17 Several years ago, in fact, in 2002, we
18 did have a study between the top radiation oncologists
19 in the field. We got together at one of the meetings.
20 We took I believe eight different post-prostate
21 contours, and we -- each of us identified the prostate
22 independently. And I do have the result with me. It
23 is very interesting, I think you will find.
24 For a patient in whom the prostate -- 145
25 Gray was prescribed, because of the way each of us

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1 contoured the prostate, the dose that finally turned
2 out between -- was between 91 Gray and 260 Gray.
3 There was that much of variation.
4 On the same prostate, if you do the same
5 -- you can tell there is a standard deviation of 15.
6 Okay? The other one, which is the volume, that we
7 point to it, it would be between 41 to 63 ccs with a
8 standard deviation of 5.5.
9 So this would not even take into account
10 different planting -- whether you are implanting
11 prostate, so all of that, you know, would have to be
12 taken into account. These are all of the reasons why
13 I am requesting that you apply the -- on something
14 like this, it would be a medical event, it would be a
15 medical event no matter how you define it. But some
16 of the others may have been caught in the net.
17 CHAIRMAN MALMUD: Dr. Welsh.
18 MEMBER WELSH: If I might make a quick
19 comment to what Dr. Nag was saying. That appears to
20 be a gross medical event, if the red is truly
21 correctly contoured and it doesn't extend two or three
22 centimeters inferiorly to where it ends up there. And
23 that is the question that I think does remain on the
24 table.
25 MR. LEWIS: We have -- this is information

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1 that the VA has produced, not the NRC staff. At this
2 point in time, we have issued our inspection report,
3 and we will be looking for VA to respond to it.
4 MEMBER NAG: I think here not only -- you
5 don't even have to contour the prostate. The bladder
6 itself, the prostate is always immediately below
7 interior and posterior to the bladder. You know, that
8 -- the bladder itself is a very good -- I always like
9 to have a contrast in the Foley balloon, because even
10 if you make a mistake with the ultrasound, a second
11 backup would be a fluoroscopy image with a Foley
12 balloon in the bladder.
13 And if your needles are way below that, or
14 way above that, you know no matter what you see on the
15 ultrasound there is a mistake. So very often I tell
16 the new practitioner, even though you do have the
17 ultrasound, for the first few patients to be very on
18 the learning curve, take a fluoro just to make sure
19 you are not making a gross mistake. You know, I think
20 a fluoro is still helpful, at least for the beginners.
21 CHAIRMAN MALMUD: Dr. Suleiman.
22 MEMBER SULEIMAN: I want to just clarify a
23 couple of points. You had said that other sites had
24 been inspected, and this -- these sites clearly were
25 out of the normal range of what you were seeing. So

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1 there is that standard for comparison in terms of
2 inspections.
3 MR. WIEDEMAN: The degree of medical
4 events was not as significant as Philadelphia. We
5 found sort of a generic problem, such as Jackson,
6 Mississippi. They also had problems with their
7 computer interface. We also found the same problem
8 out in Reno. But, once again, there were no medical
9 events associated with the Reno, but there was a
10 couple down in Jackson.
11 MEMBER SULEIMAN: Now, the other thing,
12 you had mentioned that in one case they had delivered
13 80 percent lower dose, and they decided that that was
14 just normal uncertainty in the practice of medicine,
15 so they were not distressed by the fact that they had
16 given a much much lower dose?
17 MR. WIEDEMAN: Correct.
18 MEMBER SULEIMAN: That was due to
19 placement or calculation of the seeds?
20 MS. PELKE: Placement.
21 MR. WIEDEMAN: Placement, yes.
22 MS. PELKE: Exactly. That is the
23 clinician, the physician, the Authorized User made
24 that call.
25 MEMBER SULEIMAN: And that picture was

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1 taken one year after the implant?

2 MR. WIEDEMAN: Approximately a year later.

3 MEMBER SULEIMAN: Obviously, I think for

4 some of the reasons Dr. Nag raised -- I mean, it

5 raises questions. It raises questions.

6 Thank you.

7 CHAIRMAN MALMUD: We have a member of the

8 public who wishes to say something.

9 MS. FAIROBENT: Yes. Lynne Fairobent of

10 AAPM. I just had a question about the comment you

11 made regarding a follow-up by a medical physicist

12 being there or not being there. Under Part 400, an

13 AMP is not required. So could you clarify what you

14 were saying about the reference to an Authorized

15 Medical Physicist? It is only required under Part 600

16 for NRC.

17 MS. PELKE: That is correct, and that was

18 how I was qualifying my remarks. They had medical

19 physicists involved, and in this case they were

20 Authorized Medical Physicists, which I was trying to

21 qualify indicative of meeting training and experience

22 requirements under Part 35. But I recognize that for

23 35.400 modalities, the Authorized Medical Physicist is

24 not required for those treatments. Does that clarify

25 things?

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1 MS. FAIROBENT: That clarifies it. But
2 that was not the impression I was getting --
3 MS. PELKE: Oh, I am sorry.
4 MS. FAIROBENT: -- listening to what you
5 were saying in tying an AMP to Part 400.
6 MS. PELKE: Right, right. Thank you for
7 that. Thank you.
8 CHAIRMAN MALMUD: Mr. Lieto?
9 MEMBER LIETO: Yes. I had another
10 question or two. I guess I am trying to understand
11 these causes here. There is indicated a lack of
12 safety culture. Was this from top down, in other
13 words from the national -- was it this NRSC on down?
14 Was it the health physics service? Was it just in the
15 RSO on the site? Because I think it is kind of
16 important, because I think it gets to a lot of I think
17 the causes of this action.
18 MS. PELKE: Shall I?
19 MR. WIEDEMAN: The RSO, according to what
20 she told me, they claim that they hired the experts.
21 They got the best that money could buy from the local
22 university. So, therefore, they didn't really require
23 a lot of training or oversight, because they were the
24 experts. And there was a lot of little problems that
25 they ran into that were taken to the Radiation Safety

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1 Committee. The Committee did nothing about it.
2 Sometimes they didn't even discuss it, but yet it was
3 on the agenda.
4 And so, all in all, the safety culture
5 just wasn't there, starting with the RSO, their staff.
6 Yes, Ralph?
7 MEMBER LIETO: Just a followup question on
8 this. In the National Health Physics Program, do they
9 have board certified medical physicists as a part of
10 the group? Or are they certified HPs?
11 MS. PELKE: Well, they certainly have a
12 diverse experience group that works within the VA
13 organization. And they have a -- I am not sure if he
14 is certified or not, but he is a specialist in
15 prostate brachytherapy, so he certainly is involved.
16 But I think that what probably impressed
17 me more than anything as a result of these inspection
18 activities is how much expertise within the VA
19 organization itself, and other permittees, relative to
20 prostate brachytherapy, and physics -- physicists
21 involved. Excuse me.
22 They certainly have the experts within
23 their own organization to set standards and threshold
24 and expectations for performance going forward. And
25 as far as the safety culture, I would like to qualify

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1 that somewhat more in that, you know, we had
2 indications that during initial treatments back in
3 2002, the physicists involved with the Authorized User
4 had some questions about the quality of the implants,
5 mentioned it to the Authorized User, but didn't take
6 it any further within the organization.
7 And that happened periodically, and it
8 appears that there was not an environment that
9 fostered, look, if you bring an issue up and you are
10 dismissed or you believe that it hasn't been
11 appropriately characterized and followed up on, that
12 you shouldn't stop there, that you should take it
13 further up the organization. So that was missing
14 there.
15 But as far as NHPP, because they actually
16 responded to this initially back in May, and then in
17 June, and when they responded back in May they took a
18 look at an index case where seeds of different
19 activity were ordered, and what was the root cause
20 there. That was really a different track than really
21 where this got us.
22 But as a result of their reactive
23 inspection activity, they asked the permittee, "Hey,
24 go back and look at the last 10 you have done." And
25 based on that assessment, they were identifying

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1 medical events that they hadn't been -- that hadn't
2 been identified in the past, so then NHPP said, "Well,
3 expand the scope a little bit further."
4 And as they uncovered more and more
5 problems, a decision was made by the permittee, that
6 being VA Philadelphia management, to suspend the
7 program, and that was suspended last June, early June,
8 and is still suspended.
9 MEMBER LIETO: So your assessment, then, I
10 gather is that the NHPP has the expertise to do sort
11 of a top-down type of an audit of the various
12 facilities and programs.
13 MS. PELKE: Yes.
14 MEMBER LIETO: Okay.
15 CHAIRMAN MALMUD: Any other questions?
16 Dr. Suleiman?
17 MEMBER SULEIMAN: I see several areas to
18 focus on. Number 1, did they image properly? Did
19 they place the seeds properly? Or did they rely on
20 software too much? Today's culture is I think people
21 think software will do everything automatically. And,
22 I mean, I have had a lot of therapy colleagues tell
23 me, "It is frustrating. I can't -- I am completely
24 dependent on the software." But, still, there are
25 things they can do to verify that it is working.

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1 Probably the thing that bothers me the
2 most is the consulting physicist had identified some
3 problems earlier on, and somehow that -- aside from
4 making a comment and assuming that somebody is going
5 to grab it and follow up with it, was there -- were
6 they aware that there was a chain of command, or there
7 was -- if they had a concern, who did they report that
8 to? And why didn't it get to where it was supposed
9 to?
10 You said it should have gone up the chain
11 of command. Were they aware that they had that
12 responsibility? And who is it they should have
13 contacted to bring that point home?
14 MS. FRAZIER: Well, I think part of the
15 issue is that, if you look at their corrective action,
16 they are providing training to their staff as part of
17 their corrective action. And I think just -- part of
18 that is that the staff did not receive training in
19 order to know that they were -- they had to bring
20 these issues up.
21 And normally they would bring the issues
22 up to the radiation safety staff, or, if they didn't
23 get an answer there, they should be told to go higher
24 than the radiation safety staff. But normally they
25 would bring it up to the radiation safety staff.

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1 MS. PELKE: Also, I will offer -- in this
2 case, there was no internal peer review on
3 brachytherapy, and that was at this institution one of
4 the most highest risk activities they did, yet they
5 had not instituted any form of peer review, which is
6 outside of the norm.
7 They did do peer review for external
8 being, but they didn't do it for prostate
9 brachytherapy.
10 I am trying to stay with my train of
11 thought, so -- as far as the reporting, no, there was
12 not a -- there was not a management presence there on
13 the part of the permittee, VA Philadelphia. As we
14 stated earlier, they believe that they hired experts,
15 and that they were running the program in an expert
16 fashion.
17 So there were -- and there were audits
18 being done. I don't know that the audits were
19 necessarily -- by the permittee, VA Philadelphia. I
20 don't know that these audits didn't reveal any of
21 these problems, so there is a question about the
22 training that was being provided by the radiation
23 safety staff on the audit, the purpose of the audit,
24 and what to look at for the audit, as you are looking
25 at that.

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1 MEMBER SULEIMAN: But there were some
2 early warning indicators, obviously, that they just --
3 it is great in retrospective analysis, but it didn't
4 help any.
5 MS. PELKE: Correct. Yes.
6 CHAIRMAN MALMUD: Debbie Gilley.
7 MS. GILLEY: Yes. In response to your
8 lack of safety culture, did you take a look at other
9 modalities such as HDR, LDR, or teletherapy as
10 potential issues?
11 MS. FRAZIER: Well, we did look at the
12 Nuclear Medicine Department, and what we found --
13 MS. PELKE: Well, first of all, I just
14 want to preface this that prostate brachytherapy was
15 the limit as far as therapeutic applications at this
16 facility. So they did no teletherapy, no HDR, no
17 gamma knife. Yes, that would have been a concern.
18 MR. WIEDEMAN: But we went back and looked
19 at the nuclear medicine to --
20 MS. PELKE: And we also looked at the
21 nuclear medicine program.
22 CHAIRMAN MALMUD: And did you find a
23 culture of safety with regard to radiation handling in
24 nuclear medicine?
25 MR. WIEDEMAN: In nuclear medicine, it was

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1 a completely different program. In that case, every
2 one of the technologists and the staff down there knew
3 exactly what a medical event was, could quote it word
4 for word, and they knew exactly who to report it to.
5 CHAIRMAN MALMUD: An entirely different
6 culture.
7 MS. PELKE: Right, right.
8 CHAIRMAN MALMUD: Dr. Fisher?
9 MEMBER FISHER: Fisher. I looked at the
10 list of causes of medical events. I am surprised one
11 is missing, and that would be no post-implant
12 verification of seed implant, which I would consider a
13 cause.
14 Did you look at the prior experience of
15 the implant physician?
16 MS. PELKE: This physician had received
17 training back in --
18 MR. WIEDEMAN: 2002.
19 MS. PELKE: -- yes, 2002, and -- but from
20 the time the physician had received training to the
21 time they started the implant program, there was some
22 delay. And there was no -- there was no effort on the
23 part of the physician to maybe proctor or observe or
24 be involved with some implants before they decided to
25 go and proceed and treat their first patient. so, and

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1 that was a decision that was made by the Authorized
2 User.
3 MEMBER WELSH: So, therefore, there would
4 be lack of experience by the physician doing the
5 surgical implants.
6 MS. PELKE: Well, the physician met our
7 training -- at the time met the training and
8 experience requirements.
9 MEMBER WELSH: Was the surgeon a
10 contractor or a VA employee?
11 MS. PELKE: Contractor.
12 MEMBER WELSH: Okay.
13 CHAIRMAN MALMUD: Dr. Nag.
14 MEMBER NAG: Now, you are focusing mainly
15 on the Philadelphia, but you added the other VAs as
16 well. The contractor was -- he was a contractor, not
17 a VA employee, right?
18 MS. PELKE: Well, within the VA
19 organization there is a number of different scenarios.
20 You can -- they fully contract some services, or they
21 may have a physician that is partial contract,
22 partially funded FTE. So, and there is different
23 variations of that throughout the organization.
24 MEMBER NAG: The question I have is: does
25 this contractor provide service elsewhere, either on

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1 an outpatient or in a hospital or --

2 MS. PELKE: Yes.

3 MEMBER NAG: And, if so, have those

4 implants been checked, even though you are concerned

5 only with the VA? Those or any other additional

6 medical events?

7 MS. PELKE: Yes. We were concerned about

8 affiliate institutions that the Authorized User may

9 practice at. We did inform the affiliate institution,

10 which is an Agreement State licensee, of the

11 circumstances. The Agreement State also had a

12 representative onsite at Philadelphia when we exited

13 during our special inspection that was last fall. So

14 we attempted to inform all of the organizations

15 necessary to -- relative to where the Authorized User

16 had privileges.

17 MEMBER NAG: That didn't answer my

18 question. My specific question was: have the other

19 implants done by this Authorized User, or this group

20 of Authorized Users, at other sites been inspected?

21 And, if so, have they caught additional medical

22 implants? Not that they were informed or not, but

23 have they been inspected?

24 MS. PELKE: They will be going out, it is

25 my understanding, in early June for an inspection at

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1 that facility. Also, it is our understanding that the
2 affiliate institution primarily treats external beam
3 for prostate brachytherapy. They do few implants.
4 CHAIRMAN MALMUD: Does that answer your
5 question? This is a very disturbing discussion, as
6 you can gather from the questions being raised.
7 Clearly, there are two issues. One is the medical
8 issue, and the competence of the physician who engaged
9 in this practice. And the second one is the radiation
10 issues. The two are related, obviously.
11 Our concern is the radiation issue, which
12 is an outgrowth of the practice of the physician. Do
13 we agree so far, Dr. Nag?
14 Now, the concerns that are being raised
15 are, number 1, how could this happen in an institution
16 which is, number 1, inspected by the JC, and should
17 meet the practice standards of the JC? Which is a
18 medical issue, not for us.
19 And the second one is, with respect to the
20 radiation concerns, which are ours. One can
21 understand that if the physicist was not able to
22 communicate the physicist's concern about what was
23 going on directly to the physician in charge, because
24 the physician in charge either did not know what he
25 was doing or didn't want to hear any complaints, is

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1 there not in the management system or structure that
2 we have in the NRC some route for that physicist to go
3 when the physicist needs silence or a stonewall with
4 regard to his or her observations?
5 So let's put aside the medical issue for
6 a moment. What should the -- well, let's say this
7 happened today in another institution. The physicist
8 recognizes a problem is occurring, tells the attending
9 physician. The attending physician stonewalls the
10 physicist. What should that physicist be doing next?
11 MS. PELKE: The physicist could pick up
12 the phone and call the NRC with their concerns.
13 CHAIRMAN MALMUD: Did that physicist not
14 know that?
15 MS. PELKE: I --
16 CHAIRMAN MALMUD: Was that a trained
17 physicist?
18 MR. WIEDEMAN: As a minimum, the physicist
19 should have gone to the Radiation Safety Officer.
20 That was her job, to look into these issues.
21 CHAIRMAN MALMUD: The Radiation Safety
22 Officer of the VA or of the --
23 MR. WIEDEMAN: The VA.
24 CHAIRMAN MALMUD: -- mother institution?
25 Of the VA. Was it possible that the physician was the

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1 chief -- was the chairman of the committee of the RSO?
2 Who knows? I don't know.
3 MR. WIEDEMAN: They are in some sense.
4 "Well, you know, I couldn't do anything, because no
5 one ever told me we had a problem." And I hired the
6 very finest, so you can buy that these were the
7 experts. So I assumed that they were doing it the
8 right way.
9 CHAIRMAN MALMUD: What would we do if that
10 happened again today at another institution? After
11 all, that is our role, which is --
12 MR. WIEDEMAN: Same thing.
13 CHAIRMAN MALMUD: -- to say -- what would
14 we do?
15 MS. PELKE: Well, I can -- as a result of
16 our followup inspection activities, we typically go
17 out and do risk-informed inspections. We don't -- you
18 know, we are going out and looking at a slice of time.
19 And if there have been medical events at an
20 institution in the past, we would evaluate those in
21 the program when we go out during a routine.
22 Beyond that, you might be doing a
23 sampling. So as a result of this information, we are
24 informing our inspection process to be more intuitive
25 in that program, to ask more questions, and to pull

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1 more strings than maybe we have done in the past. And
2 we are going to share that with the Agreement States
3 as well as the other regions. But that is something
4 that we are going forward with, forward-looking.
5 CHAIRMAN MALMUD: If today a patient were
6 treated at another institution with a prescription for
7 94, and received only 20 percent of those, would that
8 not be an automatic alert to the NRC, if it inspected
9 that institution? And whether the order was rewritten
10 or not, it doesn't make sense that 20 percent of the
11 dose is acceptable.
12 MS. PELKE: I would agree that 20 percent
13 of the dose is not acceptable. If there --
14 CHAIRMAN MALMUD: But do the physicists
15 and the radiation oncologists agree? Dr. Vetter?
16 VICE CHAIRMAN VETTER: The problem in that
17 example you just cited is that, first of all, the
18 radiation oncologist needs to notify someone that only
19 20 percent of the seeds are in the prostate. And if
20 he or she fails to do that, no one will know.
21 CHAIRMAN MALMUD: Not even the physicist.
22 MEMBER NAG: Because you can draw a circle
23 wherever you want. Even though I see the prostate
24 there, I draw my circle, you know, who is going to
25 know? I mean, I would know, but who else is going to

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1 know that --

2 CHAIRMAN MALMUD: So if I am a patient

3 going in for a treatment of prostate cancer, I have a

4 choice of multiple therapies, the therapy that I

5 choose is seed implantation, I think we have

6 confidence in the system, as it is described today, is

7 close to zero.

8 MEMBER NAG: Well, but the same if you are

9 doing with external beam. If I brought the external

10 beam, my prostate field would be the bladder, and I

11 pick the bladder, let me know. So, I mean, that is

12 not a question of prostate or seed implant. It is a

13 question of the integrity of the condition.

14 CHAIRMAN MALMUD: But in this case -- I

15 agree about that. But in this case, the physicist

16 became aware of it and says that the physicist -- you

17 reported to us that the physicist was concerned,

18 expressed concern, and it ended there. Is that a

19 correct interpretation of what you described?

20 MS. PELKE: Yes.

21 CHAIRMAN MALMUD: Now, when that happens,

22 there should be a route for the physicist to bypass

23 with protection. I mean, otherwise, if the physicist

24 knows he will be fired for reporting something that

25 the attending didn't want him or her to, then we --

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1 there needs to be something in -- to protect this
2 person with regard to the chilling effect. But what
3 is the routine?
4 MR. LEWIS: Dr. Nag, can I offer to help
5 respond to this?
6 CHAIRMAN MALMUD: Yes.
7 MR. LEWIS: I am sorry. Not Dr. Nag, Dr.
8 Malmud. In our regulations, if a licensee is
9 following our regulations, which is one of the things
10 we inspect at each inspection, in Part 19 of our
11 regulations, which apply to all licensees, not just
12 medical, it requires the licensees to post notices to
13 the workers of how to raise a concern. It is on the
14 NRC Form 3.
15 It also requires licensees, in the next
16 part of Part 19, to give training to workers. Part of
17 that training should be how to raise an issue. So all
18 of those things should have happened, according to the
19 regulations. In this case, we had a licensee who was
20 not following the regulations in terms of training.
21 That is one of the findings. So there was a breakdown
22 there.
23 It is one of the things we inspect in all
24 of our inspections, and all of the Agreement States
25 also inspect similarly. Because this was a Master

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1 Materials License, we had kind of a mini-NRC within
2 the VA that was doing that function. And that is one
3 of the things we are looking at is how they were doing
4 that job.
5 CHAIRMAN MALMUD: So in this particular
6 case, because it was a VA with a master license, it
7 was not handled the way it would have been handled in
8 another department?
9 MR. LEWIS: Well, that may be a
10 contributing issue, but I think that is not to say an
11 NRC licensee could also not be following the regs, but
12 presumably our inspection program is designed to
13 capture that.
14 CHAIRMAN MALMUD: Dr. Vetter?
15 VICE CHAIRMAN VETTER: Yes, just to
16 reflect on your expression of the lack of confidence
17 in prostate brachytherapy in this country. I think
18 what we are looking at here is an extremely unusual
19 case. I think in most -- in nearly all hospital
20 systems, you have a very good working relationship
21 between the Radiation Safety Officer, the physicist,
22 and radiation oncologist. And the physicist and
23 radiation oncologist are working side by side, so
24 everyone really does know what is going on.
25 CHAIRMAN MALMUD: What we are learning is

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1 that some departments use CT for localization. Some
2 that do not have CTs available are using ultrasound
3 still?
4 MEMBER NAG: No, no, no.
5 CHAIRMAN MALMUD: Ultrasound is --
6 MEMBER NAG: The implantation is done, in
7 most center, under ultrasound guidance. But the dose
8 implant, whether it is the same day a few hours later,
9 same day one hour later, or same -- or a month later,
10 it is done under CT to confirm and do the dosimetry of
11 where the seed went. The needle localization and the
12 driving force is the ultrasound, but the analysis is
13 done later under CT.
14 CHAIRMAN MALMUD: When you say that most
15 institutions do the seed placement under ultrasound,
16 what does the minority do? Is that --
17 MEMBER NAG: The minority can do the seed
18 implantation under MRI. I know some institutions are
19 doing it under MRI. Some institutions are doing it
20 under CT. So, but the reason why we don't do it under
21 CT is because that would take a longer time, putting
22 each needle, doing a CT, putting each needle, doing a
23 CT. But I have done it under CT in a patient who we
24 couldn't do an ultrasound. So, but that is the
25 minority.

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1 Only very few institutions in the whole
2 country have an MRI, and an MRI is much more accurate
3 in defining a prostate volume than CT or ultrasound,
4 you know, but then there are only I think one or two
5 MRI-based institutions in the whole country. So most
6 of them do it under ultrasound guidance.
7 CHAIRMAN MALMUD: So they are done under
8 ultrasound. The CT is used only to determine the
9 post-therapy location of the seeds.
10 MEMBER NAG: Right.
11 CHAIRMAN MALMUD: Is that what all
12 institutions use, the CT?
13 MEMBER NAG: No. Again, if you have an
14 MRI, and you can do it -- you can do the dosimetry
15 under MRI or CT. Most of them doing it are doing it
16 under CT, because that is most widely available, even
17 though there is ultrasound-based dosimetry.
18 MEMBER FISHER: Yes. The problem with
19 ultrasound dosimetry is finding the seeds. You often
20 cannot see particular seeds under the ultrasound.
21 The problem in doing dosimetry with the MR
22 is the axial position of the seeds becomes very
23 uncertain, because they cast shadows well outside of
24 the slice that they occur.
25 CHAIRMAN MALMUD: Dr. Welsh?

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1 MEMBER WELSH: Just one comment in this
2 discussion. We are talking about well over 99 percent
3 of practitioners use ultrasound in the operating room,
4 and over 99 percent are using CT for post-implant
5 dosimetry. So when we talk about the small minority,
6 it is a very small minority.
7 CHAIRMAN MALMUD: What about the therapy
8 planning, what did they use?
9 MEMBER WELSH: It is the post-implant CT.
10 CHAIRMAN MALMUD: No. Aren't there three
11 basic, therapy planning --
12 MEMBER WELSH: Yes.
13 CHAIRMAN MALMUD: -- therapy planning,
14 then the implantation, then the post therapy?
15 MEMBER WELSH: Yes. That is using the
16 ultrasound.
17 MEMBER NAG: Ultrasound.
18 CHAIRMAN MALMUD: Ultrasound for the
19 planning as well?
20 MEMBER WELSH: With the planning and the
21 CT for the dosimetry.
22 CHAIRMAN MALMUD: And did they have all of
23 these techniques available to them when they were
24 doing this at that institution?
25 MS. PELKE: They did not have MRI. They

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1 used --

2 CHAIRMAN MALMUD: Not MRI. CT and

3 ultrasound.

4 MS. PELKE: Yes.

5 CHAIRMAN MALMUD: But I thought I heard

6 somewhere in the story that the CT was not available.

7 MS. PELKE: No. The CTs were available,

8 but the problem was the treatment planning system they

9 used to determine dose, VariSeed was the product that

10 they used. They had an information transfer problem

11 where they could not import CT images into their

12 treatment planning system, and, therefore, they were

13 doing no dose determinations at the completion of the

14 implants for approximately a year.

15 CHAIRMAN MALMUD: Is that acceptable in

16 the world of radiation oncology?

17 MEMBER NAG: It is not acceptable, but the

18 CT would have picked up that the seeds were in the

19 wrong place. It would not have given you the exact

20 dose, but if you know that half of your seeds are

21 outside the prostate, it would have picked up that it

22 is in the wrong implant, regardless of what the

23 dosimetry showed.

24 So they were not able to perform the

25 dosimetry, the exact dose distribution. But the CT

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1 would have shown where the seeds were in relation to
2 the prostate.
3 CHAIRMAN MALMUD: So I thank you for the
4 educational process. Now my question is: what do we,
5 as the ACMUI, do to reassure the public that this will
6 not happen again? Isn't that our responsibility, to
7 advise the NRC, so that this will not happen again?
8 What do you suggest that we do?
9 MEMBER NAG: Before that, you had
10 mentioned that you had two concerns, one with the
11 medical and one with the radiation. I have a third
12 concern, and the third concern is that while we have
13 found some gross errors, like these where the seeds
14 are outside, unfortunately the method by which we went
15 by, you know, following the previous rules, we also
16 caught a few or many that are probably not a real
17 medical event, but met the definition. And,
18 therefore, it is creating a lot of fear in the
19 community, in the medical community, and how do we
20 also take care of that fear?
21 CHAIRMAN MALMUD: I understood that
22 concern, because you expressed that early on in the
23 comments, and that there may be some cases which
24 really were not medical events from a medical
25 perspective, though they may have been -- appeared to

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1 be from the radiation perspective.

2 But putting those aside, I am still trying

3 to focus on a problem having been brought to out

4 attention, we being the ACMUI, not a governing board

5 for radiation oncology. What should our role be in

6 helping to prevent this from recurring ever again in

7 any institution?

8 And I think Dr. Suleiman was next, then

9 Mr. Lieto.

10 MEMBER SULEIMAN: Okay. I think the first

11 step in solving any problem is defining it. I am not

12 sure we have clearly defined why this happened. When

13 it was brought to the attention of the Authorized

14 User, why he or she didn't do what they should have

15 done.

16 The same thing with the physicist who

17 verified that there were some questions. Who did they

18 go to? Why didn't they, you know, follow up on it?

19 So I think probably I am answering part of the

20 question. You have got to give some avenues or paths

21 for reporting to some authorities where something is

22 going to get done.

23 CHAIRMAN MALMUD: Well, it has been

24 explained to us that this is an ongoing investigation.

25 It is not completed, am I correct?

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1 MS. PELKE: That is correct.

2 CHAIRMAN MALMUD: So we have to let them
3 move ahead with what they are doing. I believe this
4 information was transmitted to us because some members
5 of this Committee were concerned that we were not
6 being kept posted on what was going on at the
7 Philadelphia VA. So we have to let those who are
8 responsible move ahead with it.

9 But, clearly, it is going to be our role
10 not to establish practice standards for the American
11 Board of Radiation Oncology, but for us to help
12 prevent this from happening again, to the extent that
13 it is a radiation safety issue.

14 Dr. Nag?

15 MEMBER NAG: Yes. I feel the rules are in
16 place. For example, whenever you are doing any form
17 of radiation therapy, whether it is external beam or
18 implant, there is a rule that you are supposed to have
19 peer review. So if I do an implant and I -- you know,
20 I want to fool people, like they are way outside the
21 prostate, in the peer review process, when one of my
22 other colleagues looks at that, they will find that
23 that is not the prostate.

24 The system is in place, but, like any
25 other thing, how do you prevent the test? If someone

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1 wilfully wants to disobey the rules that are in place,
2 you know, that is a problem. And definitely -- you
3 know, that rule is already in place. The other
4 problem about the rules is most -- I mean, this would
5 be primarily to do the calculations.
6 But if an M.D., the person who is
7 employing him, tells him, "Well, this is the seed.
8 This is the prostate. You don't worry -- this is -- I
9 am supposed to draw my outline of the prostate. Here
10 is" -- some of them at least will have a difficult
11 time saying, "I override your medical knowledge." I
12 say, "This is the prostate. What you are saying is
13 wrong. I am going to report you to the NRC." Some of
14 them may, but some of them won't. It is a very hard
15 thing to do.
16 CHAIRMAN MALMUD: I understand all of
17 that, and I understand your comment that the rules are
18 in place. But, clearly, with the rules in place, this
19 has occurred. How do we assure the public that this
20 will not happen again? It may require a change in the
21 rules. I don't know whether that change will come
22 from the American Board, or whether it needs to come
23 from us. But, clearly, the rules being in place have
24 not prevented this from occurring.
25 Mr. Lieto?

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1 MEMBER LIETO: I have two questions. One
2 is a general in terms of this master medical license,
3 and I don't know if it is headquarters staff or region
4 staff that can answer this best. But the master
5 medical license that the Department of Veterans
6 Affairs has, are the only ones with a master medical
7 license? Or is it just government entities like
8 Department of the Army and whoever? And are there any
9 master medical licenses that are not government
10 entities?
11 MS. FRAZIER: Well, it is a Master
12 Materials License, and they are just for federal
13 organizations. And we do have two other federal
14 organizations that have a Master Materials License,
15 the Department of Navy and the Department of Air
16 Force. And the Department of Air Force is handled out
17 of the Region IV office, and the Department of Navy is
18 out of the Region I office. Now, they have been
19 Master Materials Licensed for quite some time.
20 MEMBER LIETO: My follow-up question,
21 then, from the medical side is you have a list of
22 corrective actions being implemented or intended to be
23 implemented regarding this specific incident. Is this
24 being taken up also by all of the VAs? Is it
25 something that is just being applied to the

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1 Philadelphia VA?

2 I think it might go maybe to the question

3 that Dr. Malmud has in terms of restoring -- or I

4 shouldn't say restoring, but assuring confidence

5 regarding not only the VA system but other licensees

6 that -- where the Master Materials License may have a

7 medical component.

8 MS. PELKE: Well, certainly, the

9 corrective actions that were outlined in the

10 presentation were specific to the events that occurred

11 at Philadelphia. But the VA, as a regulating

12 organization, is using that information to inform the

13 rest of their permittees. And they are looking at

14 options available to them in the future as far as how

15 they want to proceed with permanent prostate

16 brachytherapy as they move forward.

17 If they have -- they had 13 permittees.

18 They have approximately I would say probably between

19 112 to 115 permittees that they cover under their

20 master material license. Of those, 13 were authorized

21 to conduct permanent prostate brachytherapy. And for

22 some of those institutions, they didn't have very

23 active programs, and others were very, very active.

24 So they are considering possibly going to centers of

25 excellence.

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1 We also had a concern in that if you are
2 familiar with the VA organization, they are affiliated
3 with large teaching institutions. And they provide a
4 variety of medical care to our veterans, so initially
5 -- and as we move forward, we are very, very concerned
6 with the impact these events have had on patient care.
7 Some programs voluntarily suspended their
8 treatment, and our next question was, well, where are
9 those patients being treated? Has that imposed a
10 hardship to the VA organization? But they have
11 adapted and continue to treat patients successfully at
12 other institutions?
13 CHAIRMAN MALMUD: I think Dr. Thomadsen
14 was next.
15 MEMBER THOMADSEN: I have a question and a
16 comment. First, you said of the physician that
17 performed these that he stood by the doses and the
18 implants. He does not acknowledge that there was any
19 problem with these implants? Was that the case?
20 MR. WIEDEMAN: No. According to him, it
21 was clinically acceptable. As a matter of fact, his
22 exact words are, "43 Gray is better than zero Gray."
23 MEMBER THOMADSEN: But he is giving almost
24 that much dose to everybody else in the OR.
25 (Laughter.)

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1 Obviously, that is not doing them much
2 good.
3 The comment is to Dr. Malmud, and that I
4 don't think we are in a position to assure the public
5 everything is fine or to make a statement about that,
6 to make recommendations for what to do. It would be
7 firing off half-cocked from the hip at the wrong
8 targets. I think that we should wait until we have
9 data. And even when we have data, I am not sure that
10 we will have the information to do what you want to
11 do.
12 CHAIRMAN MALMUD: I agree with you. We
13 are waiting for the investigation, at which point we
14 will do something. But if it is in our purview, we
15 will do something or make some recommendation, but not
16 yet.
17 But clearly, I mean, I am not easily
18 shaken in terms of medical competence, having
19 practiced for as long as I have and seen as much as I
20 have. But this is a very anxiety-provoking story.
21 Dr. Welsh?
22 MEMBER WELSH: So this -- I can see this
23 discussion could go on for hours. It is very
24 important. There is a lot of relevant issues that
25 need to be contemplated and discussed. But as far as

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1 the important question at hand, which is, is there any
2 advice that we can provide to prevent this from ever
3 happening again? I think that we have suggested
4 something about Part 19, about making sure that
5 physicists are aware that there are avenues to go
6 through, including the RSO, and to the NRC if
7 necessary.
8 But I might propose something here that
9 may not be the -- within the purview of the NRC and
10 this Committee. But it is mindboggling to me that a
11 physician could say that a dose of 40 Gray, 24 Gray,
12 is acceptable, and then look at these implants and not
13 realize that this is gross incompetence.
14 And in every facility that I have ever
15 practiced or seen, there is some form of active peer
16 review going on, so that if something like this was
17 presented to me I would say that that is obviously a
18 suboptimal implant, and I would never want to see that
19 again in any physician that I am associated with as a
20 partner.
21 Therefore, perhaps to prevent something
22 like this from ever happening again, there should be
23 an insistence, or at least a recommendation, that X
24 percentage of brachytherapy procedures undergo peer
25 review by another qualified Authorized User who is

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1 familiar with the procedure, because I can tell you I
2 would not agree with the physician who says that 24
3 Gray is better than zero. I would not agree with
4 somebody that is showing an attitude with dosimetry
5 rounds and saying that he stands by that.
6 He would come under heated criticism, and
7 I think that maybe we could make a recommendation that
8 peer review is part of the standard of care for this.
9 CHAIRMAN MALMUD: Dr. Eggli first, and
10 then Dr. --
11 MEMBER EGGLI: I would like endorse what
12 Dr. Welsh just said. I would make it a little broader
13 and say that every brachytherapy program should be
14 required to have a quality management component, which
15 includes peer review. I would like to, though, ask
16 one yes or no question that is -- is it acceptable
17 medically not to do post-implant dosimetry?
18 MR. WIEDEMAN: Not in 2009.
19 MEMBER EGGLI: And then, that could be a
20 second part of the specification for brachytherapy is
21 that if you are going to do brachytherapy you must do
22 some form of post-implant dosimetry.
23 MEMBER NAG: I can address that. The ABS
24 has the recommendation that what -- from the paper in
25 1999. I was the lead author on that. And it does

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1 state you need peer review, you need post-implant
2 dosimetry.
3 The other thing is there I am seeing the
4 list of corrective actions that you have in here, and
5 the recommendation that the ACMUI needs to make is
6 that these are the same recommendations we would have
7 made. We can reinforce these. You know, all of those
8 are already written here.
9 MEMBER WELSH: Yes. If I might expand on
10 that.
11 CHAIRMAN MALMUD: Dr. Welsh? Oh, Debbie,
12 I am sorry.
13 MS. GILLEY: Want me to go ahead now?
14 Excuse me. One of the things that I think would be a
15 good recommendation, and it has always struck me as
16 being ironic, that we don't require an Authorized
17 Medical Physicist for participation in brachytherapy,
18 low dose or permanent brachytherapy. We do require
19 them in HDR and gamma knives, but we don't require
20 them in these activities.
21 I have no reason why, but as you can see,
22 if the medical physicists had been a key player as
23 required by regulations, maybe they would have taken
24 this another step and another initiative. And from my
25 conversation here, it appears that the radiation

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1 oncologists do depend on that medical physicist to
2 provide them some expertise in doing this treatment
3 planning.
4 CHAIRMAN MALMUD: I think Dr. Nag wants to
5 address your point.
6 MEMBER NAG: Yes. I don't necessarily
7 agree with you. The medical physicists are definitely
8 required in the planning process. So they are
9 involved in how many millicuries need to be ordered,
10 and so forth. They are involved in the post-planning
11 process, but they are usually -- in some institutions,
12 I have seen they do have a medical physicist there.
13 But they are not required in the placement of the --
14 placement of the application. That is a medical
15 decision.
16 So, and having a medical physicist there
17 would not necessarily have brought this. So I agree
18 with you that the reason why we have an Authorized
19 Medical Physicist for the HDR is that the treatment
20 occurs instantaneous, that you have no time to get a
21 consultation of a medical physicist later on. So that
22 is why we have both for HDR, because the dose rate is
23 so rapid.
24 But for a no dose rate implant where we
25 place the applicator, and, you know, you have an

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1 X-ray, and then you can decide how many millicuries
2 you want to put, there are both sides of the story.
3 Some places have a medical physicist in there, and
4 then at others they don't.
5 CHAIRMAN MALMUD: Dr. Thomadsen?
6 MEMBER THOMADSEN: I would just take issue
7 that there is a difference there. With the high dose
8 rate it is all instantaneous. With a prostate
9 implant, it is all instantaneous. You put the seeds
10 in, and they are there.
11 MS. GILLEY: But it is radiation. I mean,
12 it is -- you know, the method or the length of time it
13 takes, it is still the necessity of having good
14 quality assurance up front.
15 MEMBER THOMADSEN: It is a creative dose.
16 CHAIRMAN MALMUD: May I ask a question?
17 What is the standard of practice in Canada and in
18 Europe with regard to brachytherapy, and the presence
19 and participation of physicists? Does anybody know
20 the answer to the question?
21 MEMBER NAG: In patients, I have observed
22 -- I mean, I haven't observed every center, but I have
23 observed some centers in Europe, some centers in
24 Canada. It is both ways. There are some centers
25 where the position is quite comfortable. They want to

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1 know how many millicuries they need to put. The
2 placement of the applicator is on their own. In other
3 centers, they do have a medical physicist there.
4 CHAIRMAN MALMUD: So it is not a
5 requirement.
6 MEMBER NAG: It is not a requirement any
7 place.
8 CHAIRMAN MALMUD: Thank you. Somebody
9 else want to make a comment? Who was next? Dr.
10 Suleiman?
11 MEMBER SULEIMAN: Okay. If the standard
12 of practice doesn't address it, and this may be a case
13 where sometimes you get into the discussion about
14 voluntary standards, the problem with voluntary
15 standards is they are voluntary. And so maybe this
16 post-therapy validation can be made a regulatory
17 requirement. I mean, that is what was mentioned
18 earlier.
19 MEMBER WELSH: So if --
20 CHAIRMAN MALMUD: Dr. Welsh?
21 MEMBER WELSH: Perhaps we could frame this
22 in the form of a motion, that the ACMUI recommends
23 that for programs that wish to participate in
24 brachytherapy that there be some form of peer review
25 required, and I would recommend that we -- for

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1 prostate brachytherapy that we use the published
2 American Brachytherapy Society recommendations, and
3 that that would be a minimum standard for
4 brachytherapy programs in the United States.
5 CHAIRMAN MALMUD: Comments regarding Dr.
6 Welsh's recommendation? Dr. Zelac?
7 DR. ZELAC: For those that have a
8 recollection of what the NRC's medical policy
9 statement includes, it does indicate in one of the
10 four points that there will not be interference with
11 medical judgment except to the point where it involves
12 patient safety. And then, clearly, I think that we
13 are at that point when we are having this discussion.
14 Now, there is already a section in the
15 regulations under the 400 series called Safety
16 Precautions. And a recommendation for an additional
17 rule, as Dr. Welsh has suggested, could probably very
18 easily fit in as another subsection of that existing
19 safety precautions recommendations.
20 CHAIRMAN MALMUD: Thank you, Dr. Zelac.
21 Dr. Howe:
22 DR. HOWE: I think we would have a very
23 difficult time putting into regulations a standard of
24 care that was based on somebody else's procedures, and
25 how would we enforce it, and how would we inspect

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1 against it. But you could require an Authorized
2 Medical Physicist.
3 You don't have to require them to be
4 physically present, but you could require the manual
5 brachytherapy programs to have an Authorized Medical
6 Physicist, and you could specify what his duties are
7 in the pre-implantation part, in the post-implantation
8 part.
9 So I think regulatory-wise you could do
10 that. I am not sure for NRC purposes whether you could
11 impose a standard of care that is based on medical
12 care.
13 CHAIRMAN MALMUD: Who was next? Dr.
14 Welsh?
15 MEMBER WELSH: If I might comment on that.
16 I think that I agree that it makes a lot of sense,
17 but I think that there might not be a substitute for
18 physician input in terms of the peer review. For
19 example, in this particular example on the screen, a
20 physician would be expected to have the training and
21 knowledge to say that that prostate is not implanted
22 with the seeds.
23 Not all physicists -- many of them will,
24 but not all physicists will know prostate anatomy
25 sufficiently on CT or ultrasound to really comment on

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1 the physician's quality of implant. I think only
2 another physician who is familiar with the procedure
3 and fluent with CT and ultrasound imaging would be
4 able to really provide appropriate peer review in this
5 context.
6 CHAIRMAN MALMUD: Dr. Eggli?
7 MEMBER EGGLI: I don't think that
8 requiring a quality management program, including peer
9 review, constitutes infringement on the practice of
10 medicine, because each licensee could design their own
11 quality management program. I mean, we do that with
12 our administrations of radioactive iodine.
13 We have a quality management program that
14 we design and implement internally, but I don't think
15 that it is an infringement on practice to require one,
16 nor as a patient safety issue do I think it would be
17 an infringement on practice to require documentation
18 of post-implant dosimetry. That is a radiation safety
19 issue that I don't believe interferes with medical
20 practice.
21 So I think that I -- although I
22 wholeheartedly agree that NRC should not be in the
23 business of regulating practice, but I don't see
24 either of these suggestions as interfering with the
25 practice of medicine, but they are very much patient

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1 safety oriented. I don't think the Joint Commission
2 would have any difficulty imposing that kind of
3 requirement on us.
4 CHAIRMAN MALMUD: Dr. Nag?
5 MEMBER NAG: I think adding extra
6 regulation is not going to solve the problem, because
7 quality management programs already have been built
8 into that. The problem here was that the person was
9 not following that quality management program. So the
10 problem we have to address is how to enforce the QMP
11 that was already there, so we don't have to
12 reinvent --
13 MEMBER EGGLI: Forgive me for speaking out
14 of turn, but I am not sure that there is any evidence
15 that the VA medical center in Philadelphia had an
16 established quality management program that reviewed
17 the brachytherapy -- the use of brachytherapy or did
18 any peer review.
19 MS. PELKE: That is correct. They did no
20 peer reviews.
21 MEMBER NAG: But you were supposed to
22 have --
23 MEMBER EGGLI: I know, but -- no. By
24 regulation, brachytherapy does not require a quality
25 management program. NRC cannot go out and inspect

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1 against that requirement and say, "Show me the
2 documentation that you have a quality management
3 program."
4 Now, admittedly, NRC can't go and inspect
5 how the quality management program operates on a
6 professional level, but they can at least say, "Show
7 me the documents which describe the quality management
8 program." And right now, in regulation, they can't do
9 that for brachytherapy.
10 MEMBER NAG: I would like for the NRC
11 official there -- whenever we -- whenever I have
12 gotten a brachytherapy program, we have a QMP that we
13 had to develop as part of the licensing. So they
14 don't need the QMP to start the program.
15 DR. HOWE: Let me respond to that. Back
16 in probably 1992, 1994, we implemented a quality
17 management program. And that was to ensure that the
18 administration was in accordance with the written
19 directive.
20 In 2002, we took the main "quality
21 management program" away. There is still a program,
22 and it is in 35.41. It says that you must have
23 written procedures that provide high confidence that
24 the administration is in accordance with the written
25 directive. It is performance-based. We don't

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1 specifically say what has to be in that procedure
2 other than a very few things.
3 Now, it may be that the ACMUI believes
4 that there is something else that needs to be
5 specifically in there, and that could be in
6 regulations. But we do have a program. It is not
7 called a quality management program anymore, but it is
8 in 35.41.
9 CHAIRMAN MALMUD: Thank you.
10 Mr. Lieto?
11 MEMBER LIETO: Well, Donna-Beth stole my
12 thunder, but the written directive, what we call
13 written directive assurance program, has been there in
14 the regulations. I think maybe rather than going into
15 regulatory space, maybe it might be something that can
16 be done quicker and also have flexibility in the
17 future, is to say what we consider to be components of
18 that written directive assurance program for, say,
19 brachytherapy.
20 I am sure most places already have it for
21 your iodine therapies, your dual verifications, all of
22 these other types of things that go into place, but
23 maybe have something that might be specific to a
24 brachytherapy program. Maybe there should be
25 something also for gamma knives, and so forth and so

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1 on. But maybe just do it in guidance space as a
2 regulatory -- in the NUREG amendment, or revision if
3 you will, rather than try to do it through rulemaking,
4 which could take years.
5 CHAIRMAN MALMUD: Thank you.
6 Well, you have certainly presented a very
7 stimulating topic to us. Oh, Dr. Thomadsen.
8 MEMBER THOMADSEN: I think you have a
9 motion on the floor.
10 CHAIRMAN MALMUD: And what is the motion?
11 MEMBER THOMADSEN: Well, you don't quite,
12 because I don't think it was ever seconded.
13 CHAIRMAN MALMUD: The motion was?
14 MEMBER THOMADSEN: Jim?
15 CHAIRMAN MALMUD: Dr. Welsh?
16 MEMBER WELSH: ACMUI advises, as a means
17 of preventing this from happening in the future, that
18 peer review or some form of formalized quality
19 assurance program be mandated in any brachytherapy
20 program.
21 CHAIRMAN MALMUD: Is there a second to the
22 motion?
23 MEMBER SULEIMAN: Second.
24 CHAIRMAN MALMUD: Any further discussion
25 of the motion? Dr. Thomadsen?

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1 MEMBER THOMADSEN: Yes. I would suggest
2 postponing this and trying to establish a more
3 coherent, comprehensive, and consistent recommendation
4 looking at at least the three standards that are out
5 there and seeing what accepted standards of care would
6 be and making a single proposal that might encompass
7 something that would cover all of the places of risk
8 that we would identify.
9 CHAIRMAN MALMUD: Dr. Vetter?
10 VICE CHAIRMAN VETTER: I support Dr.
11 Thomadsen's suggestion. I think we also need to
12 provide an opportunity for stakeholder input. I do
13 really like the idea of peer review, but I have --
14 sitting around this table, I really have no idea how
15 it would affect so many practices.
16 CHAIRMAN MALMUD: Dr. Nag?
17 MEMBER NAG: Yes. I would support
18 delaying any decision at the moment, because we
19 already have many of the rules in position. We have
20 to learn how to apply and enforce the rules rather
21 than making up a new rule.
22 CHAIRMAN MALMUD: Dr. Suleiman?
23 MEMBER SULEIMAN: I sort of agree to wait,
24 because I have an aversion toward adopting some sort
25 of general peer review process. I think it would be

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1 more important to identify what the critical
2 requirements would need to be, and address it maybe
3 from a regulatory point of view. And that would be
4 the linchpin that would hold it together.
5 But just requiring some sort of general
6 peer review process or document is going to require
7 another major effort, and somewhere in there there is
8 something -- the critical things. Let the practice of
9 medicine address most of the deficiencies, but some of
10 the issues here may -- the safety issues specifically
11 could conceivably boil down to one or two very
12 specific recommendations. I think that would make the
13 process a little bit simpler and more ready -- easily
14 enforceable.
15 CHAIRMAN MALMUD: Dr. Welsh, would you
16 like to table your motion, or move it forward?
17 MEMBER WELSH: I would. I would like to
18 say that perhaps it is wise to wait until we have a
19 bit more information and discuss it again in the
20 future. The numbers are alarming to me. Ninety-two
21 medical events makes me wish to move faster rather
22 than slower.
23 Therefore, when you asked the question
24 about, how can we prevent this from happening again, I
25 put forth this motion. But I am comfortable with

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1 tabling it and bringing it to the surface again. But
2 92 medical events is 92 medical events.
3 CHAIRMAN MALMUD: So Dr. Welsh is
4 recommending that his motion be tabled. Is that
5 acceptable?
6 MEMBER NAG: It means that motion has been
7 tabled. I would like to make a separate motion. I
8 would like to make a recommendation to the
9 investigative authority at the VA -- and I am not sure
10 who -- which body that is, whether it is the NRC or
11 the master licensee, or whatever -- that when they are
12 investigating and going into further details on this
13 series of medical events, that they try to separate
14 the errors of placement versus errors that are due to
15 the difference in the definition of what a medical
16 event is.
17 I don't know if that is -- if that was --
18 otherwise, what will happen is that you are going to
19 hear 92 -- the number 92 medical events out of 114,
20 and there may be quite a few of these that were really
21 not medically events, but because of the definition of
22 20 percent would maybe -- if all of the seeds are
23 still in the prostate, but because of the swelling of
24 the prostate or having done it one year later, and so
25 forth, they became medical events.

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1 MR. LEWIS: From the NRC staff's point of
2 view, before that motion is seconded, if it is, that
3 might be a motion that is kind of outside of the roles
4 and responsibility of the Committee perhaps, because a
5 recommendation by the Committee to a particular
6 licensee would be very awkward.
7 If the Committee wanted to make a
8 recommendation to the NRC staff to consider such
9 thing, that might be appropriate.
10 MEMBER NAG: Okay. It may be -- that is
11 why I said I did not who -- whether it is the NRC
12 staff, or whomever, but someone needs to differentiate
13 the two. And if you want -- I have done a lot of
14 these. If you want my assistance, I am willing to
15 volunteer some of my time, if needed.
16 CHAIRMAN MALMUD: Thank you.
17 May I ask another question, which is kind
18 of -- crosses two different subjects? Isn't the VA in
19 Philadelphia a teaching affiliate of the University of
20 Pennsylvania?
21 MS. PELKE: Yes, that is correct.
22 CHAIRMAN MALMUD: And did Penn's residents
23 in radiation oncology rotate through the VA for their
24 experience in prostate treatment?
25 MR. WIEDEMAN: For external treatment.

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1 CHAIRMAN MALMUD: Only external, not
2 implants. Thank you.
3 Thank you very much. Does that complete
4 your presentation?
5 MS. PELKE: Yes, it does. Thank you.
6 CHAIRMAN MALMUD: Oh, I am sorry. Mr.
7 Lieto?
8 MEMBER LIETO: Just one quick question.
9 When do you expect to complete your investigation
10 report? Or is that an unfair question?
11 MS. PELKE: No, it is a fair question. It
12 is difficult to project, because we have a number of
13 activities that are ongoing. But we are hoping to
14 wrap things up by the fall. That may not be as soon
15 as a number of people would like, but we have a number
16 of matters that we are still considering.
17 And also, in closing, I would still like
18 to remind everybody that we had 92 medical events
19 reported. That was as of, I would say, the early part
20 of October. And to date none of those have been
21 retracted, so I -- and that is based on the criteria
22 that is currently in the rules, in Part 35, for
23 reporting medical events.
24 MEMBER NAG: Thank you for that
25 information.

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1 CHAIRMAN MALMUD: I think I would be
2 remiss in not telling you that the Committee is very
3 supportive of your investigation of this, and we
4 appreciate -- you know, it is a very unpleasant
5 ordeal, but we appreciate your effort, because our
6 concerns are the same as yours, which is the health
7 and safety of the public and those who work in
8 radiation.
9 MS. PELKE: Thank you.
10 CHAIRMAN MALMUD: Thank you.
11 Now, is the next presenter here? Kevin
12 Crowley?
13 Do you want to take a break for five
14 minutes, or do you want to move on? Okay. We will
15 take a break for no more than 10 minutes.
16 (Whereupon, the proceedings in the foregoing matter
17 went off the record at 3:11 p.m. and went
18 back on the record at 3:32 p.m.)
19 CHAIRMAN MALMUD: We have juggled the
20 schedule today, and Dr. Crowley has accommodated to
21 it, and we appreciate that.
22 So we will move back to agenda item number
23 seven, and if you will turn to Tab 7. No? CR-7.
24 MS. COCKERHAM: Six.
25 CHAIRMAN MALMUD: Excuse me. There we

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1 are. The woman says no handout.

2 MS. COCKERHAM: Tab 6.

3 CHAIRMAN MALMUD: Thank you.

4 MS. COCKERHAM: I have handouts for

5 everyone on these.

6 CHAIRMAN MALMUD: Do you want to pass them

7 out now?

8 MS. COCKERHAM: Two pages or three pages.

9 CHAIRMAN MALMUD: Two pages? Thank you.

10 And we will then get started.

11 MR. CROWLEY: Are you ready for me to

12 begin?

13 CHAIRMAN MALMUD: We are ready. Yes,

14 thank you very much.

15 MR. CROWLEY: Well, thank you very much

16 for the invitation. I am sorry I'm late. I got hung

17 up on the Metro when they closed one of the Metro

18 stations.

19 What I'd like to do is talk to you today

20 about a study that we finished in January of this year

21 called "Medical Isotope Production Without Highly

22 Enriched Uranium."

23 I was the study director for that study.

24 So I have a fairly in depth understanding of what's in

25 the report, and hopefully I'll be able to answer your

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1 questions.

2 When you get my handout, you're going to

3 see that I've got 26 pages of fairly detailed

4 information. I do not intend to read all of that to

5 you. I've put this together to make it self-

6 contained, and what I hope to do in the next 15 to 20

7 minutes is to go through this and just highlight some

8 things.

9 And I guess I'm responsible for making

10 sure that I check the slides here.

11 So here is the outline of my presentation.

12 I'm assuming that you're not all experts in medical

13 isotope production. So I will provide a little

14 background. Then I'll talk about the study charge,

15 the study plan, and I'll spend most of my time talking

16 about the results.

17 This is just for your information, some

18 organization information. We are the National

19 Academies, and as I think you know, that's both an

20 honorary organization and working arm. We're a

21 private, nonprofit organization. We were created by

22 the government to provide advice to the government,

23 and Congress, as you will see, Congress came to us in

24 this case and asked us to do this study.

25 All right. so let me give you a couple of

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1 slides of background. The request for this study came
2 to us from Congress in the Energy Policy Act of 2005.
3 It was sponsored by the Department of Energy, and
4 Congress, I think, was trying to strike a balance
5 between two national interests when they asked us to
6 do the study. The first one was insuring the
7 availability of reasonably priced medical isotopes.
8 Congress had been told by industry that if they were
9 forced to convert medical isotope production from
10 highly enriched uranium -- and I'll tell you what that
11 is in a second -- that it would be very expensive.
12 And the medical societies were concerned
13 about supply reliability if, in fact, the companies
14 were forced to convert. On the other hand, we have a
15 national policy top minimize the civilian use of
16 uranium that has been enriched in Uranium-235, and
17 highly enriched uranium is uranium that's been
18 enriched in Uranium-235 to greater than or equal to 20
19 percent.
20 The HEU, and I'm going to use the word
21 "HEU" for highly enriched uranium, that is used to
22 produce medical isotopes is almost entirely 93
23 percent. That's weapon grade HEU, and there's a
24 concern that that HEU could be diverted for use in
25 improvising devices.

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1 All right. Well, the isotope of primary
2 concern here is Molybdenum-99, which as you know
3 decays to produce Technetium-99m, which is used in
4 medical isotope treatments. Both of those isotopes
5 have very short half-lives shown there, 66 hours for
6 Moly and six ours for Tech. So they require a very
7 sufficient supply chain and any disruption can have a
8 great impact on medical practice.
9 The primary method of production of this
10 isotope is by taking targets made of highly enriched
11 uranium, irradiating them in research and test
12 reactors. Around the world we use between 40 and 50
13 kilograms of HEU every year. Most of that HEU is U.S.
14 origin. The quantity of concern of HEU by the IAEA is
15 25 kilograms, and the quantity of concern is a concern
16 for using material to make improvised nuclear devices.
17 This agency, the Nuclear Regulatory
18 Commission, actually regulates quantities greater than
19 five kilograms of HUE, comes under tighter regulatory
20 control by this agency. Again, the concern is this
21 material can be used to produce improvised nuclear
22 devices.
23 The other point I want to make on this
24 slide is that not only are we using 40 to 50 kilograms
25 annually of HEU, but the waste for medical isotope

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1 production is also HEU; that during the irradiation of
2 the targets in the reactor, only about three percent
3 of the Uranium-235 is consumed. So you go in with
4 about 93 percent HUE; you come out with about 90
5 percent HEU. It's still weapon grade.
6 There are hundreds of kilograms of that
7 material sitting in solid and liquid form around the
8 world. Now, it's protected, but nevertheless, there
9 is a very large inventory of this material out in
10 civilian commerce.
11 The other point to make from this slide is
12 that between 95 and 98 percent of the world's supply
13 of Moly-99 is made using HEU, and it's made by there
14 are four organizations, one in Belgium, one in Canada,
15 one in South Africa, and one in the Netherlands.
16 And the next slide is a schematic showing
17 you where these organizations are and what the primary
18 supply chains are. There are some secondary supply
19 chains that aren't shown.
20 A couple of points to make from the slide.
21 The United States market shown in the upper right
22 accounts for about half of moly use. The rest of the
23 world uses about half.
24 Almost all of the moly used in the United
25 States is produced by two producers, MDS Nordion in

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1 Canada and Covidien, Mallinckrodt Covidien. They
2 actually produce it in the Netherlands, but they also
3 have a manufacturing facility here in the United
4 States for making technetium generators.
5 The other two producers are IRE in Belgium
6 and NTP in South Africa. You can see that MDS Nordion
7 produces about 60 percent of the medical isotopes used
8 in the U.S., and Covidien makes about 40 percent.
9 The left column shows the reactors that
10 are used to produce these isotopes. The world's
11 supply of isotopes is produced in about five reactors,
12 one in Canada, three in Europe, and one in South
13 Africa. All of these reactors are 40 to about 52
14 years old. They are, for the most part, past their
15 useful lifetimes, and as you practicing physicians
16 know, there's a supply reliability problem, and that
17 problem is primarily because of these aging reactors.
18 And I'll have a little more to say about that later
19 in the talk.
20 Break this up a little bit with some
21 pictures. I'm assuming that you're not all familiar
22 with how this material is produced. So I've got four
23 pictures here that illustrate some important points.
24 The picture in the upper left-hand corner is an HEU
25 target. So a target is basically typically a flat

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1 plate. It's a uranium-aluminum alloy clad in an
2 aluminum cladding. The targets are typically about 15
3 centimeters long and a few centimeters wide, and
4 several of those targets would be placed into a
5 reactor, and they would be irradiated for about five
6 days.
7 In the upper right-hand corner is a
8 picture into the core of the research reactor at the
9 University of Missouri, and some of you may know that
10 the University of Missouri is trying to actually start
11 Moly-99 production, but these reactors are relatively
12 small. They're much, much smaller than a power
13 reactor. They typically sit in pools, and you can see
14 them from the surface as you can see down here in the
15 picture.
16 The targets are either put into the core
17 of the reactor or they're put into the reflector
18 region around the core, and they are put in remotely,
19 and they're removed remotely, and again, they're
20 irradiated for about five days.
21 The picture in the lower left corner shows
22 a processing facility. This particular facility is in
23 Argentina. Once the targets come out of the reactor,
24 they are very radioactive. They can't be handled.
25 They have to be processed remotely, and so they're

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1 processed in these heavily shielded facilities called
2 hot cells, and these can have several feet of
3 concrete, and the windows can be many inches to feet
4 of leaded glass.
5 And the apparatus in the hot cell, which
6 is shown in the lower right corner, is actually very
7 simple. It can sit on this table top, and the targets
8 are basically dissolved, and they are chemically
9 processed, and the Moly-99 is absorbed onto an
10 aluminum column. All of that happens within the hot
11 cell.
12 So this process, two components of this
13 process are very expensive. The hot cells are very
14 expensive, and the reactors are very expensive. Hot
15 cells, tens of millions of dollars to build; reactors,
16 hundreds of millions of dollars to build.
17 All right. Well, let me now turn quickly
18 to the study charge. We had a five-part study charge.
19 Four of the charges were given by Congress. One of
20 the charges we negotiated with the sponsor.
21 Charge number one, we were asked to assess
22 the feasibility of procuring supplies of medical
23 isotopes from sources that don't use highly enriched
24 uranium, and Congress had a three-part feasibility
25 test. You can read the first two parts. The third

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1 part, which is the third bullet, is really key, and
2 that is is the average anticipated total cost increase
3 from production of medical isotopes without HEU less
4 than ten percent.
5 So Congress is asking if we forced
6 producers to switch to, say, low enriched uranium or
7 some other way of making medical isotopes, would the
8 resultant cost increase be less than ten percent?
9 Congress did not specify the point in the
10 supply chain or the time scale for the feasibility
11 determination. So that was one of the things that we
12 had to determine for ourselves.
13 Okay. Charge two was the current
14 projected demand and supply for medical isotopes in
15 domestic use.
16 The third charge is really not relevant to
17 this, the interest of this group. So I'll skip over
18 it.
19 The fourth charge is the potential cost
20 differential of the medical isotope production in
21 reactors at target processing facilities, if the
22 products are derived from systems that don't involve
23 fuels or targets that use HEU. So we actually had to
24 do a cost calculation, and I will explain how we did
25 that a little later.

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1 And then the fifth charge, which is the
2 charge that we negotiated with the sponsors, was to
3 identify additional steps that could be taken by DOE
4 and medical isotope producers to improve feasibility
5 of conversion and to identify any reliability of
6 supply issues that could arise as a result of such
7 conversions.
8 All right. Well, as we do for most of our
9 studies, we put together a committee of experts. We
10 had a committee of 14 experts. One of the points I
11 want to make here is that two of those experts were
12 nuclear medicine physicians. We understood that the
13 implications of this study were quite significant for
14 medical practice, and we wanted to make sure that we
15 have medical experts on the committee both to keep the
16 committee honest and also to provide a very important
17 medical perspective.
18 This was more than just a paper study. We
19 did extensive fact finding. We visited all of the
20 major medical isotope facilities except South Africa.
21 They wouldn't cooperate with us.
22 In addition, we visited medical isotope
23 production facilities in Argentina and Australia.
24 Those two are significant because they're not
25 producing medical isotopes with low enriched uranium,

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1 and, in fact, Argentina produces only for its own
2 market, but Australia actually has plans to become a
3 global producer. So we wanted to understand exactly
4 what their plans were.
5 Also, before our report came out, it
6 received extensive peer review. We had 14 committee
7 members and 14 peer reviewers. So the report got a
8 good vetting.
9 And here is the committee membership. The
10 medical physicians were Steve Larson from Memorial
11 Sloan-Kettering. He was the Vice Chair, and Dick
12 Rieba from Med Star, Georgetown Hospital.
13 All right. Now, let me just turn to the
14 results. So with respect to the second charge on
15 projected demand and availability, I need to give you
16 a definition, and that definition is six-day Curies
17 rates. Moly-99 is sold in terms of six-day Curies,
18 and six-day Curie is the number of Curies remaining
19 six days after the shipment leaves the producer's
20 facility. So remember it has a 66 hour half-life,
21 which is about two and three-quarters days. So, you
22 know, it is decaying away even while they are
23 transporting the targets to the processing facility.
24 They're processing the targets. They're shipping it
25 out.

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1 By the time they ship it from their
2 loading docket to the technetium generator producer it
3 may have undergone one or maybe even one and a half
4 half-lives. So you don't have very long to work with
5 this stuff.
6 So the global supply of Moly-99 in 2006
7 was about 12,000 six-day Curies per week. As I said
8 before, the U.S. market uses about half of that 5,000
9 to 6,000 six-day Curies per week. There hasn't been
10 much of a change in the supply since 2006, and as I
11 said earlier, the great majority of this isotope is
12 produced using HEU targets.
13 In terms of demand, we look both at
14 estimates that had been made by others, and then the
15 committee made its own estimates based on information
16 available to it, and we heard estimates of demand
17 growth for Moly-99 in the range of three to ten
18 percent. The committee thought that the demand
19 growth, particularly in the U.S., would be lower than
20 that, zero to five percent with most likely three to
21 five percent.
22 The committee thought that the demand
23 would continue to rise as the U.S. population ages,
24 and also they thought that because of the current
25 practices favoring the clinical use of Tech-99

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1 radiopharmaceuticals, that they probably wouldn't be
2 displaced, at least in the foreseeable future by other
3 modalities, and there's actually a fairly extensive
4 discussion in the report about other modalities and
5 the pros and cons of those relative to Tech-99 system.
6 All right. With respect to the
7 feasibility of conversion to LEU, if you remember, we
8 were asked to assess the cost of conversion, and what
9 we decided to do was to look at cost at three points
10 in the supply change: the cost for producing Moly-99,
11 the cost of the technetium generator, and the cost of
12 a Tech-99 dose. So we basically hit the entire supply
13 chain by considering those three points.
14 And then in addition to evaluating cost,
15 we also looked at other potential impediments to
16 conversion, technical regulatory timing and impacts on
17 supply reliability, and there's a separate chapter in
18 the report on all of those.
19 We also looked at the experience of the
20 large scale producers. These are those four global
21 producers that I told you about before, and the
22 regional producers like Australia and Argentina.
23 So remember I told you that Congress gave
24 us three tests for feasibility, and I'd like to run
25 through those now fairly quickly. Test one was have

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1 targets been developed and demonstrated; have LEU
2 targets been developed and demonstrated for use in
3 targeting processing facilities that produce medical
4 isotopes to serve U.S. needs.
5 The short answer is, no, neither MDS
6 Nordion nor Mallinckrodt are producing moly with LEU
7 targets. However, LEU targets have been developed,
8 and they have been demonstrated. They're being used
9 in Argentina and Australia. We don't see any
10 technical barriers to their use by producers that
11 currently supply the U.S. market, and we believe that
12 at least three of the four current large-scale
13 producers -- and this would be MDS, Nordion,
14 Mallinckrodt, and IRE -- could convert to LEU based
15 production within their current facilities. They have
16 extra hot cells, although some modification to the
17 process equipment might be required, and the
18 conversion will take several years.
19 All right. The second feasibility test:
20 are sufficient quantities of medical isotopes
21 available for LEU targets and fuel to meet U.S. needs?
22 The short answer again, not at present.
23 No technical reasons it couldn't be done, and no
24 demonstrated evidence that the large-scale producers
25 were taking any steps to convert.

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1 And with respect to that last point,
2 there's a good reason that the large-scale producers
3 aren't taking any steps. There's really no business
4 reason for them to do so. They have their systems in
5 place. They've optimized their systems. It will cost
6 money and it will take time to convert, and in the
7 business perspective there's really no reason to do
8 that.
9 All right. Test three is the average
10 anticipated total cost increase from production of
11 medical isotopes, less than ten percent, and basically
12 what we did here was a present value calculation. We
13 said let's assume that prices increase by exactly ten
14 percent for producing moly for buying the cost of a
15 technetium generator and the cost of a dose, and then
16 we amortized that over the life of a facility, and we
17 look at its present value and then we ask are the
18 present value revenues sufficient to convert, and we
19 concluded that conversion is feasible with a ten
20 percent cost increase if conversion was carried out at
21 producers' existing facilities.
22 It might also be feasible even if
23 extensive modification or new construction is
24 required, and that a ten percent increase would have a
25 negligible, a bout a .1 percent impact on costs of

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1 typical U.S. medical isotope procedures,a dn the
2 numbers are described in detail in the report.
3 All right. If you remember, the last
4 charge asked us to recommend steps to DOE and
5 producers for improving their feasibility, and I want
6 to run through these slides very quickly. I've got
7 several slides, and I just want to make a couple of
8 points.
9 Our advice to Moly-99 producers is
10 basically, look, conversion isn't going to happen
11 until you make a commitment to make it happen. So we
12 recommended that the producers announce a commitment
13 and a best effort scheduled conversion, and we also
14 recommended that they work with the industry
15 organizations and the scientific and medical societies
16 for marshalling, coordinating and supporting
17 conversion.
18 To the Department of Energy, we also made
19 several recommendations, and I want to just focus on a
20 couple here. It was clear from our data gathering
21 that the medical isotope producers do not have all of
22 the necessary in-house technical R&D that they need to
23 actually convert, whereas a lot of that necessary R&D
24 expertise lies within the national laboratories.
25 So we recommended that DOE make the

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1 expertise of the national laboratories available to
2 producers and that they examine options to share R&D
3 costs with the producers.
4 To Congress we said, you know, if DOE is
5 going to share R&D costs, you've got to appropriate
6 the money. So from government cost sharing, and we
7 also recommended that they consider -- and we didn't
8 say do this. We said consider doing this -- condition
9 supply of U.S. origin HEU, and I didn't mention this
10 earlier, but almost the entire world supply of medical
11 isotopes is made with U.S. origin HEU. South Africa
12 uses its own HEU. The rest of it is U.S. origin HEU.
13 We recommended that Congress consider
14 conditioning supply of U.S. origin HEU for medical
15 isotope production. There was the Schumer amendment
16 in the 1992 Energy Policy Act, actually conditioned
17 the supply of U.S. origin HEU on producers' progress
18 in converting to LEU, and the Schumer amendment was
19 vitiated by the 2005 Energy Policy Act, and we said,
20 Congress, consider reinstating that with a phaseout
21 period, perhaps a seven to ten-year phaseout period.
22 We also suggested that they consider
23 prohibiting the export of HEU for medical isotope
24 production to new reactors. There are two new
25 reactors under construction in Europe. They will come

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1 on line starting in, I guess, 2015 to 2018. They will
2 both come on line. They will probably replace the
3 reactors that are being used now to produce medical
4 isotopes, and we said, you know, one of the things you
5 could do is make it clear early on that you are not
6 going to export HEU for medical isotope production in
7 those new reactors. It's a clear signal to the
8 producers that they need to convert.
9 Okay. One other suggestion we made to
10 Congress was that Congress could consider a temporary
11 financial incentives for production or purchase of
12 LEU-based Moly-99. For example, they could provide
13 technetium generated producers with a tax credit if
14 they had purchased LEU based 99. So that's kind of a
15 market pull for LEU based medical isotope production,
16 and we made a recommendation to the Food and Drug
17 Administration that it work with industry and DOE's
18 technical experts to insure that there's a common
19 understanding of LEU based processes and requirements
20 from FDA requirements.
21 One of the things we heard from the
22 producers was that they thought that FDA approval was
23 a substantial barrier to conversion from HEU based
24 production to LEU based production. The committee did
25 not see the barrier, but the committee thought that by

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1 getting FDA in through the door early to talk with
2 industry, perhaps that could smooth the way for
3 conversion.
4 And I know Orhan actually briefed our
5 committee, and he may have something to say about that
6 during the Q&A period.
7 All right. Well, let me just finish up
8 with a couple of slides on reliability of Moly-99
9 supply. As I mentioned earlier, the supply of Moly-99
10 to the U.S. is very fragile. Actually during the
11 course of this two-year study, we had substantial
12 outages at reactors, unplanned outages that created a
13 real shortage, a global shortage situation.
14 And this reliability problem is primarily
15 a problem with aging reactors, as I've said before.
16 All of these reactors are older than 40 years. They
17 are nearing the ends of their lifetimes, and they are
18 now encountering unanticipated maintenance issues that
19 are forcing them to shut down, in some cases for
20 extended periods of time.
21 The committee thought that supply
22 reliability was likely to become a serious problem in
23 the early part of the next decade without newer or
24 refurbished reactors, and it will take five to ten
25 years for substantial new sources of supply to come

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1 onto the market.

2 AECL in Canada had hoped to start up two
3 new isotope producing reactors in the 2003-2005 time
4 frame, the Maple reactors. They have never been able
5 to get them to run properly, and in October of last
6 year they pulled the plug on the reactors.

7 So right now, MDS Nordion is relying on a
8 52 year old reactor whose license expires in 2011 to
9 produce 40 percent of the world's supply and 60
10 percent of the U.S. supply of medical isotopes.

11 The other point that the committee made
12 was that this reliability of supply issue is not a
13 conversion issue. When you talk about conversion,
14 you're talking about really changing the targets that
15 you're using and altering the processes in your hot
16 cells to recover the moly. The reactors stay the
17 same. So conversion would not have an effect on
18 reliability of supply unless, of course, you did the
19 conversion very, very poorly.

20 The other thing that the committee pointed
21 out was that government assistance might be required
22 to improve supply reliability because all of these
23 reactors that are being used to produce medical
24 isotopes are government built reactors, and they are
25 funded by the government. So it's very hard to get

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1 the private sector to spend hundreds of millions of
2 dollars to build one of these reactors. The
3 government is probably going to have to stay involved
4 at least on the reactor side.
5 All right. So let me end there. I
6 mentioned that the report was issued in January of
7 2009, and if you don't have a copy and you're
8 interested in it, you can download it at the URL shown
9 there, and the report will be issued in final form
10 before the end of this month.
11 Thank you very much.
12 CHAIRMAN MALMUD: Thank you.
13 Questions or comments?
14 Dr. Nag.
15 DR. NAG: You mentioned that the U.S. is
16 using up about 50 percent of the world's HEU produced
17 molybdenum and using more of the HEU. If that's the
18 case, why hasn't the U.S. been using HEU in the
19 ordinary act rather than importing it? Is it a
20 question of cost or what?
21 And the second part is why are we now
22 trying to use any new and why not just try to use HEU
23 in the reactor here.
24 MR. CROWLEY: Well, we have not produced
25 medical isotopes domestically since 1998. The

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1 Cintichem was producing those isotopes in a reactor in
2 New York. It shut down, and then DOE looked at the
3 possibility of using some of its reactors to produce
4 medical isotopes. They did a feasibility study. The
5 looked at the cost. The medical isotope producers
6 looked at that and said, "We're not interested. It's
7 too expensive."
8 Research and test reactors in this country
9 have been shutting down over the past ten or 20 years
10 because a lot of them are very old, and until
11 University of Missouri stepped up and said, you know,
12 "We're interested in doing this," there was not really
13 a viable alternative.
14 In addition, there's another company,
15 Babcock & Wilcox that is proposing to build what is
16 called a solution reactor, which basically doesn't
17 have fuel, but it's a solution that has LEU dissolved
18 in it, and they would run that and then separate out
19 the Moly-99.
20 So we now have two viable proposals on the
21 table for producing medical isotopes in this country.
22 As to why we don't do this with HEU, it's because the
23 government has made a policy decision to eliminate
24 civilian use of HEU.
25 DR. NAG: And why is that? Why that

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1 policy?

2 MR. CROWLEY: It's because HEU can be used

3 to make improvised nuclear devices and used in

4 terrorist attacks against the country.

5 CHAIRMAN MALMUD: Other questions? Dr.

6 Van Decker.

7 DR. VAN DECKER: I thought your summary

8 and your report was great, and we appreciate --

9 MR. CROWLEY: Thank you.

10 DR. VAN DECKER: -- the efforts of

11 everybody because I think everyone around the table

12 realizes that the supply is unreliable, and we have

13 major problems here.

14 You know, in addition to reporting some

15 public-private ventures here for intellect, which I

16 think it's going to take, and I'm interested in your

17 outlook on how that's going to happen with overseas

18 reactors for some of the switch-over which is not

19 within the country, and the other part of this is not

20 just the cost of the R&D and getting these things

21 running, but it's the pass-through cost on each dose

22 that eventually comes down the line in the current

23 environment of health care reform and costs. You

24 know, ten, 20 percent on the cost of each individual

25 dose for a patient study, especially in a diagnostic

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1 realm where, you know, it's not a small number is a
2 big deal, and so, you know, that needs to be thought
3 about as we try to do all of this as to how we can
4 really make this happen.
5 MR. CROWLEY: Let me take your first
6 comment first and just respond to that. In terms of
7 the fact that most of the world's supply is made in
8 these foreign reactors, as you may have noticed from
9 the slide that I showed toward the beginning of my
10 talk, this is really a global industry, and it's a
11 global supply chain, and there's a lot of global
12 interest in having redundancy.
13 So it's good, the fact that there are a
14 number of foreign reactors that make this stuff.
15 Al;so, one of the things that we learned during the
16 study is that the irradiation of these targets is a
17 very important revenue producer for these reactors.
18 These reactors are multi-purpose reactors, and one of
19 their more important missions, besides medical isotope
20 production, is research, materials research, academic
21 research.
22 And particularly for the academic
23 research, people don't come to the table with big bags
24 of money to support the reactor. So the work on
25 medical isotope production really helps to support the

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1 continued operation of these reactors.

2 CHAIRMAN MALMUD: Thank you.

3 Dr. Welsh.

4 DR. WELSH: Thank you, Dr. Crowley.

5 If you could explain to me or answer the
6 question about whether or not when cost effectiveness
7 was being analyzed if they took into consideration the
8 full big picture matter, meaning a reactor might not
9 turn a profit by selling medical isotopes, but the
10 cost to the nation as a whole by reducing production
11 of HEU and the concomitant shipping costs and security
12 costs, as well as having that material shipped back
13 over international borders, makes me wonder if it
14 would be actually cost effective to produce the
15 isotopes here, despite the initial superficial belief
16 that it's just not cost effective.

17 So has cost effectiveness been looked at
18 from a global perspective?

19 MR. CROWLEY: When we embarked on this
20 study, our initial approach for estimating cost was to
21 do a bottoms-up roll-up, to do exactly what you said:
22 look at every part of the production process, look at
23 what does it cost for the HEU, what does it cost to
24 transport the HEU, what are the security costs;
25 compare that to LEU; go all the way down the supply

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1 line.

2 And what we realized very quickly was that

3 was not possible to do because people didn't know what

4 these things cost.

5 Basically these reactors were about four

6 decades ago. They were funded by the government. The

7 money that the medical isotope producers paid to

8 irradiate their targets do not cover the costs of

9 running those reactors. So the government is

10 subsidizing this process.

11 This is a very unusual public-private

12 partnership where you have the government paying for

13 the upstream end of medical isotope production and you

14 have private enterprise that is then from the target

15 on forward taking that material and selling it and

16 making a profit.

17 The companies are subsidized by the

18 government to do that, and I think at least as long as

19 we continue to rely on these large, multi-purpose

20 reactors that will continue.

21 DR. WELSH: If I might ask a follow-up

22 question, under steps to improve feasibility, Step 2,

23 Department of Energy, the last bullet item there says

24 maintain consistent pricing for LEU versus HEU on a

25 common U-235 mass basis.

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1 But shouldn't LEU be far more affordable?
2 Why consistent? Why not wait for the obvious?
3 MR. CROWLEY: Well, right now,
4 unfortunately when we did the study what we learned
5 was it was cheaper for countries to buy HEU than it
6 was LEU. So LEU was more expensive than HEU. You're
7 absolutely right. It should be less expensive, but it
8 is not. It's more expensive, and we're saying at
9 least make it, you know, the same cost on a per mass
10 basis.
11 As it turns out, the cost of the material
12 is only about ten percent of the cost of producing the
13 medical isotope, but you know, it sends the wrong
14 market signal.
15 CHAIRMAN MALMUD: Dr. Fisher.
16 DR. FISHER: Mr. Chairman, with your
17 permission I have maybe four questions that will be
18 fairly quick.
19 And with no disrespect for the National
20 Academies, you're aware of a number of criticisms of
21 this report by either groups or companies involved in
22 Moly-99 production that disagree with the basic
23 assumptions, the data that you used.
24 MR. CROWLEY: Yeah, why don't you --
25 DR. FISHER: I'm coming to that.

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1 MR. CROWLEY: Okay.

2 DR. FISHER: And your final conclusions.

3 First of all, I noted that the committee

4 membership did not include representatives from the

5 producers of Moly-99 who are most intimately

6 associated with the costs of doing business and the

7 technical obstacles involved --

8 MR. CROWLEY: That's correct.

9 DR. FISHER: -- not only in upgrading

10 reactors, but in making conversions to an alternate

11 target form and in some cases fuel form.

12 MR. CROWLEY: It would have been a

13 conflict of interest for them to be involved on the

14 committee.

15 DR. FISHER: And to involve that

16 expertise.

17 MR. CROWLEY: Yes. We did involve the

18 expertise by seeking briefings from them and by

19 visiting their facilities.

20 DR. FISHER: And you're aware that these

21 producers have criticized the report for the reasons I

22 mentioned?

23 MR. CROWLEY: I'm aware of some of the

24 criticisms, but you might want to say exactly what

25 they are for the benefit of the rest of the group.

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1 DR. FISHER: Secondly, you speak of a
2 government policy against using HEU, but you did not
3 acknowledge that our unstated policy is to use HEU for
4 other purposes, in particular, the operation of our
5 naval submarine fleet.
6 So I think the Committee should be aware
7 that this is a largely political policy rather than a
8 well established federal policy, and we're all subject
9 to the politics of those members of Congress who have
10 various political leanings.
11 MR. CROWLEY: I want to correct what you
12 just said because I disagree. What I said was that
13 there is a national policy to minimize the civilian
14 use of HEU. Naval reactors is military use of HEU.
15 DR. FISHER: I understand.
16 MR. CROWLEY: Okay.
17 DR. FISHER: I'd like you to maybe
18 address, and maybe the final report will do that, but
19 the --
20 MR. CROWLEY: What you see now is the
21 final report.
22 DR. FISHER: The Society of Nuclear
23 Medicine, as you know, issued a press statement
24 strongly criticizing the assumptions based on flood
25 data. Would you address that criticism?

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1 MR. CROWLEY: Well, I'll tell you what I
2 know about it. One of the criticisms from the Society
3 for Nuclear Medicine was that they thought that we
4 underestimated the cost of the technetium generator.
5 Is that what you're referring to?
6 DR. FISHER: That's one of the criticisms.
7 MR. CROWLEY: Okay. What is the other
8 criticism or the others?
9 DR. FISHER: Well, the assumptions
10 involved in the cost of Moly-99 production using oil
11 enriched targets.
12 MR. CROWLEY: The cost of production using
13 low enriched targets?
14 DR. FISHER: Let me not go into the
15 details of -- I'm aware of --
16 MR. CROWLEY: Let me respond to your first
17 one, Darrell. One of the criticisms of the Society
18 for Nuclear Medicine was that they thought that the
19 price that we quoted for a technetium generator, a 10
20 Curie technetium generator, we said that in 2006 the
21 price of that was 1,900 U.S. dollars, and they said
22 that's too low, and what they didn't realize was that
23 actually if we had used the higher price, it would
24 have made conversion look even more feasible because
25 what you're doing is you're taking the cost of the

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1 technetium generator, you're adding ten percent,
2 you're amortizing; you're multiplying that by the
3 number of technetium generators that are sold every
4 year. You're amortizing that over some period of
5 time, and then you're calculating the present value.
6 So what we were trying to do was to be
7 conservative. We used what we thought was the lowest
8 reasonable cost for a technetium generator so that we
9 wouldn't be accused of cooking the books. If we had
10 used the higher cost for the technetium generated, the
11 numbers would have come out better. It would have
12 been more feasible. So that was an indication where I
13 think perhaps the society didn't read the report very
14 carefully.
15 So for the cost of producing medical
16 isotopes using LEU, we did not provide a cost estimate
17 in the report. What we did was we estimated the
18 amount of revenue that would be available to a moly
19 producer if they raised their prices by ten percent.
20 We looked at their facility. So the next present
21 value of that revenue, and I should tell you that
22 revenue is hundreds of millions of dollars, and then
23 we looked at what are the producer's facilities now.
24 Could they convert within their existing facility.
25 They have extra hot cells, and it's just a matter of

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1 doing the R&D, and you're changing the processing
2 equipment in the hot cells. You're looking perhaps at
3 few tens of millions of dollars. That's a no brainer
4 if you've got hundreds of millions of dollars of
5 revenue.
6 The other thing that we did was we looked
7 for information from the two producers that are now
8 making Moly-99 from LEU. What does it cost them to
9 produce moly from LEU compared to what it cost them to
10 produce from HEU. The only data point we were able to
11 find was Argentina.
12 Argentina converted in 2005, and they did
13 a study where they looked at what did it cost them to
14 produce moly net present value, HEU 2002 to 2005 and
15 then 2005 to 2007, and the cost difference was on the
16 order of five percent. It was a five percent
17 increase, and that increase came about -- the only
18 reason for that increase was because of the way they
19 made their targets it was more labor intensive.
20 So it wasn't really a matter of the
21 process costing any more. It was just that they
22 changed the way they made their targets, and it was
23 more labor intensive.
24 DR. FISHER: Finally, Mr. Chairman, one
25 last question.

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1 Speaking directly to the Argentinean
2 experience, Dr. Von Saal DeVilliers of NESCA South
3 Africa at a meeting I attended earlier this year made
4 the comment that that cost of production, that small
5 scale does not scale linearly to a full commercial
6 scale operation, which would be far more expensive and
7 cost prohibitive, and what he said was that although
8 technologically feasible to produce Moly-99 using low
9 enriched uranium, it is not commercially feasible on a
10 large scale, and I quote, "without substantial federal
11 subsidy."
12 And he wasn't talking ten percent. He was
13 talking multiples of the cost of presently producing
14 Moly-99. Now, I'd like to --
15 MR. CROWLEY: Let me respond to that.
16 DR. FISHER: -- say that those are not my
17 words.
18 MR. CROWLEY: Because --
19 DR. FISHER: I'm not finished.
20 Those are not my words. Those are the
21 words of a recognized world expert in the topic who
22 I'm not sure was consulted in the production of --
23 MR. CROWLEY: You're right. He wasn't
24 consulted. The South Africans would not cooperate
25 with us. We asked for their cooperation, and they did

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1 not cooperate.

2 With respect to your first assertion that

3 it would be more expensive to scale up, actually

4 scaling up reduces costs because you get economies of

5 scale that you don't have in a small scale operation

6 like you do in Argentina. One of the reasons that

7 they spend more to produce their targets is because

8 they're a small scale producer, and it's a very labor

9 intensive process.

10 If you go to larger production, you have

11 opportunities to automate that you don't have with

12 lower scale production. During the course of the

13 study we heard over and over again from the other

14 large scale producers it is more expensive to produce

15 this stuff with LEU, and we asked, all right, show us

16 your cost calculations. And it was pretty clear they

17 hadn't done any.

18 These are assertions that as far as we

19 could tell had no technical support or they weren't

20 willing to share the technical support with us.

21 CHAIRMAN MALMUD: That completes your

22 questions. Dr. Welsh.

23 DR. WELSH: Maybe a quick related

24 question, and maybe you don't know the answer, but I'm

25 wondering why AEC Canada decided to ditch the Maple.

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1 Does anybody know?

2 MR. CROWLEY: Well, the problem with the

3 Maple was that it had what is called a positive

4 coefficient of reactivity, which was not a design

5 feature of the reactor. What it means is that as you

6 increase the power, the reactor becomes more reactive

7 rather than less reactive. So it becomes harder to

8 control.

9 And because it was not a design feature of

10 the reactor and because they didn't understand the

11 origin of that, the regulator said, "Look. You can't

12 run this thing at full power. They put a lot of

13 effort into understanding the problem. They consulted

14 with a couple of national labs and with a company in

15 Argentina,a nd I think they just decided that it was

16 just going to cost too much to fix the reactor.

17 It was also clear to the committee toward

18 the end of the study that the Canadians may not be

19 interested in staying in the business, not MDS Nordion

20 but AECL may not be interested in staying in the

21 business.

22 CHAIRMAN MALMUD: Thank you very much.

23 Steve.

24 MR. MATTMULLER: I have a few questions

25 also. You talk about the useful life of a reactor,

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1 and I'm curious because I am concerned of the canadian
2 reactor. It's the oldest and the biggest supplier
3 that we have, but given current good maintenance, I
4 mean, does anyone really know what the life of the
5 reactor is or is it specific to that individual
6 reactor?
7 MR. CROWLEY: It's reactor specific. If
8 the reactor is well designed, you can basically
9 replace almost everything, and in fact, that's one of
10 the nice features about the University of Missouri
11 research reactor. Just about everything can be
12 replaced, including the tank, and that means that the
13 reactor can run for a long time.
14 In the case of some of the other reactors,
15 the problems that you're having are, for example,
16 aluminum corrosion. Some of the pipes are corroding
17 particularly where they come in contact with the
18 concrete. There is a chemical reaction there. Some
19 of those pipes are encased in the concrete, which
20 means if you have a leak, it's really hard to get at
21 it, and that is, in fact, what happened with the HFR
22 reactor later last year. They were shut down for
23 several months because of a corrosion problem.
24 With respect to the NRU reactor, we were
25 never able to get in depth information about what

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1 would be required to continue operating that reactor
2 for a long period of time. We were told by the
3 Canadian government that they thought it would cost
4 hundreds of millions of dollars, and they confirmed
5 that in a subsequent conversation, to get the reactor
6 re-licensed for another five years beyond 2011.
7 We don't know whether or not putting in
8 hundreds of millions of dollars would mean that, you
9 know, it could run for another 20 or 30 years. We
10 just do not have that information.
11 One of the concerns about refurbishing the
12 reactor, that reactor sits in a tank, and that tank
13 was last replaced 30 years ago, and the last time they
14 replaced that tank the reactor was shut down for two
15 years. So I think the issue with NRU is the
16 government seems willing to put the money into it to
17 maintain it at least for another five years, but the
18 question is can they do that without shutting down the
19 reactor for an extended period of time.
20 If they can't, there's a real supply
21 reliability issue here because for the rest of the
22 world capacity is not sufficient to produce. All of
23 these reactors have to shut down. Every month they've
24 got to shut down for a week or two for maintenance.
25 So you'll have shortages if NRU goes down for extended

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1 periods of time.

2 I think it's fair to say that the Canadian

3 government lat this point doesn't know. I think

4 that's what they're looking at now, is trying to

5 figure out what is it going to take to get this thing

6 re-licensed, and they're working with the regulator on

7 that.

8 MR. MATTMULLER: In regards to Australia,

9 the new moly process is up and working now?

10 MR. CROWLEY: That's correct, yes.

11 MR. MATTMULLER: And do you know, do you

12 have an update on what they're thinking about for

13 their mega moly process and how much that would cost

14 them to get that up and running?

15 MR. CROWLEY: I have that information.

16 It's proprietary. I can't share it. What I can tell

17 you is that if they decide to go to mega moly, it will

18 be expensive. In other words, there will be

19 substantial upgrades. It will take several years to

20 make those upgrades, and at the end they would be able

21 to supply a good portion of the current world supply

22 of Moly-99.

23 The other thing I can tell you is that

24 they are looking at the U.S. market as a potential,

25 you know, new market for them.

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1 MR. MATTMULLER: You also mentioned two
2 new European reactors under construction. From the
3 report I saw where the French are rebuilding one or
4 building a new one.
5 MR. CROWLEY: The Jules Horowitz, yes.
6 MR. MATTMULLER: And then what was the
7 second one?
8 MR. CROWLEY: The second reactor actually
9 right now it's a paper reactor. It's called the
10 Pallas reactor, P-a-l-l-a-s, and it's planned to be a
11 replacement to the HFR reactor at the Petten site.
12 They have not yet decided where it will be built, but
13 they are thinking that it will probably be the Petten
14 site.
15 In January of this year, they received
16 design proposals from three companies, and I think
17 they are now having a discussion with the European
18 Commission about funding, and I think they hope to go
19 forward and have something on line by 2018, 2017.
20 CHAIRMAN MALMUD: Thank you very much.
21 MR. MATTMULLER: I'm sorry.
22 CHAIRMAN MALMUD: Another question?
23 MR. MATTMULLER: Yes, I'm sorry. I
24 actually did download the report and read it. You
25 might have noticed that.

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1 I guess just to summarize quickly, I think
2 the most important statement you made in your report
3 is the last statement in your preface in that in
4 essence the cost difference is really inconsequential,
5 and if I can go off the record for ten seconds, I just
6 came back from an APA training meeting with a lot of
7 pharmacists, and they would gladly pay a lot more than
8 ten percent for a technetium generator if they could
9 get it.
10 MR. CROWLEY: That's what we heard, too,
11 yes.
12 MR. MATTMULLER: But reliability is our
13 whole issue, and I hope in any further conversations
14 you have with Congress in regards to this issue that
15 that's the number one priority, is increased
16 reliability, and we'll deal with costs later.
17 MR. CROWLEY: When we briefed Congress, we
18 made it very clear that we thought reliability was
19 very important, and I can also tell you the other
20 thing that we heard from a lot of the users of medical
21 isotopes is, "Ten percent? You've got to be kidding.
22 Why are we worried about ten percent."
23 MR. MATTMULLER: Thank you.
24 CHAIRMAN MALMUD: Dr. Welsh?
25 DR. WELSH: Thank you.

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1 Well, I fully appreciate and understand
2 the sensitivities surrounding the issue of national
3 security, and I think the Schumer amendment is a
4 reasonable step, provided we have some backup plan if
5 those who do produce methyl isotopes do not wish to
6 convert over from HEU to LEU because although national
7 security is certainly an issue, this Committee is
8 concerned with medical use of isotopes, and we might
9 not have jobs if the Schumer amendment is put back on
10 the table and nobody wants to switch over.
11 So is there a backup plan? Obviously the
12 solution is to produce the isotopes in this country
13 and use LEU, but what if that's not in the near
14 future?
15 MR. CROWLEY: Well, actually, there are
16 several efforts underway in addition to the two that I
17 spoke about with the Missouri University reactor and
18 the Babcock & Wilcox reactor. Triumph in Canada now
19 is examining the feasibility of producing these
20 isotopes using photofission, using accelerators and
21 photofission. We know it can be done. It's just a
22 question of can you produce the quantities and what is
23 the cost of doing that. You know, you might have to
24 build a lot of accelerators to get that done.
25 More generally though to answer your

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1 question, I think, you know, this Committee was not
2 asked is this the right national policy. Congress
3 said, "Look. This is our policy. we want to phase
4 out civilian use."
5 On the other hand, they made it very clear
6 to us we don't want to do anything that is going to
7 impact patient care, and this debate is going to play
8 out in the halls of Congress.
9 DR. WELSH: And if you could make a
10 comment on the non-moly isotope issues. Anything that
11 we should be aware of from the proposed conversion
12 from HEU to LEU in terms of availability and
13 reliability of the sources for non --
14 MR. CROWLEY: You mean like iodine? Yeah.
15 Actually, you know, Congress asked us to look at
16 medical isotopes, and initially we had gone in with
17 the idea that we would look at all of them, and we
18 very quickly convinced ourselves that, you know what?
19 If you look after moly, you've looked after all the
20 others because the others just come along as a
21 byproduct, and as long as you're making moly using
22 fission, you'll make the others. If you switch to
23 LEU, you'll make the others in the same proportion
24 that you make moly just as you do with HEU. It
25 doesn't matter whether it's HEU or LEU.

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1 As it turns out, a lot of the producers
2 don't even recover those other isotopes. They are
3 just so cheaply available from some other sources. So
4 they're byproducts, never get recovered, never get
5 sold.
6 CHAIRMAN MALMUD: Thank you very much.
7 DR. HOWE: Dr. Malmud, can I ask a
8 question?
9 CHAIRMAN MALMUD: Oh, another question.
10 Dr. Howe.
11 DR. HOWE: Yes, I also read the report
12 from beginning to end, and there's one point I'd like
13 to get clarification on. In the report you considered
14 a world producer to be 1,000 six-day Curies, and you
15 talked about Australia becoming a world producer, the
16 implication being that they would get up to the 1,000
17 six-day Curies. Are you saying today that you think
18 Australia will produce way in excess of 1,000 six-day
19 Curies?
20 Because to really be a major producer,
21 you've got to be up on the level of Petten and NRU.
22 MR. CROWLEY: From a capacity point of
23 view, Australia is capable of being a major producer.
24 They've got a very nice reactor, brand new reactor
25 and refurbished hot cells. They could really ramp up

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1 production if they wanted to.

2 Somebody mentioned mini moly. Mini moly

3 will just about bring them up to that threshold. They

4 will be just slightly below the threshold. Mega moly,

5 if they decide to implement it, which would require

6 not really reactor upgrades, but some other facility

7 upgrades, would take them well over that 1,000 Curies

8 per week.

9 DR. HOWE: So it appears as if you have a

10 real example of the cost of going from low production

11 to higher production, and have you factored that in?

12 MR. CROWLEY: Well, you know, none of the

13 producers would tell us what their costs were, and so

14 we had to sort of figure that out indirectly, and one

15 of the ways we were able to do that was to look at the

16 processes, look at the costs at some points in the

17 processes and then make some extrapolations.

18 Now, I'm giving you my own personal

19 opinion here because it didn't appear in the report.

20 I think probably the Australians are at or below ten

21 percent in terms of the difference in cost.

22 But one of the other points I would make

23 is if you look at cost for Moly-99 across the world,

24 as far as we can tell they vary by about plus or minus

25 40 percent. This is a market item, and they mark it

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1 up to get whatever they can get for it.

2 So when Australia shut down for two years

3 to convert to LEU, they were buying from the South

4 Africans and they were spending a lot more than what

5 we quoted in the report as the cost of Moly-99

6 production.

7 CHAIRMAN MALMUD: Dr. Suleiman.

8 DR. SULEIMAN: I want clarification. When

9 you say ten percent increase in cost or 40 percent,

10 that's just for the radionuclide itself. Radiolabeled

11 drugs have a drug component. You're not factoring

12 that in at all, and the drug component is far, far,

13 far more expensive, constitutes a much larger

14 proportion.

15 So the cost would not be an increase of

16 ten percent for the entire drug. It would only be ten

17 percent for the radionuclidic portion of the

18 radiolabeled drug.

19 MR. CROWLEY: Well, that's absolutely

20 right, and in the report we give two example of common

21 cardio procedure and common bone scanning procedure.

22 We looked at the Medicare reimbursement rates were

23 like $250, and we said all right. If you take the

24 cost of Moly-99 and you increase it by ten percent,

25 what does it do to the cost of that procedure?

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1 Well, it increased the cost of that
2 procedure by about one-tenth of one percent. And then
3 we said, well, what if you increase the cost of the
4 dose of moly or dose of Tech-99 by ten percent. What
5 does it do to that cost of procedure?
6 It increases the cost of that procedure by
7 about four-tenths of a percent. So you can really
8 raise the cost of Moly-99 and not have a huge impact
9 on it, assuming that you pass those costs down and
10 don't add anything on top of them. You just pass them
11 down and it doesn't really have an impact on the end
12 cost of the procedures.
13 CHAIRMAN MALMUD: Dr. Welch.
14 DR. WELSH: If I might ask Dr. Suleiman a
15 question, does it make any difference in the net cost
16 of the drug production, the radiopharmaceutical
17 production if the isotope is coming from overseas,
18 Belgium, Africa, South Africa, Australia, Canada
19 versus coming from Missouri? Is there any expectation
20 that the price could be a net reduction?
21 DR. SULEIMAN: Well, I'm not an economist.
22 So I assert I have no expertise in this area other
23 than my own interest. Clearly, we get it from Canada
24 now, but I would think I don't know how much damage it
25 would be, but I don't anticipate any major difference

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there. I think coming from Australia could be -- I mean, there's a longer time period, but I guess the NRC would have the export-import licenses to get them into the country.

MR. CROWLEY: They basically put this stuff on commercial aircraft and fly it in. MDS Nordion uses its own charter aircraft to go from Canada to the U.S., but again, understand that companies will charge what the market will bear, and so even if Missouri can produce the isotope more cheaply, it may slightly try to undercut to establish market share, but you know, if people are willing to pay, they're going to charge.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Yes. I think the cost is not the major issue here. I think the major issue is the strategic importance of being self-sufficient. For example, if other countries for one reason decide to stop the exportation of the moly to this country, you know, I think, the Congress is trying to find ways not to have to import for strategic reasons.

CHAIRMAN MALMUD: Steve.

MR. MATTMULLER: I'm sorry. One more, the last one. This is in regards to the Petten reactor that had the major shutdown that caused the latest

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1 problem, is from what I've read and heard that it was
2 due to a pipe encased in concrete that was generating
3 a source of bubbles that had everyone concerned.
4 MR. CROWLEY: Corrosion products, yes.
5 MR. MATTMULLER: And so at this point they
6 haven't fixed that.
7 MR. CROWLEY: They have fixed it.
8 MR. MATTMULLER: They have fixed the
9 corroded pipe?
10 MR. CROWLEY: Yes.
11 MR. MATTMULLER: Okay.
12 MR. CROWLEY: We have a couple of reactor
13 experts on our committee, and this is not Petten's
14 view, but our committee experts' view was when
15 reactors start having this problem, that's a real
16 indication that you're facing end of life issues.
17 CHAIRMAN MALMUD: Does that complete the
18 discussion? Dr. Suleiman.
19 DR. SULEIMAN: So my perception, so at
20 least when I explain it to other people, the
21 Australians really have come up with the newest and
22 theoretically have the capacity to help alleviate the
23 problem. However, right now with the four or five
24 existing ones we're really very, very vulnerable
25 because none of them plan to shut down intentionally,

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1 but unintentional shutdowns are unanticipated.

2 MR. CROWLEY: That's right, yes.

3 DR. SULEIMAN: So until others step up to

4 the plate.

5 MR. CROWLEY: Well, in this country there

6 are two that might step up, would be Murr and Babcock

7 & Wilcox, and it will take them a minimum of five

8 years to step up. So keep your fingers crossed.

9 CHAIRMAN MALMUD: If I may, I believe that

10 the issue started in 1979 when TMI went. The public

11 turned away from investing in nuclear energy. The

12 icing on the cake came when the Russians allowed

13 Chernobyl to occur, which made the whole world very

14 suspicious of nuclear power.

15 We will have ample supply of isotopes when

16 our nation decides that it will use nuclear power for

17 generating electricity and when one of the byproducts

18 will be isotopes. But that also means it has to

19 overcome a major political question, which is not in

20 my backyard. You're not going to put a reactor in my

21 backyard, and I don't want the nuclear waste in my

22 backyard.

23 So until the public is convinced that the

24 risks of nuclear power are less than the risks of

25 entering another war to maintain its supply of fossil

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1 fuels, the problem won't be solved. It's 30 years
2 since TMI, and the issue is moving toward a
3 resolution. If I live long enough I'll see us reenter
4 the world of nuclear power. We'll buy our technology
5 back from the Japanese who are using it well. The
6 French are producing what, 90 percent of their
7 electricity from nuclear power, and we're sitting here
8 on our hands because we had an accident in 1979 that
9 killed no one.
10 The mining of coal and the drilling of oil
11 destroys many more lives. However, we have a public
12 which is not educable. We have a public which is
13 partly illiterate. We have high school kids coming
14 out with fifth grade education. So until we correct a
15 few of those problems, which it appears the present
16 administration is interested in curing but I don't
17 know if it has the ability to do it, but if they do,
18 we'll all be fine. We'll all have all of the isotopes
19 that we need.
20 Until then all that we say means very
21 little, and you are correct. It's a matter of cost,
22 and what's needed is for someone to invest. Usually
23 it's the private sector, but the private sector won't
24 invest not because of the cost of the investment but
25 because of the risk and the liability of investing.

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1 So it's the government that has to do it.
2 When the government does it, then somebody will come
3 in and live off of the investment that the government
4 has made. It's an economic issue. It's not a medical
5 issue.
6 Unfortunately, we are the ones at the end
7 of the pipeline who suffer the medical consequences of
8 it, and that's not us. Actually it's the patients.
9 So that we wish our politicians well in dealing with
10 the public and helping to educate the public with
11 regard to the uses of nuclear energy for the good as
12 well as for defense, and until then we are prisoners
13 of this system.
14 PARTICIPANT: Is that a motion, Mr.
15 Chairman?
16 CHAIRMAN MALMUD: All that we say, it
17 means absolutely nothing.
18 DR. WELSH: I second the motion.
19 (Laughter.)
20 CHAIRMAN MALMUD: But it's good to be able
21 to talk. It makes us all feel better.
22 Dr. Welsh.
23 DR. WELSH: Just a quick editorial here.
24 (Laughter.)
25 DR. WELSH: The present economic crisis

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has changed the public attitude and the politics surrounding this to the point where I am actually hearing for the first time in many years people and towns and locations in general who are saying, "I used to say not in my backyard, but if I could get a job there, by all means."

CHAIRMAN MALMUD: Maybe so. I hope that you're correct, but we'll give it a few more years. The price of oil had to go back up again, and when that happens we will hopefully have a nuclear power industry again, and we will enjoy the byproducts of that nuclear power industry.

Until then, no one in his right mind would put any of his own money into doing this because it's too risky. The profit can be made once the product is on line because then the marketplace will take over, but I took advantage of my position as Chairman just to ventilate. But it's 30 years. It's 30 years. No one has lost his life in any of this in the United States, and yet the public still seems very frightened of nuclear energy.

DR. EGGLI: It's in my backyard. I look at it every day.

CHAIRMAN MALMUD: Yes, you do. You do. You live right near TMI. So if I may, having had the

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1 last -- may I have the last word here or do you want
2 to discussion some more? We'll move on to the next
3 topic.
4 Dr. Nag wants to have the last word.
5 DR. NAG: I do have -- it's very
6 interesting about what you said. However, we are the
7 advisory committee for the medical use of isotopes,
8 and therefore, rather than just throwing up our hands
9 and saying, well, there's nothing we can do, why not
10 make a recommendation, whether the politicians will
11 deal with it or not; make a recommendation that from
12 the Medical Use of Isotope Committee this is what we
13 feel?
14 They may not hear it.
15 CHAIRMAN MALMUD: We did.
16 DR. NAG: But we can do it as a formal
17 recommendation and put it in our minutes.
18 CHAIRMAN MALMUD: We already did that. We
19 did that in one of the items that was very eloquently
20 summed up for us a little bit earlier.
21 MS. COCKERHAM: Item 6.
22 CHAIRMAN MALMUD: We expressed our
23 concern, haven't we?
24 MS. COCKERHAM: Item 6.
25 CHAIRMAN MALMUD: Item 6. We already did

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1 it.

2 DR. WELSH: We'll do it every meeting

3 until --

4 (Laughter.)

5 DR. NAG: Do it every meeting until they

6 hear us.

7 CHAIRMAN MALMUD: Fine. We ought to make

8 that a five minute agenda item for each succeeding

9 meeting, but we'll limit it to five minutes because

10 you don't want to hear me talk, and we'll be able to

11 present it. Because it's the only way anything will

12 ever happen. It's not under our control.

13 It's as much under our control as

14 fingerprint for using an irradiator under our control.

15 (Laughter.)

16 CHAIRMAN MALMUD: Dr. Vetter will attest

17 to that.

18 There are some things we simply can't

19 control, but we can remind our elected officials via

20 the Commission that it is an issue of great concern to

21 the public.

22 May we move on? Thank you very much.

23 MR. CROWLEY: Thank you.

24 (Applause.)

25 CHAIRMAN MALMUD: What's the next item on

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1 the agenda? We juggled our agenda.

2 MR. EINBERG: It will be the status of the

3 current and future 10 CFR Part 35 Rulemaking.

4 MS. BHALLA: Good afternoon, Dr. Malmud

5 and the respected members of ACMUI. It has been a

6 long day for you all, and after this very stimulating

7 discussion, I'm just going to make a very short and

8 just provide you the status of the Part 35

9 rulemakings. As you all know, Part 35 relates to the

10 medical uses of isotopes.

11 This is by Ed Lohr also, and Ed is not

12 here. He had to leave for some things, but anyway, we

13 are both from the Division of Intergovernmental

14 Liaison and Rulemaking, and I'm going to give you just

15 a quick update.

16 Right now there are three Part 35 related

17 rulemakings. The one that's in the proposed rules

18 state is the medical event definition rulemaking.

19 Then we have a direct final rule, and I'll go over a

20 little bit about what a direct final rule is as

21 opposed to our proposed rule and final rule process.

22 And then we have plans to do another rulemaking on

23 Part 35 related issues.

24 With regard to the medical event

25 definition, it's a proposed rule, and the provisions

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1 of the rule are to change most of the medical event
2 criteria from dose based to activity based for Part 1
3 and brachy implants, and this rulemaking is also going
4 to make some clarifications related to the written
5 directives which are needed for Part 1 and brachy
6 implants.
7 And also one of the provisions is to add
8 medical event criteria for failure to prepare for
9 written directive when one is required.
10 The proposed rule was publishes in the
11 Federal Register in August of last year. As you know,
12 proposed rules really solicit comments from all the
13 stakeholders, and it's pretty much for 75 days, and
14 the comment period ended in November.
15 And right now the staff is working on
16 resolution of those public comments, and after the
17 resolution, the package will move to, you know, the
18 Commission as some point.
19 And a kind of schedule right now is that
20 we hope to have that published by August, but then as
21 we discussed earlier, the VA events were all discussed
22 in an earlier presentation, and that may delay the
23 publishing of this final rule because, as you know,
24 the VA events did involve medical events, and the
25 question is a little bit that without, in fact, this

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1 rulemaking, do we need to -- may we rate a little bit
2 more on that or move forward.
3 So, therefore, the schedule is somewhat
4 dependent on that, but hopefully we'll complete it by
5 August or so.
6 Now, once we get a final rule that we are
7 working on, that rule clarifies the Part 35.57. There
8 is the -- actually Part 35.57 itself has to do with
9 grandfathering of the authorize user's medical
10 physicist, RSOs and so on, but the way the rest of
11 Part 35 is written, it seems like it needs a
12 clarification that the individuals who are
13 grandfathered, that they are able to do the preceptor
14 statements for those people who want to come now and
15 get these authorizations.
16 So the technical basis for this rulemaking
17 was accepted in January. For those of you, this is a
18 little bit of our internal mechanisms, so to speak.
19 When we get a request for rulemaking, we also now ask
20 for a very good technical basis because sometimes we
21 start a rulemaking and in the middle realize that
22 there's not enough technical basis, and so therefore,
23 now we are quite particular with that. and this was
24 accepted in January.
25 And this particular rulemaking has been a

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very high priority on our list of things to do, and right now we are working on the rule language so that this clarification can be made.

Just a little bit about what is our direct final rule. Frankly, before I came to Rulemaking, although I was in NRC for many years, I myself didn't know the difference between some of these things: what is a direct final rule; what's a proposed rule; what's a rulemaking plan, and so on?

So here just for, you know, everyone's knowledge, we have put a slide up, "What Is a Direct Final Rule?" So a direct final rule, we pretty much make use of this process, where we are not expecting a lot of comments, it's noncontroversial in nature, and sometimes it's minor in nature.

What we do at that time -- and this is a bit of mechanics -- that we prepare both our proposal and a final rule, and it goes to the Federal Register together.

And when we publish it, we again open it for comments so that the Administrative Procedure Act is met with. So folks have an opportunity to make a comment, and if there are no significant comments, then the rule becomes -- we give an effective date pretty much 75 days, and those are the things. Our

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1 folks from ODC, they keep us on the right track.

2 So in this rule we are pretty much not

3 expecting any adverse comments. So it should become

4 effective if things go the way we are planning. It

5 should be good to go November 2009.

6 Now, if we do get some adverse comments,

7 then we'll have to pull this final rule version back,

8 and then it follows the proposed rule, final rule

9 process, and that really means we need to resolve each

10 and every comment that has come.

11 What really is an adverse significant

12 comment, and that is, again, we follow OGC, the Office

13 of General Counsel, to decide on what the comment is

14 and do we need to follow up on that, and if that

15 happens, then it's going to throw us behind, and

16 hopefully we'll do it by next year.

17 Then a little bit about what's the next 35

18 rulemaking going to be. We have a user need memo.

19 This is, again, a little bit of our internal process

20 when a division or an office comes to ask for

21 rulemaking. It's done through that memo, and there

22 have been a lot of amendments which are needed, and

23 they pretty much have come from, as you all know, in

24 2002, Part 35 was revised in total, and also then the

25 T&D rule was revised and went in effect in 2005.

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1 So in the implementation process, the
2 staff and stakeholders, they have brought to our
3 attention that amendments are needed at several
4 sections of Part 35. So we propose to handle those,
5 and then there is going to be also consideration of
6 Rittenouer petition, which was resolved last year, but
7 it needs more information, and the plans are going to
8 include that.
9 Also, there is the plan to include the
10 preceptor attestation requirements, and that the
11 Commission has approved, and I gave the SECY number in
12 there for if there is any further interest to know
13 exactly what's in the SRM we can provide it for you.
14 So these are the plans. They are all to
15 be included in the next rulemaking. When do we plan
16 to do it? Hopefully the technical basis development
17 is somewhat going on right now. We hope to start it
18 more fully in summer, and then also we pretty much
19 must finish one rulemaking for a particular part.
20 Then we start the next one. So, therefore, as soon as
21 the Part 35 medical event rulemaking is out the door,
22 we start work on this one, which would mean pretty
23 much for all of this year, and then we will complete
24 the proposed rule by fall of next year, and then the
25 final year, the year after.

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1 So those are the kinds of plans to do our
2 rulemakings.
3 CHAIRMAN MALMUD: Are there any questions?
4 If not, we thank you for the least
5 controversial presentation.
6 (Applause.)
7 CHAIRMAN MALMUD: The clarity speaks for
8 itself. Thank you.
9 The next item on the agenda, I think this
10 will be the closing minutes of this meeting. We will
11 regroup tomorrow at 8:00 a.m. and pick up on the
12 program and also catch up on the Commission briefing,
13 which is a closed session, but we will begin at eight
14 o'clock with the open session.
15 Any questions?
16 MR. LIETO: Go ahead. You may answer my
17 question.
18 MS. COCKERHAM: No, go ahead.
19 MR. LIETO: Well, I'm just curious what is
20 going to be the timing of the closed session because I
21 would think members of the public would want to know
22 sine they're going to be invited out.
23 MS. COCKERHAM: I'm expecting that it
24 would be at the end of the day because the morning
25 session cannot be changed due to a funeral that many

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1 staff members will be attending tomorrow. So we need
2 to keep on schedule in the morning, and I don't see us
3 closing the session in the middle of the afternoon and
4 then opening back up.
5 CHAIRMAN MALMUD: No, I announced that we
6 would have the open session beginning at eight.
7 MS. COCKERHAM: Yes.
8 CHAIRMAN MALMUD: Yes.
9 MS. COCKERHAM: So we'll do the closed
10 session at the end of the day.
11 CHAIRMAN MALMUD: Any other questions
12 about that?
13 So we thank you for a very productive day,
14 and we'll see you tomorrow morning at 8:00 a.m.
15 Another announcement, Ashley?
16 MS. COCKERHAM: This is Ashley. I have
17 two things.
18 First of all, here are your time sheets.
19 If you can guesstimate your time, it's eight hours
20 today and eight hours tomorrow. There's no question
21 about that. Saturday if you can guesstimate how long
22 it will take for you to get home on Saturday, fill
23 this out, sign it, and give it back to me and I'll
24 make sure that it gets to Shayla. So I'm going to
25 pass these around.

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1 The second one is for the luncheon
2 tomorrow.
3 (Whereupon, at 4:52 p.m., the meeting was
4 adjourned, to reconvene at 8:00 a.m., Friday, May 8,
5 2009.)
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