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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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WEDNESDAY,

OCTOBER 26, 2005

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The meeting was convened in Room T-2B3 of
Two White Flint North, 11545 Rockville Pike,
Rockville, Maryland, at 8:19 a.m.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., ACMUI Chairman

EDGAR D. BAILEY Member

DAVID A. DIAMOND, M.D., Member

RALPH P. LEITO Member

SUBIR NAG, M.D. Member

SALLY WAGNER SCHWARZ, Rph, Member

ORHAN SULEIMAN, Ph.D Member

WILLIAM VAN DECKER, M.D., Member

RICHARD J. VETTER, Ph.D, Member

JEFFREY F. WILLIAMSON, Ph.D, Member

1 SPEAKERS AND PARTICIPATING NRC STAFF:

2 RICHARD BLANTON NMSS/IMNS
3 TERENCE BEVEN, M.D. Society of Nuclear Medicine
4 THOMAS H. ESSIG NMSS/IMNS/MSIB
5 CINDY M. FLANNERY NMSS/IMNS/MSIB
6 ROBERT L. GALLAGHAR State of Massachusetts
7 PATRICIA K. HOLAHAN, Ph.D, NMSS/IMNS/MSIB
8 DONNA-BETH HOWE, Ph.D NMSS/IMNS/MSIB
9 ANGELA R. MCINTOSH NMSS/IMNS/MSIB
10 MOHAMMAD SABA NMSS/IMNS/MSIB
11 RONALD E. ZELAC NMSS/IMNS/MSIB

12

13 ALSO PRESENT:

14 CHARLES L. MILLER, Ph.D

15 LYNNE A. FAIROBENT

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Discussion of Congressional Energy Bill:

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8:06 a.m.

CHAIRMAN MALMUD: On the record. We have a full schedule today. The schedule for today has been amended so that Item 14, just to remind you what was discussed yesterday, will go from 8:00 a.m. until 10:00 a.m. Item 15 will from 10:00 a.m. to 11:15 a.m. Excuse me. There will be a break at 10:00 a.m. and then 10:15 a.m. to 11:15 a.m. is Item 15. Item 16 has been removed from the schedule and then we'll resume with Item 17.

The first item on this morning's agenda is a discussion of the Congressional Energy Bill, the NRC Regulation of Accelerator Produced Isotopes and Nuclear Medicine Perspective, the NRC Regulation of Accelerator Produced Isotopes open session. Mr. Blanton will discuss portions of the Energy Policy Act of 2005 which was signed into law by President Bush in early August.

Mr. Blanton's presentation will focus on Section 170H, Radiation Sources Protection. He will focus on the NRC's newly acquired regulatory authority over naturally occurring and accelerator produced radioactive material and this is called NARM. Mr. Blanton.

1 MR. BLANTON: Good morning. I'm Richard
2 Blanton. I'm Health Physicist with the Office of
3 State and Travel Programs NRC and currently on
4 assignment to the Energy Policy Act Task Force to
5 implement the new provisions of the Energy Policy Act
6 of 2005. I'm filling in today for Douglas Broaddus
7 who is in France.

8 The Energy Policy Act was enacted on
9 August 8th. The Act is a significant legislative act
10 that indirectly affects Nuclear Regulatory Commission.
11 It also contains specific requirements which directly
12 affect the NRC. One of the many provisions is that it
13 gave the NRC for the first time regulatory authority
14 and jurisdiction over certain accelerator produced
15 materials and certain naturally occurring radioactive
16 materials. In response to this provision, the
17 Commission initiated two activities. One, we formed
18 a rulemaking working group and second, we formed the
19 Implementation Task Force which of I am a member.

20 Section 651(e) of the Energy Policy Act
21 amended the definition of byproduct materials
22 (Inaudible.) for the detection of (Inaudible.) of the
23 Atomic Energy Act. The definition now includes
24 certain naturally occurring and accelerator produced
25 radioactive materials. Specifically the definition of

1 byproduct material now includes accelerator produced
2 materials such as sodium-22, cobalt-57, gallium-67 and
3 fluorine-18. It also includes discreet sources of
4 radium-226. The third new form is discreet sources of
5 naturally occurring radioactive materials other than
6 radium-226 which the Commission determines in
7 consultation with the Environmental Protection Agency,
8 the Department of Energy, the Department of Homeland
9 Security and any other appropriate Federal agencies to
10 pose a threat similar to radium-226.

11 (Inaudible.) form other than radium-226.
12 Just one note that the definition only applies to the
13 accelerator materials produced for use in commercial,
14 medical or research activity. The definition of
15 discreet source is not specified in the Act. The Act
16 instead specifies that NRC must establish the
17 definition by rulemaking.

18 In order to avoid a gap in the regulation
19 of NARM during this transition period from the
20 previous regulating scheme to the new one, the Act
21 allowed the Commission to grant a waiver that allows
22 current users and current state regulatory programs to
23 continue using and regulatory the certain NARM for up
24 to four years through August 7, 2009. Unless
25 terminated earlier by (Inaudible) and the Commission

1 required by the Act to terminate the waiver in case of
2 an agreement state, if the governor certifies that the
3 agreement program covers this new NARM material as
4 defined in the Act; and the state program is adequate
5 to protect public health and safety with respect to
6 this new material. The Commission issued the waiver
7 on August 25th. It was published in the *Federal*
8 *Register* on August 31st.

9 The definition of byproduct material, as
10 amended by the Act applies to this certain NARM
11 regardless of when it was produced, extracted or
12 converted after extraction. However, the materials,
13 as I noted before must be for use in commercial,
14 medical or research activity. And, as an example, the
15 Legislation does not give NRC authority over NARM,
16 such as radium-226 that might be filtered out of water
17 during drinking water or waste treatment processes.

18 The Act specifically excludes NARM from
19 the definition of low-level radioactive waste. The
20 Act does not give NRC regulatory authority over the
21 accelerators themselves, only over the material that
22 they produce. Now this is different from the case of
23 reactor produced material because reactors are
24 licensed by NRC. So we have the case of the material
25 being produced in those reactors going essentially

1 from one license to another. Here since we don't
2 license and will not license the accelerators, we're
3 having unlicensed material all of a sudden becoming
4 licensable and defining exactly where that authority
5 begins is one of the things we're going to have to
6 address in rulemaking. Again, the Act does not give
7 NRC regulatory authority over any naturally occurring
8 material other than radium-226 or any material that we
9 determine poses a threat similar to radium-226.

10 Section 274 (b) of the Atomic Energy Act is
11 one under which the agreement state program operates.
12 It was amended to include the expanded definition of
13 byproduct materials. There is a transition plan
14 required that we have to create in order to transition
15 the authority from the states and back to the states
16 and we're working on that.

17 The Act requires NRC to consider as part
18 of this the impact of the availability of
19 radiopharmaceuticals to physicians and patients from
20 promulgating our regulations and our programmatic
21 changes. Now there are other provisions of the Act
22 which address radiopharmaceuticals, but those
23 provisions are outside the charter of this task force.
24 So I'm not going to address them any further.

25 The Act requires NRC to consult with

1 states and other stakeholders on its NARM regulations.
2 Now in this line, NRC will hold a public meeting here
3 at headquarters on November 9th. The agenda for that
4 meeting is expected to be posted on the NRC website
5 shortly.

6 The working group for the NARM rulemaking
7 include representatives from NRC's headquarters and
8 regions and also from the states. The Act requires
9 the final NRC regulations to be in place 18 months
10 after the effective date of the Act which works out to
11 be February 7, 2007. This schedule for accomplishing
12 this is currently in the process of being approved by
13 the Commission but at this time. It is estimated that
14 the proposed rule will be published in April of 2006
15 and the final rule will be published no later than
16 February 7, 2007. Now those of you who have been
17 involved in Federal rulemaking probably realize that
18 is a very tight schedule.

19 The Energy Policy Act 2005 contains a
20 multitude of significant activities like the new
21 rulemaking for the redefinition of byproduct material,
22 activities which require significant NRC and state
23 cooperation in order to accomplish. Recognizing that
24 the close association of these activities, the NRC
25 established a multi-organizational task force under

1 the direction of the Director of the Division of
2 Industrial and Medical Nuclear Safety within the
3 Office of the Nuclear Material, Safety and Safeguards
4 and that is the task force that I am assigned to.

5 The task force has been charged to develop
6 a framework under which the activities will be
7 planned, managed and implemented. The task force
8 within one year is expected to develop and perform the
9 activities that insure timely complete implementation
10 of the Act and the transition plan.

11 Various actions will take place and will
12 be completed by the task force over the next year.
13 Significant activities of the task force applicable to
14 the NARM legislation include: preparation of the
15 technical basis of the NARM rulemaking, this is an
16 explanation of why we think the rules that we're going
17 to pose will be the correct ones, this should be then
18 sometime early in November; development of a
19 definition and description of discreet source, (We're
20 very much engaged in that and again we hope to have
21 something by early November); development of the
22 Section 651(e)(4) transition plan to allow orderly
23 transition of the regulatory responsibility from the
24 old format with the states being primarily responsible
25 to the new format with NRC being primarily

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1 responsible. (Again we hope to have that completed by
2 September of `06); development of Commission policy
3 regarding new state agreements that govern NARM only.
4 (We thought that this might be very straightforward,
5 but it turns out there's some language in the Act that
6 we're going to have to look closely at, but we will
7 expect to have something in the final decision by
8 September of `06); development of the NARM rule
9 guidance in areas of inspection, licensing and
10 enforcement, (This will be done concurrently with the
11 NARM rule and should be available for people to look
12 at by the time the rule is final); and finally,
13 identification of other NRC regulatory program changes
14 that need to be made, this would include things like
15 changes to the Nuclear Materials Events database to
16 incorporate NARM events and regulations of the sealed
17 source and device registry system, training for
18 nonagreement states and any modifications that might
19 be necessary to the general license tracking system.

20 That's pretty much concludes my prepared
21 comments. If there are any questions, I'm not sure if
22 we're going to take them now or hold them for later.

23 CHAIRMAN MALMUD: Thank you, Mr. Blanton.
24 I think that if you'll entertain questions we'll open
25 the floor to questions. Is that acceptable, Dr.

1 Miller?

2 DR. MILLER: Sure.

3 CHAIRMAN MALMUD: Are there any questions
4 from the floor? Dr. Williamson.

5 MEMBER WILLIAMSON: What is your plan in
6 the medical use area? Are you going to change, amend
7 or revise Part 35, section by section to include the
8 new sources; or would you create a new part for
9 medical use of NARM that would be parallel to Part 35
10 for byproduct material?

11 DR. MILLER: Jeff, as we develop
12 regulations, we'll make the appropriate changes to
13 whatever portions of our regulations that we feel we
14 need to do so. Right now, we're very much in the
15 intake mode. Congress has given us this task and has
16 given us a short time to do it.

17 What everyone has to recognize is this is
18 not an area that NRC has regulated before. However,
19 the states have. So the states have a lot more
20 experience in the regulation of this than we do and
21 Congress in its wisdom wants to make sure that the NRC
22 to the maximum extent possible uses the states'
23 regulatory structure that has been developed. So
24 we're to receive that in. So we're trying to evaluate
25 that.

1 Maybe Mr. Bailey can address it from a
2 California perspective on where have medical
3 regulations that you have to be compatible with but
4 yet you've regulated NARM and we haven't. How do you
5 deal with that within a state structure? Do you see
6 a need for Part 35 to potentially be changed from your
7 perspective, Ed? We don't know yet the answer.

8 MEMBER BAILEY: Yes, because I believe
9 there are certain isotopes mentioned in 35 and so you
10 have to take a look at them. The states don't
11 typically mention the isotopes. They just say
12 radioactive material. So it's a much easier fix for
13 us.

14 DR. MILLER: Since Congress has redefined
15 byproduct material, we're trying to see where we can
16 get the regulations changed with as a minimal
17 disruption as possible. We're very much in an intake
18 mode trying to hear from all stakeholders on their
19 views. That's one of the reasons why we're holding a
20 public meeting in November. We want to get input and
21 get various stakeholders' views. To the extent that
22 the medical community wants to have input to this, I
23 encourage them to please give us their views.

24 CHAIRMAN MALMUD: Mr. Bailey.

25 MEMBER BAILEY: After I woke up, I think

1 the biggest challenge --

2 DR. MILLER: I'm sorry to put you on the
3 spot.

4 MEMBER BAILEY: I had to get a new badge
5 and everything. The biggest challenge will be in the
6 area of PET and at what point in the PET production
7 process will NRC say that they are now regulating? It
8 was mentioned the discreet sources; and I've sat in on
9 a couple of those phone calls discussing discreet
10 sources. It sounds on the surface like a very easy
11 thing to say. I know what something discreet is. It
12 has boundaries and all. But that will be the
13 challenge.

14 Where will NRC start regulating it? Will
15 it be immediately after the targets are taken out of
16 the accelerator? Will it be somewhere down the
17 process route? Or where? That's going to be the big
18 issue because the Act, I believe (and kick me if I'm
19 wrong) did not give them the authority to actually
20 regulate the production accelerator.

21 DR. MILLER: That's correct.

22 CHAIRMAN MALMUD: Excuse me. I just
23 wanted to ask a question first if I may. How many
24 states currently have accelerators producing these
25 kinds of radioisotopes?

1 DR. MILLER: Do you know? I don't know
2 off the top of my head.

3 MEMBER BAILEY: I'm not sure how many
4 states have them but it's a large number of the 33.
5 Certainly, California, Texas, Florida, on and on. I
6 would be surprised if any "major", I shouldn't say
7 that, any of the "larger" states with larger
8 populations with larger medical communities do not
9 have a PET production facility; and, probably if they
10 have VA hospital, they probably have a PET production
11 facility.

12 CHAIRMAN MALMUD: The reason that I ask
13 the question is that we obviously already have a
14 database and that is, as you alluded to the states
15 currently regulating this to some degree or another.
16 And it would be most interesting if we could obtain
17 the regulations of each of the states that we
18 currently at least overseeing the production of these
19 isotopes so that a spreadsheet could be developed. A
20 large one obviously, if 33 states are doing it
21 currently!

22 DR. MILLER: Actually, it could
23 potentially be all 50 states. It's not just agreement
24 states. It's non agreement states also. So we have
25 to interface.

1 CHAIRMAN MALMUD: An even larger
2 spreadsheet.

3 DR. MILLER: Yes, United States.

4 CHAIRMAN MALMUD: So that the regulations
5 that are developed are in recognition of methods that
6 have already been tried, tested and implemented and
7 also are encouraging of, rather than unintentionally
8 suppressing, medical research and the application of
9 these isotopes to the provision of diagnostic
10 healthcare.

11 I think this committee would be most
12 interested to assist in the process, since we will
13 require education ourselves in formulating a national
14 policy which would encourage the continued production
15 of the use of these isotopes and encourage it in a way
16 which would advance the healthcare needs of the nation
17 without undue regulation and without undue
18 restrictions on isotopes simply because they're
19 isotopes. By that what I'm alluding to is that some
20 of these isotopes have half lives of seconds. So even
21 if large amounts are produced, they have a potentially
22 inconsequential effect on the health and welfare of
23 the public in terms of their short half life . Perhaps
24 regulatory methods could be developed which would
25 differentiate that with a potential risk versus that

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1 which does not present a potential risk so that there
2 would be logic to the restrictions and rules governing
3 the use of these isotopes. Dr. Suleiman.

4 MEMBER SULEIMAN: FDA has proposed draft
5 guidance on the radiopharmaceutical manufacturing of
6 positron drugs. It's currently out for comment right
7 now. Of course, FDA is concerned more about the
8 radiopharmaceutical medicinal aspects of it but I
9 think that clearly would help out somewhat and I think
10 they're just not interested obviously in the PET
11 drugs. But I also think that most states, I don't
12 have that number, but we're pushing 50 and I think
13 that information is readily available.

14 CHAIRMAN MALMUD: Dr. Vetter.

15 MEMBER VETTER: Just to reassure anyone
16 who might be concerned about lack of control of PET
17 production, if for example the NRC does not regulate
18 the emissions from the production of PET
19 radiopharmaceuticals, the state still does. So it's
20 not that it's not going to end up not being regulated.
21 It's just a matter of who is going to regulate what
22 part of it.

23 The question I have relates to the waiver.
24 I assume from your comments that NRC granted a waiver
25 for all agreement states. Is that what this says, a

1 waiver granted August 25th?

2 MR. BLANTON: I believe that's correct.
3 There's a waiver. It was published in the *Federal*
4 *Register* and then I did personally work on development
5 of that waiver and as I recall, it was intended to
6 allow basically the status quo as of the date the bill
7 was signed to continue until we have the new
8 regulatory scheme in place.

9 MEMBER VETTER: Does anyone know at this
10 time what happens at the end of that four year period?
11 And will agreement state, still have their regulatory
12 structures.

13 DR. MILLER: If you look at the schedule
14 that Congress put us on, they put us on a pretty fast
15 track to conduct rulemaking with the knowledge of that
16 once the rulemaking is promulgated, the states have
17 three years to implement it. I think that's how they
18 came up with the four years, a little more than a year
19 to promulgate a rule and then three years to get it
20 implemented in the states. Dr. Malmud, may I respond
21 to your query?

22 CHAIRMAN MALMUD: Please do.

23 DR. MILLER: Okay. First I want to say
24 that I agree with you. We need the maximum
25 intelligence from what the states are doing. I have

1 been assigned the leadership for this task. The task
2 force reports to me so I have a very large stake in
3 this.

4 What we have done to try to gain that is
5 we've worked with the Organization of Agreement States
6 and we've worked with the CRCPD, the Conference of
7 Radiation Control Program Directors, so that we
8 capture all 50 states, and, we have solicited
9 participation from the states in that respect. The
10 states have assigned basically, or have been willing
11 to strike an agreement with us, to have an individual
12 come here and work full-time with the NRC to be the
13 liaison back to the states. In addition, the
14 Organization of Agreement States has assigned an
15 individual that will come up here on a periodic basis
16 to work with us.

17 We're going to try to use them to the
18 maximum extent possible for lack of a better word to
19 "pick the brains" of the states for how we do it.
20 It's a fully dedicated task force to get this done.
21 This is all they're working on.

22 I have a question for the committee. You
23 raised the concern about not promulgating a regulatory
24 requirement that would inhibit the medical practices
25 and patient care. Does the committee have a view on

1 the current status quo? In other words, it's
2 regulated by the states. Do you believe that there
3 are any state regulations that currently do that? I
4 recognize that puts you on the spot; but what we're
5 looking for is a practical regulatory scheme here
6 that's going to work. So we need to know what's
7 working and what isn't as a starting point.

8 CHAIRMAN MALMUD: I don't feel competent
9 to answer your question with respect to the production
10 of PET radiopharmaceuticals. But there are members of
11 the nuclear medicine community, both physicians and
12 scientists, who have vast experience over decades in
13 the production of and application of PET
14 pharmaceuticals to research and clinical care. It
15 would seem to me that in the course of collecting data
16 from the states we should also invite for their
17 opinions those leaders in this nation who are easily
18 identified who have had a vast experience and who can
19 give us their views on how their individual states
20 have interacted with them in the encouragement of the
21 research and at the same time, maintaining public
22 safety.

23 DR. MILLER: Because I do not believe that
24 it was Congress's intent to inhibit the process. I
25 think they just determined that they wanted the NRC to

1 pick up this regulatory function for whatever reason.

2 CHAIRMAN MALMUD: I think that the members
3 of the medical community are certain that it was not
4 the intent of Congress to inhibit. What always
5 concerns us with new regulations whether they be
6 federal, state, local or institutional is the concept
7 of unintended consequences.

8 DR. MILLER: Understand.

9 CHAIRMAN MALMUD: And therefore it's my
10 belief and I think I speak for the members of the
11 committee who are practicing physicians and scientists
12 in medical care, that we come up with a policy that
13 will protect the public safety and at the same time
14 not discourage research or application, by undue
15 regulation and undue expenses entailed in documenting
16 the regulation.

17 So it would be interesting to see how
18 each of the states has managed this. Some states I'm
19 certain have done better in some areas than others. In
20 addition to get the perspective not only of the state
21 regulatory agencies, but the leading individuals in
22 research institutions who could attest to their views
23 with regard to current regulations in their own
24 states, so that we see both sides of the picture.
25 There may be only one side. In other words, there may

1 be agreement between the investigators and the
2 physicians and the state. On the other hand, there
3 may be a difference. If we simply poll the state, we
4 may miss that important input.

5 DR. MILLER: Thank you.

6 CHAIRMAN MALMUD: Do I speak for the
7 members of the committee? Dr. Diamond?

8 MEMBER DIAMOND: Yes, I would actually say
9 that it may be very interesting. We may find that
10 there is a wide disparity in how these materials are
11 handled among the agreement states and this may be
12 actually a very nice opportunity for us to develop
13 some common sense pragmatic regulations that will be
14 useful for all parties, given the explosion in the
15 use, for example, of PET and other modalities.

16 My question is I'm actually just reviewing
17 this document from the Society of Nuclear Medicine and
18 within the document, there is some common sense
19 language in which there's a recommendation that
20 certain very short-lived radioisotopes that have very
21 low threat concerns (and they would include some of
22 the PET isotopes) that within this document there's a
23 recommendation that actually these particular
24 radioisotopes be exempted because of the very low
25 risk. And the question I would pose is within the

1 rubric of your mandate from Congress in which they ask
2 you to now oversee the materials, can you then in turn
3 say yes, we accept this responsibility but for these
4 particular materials there's no need for a specific
5 regulation because the threat is so low? Is that a
6 potential within the framework of the Act?

7 DR. MOORE: Dr. Malmud, I could answer
8 that. This is Scott Moore over here.

9 CHAIRMAN MALMUD: I'm sorry. Go ahead.

10 DR. MOORE: Hi. I'm Scott Moore. I'm
11 chief of the Rulemaking Guidance branch in Dr.
12 Miller's division. I'm Tom Essig's colleague.
13 Anything's on the table. At the November 9th
14 roundtable discussion, we can discuss any
15 possibilities. I would say that the Legislation gave
16 us, the NRC, authority and jurisdiction over all
17 accelerator produced material. But we could discuss
18 any regulatory scheme.

19 If the ACMUI or if any individuals in the
20 round table discussion wanted to bring any regulatory
21 framework or thoughts up for discussion, then that
22 would certainly be open for discussion and we could
23 consider any framework and especially if the states
24 are doing that now, then that would be a model that we
25 could consider. But the Legislation gave us authority

1 over all accelerator produced material.

2 I would add a few other things to this
3 discussion that's been going on. The roundtable
4 discussion on November 9th is in fact a roundtable
5 discussion that we're inviting key players that we
6 feel have stakes in the outcome of the regulation.
7 They include the states, the OAS, the CRCPD and
8 individual states, SNM, CORAR, Double APM, HPS, the
9 waste industries, NEI, other industries that we feel
10 are of particular interest and Dr. Malmud has
11 identified another one that maybe we need to think of,
12 individuals in the research community that we need to
13 consider.

14 So if you have suggestions, we'd like to
15 know that. We need to know who we ought to consider
16 inviting. Chip Cameron is going to facilitate that
17 meeting. We will be inviting and maybe Chip has
18 already gotten in touch with you, the ACMUI, to sit in
19 in the roundtable discussion as a member of the
20 roundtable. So the ACMUI will be asked to be
21 represented in the roundtable discussion.

22 There's a very fast time schedule for
23 production as Mr. Blanton mentioned. We will be
24 putting a proposed rule to the agreement states and
25 you will see your copy in the ACMUI in the January

1 time frame. So you'll get a copy of the proposed rule
2 before it goes out to the Commission and to the
3 public. So this would be a predecisional copy in the
4 January time frame to review. This is a single
5 opportunity to get input and we have not made any
6 decisions yet on the kinds of questions you're asking,
7 Dr. Diamond.

8 CHAIRMAN MALMUD: Thank you. Dr.
9 Williamson.

10 MEMBER WILLIAMSON: Maybe this gets to the
11 definition of discreet source but what is your plan to
12 respect to radionuclides that are produced
13 inadvertently as a result of accelerated producing
14 radiation via accelerators. For example, high energy
15 medical Linax will produce certain quantities of very
16 short-lived radionuclides, oxygen-15, which is
17 essentially a level of contamination.

18 DR. MILLER: You're getting into a level
19 of detail that we haven't developed yet. But that's
20 the kind of input that we need to make sure that we
21 think about all aspects.

22 CHAIRMAN MALMUD: Dr. Williamson, it may
23 be early for that kind of consideration, but I'm
24 certain that it will be considered and I suspect that
25 the states themselves have recognized this issue in

1 the past. But it will come forward. Right now, we're
2 in a first step and if I may, it would seem to me the
3 most important is the one that -- Is it Dr. Mower? I
4 couldn't hear your name clearly when you spoke?

5 DR. MOORE: I'm sorry. I'm Dr. Scott
6 Moore.

7 CHAIRMAN MALMUD: Scott Moore. Excuse me.
8 That Dr. Moore indicated that there will be a meeting
9 at which all interested parties could have a voice in
10 beginning this process. That would seem to me to be
11 the most important element that we deal with right
12 now, and that there be broad representation from each
13 part of the medical community, and scientific
14 community so that we have a process in which all
15 interested parties have a voice and expressed their
16 concerns. I think that might be the first step, Jeff,
17 and then what you are alluding to-being a physicist,
18 as you are will eventuate and I'm sure be addressed.

19 DR. MOORE: That's correct. I can answer
20 Dr. Williamson's question. The discreet definition
21 only applies to the naturally occurring materials.
22 The accelerator produced materials in the legislation
23 do not have the discreet attached to them. So the
24 legislation applies to all accelerator produced
25 materials. However, the legislation also only applies

1 to materials for commercial, research and medical use;
2 and so we will have figure out how it applies to
3 material for commercial, research and medical use.

4 CHAIRMAN MALMUD: Thank you. Other
5 questions? Dr. Suleiman.

6 MEMBER SULEIMAN: I just want to add for
7 the record not to forget the science, but I think PET
8 Nuclides are very energetic and even though they're
9 low quantities, they give some of the highest doses in
10 medical diagnostic procedures. Separate from that
11 though, the radiation safety issues are not going to
12 go away. They're probably more significant for PET
13 nuclides than they are. People think they're so quick
14 that you don't have to worry about them. Well, you'll
15 get the dose very quickly and you may not be able to
16 measure them. So there are some real technical
17 challenges there. But the safety issues I think we're
18 all concerned and, Ed, doesn't the CRCPD have model
19 bylaws for PET or not?

20 MEMBER BAILEY: May I respond to that?

21 CHAIRMAN MALMUD: Yes. Mr. Bailey.

22 MEMBER BAILEY: Not entirely and I was
23 just glancing through Part 35. There's very little
24 that I can see that would be changed in Part 35. The
25 challenge I think has been to the regulators the first

1 time they get one of these cyclotrons. It's a black
2 box that you put inert material in and get radioactive
3 material out.

4 There's always a tendency to want to try
5 to reinvent the wheel and I think the states do not
6 have a suggested state reg at this time on it, but
7 there has been enough interchange because we do go to
8 our colleagues in the other states and say what did
9 you do when it occurred. It's just an extension of
10 health physics. It's higher energy and that's the
11 difference. You're going to have to look at
12 shielding. You're going to have to look at personnel
13 exposure. All of those things have to be increased or
14 are increased.

15 So I don't see that as a real big
16 challenge to coming up with brand new regulations.
17 The difficulty will be carving up of the norm portion
18 what's not a discreet source and what you're not going
19 to regulate.

20 MEMBER SULEIMAN: I think the anxiety here
21 is really among the facilities that were not regulated
22 by the NRC, that now will have to be regulated by the
23 NRC, because I think the agreement states they're
24 already under agreement state oversight.

25 MEMBER BAILEY: Right. And there are some

1 other pharmaceuticals or other radionuclides other
2 than just the PET radiopharmaceuticals that will come
3 into play, the gallium and the iodine-123 and so
4 forth. But those should not cause much of a
5 perturbation. They will have to look at exemptions
6 under the Biomedical Waste Rule. They'll have to look
7 for the quantity that can be distributed in in vitro
8 kits as exempt and on and on. But that should not be
9 a big deal because the states have already added that
10 in for the most part.

11 DR. MILLER: Dr. Malmud, one thing I want
12 to make clear is that while the NRC has been given
13 authority for this, it would be our intent, once the
14 regulations are promulgated, to enter into agreements
15 with the states so that the regulation of this
16 material would revert back to any state who so signs
17 an agreement with us in that regard. That's the
18 reason for the waiver period and the transition period
19 and all of that so that all of that activity can take
20 place.

21 CHAIRMAN MALMUD: Thank you. Dr.
22 Williamson.

23 MEMBER WILLIAMSON: I guess I'll try to
24 ask a very general question. What is the intent of
25 this legislation? Obviously Congress thought

1 something was broken and needed to be fixed. So
2 what's broken?

3 MR. ESSIG: May I speak to that?

4 CHAIRMAN MALMUD: Mr. Essig.

5 MR. ESSIG: Having been involved in some
6 of the early discussions of the Legislation, this is
7 a bill we had asked for and we received. But it's
8 been through several Congresses and it finally made it
9 to the point where it was passed. One of the concerns
10 that we had or the questions that was raised is we
11 have the IAEA Code of Conduct which speaks to a
12 certain list of radionuclides and it focuses on the
13 safety and security of those with a focus on the
14 potential consequences of malevolent use of the
15 material. That is some organization or individual
16 taking material and either dispersing it via
17 radiological dispersion device or taking the source
18 and putting it in a public place and exposing members
19 of the public overtly.

20 The question was raised. We have this
21 list of radionuclides. The NRC has certain regulatory
22 authority in the Atomic Energy Act which doesn't
23 include all of the radionuclides and radium-226 came
24 out in that discussion. So the question was raised.
25 Since we have applied additional security measures to

1 these radionuclides that we regulate and if radium-226
2 if it's present in that same quantity would pose the
3 same risk of some of the radionuclides that are on the
4 list that we do regulate such as some of the alpha-
5 emitters like curium-244 and californium-252 and
6 plutonium-239 and so one, so the idea was that we
7 would add radium-226 recognizing of course that it's
8 not in the widespread use that it once was.

9 As part of that same discussion it was
10 raised what about accelerator produced radioactive
11 materials and this speaks somewhat to Dr. Diamond's
12 question. The impetus for adding accelerator produced
13 materials, at least the initial focus, was on those
14 materials that could be used in a similar manner that
15 would pose a similar risk and it was mentioned that
16 sodium-22 for example. That's a good gamma-emitter,
17 511 KEV photon and two and a half year half-life and
18 if I had a source of sodium-22, obviously sodium is
19 normally the chloride form, very soluble, could be
20 used, might be attractive as a material for malevolent
21 use.

22 So the thinking was that we would focus on
23 that type of material and originally the word
24 "discreet" was in the legislation for the accelerator
25 produced material. But along the way, the word

1 "discreet" was removed by Congress. So I think our
2 going-in position was to regulate these materials so
3 that we level the playing field from a security point
4 of view so that we had some materials out there that
5 we regulated. If they posed the same risk of
6 malevolent use for the same consequence of malevolent
7 use, that they would be regulated much in the same
8 way.

9 So the point that Dr. Diamond was raising
10 about the very short-lived radionuclide such as
11 fluorine-18, certainly we have to decide how to
12 regulate that and the radionuclides that you mentioned
13 that are produced as byproducts from Linax certainly
14 are obviously present and we'll have to decide. That
15 will be one of the considerations that we'll have as
16 part of the rulemaking effort to decide. The reason
17 we wanted it because of this and now we have this
18 large authority that we asked for and we have to sort
19 out what regulatory emphasis would be placed on that.
20 So it will be a major challenge, that rulemaking.

21 MR. MOORE: In addition, I think Health
22 Physics Society and the CRCPD jointly approached
23 Congress and pointed out that radioactive material
24 produced in different manners but of similar risks and
25 then in some cases even in greater occupation risks

1 are regulated in entirely different schemes and
2 suggested that they be regulated in the same manner.
3 So the CRCPD and HPS are due some credit in pushing it
4 through Congress. OAS instead of CRCPD.

5 CHAIRMAN MALMUD: So in summary, Mr.
6 Essig, the stimulus for this was national security.

7 MR. ESSIG: Yes.

8 DR. MILLER: Dr. Malmud, if you read the
9 Energy Act which has many parts of which we're only
10 talking about one portion, it has a very security bed
11 to it in other aspects of the national security also.

12 CHAIRMAN MALMUD: So Dr. Williamson's
13 question could be answered in a phrase with "national
14 security" was the concern. That being the concern,
15 there is still obviously an opportunity that some of
16 the shorter half-lived pharmaceuticals, which have
17 very little potential use by terrorists for lack of a
18 better term, may be of disinterest with regard to the
19 reason for the legislation. So we'll see how this
20 evolves as the policy develops.

21 MR. ESSIG: And one more point I would add
22 and that when the IAEA Code of Conduct was developed,
23 I was a participant in more or less the final meeting
24 that brought it fruition. One of the considerations
25 that we made in coming up with a list that's in the

1 table that's appended to the Code of Conduct was the
2 going-in position was that there were some shorter-
3 lived radionuclides that were in a tech doc 1344 that
4 provided the categorization scheme that the IAEA uses
5 and some of those, there was a summary table and we
6 made a conscious decision, we the members who were
7 present at this meeting in July 2003, to not transfer
8 from that table to the Code of Conduct some of the
9 very shorter-lived radionuclides such as tech-99m.
10 Gold-198 was another one that was on the list that
11 didn't get transferred and so forth. So that flavor
12 has already been captured in the Code of Conduct, that
13 thinking.

14 CHAIRMAN MALMUD: Thank you. So the next
15 step in the process is the meeting to be held on
16 November 9th and may other interested parties in the
17 public request a presence there and to whom would they
18 make the request?

19 MS. KERR: Yes. All members of the public
20 can attend the meeting and there will be different
21 times during the day when we will ask for public
22 comments or questions. If they go to the NRC's public
23 meeting website, there is a meeting notice that gives
24 all the information. The meeting is also available
25 via teleconference for those who can't attend in

1 person.

2 CHAIRMAN MALMUD: Thank you.

3 MR. ESSIG: Leslie, you should mention
4 your name.

5 DR. MOORE: Leslie Kerr is the project
6 manager for the rulemaking itself and the public
7 meeting as I mentioned is a roundtable discussion.
8 The meeting announcement, has it been run in the
9 *Federal Register*? Is it being run? Okay, it's about
10 to be run in the *Federal Register*. We'll give
11 information about how people can get in touch with the
12 facilitator for attendance at the public meeting.

13 CHAIRMAN MALMUD: Thank you, Dr. Moore.

14 MEMBER SULEIMAN: Dr. Malmud.

15 CHAIRMAN MALMUD: Dr. Suleiman.

16 MEMBER SULEIMAN: I would like to make one
17 suggestion. I had a chance to look at the Energy
18 Bill. It's 500 some odd pages; but the sections that
19 are relevant to this are only a few pages or a few
20 paragraphs. So I would encourage anybody who is going
21 to participate in this at least as a minimum read that
22 and get an appreciation for what it actually says.

23 CHAIRMAN MALMUD: Do you recall which
24 pages?

25 MEMBER SULEIMAN: I can actually get you

1 that information but Tom Essig got me that.

2 MR. ESSIG: It's a 550 page document and
3 I think it starts --

4 MEMBER SULEIMAN: Took me as long to find
5 it as to read the small sections.

6 CHAIRMAN MALMUD: That's why I asked which
7 pages.

8 MEMBER SULEIMAN: It depends on what
9 format. Probably the paragraph number is more
10 accurate.

11 DR. MOORE: Dr. Malmud, we can post that
12 on the website when we post the meeting notice on
13 NRC's website.

14 CHAIRMAN MALMUD: Thank you. That would
15 be very helpful since I believe the average individual
16 may not have the time to find that.

17 MR. ESSIG: That would be the section that
18 Mr. Blanton referred in his presentation, Section
19 170H.

20 CHAIRMAN MALMUD: One seventy H.

21 MR. BLANTON: That's the section of the
22 Atomic Energy Act that was amended. The section of
23 the Energy Policy Act I believe is Section 651.

24 CHAIRMAN MALMUD: That's Section 651.
25 Thank you. That's now in the minutes.

1 MEMBER WILLIAMSON: Could you distribute
2 that to the Committee?

3 CHAIRMAN MALMUD: Dr. Williamson asked if
4 those pages could be distributed to the members of the
5 committee.

6 MR. ESSIG: I have it right in my office
7 and we can get it copied.

8 CHAIRMAN MALMUD: Can we get that done
9 today?

10 MR. ESSIG: Yes.

11 CHAIRMAN MALMUD: Thank you. Mr. Leito.

12 MEMBER LEITO: Just a question. When you
13 talked about the definition, it was not applicable to
14 low-level radioactive waste. Could you expand on that
15 little bit? It sounds like it's the reverse of the
16 accelerator situation at the production. But once you
17 declare its waste, it's not applicable. That's almost
18 what it sounds like in here. But I'm sure this might
19 be abbreviated.

20 MR. ESSIG: I'll start the discussion.
21 Maybe others can add to it as they see fit. But I
22 know one of the unintended consequences of the early
23 version of the legislation which was called to the
24 attention of the Congress was the fact that if it was
25 enacted as worded it would prevent radium-226 from

1 being disposed of at the U.S. Ecology site in
2 Richland, Washington which, now accepts the waste
3 nationwide, and unless it was excluded it would be
4 contrary to the Low-Level Waste Policy Amendments Act
5 of 1985. So it was an unintended consequence which
6 was fixed. So the radium-226 can continue to be
7 disposed at the U.S. Ecology site across the U.S. as
8 it currently happens.

9 MEMBER LEITO: So the issue really only
10 addresses radium.

11 MR. ESSIG: As I understand it. That was
12 the driver.

13 CHAIRMAN MALMUD: Dr. Bailey.

14 MEMBER BAILEY: Thank you for the
15 promotion.

16 CHAIRMAN MALMUD: You're welcome.

17 MEMBER BAILEY: It was not only radium.
18 Because of the odd quirks of the compact system,
19 Richland, Washington was able to accept any naturally
20 occurring material from wherever it occurred or was
21 produced anywhere in the United States. It was not
22 restricted to that compact area because low-level
23 waste was only AEA regulated material. So any
24 naturally occurring material that was radioactive
25 could go there. There was a great desire not to have

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1 that disposal option cut off and so that was
2 identified early on by the states as one of the
3 unintended consequences of the early language.

4 CHAIRMAN MALMUD: Any other questions from
5 members of the panel? From other attendees here? If
6 not, Dr. Williamson.

7 MEMBER WILLIAMSON: Has anyone from this
8 committee been invited to participate in the November
9 9th meeting?

10 MS. KERR: I believe Chip Cameron has
11 contacted Dr. Malmud and we're in the process of
12 getting someone from ACMUI to participate.

13 DR. MILLER: Is that accurate, Dr. Malmud?
14 Did you receive a call from Chip yet?

15 CHAIRMAN MALMUD: I have not received a
16 call. No.

17 DR. MILLER: Okay. By virtue of this
18 meeting, I am formally inviting ACMUI to participate
19 if a member wants to represent the committee or more
20 than one member. If the whole committee wants to
21 come, that's fine also. I recognize everyone's busy
22 schedules.

23 MR. ESSIG: But I think, Charlie, there
24 would only be a seat for one at the table.

25 DR. MILLER: Yes, since it's a round table

1 discussion we're going to try to have key
2 representatives from all stakeholders in the
3 roundtable for the discussions and then at various
4 points in the day, any member of the public can get up
5 and make comments, statements, whatever it is they
6 want.

7 CHAIRMAN MALMUD: We will produce a member
8 of the ACMUI to attend the meeting on the 9th.

9 DR. MOORE: The meeting's going to be held
10 here in this room.

11 CHAIRMAN MALMUD: So the environment will
12 be familiar. I believe that that ends the questions
13 for you, Mr. Blanton. We thank you for having
14 presented the material on rather short notice and it
15 was a very stimulating presentation in terms of the
16 discussion that was generated and I'm certain it will
17 be an ongoing topic of interest to this committee and
18 the public at large for the next several years. Thank
19 you for kicking it off for us.

20 We are now ahead of our agenda. We now
21 have Roy Brown, Senior Director of Federal Affairs,
22 Council on Radionuclides and Radiopharmaceuticals.
23 Before you begin, Mr. Brown, it will be necessary for
24 me to leave this meeting at 9:15 a.m. for a period of
25 time at which time Dr. Vetter has agreed to continue

1 chairing the committee. I make the statement in
2 advance so that you will recognize that my departure
3 is not related to your presentation.

4 MR. BROWN: I understand. Good morning
5 and first of all, let me thank the committee and NRC
6 staff for CORAR to come to the meeting this morning
7 and present our views on the NRC's new jurisdiction
8 over NARM, as I call ARM, accelerator produced
9 radioactive material.

10 Let me start off with a little bit of
11 background about CORAR, who we are and what we do.
12 CORAR is the Council on Radionuclides and
13 Radiopharmaceuticals. It is the North American Trade
14 Association for the manufacturers and distributors of
15 radionuclides and radiopharmaceuticals. All the major
16 manufacturers are members of CORAR. These include
17 companies like GE Healthcare, Bristol Myers Squibb,
18 Tyco Healthcare Malinckrodt, Nordion, Cardinal Health
19 and others. The members of CORAR utilized
20 radionuclides to produce radiopharmaceuticals for
21 medical diagnosis and therapy as well as radionuclides
22 for medical and life science research.

23 Let me skip over this. We already heard
24 about a background about the Energy Policy Act of
25 2005. But let me do point out that CORAR has been

1 very supportive of adding ARM to Atomic Energy Act for
2 several years and in my presentation, you'll
3 understand why we've had concerns for the last several
4 years. There's been some inconsistencies in
5 regulations of accelerator produced materials from
6 state to state, more from a licensing standpoint than
7 a clinical use standpoint and that's why CORAR has
8 been supportive of amending the Atomic Energy Act to
9 include NARM products.

10 One of our main focuses has been CORAR is
11 seeking uniformity in the regulation between byproduct
12 material and ARM material and this is really the focus
13 of my presentation this morning.

14 Let me spend a few minutes talking about
15 problems we've seen with the states. I made a very
16 similar presentation of this to the OAS meeting last
17 month in San Diego. So several of you at the table
18 today were present at that meeting. So I appreciate
19 your indulgence in hearing pretty much the same speech
20 over again.

21 We've had trouble. One of the major
22 problems CORAR has had over the years has been getting
23 new radiopharmaceuticals licensed by the states. As
24 you know the process, first of all, the manufacturers
25 go to FDA and get the radiopharmaceutical approved by

1 FDA. Then in the case of what works for a NARM
2 product or accelerator produced product, we have to go
3 then state by state to the individual states and say
4 what does this take to get this product into your
5 state. For an old definition byproduct material, it's
6 very easy. You go to the NRC, amend your license and
7 then you're good for all 50 states. In the case of an
8 accelerator produced new radiopharmaceutical, you have
9 to go state by state and say what does it take to get
10 it into California, into Texas, into Oregon, into
11 North Dakota, Montana and in most cases, the agreement
12 states are very good and very capable of bringing new
13 radiopharmaceuticals in. But in the case of the
14 nonagreement states, we've had troubles sometimes
15 getting approval in that individual state.

16 What that's resulted in delays of getting
17 new radiopharmaceuticals into some states where for
18 example as soon as it's FDA approved and it's approved
19 by many agreement states, they can go for sale in many
20 states. But there are other states that are not sure
21 how they want to approve it or what they need, whether
22 they need a copy of the package insert and the
23 labeling or the material safety data sheet. They're
24 not really sure what they want and consequently that
25 causes some delays and in some cases we've had new

1 radiopharmaceuticals being introduced in many states
2 after FDA approval and then taking another three,
3 four, five, six or eight months to get into all 50
4 states. And we don't see that as a very good public
5 policy and this is one of the main reasons CORAR has
6 been supportive of amending the Atomic Energy Act to
7 include NARM products.

8 One of the other problems we've had, as I
9 mentioned before was, nonuniformity in the agreement
10 state regs and in some cases, the NRC states not
11 having the expertise to approve. The agreement states
12 we've had very good experience with but I'm talking
13 about the nonagreement states and those states that
14 are NRC states that may not have a very strong
15 radiation protection program and I really don't want
16 to mention states we've had troubles with.

17 We've also had problems with operational
18 difficulties in individual states and I have some
19 examples here and once again, I won't name any names
20 to embarrass any states. But we've had problems in
21 some cases where we have an RSO at a nuclear pharmacy
22 and one state may have a requirement for an RSO and
23 that nuclear pharmacist has been an RSO for that
24 nuclear pharmacy in that state for many years. If the
25 company chooses to transfer him to another company-

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1 owned nuclear pharmacy in another state, all of a
2 sudden he may not be qualified to be an RSO even
3 though he may have been RSO for many years in another
4 identical pharmacy in another state.

5 Some states require that an RSO have a
6 Bachelors of Science in Health Physics or Radiological
7 Health and other states may not have that requirement.
8 It's the disparity. It's the nonuniformity that we've
9 had troubles with.

10 Also we've had troubles with states
11 changing requirements for facility decommissioning.
12 We've had some nuclear pharmacy try to be
13 decommissioned. You get the decommissioning permit
14 and then as you start that decommissioning process the
15 state comes back and says wait a minute. We've
16 changed the requirement. We want you to do things
17 differently and that's required us to go back and
18 refile an new application for a decommissioning plan
19 and that's very costly and sometimes very time
20 consuming as well.

21 We've also run into problems with state
22 specific product approval and labeling requirements.
23 I've already talked to you about the product approval
24 requirements we've had. We also have had some very
25 specific state labeling requirements. Some states for

1 example only recognize SI units on product labels
2 where other states can take kinds of units. So in
3 some cases, we have had to relabel products and
4 package inserts going to some states and that creates
5 other problems with the FDA for example where labeling
6 is very critical.

7 We've also had issues with state specific
8 protocols for reciprocity and in many cases, this
9 deals with going in and servicing sealed sources in
10 different states. Different states have different
11 requirements if you have to go in and perform some
12 emergency service. Some states require preapproval
13 before the technician goes in and does repair work on
14 a source. Other states don't. So once again, you
15 have to go in and say what state am I going into,
16 what's that state requirement today, for this week and
17 this month and sometimes it's very difficult to stay
18 on top of this.

19 Also we run into problems with differing
20 approaches to the level of detail for sealed sources
21 and sealed source registry and device registries. In
22 some cases if a sealed source or a device is
23 registered in one state, another state may not
24 necessarily recognize that. If the NRC recognizes it,
25 usually states will recognize it and in some cases,

1 the state will recognize it and the NRC won't. So
2 there's once again a disparity in sealed sources and
3 device registry that we would like to see more
4 uniformity rather than just consistency.

5 One more example, we have one state in our
6 country that before the Atomic Energy Act was amended
7 actually defined byproduct material to include
8 chlorine-18, nitrogen-13 and carbon-11. So we have
9 one state that defines some of these PET isotopes as
10 byproduct material and you can imagine the licensing
11 problems they created for the manufacturers.

12 Some more problems. What this has led to
13 is when states have different regulations, the
14 manufacturers have to stay current with all these
15 regulations as they change. That requires us to stay
16 current with the state activities, what they're doing
17 to change the regulations, the rulemaking, what
18 they're doing with radioactive waste and it's very
19 time consuming and very expensive for the
20 manufacturers to do this.

21 Also our concern with the states' handling
22 technology differently and handling regulations
23 handling, when new technologies come along, sometimes
24 we've seen them being handled differently by different
25 states. Once again, this is very frustrating and very

1 time consuming.

2 Also some of these problems, some of this
3 disparity from one state to another has created
4 competitive advantages and disadvantages doing
5 business in one state versus another. If you're in a
6 nonagreement state and trying to get a new
7 radiopharmaceutical approved, it's very difficult
8 sometimes and sometimes you have to go an agreement
9 state to work with them even though the facility and
10 the manufacturing is done in a nonagreement state. So
11 this is a very bizarre regulatory scheme and it's
12 really created some problems for the manufacturers.

13 Also a lot of times customers were call
14 the manufacturer looking for licensing help. They ask
15 a question about what does it take to get your product
16 into my facility, things like that, and it's very
17 difficult. The manufacturers' customer service people
18 have to stay on top of all 50 states and the
19 regulations. If the agreement state program was more
20 uniform and the regulations were identical state to
21 state, it would be very easy to do. But with this
22 nonuniformity, it creates a situation where we have to
23 stay current with 50 states making an easy question
24 that comes into your customer service department very
25 difficult to answer sometimes.

1 This nonuniformity in regulations, we have
2 some recommendations or some consequences from this
3 that I would like to discuss as well. As I've talked
4 about before, some of the disparity in labeling is
5 very difficult to cope with and in some cases, you
6 have to have different versions of products and
7 different labeling to comply with different
8 regulations.

9 This is very similar to what the
10 manufacturers have seen working with the EC for
11 example in Europe where you're trying to distribute
12 products in Europe where one country wants their local
13 language but another country wants it in French and
14 English. So this is very difficult to deal with at a
15 state level where we have different states having
16 different regulations.

17 We feel that the regulations should focus
18 on generally accepted safety standards and protection
19 standards. We feel this is very important and really
20 needs to be considered in this new rulemaking.

21 Also establishing one set of comprehensive
22 regulations, we feel will conserve the NRC's limited
23 agency resources and also licensee resources for
24 dealing with this issue.

25 And lastly, states with uniform

1 regulations are better able to be compatible with new
2 requirements that come from NRC. So we're pushing
3 very hard for not just consistency which we know CRCPD
4 and OAS very often goes for. We want to see
5 uniformity from state to state.

6 Let me talk for a few minutes about what
7 we understand NRC's plan to be with the implementation
8 of the NARM rulemaking. It appears that NRC staff is
9 looking at a fast track program for new states to
10 become agreement states and for new states to be able
11 to regulate ARM products. We're afraid that the
12 creation of more agreement states, new agreement
13 states, will actually lead to more nonuniformity than
14 less nonuniformity. If we have new agreement states
15 coming online very quickly, we're afraid that they're
16 going to have more nonuniform regulations and this is
17 going to exacerbate the problem rather than fix the
18 problem and remember going back to my initial
19 statement, CORAR in the past has been very supportive
20 of including NARM products in the Atomic Energy Act.
21 So once again, we're looking for uniformity and we're
22 afraid a fast track problem may create more
23 nonuniformity.

24 Also the new fast track agreement state
25 program may create NRC state ARM regulations versus

1 agreement state ARM regulations and there may be a
2 disparity in that. Once again, we would like to have
3 NRC staff look at this very closely and have
4 uniformity across the board with NRC states, agreement
5 states, nonagreement states, everyone. We would like
6 to see uniform regulations across the board. Once
7 again, CORAR is pushing for uniformity rather than
8 just consistency between the states.

9 I originally had a slide in here about the
10 Society of Nuclear Medicine. I'm going to jump over
11 this slide because SNM will follow my presentation.
12 But I do want to say that CORAR has been very
13 supportive of SNM's position on this and SNM will
14 elaborate on that in the next presentation. What
15 CORAR's concern is we want to make sure that nuclear
16 medicine, both diagnostic and therapeutic nuclear
17 medicine, is available to physicians, nuclear
18 pharmacists and the patients and that really needs to
19 be considered in this rulemaking and we have been very
20 supportive and we will continue to be supportive of
21 SNM's position on this.

22 Let me talk about an imperative regulatory
23 matrix that I discussed, I brought up at the OAS
24 meeting last month. Once again, CORAR's biggest
25 concern with this rulemaking process is

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1 inconsistencies between state regulations. What CORAR
2 is doing is we're encouraging OAS and CRCPD to develop
3 a matrix in which specific regulations for different
4 states are compared against NRC regulations. For
5 example, we can look at labeling regulations. We can
6 look at licensing regulations. We really think these
7 states should be compared regulation by regulation to
8 see where the discrepancies are and to try to get
9 these resolved in the new rulemaking.

10 By developing this matrix, we think
11 important differences in regs could be identified and
12 addressed in the rulemaking. Once again, I'll make
13 this offer to NRC and to ACMUI. CORAR is very ready
14 to work with OAS, CRCPD and NRC on the development of
15 this regulatory matrix.

16 Just in summary, CORAR would like to
17 continue to work with NRC, OAS and CRCPD on the
18 implementation of these new regulations. CORAR will
19 continue to push for uniformity over just consistency.
20 Once again, we would like to see these new regulations
21 implemented without hurting physicians and patients in
22 the use of PET radiopharmaceuticals which has been a
23 great success in this country. We would like to push
24 for a comparative regulation matrix comparing state
25 regulations with the NRC regs. Lastly, we have been

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1 invited and we will participate in the November 9th
2 meeting and we think it's a very good idea to have the
3 stakeholders present there and to have this type of
4 workshop. The NRC has been very successful with these
5 in our opinion in the past and we're very encouraged
6 by that. But we don't think this is enough. We would
7 like to see continued stakeholder involvement beyond
8 that process.

9 Thank you. I'll be glad to take any
10 questions at this time.

11 CHAIRMAN MALMUD: Thank you. Are there
12 questions? Dr. Williamson.

13 MEMBER WILLIAMSON: My impression is that
14 the existence of Part 35 NRC regulations for byproduct
15 material has not resulted in a great deal of
16 uniformity among the states because so many of the
17 components of Part 35 are at a very low level of
18 compatibility. So what assurance is there that this
19 expansion of NRC authority will have a good effect on
20 that in the NARM area?

21 MR. BROWN: Are you asking me or NRC?

22 CHAIRMAN MALMUD: To whom was your
23 question addressed?

24 MEMBER WILLIAMSON: I'm asking you I
25 guess. Do you think your expectation is realistic and

1 I'm asking NRC to comment.

2 MR. BROWN: Yes, I would share that
3 concern.

4 MEMBER DIAMOND: If I could just speak to
5 that, that was the whole point of my statement a
6 little while ago to Charlie. This is a really good
7 opportunity as we're looking at all these different
8 methodologies that the states use to perhaps relook at
9 this issue, come up with some new guidance or new
10 regulation and perhaps some of those will be
11 implemented in a more uniform and logical fashion
12 throughout the country.

13 CHAIRMAN MALMUD: Thank you, Dr. Diamond.
14 That was Dr. Diamond. Other comments? Mr. Leito.

15 MEMBER LEITO: A couple of observations
16 and a comment. It seems like your statement here is
17 a little inconsistent with the purpose of your
18 presentation. You say you don't want any more new
19 agreement states but you want consistency of the
20 regulations. It seems like if you're going to have
21 this group of nonagreement states or states that are
22 still NRC states so to speak and yet you're going to
23 have this larger group of agreement states because
24 they're not going away, that it seems a little
25 inconsistent there in terms of what you're trying to

1 achieve here.

2 I do agree with your statement about the
3 workshop on November 9th. I was going to mention this
4 earlier. I think the fact that this has not even been
5 announced to the general public and you have probably
6 less than two weeks before, probably on the order of
7 maybe a week notice, I think it's not going to
8 facilitate attendance by stakeholders who may be
9 interested and want to attend on such short notice.

10 One question I had was I'm a little
11 confused. What do you mean by the difference between
12 consistencies and uniformity?

13 MR. BROWN: Let me address your first
14 point first. CORAR doesn't really care whether
15 there's more agreement states or less agreement
16 states. We're just looking for consistency. We're
17 looking for uniformity and maybe I ought to explain at
18 least the difference between the two. We've always
19 seen in the past CRCPD and OAS looking for
20 consistency. They've been calling for consistency in
21 the regulations and I guess what we've seen from that
22 so-called consistency is nonuniformity where they may
23 be compatible with NRC or they meet a minimum set of
24 NRC requirements but they're not uniform from one
25 state to another. So they may be compatible meaning

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1 the compatibility rule but they're not really
2 consistent because they're different from one state to
3 another. That's why we coined or started using the
4 word uniformity where they are really uniform from
5 state to state.

6 MEMBER LEITO: I'm still confused.

7 MR. BROWN: Let me maybe expand on that.
8 Some of the examples I cited when an RSO can't even
9 move from one state to another, he's qualified in one
10 state but not qualified in another state just because
11 he crosses the border, that's inconsistent.

12 MEMBER LEITO: I also think it nonuniform
13 too. But my other concern, I don't know if it's a
14 question or a comment, this comparative regulation
15 matrix, is this something that CORAR has already
16 started to put together or are you asking ACMUI or NRC
17 to put this together? Who are you directly that to or
18 is it a statement of your organization?

19 MR. BROWN: It's a statement of a wish to
20 do it. We'd be glad to do it if OAS or NRC asked for
21 it or ACMUI asked for it. We'd be glad to do it. We
22 have reams of examples of inconsistencies that we can
23 deal with.

24 MEMBER LEITO: I would consider or I would
25 ,recommend to you that considering the short time

1 track that this regulation is on' that if you have
2 something already in a developmental state, I would
3 greatly encourage you including naming states to
4 present this at the stakeholders meeting because they,
5 they being the NRC, can use this as somewhat of a
6 template to address some of these issues.

7 I agree with you. You definitely want
8 this reciprocity between states of RSOs and I would
9 think also nuclear pharmacists it might apply to also
10 in commercial nuclear pharmacies. Again, I greatly
11 encourage to have that and present it and let the
12 chips fall where they may as far as the states are
13 concerned. Don't be offended by that.

14 MR. BROWN: That's one thing we'd be glad
15 to do, but what our fear was is we could turn that over
16 NRC and NRC would say there are inconsistencies; but
17 it's compatible with NRC regs and we can't tell the
18 states what to do. So if the states want to do more
19 or do something different, we can't control it and
20 then all that effort would be for nothing. I guess
21 that's why we haven't done it to date.

22 MEMBER VETTER: Dr. Nag.

23 MEMBER NAG: A clarification. You had
24 mentioned about the agreement states, the NRC states
25 and the nonagreement states. Would you tell me what

1 the difference is? I thought all the NRC states were
2 the nonagreement states. Are they one and the same or
3 not?

4 MR. BROWN: Yes. I believe they're one
5 and the same. I was thinking of examples like the
6 State of Texas. The State of Texas and the State of
7 California are agreement states and then you have a
8 state like Missouri that I would consider an NRC state
9 because they're not an agreement state. Then there's
10 another category of states that shall remain nameless
11 that really don't have a very strong program. So the
12 program for the NARM products is really not very well
13 developed.

14 MEMBER NAG: Yes, but all the nonagreement
15 states are licensed by the NRC. Right?

16 MR. BROWN: That's correct.

17 MEMBER VETTER: Other questions? Dr.
18 Schwarz.

19 MEMBER SCHWARZ: I don't know a question.
20 Maybe just a comment. I think this whole undertaking
21 seems huge to accomplish in this short period of time
22 to me realizing that you're dealing with all of these
23 agreement states who certainly are strong states. The
24 nonagreement states probably being the weak group of
25 states at varying levels and I'm sitting in one of

1 those nonagreement states, Missouri. So for my
2 practice and I'm in PETs, I'm managing a clinical
3 production of PET radiopharmaceuticals, certainly all
4 of this is of concern to me because obviously what
5 happens will happen in our State of Missouri. So it's
6 just a concern.

7 Certainly Missouri, I believe, acts kind
8 of like the agreement states in that essentially a lot
9 of materials are managed similar to NRC regulation for
10 accelerator produced materials. But it's just, I
11 think, an overwhelming task to take on and as a user,
12 I am concerned that this whole field of PET will get
13 caught and that the patients will be the ones that
14 will end up at the disadvantaged end.

15 I think certainly what Dr. Diamond
16 suggested in terms of exemption potentially for these
17 short-of-life materials might be something to consider
18 at least for an interim period of time until some of
19 them, maybe the organizational structure is better
20 defined or defined.

21 MR. BROWN: We certainly share your
22 concerns.

23 MEMBER VETTER: Dr. Nag.

24 MEMBER NAG: For the byproduct materials,
25 the agreement state has up to three years to comply.

1 For NARM material since the NRC is taking over new and
2 the agreement states are already relating it, how is
3 that? Will NRC now have three years or the
4 nonagreement state have three years to comply with
5 whatever the NRC comes up with?

6 DR. MILLER: I think our expectation is
7 yes that's true. As I mentioned earlier, Congress put
8 the rulemaking on a very fast track so that after four
9 years, I think what they were thinking about was
10 getting a rulemaking done in a little over a year and
11 then that allows three years for the states to become
12 compatible with the rulemaking.

13 MEMBER NAG: Yes, but in this phase, the
14 states already have most of the rules and NRC now has
15 to catch up with the agreement states.

16 DR. MILLER: Absolutely correct. But what
17 it would mean in that period is for the states to
18 become, during the period by which the states would
19 become compatible, the existing regulations in those
20 states would get transitioned over those three years
21 to the NRC requirements whatever the compatibility
22 level is determined to be. CORAR is asking for the
23 highest compatibility level. We have to go through
24 all of that and the Commission makes the decisions on
25 the compatibility level. It's a real challenge.

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1 MEMBER VETTER: Mr. Bailey.

2 MEMBER BAILEY: I think one of the things
3 that might not be obvious to people who haven't been
4 involved in this is NRC is showing a great deal of
5 concern not about what the agreement state program is
6 for regulating these materials but also taking into
7 account existing NARM programs in the nonagreement
8 states and it's a delicate balance there because there
9 are some states that have programs and they may not
10 look like agreement state programs and how NRC is
11 going to interface with those programs. I have to
12 commend them from what I've seen. They're really
13 seeking to get that information about what the
14 differences are in these nonagreement state programs.

15 MEMBER VETTER: Dr. Suleiman.

16 MEMBER SULEIMAN: Yes, I empathize with
17 your concerns but sometimes it's Civics 101. I mean
18 the states have quite a lot of rights. So I think the
19 states how they control, how they license their
20 practitioners, how they license their healthcare
21 people, it's going to differ. Maybe you'll see, I use
22 the word harmonize where regulations are not
23 incompatible with each other though they may not be
24 the same. But I don't see how you're ever going to
25 avoid differences from one place to another. But I

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1 think the overall premise here is radiation safety and
2 standards which really ignore the source.

3 In this case, you happen to have some
4 vary, the way the sources are generated. But in terms
5 of how health physics has operated over the years, I
6 think where you're going should be easy. It's the
7 legal, regulatory issues that are going to have to
8 resolve and work it out in a simple way. But I don't
9 see it all that difficult except for your legal issues
10 in terms of defining what's what. The safety issues
11 are going to be there.

12 MEMBER VETTER: Dr. Moore.

13 MR. MOORE: Dr. Suleiman makes a good
14 point. The legislation requires us to consult and
15 cooperate with the states and to use model state
16 standards to the extent possible. The states are a
17 key stakeholder in the rulemaking process and Ed
18 Bailey's on the ACMUI but the states would tell you,
19 we just had the OAS meeting, that the only way to get
20 uniformity in the regulations is to have a
21 compatibility level B and by and large, the states
22 object to compatibility level B in most cases. We'll
23 hear from the states at the November 9th stakeholders
24 meeting but I would expect that the states would not
25 be in favor of compatibility level B on these

1 regulations since they already have in place
2 regulations themselves for accelerator produced
3 radioactive materials.

4 MEMBER VETTER: Mr. Brown, we thank you
5 very much for taking the time to share with us today
6 the position of CORAR and we're happy to hear that
7 you'll be participating in that November 9th workshop.
8 Thank you very much.

9 MR. BROWN: Thank you.

10 MEMBER VETTER: We now have a presentation
11 from Dr. Terence Bevin speaking on behalf of the
12 Society of Nuclear Medicine and the American College
13 of Nuclear Physicians. He will present on the Nuclear
14 Medicine community's desire to work cooperatively with
15 the NRC to insure the public safety from unnecessary
16 exposure to radiation while simultaneously protecting
17 medical and scientific accessibility to short-lived
18 accelerator produced radionuclides.

19 DR. BEVEN: Thank you very much for the
20 opportunity to present SNM's views this morning. The
21 Society is an international scientific and
22 professional organization with over 16,000 members
23 dedicated to promoting the science, technology and
24 practical application of nuclear. The Society
25 supports regulations which would insure public safety

1 from unnecessary exposure to radiation while
2 simultaneously protecting medical and scientific
3 accessibility to short-lived accelerator produced
4 materials for nuclear medicine procedures and
5 research. To achieve this common goal, SNM will work
6 cooperatively with the NRC staff, the states and
7 fellow medical associations throughout the public
8 rulemaking process.

9 I think the NARM language has been
10 covered; but just to reiterate the section D of 170H,
11 in promulgating regulations under subparagraph A, the
12 Commission shall consider the impact on the
13 availability of radiopharmaceuticals to physicians and
14 patients, the medical treatment of which relies on
15 radiopharmaceuticals. Of course, in our view, we put
16 the patients as number one and the physicians would be
17 number two.

18 Our recommendations are to fulfill the
19 requirements outlined in subparagraph D. SNM
20 recommends that the NRC offer exemptions for isotopes
21 with short half-lives and for isotopes with low levels
22 of radioactivity. These accelerator produced products
23 pose no conceivable threat to the public.
24 Additionally, SNM recommends a full threat assessment
25 of each medically-used isotope included within the

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1 NARM regulations.

2 This is a list of the isotopes which we
3 feel generally fit into this category. I won't read
4 the whole laundry list and certainly some of them like
5 fluorine-18 and a few others are in general use and
6 others are being used in various experimental
7 protocols. Additionally, other radionuclides such as
8 gallium-66, Zr-89, Cobalt-55, may be used for medical
9 applications in future years. Therefore, any list of
10 exempted isotopes cannot be considered exclusive, but
11 must evolve along side with scientific innovation.

12 In conclusion, SNM asks the members of the
13 ACMUI to endorse exemptions for medical use isotopes
14 with short half-lives and isotopes with low levels of
15 radioactivity in adherence to subparagraph D of
16 section 170H of the Energy Policy Act of 2005. If the
17 exemptions are not offered for these products, the
18 regulations could have an unintended but highly
19 detrimental impact on American patients, indeed on
20 access to life-saving diagnostic and therapeutic
21 nuclear medicine procedures. I'll be happy to answer
22 any questions.

23 MEMBER VETTER: Questions from members of
24 the committee? Dr. Williamson.

25 MEMBER WILLIAMSON: To what extent is your

1 proposal consistent with the suggested state
2 regulations which must already address this issue?

3 DR. BEVEN: We have not, the SNM task
4 force has not, had the opportunity to look at the
5 existing state regulations to see whether they
6 accomplish this purpose in part or entirely.

7 MEMBER VETTER: Mr. Bailey.

8 MEMBER BAILEY: Yes, I was going to,
9 before the question was asked. I was going to respond
10 to Scott. If these exemptions were put in and it was
11 a category B, I think most of the agreement states
12 would object to that being a category B and the reason
13 is that they are not exempted now and we don't see
14 that there's any problem with their not being
15 exempted. Quite frankly, we don't see a lot of any of
16 these. So we don't see they've being regulated in
17 name is a real problem. They're just like any other
18 radioactive material to us and there would be exempt
19 concentration and exempt quantities and on and on.
20 But to exempt them simply because they happen to be
21 that radionuclide doesn't fit into our normal scheme
22 of like even byproduct material which they're not
23 isotopes by name exempted.

24 MEMBER WILLIAMSON: Carbon-11 is one I
25 saw. That is used in imaging procedures. Carbon

1 acetate is experimental. That's a pharmaceutical.

2 MEMBER BAILEY: Right. I'm just saying
3 this whole list, we don't see very many coppers for
4 instance. I was just commenting in general on the
5 list.

6 MEMBER VETTER: Yes, fluorine-18 is used,
7 for example, very commonly. Dr. Nag.

8 MEMBER NAG: I saw palladium-103 on your
9 list. Now palladium-103 is used very commonly for the
10 400 level brachytherapy as a substitute for I-125
11 brachytherapy, probably one of the most common
12 isotopes being used for radioactive implant. Why did
13 you have palladium-103 there? It has a half-life of
14 17 days, a reasonably long half-life, not a short
15 half-life, the Energy 21 KEV.

16 DR. BEVEN: I cannot answer that question
17 because this list was compiled by a number of
18 individuals engaged in the research and that
19 particular one I just have no explanation for.

20 MEMBER SULEIMAN: Again, it's the question
21 I said before. I briefly looked at what you passed
22 out but there's another section in the Energy Act that
23 describes radiopharmaceutical to include all the
24 product materials. So whatever applies to
25 conventional radiopharmaceutical would apply to the

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1 PET nuclides and from a terrorist's point of view, the
2 PET nuclides are trivial obviously. But from the
3 medical side of it, you may want to use very large
4 quantities in terms of medical doses just to get the
5 imaging even. So again without going into the details
6 of the science and the dosimetry, PET nuclides give
7 the highest doses of all medical pharmaceuticals out
8 there and the beauty of this authority is that now you
9 don't have to worry about breaking out the different
10 nuclides, just assess them basically in terms of their
11 hazard, what's acceptable and that way you have a
12 uniform playing field in terms of the radiation safety
13 assessment and not worry about the activity. Because
14 then you're going to need the decay characteristics
15 and go through the whole exercise.

16 DR. BEVEN: I would only observe that when
17 you are working with short-lived radionuclides there
18 are regulations imposed that would delay the delivery
19 of these nuclides to the target individuals, the
20 patients that would be a concern.

21 MEMBER SULEIMAN: I think that's a valid
22 concern, but by exempting them doesn't solve the
23 problem. You may create safety hazards if you exempt
24 them completely.

25 MEMBER VETTER: Dr. Miller, you want to

1 comment.

2 DR. MILLER: Yes. I like Mr. Bailey. I'm
3 an engineer. I need some help from a practical
4 application. I've heard a lot of concern about the
5 short-lived radionuclides and possible unintended
6 consequences. Can anyone give me an example of where
7 an unintended consequence might occur? You talk about
8 the delivery. How might that happen? How might an
9 inappropriate regulation from your perspective cost
10 something unintended to happen? Can anyone think of
11 an example to help me understand it better?

12 MEMBER VETTER: Dr. Schwarz.

13 MEMBER SCHWARZ: I don't know that it's --
14 I guess what I'm thinking in terms of for specifically
15 states that are nonagreement states, essentially NRC
16 states. I'm not speaking in terms of the agreement
17 states. I think they do have a program that
18 essentially accommodates all of the isotopes. So for
19 us, I think the situation in terms of needing possible
20 exemption of these products will be just that in this
21 interim period where regulations are being written and
22 everything is being defined, it just might be a time
23 frame that if there is regulation and an institution
24 has to accommodate all the regulations and how
25 everything is supposed to be addressed. So it seems

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1 that maybe it's a year-long period time that
2 regulations are getting written and we're trying to
3 come on board and fit in place.

4 It may be easier not to include these
5 particular isotopes in the beginning until there's
6 framework for this regulation in place than to take on
7 the short-lived isotopes because I think we're
8 managing at this point in time without this new
9 regulation and your focus was essentially the
10 terrorist's activities. These isotopes really are not
11 prime concern for the terrorist's activities but for
12 medical purposes.

13 So just thinking in terms of a facility
14 that's going to have to accommodate to new regulations
15 and new ways of doing things not necessarily totally
16 different, but just in an interim period, it might be
17 wise.

18 MEMBER VETTER: Dr. Miller, this is just
19 purely speculative. But some hospitals get their
20 fluorine-18 from a PET production facility. They
21 don't make it onsite. If, for example, the new
22 regulation required some onerous security requirements
23 for the transportation of that material that would
24 delay the delivery of the material, that would be
25 problematic. That's purely speculative. I don't know

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1 what your regulation will require. I think there was
2 a member of the public. Mr. Brown.

3 MR. BROWN: Roy Brown with CORAR. One of
4 the concerns we have is the transition that's going to
5 have to happen in the NRC or the nonagreement states.
6 For example, there are a couple of states out there
7 now that don't even license these accelerator produced
8 materials like thallium and indium and I-123. There's
9 no license required. There's no registration.
10 There's virtually nothing.

11 So to have them go from that status to
12 regulating all these products by 2007, they have to go
13 through their state legislature to get funding to hire
14 people to get expertise and we're concerned that's
15 just too much to happen too fast and we're concerned
16 that they're going to from nothing to going 100 miles
17 an hour in a short period of time. That's an
18 unintended consequence or that's a concern we have
19 that they have to go so far in such a short period of
20 time.

21 MEMBER VETTER: Dr. Suleiman.

22 MEMBER SULEIMAN: Yes, I was going to say
23 the same thing. Let me hazard my concerns. Yes,
24 you're going to have facilities that now are going to
25 have to go through the whole licensing process and the

1 fear, the anxiety, we're back to anxiety here, but I
2 think the anxiety there is that all of a sudden they
3 will not be able to get licensed in time and,
4 therefore, they won't be able to do their medical
5 practice. I think that's the underlying fear here.
6 So I think the NRC has to be very sensitive to that in
7 terms of the transition and accommodate them as much
8 as possible.

9 MEMBER VETTER: Dr. Williamson.

10 MEMBER WILLIAMSON: I stepped out of the
11 room and maybe I missed something. But is the focus
12 of your statement current agreement states and the
13 assumption that there are agreement states which
14 regulate only the byproduct materials and ignore all
15 the non-byproduct materials? Is there such a state or
16 do you apply uniformly byproduct type of regulations?

17 MEMBER VETTER: Mr. Bailey.

18 MEMBER BAILEY: Yes, to the best of my
19 knowledge, and I think NRC's Office of State and
20 Travel Programs can verify this, there's not a single
21 agreement state that does not already regulate NARM
22 and ARM in the same manner that they regulate the
23 traditional byproduct material. In fact, during IMPEP
24 reviews of agreement state programs, that is looked
25 at. Generally, the agreement states, and I think 100

1 percent of them, if they are doing sealed source and
2 device review, are using the same criteria and are
3 putting it in the sealed source and device registry,
4 just as if it were the traditional byproduct material.

5 MEMBER WILLIAMSON: So why is there a
6 concern about the nonagreement states, because what
7 would happen is NRC would simply expand their already
8 existing authority to just cover these new facilities
9 the same? I'm a little confused.

10 MR. ESSIG: If I could comment.

11 MEMBER VETTER: Yes, Mr. Essig.

12 MR. ESSIG: The fast track authority that
13 Mr. Brown referenced before that's referenced in the
14 Energy Policy Act is I believe really directed at
15 those states, the 33 who are currently agreement
16 states to get them on board. It's a letter from the
17 governor basically firming that they have a program
18 that would give them authority to put in place as an
19 agreement state this new material using their current
20 suite of existing regulations. We then have in
21 parallel a regulatory process where we're going to be
22 developing regulations and depending on the capability
23 level that ends up in each section of the regulations,
24 those states that have entered into that fast track
25 agreement may have to make adjustments to their

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1 regulations based on however the compatibility level
2 comes out.

3 The other 17 states who are currently what
4 we've labeled nonagreement states can come in and
5 express interest to become agreement states for the
6 new material, the entire suite of byproduct material.
7 Personal speculation is that --

8 DR. MILLER: Can I correct you on that?

9 MR. ESSIG: Go ahead.

10 DR. MILLER: That's going to be a
11 Commission policy decision. One of the things that
12 we're working is getting a paper before the Commission
13 on a policy decision concerning nonagreement states
14 and whether the Commission will allow a nonagreement
15 state to enter into an agreement for this aspect only
16 or whether they have to enter into an agreement for
17 the whole suite of issues that an agreement state has
18 to meet in order to become an agreement state. That
19 will be a Commission policy issue.

20 MR. ESSIG: Good point. But the only
21 thing I wanted to suggest there, it's possible that we
22 could have a large number of additional agreement
23 states. Of those pool of 17 that are currently
24 nonagreement states, many of them could, to the extent
25 that some of them are already, regulating accelerated

1 produced material they may see it as attractive. I
2 have to sign up now to become an agreement state for
3 this government produced material. I might just then
4 decide to regulate all of the byproduct materials. So
5 we could end up with a number of additional states and
6 there may be a few states, some of the lesser
7 populated states, that we were referring to in kinder
8 terms that may not ever want to become an agreement
9 state for anything. Some of the western states for
10 example may not want to.

11 MEMBER VETTER: Mr. Blanton.

12 MR. BLANTON: Just to follow-up on what
13 Mr. Bailey said. The agreement states to the best of
14 our knowledge in the Office of State Programs, they
15 generally regulate radioactive materials which they
16 define to include byproduct, source, small amounts of
17 special nuclear material and the naturally occurring
18 materials and accelerator produced materials, all
19 lumped together. So they basically don't distinguish
20 the way NRC does.

21 MEMBER VETTER: Other questions? Dr.
22 Miller.

23 DR. MILLER: Maybe if I could just recap
24 to make sure I understand. I think what I'm hearing
25 is anxiety over the potential to put regulations in

1 place that would inhibit the practice of medicine and
2 patient care that currently exists or delay patients
3 from being able to receive these kinds of treatments
4 and to make sure that when the regulations are put in
5 place that there's an implementation. It's the
6 implementation period that I think that we're talking
7 about such that an implementation period doesn't
8 create that unintended consequence.

9 One comment that I would make listening to
10 the whole discussion is while we recognize that the
11 Energy legislation was aimed a lot at security and
12 building on Dr. Suleiman's comments earlier on some of
13 these short-lived radionuclides, when the NRC
14 inherited this authority we didn't just inherit the
15 security aspects of it. We got it all. So we got all
16 the health and safety aspects of all of this also.

17 Inheriting that we have to put a program
18 into place that's going to insure that aspect of the
19 things that we inherited under the byproduct material
20 safety for that. So we have to consider all of this
21 and balance it all as we go forward.

22 MEMBER VETTER: Right and that thought
23 needs to be carried forward to that November 9 meeting
24 so that everyone hears that. Dr. Suleiman.

25 MEMBER SULEIMAN: Yes, I wanted to

1 clarify. Don't confuse the negligible terrorist
2 threat associated with short-lived nuclides with the
3 real radiation safety issues associated with them.
4 Those are two separate issues and that's it.

5 MEMBER VETTER: In that regard, is it
6 possible to consider exempting short-lived
7 radionuclides from security provisions without
8 exempting them from all of the other safety
9 regulations?

10 DR. MILLER: Like we do with safety, we
11 have to look at it from a security perspective of what
12 is the risk and obviously since they're short-lived
13 radionuclides, that contributes to the overall risk
14 factor. So we have to evaluate all of that. And
15 what's appropriate? Given the nature of the beast,
16 what is the appropriate security that needs to be put
17 in place. And I don't want to get too hung up on the
18 word security because a lot of what you do for public
19 health and safety and the control of materials also
20 gives you security of these materials.

21 You're doing it for a dual purpose; not
22 just to protect it from terrorists, but to protect the
23 public health and safety from unintended consequences
24 and coming into contact with the material that's not
25 controlled. That's a public health and safety

1 concern.

2 MEMBER VETTER: Right. I'm not sure
3 anyone here is concerned about the current
4 requirements for Department of Transportation,
5 Security, that level of security. It's the unknown,
6 the anxiety as Dr. Suleiman said, about what sort of
7 security requirements might be implemented as a result
8 of this Act that would become onerous and result in a
9 patient not getting a dose of fluorine-18 for example.
10 That's a real serious concern for us.

11 DR. MILLER: And that's where you have to
12 balance the risk. What's the greater risk, the
13 overall? And we have to evaluate all of that. Is the
14 risk the patient not getting the intended treatment
15 more consequential than the risk of a terrorist
16 activity and the reality of it all? I mean all of
17 that has to get put together. There's a common sense
18 that has to get put to it, at least, from my
19 perspective.

20 MEMBER VETTER: Dr. Schwarz.

21 MEMBER SCHWARZ: Just one other comment
22 too is to just keep remembering these states that are
23 not agreement states and don't have personnel involved
24 in the states enough to be able to take on all this
25 new regulation in a very quick period of time.

1 DR. MILLER: One of the reasons that we
2 were so aggressive in trying to seek state support for
3 this and we sought it from not only the OAS, from the
4 agreement states, but from the CRCPD. The CRCPD
5 represents the nonagreement states also. So we want
6 to make sure that we have the picture for all 50
7 states, not just the agreement states.

8 That's why we felt that it was important
9 to have represent from both groups recognizing that
10 many of the people, the functions of many of the
11 people in the agreement states, are also very acted in
12 the CRCPD not to mention any names like Ed Bailey.
13 But we want to make sure that the whole family of
14 states is captured and we don't miss something.

15 MEMBER VETTER: We appreciate that.

16 DR. BEVEN: I would like to thank the
17 members of the committee for their questions and I
18 think this is a good beginning to our discussions.

19 MEMBER VETTER: Great. Any other
20 questions? Yes, Mr. Essig.

21 MR. ESSIG: Just to follow on Charlie
22 Miller's comment, I think, Sally, maybe I was reading
23 something. I just want to understand the nature of
24 your concern. I had the impression that you were
25 offering that the State of Missouri was going to be

1 forced to become an agreement state in very short
2 order.

3 MEMBER SCHWARZ: No.

4 MR. ESSIG: That's what I read into your
5 comment.

6 MEMBER SCHWARZ: Not forced to become an
7 agreement state.

8 MR. ESSIG: That's a state decision as to
9 whether or not they want to become an agreement state.

10 MEMBER SCHWARZ: Correct, but I'm just
11 thinking in terms of administering new policies and
12 things like this that will become reality and that it
13 does take time for these regulations and people to get
14 on board and that the enduser can be the person.

15 DR. MILLER: If I looked at your concern,
16 I think you have someone in an agreement state who
17 currently is allowed to do this and if we put a
18 regulation in place such that they didn't have a
19 license in place to do it and they had to stop that
20 activity, that would interfere with patient care.

21 MEMBER VETTER: Mr. Bailey, did you have
22 a comment?

23 MEMBER BAILEY: Yes. What you just said
24 brought up something to me. Luckily I think in the
25 licensing process that we use now, we talk about uses,

1 100, 200, so forth. The authorization will already be
2 there basically to use these radioactive materials for
3 those processes. So there should be very little that
4 has to be done in the way of amending licenses to
5 allow the people to do it and the same goes with the
6 broad scope licenses. Broad scope licenses which are
7 now three to 83 but you really didn't regulate some of
8 them before. So I don't think it's a big deal for
9 existing facilities that have an NRC license or in
10 most cases, an agreement state license.

11 MEMBER VETTER: Other questions from
12 members of the committee or the public or the staff?
13 Yes.

14 DR. MILLER: If there are no more
15 questions, I'll make a closing remark if it's okay.
16 I think from the staff's perspective, from myself and
17 my staff who is represented throughout the room, I
18 think the discussion today was an extremely good forum
19 because I think it allowed some of the stakeholder
20 issues to be put on the table and that's what we're
21 seeking. So from my perspective, I felt the
22 discussions were a huge success. I appreciate the
23 committee's willingness and interest in discussing
24 this matter today. Thank you.

25 MEMBER VETTER: Dr. Beven, thank you very

1 much for taking time out of your schedule to present
2 this material for us. We are five minutes ahead. Mr.
3 Essig, is it okay if we take a 20 minute coffee break
4 to get back on schedule to start sharply at 10:15
5 a.m.? Thank you. Off the record.

6 (Whereupon, the foregoing matter went off
7 the record at 9:56 a.m. and went back on the record at
8 10:16 a.m.)

9 DR. VETTER: The next item on our agenda
10 is the presentation by Cynthia Flannery on recognition
11 of foreign trained physicians and physicists as
12 authorized users or authorized medical physicists.

13 Cynthia.

14 MS. FLANNERY: Thank you.

15 The discussion this morning will be on the
16 recognition of physicists and physicians who are
17 seeking approval under the alternate pathway as AMPs
18 and AUs.

19 The requirements for physicists to get
20 recognition as AMPs in 10 CFR 35-51 are listed here.
21 That individual must hold a Master's or a Doctor's
22 degree in one of the listed degrees. That individual
23 must also have one year full-time training in medical
24 physics, one year full-time work experience under the
25 supervision of an AMP, and written attestations signed

1 by a preceptor AMP.

2 So what about approval for physicists and
3 physicians who receive their training outside of the
4 U.S.? There are three questions that were considered
5 by staff.

6 May NRC or a broad scope licensee accept
7 foreign degrees?

8 May NRC or a broad scope licensees accept
9 a degree not specifically mentioned in the regulations
10 if that degree can be shown to be equivalent to the
11 degrees listed in 35-51, in the first bullet here?

12 And may NRC or a broad scope licensee rely
13 on a preceptor statement from a foreign physician?

14 And the reason why broad scope licensees
15 are listed in these questions is because the broad
16 scope licensees have the authority to approve AUs --
17 I'm sorry -- approve physicians and physicists as AUs
18 and AMPs internally through the Radiation Safety
19 Committee.

20 So the first question: may NRC for broad
21 scope licensees accept foreign degrees?

22 NRC staff did not identify any prohibition
23 against the acceptance of foreign degrees, and the
24 same thing with degrees not specifically mentioned in
25 the regulations because the physicists are the only

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1 ones that have degree requirements in Part 35.

2 So, again, here there's no prohibition
3 against the acceptance of a degree found to be
4 equivalent to those listed in 35-51.

5 And may NRC or broad scope licensees rely
6 on preceptor statements from foreign physicians?
7 Again, there's no prohibition against a preceptor
8 statement from a foreign born or a foreign trained
9 physician. However, the definition of an authorized
10 user in 35-2 states that that individual must be
11 licensed in the U.S.

12 So although foreign training of a
13 preceptor AU may be acceptable, that individual must
14 also hold a U.S. license.

15 DR. NAG: Excuse me. Are you talking now
16 only about the AU or the AMP and AU? The two have
17 slight different connotations.

18 MS. FLANNERY: Here I'm talking about the
19 physician.

20 DR. NAG: Okay. After you finish I will
21 have some comments about the physicians.

22 MR. BAILEY: Cindy, did you mean both the
23 applicant and the preceptor must have U.S. licenses?

24 MS. FLANNERY: No. The preceptor.

25 (Participant speaking from an unmicked

1 location.)

2 MS. FLANNERY: Yes, yes, both, but the
3 question is having to do with the preceptor, yeah.

4 MR. BAILEY: And the answer wasn't. The
5 preceptor must be licensed in the U.S.

6 MS. FLANNERY: Yes. when the regions
7 receive request for approval of physicians and
8 physicists with foreign training, the current practice
9 is for the regions to submit a technical assistance
10 request to the headquarters to present the technical
11 assistance request or this case to the Advisory
12 Committee. And they are reviewed on a case-by-case
13 basis.

14 And in an effort to have consistency among
15 the regions and the broad scope licensees, what NRC is
16 proposing is to allow the same authority between the
17 broad scope licensees as well as the regions in terms
18 of approving the training and experience requirements
19 of foreign trained physicians and physicists.

20 Because currently the broad scope
21 licensees have an authority of reviewing the training
22 experience and approving these individuals that
23 regions currently are presenting to the ACMUI. So in
24 an effort to have this consistency among the regions
25 and the broad scope licensees, NRC's staff is

1 requesting that the regions have the same authority as
2 the broad scope licensees and being able to review the
3 training and experience of physicists and physicians
4 and approving these individuals as AMPs and AUs.

5 Now, having said that, if there are
6 circumstances that warrant a further review, say, for
7 example, there's a question on the validity of the
8 degree that was received overseas, for example, or
9 outside the U.S., the regions could still submit a
10 technical assistance request and present it to the
11 Advisory Committee for review and approval, and the
12 other consideration is that only attestations by a
13 preceptor licensed in the U.S. will be accepted.

14 So under no circumstances will a non-U.S.
15 licensed preceptor be acceptable.

16 That concludes my discussion. I wanted to
17 open it up.

18 DR. VETTER: Dr. Nag.

19 DR. NAG: I would probably like to
20 decouple the AMP from the AU because, first of all, I
21 have more detailed knowledge about the physician's
22 training requirement, and I have less with the foreign
23 trained physician requirements.

24 Irrespective of the NRC license, any
25 foreign trained physician would be allowed to practice

1 in the U.S. only after extensive retraining in the
2 U.S. So that the M.D. degree, the basic degree is
3 recognized, but the residency requirement, et cetera,
4 will have to be redone all over again.

5 So that even if someone is a practicing
6 radiation oncologist outside the country, when they
7 come into this country, they will have to fulfill
8 again the four years of retraining before they can be
9 granted or before they can practice radiation oncology
10 in this country.

11 So, therefore, you really do not have to
12 depend on any of the foreign training. They will be
13 retained in this country. So they will still have
14 that four years of training in this country. They
15 will still have preceptor statements from this
16 country.

17 So I think as far as the AUs are
18 concerned, that should not be a problem for the NRC.
19 I'm not fully aware about the AMP, you know, what
20 their training requirements are.

21 DR. DIAMOND: I would just like to make a
22 clarification.

23 DR. VETTER: Sure, Dr. Diamond.

24 DR. DIAMOND: There are a few exceptions
25 to that. For example, I believe physicians that are

1 trained in Canada --

2 DR. NAG: Right.

3 DR. DIAMOND: -- do not necessarily need
4 to go through that, but, for example, if you had, for
5 example, a radiation oncologist who was licensed to
6 practice radiation oncology in the nation of Germany
7 and that individual wanted to practice radiation
8 oncology in the United States, that physician would
9 come to the United States. He would recognize his or
10 her medical doctor degree, but if he wanted to
11 practice radiation oncology, he would have to go
12 through the entire radiation oncology training program
13 again.

14 DR. NAG: Right. That's what I mentioned,
15 that the M.D. degree will be recognized, which is the
16 basic medical degree, but the specialty degree,
17 whether it's radiation oncology or medicine or surgery
18 would have to be retained all over.

19 DR. VETTER: Dr. Miller.

20 DR. MILLER: I need to ask a question of
21 the medical doctors. Just prompted something in my
22 mind.

23 So if someone were a practicing physician
24 in a foreign country, even if they were the world's
25 foremost expert in something, they could not come here

1 and perform a procedure without going through the
2 residency program?

3 DR. DIAMOND: To answer your question --

4 DR. MILLER: Yes.

5 DR. DIAMOND: -- with the exception of,
6 for example, Canada, we have had examples in the State
7 of Florida where we have had a world famous
8 subspecialist surgeons who wanted to relocate to the
9 State of Florida. Let's say I know of the example of
10 a physician, a surgeon from Venezuela who had to leave
11 because of the civil unrest there, and the only way
12 this individual could practice his subspecialty of
13 surgery is he had to go and join the faculty of one of
14 the state medical schools and the state legislature
15 had to pass an exemption for him to be able to
16 practice surgery without going through the entire
17 training process even though most of the individuals
18 that would have trained him he had trained himself.

19 DR. MILLER: How about an individual who
20 like is there ever a situation where someone is flown
21 in on a one time basis because of their expertise, you
22 know, to perform one special kind of procedure?

23 DR. NAG: I can address that. I mean, I'm
24 in a university setting. I have this happening all
25 the time. I do have people who visit us who are well

1 recognized all over the world for their expertise, but
2 they cannot touch a patient. So they can see me
3 perform an implant or they can probably, if you are
4 not an expert, they can probably look over your
5 shoulder, but they cannot touch the patient.

6 DR. VETTER: Dr. Williamson -- I'm sorry.
7 Were you finished? Yeah. Dr. Williamson.

8 DR. WILLIAMSON: Yeah, I have a question
9 for either Dr. Diamond or Dr. Nag. I guess I would
10 like to know the mechanism by which foreign trained
11 radiation oncologists, for example, can't practice.
12 I am aware that the American Board of Radiology will
13 not accept a foreign residency except Canadian
14 residency as eligibility for sitting for the boards,
15 but I'm not aware that the state per se licenses
16 radiation oncologists directly. It only licenses
17 physicians in general.

18 So what is the mechanism that precludes a
19 foreign physician from practicing?

20 DR. NAG: First of all, they will not be
21 able to get a specialty board. So they will not be
22 board certified, and a hospital would not accept them
23 because they are not board certified or board
24 eligible. It will be if that person was only an M.D.
25 with no training in radiation oncology.

1 Now, if he uses to practice on his or her
2 own, he will not have the credentialing process of a
3 radiation oncologist. He'll have the credentialing
4 process of only an M.D., but he will still need an
5 approved internship before he could even practice
6 medicine at a family practice level.

7 PARTICIPANT: Who controls that?

8 DR. DIAMOND: So, for example, world
9 famous doctor from another country other than Canada
10 comes to the United States because of civil unrest in
11 his home. That individual needs to at least complete
12 an internship, and after that one-year internship can
13 practice basic medicine in, for example, a clinical
14 setting, but that individual until he or she becomes
15 board eligible or board certified, would not be able
16 to get hospital privileges, would not be able to get
17 state credentials to practice in that subspecialty.

18 So for example, there are some individuals
19 of this ilk that practice general medicine in
20 communities but really can't do anything beyond that.

21 DR. VETTER: So the control of all of this
22 actually is over and above or lies outside the NRC
23 rules and regulations. It's over and above that.

24 DR. WILLIAMSON: It lies outside the
25 state, too, because it's a function of the hospital.

1 DR. NAG: A statement requirement, because
2 you cannot get a state license without your internship
3 or without any other training.

4 DR. WILLIAMSON: But who licenses private
5 practice radiation on free standing radiation
6 oncologists who have the internship in basic medical
7 license? What prevents them from practicing?

8 What legal barrier prevents a foreign
9 trained radiation oncologist with a U.S. license to
10 practice medicine from practicing in a free standing
11 facility?

12 DR. NAG: Well, first of all, I think that
13 person would not be allowed to call himself a
14 radiation oncologist by the state. Okay? He can --

15 DR. WILLIAMSON: I don't think the state
16 licenses subspecialties.

17 DR. NAG: Yeah, but that is to practice
18 medicine. You know, he can practice medicine, but
19 first of all, none of the hospitals will give him any
20 privilege.

21 DR. WILLIAMSON: Free standing.

22 DR. NAG: I don't know anyone who is that
23 -- malpractice, he will not be on my malpractice,
24 definitely.

25 DR. VETTER: I think in terms of trying to

1 relate it to the discussion here, is there a nuclear
2 medicine physician or radiation oncologist who is
3 foreign trained who could open up a practice in a
4 lesser populated state, a free standing practice.

5 DR. NAG: Not that MOA.

6 DR. VETTER: So they would be able to do
7 that?

8 DR. NAG: I don't think so.

9 DR. VETTER: And what precludes them from
10 doing that? Mr. Bailey?

11 MR. BAILEY: I can tell you that we do
12 have free standing therapy facilities where the
13 radiation oncologists or whatever you want to call
14 them are not board certified, and in a couple of cases
15 are not using radioactive material probably for that
16 very reason. They're going with accelerators.

17 DR. NAG: Yeah, but they are board
18 eligible. You are not board certified.

19 DR. DIAMOND: Not necessarily, not
20 necessarily. For example, I know of circumstances as
21 Mr. Bailey does of individuals who train in the United
22 States, never passed their examinations in the
23 American Board of Radiology. So they completed the
24 residency program, but by virtue of not passing their
25 boards or not board certified and then after a period

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1 of time if you have not passed your boards you no
2 longer are board eligible. So they are not board
3 eligible radiation oncologists, but they are
4 practicing radiation oncology, but they are not able
5 to use the byproduct material.

6 I don't know, to answer your question, Dr.
7 Williamson, I don't know exactly the mechanism that
8 would prevent a foreign trained radiation oncologist
9 who, let's say, completed a medical internship in the
10 United States and, therefore, has a valid state
11 medical license of practicing radiation oncology. I
12 just am not familiar enough with the state
13 regulations.

14 I myself am not familiar with any
15 circumstance of that happening. I can tell you that
16 from a practical point of view that person would never
17 be able to see a patient in a hospital and also would
18 basically not be able to get on any of the insurance
19 plans, and that perhaps is the most important factor
20 of all, isn't it?

21 So the question is if you ran your own
22 private, for cash clinic, I just don't know. I'm
23 sorry.

24 DR. WILLIAMSON: I thought there was
25 provision. Why I asked the question is that I thought

1 academic institutions had the option of credentialing
2 on a short-term, sort of supervised basis foreign
3 trained radiation oncologists and that the issue might
4 be relevant here.

5 DR. DIAMOND: Again, Dr. Williamson, like
6 I said, there are examples. In the State of Florida,
7 my home state we have had very prominent physicians
8 that foreign nationals come, and then based upon their
9 expertise, the actual statute is written. Legislation
10 is passed through our state legislature that exempts
11 them as individuals, and those are generally at state
12 hospitals or teaching hospitals.

13 DR. VETTER: Well, a broad scope license,
14 is it not true that they could require this foreign
15 trained physician to practice under the direction of
16 an authorized user for a period of time, and that
17 authorized user, knowing about the background and
18 training that this foreign physician had obtained
19 could as the preceptor verify that the training had
20 occurred and, in fact, then they have their one-year
21 of experience under the direction of that authorized
22 user.

23 Couldn't that authorized user sign the
24 preceptor statement? They're simply verifying that
25 the training had occurred, and they have personal

1 knowledge that it did. They have transcripts and so
2 forth.

3 DR. WILLIAMSON: I guess there is the
4 Canadian trained physicists and physicians, you know,
5 who are allowed to practice by other practice
6 mechanisms in this country that it would seem to me
7 would be reasonable for the regulations not to punish.

8 DR. VETTER: But without focusing on any
9 country, just foreign trained, if an authorized user
10 on a broad scope license in this country has
11 verification that the individual completed the
12 training in the foreign country comes and practices
13 for a year under the direction of that authorized
14 user, why can't the authorized user act as the
15 preceptor?

16 MS. FLANNERY: Well, in the case of -- and
17 let me just give you a little history on how this came
18 up. This really applied to a physicist rather than a
19 physician.

20 DR. VETTER: Okay. If it's only
21 physicists, let's take that later. We're just
22 focusing on physicians now, and we'll try and separate
23 the two.

24 DR. NAG: That is why I said we should
25 decouple the physician from the physicist because the

1 physician requirements to practice in this country
2 are so strict that they are more strict than the NRC
3 regulations. I felt that for the physician that would
4 not be a problem.

5 To answer the question about the academic
6 radiation oncologist, there is a provision that if you
7 are an academic radiation oncologist outside this
8 country and you are coming here at the academic
9 appointment, you could be on the faculty for four
10 years and the you can apply for a board certification
11 without doing a residency, but then you would have to
12 be on the faculty of the university.

13 DR. VETTER: Mr. Bailey had a comment.

14 MR. BAILEY: I'm sorry. I don't remember
15 whether it was oncology or just diagnostic, but I do
16 know that we had a physician come in, foreign trained.
17 His partner wanted to be his preceptor, and we
18 basically said, no, that for a preceptor it really
19 should be someone from a teaching institution and
20 suggested that they make some arrangements for someone
21 at a teaching institution rather than simply having
22 which, with all due respect for cardiologists, we had
23 the same problem where a cardiologist wanted to be the
24 preceptor for his partner, and we sort of frowned on
25 that and said, "Hey, you should get some independent

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1 training or get some training from a facility that is
2 in the business of education."

3 So it can occur. I mean, it does occur

4 DR. VETTER: I think it can occur. It's
5 unusual. These are unusual, and the impact on a
6 patient receiving care from one of these or from a
7 foreign trained physician who perhaps can't practice
8 in a lesser populated state because of the lack of
9 ability to get the additional training, I think that's
10 remote. In most cases they'll be able to go to a
11 broad scope licensee or somewhere to get that training
12 under an authorized user.

13 So the question was can -- the NRC is
14 interested in allowing regions to make that
15 determination for physicians as well as physicists; is
16 that correct?

17 MS. FLANNERY: Yes, that is correct.

18 DR. VETTER: So now the physicist. We
19 have kind of --

20 DR. WILLIAMSON: Have we settled the issue
21 of the physician though, the Canadian physician who
22 does the Canadian residency, can become ABR certified,
23 can have all privileges of a radiation oncologist now,
24 except, I guess, being able to use byproduct
25 materials?

1 I think it would seem to me it would be
2 reasonable for such an individual to have some route
3 for becoming an authorized user.

4 DR. NAG: I think for all practical
5 purposes that group, the Canadian physician who is
6 trained in Canada and came to the U.S., that would be
7 the only group that you will have to think about
8 because any other group of physicians will have to do
9 their residency of four years of training all over
10 again.

11 And I think for the group from Canada who
12 are coming here and, therefore, are board certified,
13 I think you could have a provision that they practice
14 one year under a preceptor to get the license.

15 MS. FLANNERY: And I would like to clarify
16 that the request that's being made is really going to
17 be for the physicists.

18 DR. VETTER: Okay. So you were about to
19 answer a question asked earlier, if you will recall,
20 to explain what the issue was with that physicist.

21 MS. FLANNERY: Yes. The reason why this
22 came up is there was a physicist who received a degree
23 in Dublin and that degree was not one of the listed
24 degrees in 35-51. So that was what brought up one of
25 the questions.

1 And also this individual got their degree
2 in Dublin rather than here; also did their one-year
3 training overseas, and then came here for the work
4 experience, and this was for a broad scope licensee,
5 you know. This individual did meet all of the
6 criteria. I don't think it was questionable in any
7 way, but the issue is if that same situation had
8 happened for, say, a non-broad scope licensee,
9 specific licensee, that would have been, you know,
10 submitted to headquarters as a technical assistance
11 request and presented to the ACMUI for approval.

12 DR. VETTER: Okay, and currently that
13 can't go to the regions. Is that --

14 DR. WILLIAMSON: What's the question you
15 have?

16 DR. VETTER: Yeah, I'm not sure what the
17 question is.

18 DR. MILLER: What happens in those
19 situations is the regions do the reviews, but in
20 certain unique cases the regions will write what she
21 has referred to as a technical assistance request to
22 headquarters for guidance on what they should do, and
23 then we do a review, and part of that review would
24 include -- correct me if I'm wrong -- giving the
25 committee's views on the matter, and then we respond

1 back to the region with regard to what action we
2 recommended.

3 DR. VETTER: So that's the current
4 standard operating procedure.

5 DR. MILLER: Yes.

6 DR. VETTER: And you'd like our input on
7 whether or not it would be appropriate to simply allow
8 the regions to make that determination.

9 MS. FLANNERY: Correct.

10 DR. VETTER: Okay. Thank you.

11 Mr. Leito.

12 MR. LEITO: Right now the current policy
13 is ACMUI looks at these on a case by case; is that
14 correct?

15 MS. FLANNERY: Correct.

16 MR. LEITO: Okay. I'm kind of sitting on
17 the fence on this one because I think if you have
18 ACMUI doing it, you've got a consistency whether it
19 happens in Region I, Region II, Region III, and so
20 forth.

21 Right now I don't think there's any
22 specific guidance that is actually out there that is
23 a written document that the regions go by, and if
24 you're also having all the broad scopes develop their
25 own criteria to some degree as to what they're going

1 to accept, you get this variation that once this
2 person, this AMP or AU is on a broad scope license,
3 okay, the assumption is that they've met all of the
4 criteria that would have been the same as if they went
5 to the region, and I don't think that's a fair and
6 accurate conclusion.

7 So my initial feeling is I would not have
8 an objection if the regions or a broad scope license
9 were given that ability, providing they are all
10 following the same guidance in terms of what they
11 needed to do, you know, to look at these credentials.

12 One of the questions that Cynthia had in
13 her third slide here -- actually the first two bullets
14 I think we could group together -- was can the region
15 or the broad scope licensee accept a foreign degree or
16 degree not specifically mentioned in the regulations.

17 The consensus I have from the committee is
18 that, yes, that would be acceptable. The second
19 bullet, I don't think we really reached a conclusion
20 on regarding the preceptor statement, and I think that
21 might need some further discussion, but again, I think
22 it's still going to go to if the committee is
23 recommending that this responsibility that currently
24 is ours is now going to be delegated to the regions
25 and broad scopes, then I think if we're going to

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1 delegate that, we need to delegate it with guidance.

2 DR. VETTER: Dr. Malmud.

3 CHAIRMAN MALMUD: I have a question, and
4 that is we recognize that the ACMUI is made up of
5 specialists from varying areas. Do the regions have
6 that breadth of talent available to them to make those
7 decisions on a standing basis?

8 DR. MILLER: Obviously the regions don't
9 have the talent that's at this table, given the fact
10 that the regions do not necessarily have physicians on
11 their staff. They have people who are knowledgeable
12 about all of that, as we do in headquarters. Part of
13 the purpose of this committee is obviously to bring
14 that talent to bear to help us with our regulatory
15 process.

16 CHAIRMAN MALMUD: That's part one of my
17 question.

18 Part two, if there were a means of
19 expediting the process whereby it could come to this
20 committee even with an E-mail review and then a --
21 would a public meeting be required to review this?
22 No, I would assume not.

23 PARTICIPANT: No.

24 CHAIRMAN MALMUD: So if this could be done
25 expeditiously through the ACMUI communicating with us

1 by E-mail, we could review it and have a telephone
2 conference call, probably do it more quickly than the
3 region with a greater breadth of talent to review the
4 CV of the individual.

5 For example, I'd be hesitant to judge the
6 qualifications of a physicist, but I'm certain that
7 Mr. Leito and Dr. Williamson would not be the least
8 bit hesitant, and similarly for a nuclear physicians
9 or radiation oncologist.

10 So I think this committee has a breadth of
11 talent, breadth of talent which could address these
12 issues. They don't arise very often, do they?

13 MS. FLANNERY: No.

14 CHAIRMAN MALMUD: About how many a year?

15 MS. FLANNERY: I couldn't tell you. I
16 think we may have seen one case in the last year.

17 CHAIRMAN MALMUD: So one or two a year.
18 It would seem to me it wouldn't be particularly
19 burdensome, and since people's careers and their
20 ability to move forward depends upon the decision, I
21 would recommend that we review it.

22 DR. VETTER: Dr. Williamson.

23 DR. WILLIAMSON: Yeah, I just have a
24 question of clarification. I'm unclear what the
25 question is you're asking us. Is the question whether

1 all foreign degrees should be reviewed by the ACMUI,
2 the office via a TAR or be reviewed independently by
3 the rod scope or the license or the licensee or the
4 region? Is it the one year of training that needs to
5 be addressed?

6 So are you asking about the mechanism of
7 approval for alternative training types? And are you
8 also asking our opinion on the issue of non-United
9 States license preceptor?

10 There are so many questions I'm really not
11 clear which one you're asking us.

12 MS. FLANNERY: We are trying to have
13 consistency among the regions and the broad scope
14 licensees. So this is really geared more towards the
15 physicist rather than the physicians. So the question
16 is, you know, would it be acceptable for the regions
17 to be able to exercise the authority or reviewing the
18 training and experience of these physicists without
19 having to submit a technical assistance request and
20 presenting it to the ACMUI in more clear-cut
21 circumstances?

22 And as I mentioned in my last slide,
23 certainly in unusual ones, and I used the example like
24 questioning the validity of a degree, we certainly
25 would still do that, but in this case, like I

1 mentioned, this physicist who received their degree in
2 training in Dublin, it seemed pretty clear cut that
3 that would have, if it had not been a broad scope
4 licensee, that would have been a case that we would
5 have presented to the ACMUI.

6 DR. VETTER: Ms. Fairobent.

7 MS. FAIROBENT: Yeah, Lynne Fairobent
8 with AAPM.

9 A couple of comments because we're getting
10 questions at AAPM obviously on this. One, I think the
11 number of instances for a physicist is going to be on
12 the rise, and the reason I say that is because we have
13 not had physicists on licenses before. We've not
14 required a preceptor statement.

15 In the four states that license
16 physicists, okay, in order to be licensed you have to
17 be board certified. There's nothing to say that you
18 have to have studied or performed a clinical rotation
19 to my knowledge in the U.S. So that a foreign trained
20 physicist who does his clinical fellowship or rotation
21 outside of the U.S. comes and is eligible for board
22 certification by ABR or ABMP because they do an
23 equivalency on the degree in the program, sits for the
24 exam and passes, can't be licensed, for example, in
25 the State of Florida or Texas or New York or Hawaii,

1 and yet they would not, without doing what I'm hearing
2 -- and I'm asking for clarification -- without doing
3 another year under an AMP be able to be an AMP if
4 byproduct material was in use.

5 I do think this is going to be an increase
6 problem, and I do think you're going to see more
7 circumstances.

8 I know, for example, when I spoke a year
9 ago at the Florida chapter, I had five people come up
10 to me to ask me what their situation would be under
11 the new regulation.

12 We have an awful lot that are trained in
13 South America that practice in the southern state
14 areas. I don't think it's a problem for the Canadians
15 so much up in New York, but it is going to be a
16 problem in California, Texas, Florida, where many of
17 these folks come in and practice. And we have not had
18 this situation before.

19 DR. VETTER: Point of clarification, if I
20 may. So if a licensee in a region needs clarification
21 or needs approval to license a physicist on a license,
22 they would currently request that through their
23 region.

24 If the region, if it isn't real
25 straightforward, they need to apply for a technical

1 assistance request, which then would come to
2 headquarters and might involve us. So there's an
3 additional lag there. Even if we handled this by
4 conference call, there would be a lag that would delay
5 approval of a physicist. We don't know if that would
6 be a problem for the licensee or not, but it could be,
7 I guess.

8 MS. FLANNERY: Yes, that is correct.

9 DR. VETTER: Okay. Dr. Suleiman.

10 DR. SULEIMAN: I'm going to share my own
11 personal thoughts. I'm a little troubled that the
12 ACMUI would even review or approve specific
13 physicists, but that's just how I feel.

14 I think you should be able to have
15 internal criteria for the regions that say if it's an
16 outside university, international university, it would
17 probably have a list of universities that are
18 accredited or qualified or whatever. Otherwise, how
19 do you -- you know, so the number one criteria would
20 have to be a university or college that is legitimate.

21 Number two, obviously, if the degree
22 doesn't meet what you want, you'd have to go through
23 the transcript and see that they meet so many hours of
24 physics or whatever. So you could be prescriptive.

25 I think if they meet those criteria, then

1 we shouldn't be bothered, you know, with it. I think
2 at that point you could come here for clarification on
3 maybe new policy, but you have to have some structure
4 to this whole review process.

5 DR. VETTER: Mr. Bailey.

6 MR. BAILEY: I hate to further complicate
7 this, but there are states such as California that do
8 have a list of, for lack of a better word, approved
9 physicists, and at this point we would tend to put
10 them on as authorized users if they were requested to
11 be put on because we do have some knowledge of them,
12 and they have filled out essentially a registration
13 form and so forth.

14 Probably even more unsettling, if you're
15 looking for uniformity and consistency is you've got
16 33 states to deal with, and depending upon the local
17 state situation, that physicist may be approved with
18 credentials that you would not approve.

19 So it's going to be a while before there's
20 uniformity and consistency, particularly among
21 physicists. And many of us don't have as much
22 difficulty making a decision about whether we think a
23 physicist is qualified, as we do, making a decision
24 about whether a doctor is qualified.

25 DR. VETTER: Dr. Williamson.

1 DR. WILLIAMSON: I think the reason the
2 ACMUI is involved and the TAR is involved is because
3 it's sometimes very difficult to lay down hard and
4 fast criteria or policy as to why a variance should be
5 given from a regulation. So I think basically Ralph
6 is right. If you want to institutionalize or somehow
7 codify the range of allowed options that broad scope
8 licensees and individual regions have, you know, you
9 are then going to have to sit down and create some
10 kind of guidance document for them to follow or it
11 won't be very consistent.

12 Because right now what you do is you bring
13 many of them to the full committee. Sometimes I'm
14 aware you just may ask the specialist or the one or
15 two individuals on the committee what their opinion is
16 of a particular question rather than bringing it
17 before the committee, but this system allows you to
18 proceed with this what may be growing but still
19 relatively small number of cases without having to go
20 through the trouble of creating a more formal guidance
21 document.

22 So that would be, I guess, one issue you
23 would have to decide. I would be concerned that many
24 qualified physicists could be unnecessarily rejected
25 by the fact that the regions, who are not specialists

1 or do not have representation from our field to judge
2 these credentials, or on the other hand, they might
3 let some individuals through that, you know, we think
4 couldn't pass successfully through our board
5 certification process.

6 That would basically, I think, be the
7 criteria we would use, is could this person, if they
8 did sit for our examination process, pass it.

9 DR. VETTER: Dr. Miller.

10 DR. MILLER: Yes, just a couple of other
11 points to think about, embellishing some of Ed
12 Bailey's comments. For the 33 agreement states, when
13 they encounter such a situation, that doesn't come
14 into the process to the committee. The decision is
15 made in the states.

16 So for the majority of licensees, that's
17 not the case. That being said, also, you know, if you
18 look at the provisions of the regulations, people
19 could be on an agreement state license and move to
20 another jurisdiction, whether it be an agreement state
21 or NRC jurisdiction, but because they remained on that
22 license, that's an avenue for being put on a license
23 in an NRC or another agreement state. That wouldn't
24 come to the committee.

25 So all of these factors weigh in also to

1 the fact that the committee itself doesn't get to see
2 all of the applications nationally, and it's just food
3 for thought.

4 DR. VETTER: Mr. Leito.

5 MR. BAILEY: As we have to try to wrestle
6 through this.

7 MR. LEITO: A couple of questions. I
8 guess this would be mostly for Cindy. Are these
9 applications almost at least for the physicist, are
10 they being applications under the alternate pathway,
11 and is that a fair assumption that these all come --

12 MS. FLANNERY: Yes, it is.

13 MR. LEITO: And for the broad scope
14 approvals, the NRC still has to be notified regarding
15 the AMPs being put on the license, correct?

16 MS. FLANNERY: No, they do not.

17 MR. LEITO: Okay. So how is NRC --

18 MS. FLANNERY: That may be reviewed
19 during, say, an inspection.

20 MR. LEITO: So you don't have necessarily
21 a sense of how many broad scope reviews are now --
22 well, for AMPs occur.

23 MS. FLANNERY: No.

24 MR. LEITO: All right.

25 DR. VETTER: I can comment from personal

1 experience that when our broad scope license is
2 inspected, the inspector always pulls a few authorized
3 users somewhat at random. I would suggest if it were
4 a foreign trained physicist, it probably wouldn't be
5 at random, and we would have to defend the process by
6 which we approved that AMP. That's broad scope.

7 Dr. Nag.

8 DR. NAG: Yeah. I think from what we've
9 heard, I think the present requirement is not a
10 problem because the safeguards and the training
11 requirement for qualification is so tight that you are
12 very, very unlikely to cause anyone who would maybe
13 got the license and practicing not in a hospital, but
14 maybe on his own in a free standing place. So that's
15 really, really there.

16 So I think you should concentrate on the
17 physicist and the only group from the medical field
18 which we know who are trained in Canada and has their
19 full training in Canada and is now coming here,
20 whether you need one year extra for that person to be
21 under a preceptor or not. I think those are the two
22 questions you need to look at.

23 And I guess those who are coming from
24 Canada in some of the licensing requirement and
25 handling requirements may be different in the two

1 countries even though the magical pot is one thing
2 that's equivalent. I suggest that those who thought
3 they -- those reports certified in Canada and after
4 coming here and, therefore, certify you have a one-
5 year receptor who would want them.

6 DR. VETTER: Ms. Fairobent.

7 MS. FAIROBENT: Yeah, Lynne Fairobent,
8 AAPM.

9 Just another question because let's talk
10 about an AMP who's already on the license for, say,
11 one modality, and a new modality comes along and we
12 have the provision of requiring vendor training, and
13 what has brought this up to mind is I know in the
14 past, several of our physicists have gone to a foreign
15 country where the vendor-manufacturer lives in his
16 house, maybe the first use in the U.S., gets their
17 vendor training overseas. The preceptor would have to
18 be somebody from that institution. There is nobody in
19 the U.S.

20 Is that going to be accepted since you
21 said no foreign preceptors?

22 PARTICIPANT: That's a very good question.

23 MS. FAIROBENT: And I don't think that's
24 an uncommon practice.

25 DR. WILLIAMSON: And it does say here that

1 the device specific training can be supplied by a
2 vendor, and so when the vendor is not an authorized
3 user, you know, you have a contradiction because then
4 you say the preceptor who must be an authorized user
5 has to attest to Part C.

6 DR. VETTER: Yes, Cynthia.

7 MS. FLANNERY: Well, I would think that
8 that would fall under one of those unusual
9 circumstances.

10 DR. WILLIAMSON: It's very routine, and in
11 fact, say, a nucletron representative gives the
12 training, devices specific training, Part C. You
13 know, the logical person to sign off that that
14 training was delivered is, in fact, the vendor and not
15 some authorized user who had nothing to do with it.

16 DR. NAG: But then I think that --

17 DR. HOWE: Excuse me. If I could just
18 add.

19 DR. VETTER: Dr. Howe.

20 DR. HOWE: The regulations do not require
21 the preceptor to have provided the training. The
22 preceptor has to verify, and so if the preceptor
23 verifies that the individual received the training
24 from the vendor and knows what the vendor is
25 providing, then the preceptor can be the authorized

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1 use or the authorized medical physicist, whatever the
2 requirement is.

3 DR. VETTER: I think that answers that
4 question.

5 DR. WILLIAMSON: Okay. I think so.

6 DR. MILLER: Yes. I actually agree with
7 that. I think that works.

8 DR. VETTER: Yes. Now, relative to the --
9 yes, Dr. Miller.

10 DR. MILLER: Another scenario, this is
11 something I've been wrestling with personally and
12 mentally, and maybe I just don't understand. Can
13 anyone postulate a scenario whereby somehow someone
14 could find themselves on an NRC or agreement state
15 license as an authorized user or an AMP, but yet not
16 be licensed to practice in that state. In other words
17 the way I think about it is if you're not licensed to
18 practice medicine in the state, even if you found your
19 way somehow on an NRC license, from a practical
20 perspective it would never happen. Is that true or is
21 that a problem or --

22 DR. VETTER: Dr. Malmud.

23 CHAIRMAN MALMUD: Yes. That could occur.
24 For example, let's say that I am an authorized user
25 and I move to Florida where I'm not licensed to

1 practice medicine, but you see there I'd be prevented
2 from practicing medicine because the credentialing
3 process in Florida would exclude me from the practice
4 of medicine. Hence my authorized user status is
5 irrelevant because in the practice of medicine there's
6 a credentialing process.

7 Now, I can't speak to an analogous
8 situation for physics because I'm not familiar with it
9 -- for physicists.

10 DR. VETTER: Mr. Bailey.

11 MR. BAILEY: Yeah, I think that occurs all
12 the time. We have many physicians practicing at VA
13 and military facilities in California who are not
14 licensed to practice medicine in California. They're
15 not required to be.

16 Similarly, with pharmacists and one of the
17 large pharmacies wanted us to recognize the NRC
18 license which named 20 or 30 pharmacists. They were
19 a little miffed at us when we asked that they provide
20 us with information that all of those people were
21 licensed to practice pharmacy in the State of
22 California. So that occurs all the time.

23 DR. VETTER: Dr. Howe?

24 DR. HOWE: My comment or my response is
25 very similar to what Ed Bailey has said about the

1 physicians at the federal facilities. You're not
2 required to have a license for the state in which
3 you're living because you may move around.

4 For the pharmacy issue, I was involved in
5 the development of the radiopharmacy rule, and we
6 actually assumed that there would be cases in which
7 there might be two pharmacists required, one licensed
8 in the state to meet the state pharmacy requirements,
9 and he would act as a supervisor for a nuclear
10 pharmacist that would meet our requirements but
11 couldn't practice in that state. So he would act as
12 not a pharmacist under the state license, but for the
13 NRC he's acting as a pharmacist, but he wouldn't.

14 So we had assumed that there would be some
15 pharmacists that wouldn't be licensed, but they would
16 have to operate more as pharmacy techs under state
17 rules.

18 DR. VETTER: And, Dr. Miller, relative to
19 physicists, most states do not require the licensure
20 of physicists.

21 DR. MILLER: My primary concern was as
22 authorized users, you know, is problematic.

23 DR. VETTER: Dr. Williamson.

24 DR. WILLIAMSON: Well, it sounds like in
25 the physicist case if we divide it into -- if physics

1 boards become recognized as they hopefully will the
2 board certified route and the alternative pathway
3 route. So it sounds like for the board certified
4 route, they still have to have a preceptor's
5 statement, but the preceptor's statement would be
6 essentially one of verifying that the training,
7 wherever it was received, that constituted the grounds
8 for sitting for the boards was appropriate, and that
9 would be that. So there doesn't seem to be a problem
10 at the local level, at any level for a board certified
11 physicist.

12 So I think the question comes in the
13 alternative pathway, where it says clearly both the
14 practical training and year of supervised experience
15 has to be done under the supervision of an authorized
16 user or medical physicist, which presumes, you know,
17 a United States practitioner.

18 So there would have to be, I think, a
19 system or some approach for exemptions, I think, from
20 some or part of that process in the case that a
21 foreign trained medical physicist came to the United
22 States that wasn't board certified.

23 DR. VETTER: Ms. Fairobent.

24 MS. FAIROBENT: Yeah, Lynne Fairobent.

25 Just to follow up on Donna-Beth's answer

1 on the vendor training, in order to be a preceptor,
2 yes, you only have to verify that the training
3 occurred, but you have to be an AMP preceptor for that
4 modality of which you're verifying the training. So
5 I don't think that is a solution if you are the first
6 user of a modality and are trained in a foreign
7 vendor.

8 There may not be a preceptor on a license
9 who could serve to verify your training by virtue of
10 being an AMP in that modality.

11 DR. HOWE: I just want to make a quick
12 comment, and that is we consider modalities in a very
13 broad definition. So if you're talking about a new
14 HDR unit, then the preceptor could be an HDR
15 authorized user or medical physicist. He may not be
16 approved on that new HDR unit, and if you're talking
17 about a brand new modality, then we're in 35-1000
18 space. In 35-1000 space we don't have specific
19 training and experience requirements that require a
20 preceptor statement because we recognize there is at
21 some point a first, and if there's a first, there's no
22 one to sign off for him.

23 So we do interpret the modalities very
24 broadly. So if it's a new version or a new
25 manufacturer for an existing modality like HDR gamma

1 knife teletherapy, we could still have someone that
2 could sign off for that individual.

3 MS. FAIROBENT: But then I guess I
4 question what the purpose of the vendor specific
5 training is on that piece of equipment which may be
6 different than an existing one.

7 DR. HOWE: I don't think the preceptor
8 statement is necessary for somebody that knows that
9 piece of equipment because you have to have a system
10 that allows for growth.

11 DR. WILLIAMSON: That would be important
12 to be more flexible like this.

13 DR. DIAMOND: This is Dr. Diamond.

14 Donna-Beth, I think that this flexibility
15 satisfies me. For example, let's say that there is
16 the next generation of a gamma knife unit that comes
17 out. Let's say we're now in the Unite 4Cs. Let's say
18 in the future a Model 5 comes out. The first users of
19 the Model 5 will need to go to Sweden to be trained by
20 ELEKTRA (the vendore).

21 As long as you tell me that a preceptor
22 who is authorized for gamma knife in the United States
23 can sign off that that treatment was being done and as
24 long as you tell me that the vendor training can be
25 satisfactorily completed in the country of Sweden,

1 there is no issue whatsoever.

2 DR. HOWE: I think we would accept that.

3 DR. DIAMOND: Okay.

4 DR. VETTER: Okay. To get back to the
5 original question, if I can stick my neck out, I think
6 the sense of the committee is that this isn't an issue
7 for physicians because there are so many outside
8 controls on licensing and so forth. Relative to
9 physicists, it's a little grayer, but I think the
10 sense of the committee is we would be okay with
11 regions making decision if there were some guidelines
12 put together to assure uniformity of decision making
13 across the country. Is that -- is that close to the
14 sense of the committee?

15 DR. WILLIAMSON: I think so.

16 DR. VETTER: Okay. Any other discussion
17 on this topic or related questions? Yes, Mr. Leito.

18 MR. LEITO: You know, one of the things,
19 just a comment is that I think in doing these reviews
20 from the alternate in this case-by-case basis that we
21 need to recognize that the issues that we're
22 addressing are not so much the practice of medicine or
23 physics to some degree, but the health and safety
24 issues of that modality and what that person would be
25 overseeing.

1 You know, I would think that there would
2 necessarily -- that there shouldn't be, I should say,
3 any exemptions to training and experience under an AMP
4 or an AU, you know, for these case-by-case reviews.
5 So I think it's really important that those
6 individuals have a sense of the safety considerations
7 of the regulations for the modality for which they're
8 getting approved, which are not necessarily going to
9 transfer from a foreign country to the United States.

10 DR. VETTER: Thank you, Ms. Flannery, for
11 bringing the question to us and for giving us the
12 opportunity to comment.

13 MS. FLANNERY: Thank you.

14 DR. VETTER: I'll turn the chair back over
15 to Dr. Malmud.

16 CHAIRMAN MALMUD: Thank you, Dr. Vetter.

17 If we may, we'll move on to the next item
18 on the agenda, which is Item No. 17, status of medical
19 events, which is a standing item, open session. Dr.
20 Howe.

21 Dr. Howe is going to seek our advice,
22 recommendations and insights regarding the cause of
23 medical events and possible methods to reduce them.

24 DR. HOWE: Sorry, folks.

25 CHAIRMAN MALMUD: If I may, I'll just use

1 a few minutes while Dr. Howe is getting the slides
2 ready to let you know that I met with one of the
3 Commissioners, which is why I was out for a few
4 minutes, and one of the suggestions that he made was
5 that in addition to requesting the information from
6 the states as to how they're dealing with accelerator
7 produced products, that we might wish to find out, if
8 possible, how other nations are dealing with
9 accelerator produced products, including those who
10 have the largest volume of production: Canada, for
11 example, United Kingdom, France, and Japan.

12 It doesn't mean that the models that they
13 use are at all applicable here. On the other hand, it
14 would be of interest to know how they are dealing with
15 the issue in addition to our survey of the states.

16 The Commissioner asked me what I thought
17 would be occupying our effort in the near future, and
18 I said certainly the issue of accelerated produced
19 products would consume an enormous amount of time, and
20 that we had already begun to discuss the process here
21 at the meeting and we were looking forward to trying
22 to work out something that would be able to be applied
23 nationally and to absorb as much as we could from each
24 of the state regulations that we thought was a good
25 role model, and then, of course, try to achieve some

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1 degree of conformity.

2 I explained that there were different
3 interested parties, industry looking for more
4 uniformity with respect to marketing their products
5 from one state to another, concerns, on the other
6 hand, on the part of some research institutions that
7 the regulations not be onerous, not add additional
8 expense or layers of administration, and that clearly
9 the concern of all parties, ourselves in particular,
10 are that accelerator produced products continued to
11 flow into the areas of medical research and medical
12 care, and that we attempt to work out a system that
13 achieved this at the least expense and the least delay
14 in producing the end product for the betterment of
15 patients.

16 We also described the working relationship
17 between the NRC representatives here and the members
18 of the ACMUI, and it was, in general, a very positive
19 discussion.

20 DR. HOWE: I now have slides.

21 I'm bringing you essentially an update
22 that we give once a year to the status of medical
23 events for the preceding fiscal year, and the first
24 slide is a summary slide that lets you know that we
25 had essentially 40 medical events in FY 2005, and you

1 may have a question of, well, how does that compare to
2 FY 2004. We only had 35 medical events in FY 2004.

3 Another major difference is that in 2004
4 for 35-600, all of our medical events were under HDR,
5 and now we're beginning to see a few more events for
6 gamma knife. Even though we only have three
7 teletherapy units, we managed to have a teletherapy
8 unit medical event last year, and we considered our
9 first LDR.

10 The other major changes last year, we had
11 a significant number of medical events that were in
12 35-1000 because of intervascular brachytherapy,
13 specifically the Novos device. The Novos device is
14 essentially gone, since Novoste has gone into a
15 different business, and the Novos device is not
16 available at this time.

17 So we have two medical events for the
18 microspheres. It ends up that the microspheres are
19 now coming up into a larger use. They're getting out
20 into some of the smaller hospitals.

21 For about a year and a half, Medicare or
22 Medicaid -- yeah, Medicare had identified microspheres
23 as more or less a diagnostic nuclear medicine
24 procedure and, therefore, wasn't reimbursing for even
25 a small fraction of the total cost of the

1 microspheres, and that got rewritten about a year and
2 a half ago. So microspheres are now a technology
3 that's coming back into use.

4 Now, one of the other things I did this
5 year, and last year, I think, if you'll remember, we
6 had a significant number of 35-200 events that were
7 due to diagnostic IO-131 treatments being prescribed,
8 but therapeutic doses of I-131 being delivered.

9 We're not seeing that this year, but the
10 thing that seemed to pop out was that this year we
11 seem to have a significant number of events that were
12 not identified rapidly. About 40 events, about 50
13 percent of them were identified on the same day that
14 they occurred. We consider that the events that are
15 identified within the same day or two to four days
16 later could be patients coming back and realizing at
17 that point that the events aren't correct or a rapid
18 review of the administrations and realizing that in
19 that review that there was an event that occurred.

20 We had two events that were out 15 to 60
21 days. One of those events was an internal audit. The
22 60-day event was a patient that came back with actual
23 patient injury, and at that point there was a
24 recognition that there was something wrong with the
25 initial treatment.

1 One of our same day events was an HDR unit
2 in which the medical physicist put the wrong
3 parameters in back in October of 2004. Since that
4 time we've done inspections, and the licensee has gone
5 back to reevaluate its previous records, and so many
6 of the events down -- two of them in the one to two
7 years are from the same institution, and three of them
8 in the two-year greater are at that institution, and
9 they have to do with the medical physicist improperly
10 inputting various parameters into the HDR procedures.

11 So a total of six patients were involved
12 in that particular facility.

13 One of our facilities for the one to two
14 years later, and we'll talk about this a little bit
15 later, was essentially another patient injury. They
16 recognized at 30 days they had a potential patient
17 injury, and a year later they had radiation burns that
18 hadn't healed, and they realized that at this point
19 they would have to report to the NRC because they had
20 what they thought might be a reportable event.

21 That particular event involved five
22 different patients. We've done an information notice.
23 It was a manual brachytherapy event that I'll describe
24 a little bit later.

25 MR. BAILEY: That only adds up to 37.

1 DR. HOWE: Do I have all of my numbers in
2 here? Maybe I have a number missing somewhere, but I
3 do have 40 events.

4 MR. BAILEY: There were 40? Okay. And
5 these were only NRC?

6 DR. HOWE: These are both NRC and
7 agreement state.

8 DR. NAG: Do all of the agreement states
9 report to you or only if they want to?

10 DR. HOWE: All of the agreement states are
11 supposed to report to us. We do notice that for
12 different years all of a sudden you'll see a rash of
13 reports coming from one state or the other, and that's
14 generally a year there was an impact done.

15 DR. WILLIAMSON: I think there are only 39
16 altogether. In the second slide there's --

17 DR. HOWE: Are there?

18 DR. WILLIAMSON: There's a miscount here.
19 So it's 39 versus 35, I guess.

20 MR. BAILEY: But there are actually under
21 35-600, there are actually 18 identified in the
22 breakout, but only 17 included in the --

23 DR. WILLIAMSON: I see. You're right.

24 DR. HOWE: Okay. Then that's where I --

25 DR. WILLIAMSON: That is 40.

1 DR. HOWE: That's where I have an errors.

2 Ralph, did you have a question?

3 MR. LEITO: I just wanted to clarify for
4 my information and understanding. Fiscal year 2005,
5 is that September to October?

6 DR. HOWE: October 1 to September 30.

7 DR. DIAMOND: Donna-Beth.

8 DR. HOWE: Yes.

9 DR. DIAMOND: I think it deserves some
10 comment regarding why, for example, there were three
11 medical events reported over two years later. It's my
12 understanding that at least two of those three had to
13 do with very reasonable licensee interpretations of
14 what, indeed, constituted a medical event. I think
15 perhaps you'd like to comment on that.

16 DR. HOWE: And I'll comment further when
17 I get to them. Two of them in the one to two years
18 later were identified at -- they were gamma knife
19 procedures -- they were identified at the time as
20 medical events, but they were thought not to be
21 reportable medical events, and I'll go into a little
22 more detail as we get to -- because I am going to go
23 through very briefly what kind of events we were
24 looking at.

25 In 35-200, we saw one of our diagnostic I-

1 131s were a therapeutic I-131, which gives -- no, in
2 that case the iodine was ordered for the wrong
3 procedure. We saw what we typically think of as a 200
4 medical event, and that is either the whole generator
5 elution is given to a patient or a bulk technetium
6 dose is given to a patient.

7 We did see two pediatric cases. We don't
8 normally see pediatric medical events. So that's kind
9 of a new one for us, and it's typical for us within
10 one or two years to see one of these Technetium-99
11 bulk doses or entire generator given to a patient when
12 you have technicians that are for the first time on
13 call by themselves. They've been shown how to elute
14 the generator. Everybody thinks they understand
15 what's happening. They elute the generator, put that
16 in the kit and give the whole thing to the patient.

17 In this case they had a syringe that came
18 in from the pharmacy with a bulk dose. The corrective
19 action is for the pharmacy to send the bulk doses in
20 a vial so that the licensee can now split the dose.

21 Dr. Malmud, you look very puzzled.

22 CHAIRMAN MALMUD: Yes. What's the amount
23 of activity in a bulk dose?

24 DR. HOWE: It can vary. In this
25 particular bulk dose, it was 400 millicuries.

1 CHAIRMAN MALMUD: Thank you.

2 DR. HOWE: So you have to give a
3 significant amount of technetium for an adult to
4 trigger the medical event reporting requirements.

5 CHAIRMAN MALMUD: Four hundred millicuries
6 is significant.

7 DR. HOWE: Yes.

8 DR. WILLIAMSON: Just out of curiosity,
9 what is the criterion for a 200 medical event?

10 DR. HOWE: Two hundred has to exceed 50
11 rem to an organ and five rem whole body.

12 DR. WILLIAMSON: I see. Got it.

13 DR. HOWE: So you're up in that 350, 400
14 range before you even start to trigger it, but we do
15 get cases where people elute the whole generator and
16 give it to a patient. It doesn't happen often, but it
17 does happen.

18 Three hundred, we have essentially your
19 typical sodium iodide medical events. We did have one
20 where they were supposed to be giving sodium iodide.
21 They gave technitium instead, but it's still a medical
22 event because the dose that they delivered was
23 significantly less.

24 We're starting to see some of the new --
25 well, they're not new anymore, but some of the

1 slightly different drugs like samarium with
2 calibration errors. We did put an information notice
3 out a number of years ago about problems associated
4 with calibrating samarium with those calibrators, and
5 you have to be very careful with that.

6 The Yttrium-90 Zevalin, they gave the
7 maximum dose possible to an individual because they
8 had failed to write a written directive, and there was
9 confusion between the ordering of the procedure and
10 the activity that should have been given and the order
11 that went to the pharmacy.

12 For brachytherapy --

13 DR. NAG: What do you mean by eight and
14 12?

15 DR. HOWE: There were eight events, but
16 one event involved five patients, and so that's why
17 you'll see that there were five patients in which the
18 source moved to the wrong site. That was a Wang
19 applicator situation where the medical physicist did
20 not realize that there was a difference in size for
21 sources, and the source was small enough that it slid
22 right down the inside of the spring in the Wang
23 applicator.

24 And so once the patient was elevated above
25 20 degrees, the source slide down to the end and

1 stayed there for the rest of the treatment, and this
2 is one of the cases where they had radiation burns
3 within 30 days of the initial treatment. They didn't
4 recognize them as radiation burns, and they didn't
5 call it in as a reportable event until well over a
6 year later, and that particular facility was very
7 confused as to how to interpret a medical event and
8 patient intervention.

9 They combined the patient intervention
10 with the medical event reporting requirements, and
11 didn't think they needed to report. We put a
12 paragraph in the NMSS newsletter to clarify how to
13 interpret the medical event.

14 We had a leaking source in the prostate.
15 It was I-125 using a MIC applicator, probably got
16 stuck. The source actually was leaking in the
17 patient. We had our typical prostate problems with
18 ultrasound. Providing the interpretation of the
19 ultrasound was not appropriate, and so the sources
20 went into the wrong place.

21 We had cartridges being used, and the
22 cartridges for the I-125 sources looked the same as
23 the cartridges for the Palladium 103, and so when
24 they picked up the cartridges to give all 1-I-125,
25 they gave in some Palladium 103 seeds also.

1 We had a facility that sent the wrong
2 activity of sources to an authorized user, and then
3 down in the wrong size applicator, they were supposed
4 to use a cylinder of a certain size. They used a
5 different cylinder. They grossly overexposed the
6 patient, and then they had a fouled up treatment in
7 which the ribbon moved.

8 We had a lot more HDR units than we've had
9 before, and I'm including the HDRs. The numbers look
10 a little high because six of the HDRs were from the
11 same licensee, and this is where the medical physicist
12 entered in a various set of erroneous data. He did
13 make the same mistake twice. He put in the wrong
14 distance. He put in the wrong spacing. He varied it.
15 So he had lots of errors.

16 We had a case that was discovered the same
17 day that it happened, but the others were when they
18 went back and looked at the files.

19 DR. NAG: Was that a new radiation
20 physicist? Was that someone who just came into that
21 department recently or is it someone who's used to it?

22 DR. HOWE: Well --

23 DR. NAG: What I'm trying to see is
24 because he's not familiar with this new equipment or
25 is it someone who is not trained overall?

1 DR. HOWE: I can't answer that. I can
2 tell you that the events that were affected by wrong
3 data input over a two-year period of time. It wasn't
4 really identified as a problem until 2004. There were
5 additional problems in 2005 with data entry, and then
6 the licensee went back and did reviews and identified
7 four more cases that were earlier. So this was a
8 prolonged period of time with --

9 DR. WILLIAMSON: Is this an agreement
10 state or non-agreement state?

11 DR. HOWE: No, this is an NRC licensee.

12 DR. WILLIAMSON: Yeah, I would be curious
13 to know more details, especially about the background
14 personnel issues there.

15 DR. HOWE: Yes. I have a call in to
16 Region III, but I haven't got an answer back, but,
17 yes, it is an interesting question. I'm assuming it's
18 in inspection enforcement space.

19 And then we had other problems where they
20 put the wrong distance in for the catheter, something
21 called the wrong orientation. So the sources were in
22 the wrong location. One catheter wasn't fully
23 inserted. It was wrapped around the toe. They
24 unwrapped it from the toe and they gave the procedure,
25 and then they came back later and discovered it wasn't

1 in the location at all.

2 One was a software problem where they had
3 a new software package, and they had entered a
4 diameter, not a radius. So they gave a quite high
5 overdose on that one.

6 And then the wrong source travel distance.

7 Gamma knife, we had five this year. We
8 haven't had one for a while where they transposed the
9 Y and the Z coordinates, but that problem is always
10 out there. It came back again in 2005.

11 We very rarely have equipment problems,
12 but there was a clip on a microphone that fell into
13 the gamma knife, jammed the device, and so the
14 facility was not able to give all of the positions
15 that it was supposed to give.

16 In one case there was a records review
17 later, and they discovered there was quite a large
18 error in the gamma knife procedure, and they
19 attributed that to it was in an agreement state, and
20 they attributed it to poor communication between the
21 neurosurgeon, the oncologist, and the team that was
22 delivering the procedure.

23 We had two wrong sites. In both of those
24 cases, the event was recognized right away, but the
25 fact that it was a reportable medical event was not

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1 recognized. There was an interpretation by two
2 different licensees that patient movement, although
3 NRC considered them a contributing factor, they
4 attributed patient movement to patient intervention
5 and did not report them.

6 DR. VETTER: Why wouldn't that be patient
7 intervention?

8 DR. DIAMOND: I can speak to that. I was
9 asked -- this is Dr. Diamond -- I was asked to look
10 into these cases. As you know, there is very specific
11 language in the rules that patient intervention is
12 specifically excluded as a reportable medical event.
13 In other words, let's say you're doing a low dose rate
14 time to no void procedure on a gynecologic oncology
15 patient. That patient is given very strict
16 instructions regarding bed rest and so forth.

17 The language was inserted in case that the
18 patient did not follow your instructions and she
19 decided to move or pull the thing out that you as the
20 licensee would not be penalized.

21 In these two particular cases, the
22 circumstances are fairly similar. These were cases in
23 which all of the standard operating procedures were
24 followed as far as placement of the frame, checking of
25 the coordinates, checking of the bolts to make sure

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1 the frame was on tight. These were both very
2 experienced center.

3 And what happened is that during these
4 gamma knife procedures they can get quite long, and of
5 course, the table is quite hard, and you can start
6 having some back pain, and it's very common, for
7 example, when you do these procedures that halfway
8 through you stop or between fractions you take a
9 break, and obviously you're monitoring the patient in
10 real time and will give the patient some Versed or
11 some Demerol to relieve their discomfort.

12 In these particular cases, the patient --
13 in one case the patient did not follow instructions
14 and started twisting and squirming in real time. In
15 fact, was a heavysset fellow who basically lifted up
16 the entire small of his back so that all of the
17 pressure of the force of his body rested on those
18 frames, and what happened was in real time the frame
19 slid, and so for the remainder of that particular
20 fraction there was a movement.

21 So was that patient intervention, meaning
22 did the patient not comply with your instructions?
23 You're telling them in real time to stay still, stay
24 still, or was that actually a licensee error because
25 they should have had the foresight to recognize the

1 person was uncomfortable and perhaps they should have
2 done some other steps to make the person less
3 uncomfortable?

4 DR. HOWE: And in that particular case,
5 the frame slid seven centimeters.

6 DR. DIAMOND: It slid completely until it
7 hit the table. Now, as it turns out, it appears that
8 that happened towards the very end of treatment. It
9 turns out that it would have placed the isocenter in
10 a portion of the skull where there was no physiologic
11 consequence, and it turned out that the treatment was
12 efficacious.

13 So it was really a matter of
14 interpretation. Was it the patient not complying with
15 your direct repeated requests and was patient
16 intervention or not? And that's an example where in
17 real time the licensees spoke about it internally.
18 They talked about it within the review committee, and
19 they felt that it, indeed, met the patient
20 intervention criteria.

21 The second case was sort of similar. The
22 patient was coughing, and in this particular case the
23 licensees had to use a three pin technique. Usually
24 when we do these gamma knife procedures there are four
25 pins, two in the front and two in the back, for

1 maximum stability, but because of the geometries
2 occasionally we have to take one of the four out so
3 that there's no collision. And we do that all the
4 time.

5 In this particular case, the person
6 started coughing and was coughing apparently fairly
7 vigorously, and at the end of one of the fractions,
8 because of the vigorous movement of the head within
9 the frame with the cough, the pins that are inserted
10 into the calvarium slid a little bit, and of course
11 you know the skull is not solid. It's not solid bone.
12 It's an inner table, marrow, and outer table, and even
13 with these screws, they can slide just like a screw
14 can have some launch and movement if the threads are
15 not secure.

16 So, again, was this a patient intervention
17 or not, and again, they went internally to the
18 committee and they thought it was not a reportable
19 medical event, but then there was an NRC inspection,
20 and during the course of just a routine review, this
21 came up.

22 So these I do not think were any
23 malevolent attempts to hide, cover up. They had been
24 reported and discussed widely within our institutions.
25 They had shared the information with the patients and

1 so forth, and I think these were both instances of
2 individuals feeling that it really just met the letter
3 of the law but not reportable medical event.

4 DR. WILLIAMSON: So is this -- it says
5 11th stage. Is that 11th isocenter or 11th --

6 DR. DIAMOND: Yes, in that particular case
7 that you're looking at, Dr. Williamson, that was the
8 11th and final shot of a gamma knife procedure for an
9 acoustic neuroma, and that actual transposition or
10 movement of the screw happened at the very end of the
11 11th shot.

12 So, once again, the physiologic
13 consequence was essentially nil.

14 DR. VETTER: Dr. Nag.

15 DR. NAG: Yes, a question. If these are
16 patient interventions, and I agree with you that these
17 are patient interventions and I would have classified
18 similarly if it had happened in our place, why are
19 they coming up in here as a medical event?

20 DR. HOWE: Because we did not consider
21 them patient intervention. We considered them --
22 well, the one with the seven centimeters, we think
23 that there was some equipment failure. We have not
24 seen any other movements on the level of seven
25 centimeters for a gamma knife. The device is designed

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1 to hold people in place.

2 We think that on the -- we think that
3 patient movement is a contributing factor, but we
4 don't think patient movement is an intervention in
5 these cases.

6 DR. DIAMOND: This is Dr. Diamond.

7 So, Dr. Howe, this is an example where the
8 NRC staff holds one position and I, who was asked to
9 review it as a clinician, hold a different opinion.
10 To me the difference in the movement, whether it would
11 have been a centimeter or seven centimeters, is
12 irrelevant. The real question is what was the
13 causation. What was the root cause, and making sure
14 that experience is not replicated anywhere.

15 And number two, just from a regulatory
16 point of view, did it fit or did it not fit a
17 reportable medical event? And my feeling was it did
18 not meet a reportable medical event for the reasons
19 that I mentioned.

20 DR. NAG: I think that it is important to
21 discuss in the ACMUI because, you know, from the
22 physician's standpoint I agree that if the treatment
23 was started correctly, if all the parameters were
24 started correctly, and the whole basis of
25 intervention, whether movement, accidental or not

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1 accidental, that caused a failure or that caused a
2 movement of the device, whether the HDL gamma knife,
3 that really should not be a medical event.

4 And the intention --

5 DR. DIAMOND: Reportable, reportable
6 medical event.

7 DR. NAG: Right, reportable medical event.
8 And I don't think this should be.

9 DR. WILLIAMSON: Well, actually it should
10 be medical event. It does say that it's included in
11 the definition of medical event, specifically the
12 exclusion of patient intervention.

13 DR. NAG: Right.

14 CHAIRMAN MALMUD: Again, Dr. Williamson,
15 you were making a case that it is or is not a medical
16 event that's reportable?

17 DR. WILLIAMSON: Well, a licensee shall
18 report any event except for an event that results from
19 patient intervention. I guess if you consider that to
20 be the definition, then it goes on with a more
21 detailed definition of medical event.

22 So I see that this definition does not
23 actually contain the phrase "medical event," except up
24 in the title, 35.305.

25 DR. DIAMOND: Right. I refer to it as a

1 reportable versus nonreportable because of that
2 language.

3 DR. WILLIAMSON: I'm curious to know what
4 the staff's definition or characterization is of
5 patient intervention and under what conditions it
6 needs to be reported and in which conditions the
7 language can be accepted literally as it states here
8 and it need not be reported.

9 DR. HOWE: We're intending to write an
10 information notice on our cases, on the case history
11 that we have to give some inclination as to indication
12 from the NRC perspective what the medical events are
13 and what is not patient intervention.

14 We have a history going back. Most of our
15 patient interventions that we have considered patient
16 intervention in the past have been actual patients
17 that have ripped out manual brachytherapy sources or
18 ripped out templates for other sources. Some of these
19 patients have not known what they were doing because
20 they have been older patients and confused. We've had
21 patients rip things out, pass them to the nurse,
22 thinking the nurse asked for it when the nurse didn't.

23 We have a wide variety of cases. We don't
24 necessarily consider patient movement in and of itself
25 to be patient intervention. We've had a number of

1 cases where patients have moved, and the sources have
2 moved, and they have not been considered patient
3 intervention.

4 DR. WILLIAMSON: And why is that? That
5 doesn't seem reasonable.

6 DR. DIAMOND: That's not --

7 DR. NAG: Excuse me. I would strongly say
8 that patient intervention would be, whether voluntary
9 or involuntary movement, would be a patient
10 intervention. I mean, if a patient is coughing, I as
11 a physician cannot control the cough. If a patient is
12 really cold and is shivering and because of that the
13 application is moving, that is not the licensee's
14 fault. It is not something the licensee can control,
15 and basically that is a patient intervention, whether
16 voluntary or involuntary on the patient's part.

17 DR. DIAMOND: This is Dr. Diamond again.

18 The way I look at these is, "Did the
19 licensee in a correct and appropriate manner instruct
20 the patients before the initiation of the procedure as
21 to what was expected, what to do if they had a
22 problem, explain the risk involved in the procedure?"

23 For example, we always tell our patients
24 as was done in one of the cases I mentioned, "We are
25 listening to you. We are watching you. If you have

1 any problems, we're listening. Tell us what's going
2 on," and this way if there's a problem about to
3 happen, you can stop the procedure.

4 If the person says, "I'm in pain. I'm
5 hurting," they say it; you stop the procedure; you
6 rectify the problem, you fix the problem; and that
7 squirming does not happen.

8 I think it's wrong, Donna-Beth, to say
9 that patient movement itself, provided the patient was
10 adequately informed about the expectations and you
11 took reasonable precautions to make the person
12 comfortable, that to me is patient intervention.

13 If you tell a lady whose lying in a
14 shielded room with a GYN applicator in place that this
15 source is, for example, in the vagina. It's packed,
16 but you need to stay still. This is why you need to
17 stay still. If you're having pain or problems, call
18 the nurse or call us and we'll come in and take care
19 of it, and that person wilfully does not follow those
20 guidelines, to me that patient movement would fall
21 into the rubric of being a patient intervention
22 without any question at all, without any question
23 whatsoever.

24 DR. NAG: I agree wholeheartedly.

25 DR. WILLIAMSON: I agree, yeah.

1 DR. HOWE: The ones that we've had in the
2 past, most of our ones in the past that have been like
3 that have been patient intervention, but there have
4 been a few where they knew the patient was not going
5 to follow directions. I think in one case there was
6 a sedative that was supposed to be given to the
7 patient and the nurses didn't give the sedative. So
8 there are a few of those that in those cases we have
9 not considered.

10 DR. DIAMOND: Right. In that specific
11 case, I agree with you. Again, if the patient was not
12 informed or if the licensee did not take reasonable
13 action, so, for example, if the patient was saying on
14 the table, "My back is hurting. I need a break," and
15 you did not interrupt the treatment and give some
16 medicine; if you did not go and give reasonable
17 sedation or pain medicines in advance to a woman who
18 is about to start a 48-hour GYN application, I would
19 agree with you.

20 What other example?

21 DR. WILLIAMSON: Or if you didn't take
22 reasonable precautions to observe and follow up with
23 the patient periodically to detect the event at a
24 proper time.

25 DR. DIAMOND: And a reasonable sense that

1 the patient would not be able to follow your
2 instructions to me is a contraindication for doing the
3 procedure. If you have a woman, for example, who,
4 let's say, has some mental disorder, let's just create
5 a hypothetical of a woman with paranoid schizophrenia.
6 That's probably not the best person to do a low dose
7 brachytherapy implant upon.

8 DR. HOWE: I think one of the things that
9 contributed to these events, especially the one with
10 the seven centimeter movement was I don't believe the
11 licensee had , that the coordinates were going to
12 shift. Their expectation-they knew the patient
13 moved, the patient asked to move-they knew the patient
14 moved. They knew they moved a lot. They did not stop
15 the procedure to check the patient again. They
16 continued.

17 Their expectation was that the head frame
18 would hold the patient in place. The same thing with
19 the coughing patient. There was no expectation that
20 there would be any change in the coordinates, and a
21 recognition that the system was not as stable as it
22 would have been in other cases.

23 DR. DIAMOND: This is Dr. Diamond again.

24 In that particular instance, the real
25 question was this, and I commented upon this very

1 specifically in my report. Should the licensee have
2 had the foresight to interrupt the treatment when they
3 saw the patient was squirming or not?

4 And I can tell you as someone who has done
5 a lot of these procedures, it is a simple judgment
6 call. Any of us lying on this table for a period of
7 time would start to have some discomfort and the
8 question is at what point do you break it. If someone
9 is 90 percent of the way through a treatment,
10 oftentimes it's much better just to say, "Hang in
11 there," encourage a patient and finish it up.

12 It is purely judgment, and this is an
13 example of -- again, I'm not trying to be difficult,
14 but unless you've done, you know, two or three or 500
15 of these, it's hard to kind of give you a little bit
16 of clinical context, and that's just a professional
17 opinion.

18 DR. NAG: Yeah, I think this is a
19 situation where ACMUI members' input should be allowed
20 to stand. Here we have an expert who has reviewed the
21 case who is an ACMUI member, who hopefully has no
22 ulterior motive, and is saying that this is something
23 that happens in a medical treatment situation, and I
24 think that should be allowed to stand. Otherwise,
25 what are we doing here?

1 DR. HOWE: Orhan.

2 DR. SULEIMAN: Yeah, I think we've had
3 this --

4 CHAIRMAN MALMUD: Dr. Suleiman.

5 DR. SULEIMAN: Yes, I think we've had this
6 philosophical discussion before, but I'm going to say
7 it again. With FDA we have severe, life threatening,
8 adverse events report, adverse events. It's not a
9 perfect system by anybody's stretch of the
10 imagination, but the purpose of this is to report the
11 medical events. Then you do an analysis. Is it a
12 device specific problem? Is it a drug related
13 problem? Is it a user problem?

14 And then if we get into the user
15 situation, is it within that gray area of practice of
16 medicine, this is tolerable, this is acceptable, or is
17 it really something that's beyond the scope of normal
18 practice and, in fact, represents a serious, you know,
19 issue that needs to be addressed?

20 So did you categorize these in any way
21 like that or just trying to evaluate them on a case-
22 by-case basis?

23 DR. HOWE: We normally evaluate reports of
24 potential medical events on a case-by-case basis. We
25 do think that there were equipment maybe not failures,

1 but incorrectly -- either equipment wasn't set up
2 correctly or there were equipment failures.

3 DR. SULEIMAN: Well, was it a design
4 problem or was it a misuse; was it a use problem, you
5 know? Or was it inadequate instruction, too,
6 obviously?

7 MR. LEITO: What was the failure
8 specifically?

9 PARTICIPANT: Of the equipment.

10 MR. LEITO: I mean, in your judgment --
11 this is Ralph Leito -- what specifically in NRC's
12 judgment was the failure of the equipment that you're
13 sort of overruling or setting aside Dr. Diamond's
14 judgment?

15 DR. HOWE: We believe on the seven
16 centimeter case that there probably was not correct
17 tightening of the screws and the patient movement
18 exasperated the problem.

19 We believe on the three pin, although
20 three pin is a common thing, we believe that maybe the
21 pins were not put in tight enough because they
22 adjusted the pins and then they took the pin out. So
23 they've got a totally different dynamic force than
24 taking the pin out and then tightening the three
25 remaining ones.

1 DR. DIAMOND: And, again, Donna-Beth, this
2 is Dr. Diamond. I'm trying to do this as respectfully
3 as I can.

4 But I'm telling you as someone who has put
5 in a lot of pins in people's skulls --

6 DR. HOWE: It's an art.

7 DR. DIAMOND: Not only is it an art, but
8 the anatomy is such that there can be some slight
9 movement of these pins. That's it. You're not taking
10 a screw and going in through a solid piece of oak.
11 These are human skulls that have inner tables and
12 outer tables and --

13 DR. HOWE: We recognize that.

14 DR. DIAMOND: -- and marrow, and it
15 sometimes can happen.

16 In the other example that you referenced,
17 I would put it to you that if the normal strength
18 human being places torque on these pins and secures
19 the frame and then you have someone who is 275 pounds,
20 five foot, nine, and is pulling the small of their
21 back up so that the entire weight and force of their
22 body is resting on those things, it's just like if I
23 were to go and stand on this head frame. I could
24 certainly imagine that appropriately manufactured
25 equipment that are tied in with the appropriate degree

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1 of torque could certainly slide.

2 They're not designed for that type of
3 stress, in my opinion.

4 DR. WILLIAMSON: Do you have evidence that
5 the screws were improperly tightened?

6 DR. HOWE: The licensee has sent the Y-Z
7 bars back to the manufacturer, but they just sent them
8 back to the manufacturer for review in the last month.

9 But we were concerned that so far the
10 manufacturer's information and other tests that have
11 been done -- and the licensee themselves took a new Y-
12 Z bar, and they had the RSO really pulled tight on it
13 and tried to move it, and they demonstrated it could
14 move, but it only moved millimeters.

15 But, again, the issue is not the distance
16 that was moved. It's whether it was an equipment
17 failure because once you have movement, all that
18 happened is that those Z bars slid down until the
19 frame hit the base of the gamma knife unit. So it
20 doesn't matter if it was one centimeter or a seven
21 centimeter translational movement. It was whether the
22 equipment failed or not.

23 I mean, that's the basic issue, and I'm
24 saying to you if I went and stood on this frame and
25 the frame was manufactured correctly and tied in with

1 the appropriate degree of torque, I would think that
2 it's perfectly understandable that that equipment at
3 that point would start to slide, and again, in this
4 particular instance with the specifics involved of a
5 very heavy man rising his whole body up, I could see
6 how that would happen in the case of appropriate
7 procedures.

8 CHAIRMAN MALMUD: If I may, it sounds as
9 if you have opinion from three members of the ACMUI
10 that in this one case of the five that you've cited,
11 that they perceive it to be a patient movement issue
12 rather than a licensee responsibility, and we would
13 hope that you would bring that into consideration in
14 this one out of five cases.

15 DR. HOWE: Okay.

16 CHAIRMAN MALMUD: May we move on to your
17 next item?

18 DR. HOWE: Our next one is the Yttrium
19 microspheres. In this case both of our medical events
20 were with the serospheres. We don't think the
21 Theraspheres (phonetic) are being used very much right
22 now. We think FDA is -- FDA approved the Theraspheres
23 under an HDE, which is a humanitarian device
24 exemption, and they're only supposed to be used for
25 specific types of diseases that -- for one disease

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1 under the humanitarian device exemption, and otherwise
2 they go into research, and we think FDA has probably
3 gone back to Theraspheres and making sure that
4 they're only being used for this one particular use it
5 has been approved for.

6 Serospheres, on the other hand, came
7 through a PMA, and once it comes through a PMA, then
8 under the practice of medicine, a physician can decide
9 to use it for a different treatment than it was
10 approved for. So we think there are probably more
11 serospheres applications out there now, and there are
12 very few Theraspheres.

13 In the first case there was a pressure
14 build-up, and the description was it was from the
15 liver catheter, and as a result one of the tubes on
16 the V value -- V vial popped off, and the microspheres
17 spilled out of the V valve, and they lost about 25
18 percent of the microspheres, and they continued the
19 procedure. So it was a medical event. They weren't
20 able to deliver the entire dosage.

21 The second one, the licensee had
22 difficulty measuring to the precision that they
23 believe they should have the Yttrium in the V vial
24 before they went to the OR space to deliver it, and
25 they came to a decision that they should use a visual

1 method of estimating how many spheres were left in the
2 V vial to determine the dose that they were going to
3 deliver.

4 They did not want to deliver the entire
5 dose. They only wanted to deliver a fraction of the
6 dose. So they carefully monitored the volume of the
7 V vial. They stopped the procedure when they thought
8 they had it at that point. They pulled the catheters
9 out. They ended the treatment, and then in accordance
10 with the manufacturer's instructions, they do a
11 measurement of the tubes and the materials afterwards,
12 and they found that the readings were much higher than
13 they had expected, and that a significant number of
14 the microspheres had caught up in the valve going into
15 the patient and had not, in fact, reached the patient.

16 So that was our second medical event.

17 CHAIRMAN MALMUD: So if I understand you
18 correctly, what happened is they did a visual estimate
19 of the amount of the activity delivered and then
20 discovered afterwards they had given a smaller amount
21 than they had anticipated giving to the patient.

22 DR. HOWE: Significantly smaller because
23 they had not realized -- and the manufacturer's rep.
24 was with them at the time, and they had not realized
25 that there would be as many of the microspheres caught

1 up in valve as there were.

2 CHAIRMAN MALMUD: Delivery device.

3 DR. HOWE: Yes.

4 DR. WILLIAMSON: Excuse me. What would
5 have been the normal pattern of use that would have?

6 DR. HOWE: The normal pattern of use would
7 have been using a radiation detection measurement to
8 verify how many, or the relative percentage, of the
9 microspheres that were delivered. So you put a meter
10 in a certain place, and you'd still be measuring all
11 of the spheres that are still within the delivery box
12 system.

13 CHAIRMAN MALMUD: That's a calibrated
14 approach to seeing what's left in the box versus
15 what's the identified.

16 DR. HOWE: Yes. It's not necessarily
17 calibrated because these are Yttrium microspheres. So
18 that you're not going to really measure that much in
19 the patient. You're not going to get that much of a
20 measurement coming off of the patient.

21 CHAIRMAN MALMUD: Scatter.

22 DR. HOWE: But you can use it to do a
23 more --

24 CHAIRMAN MALMUD: Thank you.

25 Dr. Nag, you had a comment?

1 DR. NAG: I do. I do the procedure
2 routinely, and therefore, I'd like to comment. First
3 of all, visually you cannot see what percentage. I
4 mean, I have tried making some estimations. You can
5 never make a visual guesstimate.

6 But the more important thing is that while
7 you're injecting, you really cannot say how many
8 microspheres put in. The only way you know it is
9 after the fact when you measure the V vials later,
10 within after a few minutes.

11 So, therefore, from my standpoint, what we
12 do is we write a prescription or the interactive as to
13 the total amount you wish to give, but at the end of
14 the procedure, you accept whatever you did here.

15 So let's say I wanted to give most of the
16 time it's about two Giga Becqerel to inject, and as
17 you're injecting, you're looking into the flow, and if
18 you see that the flow is not going well, you stop the
19 procedure irrespective of whether you are anywhere
20 near that two Giga Becqerel or not.

21 So you stop the procedure as soon as you
22 see medically you should not give any more, and then
23 you measure whatever is left, and you deduct that and
24 say we gave X number of Giga Becqerel , and you sign,
25 and if it is more than 20 percent below, then you say,

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1 well, you know, you are allowed to rewrite the
2 prescription because there was stasis or because you
3 cannot give any further dose.

4 So on the first patient I have no problem
5 because, you know, that was an absent thing, and there
6 was spillage, but on the second patient, you know, you
7 are allowed to, you know, rewrite your prescription
8 because you stopped it when you felt that, you know,
9 you had given enough, and you remeasure whatever is
10 left. You really cannot judge what you have given.

11 DR. HOWE: Dr. Nag, the guidance that we
12 have -- and your original statement was a little
13 questionable, but as you described it, it is in
14 accordance with our guidance. Our guidance is written
15 because we recognize that the serospheres is monitored
16 with fluoroscopy, and it is not important to give the
17 total dose. It's important to give the dose until you
18 see back scatter.

19 And that wasn't what happened in this
20 case, and we do expect people to report medical events
21 if they don't give what they expected because there is
22 a problem in the delivery versus your medical
23 endpoint, which is accepted by the NRC and it should
24 be part of your written directive, and that's stasis.
25 We recognize that as a part of medical practice.

1 But in this particular case, they weren't
2 monitoring for stasis.

3 DR. DIAMOND: So this would be an example
4 -- this is Dr. Diamond -- where I would agree with
5 you, Donna-Beth, because the intent to deliver was not
6 what was actually done. It's a matter of intent.

7 I would put it to you probably to say that
8 this was an example of an inexperienced team not fully
9 understanding it. So they were probably a little
10 conservative, a little tepid. They didn't want to go
11 and continue the administration of the isotope until
12 stasis had been achieved. They went in and probably
13 said, "let's just go and stop it once we estimate that
14 so-and-so activity has been delivered."

15 And then, lo and behold, they realize that
16 visual estimates of the V valve are very difficult to
17 make. So --

18 DR. NAG: Impossible.

19 DR. DIAMOND: It's impossible to make. So
20 this I would agree with Donna-Beth would be an example
21 that would meet the criteria.

22 DR. HOWE: And I think we were especially
23 concerned on this particular case because the
24 manufacturer was with them, and we would have expected
25 better guidance out of the manufacturer.

1 MR. LEITO: I was just mentioning that I
2 agree with that wholeheartedly because if the vendor
3 was here and they're not following a standard
4 protocol, they should have kind of said, you know, is
5 this really what you want to do, and caution them on
6 that.

7 It's very bothersome that the vendor was
8 there and didn't interact.

9 DR. HOWE: In this particular case, they
10 wanted to give a certain activity, and they believed
11 they had given that activity based on a less than
12 routine method of determining what that activity was,
13 and in fact, they had not because of equipment
14 problems.

15 DR. NAG: So they didn't up the activity
16 they wanted to. Normally --

17 DR. HOWE: No, they did not. They had a
18 vial with a set amount of activity. They tried
19 measuring it, and determining the activity they were
20 going to use. They were having a lot of problems
21 doing that to the level of expertise they wanted, and
22 so in the end, they decided we'll take it to the OR,
23 and we'll give 65 percent, and they didn't.

24 DR. NAG: But the question is if they
25 didn't know how much they drew up, then how could --

1 they measured the amount of residual. What did they
2 subtract from? Do you mean they took the whole vial
3 instead of drawing up a second amount?

4 DR. HOWE: That's correct.

5 DR. NAG: Well, that's not -- that's not
6 acceptable.

7 DR. HOWE: And that's part of their --
8 their corrective action is to take the time, draw up
9 the right amount, and deliver it. They, too, have the
10 ability to stop at stasis, and no one wants to have
11 medical events reported when the physician is making
12 the determination that stasis is reached, and that's
13 why we put that in the guidance. We're hoping that
14 the physicians are putting that in their written
15 directive.

16 So you're not really revising the written
17 directive, Subir. You are actually -- the written
18 directive should say you're going to deliver this
19 amount --

20 DR. NAG: Or stasis.

21 DR. HOWE: -- or stasis, and allows you to
22 write how much you delivered if you went to stasis.
23 So you're not really revising the written directive,
24 but you are recording exactly what you intended to do.

25 CHAIRMAN MALMUD: Dr. Howe, let the record

1 show that the members of the committee are fully
2 supportive of your recommendation in this case.

3 DR. HOWE: Okay.

4 CHAIRMAN MALMUD: May we move on to the
5 next one?

6 DR. HOWE: I think that may be the end.

7 CHAIRMAN MALMUD: Thank you very much.

8 DR. HOWE: Okay.

9 CHAIRMAN MALMUD: It being 12:10, I will
10 turn the opportunity over to Mr. Essig if he wants to
11 say anything. If not, we'll adjourn for lunch.

12 MR. ESSIG: We can adjourn.

13 CHAIRMAN MALMUD: We are hereby adjourning
14 for lunch. We'll return promptly at 1:15.

15 Thank you all. Thank you, Dr. Howe.

16 (Whereupon, at 12:10 p.m., the meeting was
17 recessed for lunch, to reconvene at 1:15 p.m., the
18 same day.)

19 CHAIRMAN MALMUD: Okay. Let's get moving.

20 DR. ZELAC: I'm sorry that Dr. Nag isn't
21 here for these opening remarks. But I will proceed
22 anyway.

23 CHAIRMAN MALMUD: He is here. We had
24 lunch together.

25 PARTICIPANT: He was here just a moment

1 ago.

2 DR. ZELAC: Okay. There he is. Good
3 timing. We held up the meeting just for you.

4 (Laughter.)

5 DR. ZELAC: Okay. I wanted to start by
6 once again thanking the Advisory Committee for the
7 recommendations which it provided and particularly for
8 the efforts of the Medical Events Subcommittee. The
9 document that was produced, and I know a lot about the
10 effort that went in since I was the assigned staff
11 member, really makes it easy for us to utilize this
12 information and move ahead.

13 This morning or this afternoon, this is
14 the next step in this ongoing process of looking at
15 the medical event definitions and, when necessary,
16 suggesting modifications that the Commission can
17 consider.

18 Where we are at the moment, as you can
19 appreciate, is staff having received the
20 recommendations from the Subcommittee -- from the
21 Advisory Committee, has now drafted a Commission paper
22 which you on the Committee have had an opportunity to
23 see.

24 And I'm going to review what the paper
25 says essentially, this draft paper, with respect to

1 the various recommendations that were included in the
2 document that we received from you.

3 Just in the way of background, you, the
4 Advisory Committee, in looking at a specific event and
5 in response to our desire for input from you,
6 recommended in November of `03 that D90 be utilized as
7 the criteria for prostate therapy under-dosing. The
8 same criteria, however, was recognized immediately as
9 not appropriate for the overdosing situation.

10 In March of `04, at the time of your
11 opportunity to speak with the Commission, we, the
12 staff, received direction from the Commission to
13 consider the basis and adequacy of medical event
14 definitions as they appeared in the regulations and as
15 well to look at communicating associated risks to the
16 public. And these efforts on our part were to be done
17 in conjunction with input from you as the Advisory
18 Committee.

19 From the period of October of `04, a year
20 ago, to the end of this past July, the Advisory
21 Committee, you, developed recommendations on these
22 issues for staff's use. There are actually several
23 categories that were considered in these overall
24 recommendations.

25 The first was the basis for the plus or

1 minus 20 percent of prescribed dose reporting
2 threshold for medical events that appears in the
3 current regulation. The Commission wanted us to look
4 at it again and determine whether or not this indeed
5 was an appropriate threshold for medical event
6 reporting for all modalities.

7 The second area in which you provided
8 recommendations were on specifically the current
9 definition itself. When it was appropriate and when
10 it might not be appropriate.

11 And finally, you provided recommendations
12 on the last question that the Committee posed to us
13 which was improving public understanding of the risks
14 associated with medical events.

15 Now I'm going to essentially tell you what
16 our response is to these three different areas or
17 categories on which you provided recommendations.

18 The first, the basis for the plus or minus
19 20 percent of prescribed dose as the reporting
20 threshold for medical events. You recommended that we
21 retain it -- plus or minus 20 percent of the delivered
22 dose variation from prescription as an appropriate
23 threshold for medical event reporting for all
24 modalities except permanent implant brachytherapy.
25 Staff endorses and supports this ACMUI recommendation.

1 CHAIRMAN MALMUD: Malmud, thank you.

2 DR. ZELAC: You included in your
3 recommendations a caveat that medical events should
4 not be treated by us as surrogates or harbingers of
5 patient harm. Or even necessarily of increased
6 probability of patient harm.

7 You indicated that medical events, in your
8 judgment, should be considered as a quality assurance
9 performance index indicative of technical or QA
10 problems and accurately realizing the authorized
11 users' intentions.

12 We, staff, endorse and support this ACMUI
13 position which is, in fact, consistent with NRC's
14 previously stated position.

15 CHAIRMAN MALMUD: Thank you Dr. Zelac.
16 Next, permanent implant brachytherapy. Your
17 recommendations for reformulating the medical event
18 reporting rule with respect to this modality as well
19 as associated definitions. You provided six
20 recommendations, and I'll start by telling you that we
21 endorse and support all of these recommendations in
22 this item.

23 And I'm simply going to reiterate them in
24 the way that I have, in some cases, reworded them
25 perhaps, hopefully, adequately to reflect your intent

1 from your recommendation sheet that we received in
2 July.

3 The first, for all permanent implants,
4 medical events should be defined in terms of the total
5 source strength implanted in the treatment site, not
6 in terms of absorbed dose.

7 At any time, if you wish to interject,
8 please feel free to do so.

9 Continuing, second, any implant in which
10 the total source strength implanted in the treatment
11 site deviates from the written directive, and that
12 means the written directive prepared prior to the
13 implantation, where there is deviation from the
14 written directive by more than 20 percent in either
15 direction, this treatment should be classified as a
16 medical event.

17 However, as in the current medical event
18 rule, the Advisory Committee intends that seed
19 migration be specifically excluded as grounds for a
20 treatment site accuracy medical event. Again, we
21 completely accept this recommendation.

22 Third, implants in which more than 20
23 percent of the total source strength documented in the
24 pre-implantation written directive is implanted in
25 tissue or organs adjacent to the treatment site, which

1 means within three centimeters of the treatment site
2 boundary, these implants should be classified as
3 medical events.

4 In other words then if more than 20
5 percent of what the physician had indicated would be
6 used in terms of the amount of activity in the pre-
7 implantation written directive winds up in tissue or
8 organ adjacent to the treatment site, that treatment
9 should be classified as a medical event.

10 And again, seed that were correctly
11 implanted but subsequently migrated are excluded as
12 grounds for a medical event.

13 Ralph?

14 MEMBER LEITO: I think the words greater
15 than should be in there. This makes it sound like if
16 it is within three centimeters it is a medical event.

17 DR. ZELAC: That was the intent. That was
18 the intent of the recommendation. Not in the target
19 volume but in the tissues or organs that would be
20 surrounding the target volume but within three
21 centimeters, i.e., those that were nearby.

22 If 20 percent of the total --

23 MEMBER LEITO: You can't have more than 20
24 percent --

25 DR. ZELAC: -- activity --

1 MEMBER LEITO: -- that's correct.

2 PARTICIPANT: It was greater than.

3 DR. ZELAC: Yes, if 20 percent of the
4 total activity that had been prescribed for putting
5 into target volume wound up in this adjacent treatment
6 site --

7 MEMBER WILLIAMSON: We had two criteria
8 for wrong site. There was an adjacent tissue wrong
9 site and a distant organ wrong site.

10 DR. ZELAC: This is the first of those
11 two.

12 MEMBER WILLIAMSON: Yes.

13 DR. ZELAC: So it doesn't go into the
14 target, it goes into the tissues or organs surrounding
15 but near to the target. If you exceed 20 percent
16 going into that perimeter, if you will, that becomes
17 a medical event.

18 Next, and here we are to the other one,
19 this one is longer because this is not only a
20 placement but also then has some dose criteria
21 associated with it. Implants should be classified as
22 medical events if:

23 One, the sealed radioactive sources are
24 implanted in distant tissues or organs, meaning beyond
25 three centimeters from the treatment site;

1 Two, the excess dose to the distant tissue
2 or organ exceeds .5 sievert, 50 rem; and

3 Three, the excess dose to the tissue or
4 organ is at least 50 percent greater than the dose
5 that would have been delivered had the seeds been
6 implanted in the correct tissue volume.

7 The last two of those three conditions, of
8 course, mirror what exist in the regulation today.

9 Seeds that were correctly implanted but
10 subsequently migrated are excluded as grounds for a
11 medical event.

12 Next, the authorized user is to complete
13 any revisions to the written directive for permanent
14 implants to account for any medically necessary plan
15 adaptations or by the wording of our current regulation,
16 the authorized user is to complete the written
17 directive before the patient is released from licensee
18 control following the implantation procedure and
19 immediate postoperative period.

20 The switch from a dose based to an
21 activity based permits the practitioner to account for
22 what went where it should and what went somewhere else
23 as soon as the implementation is done and to so make
24 modifications if necessary to the written directive as
25 opposed to weeks or months later based on a dose

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1 criteria.

2 Next, an implant is a medical event if the
3 dose calculations used to determine the total source
4 strength that is documented in the written directive
5 to achieve the authorized user's intention for
6 absorbed dose to the target volume are an error by
7 more than 20 percent in either direction.

8 Okay? Just in case you didn't know who I
9 was.

10 (Laughter.)

11 DR. ZELAC: Again, in summary, for this
12 section of your recommendations, we endorse and
13 support all of these six items that you provided. And
14 this will be reflected in the Commission paper which
15 you have seen.

16 CHAIRMAN MALMUD: Malmud, thank you.

17 DR. ZELAC: Now that leaves one item and
18 that has to do with improving public understanding of
19 the risks associated with medical events.

20 You may recall from the meeting or
21 meetings at which the recommendations from the
22 Subcommittee were discussed that you as a group
23 eventually provided some general guiding principles
24 and, in addition, four specific recommendations for
25 improving public understanding of these risks.

1 Before we get into the remainder of the
2 slides, let me tell you that we, staff, at this point
3 do support the general guiding principles that you
4 provided. And those will be included as
5 recommendations that we make to the Commission.

6 However, we do not support the four
7 specific recommendations that you offered in this
8 area. I will go over them one by one and provide you
9 with some reasons why I said what I just did.

10 The first of these recommendations was
11 that the patient reporting requirement which exists in
12 35.3045(e) should be amended to require informing the
13 patient and/or friends and relatives only if the
14 licensee determines that the medical event may have
15 harmed the patient, could potentially harm the
16 patient, or is materially relevant to the patient's
17 future medical treatment decisions.

18 We did not support -- we do not support
19 this Advisory Committee recommendation for the
20 following reason. The Commission has repeatedly
21 stated and endorsed its position that a patient or
22 human research subject involved in a medical event
23 should be notified of the occurrence.

24 Most recently, and this appeared in the
25 Federal Register notice for the revision of Part 35 in

1 2002, and I quote:

2 "The NRC retained the proposed
3 requirements for notifying individuals following a
4 medical event in the final rule. As stated in the
5 proposed rule," and the citation is given, "this
6 position reaffirms statements made by the Commission
7 during the mis-administration rulemaking earlier that
8 patient notification recognizes the right of
9 individuals to know information about themselves which
10 is contained in records both inside and outside the
11 federal sector."

12 There are other things that I could say
13 but that, in essence, is the reason.

14 MEMBER WILLIAMSON: Well, I haven't had a
15 chance to read your report carefully line by line and
16 I see you've put the staff's rationale for, you know,
17 rejecting our recommendation. I hope you will put our
18 rationale for proposing this recommendation in there.
19 Or have.

20 DR. ZELAC: The recommendations
21 themselves, the document that was received by us from
22 you is an attachment, in its entirety, to the
23 Commission paper. So the Commissioners and their
24 technical assistants in reviewing this entire issue
25 will have the full information and the full rationale

1 provided by the Advisory Committee as well as the
2 comments made by staff in terms of its proposed action
3 on each of the recommendations. So that was the first
4 of the four.

5 The second, NRC's medical reporting event
6 and follow-up procedures should be designed to not
7 increase licensee liability. Keeping medical event
8 reports or at least the licensee's identity out of the
9 public record is probably the single most useful
10 improvement NRC could make in this regard.

11 Again, this is a recommendation, a
12 specific recommendation that we did consider and our
13 recommendation to the Commission is that we not move
14 in this direction. We don't support this
15 recommendation because it is counter to the
16 Commission's policy of public openness in the conduct
17 of its business consistent with national security.

18 A current statement of this policy of
19 openness appears in the 2004-2009 Strategic Plan for
20 the Commission. Specifically Goal 3, Our Openness,
21 and I quote:

22 "The NRC views nuclear regulation as the
23 public's business and as such it should be transacted
24 openly and candidly in order to maintain the public's
25 confidence. The goal to ensure openness explicitly

1 recognizes that the public must be informed about and
2 have a reasonable opportunity to participate
3 meaningfully in the NRC's regulatory processes."

4 And reading on, "The NRC believes in the
5 importance of transparency in its communications as
6 well as early and meaningful public involvement in the
7 regulatory process. The agency is committed to
8 keeping the public informed and believes that a
9 responsible and effective regulatory process includes
10 an involved public that is well informed."

11 CHAIRMAN MALMUD: Dr. Williamson?

12 MEMBER WILLIAMSON: Well, all of those are
13 rationales for involving the NRC in its decision-
14 making process. I am not aware that the NRC involves
15 the public in its disciplinary or technical decisions
16 regarding individual events such as this.

17 And I will also note that, you know, you
18 certainly do not follow this statement to the point of
19 extremity that you are articulating, you know. It's
20 not -- you do withhold certain information that has
21 nothing to do with the national security. And a good
22 example is you withhold individual patient names and
23 identities.

24 DR. ZELAC: Well, that's clearly -- to do
25 other than that would be counter to everybody's

1 position not just this agency's. So I don't think
2 that's a particularly good example.

3 PARTICIPANT: Yes, right. That's a
4 privacy issue.

5 PARTICIPANT: Under HIPAA, you are
6 obligated to.

7 MEMBER WILLIAMSON: Well, I mean it points
8 out that there are other considerations besides
9 national security in not releasing information. And,
10 you know, I think the arguments about transparency,
11 you know, really have nothing to do with this
12 position.

13 The decision-making processes could be as
14 transparent as they can be but you do not have to
15 release identities in all cases of corporate entities
16 that you regulate.

17 DR. ZELAC: There's a lot that goes into
18 this. For example, say there is a medical event at a
19 hospital here in D.C., okay? And an announcement goes
20 out, a press release or whatever that this event
21 occurred.

22 Now the public is put in the position of
23 knowing that something occurred at a hospital
24 somewhere in their vicinity but not knowing which one.
25 Do you think that is very satisfying from the public's

1 point of view? I don't. I think they would lose
2 confidence frankly in us as the regulator by not
3 making this information available to them.

4 MEMBER LEITO: I think there was nothing
5 in this recommendation that precluded or said that the
6 public would not be informed. I think the issues has
7 to do with the fact of making it a public announcement
8 before any investigation has occurred. And before its
9 even actually been determined that it is an actual
10 medical event that needs to be brought to the
11 attention of the public.

12 And I think all those statements that you
13 made here I don't think anybody has a problem with
14 except the only thing is I think this national
15 security issue is really not appropriate here.
16 There's nothing that deals with --

17 DR. ZELAC: Of course not. But --

18 MEMBER LEITO: -- national security here
19 in terms of reporting. But there was nothing I think
20 in this recommendation that was intended that the
21 public would not eventually be informed of the
22 incident and maybe the licensee that was involved.

23 It's just that, like I said, how it's done
24 basically makes this a public -- a national
25 announcement, okay, on an unsecured web location that

1 precludes, you know, any determination that it's even
2 valid to begin with.

3 DR. ZELAC: Let me make two comments in
4 response. First, with respect to information being
5 made available immediately, as we pointed out quite
6 correctly yesterday, most of the licensees, and that
7 include medical licensees, are in agreement states.
8 That's not, you know, debatable. They are.

9 And the agreement states have the
10 opportunity when submitted information about an event
11 to request that it be held from posting for a period
12 of time which I believe has a limit of two days, 48
13 hours. It might be a little more but I think it's --
14 in any case, just to that exactly what you're speaking
15 about can be assessed by the regulatory group.

16 Is this, in fact, a reportable medical
17 event? No, is there any reason why we at the agency
18 couldn't do the same? I don't know but that's
19 certainly something that could be and should be
20 considered to handle the first of your comments.

21 The second is looking specifically at the
22 words of the recommendation, NRC's medical event
23 reporting and follow-up procedures should be designed
24 to not increase licensee liability. Keeping ME
25 reports out of the public record is probably the

1 single most useful improvement NRC could make in this
2 regard. That's the substance of the recommendation.

3 MEMBER WILLIAMSON: It is the substance.
4 That's correct.

5 DR. ZELAC: Don't put medical event
6 reports in the public record. And I think that is
7 extremely counter to the position that the agency has
8 and continues to have and I expect will have in the
9 future with respect to the release of information to
10 the public.

11 We used to even put out more information
12 and a lot of that has been pulled back for national
13 security reasons. But that which can be made
14 available by the Commission's policy, directive, and
15 intent is made available. So it would have to be a
16 hugely important and overriding rationale for not
17 reporting medical events. I frankly don't see it.

18 MEMBER WILLIAMSON: What actually the
19 recommendation says is to the extent possible, NRC's
20 medical event and follow-up procedures should be
21 designed to not increase licensee liability. Keeping
22 medical events reports or at least the licensee's
23 identity out of the public record is probably the
24 single most -- so it's a little more complex than you
25 presented.

1 DR. ZELAC: Yes.

2 MEMBER WILLIAMSON: It wasn't -- it did
3 not say unequivocally keep the medical event out of
4 the public record but it does suggest that in many
5 cases where there isn't any question of public safety,
6 you could do that. And that would substantially
7 improve, I think, the value of medical event reporting
8 as a quality assurance tool.

9 DR. ZELAC: Dr. Diamond?

10 MEMBER DIAMOND: Yes, Dr. Zelac, from my
11 perspective what we were trying to do -- at least I
12 was trying to do with my input was we are trying very
13 hard to make the ME reporting a quality assurance
14 indicator and in no way denote some patient error.

15 By -- I was hoping that until such time as
16 the staff could review a medical event report and, in
17 fact, conclude that it is reportable and then make
18 some basic determination whether some harm existed or
19 potentially could exist, that by going through that
20 algorithm, some basic checks if you will, that could
21 go and serve as a very reliable or robust was of
22 allowing the licensees to actually feel confidence
23 that this is a QA indicator and not necessarily
24 punitive.

25 Let's take an example.

1 DR. ZELAC: I'm actually with you with one
2 exception and that was when you put in the words
3 relating to patient harm. If you exclude that, the
4 rest of it we're right on track.

5 MEMBER DIAMOND: Well, for example, let's
6 take an example of ASTRO: Brachytherapy procedure
7 where the intent of the licensee is to go -- or the
8 authorized user is to radiate the coronary vessel.
9 And let's say you're doing the procedure and for a
10 total of 15 seconds, the source gets stuck in the
11 common iliac artery.

12 And then the flow is released. The
13 procedure is carried out. It is a reportable medical
14 event because wrong site however everyone is in
15 agreement that there was no possibility of patient
16 harm.

17 We are trying to encourage the licensees
18 to report that type of incident so that the
19 manufacturer can be made aware, the states can be
20 aware, and corrective action be taken on the
21 manufacturing side. We're trying to get these things
22 captured for the public good.

23 But to go and release that information
24 without any context I think serves to impede that goal
25 rather than promote it. There's no way that an

1 individual or a member of the public has been harmed
2 by that event. And what it actually will do is impede
3 the licensees' sense that this actually is a QA
4 indicator.

5 That's the flavor of what I was trying to
6 get through.

7 DR. ZELAC: Do you think that the event
8 that you just described is indicative of something
9 relating either to the equipment or to the procedures
10 used by the licensee as in need of improvement?

11 MEMBER DIAMOND: Certainly. And that's
12 why I want to make sure that it is captured. I want
13 all the licensees to understand that there are issues
14 either with operator or with manufacturing. We need
15 to capture those.

16 What we don't want to do is have a little
17 situation where the authorized user or the AMP is not
18 reporting that because they are so afraid that the sky
19 is going to fall down upon them.

20 DR. ZELAC: Well, that really gets to some
21 of the other recommendations that you've made
22 specifically.

23 MEMBER WILLIAMSON: Where you
24 unnecessarily --

25 MEMBER DIAMOND: I mean is that kind of

1 the sense --

2 DR. ZELAC: Yes, I understand exactly what
3 you're saying.

4 MEMBER DIAMOND: So the question is how do
5 you put that in statute? That's the tough part.

6 DR. ZELAC: Well, the other way, of
7 course, is to take a look at the other element and
8 that is the overall objective of improving public
9 understanding of what a medical event means.

10 So you remove from public thought the
11 possibility of it necessarily having any relationship
12 to patient harm. But you instill the thought that it
13 does relate to the procedures themselves and possible
14 improvements required for the procedure by the users.

15 MEMBER DIAMOND: This is Diamond again.

16 MEMBER WILLIAMSON: Or the equipment.

17 MEMBER DIAMOND: I will say that I am less
18 uncomfortable with the staff's decision because of the
19 fact that you did endorse our position very clearly
20 that we're trying to decouple this as a denotation of
21 harm.

22 So yes, if it were up to me would I keep
23 it the way that you are recommending it at this time?
24 Absolutely not. But do I feel a lot better that I can
25 go out to my colleagues and the professional societies

1 and say the NRC staff endorses this position of
2 decoupling, that's going to make everyone feel better.

3 CHAIRMAN MALMUD: Mr. Bailey?

4 MEMBER BAILEY: I too have a problem with
5 the automatic posting. And as you are aware, many of
6 the states have had problems with that. And most
7 often brought up is that we don't know what is going
8 on but we are required to report it.

9 I can tell you that we have seen two
10 negative actions to things being posted immediately.
11 The first one is the licensee instead of dealing on a
12 technical level confronts the inspectors with lawyers.
13 And the risk management people get involved. And it
14 makes the investigation more difficult.

15 The flip side of that is where an employee
16 is involved. We have a very good case now where as
17 soon as it sort of hits the press there are a group of
18 lawyers that want to make sure that someone pays.
19 Them usually. Pays to them money. And so all of a
20 sudden, the people who were there when the accident
21 occurred don't want to talk to us either.

22 So it really -- it's not conducive to a
23 good investigation. Now when you say things can be
24 withheld, I would certainly hope that -- and this is
25 sort of preaching for the agreement states and not so

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1 much you -- is that there could be a mechanism
2 generated where we say this is under investigation
3 just as we do with our own public records.

4 We say this is under investigation. We
5 will not tell you until the investigation is closed.
6 And we need the same mechanism, and I think the
7 medical facilities need the same mechanism where
8 sometimes incorrect information is put out under the
9 guise of openness and that information turns out to be
10 totally erroneous.

11 And that's all I'm saying. We need some
12 mechanism where everything just doesn't have to
13 automatically go out.

14 MEMBER WILLIAMSON: I think our whole
15 argument was it does harm to the process. It
16 diminishes and undercuts the very effectiveness of the
17 program you seek to promote. And so fine. If you
18 want to be a QA kind of process for show that's not
19 real, like window dressing, well then just keep it
20 this way.

21 DR. ZELAC: Can I make a suggestion to the
22 Committee?

23 CHAIRMAN MALMUD: Please do.

24 DR. ZELAC: The paper that you have
25 opportunity to review is a draft. And that was the

1 whole purpose of bringing it to you to see what your
2 reactions to it would be.

3 There is absolutely nothing that would
4 prohibit -- and, in fact, I am encouraging you to
5 focus some additional attention on this and to provide
6 something else as a rationale to further support what
7 you've said in your recommendations perhaps or to
8 expand on them or just amplify them or bring them more
9 to the forefront.

10 And that certainly could be included as an
11 attachment to the Commission paper or embedded in it.
12 You know obviously there are a lot of reasons why, you
13 know, this recommendation was made to begin with.

14 CHAIRMAN MALMUD: Dr. Suleiman?

15 MEMBER SULEIMAN: Yes, the way I interpret
16 what's being done here, this is raw data. I mean --

17 PARTICIPANT: Correct. It's very raw.

18 MEMBER SULEIMAN: And you've got to be
19 careful about -- even when you've analyzed and reached
20 a decision sometimes the wrong people misinterpret it
21 and it causes problems. And I think we've been the
22 victims of some of that anyway.

23 But I think it is raw data. And so there
24 wouldn't be anything improper to hold back on
25 reporting it until it has been analyzed in a more --

1 in a better way.

2 DR. ZELAC: Just for my own clarity and
3 understanding what you've just said, you're not
4 addressing the issue of the licensee contacting the
5 regulator.

6 MEMBER SULEIMAN: No.

7 DR. ZELAC: You're addressing the issue of
8 the regulator releasing this information to the
9 public.

10 MEMBER SULEIMAN: Correct.

11 CHAIRMAN MALMUD: Exactly.

12 DR. ZELAC: Okay.

13 CHAIRMAN MALMUD: Exactly.

14 Go ahead, Dr. Diamond?

15 MEMBER DIAMOND: This is Diamond. I'd
16 like to make a motion. The motion would be that the
17 ACMUI recommends to the NRC staff that the staff does
18 not make available to the general public a medical
19 event until such time as the staff has number one,
20 confirmed that it is a reportable medical event, and
21 two, that the staff concludes that there is at least
22 a meaningful likelihood that there may be a patient
23 harm.

24 MEMBER LEITO: Is there a second to Dr.
25 Diamond's motion?

1 PARTICIPANT: For the sake of discussion,
2 I'll second.

3 CHAIRMAN MALMUD: All right. Dr. Nag?

4 MEMBER VAN DECKER: No, I second it.

5 CHAIRMAN MALMUD: Oh, okay. May I address
6 the motion?

7 MEMBER DIAMOND: Of course.

8 CHAIRMAN MALMUD: The first part that's
9 reportable, I think we all agree. The problem with
10 the meaningful likelihood of patient harm is that many
11 of the exposures that we're talking about will really
12 never result in patient harm but are clearly in
13 violation of regulation.

14 So perhaps you can find some other words
15 to express the same thing rather than meaningful
16 likelihood of patient harm.

17 MEMBER DIAMOND: Well again, what are we
18 trying to do? We're trying to capture the events,
19 make sure that they are reported to the states or to
20 the NRC so that they can be evaluated, analyzed, and
21 at the same time, we're trying to prevent needless
22 anxiety and concerns by the widespread dissemination
23 of details regarding individual cases when we know
24 that there is no meaningful likelihood that any
25 potential harm could occur. That's what I'm trying to

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1 express.

2 CHAIRMAN MALMUD: Mr. Leito?

3 MEMBER LEITO: My understanding of Dr.
4 Diamond was that they are all getting reported, you
5 know, all these events are getting reported. But then
6 there is this analysis as to, you know, does this
7 really -- is there some harm or likelihood of harm
8 that needs to get out into the -- you know, needs to
9 also be reported to the -- or that the public needs to
10 be informed on.

11 Not necessarily that they are going to do
12 anything. But that as opposed to a number of these
13 events that just have nothing to do with anything that
14 the public would need to get involved in or need to be
15 informed about.

16 DR. ZELAC: Can I make a comment at this
17 point?

18 CHAIRMAN MALMUD: Yes, Dr. Zelac.

19 DR. ZELAC: Part of the reason for the
20 release of information about a medical event is to
21 raise the awareness of others promptly to this
22 occurrence so that they perhaps could consider the
23 possibility of similar things occurring at their same
24 facilities.

25 PARTICIPANT: You wouldn't need to release

1 a name to do that.

2 DR. ZELAC: No, you would not. I agree.

3 CHAIRMAN MALMUD: Whoever was next.
4 Either Mr. Leito or Dr. Nag.

5 MEMBER NAG: Okay. You know, David, you
6 made two motions within one motion, okay? I would
7 separate them. The first part of your motion was that
8 the NRC does not release the reported medical event
9 until it has the time to investigate that. And really
10 make sure that it is a reportable medical event.
11 That's one motion. And I fully support that motion.

12 The second part, I think, should be made
13 as a separate motion because there may be more debate
14 in that as like, for example, Orhan said, that do we
15 want to link this up and let people be aware that
16 these sort of events can happen so that the other
17 medical -- other authorized users are aware about
18 these possibilities. And can prevent it from
19 happening in their own place.

20 CHAIRMAN MALMUD: Dr. Diamond?

21 MEMBER DIAMOND: So if I may, I would like
22 to amend my motion. The amendment would be firstly,
23 that the NRC Advisory Committee recommends that the
24 NRC staff release the details of a medical event to
25 the general public only after such time as the staff

1 has confirmed that it is a reportable medical event.
2 That's Motion No. 1.

3 Then the second motion would be again that
4 the Advisory Committee recommend to the NRC staff that
5 the details of a given medical event be released to
6 the general public only if the staff determines that
7 there is any reasonable risk of potential patient
8 harm.

9 CHAIRMAN MALMUD: That's a motion.

10 MEMBER NAG: Two motions.

11 PARTICIPANT: I'll second the first
12 motion.

13 MEMBER DIAMOND: I decoupled it for you.

14 CHAIRMAN MALMUD: All right. Was there a
15 second to those two motions?

16 PARTICIPANT: Second.

17 CHAIRMAN MALMUD: Now may I ask a
18 question? What would happen if a patient were harmed
19 during a radiotherapy procedure and the NRC did not
20 release the information but instead the patient's
21 brother-in-law, a local lawyer, notified the press
22 that this had happened.

23 And there was no indications that the
24 responsible federal agency or state agency was
25 actively pursuing it at the time that the press

1 release came out from an interested party other than
2 the party who should be investigating it.

3 That would diminish the public's
4 confidence in the regulatory process. So how do we
5 separate what I know you are addressing, which are
6 really issues that are relatively inconsequential,
7 from significant issues. And sometimes there is a gray
8 area as to what is significant or not so as to
9 maintain public confidence in the oversight of the
10 regulatory process, and and yet not create crises
11 where there are none, which is what you are trying to
12 avoid.

13 MEMBER DIAMOND: This is Diamond again.
14 What we're trying to do is number one, make sure that
15 the information that is disseminated is meaningful
16 information. So, for example, if the release of
17 medical events to the general public is limited only
18 to events that we have confirmed to be reportable
19 medical events, that has eliminated a lot of trash.
20 Right?

21 If the staff deems that this does not meet
22 the reporting requirements, then we've been able to
23 produce data that is of true interest to the public.
24 That's number one.

25 The second point, which has to do with

1 dissemination of information regarding a given event,
2 what I am trying to do is I am trying to capture all
3 of this data for the authorities but only release the
4 details, the specific details, the details that could
5 identify the licensees, the authorized users, for
6 example, only release that type of identifiable
7 information regarding an event if there is any
8 likelihood of risk.

9 In other words, the example that I used
10 before of an Iridium-192 ASTRO; Brachytherapy source
11 being stuck in the common iliac artery for ten
12 seconds, yes, it is a medical event. It is a medical
13 event but we know that there is no potential risk
14 really to that patient of a meaningful or reasonable
15 degree. Why is it necessary that the Ohio State
16 University, Subir Nag, authorized user, da-da-da-da
17 -- be detailed.

18 Again, we want Subir to report his errors.

19 (Laughter.)

20 MEMBER NAG: I don't have any.

21 (Laughter.)

22 MEMBER DIAMOND: We're trying to encourage
23 it so we can go and fine tune the system that he
24 inadequately designed but we also don't want to go and
25 impede that so that when I go and speak to Subir all

1 I speak to is the Ohio State University general
2 counsel and the legal team.

3 So again, what I'm trying to do is the
4 information can be released as a general informational
5 summary or as a notice. But we don't need to
6 necessarily release the identifying information that
7 would cause anxiety in Dr. Nag unless there was any
8 reasonable likelihood that there could have been a
9 harm.

10 CHAIRMAN MALMUD: Dr. Diamond, I
11 understand the goal. And I agree with the intent.
12 I'm just concerned about how we achieve it. But I'm
13 not sure that it is contained in the motion.

14 But Mr. Bailey wants --

15 MEMBER BAILEY: You asked what would the
16 reporters say or whatever, I think this occurs on a --
17 well certainly not daily but fairly frequently. We'll
18 get a call about something that has occurred, whether
19 it be a traffic accident or whatever.

20 Normal response is yes, we are aware of
21 it. It's under investigation. And when more
22 information becomes available, we will give it to you.
23 And I think that works better than sometimes the
24 opposite happens when somebody puts out a press
25 release and then has to say the next day, oh, never

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1 mind, you know, it really wasn't that big a deal.

2 So I think it is the appearance of the
3 agency. If the agency seems to always throwing stuff
4 out there, it's like I want another press clipping or
5 whatever as opposed to being right up front with the
6 reporter and saying yes, we know there is this
7 allegation or we know there has been this accident.
8 And we are in the process of investigating.

9 CHAIRMAN MALMUD: So, Mr. Bailey, are you
10 supportive of Dr. Diamond's double motion?

11 MEMBER BAILEY: I think I am.

12 MEMBER DIAMOND: Let's talk about Motion
13 1 and Motion 2.

14 CHAIRMAN MALMUD: All right Motion 1, do
15 you want to take a vote on Motion 1? Or you have some
16 more to discuss on Motion 1?

17 MEMBER BAILEY: That was actually Motion
18 2 but I'm not sure.

19 MEMBER NAG: I think Motion 1 is far
20 easier.

21 CHAIRMAN MALMUD: Yes.

22 MEMBER NAG: Motion 2 has more discussion.
23 So I would like to --

24 CHAIRMAN MALMUD: Do you want to call the
25 vote on Motion 1? Okay. Just reread it.

1 MEMBER SCHWARZ: Dr. Malmud, would you
2 reread the motion please?

3 CHAIRMAN MALMUD: Could Motion No. 1 be
4 reread?

5 PARTICIPANT: Repeated perhaps as the case
6 may be.

7 PARTICIPANT: I make it up as I go along.
8 (Laughter.)

9 PARTICIPANT: He recommends that the NRC
10 staff release the details of a medical event to the
11 general public only after such time as they have
12 confirmed that it is a reportable medical event.

13 CHAIRMAN MALMUD: Thank you. That's
14 Motion No. 1. All in favor of Motion No. 1? Any
15 opposed? Any abstentions? So it is unanimously in
16 favor of the motion.

17 All right, now Motion -- oh, Dr. Miller.

18 DR. MILLER: What I'm going to do here is
19 I'm going to comment after you have voted on each of
20 the motions.

21 CHAIRMAN MALMUD: Okay. Thank you.

22 DR. MILLER: That motion is related to the
23 timing of the release of the information.

24 CHAIRMAN MALMUD: Yes.

25 DR. MILLER: That motion, I think that the

1 staff could entertain with regard to making a
2 recommendation to the Commission without prejudging
3 the conclusion that we come to.

4 CHAIRMAN MALMUD: Thank you.

5 Are we moving on to the second motion? Or
6 do you want to -- do you have discussion regarding --

7 MEMBER WILLIAMSON: I want to ask a
8 question about Motion 2.

9 CHAIRMAN MALMUD: Dr. Williamson has a
10 question about Motion 2, Dr. Diamond.

11 MEMBER WILLIAMSON: Can you clarify, Dr.
12 Diamond, if this was indeed your intent that when you
13 say release details of the procedure, you mean
14 identifying --

15 MEMBER DIAMOND: Right.

16 MEMBER WILLIAMSON: -- details that would
17 identify the patient and licensee.

18 MEMBER DIAMOND: This is Diamond again.
19 Based upon the input of my fellow members, perhaps I
20 can amend once again my second motion to improve the
21 language. Perhaps the motion should read the Advisory
22 Committee recommends to the NRC staff that the
23 identifying details of a specific medical event only
24 be released to the general public in such cases where
25 the NRC staff determines that there is a potential

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1 risk of patient harm.

2 MEMBER NAG: I would like to amend the
3 amendment. I think when you hear identifiable, I
4 would like it to be clearly stated whereby identifying
5 parameters of the patient, the authorized user, and
6 the institution. I mean these are the identifiable
7 things that should not be released.

8 CHAIRMAN MALMUD: We have to remember that
9 we shall not identify the patient. We don't have the
10 right to do that.

11 MEMBER NAG: Right. That's what I'm
12 saying. That the identifiable parameters of the
13 patient, the authorized user, and the institution not
14 be released.

15 MEMBER DIAMOND: I don't think we need to
16 worry about the patient because the patient's identity
17 is never released. I think what you're saying is the
18 identifiable details of the authorized user and
19 licensee --

20 MEMBER NAG: Okay.

21 MEMBER DIAMOND: -- not be released to the
22 general public until such time as the NRC staff
23 determines that there is a reasonable potential for
24 patient harm.

25 MEMBER NAG: Now the other question. Even

1 if there is a potential for patient harm, what is the
2 need for releasing the licensee and the authorized
3 user? Because you want to know what kind of problems
4 went on. It's just like with a patient, you know, you
5 want to know problems that have happened to a patient
6 but not who that patient is. So we --

7 MEMBER DIAMOND: All right. Let's take an
8 example. All right so there is an event at the Ohio
9 State University. It is reported to the staff. The
10 staff in one case determines it actually does not meet
11 the criteria for a reportable medical event and,
12 therefore, nothing else need be done.

13 However on the next patient that you see,
14 it turns out that it is a reportable medical event.
15 However it is a medical event involving this example
16 of the ASTRO: Brachytherapy where there is absolutely
17 no reasonable likelihood by anyone with common sense
18 that a patient harm could be reported, we want to make
19 sure that it is captured, that that information is
20 disseminated to users in industry. But there's really
21 no reason that the details of who did it and where it
22 was done be released because it's just not necessarily
23 -- it serves no public good.

24 However, the third patient that you've now
25 seen in that one week, it is a medical -- a reportable

1 medical event. You really did perform an activity
2 that really did pose a potential harm to that patient.
3 And we would all be in agreement that if there is a
4 potential for patient harm that the patient must know,
5 the referring physicians must know, you need to be
6 identified, the licensee needs to be identified so
7 that appropriate corrective action can be taken.

8 MEMBER NAG: Yes, but that needs to go to
9 the public. I'm not saying whether it needs to go to
10 the NRC. Of course it needs to go to the NRC. But
11 that information --

12 MEMBER VAN DECKER: It needs to go to the
13 public. At that point, it really does need to be in
14 the public space in my opinion.

15 CHAIRMAN MALMUD: Mr. Bailey?

16 MEMBER BAILEY: I think if you went to the
17 33 agreement states you would only find one state, New
18 York, that does not have an Open Records Act or
19 similar thing that would allow anybody to come in at
20 any time and look at anything in any licensee's file
21 that is not a patient record or security-related
22 material.

23 So I can almost tell you for sure that in
24 all of the agreement states, and I believe the same
25 thing would happen in NRC, if somebody came in with a

1 Public Records Act request or Open Records or Freedom
2 of Information, they will get it.

3 And so the patient goes and -- or the
4 patient's lawyer goes and gets it and I don't think
5 the recommendation can be carried out under present
6 law.

7 CHAIRMAN MALMUD: I have a question. Does
8 any of you have concern? If you were practicing in a
9 very short distance from another practitioner who was
10 guilty of a number of errors and that practitioner
11 were not identified as to the location of the
12 incident, wouldn't you feel smeared by a brush that
13 went across every provider in the area? That was a
14 question for --

15 (Laughter.)

16 CHAIRMAN MALMUD: -- Dr. Diamond or Dr.
17 Nag or anyone else.

18 MEMBER NAG: Well, I mean the question I
19 had was somewhat different. If we have medical
20 incidents happening, you know, all the time in a
21 hospital. Let's say this same error did not involve
22 radioactive material but involved a medicine where
23 double the dose or triple the dose was given, it would
24 come up in a QA meeting. It is a closed meeting. It
25 is not discoverable. And, therefore, it is an openly

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1 report and they openly discuss this in the closed
2 setting.

3 However, if the same incident was in
4 regard to a radioactive material, this now becomes a
5 totally open reportable incident that is open to
6 everybody.

7 So I'm wondering why should we make this
8 difference when if you are using a drug that is ten
9 times, you know, more powerful and that can cause the
10 death, that is a protected discussion. And it's not
11 discoverable by even lawyers.

12 CHAIRMAN MALMUD: Is that a question?

13 MEMBER NAG: That is an ethical question,
14 yes. That is what I'm trying to bring up.

15 CHAIRMAN MALMUD: I understand. I'll play
16 devil's advocate. We don't know the denominator of
17 the number of incidents that occur -- of the number of
18 services that are provided each year that resulted in
19 40 reportable cases this morning in this morning's
20 session. We have no idea. But it is a very small
21 percentage of the total.

22 We do know from the reports of the
23 Institute on Medicine and others that medicine,
24 medication errors are far in excess of the number
25 reported. And are a much higher percentage of errors

1 than those with using radioactive material.

2 So although we're not patting ourselves on
3 the back, we're doing a better job of it with this
4 openness than we have succeeded in doing with our
5 techniques of having quality assurance programs within
6 the hospitals where we do not report to the public the
7 number of errors that occur.

8 If the number of errors occurred in a
9 manufacturing industry comparable to those that occur
10 in a hospital, the industry would be out of business.
11 And those data are available now nationally.

12 So I'm not sure that we should use that
13 analogy because I'm not sure that analogy will carry
14 water to use another analogy.

15 But the point is I think what we have to
16 remember is that we are working within regulations
17 that have been mandated by Congress and promulgated by
18 this agency. So whatever we do has to be within the
19 rules that we are asked to function under.

20 We all agree, 100 percent agree with Dr.
21 Diamond's first motion. The problem is where do we
22 separate an incident that's truly dangerous from one
23 that isn't? And the answer is I don't think it can be
24 determined all the time in very short order.

25 There may be a long investigatory period

1 and the public may lose confidence in our willingness
2 or ability to investigate it. So I agree that we have
3 a downside currently. But I'm not sure the downside
4 is any smaller on the other side.

5 I say this as a member of the Committee
6 not as the Chair of this Committee. I'm just offering
7 my opinion.

8 MEMBER DIAMOND: I think this is an issue
9 that we will not be able to resolve today. Perhaps
10 this is something that we go back to our respective
11 societies and entities to discuss.

12 Again, what I'm trying to put into writing
13 is basically how -- by what methodology can a patient
14 in a hospital who gets a Tylenol instead of an Advil
15 with no adverse effect, how we can make the judgment
16 that there's no need for the patient to be informed
17 and the other physicians to be informed because we
18 know there is no meaningful likelihood of a harm as
19 opposed to the example of that patient who was
20 supposed to get an Advil gets some morphine and has an
21 event.

22 It's a matter of having -- of capturing
23 information but also disseminating that information
24 that serves the individual and the public good in the
25 best way. And perhaps we should just table the second

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1 motion and ruminate about it a little bit more.

2 CHAIRMAN MALMUD: So your motion is that
3 we table the motion and ruminate?

4 MEMBER DIAMOND: Correct.

5 (Laughter.)

6 MEMBER NAG: The second motion.

7 PARTICIPANT: The second motion in our
8 two-chambered stomachs.

9 PARTICIPANT: Just rumination?

10 PARTICIPANT: So can I ruminate with you?

11 CHAIRMAN MALMUD: Dr. Suleiman, did you
12 want to make a comment?

13 MEMBER SULEIMAN: Yes, yes, why not.

14 (Laughter.)

15 MEMBER SULEIMAN: This is a rumination,
16 okay.

17 PARTICIPANT: A little illumination on the
18 rumination.

19 MEMBER SULEIMAN: I think the issue is a
20 constant tension between trying to be open and being
21 so open that you contribute to the public background
22 which adds to the confusion. On the other hand, you
23 don't want to be completely closed.

24 So I think we'd have to defer to the NRC's
25 best judgment. I think it is too easy just to publish

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1 everything. I think you have to assume some
2 responsibility and say this is not going to
3 contribute, you know.

4 But if you don't have an open attitude in
5 collecting this information, how are you ever going to
6 reduce medical errors? So I don't know what the
7 answer is but I think we should appreciate the fact
8 that if you go one extreme, it's too bad, and the
9 other -- both extremes are not good.

10 But start someplace and you can adjust it
11 later on. But I think you shouldn't report
12 everything.

13 CHAIRMAN MALMUD: So, Dr. Zelac, we're
14 throwing it back in your lap.

15 Dr. Miller?

16 DR. MILLER: From my perspective, okay, as
17 a regulator and as an employee of the NRC, as a senior
18 manager in the NRC, all public servant. So while I
19 fully respect the views of the Committee on the matter
20 of what we should report and what we should not report
21 in the public forum, I think Dr. Zelac has clearly
22 articulated the agency's view with regard to openness.
23 I'm obligated to that.

24 I said I was sympathetic to the first
25 motion because I think that that was a motion that

1 related to timeliness and it related to doing an
2 investigation before you prejudge whether or not it
3 was truly a medical event.

4 But I believe that if something is
5 determined to be a medical event, since by our
6 regulation it is required to be reported, that this
7 agency has an obligation to be open about that.

8 You posed the question, Dr. Malmud,
9 concerning what would happen if it wasn't reported.
10 And then a local lawyer were to get it into the press.
11 Well, Ed Bailey gave the view from the states'
12 perspective. I'll give the view from the federal
13 perspective.

14 What would happen would be the NRC would
15 be contacted, probably through our Office of Public
16 Affairs, and then we would be answering questions as
17 to why we suppressed the information. And I don't
18 think as a regulator that is a good place for us to be
19 to continue to be credible.

20 This issue goes beyond the medical field.
21 I think it goes beyond, you know, any events that the
22 NRC gets reported and our obligation to openness.
23 From that perspective, it just may be a point of
24 departure between the views of the Committee and the
25 obligations of the NRC staff.

1 And if a motion were passed and not
2 ruminated on, if that's a word, I think, you know, the
3 one thing that I try to bring and Dr. Zelac has
4 clearly pointed out is I want to make sure that when
5 the Committees pass recommendations and you have
6 views, even if those views differ from the staff, that
7 when we send things up to the Commission for their
8 views and for their policy decisions that the
9 Committees' views are clearly articulated in what we
10 send up there so the Commission in its wisdom can
11 decide if they agree with the staff views or if they
12 agree with the Committees' views in setting policy.

13 From that perspective, I want to make sure
14 that any actions that the Committee takes is fully
15 articulated to the Commission in anything we send up.

16 CHAIRMAN MALMUD: Thank you.

17 Dr. Diamond?

18 MEMBER DIAMOND: Yes. As I continue to
19 chew my cud, the reason that I primarily withdrew the
20 motion, besides the fact that I didn't think we were
21 going to have a conclusion today, is that I happen to
22 disagree regarding the example you gave because your
23 information officer could always retort well as you
24 know, the dose that the patient received to that organ
25 is less than that of a diagnostic x-ray.

1 The reason I actually withdrew it is that
2 it would not be necessarily helpful or good regulatory
3 language to go and thrust every single reportable
4 medical event into your playing field and place the
5 onus on your staff of determining whether there is a
6 potential of a meaningful likelihood of harm.

7 That's the real hard part about it.
8 Again, we all understand by way of analogy the Advil
9 versus Tylenol example. We're in agreement versus the
10 Advil/morphine.

11 But again, is it Ron who is going to
12 decide whether 15 centigrade of common iliac versus 75
13 centigrade of the common iliac, utilizing this source
14 versus that source? Is there a potential risk for the
15 patient five years, ten years, twenty years from now?
16 What happens if the patient is 70 years old? What
17 happens if the patient is five years old?

18 That's really why I withdraw the motion
19 because it's not really good language from which you
20 would be asked to work.

21 DR. ZELAC: May I comment?

22 CHAIRMAN MALMUD: Please.

23 DR. ZELAC: A decision such as you've been
24 discussing that would have to be made is really
25 getting into the realm of practice of medicine. No

1 question from my perspective that that's where it is.

2 MEMBER DIAMOND: Of course.

3 DR. ZELAC: Secondly, we, as staff, do not
4 represent ourselves as being in a position to make
5 such decisions. What this would mean is that medical
6 consultants would be obtained, their views would be
7 obtained on all such cases. And we would be going
8 with the opinions of such a medical consultant in
9 making a decision on each and every one of these
10 cases.

11 CHAIRMAN MALMUD: Thank you.

12 Dr. Schwarz?

13 MEMBER SCHWARZ: I think that the first
14 motion that has been forwarded and approved is really
15 a step forward. That essentially the timing issue has
16 been addressed. And the remainder, as Dr. Diamond
17 suggested, the practice of medicine, will essentially
18 not be handled. It will be --

19 CHAIRMAN MALMUD: Thank you.

20 MEMBER SCHWARZ: -- it will be, you know,
21 essentially put on the web and --

22 MEMBER NAG: Sally, I didn't hear you.
23 Can you speak up through the mike?

24 MEMBER SCHWARZ: I think that the motion
25 essentially has moved us forward. Just allowing the

1 timing issue to be considered. And that the practice
2 of medicine stays with the physicians --

3 MEMBER NAG: Right.

4 MEMBER SCHWARZ: -- and that the staff is
5 not asked to perform a function that really is not in
6 their purview.

7 CHAIRMAN MALMUD: Dr. Van Decker?

8 MEMBER VAN DECKER: I just wanted to
9 reiterate, so it doesn't get lost, Dr. Diamond's other
10 point that in the first six list, the fact that there
11 is a recognition that medical event does not
12 necessarily mean medical harm to the patient is a key
13 part of this. So that the description that is made to
14 the public is a technical description of what went on
15 for their own QA type modality type stuff. And that
16 there is not -- and other assessments of that data for
17 patient harm -- there are other forums and other
18 technical expertise. And I think that is an important
19 piece of this puzzle.

20 CHAIRMAN MALMUD: Thank you.

21 Dr. Nag?

22 MEMBER NAG: Can I make a suggestion?
23 Whenever the NRC puts these out and say that this is
24 a reportable medical event, at the end of that, the
25 author puts a footnote that a reportable medical event

1 is not necessarily a harbinger of patient harm because
2 that's something that we already stated.

3 But I mean if it is put along in that same
4 context, people would remember that, you know, and
5 make that connection. Because I know we have stated
6 that in our policy. But then when you are sending out
7 the report, the public may not associate that and may
8 think that it might be a harbinger of patient harm.

9 So you can put that sort of a disclaimer
10 basically on any of the reports that go out.

11 CHAIRMAN MALMUD: Thank you for that
12 opinion, Dr. Nag. It's been heard.

13 DR. ZELAC: Does the Committee wish to
14 entertain that as a motion?

15 CHAIRMAN MALMUD: Is there --

16 DR. ZELAC: I mean that's --

17 CHAIRMAN MALMUD: -- is that a motion, Dr.
18 Nag?

19 DR. ZELAC: -- there is an action there.
20 So there's really something very concrete --

21 MEMBER NAG: Okay, if that needs to be
22 made as a motion, yes, I can make that a motion.

23 CHAIRMAN MALMUD: Is there a second to the
24 motion first? Are you seconding it?

25 PARTICIPANT: No.

1 CHAIRMAN MALMUD: Is there a second to the
2 motion?

3 MEMBER NAG: Well, I haven't made the
4 motion yet. I was making a suggestion.

5 (Laughter.)

6 MEMBER NAG: First I made a suggestion.

7 CHAIRMAN MALMUD: I apologize. I thought
8 that your suggestion was a motion. Sorry.

9 MEMBER NAG: I mean it didn't necessary
10 make that as a motion, of course I think you know
11 that. If it is necessary that I make that a motion
12 then --

13 CHAIRMAN MALMUD: If you wish it to be
14 followed through by staff, it is suggested that you
15 make it a motion.

16 Did you still -- you giving up the floor,
17 Dr. Nag?

18 MEMBER NAG: Well, he had his hand up
19 first.

20 MEMBER LEITO: Well, I think -- if I could
21 just -- I think there is a solution to this without
22 making a motion.

23 CHAIRMAN MALMUD: Okay.

24 MEMBER LEITO: Because I don't -- I didn't
25 mean to jump ahead but Dr. Zelac has, I think, already

1 addressed it to some extent in his second from last
2 slide where he talks about improving understanding and
3 publicizing these events and the wording.

4 I think if you just add to be included in
5 any future releases of medical events what he already
6 has in his recommendations, that would address -- so
7 he's already -- Dr. Zelac has already alluded to that.
8 We just need to expand where this is released at.

9 And the recommendation has already been
10 made by Dr. Zelac. So if you want to just hold off
11 until he gets to it, then, you know, we can just ask
12 if it can be included there.

13 CHAIRMAN MALMUD: Acceptable to you Dr.
14 Nag?

15 MEMBER NAG: Yes, I mean that's why I was
16 making it as a suggestion and not as a separate motion
17 because this was already included in many of the
18 discussions. I just wanted to highlight it.

19 CHAIRMAN MALMUD: Let's move forward then.
20 Dr. Zelac?

21 DR. ZELAC: Again, I think what we're
22 really getting to is the fact that the overall
23 objective is shared by all of us.

24 CHAIRMAN MALMUD: Yes.

25 DR. ZELAC: When we get down to some of

1 the specifics, there are details that we have to
2 consider as regulators that might preclude our acting
3 on some of the specific suggestions.

4 But the overall -- and in terms of, you
5 know, that's a very good suggestion. And I appreciate
6 getting it. And I think that we, you know, certainly
7 can very, very seriously consider doing it.

8 I think that we went through two of the
9 four specific suggestions and I think I will try to in
10 the no time remaining finish up as promptly as I can
11 with the other two plus the specific recommendations
12 that Mr. Leito has referenced.

13 PARTICIPANT: You've got to three o'clock.

14 DR. ZELAC: I have until three? Oh,
15 that's great.

16 (Laughter.)

17 DR. ZELAC: Since we do have just a little
18 more time than I had thought, can I -- well, Dr.
19 Diamond had made a motion which you have endorsed on
20 release and the timing of a release with the
21 implication that there are events reported by
22 licensees which, in fact, turn out not to be
23 reportable medical events.

24 And since Dr. Howe is in the audience, I
25 was wondering if she or anyone else has any feel for

1 what the percentages are for events that we become
2 aware of which turn out to not be medical events? Is
3 it 10 percent? Is it 50 percent? Or something else?

4 DR. HOWE: This is Dr. Howe. I think our
5 initial feeling is that most of the things that are
6 reported do tend to be medical events. Because I
7 think the licensees look carefully at what the
8 requirements are because they don't like to report
9 things if they don't have to.

10 Sometimes they will err on the caution
11 side. So it's probably a fairly low percent that --
12 maybe 10 percent that don't end up being medical
13 events that we're getting.

14 MEMBER BAILEY: May I?

15 CHAIRMAN MALMUD: Mr. Bailey?

16 MEMBER BAILEY: We use the NMED system for
17 lots of things. And, for instance, our medical events
18 definition is definitely different from NRC's and
19 involves a lot of diagnostic procedures. So when we
20 look at it, and this is sort of a rough estimate based
21 upon our IMPEP pecking, only about a fourth of the
22 events we end up putting in NMED are actually
23 reportable events under NRC's criteria for reporting.

24 DR. HOWE: And Mr. Bailey is absolutely
25 right on that because when I went to print out the

1 medical events, I had to exclude tons of them that
2 were in the diagnostic criteria because they were
3 things that would have been mis-administrations prior
4 to `92. But would not have been medical events after
5 --

6 PARTICIPANT: 2002.

7 DR. HOWE: No.

8 PARTICIPANT: `92 or 2002?

9 DR. HOWE: No, `92.

10 PARTICIPANT: Okay, thanks.

11 DR. HOWE: In `92 when we revised the
12 quality management rule and we deleted most of the
13 diagnostic medical events. And so the agreement
14 states are still putting in things that we no longer
15 consider medical events from 1992.

16 MEMBER BAILEY: And some of those go in
17 because we don't want to get pecked for not getting
18 them in within 24 hours so we put them in. And if
19 they don't turn out to be medical events or reportable
20 medical events, it's not big deal.

21 DR. HOWE: So I was answering more from
22 our NRC perspective of reports from our licensees.

23 DR. ZELAC: Okay. Thank you very much.
24 I think that is helpful for everybody.

25 Moving on, I think this is number three of

1 the four that will be coming up now. The
2 recommendation: NRC is encouraged to develop a more
3 graded and risk-informed process for responding to
4 medical event reports that ties the intensity and
5 immediacy of its inspection response to the individual
6 patient risk and public health implications of the
7 event. For example, for a relatively minor ME where
8 public health and safety is not in question, NRC could
9 minimize reactive inspection of the licensee pending
10 a satisfactory investigation and quality improvement
11 response on the part of the licensee.

12 Staff does not support this recommendation
13 because -- and I will expand clearly on these few
14 words -- because NRC's approach to medical event
15 assessment is already graded and risk informed. My
16 expansion: NRC already has a variable time frame for
17 initiation of medical event assessment that reflects
18 the known or potential seriousness of the occurrence
19 based on the initial assessment by NRC utilizing
20 information in the medical event report supplied by
21 the licensee.

22 Generally acceptable delay times for
23 initiating assessment range from two working days for
24 the most serious events to ten working days or longer.
25 Also, the degree and type of follow up are based on

1 the type of medical event reported. Point one.

2 Second point. Once the medical event
3 assessment is initiated, the site visit by the
4 assessment group inspector is to confirm and/or to
5 gather information to assure that all required
6 information is available to enable the assessment
7 group to complete its assessment.

8 I could go through and indicate what these
9 pieces of information are but I think you get the
10 general sense of it.

11 And finally, staff believes that the most
12 effective and efficient approach for assuring the
13 timely availability of information necessary for
14 completion of these assessment process tasks is the
15 assessment group inspector visiting the site of the
16 medical event to confirm and/or to gather information.

17 Hence even for a medical event which the
18 licensee considers to be relatively minor and not
19 involving public health and safety, staff does not
20 support this Advisory Committee recommendation.

21 That's the rationale for our position on
22 that recommendation.

23 CHAIRMAN MALMUD: Do you wish to say
24 something Dr. Van Decker?

25 MEMBER VAN DECKER: Yes, it's getting late

1 in the afternoon. I figure I'll wake people up.

2 How about you rephrase the last part of
3 what you just said to say staff does support this
4 recommendation other than the fact that we believe
5 that a site visit is necessary at least to see -- or
6 as least a point of order and maybe risk related at
7 that time.

8 Because what you've essentially said in
9 all that point fulfills the spirit of what was said
10 above except you think somebody needs to visit to be
11 sure it's not a tip of the iceberg-type issue.

12 DR. ZELAC: All right. It's taken under
13 advisement.

14 CHAIRMAN MALMUD: Thank you. Thank you,
15 Dr. Zelac, Dr. Van Decker. Can we move on to the next
16 --

17 DR. ZELAC: Yes.

18 CHAIRMAN MALMUD: -- the fourth point.

19 DR. ZELAC: I'm obviously taking notes so
20 that I can move ahead before the transcript is
21 available.

22 CHAIRMAN MALMUD: Thank you.

23 DR. ZELAC: We do have actually time
24 deadlines we try to meet whenever possible.

25 And lastly of the four specific

1 suggestions, NRC is encouraged to change the 24-hour
2 operation center reporting procedure. Specifically
3 medical events that have not harmed the patient, have
4 little potential for harming the patient, and are not
5 materially relevant to the patient's future medical
6 treatment decisions as evaluated by the licensee, are
7 to be reported to NRC by means of written notification
8 within seven days of their discovery.

9 Staff does not support this Advisory
10 Committee recommendation because the Commission has
11 previously endorsed staff's position opposing
12 different reporting periods depending on the initial
13 assessment of the event by the licensee.

14 And if I can, I'd like to expand a bit on
15 those few words. Another quote from the 2002 Federal
16 Register finalizing the revision of Part 35. All
17 medical events may not be associated with serious
18 consequences. However, we believe that a requirement
19 that allows for different reporting periods depending
20 on the initial assessment of the event by the licensee
21 would lead to differing interpretations and confusion
22 as to whether the magnitude of the event requires
23 notification of the NRC no later than the next
24 calendar day.

25 Continuing, the NRC continues to believe

1 that licensees should promptly notify the NRC of
2 medical events that trigger these thresholds because
3 the circumstances of the medical events need to be
4 evaluated as soon as possible to determine if any
5 immediate follow-up action or corrective actions are
6 necessary.

7 The telephone notification allows the NRC
8 to promptly take any necessary action based on the
9 circumstances. For example, to dispatch an inspector
10 or medical consultant or notify other licensees of
11 potential generic problems.

12 And since this is a rather contentious one
13 let me continue and give a bit more in the way of
14 explanation for our position. Further, the 24-hour
15 reporting requirement for medical events for NRC to
16 "conduct a timely, thorough, systematic, and formal
17 assessment", and I've referenced where that's coming
18 from in our documents, is consistent with NRC 24-hour
19 reporting requirements for other events involving
20 licensed material which permit NRC to promptly assess
21 the potential health and safety consequences for
22 individuals or actual impact on licensed operations.

23 For example, 30.50 for byproduct material,
24 40.60 for source material, 70.50 for special nuclear
25 material all require 24-hour reporting. And there are

1 a list of conditions under which that is required.

2 And if I could just finish, I'll then
3 certainly entertain as I know you'd like, further
4 comment. Finally, the 24-hour reporting requirements
5 for all these material use events, meaning those
6 specially called out in 30.50, 40.60, 70.50 which
7 enable the NRC to promptly assess the potential health
8 and safety consequences for individuals or actual
9 impact on license operations serve a parallel purpose
10 to NRC's 24-hour reporting requirement for medical use
11 events, to promptly evaluate the circumstances of the
12 medical events to determine if any immediate follow up
13 or corrective actions are necessary.

14 CHAIRMAN MALMUD: Does that complete your
15 comments?

16 DR. ZELAC: That completes --

17 CHAIRMAN MALMUD: Dr. Williamson has been
18 chomping at the bit.

19 MEMBER WILLIAMSON: Yes. Well, I mean all
20 of the -- this recommendation as well as the three
21 previous ones that you've rejected all flow from a
22 common base of observations by us in the Medical Event
23 Subcommittee and within the ACMUI that we hope you
24 will take the trouble to try to record accurately in
25 your white paper to the Commission so they understand

1 what our perspective is.

2 And the perspective is that even though
3 the majority of reported medical events that are, you
4 know, agreed are really medical events, don't result
5 in license infractions or actions that you view as
6 punitive.

7 I think we're trying to get the message
8 across to you that we, in the regulated community,
9 view the process as punitive. That this is not useful
10 as a QA indicator from our perspective. This becomes
11 a sort of a legal struggle where we as institutions
12 try to minimize the negative and harmful consequences
13 to our patients and to our practices.

14 This is the point we're trying to make,
15 that the process of reactive inspections, the process
16 of casting negative publicity on an entire institution
17 because of a few events which aren't representative of
18 the overall quality, all of this does harm.

19 When there is harm associated with
20 following good QA practices, this discourages people
21 from adhering to them. The industry standard
22 principles are don't punish people for trying to make
23 the process better.

24 And so we made these suggestions in the
25 spirit of trying to make the medical event reporting

1 process more effective as a quality assurance tool
2 which you have argued, I think, kind of undercuts
3 various other values that you have as a regulatory
4 agency.

5 But we would like, I think, our message to
6 get through to the Commission so I think that they at
7 least understand what the dilemma is from our
8 perspective because I think the changes, while you
9 have advanced all sorts of legal reasons which have
10 little to do with the practice of medicine, why none
11 of these -- why you can support none of these and why
12 they can't happen, I think a good case can be made
13 that the fact that you can't do this does indeed
14 undercut the effectiveness of these tools and
15 promoting good quality care.

16 And if you could figure out some way to
17 mitigate what you may not think are punitive
18 consequences but what we definitely perceive as
19 punitive consequences. If you could minimize or
20 reduce those, I think that the effectiveness of this
21 process would increase.

22 CHAIRMAN MALMUD: Dr. Zelac?

23 DR. ZELAC: Let me get back to the
24 comments that I made earlier on which Mr. Leito has
25 referenced as well, that overall the objective we

1 agree on. The tactics for getting there are what
2 we're really discussing.

3 The overall suggestions that came from the
4 Committee with respect to what we should be attempting
5 to do, we endorse. And that's going to be in the next
6 slide. And we've received even another specific
7 suggestion from Dr. Nag as to how this could, in part,
8 be accomplished.

9 With respect to why there are these
10 reactive inspections at all, I skipped over the
11 listing but I think it is probably appropriate at this
12 point to go through it quickly as to why go to the
13 licensee's facility when a medical event is reported.

14 What it is that the medical assessment
15 group, medical event assessment group is trying to
16 achieve, what its objectives are, what its goals are,
17 what it must complete in order to satisfy its charge.

18 First, identify the sequence of events
19 leading to the medical event.

20 Second, identify the root cause or causes
21 and contributing factors to the medical event.

22 Three, assess any probably deterministic
23 effects on the patient and/or other exposed
24 individuals. And recognize this is where the medical
25 consultants come into play.

1 Four, identify and determine the adequacy
2 of corrective actions taken.

3 Five, determine whether licensee
4 management was aware of the violation of NRC
5 regulations, if any, that contributed to the cause of
6 the medical event if any violations were identified
7 during the assessment.

8 And six, identify the licensee's immediate
9 and long-term corrective actions.

10 Finally, seven, determine licensee's
11 compliance with the reporting and notification
12 requirements for medical events.

13 These are the reasons why there is an
14 assessment group. And these are the things that it
15 needs to accomplish from the point of view of
16 oversight, from the point of view of encouraging good
17 quality.

18 Lastly, my comment is that I've been on
19 the other side of the fence. And unfortunately at the
20 institution where I spent most of my time, there were
21 several occasions when things didn't go quite the way
22 they should have for whatever reasons and we were
23 visited by NRC inspectors in such reactive
24 inspections.

25 It's simply something that they had to

1 deal with as part of the business of providing patient
2 care. It wasn't viewed by us at the time as being
3 onerous. It wasn't viewed -- although it did take up
4 a lot of time generally, it wasn't viewed by us as
5 being -- having an intent to find something wrong that
6 we could be cited for although that may have happened.
7 I don't recall specifically.

8 But the point I'm trying to make is that
9 we're trying to look at this -- or at least personally
10 I am from both sides. From the point of view of us as
11 a regulatory agency as well as from the point of --
12 and I'm very sympathetic to it -- the point of view of
13 the user that has to deal with these when they occur.

14 Now we get to the good stuff.

15 CHAIRMAN MALMUD: I think there's a
16 question from Mr. Leito.

17 MEMBER LEITO: Back on the last slide
18 there, Dr. Zelac, on the --

19 DR. ZELAC: I'm trying to go back but it
20 doesn't seem to be doing it.

21 MEMBER LEITO: -- I think the -- in terms
22 of the -- well, let me ask NRC staff a question. When
23 a person calls in, a licensee calls in to the 24-hour
24 operations center. Basically this person is just a
25 data-taker. I mean he's not making any assessment,

1 judgment, or whatever. He's just taking the
2 information that's coming in.

3 It's my understanding that as soon as that
4 information is taken in, it then goes out into a
5 release on the NRC website. Is that true or not true?
6 Okay. I think this gets to what we were alluding to
7 earlier in that you have this person who is very
8 competent in what they do who is taking all this
9 information, the licensee, who, what, where. And it
10 goes out onto a public forum within a matter of hours
11 of reporting.

12 And they're sort of basically taking all
13 that raw data that Dr. Suleiman referred to earlier
14 and just throws it into the public domain. And I
15 think what we were trying to get to in the
16 recommendation is that there needs to be some way that
17 there is an assessment on this before you're going to
18 do that.

19 This raw data should just be thrown up
20 there, you know, because it is not going to encourage
21 people, as Dr. Diamond said earlier, of reporting
22 these things because as you know, as soon as you hang
23 up that phone, okay, everybody in the country or for
24 that matter anyone who has internet access is going to
25 have access to that information.

1 And that's why our recommendation as
2 stated was meant to be a potential alternative that
3 yes, it can be reported maybe within 24 hours but is
4 there another mechanism similar to the way it used to
5 be before it wasn't required to go to the 24-hour
6 operation center, you reported it to the Regional
7 Office right away, okay?

8 And then you were required within -- I
9 thought it was seven days and it might have been even
10 longer -- you had to provide a written report that was
11 then sent to the Regional Office and then things went
12 from there.

13 And if there is another way that we can
14 skin this cat so to speak without the information of
15 the licensee, because as we said earlier, it may not
16 even be a reportable medical event. Until some type
17 of an assessment and the information can be obtained
18 before it goes out into that public forum.

19 So this is sort of I guess a corollary to
20 those earlier -- or a subset of that earlier
21 information or recommendation that we had that we
22 find, you know, very, very bothersome.

23 DR. ZELAC: I think your -- if I could
24 comment just for a second -- I think your comments now
25 do, in fact, reflect the motion that came to us at

1 this meeting which is different than the
2 recommendation which came to us previously upon which,
3 you know, I have provided comment.

4 The previous one said, you know, wait
5 seven days, okay? This one says wait until you've
6 assessed that it, in fact, is a medical event, okay,
7 that's fine. The Committee has essentially, if you
8 will, added something which we can further consider
9 through this meeting today and this discussion.

10 MR. ESSIG: And I would just, if I could,
11 that we have a process for reviewing events. We do it
12 every day. Every event, not only medical but
13 industrial, academic, commercial, other commercial
14 sources, we review them every day. And our management
15 is briefed on each event.

16 But where we have the -- we still have the
17 event notification form that does go on the public
18 website as you have noted. And this other process
19 goes on in parallel with it.

20 So what we could -- I see your
21 recommendation is to maybe do a little bit more review
22 of that prior to -- and we have considered that
23 particularly for events that maybe have some security
24 aspects to them. And that is looking at them
25 carefully and then deciding whether or not all of the

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1 details in there or some of the details could be
2 withheld for security reasons.

3 And we could take under advisement your
4 recommendation to look at them for the purposes you
5 have stated.

6 CHAIRMAN MALMUD: Dr. Nag?

7 MEMBER NAG: Yes. More of a
8 clarification. Now is it 24-hours or is it one
9 working day? For example, if something were to happen
10 at our hospital at say 5:30 p.m. or 5:00 p.m. on
11 Friday. I would not have many of my staff people in
12 there. I would not be able to have any details about
13 the incident until most likely the next Monday.

14 So is it 24 hours or is it one working
15 day? And if it is 24 hours, how am I expected to get
16 those details when the people involved are not there?

17 DR. ZELAC: To read from the regulation,
18 this is in 35.3045(c), the licensee shall notify by
19 telephone the NRC Operations Center no later than the
20 next calendar day after discovery of the medical
21 event. That's what we're living with.

22 To answer the rest of your question, I'm
23 not going to attempt to do that.

24 (Laughter.)

25 MEMBER WILLIAMSON: I think that you --

1 the language says discovery of the medical event. So
2 I think that traditionally you may have a suspicion of
3 a medical event that falls short of it being a
4 discovery. So I think within the context of being
5 reasonable --

6 (Laughter.)

7 MEMBER WILLIAMSON: At five-thirty on
8 Friday, one has to have all of the facts assembled in
9 order to make a determination as a licensee whether it
10 is a medical event or not.

11 DR. ZELAC: Well, as Dr. Donna-Beth Howe
12 pointed out just a few minutes ago, licensees are
13 certainly reluctant to report things in general unless
14 there is some reasonable uncertainty that it, in fact,
15 it has to be reported.

16 On the other hand, there are a few that
17 will be very conservative and report anything knowing
18 that they can always back off later on. So there are
19 some in both camps.

20 CHAIRMAN MALMUD: Mr. Bailey?

21 MEMBER BAILEY: I think my assessment is
22 a little backwards from yours. I think people report
23 things before they have all the facts and can really
24 say it is a medical event because the only violation
25 is not if you have a medical event it is if you don't

1 report it within time. So you go ahead and report it
2 and say okay, I've reported it. It turns out it
3 wasn't. Sorry for wasting your time.

4 MEMBER NAG: Yes, but then by then, it's
5 already up on the web in the whole public's eye.

6 DR. ZELAC: I think we've kind of got a
7 complete understanding at this point on this
8 particular issue. So since we are now very close to
9 3:00 p.m., I'd like to move ahead.

10 CHAIRMAN MALMUD: If I may, Dr. Zelac, it
11 is close to 3:00 p.m. I'd like to thank you for the
12 thoroughness -- oh, you have one more point?

13 DR. ZELAC: I have two good points.

14 CHAIRMAN MALMUD: Oh, I thought you had
15 four more. If you have two more beyond this, please
16 go ahead.

17 (Laughter.)

18 CHAIRMAN MALMUD: We always have more time
19 for more good points.

20 DR. ZELAC: At the very start and as I've
21 repeated a couple of times during the presentation, I
22 think we are certainly in agreement with you as to the
23 spirit and the intent with respect to informing the
24 public about the risks associated with medical events.

25 And while we couldn't, as we have just

1 painfully discussed, accept while we are not inclined
2 to accept the specific recommendations that you made,
3 you did include in your recommendations to us broad
4 overlying principles to achieve this objective.

5 And those we do agree with. And those we
6 do wish to endorse and incorporate into policy. Is
7 this it? Yes.

8 First, publicize that NRC's medical event
9 definitions provide thresholds for identifying events
10 that are indicative of technical or QA problems and
11 accurately realizing the clinical intentions of
12 authorized users and their prescriptions.

13 Secondly, publicize that thresholds in the
14 NRC's medical event definitions if exceeded, are not
15 necessary surrogates or harbingers of patient harm or
16 even increased probability of patient harm.

17 So these -- you provided these. We
18 endorse. And with respect to how we might accomplish
19 this besides the very appropriate specific suggestion
20 that we received from dr. Nag a few minutes ago,
21 vehicles for accomplishing this suggested conveyance
22 of information could include first, an article in the
23 NMSS Quarterly Newsletter which goes out to all
24 licensees.

25 Second, issuance of a regulatory

1 information summary on this whole question.

2 Third, letters to and/or discussions with
3 professional organizations that represent medical use
4 authorized individuals such as clearly WAAPM, SNM, et
5 cetera, et cetera. So there are things that we can do
6 to further is objective. And these are just some of
7 the examples of things that we would be considering
8 assuming the Commission agrees with this
9 recommendation to it.

10 So in summary, we are intending to reflect
11 in our paper to the Commission the various positions
12 that I have enumerated in this discussion this
13 afternoon. Endorsing the preponderance of
14 recommendations which came from the Advisory Committee
15 on this total issue and not recommending some of the
16 very specific things relating to the last of the three
17 points, which was informing the public about risks
18 associated with medical events.

19 Are there any additional questions?

20 CHAIRMAN MALMUD: Now I would like to make
21 a closing comment and that is to first of all thank
22 you for the thoroughness and the usual precise order
23 of your response. And particularly for explaining the
24 reasoning that didn't permit you to agree with several
25 of the recommendations as well as the reasoning which

1 allowed you to achieve or allowed the NRC to achieve
2 agreement with us at this level.

3 And then to remind anyone who reads this
4 document that it has been very clear that during this
5 discussion, although there was not agreement on
6 several issues, that the concern of each party was for
7 the welfare of the patient, the anxiety that might be
8 generated in the minds of the public, and for the
9 overall well being of those for whom we provide
10 services.

11 I didn't detect in any of the comments a
12 concern for one's own area of interest or for
13 protection of one from unnecessary observation. So it
14 was very, very enlightening, very thorough, and a very
15 comforting discussion. And a stimulating one. And we
16 thank you.

17 DR. ZELAC: Thank you very much for your
18 comments. I'd like to make one final comment just
19 simply as a reminder to those members of the
20 Committee.

21 You did receive a copy of the draft
22 Commission paper. This is definitely, definitely pre-
23 decisional information which is not to be given to
24 others or copied or disseminated in any way
25 whatsoever. Clearly we've talked about the content of

1 it based on the publicly available recommendations
2 which you have supplied previously. But keep the
3 paper close to your vest.

4 CHAIRMAN MALMUD: Thank you.

5 Mr. Essig, you had a comment?

6 MR. ESSIG: Just is there any question
7 about the timeline on the paper? When is it due to
8 the Commission? And what sort of obligation are we
9 asking -- the turnaround time on the part of the
10 Committee, is that clear?

11 DR. ZELAC: We have received -- we, staff,
12 have received from you today one additional
13 recommendation in the way of a motion which was
14 approved unanimously. That will clearly be factored
15 in and included in the paper which goes up to the
16 Commission.

17 I am not looking to the Committee at this
18 point for anything further. And we will be able to
19 proceed from this point on unless there is something
20 that you think you need to convey before we move
21 ahead.

22 CHAIRMAN MALMUD: Thank you.

23 We are adjourned until 3:30 -- no, 3:20,
24 3:20.

25 (Whereupon, the foregoing matter went off

1 the record at 3:08 p.m. and went back on the record at
2 3:29 p.m.)

3 CHAIRMAN MALMUD: This will be a
4 discussion of the guidance on I-125 seeds as markers
5 for breast cancer localization. And the presenter is
6 Robert L. Gallagher from the state of Massachusetts.
7 Is it the state or commonwealth?

8 MR. GALLAGHAR: It's the Commonwealth.
9 Please don't ask me to define a commonwealth and a
10 state. Because I'm an HP, I'm not a politician.

11 CHAIRMAN MALMUD: I'm from the
12 Commonwealth of Pennsylvania, and I have the same
13 problem.

14 MR. ESSIG: Dr. Malmud, if I may?

15 CHAIRMAN MALMUD: Yes?

16 MR. ESSIG: Just a couple of words of
17 introduction to the topic.

18 What you will be hearing about today is,
19 we have a national materials program, and it has a
20 series of projects in it, pilot projects. There are
21 five of them altogether.

22 This was a means of sharing resources
23 between ourselves and the agreement states and CRCBD.
24 Some of the projects which may have been involved in
25 producing guidance documents. It's been a shared

1 effort. Some, the NRC has the lead. One the CRCPD
2 has the lead.

3 And on this particular one, the
4 organizational agreement states has the lead. So they
5 are taking the lead on a guidance document that will
6 benefit both the NRC and the agreement states.

7 And it will be their document. It's clear
8 to us the committee has seen an earlier version of the
9 document. We were almost going to invite Mr.
10 Gallagher back I think it was the last meeting. But
11 then we elected not to, because we wanted to make sure
12 the document was a little more ripe so to speak. And
13 it is in that position now.

14 So I believe you were sent, probably
15 electronically a couple of weeks ago, as part of the
16 agenda, you were sent a copy of that.

17 And I think as you will hear from Mr.
18 Gallagher, and I will emphasize it right now, the
19 comments, if we have any on the pilot #4 are due to
20 him by November 15th.

21 CHAIRMAN MALMUD: November 15th? All
22 right, thank you.

23 MR. GALLAGHAR: Thank you, Tom.

24 As Tom mentioned this project, pilot
25 project four, is one of five projects on the National

1 Tools Program.

2 The goal of this particular pilot project
3 was to have an agreement state or group of agreement
4 states assume responsibility for the development of
5 our licensing and inspection guidance.

6 This group as Tom mentioned was led by the
7 organization agreement states, and it was composed of
8 four state members, and one NRC regional member. We
9 have representation in the state of Florida, Debbie
10 Gilly. Georgia, Eric Jameson. Gil Vincent from
11 Illinois. And Cassandra Frasier from NRC's region
12 three office.

13 Our first priority when the working group
14 was formed was to select a new medical use of
15 material, or a new modality, to focus our efforts.

16 To accomplish we reviewed regulatory needs
17 identified by the NFP pilot five working group. We
18 surveyed the agreement states, NRC headquarters and
19 regional offices. And we contacted major medical
20 institutions in the United States.

21 After reviewing a number of the new uses
22 of material, we decided to develop the guidance for
23 Radioactive Seed Localization, or RSL.

24 We chose RSL because iodine-125 and
25 palladium-103, which can also be used for this

1 procedure, are Atomic Energy Act materials, regulated
2 by both the NRC and the agreement states.

3 In addition the use of this application
4 does not fit under the current guidance under 10 CFR
5 .200 or 35.400 or the equivalent agreement state
6 regulations.

7 Therefore its use would fit into the newly
8 created 10 CFR 35.1000, other medical uses.

9 And no review by the NRC and agreement
10 states have been performed to date.

11 Radioactive Seed Localization calls for
12 the use of currently available seeds, previously
13 approved for permanent implantation for the treatment
14 of cancerous tumors.

15 Typically the activities run between 200
16 and 300 microcuries per seed, implanted into the
17 breast lesion using a standard 18 gauge needle.

18 The seed or seeds in the case of regularly
19 shaped lesions are then localized by the surgeon using
20 a technique with which they are familiar, because of
21 the similarity to sentinel lymphnode biopsy and radial
22 guide parathyroidectomy. I had to look at my notes to
23 be able to say that. And then surgically removed.

24 The seed may be removed from the specimen
25 at surgery, or the specimen with the seed or seeds may

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1 be sent to pathology for removal of the seed and
2 analysis of the tissue.

3 The seeds are then disposed per 10 CFR
4 .92, or the equivalent agreement state regulations.

5 What are the elements, key elements, of
6 the licensing guidance? As with any guidance for
7 licensing, the locations of use are very important for
8 the licensee to address. They should include facility
9 diagrams where the seeds will be stored when not used;
10 implanted into the patient; explanted from the
11 patient; removed from the tissue sample; and stored
12 for decay.

13 The authorized users, we need to know all
14 the authorized users and document his or her training.

15 The authorized user will be considered
16 qualified if they meet either the criteria in 10 CFR
17 35.490, or 10 CFR 35.290 in preceptorship training by
18 35.490 authorized user to include work experience at
19 ordering, receiving, unpacking materials safely,
20 performing surveys using proper instrumentation,
21 implanting and removing brachytherapy sources, the
22 emergency procedures, using administrative patrols to
23 prevent the medical event involving this device, and
24 maintaining running inventories of materials at hand.

25 For general surgeons who locate and remove

1 the tissue containing the seed or seeds, they should
2 complete the training that includes performing related
3 surveys, using appropriate instrumentation; preparing,
4 implanting and safely removing brachytherapy sources;
5 and emergency procedures including how to respond to
6 a leaking source.

7 This training must be performed under the
8 guidance of an authorized user qualified under 35.490
9 or 35.290, plus preceptorship training.

10 The licensee should also provide
11 procedures addressing safety procedures and
12 instructions, including survey procedures; identifying
13 individuals who must be present; source accountability
14 and leak testing; and verification of source activity,
15 either by assay prior to implantation or by the
16 manufacturer's certification.

17 They should also supply procedures for
18 responding to an abnormal situation such as patient
19 follow-up, should they not return.

20 Description of length of time the seeds
21 remain in the patient, and notification of a medical
22 emergency of a patient prior to removal.

23 In addition the licensee should describe
24 if the conditions of the use exceed those stated in
25 the SSND certificate, the limited scope licensing will

1 have to amend its license to allow for use under the
2 new conditions.

3 Some states, however, will not allow
4 variations unless the original SSND certificate is
5 amended, or custom valuation is performed.

6 We have received comments from the NRC and
7 OAS which were reviewed by the working group and
8 incorporated into the final document.

9 The draft licensing and inspection
10 documents were submitted to the NRC in September of
11 2004 as part of the final report of the National Tools
12 Program Pilot Projects.

13 The final draft of the RSL licensing
14 guidance was submitted to the OAS board for their
15 review and approval in September of 2005.

16 The OAS board approved this document, and
17 it has currently been sent out to the agreement state
18 directors, and the NRC for comment.

19 The comment period is currently open, and
20 as Tom mentioned, it will end November 15th of 2005.
21 I encourage those of you on the committee - and I
22 understand the FDA now has the document as well - to
23 provide those comments directly to me. I can give you
24 my email address, or it might be in the documents that
25 were provided to you in your handout.

1 But it is Robert.Gallagher@state.ma.us.
2 And I encourage those of you who wish to make a
3 comment to provide those to me.

4 Are there any questions?

5 Robert.Gallagher, and as you can see, the last name is
6 spelled with an a-r on the end, @state.ma.us.
7 Unfortunately I only brought one card with me, and
8 I've already handed that out.

9 MEMBER NAG: Since the activity is so low,
10 what would the licensee do if the patient did not do
11 a follow up? Because the damage- potential damage to
12 the patient if the patient never even returned, is
13 really minimal. I mean when we do prostate implant we
14 have 10 percent of patients who have one or more seeds
15 that goes to the lung and nothing happens, and these
16 are much, much lower activities than those seeds.

17 MR. GALLAGHAR: Our guidance is not
18 prescriptive in telling the licensee what they need to
19 do. All it is stating is that they have to tell us
20 what they would do in terms of follow up.

21 MEMBER NAG: I know. But if the
22 likelihood of damage is so small, and if when we are
23 doing a prostate implant we don't do anything if they
24 go to the lung, what should they be required to do?
25 Really there is nothing that they need to do.

1 MR. GALLAGHAR: I would tend to agree, and
2 I don't really have an answer for that question. We
3 would have to review that.

4 CHAIRMAN MALMUD: Dr. Williamson.

5 MEMBER WILLIAMSON: I assume this document
6 is the one that we received, and Ralph and others have
7 commented on. And I would think that since this is
8 lower activity, it would be considered lower risk than
9 regular manual brachytherapy, and that therefore you
10 would not be warranted in imposing more restrictive or
11 prescriptive requirements on this activity than are
12 present in the 35.400 precautions for regular manual
13 brachytherapy.

14 So just some little things I've noticed.
15 Why facility diagrams for all these rooms which you
16 don't have to provide for --

17 MR. GALLAGHAR: Well, these are standard
18 elements of a submittal for an amendment that exists
19 currently.

20 MEMBER LEITO: I just submitted a license
21 renewal. I didn't submit all my OR floor diagrams for
22 my operating rooms for my license renewal. And that's
23 where these things are done at.

24 And I don't think it's ever been asked for
25 in the past, and I think it's been pretty well

1 understood that you could be doing a brachytherapy
2 implant for prostate in almost any operating room of
3 the facility.

4 I guess I would ask some of the broad
5 scope people --

6 MEMBER WILLIAMSON: I've never had to
7 identify specifically the rooms I do manual
8 brachytherapy in in a license application or an
9 amendment or ever had to have drawn diagrams of them.
10 Only for HDR and fixed-source devices, but not for
11 something like this.

12 MR. GALLAGHAR: I tend to agree, and as a
13 license reviewer myself I would be much more
14 interested in where they were going to be stored than
15 where they would be implanted and removed.

16 Seriously, the procedure that we're going
17 to look at is what you would do with these temporary
18 users, if you want to call them that, if you can't
19 account for all the seeds, or if there is something
20 that goes awry.

21 MEMBER LEITO: I would ask that the
22 working group kind of look at these as how sentinel
23 node studies are done. The activities are comparable
24 - granted your using tech instead of I-125. But the
25 time periods involved are similar and the activities

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1 are quite similar.

2 In fact with sentinel nodes they are
3 unsealed. With these they are sealed, and it's a
4 little bit easier to address.

5 So I would ask that the precautions that
6 are being set up be comparable to, as you said, the
7 inventorying, the surveying before and after, those
8 types of things I think are more critical than because
9 the burden of doing all this is not trivial.

10 One of the questions I had is more of a
11 generic nature. You said that the reason these were
12 put under 1000 is because of the sealed source device
13 registry definition if you will.

14 MR. GALLAGHAR: Certification; right.

15 MEMBER LEITO: Is it - not having this for
16 the iodine seeds, is it because it says they are, (does
17 it say), for therapeutic use only?

18 MR. GALLAGHAR: All the slides you'll see
19 for example on the best certificates, it states, for
20 10 CFR 35.400 use. Period.

21 MEMBER LEITO: Now maybe the better thing
22 would be to address that the sealed source registry be
23 revised or stated to say interstitial use which would
24 then obviate all this 1000 and a lot of this, the need
25 for this --

1 MR. GALLAGHAR: That is a question that we
2 spoke to very earlier in this procedure. And one of
3 the advantages of having Gil Vincent from Illinois
4 (Best Industries is in Illinois) which manufactures a
5 large number of these I-125 seeds.

6 And they were contacted, and they were not
7 willing to amend their SSP certificate to allow that,
8 for their own reasons; I don't know what those reasons
9 are.

10 MEMBER LEITO: Again I don't have an
11 appreciation for this, so maybe NRC staff can help.
12 How difficult is it to amend the sealed source device
13 registry? Is it kind of a detailed laborious time-
14 consuming expensive effort?

15 MR. ESSIG: We have Dr. John Jankovich in
16 the audience who is a team leader for the sealed
17 source device review, if you would care to speak to
18 that, over to the microphone right on the other side.

19 DR. JANKOVICH: The NRC and the agreement
20 states issue their registration certificate in
21 response to a licensee's request and application, and
22 they specify what use they want to put those sources
23 to.

24 I point this out that the action comes
25 from the manufacturer. It is not the licensing agency

1 who is initiating the action.

2 We don't tell the licensee that you should
3 permit this, the use of these sources for something
4 else.

5 So Robert was referring to that procedure.
6 And that is what past industry was following.
7 Therefore I cannot give you a direct answer that we
8 dictate what these sources should be used for.

9 MR. ESSIG: But John, would it be fair to
10 say if Best Industries decided that it was in their
11 best interests so to speak to request an amendment to
12 their SSD certificate, that would be a fairly
13 straightforward process, would it not?

14 DR. JANKOVICH: That I can answer. If we
15 get an application to change the registration
16 certificate, we can do that fairly easily. We have
17 routine procedures to do that; not too time consuming,
18 provided that the application gives us the information
19 that these sources can be used under these
20 circumstances.

21 We usually ask for prototype testing or
22 comprehensive studies which tells us that the source
23 can be used in such an application.

24 Obviously, we are concerned, we would be
25 concerned about the structural integrity of these

1 seeds under the - if they retain their integrity.

2 Maybe you are familiar with a similar
3 situation. A manufacturer make strands out of these
4 sources so the seeds are at predefined distances from
5 each other.

6 And during the manufacture of those
7 strands they got caught in there, and several seeds
8 were damaged. Actually we had to implement preventive
9 measures, extra quality assurance measures during
10 fabrication - this is an NRC licensee in Connecticut
11 - to prevent those leaking strands to go out to
12 hospitals.

13 So of course the tissue here is different
14 than the material they are slicing these strands,
15 embedded sources, in plastic on hard surfaces, that is
16 different. That is the reason why we would ask for
17 prototype testing or cooperative studies.

18 MR. GALLAGHAR: Just before we move on,
19 one further element that would need to be considered
20 if Best for example comes in to renew or to amend
21 their certificate, as I understand it, many of these
22 sources were never tested for puncture early on. So
23 now if they are going to be approved, most likely they
24 would be required to be tested for puncture; is that
25 not correct?

1 DR. JANKOVICH: Correct. For iodine
2 seeds, we don't have a well established prototype test
3 protocol. Each manufacturer comes up with their own
4 test sequences, and either the NRC or the agreement
5 states reviews that and makes a professional judgment
6 if it is sufficient for its intended use.

7 So far, of course, the intended use is
8 implanting to prostate.

9 CHAIRMAN MALMUD: Dr. Vetter.

10 MEMBER VETTER: Yes, in that regard,
11 relative to your draft guidance, you indicate that
12 relative to puncture and that sort of thing, a broad
13 scope licensee should perform its own engineering and
14 radiation safety evaluation addressing these
15 differences, but you don't indicate what is they
16 should do. And I don't think there is an ANSI guide
17 that says how you test for puncture in seeds.

18 So it is a matter of professional
19 judgment, I guess, right? And I'm sorry you weren't
20 here at our last meeting. We actually did this sort
21 of thing at Mayo, we did some cutting and puncture
22 tests.

23 But there is no guidance to follow. There
24 is no ANSI standard to follow. So we simply tried to
25 envision under what circumstances would a seed be put

1 under a knife and so forth, and we didn't get any
2 leakage.

3 So does that satisfy this requirement? We
4 did it that way, Mr. Leito might do it a different
5 way, and Dr. Williamson a different way.

6 I'm not sure what this means when you say
7 we have to do - unless FDA has some specific guidance
8 in that regard.

9 MR. GALLAGHAR: That's an excellent point.
10 It's a point I'd like to see resolved. It's something
11 we talked about in our committee. And like others
12 have done testing on their own, in Mass General
13 Hospital, after my discussions with them, they went
14 out and did similar testing involving chicken breasts
15 and later with some sauce and things.

16 In that case also they were unable to
17 rupture a source. In all cases, no matter how
18 physically hard they tried, they were unable to
19 successfully breach a source.

20 And I will also say that in my review of
21 NMED, of all the incidents involving I-125 seed
22 rupture, there were none that were involving a
23 surgical procedure. There were some as Dr. Jankovich
24 mentioned involving scissors, but I do not believe
25 historically there has been an actual seed rupture

1 caused by a surgical removal.

2 And I also understand, and perhaps you
3 gentlemen can confirm this, there are times when a
4 prostate seed would need to be surgically removed from
5 the patient.

6 MEMBER LEITO: That is one of my comments.
7 Obviously I guess it didn't get forwarded to you yet.
8 Because I'm wondering what is the difference between
9 what you are requiring for implanting these sources
10 for a couple of days than a prostate patient that
11 comes back for some type of urinary obstruction where
12 they've got to kind of open things back up, and they
13 are digging around there in the prostate and so forth.
14 And that doesn't require Part 1000 application to be
15 able to do that.

16 And so it, I think a lot of the guidance
17 here is good, but it seems like it's just overly
18 prescriptive and burdensome for the risks that are
19 involved.

20 A question I also had was there assessment
21 done by the working group in what the dose to the
22 breast is per seed if you will for one of these that
23 are left in for what is it like one to five days, say
24 for five days, what would be the breast dose?

25 MR. GALLAGHAR: I don't remember the

1 numbers, because that was more than a year ago that we
2 did this. What we did do an assessment --

3 MEMBER LEITO: Was it more than a
4 mammogram? Less than a mammogram?

5 MR. GALLAGHAR: I'm not a medical
6 physicist. I don't know how much dose is delivered in
7 a mammogram, but we did review that.

8 CHAIRMAN MALMUD: Mr. Bailey.

9 MEMBER BAILEY: If I'm remembering
10 correctly, there were some testing procedures that
11 ANSI had for radium needles and plaques and all that
12 sort of stuff that involved crushing and cutting and
13 so forth.

14 Perhaps those might be applicable. When
15 I was listening to Dr. Vetter, I was thinking, he's
16 already got a consulting project done for Best
17 Industry.

18 CHAIRMAN MALMUD: Dr. Nag.

19 MEMBER NAG: Two questions. One is, in
20 your element for cleaning up the general surgeons, you
21 have mentioned that you need to do all that, but do
22 you have any guidance, like is there any hourly
23 requirements or anything like that?

24 Because that is the place where I as a
25 radiation oncologist with the .490 experience would

1 have to generally supervise the surgeons. What am I
2 going to tell them? What do I need to tell them? And
3 it is very difficult for us to tell the surgeons, oh
4 no no, we know the agreement, we'll just go ahead.
5 Unless I have a requirement that if I need X number of
6 hours or so on, I can only tell them, these are the
7 precautions you take. So that is one.

8 The second thing, for palladium-103, if
9 the palladium is made from a cyclotron would that
10 still come under the NRC because it's not the reactor
11 byproducts?

12 MR. GALLAGHAR: Well, under the current
13 regulatory environment, no. I think that is under
14 consideration for a change, but currently the NRC is
15 only responsible to regulate the Atomic Energy Act
16 material.

17 MEMBER NAG: So that palladium would not
18 be included?

19 MR. GALLAGHAR: Correct. But to address
20 your first point, if you recall last year when I came
21 back here in October, there was a time allotment of
22 eight hours for general surgeons, and there was
23 considerable discussion amongst the committee that
24 that was overbearing. So we listened to your comments
25 and took that under advisement, and removed that

1 hourly criteria.

2 You still have to provide what the
3 training will include, and what I provided in my talk
4 was some of the general components of that training.

5 CHAIRMAN MALMUD: Dr. Vetter.

6 MEMBER VETTER: Yes, thank you for taking
7 that hour requirement out for a couple of reasons.
8 One is, we did consider it onerous. Second is,
9 depending on where they train, the procedures that
10 they would be involved in might be quite different.

11 For instance in a large academic medical
12 center there is not a physician that orders
13 radioactive material. There is a much more or less
14 automatic process. The physician puts in an order for
15 it, internally, but they don't end up calling the
16 vendor. They don't check in the package. They don't
17 unpack it.

18 That is all being done to facilitate the
19 process to make sure that the physician in this case
20 would get the seed at the mammo suite. It would be
21 delivered ready to use.

22 So of course we would go through those
23 things so they would be aware, but they wouldn't be
24 going to the lab to unpack it, and so forth.

25 So we appreciate the flexibility that you

1 have built in.

2 CHAIRMAN MALMUD: Comments from the
3 audience? Yes, microphone right here. Please
4 introduce yourself.

5 MR. SHAY: This is Kevin Shay from NRC
6 Office of State and Tribal Programs. I just want to
7 have one clarification. It is my understanding that
8 OAS sent a guidance document to all the agreement
9 states, and then to NRC, for reviewing comments.

10 And my understanding is that when we
11 received the comment - actually the state program
12 received a comment, we distribute to NMSS and it is
13 our understanding that NRC - NMS and the state
14 program, we will consolidate all the comments from the
15 region's office, from SCMUI and from OGC and provide
16 only the final set of NRC comments to the OAS.

17 So I just wanted to make it clear that all
18 the comment maybe should go to NMSS and then NMS and
19 STP and OTC, and then we will have only one
20 consolidated set of consolidated comments back to the
21 OAS.

22 That is my understanding. And maybe Tom
23 can --

24 MR. ESSIG: We will serve as the
25 collection point for any comments from the committee.

1 MR. GALLAGHAR: So to clarify for the
2 committee, they would then send their comments to
3 Angela McIntosh or who?

4
5 MS. FLANNERY: You can send them to me,
6 Cindy Flannery.

7 MR. GALLAGHAR: And then STP will be
8 responsible for funneling them over to me in one
9 document?

10 MR. SHAW: One NRC document, consolidated
11 document.

12 CHAIRMAN MALMUD: John Jankovich wanted to
13 be recognized.

14 DR. JANKOVICH: This is John Jankovich
15 again. I'd like to give you an update on the testing
16 regarding the standards.

17 We in NRC, I am personally the NRC
18 delegate to International Standard for Sources, that
19 is ISO standard 2990. The working group responsible
20 for this standard met in February.

21 One of the initiatives there was that we
22 would include test procedure for iodine seeds.

23 One of the working group members took this
24 responsibility and said that in six months he would
25 contact all the manufacturers, get their input, see

1 what they would recommend, what they would think
2 reasonable.

3 So this is not the American ESME standard,
4 the ANSI standard; this is the international standard.

5 That was in February. We closed out all
6 the other issues for updating the standard, but I
7 haven't heard anything regarding the seeds. So it
8 looks like it is still open. And there may be some
9 progress once we conclude and finally update the ISO
10 standard.

11 Of course it is also possible that the
12 individual couldn't get any response from the
13 manufacturers. When we have some updates, I will let
14 Thomas know about it, and he can convey that
15 information to you.

16 CHAIRMAN MALMUD: Any other comments? Mr.
17 Leito.

18 MEMBER LEITO: I had a question, and I
19 didn't know if it was clear now, but in the document
20 that was forwarded to us a week or two ago, it states
21 that this performance evaluation has to be done
22 because it's under Part 1000, because as you alluded
23 to, the cutting and whatever.

24 It wasn't clear to me, does every
25 licensee, would every licensee have to do that? Or

1 would one licensee do it and sort of everybody
2 piggybacks on it? Or would the vendor have to do it?

3 From the way the document is worded, it
4 made it sound like you made your application to use
5 these sources, you had to submit your evaluation for
6 that, which makes it sound like every licensee has got
7 to do it.

8 MR. GALLAGHAR: For the use of the seeds
9 in this procedure?

10 MEMBER LEITO: Right. This engineering
11 and radiation safety evaluation addressing the
12 differences in the sealed source registry.

13 MR. GALLAGHAR: This is an area where, the
14 whole process has not been developed yet, meaning the
15 working group put together this licensing document,
16 and as I understand it early on, the intent then was
17 to post this document on the NRC's licensing website.
18 They have I believe four Part 1000 uses, the guidance
19 for them listed on that website now.

20 As I understood it then, this guidance
21 would then be posted on there as acceptable guidance
22 for the reviewers to use to approve an amendment
23 request to use as material.

24 CHAIRMAN MALMUD: Comment?

25 MEMBER BAILEY: I don't think he answered

1 your question. The ideal situation I believe would be
2 if the manufacturer came in and amended the SSND.
3 Then each individual user would not have to do it.
4 But you are thrown into the weird situation that you
5 have got, quote, a custom use. So at least in theory
6 each custom use is individually evaluated.

7 I think what in practice happens is that
8 the second guy who comes in in a state takes what the
9 first guy sent in, or the reviewer realizes it's
10 already been done and go with it.

11 MEMBER LEITO: Another question I had was,
12 the way the document is written, it's almost like a
13 new licensee coming in for this application.

14 Isn't it in actuality the only ones who
15 would be doing this are the ones that have to already
16 be licensed for 400?

17 MR. GALLAGHAR: I think that is a true
18 statement.

19 MEMBER LEITO: Some of the things that are
20 being asked for are things that should be part of the
21 license approval process already, and it's almost like
22 a new license application almost to be submitted.

23 MR. GALLAGHAR: I would agree, a lot of
24 the elements in that guidance would have already been
25 submitted to whatever regulatory agency is overseeing

1 that licensee; I would agree with that.

2 CHAIRMAN MALMUD: Other comments and
3 questions?

4 DR. ZELAC: Dr. Malmud.

5 CHAIRMAN MALMUD: I beg your pardon?

6 DR. ZELAC: Over here.

7 CHAIRMAN MALMUD: Oh, Dr. Zelac.

8 DR. ZELAC: Following up on what Mr. Leito
9 said, is it the expectation that seeds that would be
10 used for this purpose would in fact be seeds that had
11 been received by the institution, not used for therapy
12 implants, and were simply available as opposed to
13 holding them strictly for decay, no use, or returning
14 them to the manufacturer, they would be used for this
15 alternative purpose.

16 MR. GALLAGHAR: As I understand, after
17 discussing with the physician in Florida who came up
18 with this, that is exactly the case. He identified
19 these sources that were not being used for prostate
20 implantation, and saw that they might serve another
21 purpose for this localization of nonpalpable breast
22 lesions, and essentially created a procedure to
23 address both issues.

24 The fact that they are reusing what would
25 have been a waste stream into a beneficial use for a

1 medical use for a woman.

2 CHAIRMAN MALMUD: Dr. Howe?

3 DR. HOWE: Just to clarify an answer to
4 Ralph's question, if you have a 35.1000 use, you do
5 not have specific regulations that address that use.

6 So if you are using say a brachytherapy
7 source that has been approved for 400, and you are
8 already approved for 400, you are approved for use
9 under 400 for therapy.

10 Now it comes in to 1000 as a diagnostic
11 use, you may have to commit that you are doing the
12 things you did under 400 for the seed as it is being
13 used in its diagnostic purposes, because it is no
14 longer being used for a therapy seed.

15 And that is one reason you will see some
16 repetition of things that you may already have
17 requested under a 400 use, or whatever use the 1000
18 use comes under.

19 CHAIRMAN MALMUD: Mr. Leito.

20 MEMBER LEITO: Well, my reason for asking
21 that was, some of the things they were asking the
22 surgeons to do, okay, for example, performing surveys,
23 package receipt procedure, they are not going to do
24 that or be involved with that, or ever see those types
25 of - well, I shouldn't say see them but be involved

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1 with those activities.

2 Those are going to be done via other
3 licensee personnel, and areas, and so forth. So it
4 didn't seem like - it didn't seem appropriate that
5 this would be addressed to surgeons, because other
6 members - or other parties of the licensee - the
7 licensee's control would be doing those duties.

8 DR. HOWE: There is also an - when you are
9 writing guidance for 1000 there is also an expectation
10 that there is a wide spectrum of users. So they may
11 not be in a large hospital that you might be used to.

12 And so that is one reason the guidance is
13 there to make sure everybody ends up with the right
14 training. They may get it for another reason
15 somewhere else, but it's also possible you have a
16 licensee that isn't authorized, and doesn't do the
17 things that you are thinking of in a bigger hospital.

18 CHAIRMAN MALMUD: Thank you.

19 Any other comments for Mr. Gallagher? If
20 not, thank you again.

21 I believe that the next item is Angela,
22 correct?

23 MS. MCINTOSH: We're a little ahead of
24 schedule, but it's fine with me if it's fine with you.

25 DR. MILLER: Dr. Malmud, as Angela is

1 coming up, there was an issue that came up today that
2 I'm going to ask if, for those that can remain, I
3 recognize, since we're a little bit ahead of schedule,
4 there was an issue that came up today that would have
5 us go into a very short closed executive session
6 following the conclusion of the open agenda, for a
7 brief period of time.

8 MEMBER NAG: The other one was about the
9 homeland security issue, and HIPPA, the requirement
10 that you need to give permanent implant, that should
11 be in an open session. That didn't need to be in a
12 closed session.

13 DR. MILLER: Dr. Nag raised an issue to me
14 yesterday, and perhaps before Angela starts, if it's
15 okay with you --

16 CHAIRMAN MALMUD: Certainly.

17 DR. MILLER: We could have Dr. Nag frame
18 the issue for some discussion by the committee.

19 MEMBER NAG: I had sent an email to the
20 ACMUI about a week or two ago. I don't know whether
21 that was involved in the email or not.

22 But the issue is as follows. When you
23 have a patient with permanent implant, you are
24 supposed to give them instructions that tells them
25 what implant they had, the isotope, and how long

1 they've had it and so on, and the number that can be
2 contacted on for 24 hours seven days a week.

3 We did not involve them. We can identify
4 people in the hospital, and they can answer the
5 question. But the problem is, then, the - we call
6 them homeland security issues. The state was - or the
7 state had asked that there be personnel available in
8 the hospital who will be able to respond to any
9 inquiry whether from the police or airport authority,
10 et cetera.

11 The problem now is we all know HIPPA
12 regulations are based in privacy laws. If the police
13 or the hospital or the airport authority calls back
14 the hospital, the hospital cannot give out any
15 information without the patient's written consent.

16 So the requirement of the HIPPA
17 regulation, and the homeland security requirement are
18 at odds with each other unless the police would then
19 fax a release of information to the hospital, and then
20 the hospital can release that information.

21 So it does become somewhat of a problem,
22 because of this at least in Ohio, the Department of
23 Health in Ohio, which put this into effect, has
24 temporarily withdrawn or temporarily delayed the
25 institution of this rule, and I had to tell them that

1 since this is a matter and we were having an NRC
2 meeting, we would discuss at the NRC meeting to see
3 whether other states are having a problem to see how
4 either NRC states or any other state has solved the
5 problem.

6 CHAIRMAN MALMUD: Dr. Vetter would like to
7 comment.

8 MEMBER VETTER: I discussed that issue
9 with our compliance officer, and he indicated that if
10 in the set of instructions that you give the patient,
11 that you indicate that they would be giving their
12 consent for the release of pertinent information to
13 the authorities in the event of something like this,
14 that they understand they would be giving - that that
15 would be given up.

16 They sign the instructions, then they sign
17 that sheet saying I understand the instructions and I
18 give consent to give that information out if it's
19 necessary, then you have it.

20 DR. MILLER: So what that would mean, Dr.
21 Vetter, then if the hospital got a call from security
22 officials, let's say a person is standing in airport
23 security and is challenged, then the hospital would
24 already have that patient's authorization to supply
25 that information to security officials?

1 MEMBER VETTER: That is correct. And we
2 are fairly confident it would be about that patient,
3 because only that patient knows that and has that
4 information.

5 MEMBER NAG: That was one of the things
6 that was under discussion in our hospital. But we
7 still hadn't finalized anything.

8 CHAIRMAN MALMUD: Does that answer your
9 question? Okay.

10 MS. FAIROBENT: Dr. Malamud? Lynne
11 Fairobent from AAPM.

12 This question is surfacing in the
13 professional communities, because I also got an email
14 from Ask The Experts from HPS, from Genevieve, asking
15 what is being done on giving identification to
16 patients, again.

17 So it is surfacing from perhaps a couple
18 of other areas that maybe someone has been caught in
19 this dilemma situation, I don't know, and has raised
20 the question.

21 So I just want to throw it out that it is
22 surfacing in the general community again.

23 And one of the other questions that had
24 come up was the verification of you releasing that
25 information verifying that that truly is a request

1 from a legitimate authority asking you. And I don't
2 know how you resolve that issue.

3 CHAIRMAN MALMUD: Dr. Vetter.

4 MEMBER VETTER: I was going to respond
5 directly to your concern. According to my compliance
6 officer, we can be reasonably assured that it is about
7 that patient, because only that patient knows that
8 question. So it has to be - whatever authority is
9 calling about that patient, the patient has to have
10 been involved in the conversation.

11 MEMBER NAG: I think the question was
12 different. It was the policy. If I called up and
13 say, I am the policeman from so-and-so and I want to
14 know about this person.

15 MEMBER VETTER: Well, how did you know
16 about the patient? You can't just pick a name out of
17 the air and call and expect to get some information.

18 CHAIRMAN MALMUD: Mr. Bailey.

19 MEMBER BAILEY: Two items: You can't have
20 a number on that. That is unique to that patient,
21 that would also do it.

22 I believe the Southern California chapter
23 of the Society of Nuclear Medicine has a suggested
24 card or form or something on its website. The bad
25 news of that is, anybody can get it. But again then

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1 trying to correlate some code number or letters in the
2 individual name, and knowing which hospital, with
3 three things you've got to get right, is pretty small.

4 CHAIRMAN MALMUD: Thank you.

5 We are currently giving our patients a
6 business-sized card which indicates the patient's
7 name, the isotope and the dose, and the date that they
8 received it. And if they are stopped, they can show
9 that.

10 Thus far, none of our patients have been
11 stopped.

12 MEMBER NAG: In addition they need a
13 number, a name of an official and the number that they
14 can call.

15 CHAIRMAN MALMUD: Oh, our RSO office
16 number is on the card for the official to call in the
17 event that they wish to confirm that this patient has
18 in fact received the radiation.

19 MEMBER NAG: How would the RSO have that
20 information? The hospital or the department would
21 have the information, but not the RSO.

22 CHAIRMAN MALMUD: The RSO would know
23 because the dose was administered.

24 MEMBER NAG: Not for the permanent
25 implants.

1 CHAIRMAN MALMUD: Oh, I don't handle
2 permanent implants. I have them for the I-131 dose.

3 MEMBER NAG: Right. I think what I was
4 going to suggest, since Dr. Vetter had already solved
5 this problem at his institution, is that if from many
6 other institutions and many other states, if the NRC
7 and/or the agreement states would make this
8 information available so people will not be asking -
9 will not be trying to solve a problem that has been
10 solved already. Is there anything for that?

11 DR. MILLER: I think what the NRC would
12 have to do is take this matter up with the Department
13 of Homeland Security with regard to - we can certainly
14 make people aware, but that aspect of it wouldn't
15 necessarily be within our jurisdiction, I think.

16 We can make people aware, and what would
17 concern me would be, you know, someone tried to get
18 through airport security, they are probably in a hurry
19 to catch a flight. And if there is a long delay in
20 trying to check out if it's really them, they could
21 end up missing the flight. And that would be a
22 concern for one example that I would see.

23 So the other question would be, when they
24 have to call the hospital or whatever, is there
25 someone on duty who can answer that question 24/7?

1 MEMBER VETTER: In some cases, yes, in
2 some cases, maybe not. But in our case there is
3 always a physician on call, in radiation oncology if
4 it's seeds, who would be able to answer the question.

5 MEMBER NAG: Actually, we discussed that
6 in our hospital. The physician on call would not be
7 able to answer in a minute or two, number one, because
8 it may take a long time when you get the physician on
9 call.

10 Secondly, that person on call would not
11 know whether person X got an implant unless they go
12 back to the department and, what we decided was that
13 in our hospital at least that there is always a
14 nursing supervisor on call that is available for any
15 emergency question about any patient in the hospital
16 who is either in the hospital, or has been treated in
17 the hospital, who is located within the premise of the
18 hospital who has access to all the patient data on
19 computer, and that person is the one who is put in
20 charge, because we realize that if we get the
21 physician on call, let's say I'm here, or I'm at home,
22 it will take me half an hour to go to my department,
23 look up the data, and that is not really practical.

24 CHAIRMAN MALMUD: Excuse me, Dr. Nag, do
25 you have a nurse who is available 24/7 to determine if

1 an outpatient was treated with therapy?

2 MEMBER NAG: There is a nursing supervisor
3 for the entire hospital who has access to all patient
4 data for any emergency.

5 CHAIRMAN MALMUD: Including outpatient
6 treatments?

7 MEMBER NAG: Including, yes, anything that
8 is in the hospital computer system. So any treatment
9 is automatically in the hospital computer system, they
10 will have access.

11 There must be someone of similar capacity
12 in every hospital. In our hospital the nursing
13 supervisor.

14 But there is always someone on location
15 who has access to the hospital computer system.

16 CHAIRMAN MALMUD: Something to consider
17 for the next meeting.

18 MEMBER BAILEY: And Dr. Malmud, are there
19 any instances where a patient could have received the
20 radioactive treatment in other than a hospital, a
21 clinic, where it would be only open 9:00 to 5:00 or
22 something like that?

23 CHAIRMAN MALMUD: Yes.

24 MEMBER BAILEY: So that is a potential
25 problem also. I think it is an issue that we probably

1 need to look into harder. But it is an issue.

2 CHAIRMAN MALMUD: We have different
3 clinical situations. I'm treating patients with radio
4 iodine either for hyperthyroidism or for thyroid
5 cancer, and I tell them, "don't enter into any federal
6 office buildings." "Don't cross the bridges or the
7 tunnels into New York City." And, "if the president
8 is visiting town, stay in your house."

9 That is pretty effective in getting them
10 to adhere. Also, I don't want them riding on public
11 transportation, because it means they will be sitting
12 right next to somebody else, and that goes against the
13 six-foot rule which we discuss with these patients
14 post-therapy.

15 And thus far I have had no feedback in
16 terms of them having to explain why they are
17 triggering off a radioactive monitor.

18 But I do understand that patients who are
19 just getting thalium scans are triggering monitors in
20 some situations. We haven't run across that yet.

21 So it's - I don't think it's a problem
22 we'll solve here at this meeting, but it is something
23 worth looking into for a future meeting.

24 MEMBER NAG: And the problem is different
25 for I-125 implanted where the half-life is six - I

1 mean two months, so they are active for six months,
2 and the energy is fairly low, and therefore they can
3 go out in the public and sit next to a person.

4 CHAIRMAN MALMUD: Mr. Bailey.

5 MEMBER BAILEY: I think there is an
6 ongoing effort to educate all the people that people
7 have radioactive material.

8 And I know most of the states are trying
9 to get with all the different agencies. If you don't
10 have the magic black boxes that tell you what the
11 isotope is, and they are developing lists now of,
12 these are the isotopes you are looking for, if they
13 are not those, they may accept them.

14 But I think all of the states are now
15 saying, if you've got one, call us, we will send
16 somebody out to help you determine whether this person
17 has enough material there, number one, to cause a
18 problem, and number two, to identify what it is.

19 And we encourage NRC regional offices to
20 do the same.

21 CHAIRMAN MALMUD: May we go on the next
22 item on the agenda? Angela, I think you are on.

23 MS. McINTOSH: Good afternoon. My name is
24 Angela McIntosh, and I will briefly provide the
25 committee with an administrative conclusion that will

1 include the recommendations, action items and the
2 tentative scheduling for the spring 2006 meeting.

3 Feel free to jump in and add any
4 recommendations that you remember, because I'm working
5 from a very rough draft, and I have not necessarily
6 captured every recommendation. So feel free to jump
7 in if you remember one.

8 The first recommendation was actually
9 brought to the floor during a closed-session meeting,
10 and that recommendation, ACMUI requested that the NRC
11 provide a more detailed explanation of our board
12 certification approval process.

13 The next recommendation that I have
14 recorded is actually a recommendation supporting the
15 actions of Penn State University with regard to the
16 unauthorized injection of radioactive material. The
17 committee just formally made a motion to show its
18 support for how Penn State handled that situation.
19 That is actually the only other recommendation that I
20 have been able to capture.

21 Are there any others that anyone else
22 remembers that were brought forward and seconded?

23 CHAIRMAN MALMUD: Dr. Nag.

24 MEMBER NAG: Yes, I think Dr. Diamond made
25 the recommendation, you had ours. You can read ours

1 again.

2 MS. McINTOSH: Okay. I have a record of
3 Dr. Diamond making a recommendation, but was it
4 seconded?

5 MEMBER NAG: It was. It was seconded, and
6 it was unanimously accepted.

7 MS. McINTOSH: Can you -

8 (Voice speaking off-mike)

9 MEMBER NAG: The second one he would do.

10 MS. McINTOSH: Dr. Vetter.

11 MEMBER VETTER: Yes, relative to the issue
12 of physicians and physicists trained in foreign
13 institutions, the committee concluded that it was not
14 really an issue for physicians because there are so
15 many other controls. But for physicists, the issue
16 that came before us was, would we support the NRC
17 allowing regions to make a decision on whether or not
18 a physicist trained in a foreign institution should be
19 granted authorized medical physics status.

20 And the decision of the committee was to
21 support that concept as long as guidance was prepared
22 for a region so we had some uniformity of decision
23 making.

24 CHAIRMAN MALMUD: Thank you.

25 No other recommendations that are aware

1 of, Angela.

2 MS. McINTOSH: Okay, I do have one action
3 item that was captured that has already been
4 fulfilled. During the discussion on the energy policy
5 act, we requested that the ACMUI provide a member to
6 participate in that roundtable discussion. And it has
7 been decided that Mr. Leito and Ms. Schwarz will
8 attend the November 9th roundtable discussion.

9 So that is an item that is now closed.

10 CHAIRMAN MALMUD: That's correct. And Mr.
11 Leito will be at the table. And Dr. Schwarz will back
12 him up.

13 And Mr. Essig has agreed to bear the
14 expense, not personally, for their transportation.

15 MS. McINTOSH: Are there any other action
16 items that anyone remembers being brought forward?

17 DR. ZELAC: Angela, with respect to the
18 first one that you mentioned about NRC's review of
19 applications from boards recognition, there was a
20 motion made during the group presentation on the
21 question of status of board applications, but it
22 wasn't quite what you read.

23 As I have it written, it was that the
24 advisory committee wished to be advised of reasons why
25 particular groups of diplomats of a recognized board

1 cannot follow the board certification pathway.

2 Does that seem to ring a bell with anyone?

3 CHAIRMAN MALMUD: Thank you.

4 MS. McINTOSH: Okay. Now we would like to
5 discuss setting some tentative meeting dates for the
6 spring 2006 meeting. The last meeting was April 20th
7 and 21. We would like to - would someone like to
8 provide input as to whether or not that week, two days
9 in that week, would work again for the spring meeting?

10 MEMBER NAG: If you are doing it on a
11 Tuesday, it will be 18 and 19, Tuesday and Wednesday;
12 Wednesday and Thursday is 19 and 20. So I guess
13 somewhere within that 18, 19, 20 timeframe should be
14 okay.

15 DR. MILLER: I do know that that week is
16 problematic for me if you want me in attendance.

17 CHAIRMAN MALMUD: That range of dates is
18 okay with me.

19 MR. ESSIG: Angela, do we know if this
20 room is available on that date?

21 MS. McINTOSH: Not at this moment.

22 MR. ESSIG: So I'm wondering if we should
23 propose dates in two back-to-back weeks.

24 MEMBER NAG: If that is not workable, the
25 previous week is between 11 to 13 of April, so you

1 would have two weeks.

2 MS. McINTOSH: For the week - for April
3 18th - for that week of April 18th, are we proposing
4 the 18th or the 19th, or the 19th and the 20th?

5 MEMBER NAG: Whichever you have available,
6 when you can get the room available?

7 CHAIRMAN MALMUD: Do we have the dates of
8 Easter and Passover in April?

9 MEMBER NAG: Passover is the 13th of
10 April. Good Friday, 14th of April.

11 DR. MILLER: And Easter is April 16th, so
12 it would be after that.

13 CHAIRMAN MALMUD: Good Friday, therefore,
14 is the 14th as well. So it probably would be best not
15 to have it that week. Which is also the week of Good
16 Friday.

17 MEMBER NAG: That 13 and 14.

18 CHAIRMAN MALMUD: And Passover is April
19 13th - first two nights we want to avoid Passover, so
20 the night of the 12th and the day and night of the
21 13th are the ones I want to avoid.

22 DR. MILLER: And we were looking at 17,
23 18, 19, 20 somewhere in there.

24 CHAIRMAN MALMUD: That is fine from my
25 perspective.

1 DR. MILLER: 18th and 19th would be
2 Tuesday and Wednesday.

3 MS. McINTOSH: So do we want to propose
4 the 18th and 19th for the first set of dates?

5 CHAIRMAN MALMUD: It looks good so far.

6 MEMBER NAG: The following week would be
7 bad for me.

8 MR. ESSIG: Rather than the week before,
9 how about two weeks before?

10 MEMBER VETTER: No, the NCRP is here.

11 MS. McINTOSH: Well, would that work to
12 tie NCRP in with the ACMUI meeting, the week of the
13 meeting?

14 DR. HOLAHAN: Well, would that work, to
15 tied NCRP in with the ACMUI meeting that week?

16 MEMBER VETTER: The NCRP is the April 3rd
17 and 4th. The board meets on the 5th. So that would
18 put you out to Thursday and Friday of that week.

19 MS. McINTOSH: What about March?

20 MR. ESSIG: Well, wait, we're all happy
21 with 18th and 19th.

22 MEMBER NAG: Yes, but we don't know if
23 this room is available. 19th, 20, 20 or 21, you have
24 three or four possible sequences for that week.

25 MS. McINTOSH: So what are we proposing

1 for the second set of dates?

2 MEMBER NAG: So I like 18 and 19. If that
3 doesn't work, 19 and 20. If that doesn't work, 20 and
4 21. So you will have any two days.

5 MR. ESSIG: The problem with this room,
6 when it's taken, it's typically taken for the entire
7 week.

8 MEMBER NAG: It's taken for the whole
9 week?

10 MEMBER VETTER: What about the following
11 week, April 24th through 28th? Is that a problem for
12 people?

13 MEMBER NAG: The later part of the week is
14 a problem for me.

15 MEMBER VETTER: So April 24th through
16 26th?

17 MS. McINTOSH: 24th through 25th?

18 MEMBER VETTER: 26th. Within that window.

19 MEMBER LEITO: Mr. Chair, would it be
20 advisable to maybe have Angela send something out
21 after today, and have all the members respond say by
22 Monday - not even that long. Say next Tuesday,
23 because that would give them a couple of days to read
24 their email and just say, what's unacceptable. So
25 that maybe by next Tuesday you could have an answer,

1 and go from there. Would that be okay?

2 MS. McINTOSH: Yes, we would have to do
3 that. Since we have several days. We're going to
4 have to lock in one of them.

5 DR. HOLAHAN: That would give members an
6 opportunity to look at their schedules and the
7 meetings they have to go to.

8 MEMBER VETTER: But you could do that this
9 week yet?

10 MS. McINTOSH: I could do it early next
11 week.

12 MEMBER VETTER: Okay, if you do it early
13 next week then I need 2-1/2 weeks to respond.

14 MS. McINTOSH: We'll get it done.

15 CHAIRMAN MALMUD: Okay. So tentatively,
16 at least until we can confirm the availability of the
17 room, it will be the week of April 19-20.

18 MEMBER SULEIMAN: On of the last two weeks
19 in April, is that what it is, either/or?

20 MS. McINTOSH: What I have as proposed
21 dates are April 18 and 19, or April 24 and 25, 25 or
22 26.

23 MEMBER NAG: April 18, 19, or 19,20, or
24 20, 21. I mean you have those three for that week,
25 plus if that whole week doesn't work then you have

1 the following week.

2 MS. McINTOSH: Okay, so the week of April
3 18th.

4 MEMBER NAG: The week you have that big
5 window.

6 MR. ESSIG: So we'll try to get this room.
7 If we cannot assure this room, then we will work on
8 the auditorium.

9 MEMBER NAG: The other thing, if the
10 Marriott is available, is that a problem?

11 MR. ESSIG: I'd rather not do that again,
12 because it was pretty costly to do that. And we can't
13 video to the regions from there, either.

14 DR. HOLAHAN: And we have to justify that
15 nothing is available in this building.

16 MS. McINTOSH: Okay, I believe that is it.

17 CHAIRMAN MALMUD: Now, may I ask a
18 question, Angela, administrative? When we put our
19 expenses in for this meeting, do we put them in today?

20 MS. McINTOSH: That would be preferred.

21 CHAIRMAN MALMUD: Give them to you today?

22 MS. McINTOSH: That is the best way to go.

23 MEMBER NAG: Otherwise you have until
24 Friday.

25 CHAIRMAN MALMUD: Right. No, I was just

1 asking because I gave it to you and then you gave it
2 back to me.

3 MEMBER VETTER: You were talking I think
4 about motel expense.

5 CHAIRMAN MALMUD: I'm not going to do
6 anything for this committee tomorrow or the next day.
7 So I'm done.

8 MR. ESSIG: No, I was just asking, was
9 your question related to your hotel expense or your
10 time. Time is the thing that is due by Friday. Your
11 hotel can be submitted somewhat after that if you
12 need.

13 CHAIRMAN MALMUD: Okay, great.
14 Is there a motion for adjournment?

15 MEMBER NAG: So move.

16 MEMBER VETTER: I second it.

17 CHAIRMAN MALMUD: It's been moved and
18 seconded and everyone agrees.

19 Everyone have a safe trip home.

20 Now if you still want to have a closed
21 session, Dr. Diamond is not here, Dr. Williamson is
22 not here.

23 DR. MILLER: It's an informational
24 session. Once we close it, I will explain what we
25 want to discuss, and those members that want to remain

1 for the information can do so. We need to terminate
2 the video and telephone lines.

3 (Whereupon at 4:35 p.m. the open portion
4 of the above-entitled proceeding was adjourned.)

5