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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

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Tuesday, January 18, 2005

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Telephone Conference Call

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The above-entitled matter came on for hearing, pursuant to notice, at 1:00 p.m, Leon S. Malmud, M.D., Chair, presiding.

COMMITTEE MEMBERS PRESENT:

- LEON S. MALMUD, M.D. Chair
- JEFFREY F. WILLIAMSON, Ph.D., Member
- DOUGLAS F. EGGLI, M.D., Member
- RALPH P. LIETO, Member
- SUBIR NAG, M.D., Member
- SALLY SCHWARZ, R.Ph., Member
- ORHAN SULEIMAN, Ph.D., Member
- RICHARD J. VETTER, Ph.D., Member

1 NRC STAFF PRESENT:

2 THOMAS H. ESSIG, Designated Federal Official

3 IVELISSE CABRERA

4 CYNTHIA FLANNERY

5 LINDA GERSEY

6 AARON McCRAW

7 ANGELA McINTOSH

8 RONALD ZELAC, Ph.D.

9

10 ALSO PRESENT:

11 LISA DIMMICK, Nucletron Corporation

12 ROSHUNDA DRUMMOND, American Association for

13 Therapeutic Radiology and Oncology

14 LYNNE FAIROBENT, American College of Radiology

15 MELISSA MARTIN, American College of Radiology

16 GLORIA ROMANELLI, American College of Radiology

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I-N-D-E-X

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Opening Remarks (Open Session) T. Essig 4

Mr. Essig, Designated Federal Official, ACMUI, will commence the open session with introductory remarks explaining the purpose of the meeting and welcoming all in attendance

Update to Medical Event Criteria Definition (Open Session) (Presenter: J. Williamson, PhD) 9

The ACMUI's Subcommittee on review of the NRC's medical event definition will forward its recommendation(s) to the main Committee, for discussion and a final vote. The full ACMUI will then forward final recommendation(s) to the NRC staff with respect to updating the medical event definition.

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

1:10 p.m.

1
2
3 MR. ESSIG: On the record. All right. I
4 would like to open the meeting as Designated Federal
5 Official. I am pleased to welcome you to this
6 publicly noticed conference call meeting of the ACMUI.
7 My name is Thomas Essig. I'm Branch Chief of the
8 Material Safety Inspection Branch and I've been
9 designated as a Federal Official for this advisory
10 committee in accordance with 10 CFR Part 7.11.

11 This is an announced meeting of the
12 Committee being held in accordance with the rules and
13 regulations of the Federal Advisory Committee Act and
14 the Nuclear Regulatory Commission. The meeting was
15 announced in the December 22, 2004 edition of the
16 Federal Register. Today's meeting will focus on an
17 update of the criteria for definition of a medical
18 event. An ACMUI subcommittee has been reviewing this
19 area and will share its recommendations with the full
20 Committee today.

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

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

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

9 As part of the preparation for this
10 meeting, I have reviewed the agenda for members and
11 employment interests based on the general nature of
12 the discussion we're going to have today. I've not
13 identified any items that would pose a conflict.
14 Therefore, I see no need for individual members of the
15 Committee to recuse themselves from the Committee's
16 decisions making activities. However, if during the
17 course of our business you determine that you have
18 some conflict, please state it for the record and
19 recuse yourself from that particular aspect of the
20 discussion.

21 At this point, I would like to perform a
22 roll call of members that may be participating today.
23 Healthcare Administrator and Chairman Dr. Leon Malmud.
24 I think we recognize that he'll be a little bit late.
25 State Representative Mr. Edgar Bailey. Nuclear

1 Medicine Physician, Dr. Douglas Eggli.

2 DR. EGGLI: I'm here.

3 MR. ESSIG: Okay. Radiation Oncologist
4 Dr. David Diamond. Radiation Oncologist Dr. Subir
5 Nag.

6 DR. NAG: Yes, I'm here.

7 MR. ESSIG: Nuclear Pharmacist Ms. Sally
8 Schwarz.

9 CHAIRMAN MALMUD: Leon Malmud.

10 MR. ESSIG: Ah, excellent. I just called
11 your name and you are now here. Good. This is Tom
12 Essig, Dr. Malmud. I'm just going through my opening
13 remarks and I was about ready to turn it over to you
14 or chair the opening part of the meeting myself. But
15 now that you're here, I'll turn it over to you as soon
16 as I'm done with these remarks.

17 CHAIRMAN MALMUD: Thank you.

18 MR. ESSIG: Radiation and Safety Officer
19 Dr. Richard Vetter.

20 DR. VETTER: Here.

21 MR. ESSIG: Therapy Physicist Dr. Jeffrey
22 Williamson.

23 DR. WILLIAMSON: Here.

24 MR. ESSIG: Nuclear Medicine Physicist Mr.
25 Ralph Lieto.

1 MR. LIETO: Present.

2 MR. ESSIG: Okay. Patient Advocate
3 Representative Dr. Robert Schenter. Nuclear
4 Cardiologist Dr. William van Decker. Representative
5 of the Center for Devices in Radiological Health Dr.
6 Orhan Suleiman.

7 DR. SULEIMAN: Present.

8 MR. ESSIG: Okay. And let me just do a
9 quick count here. Seven. Mr. Chairman, we barely
10 have a quorum, but we do. I know ask NRC staff who
11 are present to identify themselves. I'll start with
12 the individuals in the room here and then we'll turn
13 it over to others of NRC who may be calling in from
14 elsewhere.

15 MS. CABRERA: Ivelisse Cabrera.

16 DR. ZELAC: Dr. Ronald Zelac.

17 MR. McCRAW: Aaron McCraw.

18 MS. GERSEY: Linda Gersey.

19 MR. ESSIG: Okay. Others from NRC who are
20 calling in remotely.

21 MS. FLANNERY: Cindy Flannery.

22 MR. ESSIG: Okay. Anybody else from NRC?
23 I would ask members of the public who are
24 participating if they wish to identify themselves,
25 please.

1 MS. FAIROBENT: Lynne Fairobent, ACR.

2 MS. DIMMICK: Lisa Dimmick, Nucletron
3 Corporation.

4 MS. MARTIN: This is Melissa Martin with
5 ACR.

6 MS. DRUMMOND: Roshunda Drummond with
7 AATRO.

8 MS. ROMANELLI: Gloria Romanelli, ACR.

9 MR. ESSIG: Okay. Following the
10 discussion of each item, the Chair at his option may
11 entertain comments or questions from the members of
12 the public who are participating with us today. At
13 this point, Dr. Malmud, I would turn the meeting over
14 to you.

15 CHAIRMAN MALMUD: Tom, could you just keep
16 it going? I have a problem here. I'm on the line but
17 just get it going.

18 MR. ESSIG: Sure. Will do.

19 CHAIRMAN MALMUD: Thank you.

20 MR. ESSIG: Okay. I believe that from
21 what I said earlier, the purpose of today's meeting is
22 to hear for the full Committee the recommendation from
23 the Medical Event Subcommittee on the certain criteria
24 associated with the definition of a medical event. So
25 I would turn to the Subcommittee Chair and we'll start

1 the discussion there and then Dr. Malmud will join us
2 as he can.

3 CHAIRMAN MALMUD: I'm here, but I -- Go
4 ahead.

5 MR. ESSIG: Okay. Subcommittee Chair.

6 DR. WILLIAMSON: Okay. This is Jeff
7 Williamson. I hope all of the members of the ACMUI
8 and the NRC staff have a copy of the revised report
9 that I sent out early this morning, January 18th.
10 What I will do is maybe make a few introductory
11 remarks to explain the process we went through and
12 then simply step through the different recommendations
13 in the report for ACMUI discussion. Would that be
14 appropriate, Tom?

15 CHAIRMAN MALMUD: Yes, Jeff. Thank you.

16 DR. WILLIAMSON: Oh, you're here now,
17 Leon. Okay, I didn't realize. All right. Well, this
18 task was assigned to the ad hoc subcommittee on
19 medical events at the ACMUI meeting of October 18,
20 2004. We were asked to address problems in the
21 medical event report criterion specifically focusing
22 on permanent brachytherapy implants. This issue was
23 raised originally by Dr. Nag at our last briefing with
24 the NRC Commissioners. The NRC Commissioners
25 responded with a staff requirement memo asking the

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1 staff with ACMUI advice (a) to evaluate the
2 appropriateness and justification of the 20 percent
3 threshold currently built into the Medical Event
4 Reporting Rule and (b) consider appropriate ways for
5 conveying risk, if any, associated with these levels
6 of discrepancy.

7 So to develop some recommendations in this
8 highly controversial and very technically complicated
9 area, the Subcommittee met twice, once on December 7,
10 2004 and more recently, on January 13th, I believe, in
11 a non-public telephone conference call. So the
12 lateness of this last meeting or proximity to this
13 meeting is the reason why revised recommendations were
14 not available on a more timely basis. Are questions
15 about our charge and the process by which we develop
16 the recommendations?

17 CHAIRMAN MALMUD: This is Malmud. No
18 questions about the charge. Are there questions from
19 other members of the Committee to Dr. Williamson? If
20 not, please move ahead.

21 DR. WILLIAMSON: Okay, well let me before
22 I jump in, I want to acknowledge the important role
23 played by the Subcommittee members who were Dr. David
24 Diamond, Mr. Ralph Lieto, Mr. Subir Nag in addition to
25 myself. I think this was very much a team effort.

1 So with that introduction, I would like to
2 start with the document. The document is divided into
3 important issues that we considered and then under
4 each issue, there are some recommendations that were
5 made which are indicated in bold type.

6 I think to make the flow of this most
7 logical what I would like to do is start with issue
8 number two and then after we've dealt with two through
9 four, maybe come back and pick up number one if the
10 Subcommittee agrees that's appropriate. I think some
11 of the issues depend on one another and it would be
12 helpful to get some consensus on the technical points
13 first.

14 CHAIRMAN MALMUD: Thank you, Jeff. Is
15 everyone agreeable to doing two first?

16 DR. NAG: Yes.

17 CHAIRMAN MALMUD: Thank you.

18 DR. WILLIAMSON: So the issue number two
19 can be stated as follows: "Is the 20 percent absorbed
20 dose threshold a reasonable reporting criterion for
21 over and under doses to the target volume?" And this
22 is specifically for permanent seed implant although
23 there are some comments for other types of radiation
24 medicine procedures as well.

25 So in general, the Subcommittee rejected

1 the concept of replacing a single prescribed dose with
2 a dose range. This is absorbed dose now that we're
3 talking about for brachytherapy implants on the basis
4 that this is inconsistent with the current mainstream
5 industry practices whereby a prescribed dose is
6 specified in terms of a single well-defined value
7 rather than a range. So we really didn't consider
8 that further. I guess you could take that as a
9 recommendation.

10 Maybe it would be helpful if I read the
11 recommendations under this part and then we can decide
12 what to do. The first recommendation is that "20
13 percent is a reasonable action level for reporting
14 events of QA significance to NRC for temporary
15 implants, external beam treatments and unsealed
16 radiopharmaceutical administrations." Are there
17 comments on that and specifically from our Chairman,
18 do you want to entertain votes on these piece by piece
19 or do you want to hear the whole thing?

20 CHAIRMAN MALMUD: I think it would be more
21 efficient if we did it piece by piece.

22 DR. WILLIAMSON: Okay.

23 CHAIRMAN MALMUD: Is there agreement among
24 the Committee to do it piece by piece?

25 DR. VETTER: Yes.

1 CHAIRMAN MALMUD: Thank you.

2 MR. LIETO: Yes.

3 CHAIRMAN MALMUD: Thank you. All right.
4 So, Jeff, what's the first piece?

5 DR. WILLIAMSON: The motion is that in
6 concordance with Dr. Siegel's assessment and past
7 ACMUI discussion the motion is 20 percent is a
8 reasonable action level for reporting events of QA
9 significance to NRC for temporary implants, external
10 beam treatments and unsealed radiopharmaceutical
11 administration.

12 CHAIRMAN MALMUD: Is there a second to the
13 motion?

14 MR. LIETO: Second. This is Ralph Lieto.

15 CHAIRMAN MALMUD: Thank you, Ralph. Is
16 there any discussion of the motion?

17 DR. VETTER: This is Dick Vetter. I have
18 a question.

19 CHAIRMAN MALMUD: Yes.

20 DR. VETTER: This motion seems to go
21 beyond the charge of the Committee in that it
22 recommends including (Beep sound) radiopharmaceutical
23 administrations. Since those were not addressed here
24 by this subcommittee specifically, I'm wondering
25 whether the motion shouldn't be limited to temporary

1 implants.

2 CHAIRMAN MALMUD: Is there anyone else who
3 agrees with that observation?

4 DR. NAG: I agree with Dick.

5 CHAIRMAN MALMUD: All right.

6 MR. LIETO: I -- This is Ralph Lieto. I
7 do not.

8 CHAIRMAN MALMUD: Don't agree with Dick?

9 MR. LIETO: No, I think it's within the
10 charge if you will in the March 16, 2004 notice from
11 the Commissioners as to what the question was that we
12 were supposed to address. It mentioned all
13 modalities.

14 DR. WILLIAMSON: This is Jeff Williamson.
15 As having tried to dig out from the transcript of
16 October 16 I believe what exactly our charge was, it's
17 not especially clear that it was limited exclusively
18 to permanent implants although that's certainly what
19 we emphasized in the majority of our discussions.

20 DR. ZELAC: Dr. Malmud.

21 CHAIRMAN MALMUD: Yes. Who is this?

22 DR. ZELAC: This is Dr. Zelac.

23 CHAIRMAN MALMUD: Yes, Ron.

24 DR. ZELAC: I just wanted to put in a
25 little historical perspective on this. At the October

1 meeting of the Advisory Committee, this question was
2 considered and the various modalities for which the
3 plus or minus 20 percent might be appropriate based on
4 the information from Dr. Siegel that I had provided
5 was considered.

6 The decision at that meeting of the
7 Advisory Committee was that the plus or minus 20
8 percent was an appropriate criterion of all modalities
9 with the possible exception of permanent implant
10 brachytherapy and it was on that basis that the
11 subcommittee was formed to consider that specific
12 modality. However, this recommendation from the
13 Subcommittee is in line with the earlier vote and
14 decision by the whole Committee that the plus or minus
15 20 percent was in fact an appropriate criterion for
16 all the other modalities.

17 CHAIRMAN MALMUD: Thank you, Dr. Zelac.
18 Dr. Vetter, would you care to comment?

19 DR. VETTER: I did. I'm satisfied with
20 that explanation.

21 CHAIRMAN MALMUD: Thank you. With that
22 explanation, do we accept Dr. Williamson's motion as
23 presented.

24 DR. NAG: But I think that motion is
25 repeating because that has already been accepted

1 before by the whole Committee and it was only the
2 permanent implants that was in question. So, yes, we
3 have that motion, but this has already been voted on
4 and has been accepted. We're just repeating something
5 that has been accepted in public record in the whole
6 Committee.

7 DR. WILLIAMSON: This is Dr. Williamson.
8 I would suggest if there's not opposition to it we
9 accept it so that there is a single document, kind of
10 a coherent body, of ACMUI accepted motions.

11 CHAIRMAN MALMUD: Any further discussion
12 of the motion? If not, all in favor of the motion.

13 (Chorus of yeses.)

14 CHAIRMAN MALMUD: Any opposed to the
15 motion?

16 (No response.)

17 CHAIRMAN MALMUD: Any abstentions?

18 (No response.)

19 CHAIRMAN MALMUD: The motion moves forward
20 unanimously. Thank you. Dr. Williamson, next item.

21 DR. WILLIAMSON: Okay. We continue. For
22 permanent implants, the Subcommittee did not agree
23 with the above recommendation. So basically there are
24 two recommendations. The first is "the 20 percent
25 absorbed dose threshold is not justifiable for

1 permanent implants." This was adopted on a 3/0 vote
2 with myself abstaining.

3 CHAIRMAN MALMUD: That is correct
4 historically.

5 DR. WILLIAMSON: So I think that is a
6 motion. The rationale is listed here and the reasons
7 detail reasonably well in the report but it's
8 basically felt that due to the limited control the
9 radiation oncologists have on positioning sources
10 accurately, the issues of objectively and reproducibly
11 defining the target volume and so forth, it was felt
12 that a 20 percent threshold is simply too close to the
13 kind of implant-to-implant variability seen in routine
14 clinical practice to be useful as a criterion for
15 distinguishing good implants from bad implants or good
16 QA programs from bad QA programs.

17 CHAIRMAN MALMUD: Dr. Williamson, are you
18 presenting this as a motion?

19 DR. WILLIAMSON: Yes.

20 CHAIRMAN MALMUD: Is there a second to the
21 motion? Dr. Nag?

22 DR. NAG: Yes.

23 CHAIRMAN MALMUD: It's been moved and
24 seconded by Dr. Nag. Any discussion? All in favor?

25 (Chorus of yeses.)

1 CHAIRMAN MALMUD: Any opposed?

2 (No response.)

3 CHAIRMAN MALMUD: Any abstentions?

4 (No response.)

5 CHAIRMAN MALMUD: It passes unanimously.

6 Thank you. Next, Dr. Williamson.

7 DR. WILLIAMSON: Okay. The next point is
8 a follow-on to this. "Defining medical events for
9 permanent implants in terms of percent thresholds of
10 absorbed dose delivered to the target volume is not a
11 useful and practical approach." This is basically
12 saying not only is the 20 percent not good but
13 basically this is the wrong approach conceptually to
14 defining a medical event for permanent seed implant.

15 CHAIRMAN MALMUD: Is there a second to
16 this motion?

17 DR. NAG: Yes.

18 CHAIRMAN MALMUD: Dr. Nag.

19 DR. NAG: Dr. Nag, yes.

20 CHAIRMAN MALMUD: The motion is open for
21 discussion. Is there any discussion of this motion?

22 DR. WILLIAMSON: This is an area where I
23 personally had some concerns. So for the record, I
24 would like to note my concerns.

25 CHAIRMAN MALMUD: Dr. Williamson's concern

1 is noted, though he has made the motion.

2 DR. WILLIAMSON: Well, I am Chair of the
3 Subcommittee. It is my duty to make the motion.

4 CHAIRMAN MALMUD: Yes, we recognize that
5 and appreciate it.

6 DR. WILLIAMSON: So may I state my
7 concern?

8 CHAIRMAN MALMUD: Please do.

9 DR. WILLIAMSON: Okay. The concern is
10 encapsulated in the last paragraph on page three of my
11 report. Basically, in mainstream prostate
12 brachytherapy practice, the authorized user describes
13 treatment intention in units of absorbed dose to the
14 target volume. Through treatment planning, the source
15 strength, number of seeds and seed arrangement are
16 identified to realize this prescription.

17 So the concerns that I have and this
18 foreshadows future recommendations is that if we omit
19 dose as part of the reporting criterion, then
20 essentially all error pathways related to treatment
21 planning and the conversion of the physician's
22 statement of intention from absorbed dose to number of
23 seeds and total activity will be beyond the scope of
24 regulatory oversight. This seems like a large class
25 of errors to omit from this process and inconsistent

1 with regulatory approach for other modalities. So
2 that states my concern. I will add the other
3 Subcommittee members recognize this concern and
4 likewise I recognize the appeal and simplicity and
5 unity of the majority approach.

6 DR. NAG: This is Dr. Nag. I do see Dr.
7 Williamson's point of view. However, historically if
8 you go back in time, the prescription for
9 brachytherapy used to be made in terms of millicuries.
10 Implants even now in some places the prescription for
11 the symmetry for, let's say, cervix cancer and other
12 forms of cancer are made in terms of too many
13 milligram hours. So although in most places, we do
14 prescribe in terms of how much dose, I do not see it
15 being inconsistent to prescribe in terms of
16 millicuries especially for centers that use the
17 approach that for certain volumes you need certain
18 number of millicuries.

19 CHAIRMAN MALMUD: I hear Dr. Nag.

20 DR. NAG: Yes.

21 CHAIRMAN MALMUD: Are you looking for a
22 response?

23 DR. NAG: No, not really. I just made the
24 statement that although I do see Dr. Williamson's
25 point of view, the point the Subcommittee was making

1 is not inconsistent with -- medical practice.

2 CHAIRMAN MALMUD: Thank you. Your concern
3 is noted in the record.

4 DR. VETTER: This is Dick Vetter.

5 CHAIRMAN MALMUD: Dr. Vetter.

6 DR. VETTER: I think there is a corollary
7 with radiopharmaceutical therapy. The nuclear
8 medicine physician wants to give a certain dose to the
9 thyroid for example and he back calculates activity.
10 The prescription actually indicates the activity that
11 would be administered to the patient not the dose to
12 the thyroid.

13 CHAIRMAN MALMUD: You are of course
14 correct, Dr. Vetter. The prescription however if it
15 varies by 20 percent could fall under this
16 recommendation even though the dose to the thyroid is
17 not really discussed. So that my understanding of
18 this, Dr. Vetter, is that if I were to write a
19 prescription for ten millicuries of I_{131} and if it was
20 plus or minus the ten millicuries irrespective of the
21 dose received by the thyroid, my prescription would
22 valid if it were within 20 percent of the dose that I
23 ordered, meaning the number of millicuries ordered.

24 DR. VETTER: Yes, I understand that and I
25 think the recommendation of the Subcommittee would

1 result in the same kind of a scenario for permanent
2 implants. What I'm suggesting is that the two would
3 be consistent with each other.

4 CHAIRMAN MALMUD: Thank you.

5 DR. WILLIAMSON: They would be but they
6 would be inconsistent with the current standard of
7 clinical practice. With due respect to Dr. Nag's
8 point, it's certainly true that at one time that maybe
9 a few outlying practices really don't think in terms
10 of absorbed dose for permanent implants. Basically
11 all of the literature in the field is analyzed with
12 respect to absorbed dose to a target volume and all of
13 the current recommendations for how to treat prostate
14 cancer with permanent seed implants are stated in
15 terms of absorbed dose.

16 So I think it's fine to exempt this
17 activity from regulatory practice, but one should be
18 cognizant of the significance of this. There have
19 been reported significant misadministrations and
20 medical events due to dose calculation errors which
21 would lead to an erroneous estimate of total source
22 strength.

23 CHAIRMAN MALMUD: We duly note your
24 concern, Dr. Williamson.

25 MR. LIETO: This is Ralph Lieto. I have

1 a point of clarification in terms of the report. I
2 don't know if this should be addressed to Tom Essig or
3 the Chair, but will the report itself be an attachment
4 to the minutes of this meeting or incorporated? The
5 reason being that I'm asking this is Dr. Williamson's
6 reservations would be incorporated into the record in
7 total as he specified.

8 CHAIRMAN MALMUD: It's not a question to
9 me.

10 MR. LIETO: I don't know who it should be
11 directed to, but I will direct it to the Chair for
12 appropriate redirection.

13 CHAIRMAN MALMUD: I have to direct it to
14 staff. Tom?

15 MR. ESSIG: Yes, Dr. Malmud and Mr. Lieto,
16 we can handle it one of two ways. We can, knowing
17 that all that we've said today is part of the
18 transcript. We can certainly include it. It would
19 embedded in there, but I think probably the other way
20 and the way I would prefer to do it is a memorandum
21 recommending with these recommendations that have been
22 voted on today that memorandum on ACMUI letterhead to
23 Dr. Charles Miller.

24 In fact you could include any minority
25 views as part of the recommendation. Remember in my

1 opening remarks I said that we valued dissenting or
2 minority views. So an example of that would be that
3 we could include a minority view in the recommendation
4 or as a note right after the individual
5 recommendation.

6 CHAIRMAN MALMUD: So we do have the
7 opportunity to present this as a matter of information
8 as a minority view.

9 DR. WILLIAMSON: Yes, we do.

10 CHAIRMAN MALMUD: Would that be
11 satisfactory, Mr. Lieto and Dr. Williamson?

12 MR. LIETO: That sounds fine with me.

13 DR. WILLIAMSON: Yes, no problem.

14 CHAIRMAN MALMUD: Thank you. May we now
15 move forward on this motion?

16 DR. ZELAC: Excuse me, Dr. Malmud.

17 CHAIRMAN MALMUD: Dr. Zelac, yes?

18 DR. ZELAC: I have a suggestion for
19 consideration by the Advisory Committee.

20 CHAIRMAN MALMUD: We would love to hear
21 the suggestion.

22 DR. ZELAC: The suggestion is to look at
23 the motion or the significant recommendation that's
24 being considered now and think about whether it would
25 be improved expanded to include to Dr. Williamson's

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1 concern by adding one word to it as follows. As it
2 reads now, it starts "Defining medical events for
3 permanent implants in terms of percent of thresholds"
4 etc. If we were to consider placing the word
5 "exclusively" after the word "implants" so it would
6 read as follows. "Defining medical events for
7 permanent implants exclusively in terms of percent of
8 thresholds" etc., would that be of any value?

9 CHAIRMAN MALMUD: It seems to me that it
10 would be. Dr. Williamson, your comment?

11 DR. WILLIAMSON: I - potentially but in
12 light of the recommendations downstream, I mean I'm
13 not sure it would help. I think that it will perhaps
14 be clear by the time we get to the end of the
15 recommendation I think that this cannot be handled
16 without a revision of the rule. At least, that is my
17 opinion. You will have to see for yourselves. But I
18 think at that time we might entertain additional
19 proposals to consider whether the treatment planning
20 component of the process of planning and delivering
21 such implants should have a role in the revised
22 definition of medical events should that arise in
23 these considerations.

24 CHAIRMAN MALMUD: Thank you, Dr.
25 Williamson. Dr. Nag, do you have a comment about the

1 insertion about the adverb "exclusively"?

2 DR. NAG: No.

3 CHAIRMAN MALMUD: I'm sorry. I didn't
4 hear you.

5 DR. NAG: No.

6 CHAIRMAN MALMUD: No comment. Dr. Vetter.

7 DR. VETTER: No, I have no comment.

8 CHAIRMAN MALMUD: All right. So shall we
9 move the motion forward as it is then?

10 DR. VETTER: I would suggest so.

11 CHAIRMAN MALMUD: All right. All in favor
12 of the motion?

13 (Chorus of yeses.)

14 CHAIRMAN MALMUD: Any opposed?

15 (No response.)

16 CHAIRMAN MALMUD: Any abstentions?

17 DR. WILLIAMSON: I abstain.

18 CHAIRMAN MALMUD: Dr. Williamson abstains.
19 Okay. Thank you.

20 DR. WILLIAMSON: Now we come to a more
21 positive suggestion for a replacement strategy for
22 medical events for permanent implants. This is
23 recommendation no. 3. I will read it.
24 Recommendations, here we are, the first bullet. The
25 Subcommittee proposes the following recommendation:

1 "For permanent implants, the NRC should recommend to
2 licensees that the authorized user specify in the
3 written directive the treatment site in terms of the
4 organ to be implanted (e.g. prostate), the
5 radionuclide and total source strength. A medical
6 event occurs if the source strength actually implanted
7 in the target organ is not within 20 percent of the
8 prescribed total source strength."

9 CHAIRMAN MALMUD: That is the motion. Is
10 there a second to that motion?

11 DR. NAG: I would like to modify that last
12 sentence a little bit and that is that if the activity
13 was implanted into the correct target organ, but
14 subsequently migrated to other sites that the portion
15 that migrated would not be within that 30 percent.

16 DR. WILLIAMSON: Okay. So I think the
17 proposal is to after the occurrence of "20 percent,
18 excluding seed migration,".

19 DR. NAG: Yes. I think there is already
20 some words similar to that.

21 DR. WILLIAMSON: That is correct.

22 CHAIRMAN MALMUD: So the recommendation of
23 Dr. Nag is that your recommendation, Dr. Williamson,
24 have inserted into it after the words "20 percent" a
25 comma and then a --

1 DR. WILLIAMSON: A phrase.

2 CHAIRMAN MALMUD: -- prepositional phrase.

3 DR. WILLIAMSON: Yes.

4 CHAIRMAN MALMUD: And then a comma and
5 continue on.

6 DR. WILLIAMSON: That's correct. And the
7 phrase is "excluding seed migration."

8 CHAIRMAN MALMUD: Very good. Is there a
9 second to that amended motion?

10 DR. NAG: I second.

11 DR. WILLIAMSON: Okay. Let me just note
12 a few of the remarks to start off the discussion.
13 This particular recommendation as it stands alone
14 would seem to be implementable without a rule change
15 because of a recent ruling of the Office of General
16 Counsel stating basically that total source strength
17 and absorbed dose are interchangeable in the other
18 brachytherapy category for written directive.

19 Ralph will correct me if I make any
20 mistakes here about this. There was controversy over
21 the terminology used and I want to be sure that
22 technically the motion we have is correct and precise.
23 The second technical point is in the context of modern
24 brachytherapy practice. Total source strength which
25 is used in the definition of dose for low dose rate

1 implants in Part 35 is the product of air-kerma
2 strength per see or equivalently apparent activity in
3 mCi and the number of seeds implanted.

4 This is different from the quantity
5 contained activity which is 25 to 100 percent larger
6 than the apparent activity due to self-absorption
7 infiltration. So I think I'm speaking for the
8 Subcommittee. We really didn't vote on this, but I
9 believe the intent of the Subcommittee was that the
10 concept of total air-kerma strength or equivalently
11 apparent activity was the quantity intended by their
12 recommendation.

13 DR. NAG: Yes, that is correct. This is
14 Dr. Nag.

15 CHAIRMAN MALMUD: Dr. Williamson and Dr.
16 Nag agree.

17 DR. WILLIAMSON: So maybe a question to
18 the staff would be is there any technical or juridical
19 objection to this interpretation?

20 CHAIRMAN MALMUD: Dr. Williamson is
21 addressing a question to NRC staff regarding this.

22 DR. ZELAC: Dr. Malmud.

23 CHAIRMAN MALMUD: Yes, Dr. Zelac.

24 DR. ZELAC: My opinion, we would always
25 have to get our Office of General Counsel's input, but

1 my opinion is that is not the most difficulty for this
2 particular regulation grouping. If we were talking
3 however about shipment, transportation, that would be
4 another issue. But in this context, I think using
5 apparent activity should be a satisfactory
6 appropriate.

7 CHAIRMAN MALMUD: Thank you, Dr. Zelac.

8 DR. WILLIAMSON: Okay. Well, those are
9 most of my remarks. You can read the other notes
10 those who are interested.

11 DR. VETTER: This is Dick Vetter. I have
12 a question.

13 CHAIRMAN MALMUD: Yes, Dr. Vetter.

14 DR. VETTER: Does the Subcommittee intend
15 to restrict this to organs or does organ include
16 tissues? In other words, today we're talking mostly
17 about prostate implants. Tomorrow we may be talking
18 about some other kind of an implant that might be in
19 a tissue rather than in an organ.

20 DR. NAG: This is Dr. Nag. The charge to
21 us was stated as for permanent implants especially as
22 applied to prostate. However, I do agree with your
23 concern that we do implant in other areas. For
24 example, we implant tumor beds after reception of the
25 organ because therefore there is no organ that feeds

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1 the tumor bed. But I think if we say off the target
2 area and the target would be the organ, the target
3 would be for example the area and so I think this will
4 still allow you to prescribe as a physician intends to
5 without violating that this is only an organ. I think
6 the area surrounding you can call it some very
7 prosthetic tissue. I mean I think that will be still
8 be allowed.

9 DR. WILLIAMSON: Let me suggest maybe a
10 potential modification. We could easily modify this
11 to read as follows and that would handle the
12 objection. "For permanent implants, the NRC should
13 recommend to licensees that the AU specify in the
14 written directive the treatment sites..." and then
15 "(for example, the organ to be implanted) the
16 radionuclide and total source strength." That would
17 handle it and reduce the term "organ" rather than
18 being a defining characteristic of treatment site an
19 example.

20 DR. NAG: One thing, I would say you
21 cannot say "for example, the organ" but you can say
22 "for example the prostate." Because if you say "for
23 example the organ to be implanted, well that is what
24 we are going to implant. So I would say "for example,
25 the prostate."

1 CHAIRMAN MALMUD: This is Malmud. Would
2 it be acceptable to say "the organ or tissue"? Would
3 that be sufficiently inclusive?

4 DR. WILLIAMSON: I think so.

5 DR. NAG: Yeah.

6 MR. LIETO: This is Ralph. I would
7 definitely say Dr. Malmud's suggestion for amendment.

8 DR. WILLIAMSON: Okay.

9 CHAIRMAN MALMUD: Dr. Vetter, do you
10 agree?

11 DR. VETTER: I missed part of what Ralph
12 said.

13 CHAIRMAN MALMUD: Ralph agreed with me,
14 but I had suggested inserting "the organ or tissue."

15 DR. VETTER: Yes, I prefer "the organ or
16 tissue."

17 CHAIRMAN MALMUD: I'll submit that as an
18 amendment. Are all in favor of the motion as amended?

19 (Chorus of ayes.)

20 CHAIRMAN MALMUD: Any abstentions?

21 (No response.)

22 CHAIRMAN MALMUD: Any nays?

23 (No response.)

24 CHAIRMAN MALMUD: All right. That's
25 unanimous.

1 MS. SCHWARZ: Dr. Malmud, I have just
2 joined the conference call about ten minutes ago. I
3 apologize for being late.

4 CHAIRMAN MALMUD: Thank you for joining
5 us. Is that Sally?

6 MS. SCHWARZ: Yes.

7 CHAIRMAN MALMUD: Thank you, Sally.
8 Welcome.

9 MS. McINTOSH: Dr. Malmud. This is Angela
10 McIntosh.

11 CHAIRMAN MALMUD: Yes, Angela.

12 MS. McINTOSH: Since there were a couple
13 of amendments to the original recommendation for the
14 record so that we have a clean statement about what is
15 recommended and can't be confused, can you restate in
16 one statement the complete recommendation?

17 CHAIRMAN MALMUD: Yes. Thank you. Better
18 than my restating it, I will ask Dr. Williamson to
19 restate it.

20 DR. WILLIAMSON: Okay. The amended motion
21 is as follows. "For permanent implants, the NRC
22 should recommend to licensees that the authorized user
23 specify in the written directive the treatment site,
24 in terms of the organ to be implanted (e.g. prostate),
25 the radionuclide and total source strength. A medical

1 event occurs if the source strength actually implanted
2 in the treatment site is not within 20 percent,
3 excluding seed migration, of the prescribed total
4 source strength."

5 CHAIRMAN MALMUD: Thank you, Dr.
6 Williamson. We hope that that is clear for the
7 record. May we move onto the next item?

8 DR. WILLIAMSON: Yes. The next item is
9 merely advisory. It is the second black bullet near
10 the bottom of page four. It is basically to point out
11 at this point this is a recommendation. Users could
12 continue using absorbed dose. This is simply an item
13 of information that in adjudicatory a medical event,
14 of determining whether an implant is a medical event,
15 when the AU has used absorbed dose to specify written
16 directive would require essentially the licensee and
17 the NRC to agree upon the relevant dosimetric index
18 such as D_{90} , the anatomic target volume, that is the
19 organ and any margin used, and the imaging modality
20 and timing of this imaging procedure used to visualize
21 the target volume.

22 That if you don't agree on any of these
23 things, if there is disagreement, there could well
24 easily be 20 percent discrepancies just because the
25 individuals involved are not talking about the same

1 thing. This is not a motion. It is just an
2 information item based upon our December 7th
3 deliberation.

4 CHAIRMAN MALMUD: Does the information
5 item presented by Dr. Williamson require any further
6 discussion by the members of the Committee?

7 (No response.)

8 CHAIRMAN MALMUD: The silence suggests
9 not. Thank you, Jeff.

10 DR. WILLIAMSON: All right.

11 DR. NAG: I have one question. Dr. Nag.
12 After that sentence that Jeff read, it says that
13 individual variations may and do deviate by more than
14 20 percent and these variations do not constitute a
15 medical event. Now if you put that, then if someone
16 is prescribing a dose and has to the prostate and very
17 prostatic organs, what will constitute a medical event
18 then?

19 DR. WILLIAMSON: A 20 percent variation
20 whatever the authorized user wrote in the written
21 directive. But other dosimetric quantities, other
22 deviations of these, we discussed. You were not there
23 at the teleconference but the staff agreed that under
24 the current medical event definition, 20 percent
25 variations in any of these other quantities would not

1 constitute a medical event.

2 CHAIRMAN MALMUD: Does that clarify it for
3 you, Dr. Nag?

4 DR. NAG: Yes. Just for example if
5 someone writes that the D_{90} , I'm prescribing a D_{90} of
6 145 grains and the D_{90} turns out not to be within 20
7 percent of that. That will be a medical event then.

8 DR. WILLIAMSON: That's correct.

9 DR. NAG: Well, I mean as long as the
10 authorized user realizes that, I don't know why he
11 would want to open himself to that kind of a problem.

12 DR. WILLIAMSON: Well, I think that your
13 questions will arise again. As we go through some of
14 the other recommendations, I think it will maybe
15 become clear that it might not be tenable to offer
16 even as a possibility or an alternative to the
17 authorized user to use absorbed dose. So I would
18 suggest maybe we come back to this point if it's
19 relevant after reviewing the other recommendations.

20 CHAIRMAN MALMUD: Thank you. We'll move
21 on to the next recommendation.

22 DR. WILLIAMSON: Okay. The next series of
23 recommendations is contained in Issue No. 4. The No.
24 4 issue can be stated as follows. Is the wrong site
25 medical event criterion, that is 35.3045(a)(3),

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1 workable especially in the case of prostate seed
2 implant? And the Subcommittee thought not. "The
3 Subcommittee unanimously agreed that this criterion is
4 completing impractical clinically for permanent sealed
5 source implants." That is a recommendation that dose-
6 based criterion contained in 35.3045 for wrong-site
7 medical event criterion is completely impractical
8 clinically for permanent sealed source implants.

9 CHAIRMAN MALMUD: That's a correct summary
10 of the Subcommittee's conclusions.

11 DR. WILLIAMSON: I believe so.

12 CHAIRMAN MALMUD: So do we wish to make an
13 motion that we feel that it is an impractical item?

14 DR. NAG: So moved.

15 DR. WILLIAMSON: So moved.

16 CHAIRMAN MALMUD: It's been moved and
17 seconded by Drs. Williamson and Nag. All who would
18 agree?

19 (Chorus of ayes.)

20 CHAIRMAN MALMUD: Any opposition?

21 (No response.)

22 CHAIRMAN MALMUD: Any abstention?

23 (No response.)

24 CHAIRMAN MALMUD: Thank you. Next item,
25 Dr. Williamson.

1 DR. WILLIAMSON: Okay. The next item is
2 a recommendation to fix this. So the recommendation
3 is "Permanent implants on written directives
4 specifying total source strength implanted in the
5 treatment site should be exempted from the wrong site
6 medical event reporting requirement, 35.3045(a)(3)."

7 CHAIRMAN MALMUD: Is there a second to Dr.
8 Williamson's motion?

9 DR. NAG: I think -- I'm not really -- I
10 know we went through some of this, but I don't think
11 we finalize the thing in the Subcommittee. But
12 anyway, let's go on with the discussion. Maybe we
13 come back to it.

14 CHAIRMAN MALMUD: Okay.

15 DR. WILLIAMSON: It's on the table. Let
16 me review some of the discussion points that I thought
17 of during the meeting and some that were discussed
18 during the meeting. I think Dr. Nag is right. There
19 are. This is a very complicated issue and there may
20 be some words missing that are necessary. So the main
21 rationale for this proposal is that wrong site medical
22 events would be adequately covered by treatment sites,
23 delivery criteria failures which is paragraph (a)(1)
24 of 3045. Whenever more than 20 percent of the
25 implanted seeds are placed in an organ outside the

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1 target volume, then less than 80 percent of the seeds
2 would remain in the target.

3 So in kind of why you need to have two
4 separate criteria, the thought was that since we've
5 decided to go to a geometric criterion based on what
6 fraction of the implanted activity is in the target
7 volume, why not incorporate wrong site and over/under
8 dose of the target into a single criterion? I do
9 think it makes sense.

10 A second discussion point is implementing
11 this recommendation would require a rule change.
12 Without changing recommendation three which was the
13 previous recommendation we voted on that medical
14 events should involve 20 percent error in delivering
15 the seeds to the prostate. Without changing three
16 from recommended guidance to a recommended rule
17 revision, eliminating the wrong site criterion might
18 not be practical.

19 Here we get now to this piece, as we get
20 more deeply into this to come up with a consistent
21 approach, the more radical revision of the whole
22 regulation may be needed. I will note that I had
23 personally, well, sympathetic with this whole general
24 approach of defining wrong site medical event in terms
25 of geometry, basically where the seeds are placed.

1 I had a technical concern which is at the
2 bottom of page five and top of page six which
3 basically is if an authorized user, or I'll give a
4 hypothetical example, prescribed one hundred seeds to
5 the prostate but accidentally implanted one hundred
6 seeds in the rectal wall and the observed this and
7 compensated for this by implanting an additional seeds
8 in the prostate, this individual would comply with the
9 revised 35.3045(a) (1) but by all reasonable estimates,
10 this would still involve a wrong site administration.

11 My suggestion is to tinker. Well, a
12 suggestion is to basically modify Recommendation 3 to
13 read as follows. "Any implant of the medical event if
14 (a) the total source strength implanted in the patient
15 exceeds the written directive by more than 20 percent
16 OR (b) the total source strength implanted in the
17 target volume deviates from the written directive by
18 more than 20 percent." This would exclude that rather
19 fanciful case. So personally while having sympathy
20 for this approach, I thought technically it needs some
21 work.

22 CHAIRMAN MALMUD: Any comments?

23 DR. NAG: Yeah. I think that will still
24 present some difficulty. I mean trying to weed out
25 one very unlikely scenario may introduce a practical

1 problem for the majority of the practitioners. I
2 think I'm not really happy with it the way it is at
3 the moment, but I want to hear some discussion.

4 DR. WILLIAMSON: What is the practical
5 problem, Subir?

6 DR. NAG: I think when we do an implant,
7 let's say other than prostate, we implant a tumor bed
8 and we want to lay as many seeds as we can about one
9 centimeter apart within the tumor bed. We don't
10 really know what exactly is the bond link (PH) and
11 many times technically because of other blood vessels
12 and other tissues you lay as many seeds as you can in
13 the neighborhood of the area you're treating.

14 It's not a very well-defined organ. How
15 can you say when you are outside your target, when you
16 are inside your target, and I could very easily place
17 more than 20 percent of the seeds in the tumor bed
18 because it is near the tumor bed. So I mean there is
19 a problem if you are trying to implant the prostate
20 and you're implanting the rest and implant it in the
21 wrong site or you are trying to implant the prostate
22 and you implant the penial bulb instead. That's an
23 entirely wrong site, but if you are in the vicinity of
24 that, you may have more than 20 percent of your seeds
25 just outside your target area.

1 DR. WILLIAMSON: But I would respond that
2 if you look ahead to Recommendation No. 5, that would
3 be a conscious decision on the part of the radiation
4 oncologist to put more seeds than he or she originally
5 anticipated. So a simple follow-up would be simply to
6 revise the written directive because you are able to
7 take advantage of anatomic exposure issues and so on
8 to do a better implant. So you put down 120 seeds
9 within 24 hours and that seems to me to be quite
10 appropriate.

11 CHAIRMAN MALMUD: This is Dr. Malmud.
12 Jeff, may I ask you a practical question since I'm not
13 a radiotherapist. When ordering seeds from the
14 supplier for the patient, would you normally have that
15 many extra seeds around where someone who was
16 irresponsible and planted 180 rather than 100 seeds?

17 DR. WILLIAMSON: For prostate, my
18 impression is that skilled physics and radiation
19 oncology practitioners are pretty good about
20 estimating accurately how many seeds they need and
21 depending on the level of experience and the size of
22 the inventory they have, they probably would not order
23 very many more. But I think if haste came about such
24 as Dr. Nag mentioned and the treatment team were clear
25 that the boundaries were not well defined and couldn't

1 really be appreciated fully until they were in the
2 middle or maybe even near the end of the operative
3 procedure, I think then the physicist would order on
4 the high end based on consultation with radiation
5 oncologists.

6 DR. NAG: This is Dr. Nag. For prostate,
7 usually you can emulate the prostate really well before
8 the procedure until you have an accurate idea of the
9 number of manipuly (PH) you want. But there are many
10 other times when you are implanting tumor bed where
11 the tumor has been receptive and therefore you have no
12 idea how much you are going to place, that you would
13 have higher variation, but that is not a medical event
14 because you are changing or you are making a conscious
15 decision to change at the treatment table.

16 DR. WILLIAMSON: I think that should be
17 incorporated in any legitimate cluster of definitions
18 of written directive, medical event and rules for
19 allowing revision.

20 CHAIRMAN MALMUD: Well, my concern, this
21 is Malmud, my concern is that we not become too
22 prescriptive because if we become overly prescriptive,
23 we will create unintended consequences that will limit
24 the ability of physicians to practice medicine in best
25 practice. This also should not exceed our mission

1 which is the issue of radiation exposure, not the
2 practice of radiation oncology.

3 DR. NAG: This is Dr. Nag. My feeling on
4 this is that we have said that more or less than 20
5 percent to the target area will constitute
6 misadministration or medical event. That thing itself
7 should cover ourselves because rather than placing 20
8 percent to a wrong site, that first definition is
9 enough. It will keep the bad actors away.

10 DR. WILLIAMSON: Do we have a motion on
11 the table?

12 DR. NAG: No, not really because we wanted
13 to have this discussion.

14 DR. WILLIAMSON: The motion on the table
15 is to exempt permanent seed implants from
16 35.3045(a)(3).

17 DR. VETTER: This is Dick Vetter. I'm not
18 in my office and can't grab my regulations. Can
19 anyone read that paragraph 35.3045(a)(3)?

20 DR. WILLIAMSON: I could paraphrase it.

21 DR. VETTER: All right. Could you please?

22 DR. ZELAC: Yes, this is Ron Zelac. I
23 could read it. Let me read what's in the preceding
24 materials. This is (a)(3). So (a) is "A licensee
25 shall report any event except for an event that

1 results from patient intervention in which the
2 administration of byproduct material or radiation from
3 byproduct material results in," now here is three, "a
4 dose to the skin or an organ or tissue other than the
5 treatment site that exceeds by 0.5 sievert (50 rem) to
6 an organ or tissue and 50 percent or more of the dose
7 expected from the administration defined in the
8 written directive exceeding for permanent implants
9 seeds that were implanted in the correct site but
10 migrated outside the treatment site."

11 DR. WILLIAMSON: I will note for the ACMUI
12 benefit. The reason we didn't like this is that the
13 criterion implies that even if one voxel of normal
14 tissue receives a dose that deviates by 50 centigrade
15 or 50 percent, this could constitute a medical event
16 depending on what you took to be the correct plan. So
17 to us, it seemed like this was a dose, if the dose-
18 based criterion is dubious for specifying the dose to
19 the target volume, a dose-based criterion compared to
20 a geometric criterion is even more dubious for
21 specifying the wrong site.

22 I think the sense of the Subcommittee is
23 one way or another it should be defined geometrically
24 in terms of where the source is put in the right place
25 or the wrong place and not was the absorbed dose in

1 excess of 50 percent relative to some other site which
2 is very vague and it's not really been tested by OJC
3 or anyone.

4 DR. VETTER: But as I understand it in
5 order for to be classified as a medical event, you
6 have to satisfy both criteria, 50 rem to that voxel
7 and 50 percent of the prescription, is that correct,
8 which is based on activity.

9 DR. ZELAC: The intent is 50 rem or 50
10 percent of the dose that was expected to be received
11 in the administration by that particular tissue or
12 organ.

13 DR. VETTER: Okay. So it's totally dose-
14 based.

15 DR. WILLIAMSON: It is totally dose-based.
16 The proposal, I think, the broad proposal is to, which
17 even I agree with, maybe Dr. Nag no longer does, but
18 at the time the Subcommittee agreed it was reasonable
19 to do away or exempt permanent implants at least from
20 this provision of medical event and make sure that the
21 primary definition of medical event which is activity-
22 based covers wrong site administration. So there
23 would only be essentially one criterion.

24 DR. NAG: Yes, I think the definition that
25 is there is so vague that I don't think anyone would

1 be able to enforce it anyway and I think even if we
2 leave it the way it is it doesn't add or take anything
3 away. No matter how you rewrite it, it's very
4 difficult to say what the wrong site is. So even if
5 we leave the way it is, correct me, I don't think the
6 NRC can take any actions at least with the wrong site
7 unless the seed were placed in an absolutely different
8 area of the body.

9 CHAIRMAN MALMUD: Dr. Nag, this is Dr.
10 Malmud. Do you understand your statement to be stated
11 that you believe that the current regulation as
12 written is sufficiently adequate to cover most
13 situations without restricting unduly the practice of
14 radiation oncology?

15 DR. NAG: Yes, and that's simply because
16 it's so hard to quantitate what would the dose, that
17 portion of alternated would have been because you can
18 see that. Therefore no one will be able to enforce
19 that in any way.

20 CHAIRMAN MALMUD: Let me ask a question of
21 you. Has the NRC ever attempted to enforce that in a
22 way which Dr. Williamson was concerned about with
23 respect to the burden borne by even on voxel?

24 DR. NAG: As far as I know, no, but I
25 think Ron Zelac would be able to say that better than

1 I would.

2 CHAIRMAN MALMUD: Dr. Zelac.

3 DR. ZELAC: Actually even the better
4 source of information if she were on the line would be
5 Dr. Donna Beth Howe. She's been involved in this
6 activity for a goodly long time. However, from
7 conversations that I've had with her, it is my
8 understanding that there has never been such a pointed
9 attempt to enforce this regulation. That there's been
10 the thought of reasonableness that has always entered
11 into any actions associated with events where this
12 might come into play. Keep in mind, of course, that
13 this section 35-3045(a)(3) is intended to apply to all
14 therapeutic modalities and it's in that context that
15 we're now looking at possibly a different approach for
16 permanent implant and permanent implant only.

17 CHAIRMAN MALMUD: You are correct. Thank
18 you, Dr. Zelac. Since your concern, Dr. Williamson,
19 is a theoretic one which we've not experienced to the
20 best of our knowledge, might you be willing to accept
21 the maintenance of the current wording?

22 DR. WILLIAMSON: Well, I mean the argument
23 is very strange. The argument is that the regulation
24 is so absurd no one would dare enforce it.

25 DR. NAG: Exactly.

1 DR. WILLIAMSON: I would say that's not a
2 very good basis for rule-making in my opinion.

3 DR. NAG: Yes, but the problem is to make
4 something better is going to be so difficult that I
5 don't think we'll be able to do it in the next 45
6 minutes.

7 DR. WILLIAMSON: But it's actually very
8 simple. If we simply extrapolate your very own
9 activity-based criterion one step further, you have a
10 limitation both on the total number of seeds you can
11 place in the patient and the fraction of seeds that
12 must be in the specified treatment site. If one of
13 those criterion is not met within 20 percent, it's a
14 medical event and you have now defined wrong site
15 medical event as any permanent implant in which more
16 than 20 percent of the seeds were unintentionally
17 placed by the physician outside the treatment site.

18 So now it's no more burden to go back to
19 your post-op example. The first criterion we
20 discussed is no more problem to enforce than this one.
21 So my suggestion would be that it could easily be
22 fixed.

23 CHAIRMAN MALMUD: This is Malmud. I have
24 a naive question as a non-radiotherapist. I recall
25 that the original discussion related to not only the

1 placement of the seeds but the migration. Are there
2 instances in which more than 20 percent of the seeds
3 migrate?

4 DR. NAG: Usually, they are not. The only
5 way I think more than 20 percent may migrate without
6 any harm would be if the seeds were placed in the
7 bladder and the patient automatically either passed it
8 through the urine or we usually go into the bladder
9 and retrieve the seeds. So that probably is the only
10 possible instant. Otherwise, the usual variation to
11 the number of seeds migrating is about two to five
12 percent activity.

13 CHAIRMAN MALMUD: Then the other part of
14 my question is, I ask this of the radiation
15 oncologists, in the course of good medical practice is
16 it uncommon for more than 20 percent of the seeds to
17 be misplaced.

18 DR. NAG: It's very uncommon for more than
19 20 percent to be misplaced when you're talking about
20 the prostate or any defined organ. However if you are
21 having an ill-defined organ where you don't know where
22 that organ is, you could have more than 20 percent
23 outside depending on how you define that volume. That
24 is what I'm afraid of that you can have 20/30 percent
25 outside in the immediate vicinity so that if you tried

1 to -- more than 20 percent outside the volume and you
2 say the target or the area that you want to implant
3 was in the pancreas and you have more than 20 percent
4 of the seeds just outside the pancreas, someone could
5 mistakenly or if someone wanted to say you wanted to
6 implant the pancreas and now you have 20 percent of
7 the seeds outside the pancreas or just outside the
8 pancreas.

9 DR. WILLIAMSON: You know my response to
10 that would be that this same objection could be raised
11 against the motion we voted, No. 3, where we said
12 permanent implants that the NRC should recommend to
13 licensees that they specify the written directive in
14 terms of total activity implanted in the treatment
15 site.

16 The NRC and physicians and everybody, you
17 have to realize what clinical reality is. In certain
18 setting, for example, the post-op case, there is no
19 way to define the target boundary precisely and the
20 only thing you can do is ask the question "Are the
21 seeds reasonably in the correct region of the body"
22 and that's it. You can do no more.

23 The other dilemma that I think Dr. Nag
24 raises is also false because at the time of the seed
25 implantation, the authorized user always has the right

1 to revise the written directive upwards if 20 percent
2 more seeds are needed to complete the implant in his
3 or her judgment.

4 DR. NAG: Exactly, and that is why -

5 DR. WILLIAMSON: So this is a dilemma.

6 DR. NAG: Okay. Dr. Nag. That is why I'm
7 saying that, yes, now I can place a few more seeds
8 into the area I want. But the problem is I have more
9 than 20 percent just outside the area and we are
10 making up quantities by putting more seeds inside the
11 area.

12 DR. WILLIAMSON: Well, then you say that
13 the area is expanded. You have the right to revise
14 the definition of treatment site, too.

15 DR. NAG: Well, but it's not right to do
16 that anyway. Then I can revise wrongly implanted to
17 rectal and say immediately after I did that, that now
18 I'm going to implant the prostate and the rectal. So
19 if I want to cheat, you cannot prevent me from
20 cheating.

21 DR. WILLIAMSON: That's correct. We
22 certainly cannot.

23 DR. NAG: That is why I'm saying rather
24 than making this -- not to make the thing too
25 complicated. So long we are getting to a reasonable

1 degree, I think we should stop there and not try to
2 make it over complicated.

3 CHAIRMAN MALMUD: May we get another
4 opinion besides those of Dr. Williamson and Dr. Nag?

5 DR. VETTER: This is Dick Vetter.

6 CHAIRMAN MALMUD: Yes.

7 DR. VETTER: If I may. Since
8 Recommendation 3 specifies the dose or dosage if you
9 will in terms of radionuclide and total source
10 strength, then it makes sense to me if subsequent
11 regulation are also related to radionuclide and total
12 source strength. So I'm trying to understand some of
13 the complexities that Dr. Nag is trying to educate us
14 on. But simply to be consistent, it seems to be that
15 the medical event should be based on source strength
16 rather than dose.

17 DR. NAG: Yeah, and the medical event we
18 have already discussed and we have already solved
19 that. Now we are talking about the wrong site and
20 what I'm trying to say is that it sometimes can be
21 very complex to say how exactly we define the wrong
22 site. Something that is far removed is very easy to
23 say. Something that is in the near vicinity is very
24 hard to say what exactly is the wrong site.

25 DR. WILLIAMSON: Agreed. It's very true.

1 CHAIRMAN MALMUD: Is the wrong site an NRC
2 issue or is it a medical care issue?

3 DR. SULEIMAN: This is Orhan.

4 CHAIRMAN MALMUD: Yes.

5 DR. SULEIMAN: If it's part of the
6 inherent uncertainty with performing the examination,
7 it's a medical issue. If it borders on negligence or
8 somebody did something very wrong, I think it clearly
9 is a regulatory issue.

10 And let me discuss my perception on the
11 dose. I mean the calculation of absorbed dose is very
12 complex. You have the target volume. You have the
13 activity of the source and a lot of times the activity
14 of the source is synonymously and really incorrectly
15 used as a dose when we're talking about radiation-
16 absorbed dose.

17 So why not for simplicity focus on what's
18 being administered because that's easy to verify and
19 check, but separate from that, at some point you have
20 to validate the dose that you're calculating. I see
21 these as two separate types of calculations.

22 I don't know if these recommendations are
23 really addressing that or maybe they should focus on
24 it and the site, are you talking about a proximal site
25 or something that's further away? The further away

1 you are, the contribution to the dose is going to be
2 less and less significant.

3 DR. WILLIAMSON: I think the intent of the
4 recommendation was just to basically address wrong
5 site in terms of did you implant the seeds in the
6 right site plus or minus 20 percent or did you put
7 more than 20 percent of the total by mistake into the
8 wrong site, not as a medical intention? So the burden
9 is on the authorized user to specify the medical
10 intention and if necessary, revise it at the time of
11 the procedure.

12 DR. SULEIMAN: How would this be enforced?
13 How would this be identified?

14 DR. WILLIAMSON: A typical scenario maybe
15 Ron Zelac or Donna Beth Howe could clarify, but my
16 understanding is in the series of implants mishaps
17 that were identified, prostate implants were found
18 subsequently on, I guess, day after or 30-day later CT
19 imaging. It was incidently discovered that the seeds
20 had been placed essentially in the wrong organ and in
21 some cases, the majority of seeds were placed in the
22 rectal wall or bladder wall. While at the time of the
23 procedure using only ultrasound, the physician thought
24 they were in the prostate. So this was a mistake in
25 terms of interpreting the ultrasound images I guess.

1 DR. VETTER: This is Dick Vetter. It
2 seems to me that the physician at the completion of
3 the procedure ought to be able to describe what the
4 target volume was and therefore, I'm uncomfortable
5 suggesting that we should exempt these permanent
6 implants from wrong site medical event reporting.

7 DR. NAG: Now again, I think after I -- I
8 did think about this and from what happened medically.
9 My feeling was that our previous definition of
10 administration of medical implants would catch the
11 wrongdoers and let's not rewrite the definition of the
12 wrong site. Leave the phasing as it is in the -- Part
13 35 and let's not try to redo that. Sometimes when you
14 redo something, you create more problems than you
15 solve.

16 DR. VETTER: But is that even applicable
17 since subparagraph (3) is based on dose, not based on
18 source strength?

19 DR. NAG: I don't know exactly what you're
20 talking about.

21 DR. VETTER: Well, paragraph
22 35.3045(a)(3).

23 DR. NAG: Right.

24 DR. VETTER: That says it's a medical
25 event if the dose in the extra-target volume tissue is

1 more than 50 rem or more than 50 percent of, I forgot
2 the exact words, the prescribed dose. Whereas the
3 prescription is not based on dose. It's based on
4 source strength.

5 DR. NAG: But that is why I'm saying that
6 without even writing anything, you don't even need to
7 say permanent implant at exam because permanent
8 implant are being prescribed differently. I mean this
9 paragraph is something that you really cannot enforce
10 anyway. We didn't want to waste the time trying
11 revise it because it's not applicable anyway. We can
12 put "Not applicable." But to write something that is
13 permanent implant need not or permanent implant
14 statement also at this point, I don't think we really
15 need to.

16 DR. WILLIAMSON: Well, you know I would
17 guess the reason why this has not been tested by NRC
18 is that everyone's afraid to apply it. If they did,
19 I think there could potentially be thousands and
20 thousands of implants that would agree and if one
21 person decided to test the system and the Office of
22 General Counsel ruled that that was a legitimate
23 interpretation of this, it could cause mayhem. So I
24 honestly think this is a --

25 The Commissioners have handed us an

1 opportunity to fix something that's really broken.
2 The activity-based methodology that Dr. Nag has
3 introduced is a potential fix for this. It's very
4 simple and straightforward. It doesn't have all this
5 complexity of dose calculation for permanent implant.
6 I think it's something that should be considered.

7 MR. LIETO: Jeff and Subir, this is Ralph
8 Lieto. Then basically it sounds like what you are
9 saying in answer to the Item 4 question is we've
10 already addressed it in that first recommendation and
11 really we should just kind of maybe cancel out the
12 reminder of that because what we're trying to do is
13 fix something that obviously is not going to be fixed
14 in a meeting of this length and is going to require a
15 lot more input even if it is fixable.

16 DR. NAG: Yes, I would say that let's
17 continue with our meeting because we have only half an
18 hour more and there is not going to be any major
19 problem with this the way it is now because you are
20 defining now permanent implant in terms of the termini
21 some much administered activity and you cannot now go
22 back and enforce that you are going to have more than
23 50 percent of what the dose would have been until I
24 think that it will not apply. So let's --

25 DR. WILLIAMSON: That is not true, Subir.

1 The way the rule is written certainly the two parts
2 are independent of one another and they certainly
3 could enforce this. I mean how can you say that.

4 DR. NAG: How are you going to enforce the
5 thing that you are going to have 50 percent higher
6 dose or -- The other thing is that that would be true
7 even for a removable implant. I mean in a removable
8 implant a certain portion will be getting a pretty
9 high dose. So unless you are really implanting into
10 the wrong area of the body, you really cannot enforce
11 it.

12 DR. WILLIAMSON: That's why I'm
13 recommending we change it to adhere to that insight
14 that you have just had. Because you notice the last
15 bullet under this point at the top of page six, it
16 basically says this is a problem not only for
17 permanent seed implants but perhaps for all of
18 brachytherapy.

19 So I think it seems very strange we would,
20 perhaps we can't fix it now and we just leave it.
21 We've already said it's broken. We've agreed with
22 that and we could agree we need maybe to have a more
23 detailed proposal to discuss this at some later time.

24 CHAIRMAN MALMUD: May I ask another naive
25 question from a non-radiotherapist? It is broken. Is

1 there any evidence that it has been broken?

2 DR. NAG: My feeling is that no because I
3 don't think -- You know it's very hard to identify
4 what is a wrong site unless it's totally in a
5 different place of the body. So just leave it
6 slightly vague like it is and then if there's an
7 implant on the left side of the body rather than the
8 right side, it will be applicable right away.

9 If you are implanting something that's
10 very far away instead you are implanting the liver,
11 you are implanting the pancreas, that's very
12 definite. And if there is some way it is very so
13 vague, you really cannot bring it up. So my feeling
14 is leave this out for the time being.

15 CHAIRMAN MALMUD: Thank you, Dr. Nag.
16 Let's see. Mr. Lieto, Dr. Vetter, any comments about
17 Dr. Nag's recommendation to be left as it is.

18 DR. VETTER: Well, I think we're having a
19 little trouble getting past this. So I guess I would
20 agree with Dr. Nag. If we have time, we can come back
21 to it but that we go on for the time being.

22 CHAIRMAN MALMUD: Thank you.

23 MS. SCHWARZ: Dr. Malmud. Sally Schwarz.

24 CHAIRMAN MALMUD: Yes, Sally.

25 MS. SCHWARZ: I just wanted to mention.

1 Is it possible since really other than the
2 subcommittee that's dealt with all these issues, we
3 haven't really, I mean it would be nice to have
4 additional time to kind of reread what all has been
5 presented in that maybe we could discuss this again at
6 the April meeting at least this particular point.

7 CHAIRMAN MALMUD: That's certainly
8 possible.

9 DR. WILLIAMSON: I think this is very
10 reasonable to simply table this second recommendation
11 under point number four.

12 CHAIRMAN MALMUD: All right. Let us table
13 -- All in favor of tabling it?

14 (Chorus of ayes.)

15 CHAIRMAN MALMUD: Thank you. Let's move
16 on to the next item.

17 DR. WILLIAMSON: Issue No. 5 is "Does the
18 option of revising the Written Directive as per
19 35.40(a)(6)(ii) prior to completing the procedure
20 create an opportunity for AUs to avoid reporting
21 technically inferior implants as medical events?"
22 Basically, the answer seems to be yes. There are
23 several cases in which a large fraction of the seeds
24 were implanted in the wrong organ. The AU revised the
25 written directive weeks after performing the procedure

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1 to lower the intended dose arguing that the underdose
2 would be compensated by additional radiotherapy and so
3 forth.

4 So this has happened and been a concern
5 that I think the ACMUI has been supportive of in the
6 past. The general recommendation the Subcommittee
7 made was that for your consideration "that written
8 directive revisions, intended only to avoid NRC
9 enforcement actions and that do not address legitimate
10 medically-indicated revisions of the treatment plan,
11 are not justified and that either rule changes or
12 changes in enforcement policies should be undertaken
13 to close this loophole." That's recommendation one
14 under part 5.

15 CHAIRMAN MALMUD: Are there any comments
16 about this recommendation one under part 5 which is on
17 page six of the material?

18 DR. NAG: The only question someone may
19 have is how can we say that that was made or intended
20 for only to avoid an NRC enforcement. That's the only
21 slight problem I see. I know what we mean, but it's
22 hard to say. It's like going into a legal battle.
23 You do it only to avoid the NRC rules.

24 DR. WILLIAMSON: Well, we're not making
25 the claim about any specific person. This is a

1 statement of a problem. It is not a regulation or a
2 rule. So you don't need to have a decidable criterion
3 for applying it.

4 CHAIRMAN MALMUD: Well, I understand, this
5 is Malmud, Dr. Nag's comment about intent. Perhaps we
6 should simply drop out that part of the statement and
7 leave the rest of the statement in. The SC
8 unanimously agreed that written directive revisions
9 should only at best legitimate medically-indicated
10 reasons.

11 MS. SCHWARZ: I agree with that revision.

12 CHAIRMAN MALMUD: Would that be acceptable
13 to you, Jeff?

14 DR. WILLIAMSON: Yes. Do you want to
15 propose the exact text you have in mind? It's your
16 revision.

17 CHAIRMAN MALMUD: Okay. "The SC
18 unanimously agreed that written directive revisions
19 should address only legitimate medically-indicated
20 revisions of the treatment plan."

21 DR. NAG: I think that's plain enough.

22 DR. WILLIAMSON: Yeah, I think that's
23 fine.

24 CHAIRMAN MALMUD: If that's a motion, will
25 one of you second it?

1 MS. SCHWARZ: Second.

2 CHAIRMAN MALMUD: All in favor?

3 (Chorus of ayes.)

4 CHAIRMAN MALMUD: Any nays?

5 (No response.)

6 CHAIRMAN MALMUD: All in agreement. Thank
7 you. Next item.

8 DR. WILLIAMSON: The next proposal is a
9 fix to the problem. "For permanent implants based on
10 written directives specifying total source strength
11 implanted in the treatment site, 35.40(c) and
12 35.40(b)(6)(iii) should be amended to require
13 completion of the written directive and documentation
14 of any written directive revision within 24 hours of
15 completing the source insertion procedure." That's
16 the recommendation.

17 35.40(b) and (c) are the definitions of
18 written directive for other brachytherapy. So what
19 this is a proposal to add some verbiage which for
20 permanent implants only would require written
21 directive revisions to be made within 24 hours of the
22 completion of seed insertion.

23 DR. NAG: Actually, this follows very much
24 the rules for other implants as well. That written
25 directive should be within 24 hours of completion of

1 the procedure. The only problem in the permanent
2 implant was that there was no indication as when the
3 radiation procedure ever ended and therefore it
4 created a loophole and putting the word "source
5 insertion procedure" does many to close that loophole.

6 CHAIRMAN MALMUD: This is Malmud. May I
7 make a suggestion that it be within one working day of
8 completion of the source insertion procedure? So that
9 if a department is only open Monday to Friday, it
10 could be done on a Monday for Friday's work.

11 DR. WILLIAMSON: Seems okay.

12 MS. SCHWARZ: Yes.

13 DR. WILLIAMSON: May I make a couple
14 comments about this?

15 CHAIRMAN MALMUD: Please.

16 DR. WILLIAMSON: I think in the case where
17 the physician uses source strength and number of
18 seeds, this is reasonable and it's based on the
19 assumption that any medically-legitimate deviation
20 from the original written directive would be known to
21 the authorized user during the implant procedure and
22 would be the result of a conscious decision to alter
23 the implant geometry interoperatively.

24 Okay. So there is a concern however if
25 this would not be practical for the people who choose

1 to prescribe use absorbed dose in the written
2 directive because absorbed dose is often not
3 calculated definitively until many weeks after the
4 implant. So therefore a revision of an absorbed dose
5 written directive could not be made within 24 hours of
6 a completion of a permanent prostate seed implant for
7 most practitioners. I want to basically point out
8 that this recommendation is consistent only if the
9 physician writes the written directive in terms of
10 apparent activity.

11 DR. NAG: Well, that's not necessarily
12 true. I mean first of all you don't want a situation
13 where a practitioner is doing the iso-dose (PH)
14 calculation and then finding that the iso-dose
15 calculation did not meet or did not match with what he
16 had prescribed and then he would change it. So you do
17 not want that time lag anyway.

18 Secondly, I mean that's the main thing.
19 It's immaterial when they do the dosimetry. You want
20 to know what their intent was at the time of the
21 implant and as they completed the implant. So I think
22 within the 24 hours of completion of the source
23 insertion procedure you would discover their intent.

24 DR. WILLIAMSON: I think I agree with Dr.
25 Nag's point in general. My only point is that the

1 recommendation we have voted for previously under
2 Issue No. 3 of our report was that we would recommend
3 to licensees that they specify the written directive
4 in terms of apparent activity, not require. So the
5 problem is that unless we change that recommendation
6 from recommendation to recommend to the users they do
7 this to require the users to do this, there is in
8 inconsistency in the regulations. That's my point.

9 DR. NAG: This is Dr. Nag. I don't think
10 that's a problem because if I'm prescribing in terms
11 of a dose and let's say I want to give a second amount
12 and while I'm putting my seeds in I find for whatever
13 reason I want to increase or decrease that dose, I can
14 write a revision as I finish my implant saying I
15 wanted to give 10,000 but now I want to give 12,000 or
16 15,000. But I don't need much more than 24 hours to
17 do that.

18 DR. WILLIAMSON: What if you don't do
19 imaging of the implant for 30 days and you don't have
20 a treatment plan so you'll never know whether it was
21 80 gray, 90 gray, 110 gray, 130 gray, 140 gray? You
22 might know but most people --

23 DR. NAG: Wait. But my intention was to
24 give a second dose. Now if I did not, that's the
25 reason -- I mean if I'm allowed to change my dose

1 depending on the dosimetry I do later, then I could
2 say that I implant by mistake. I implanted twice or
3 three times the amount and I doubled the dose. I then
4 go back after any implant I planned and I say I
5 initially wanted to give 125 grain. Now I'm giving
6 250 grain. So I think you are going to defeat the
7 purpose if you allow any revision beyond that 24
8 hours.

9 DR. WILLIAMSON: No, you misunderstand.
10 My proposal would be to amend the recommendation in
11 paragraph three to require authorized users to write
12 the written directive in terms of implanted activity.
13 Then there's full consistency in the regulation.

14 DR. NAG: I don't think you really need to
15 require it. I mean if someone wants to I think it is
16 in the best interest of the authorized user to
17 prescribe it in terms of millicuries but you don't
18 have to force them to use it. I don't think it would
19 be inconsistent. I think a wise authorized user will
20 write in terms of millicuries but if you don't, I mean
21 you could I think if you wanted to have the authorized
22 user avoid having too many unnecessary medical events.
23 You could put it as a suggestion and the reason why
24 you suggest to prescribe in terms of activity rather
25 than those, but I don't think you want to require

1 them.

2 DR. WILLIAMSON: I think there is a
3 dilemma here. You know not all revisions of the
4 absorbed dose written directive need be illegitimate.
5 It may be that the authorized user implanted the seeds
6 in a certain way to avoid overdosing the urethra or
7 because of unavoidable anatomic constraints and the
8 dose plan will show a reduced dose and it would be
9 reasonable to put that reduced dose in the chart and
10 maybe contemplate other actions to fix the dose
11 distribution to the prostate or improve it by other
12 treatment modalities or procedures. So I think it
13 leaves a dilemma in place and there's an inconsistency
14 which is not very satisfying which could be easily
15 remedied.

16 DR. NAG: No, but, this is Dr. Nag, I
17 still feel that if you allow to revise your dose after
18 your permanent implant, after everything has been
19 done, and then you wait a month and then you get
20 dosimetry and then you revise your dose, that is going
21 to open up to anyone who has made a mistake to revise
22 the dosimetry to cover up their mistake. I think that
23 would be major problem if you allow. I'm sorry.

24 DR. WILLIAMSON: Well, I think that I'm
25 agreeing with you and I'm suggesting it would be fixed

1 by eliminating it as a possibility.

2 CHAIRMAN MALMUD: Any other comments
3 besides those of Dr. Nag and Dr. Williamson? So is
4 there a recommendation?

5 DR. WILLIAMSON: I think there is a
6 recommendation. It's been stated on the table for
7 consideration and a vote.

8 CHAIRMAN MALMUD: It has been ruled and
9 seconded? Was there a second to that, Dr. Williamson?

10 DR. NAG: Yes, Dr. Nag seconds.

11 CHAIRMAN MALMUD: All in favor?

12 (Chorus of ayes.)

13 CHAIRMAN MALMUD: Any opposed?

14 (No response.)

15 DR. WILLIAMSON: I will abstain.

16 CHAIRMAN MALMUD: Williamson abstains.

17 All other are in favor. Thank you. Next item.

18 DR. ZELAC: Excuse me, Dr. Malmud.

19 CHAIRMAN MALMUD: Yes, Dr. Zelac.

20 DR. ZELAC: Just for clarification, the
21 recommendation that was just voted on, is it as it
22 appears on page six for permanent implant based on
23 written directives specifying total source strength
24 implanted in the treatment sites?

25 CHAIRMAN MALMUD: That's my understanding.

1 DR. WILLIAMSON: I think that's so.

2 DR. NAG: Yes.

3 DR. VETTER: That's what I voted for.

4 DR. ZELAC: Okay. Thank you.

5 MS. SCHWARZ: Was that changed for the 24
6 hours to within one working day?

7 CHAIRMAN MALMUD: Yes, it was.

8 MS. SCHWARZ: All right.

9 CHAIRMAN MALMUD: I thought it was. Am I
10 correct, Dr. Williamson?

11 DR. WILLIAMSON: Let me mention. It
12 appears that this addresses only permanent implants
13 only when the written directive specifies total source
14 strength. So what we are voting on I guess does not
15 address the issue of dose-based written directives.
16 So Dr. Nag's point is still hanging out there and in
17 fact, I can change my vote now and I can vote for this
18 as stated because it's consistent at least.

19 CHAIRMAN MALMUD: Let the record state
20 that there's unanimity in support of this and that the
21 one changed printing that you see on page six under
22 the third bullet under Item 5 is that instead of
23 saying "within 24 hours" it's "within one working day
24 of completing the source insertion procedure."

25 DR. WILLIAMSON: That's correct, but it

1 allows actually the authorized user who writes the
2 written directive in terms of absorbed dose to wait as
3 long as he or she chooses to. So I think that it
4 should be pointed out that is a consequence of this
5 motion.

6 CHAIRMAN MALMUD: Thank you.

7 DR. ZELAC: I should point out that the
8 consequence of the motion that Dr. Williamson just
9 described is understood to be an issue by us at NRC as
10 a, if you will, glaring loophole, the kind that Dr.
11 Nag was referring to that the unscrupulous
12 practitioner could take advantage of.

13 DR. NAG: I think what you could then say
14 you don't need to -- In the previous motion, you don't
15 need to say "based on written directive specifying
16 total source strength" etc. " -- for permanent
17 implant" so and so. You could do it that way.

18 DR. WILLIAMSON: So there's another new
19 proposal then which strikes out the words "based on
20 written directives specifying total source strength
21 implanted in the treatment site" which could be voted
22 on now, I guess.

23 CHAIRMAN MALMUD: I have to admit that
24 I've lost track of the statements. May we first
25 reconfirm that bullet no. 3 under Item 5 has been

1 approved with one change in wording to be "within one
2 working day"?

3 DR. WILLIAMSON: I believe that's so.

4 (Chorus of yeses.)

5 CHAIRMAN MALMUD: All right. It's been
6 approved. Now what is the next motion? Was it in
7 response to Dr. Zelac's concern?

8 (Chorus of yeses.)

9 DR. WILLIAMSON: I could make it on behalf
10 of Dr. Nag or he could make it since it's his
11 proposal.

12 DR. NAG: Yeah. My proposal is that on
13 the previous item that we voted on to prevent the
14 loophole preclusion of striving in terms of dose, we
15 restate that paragraph to say "For permanent implants
16 item 35.40(c) and 35.40(b)(6)(iii) should be amended
17 to require the completion of the written directive and
18 documentation within one working day of completion of
19 the source insertion procedure," basically striking
20 out "written directives specifying total source
21 strength" etc. so that it will apply for both those
22 who are prescribing in terms of dose and to those who
23 are prescribing in terms of activity.

24 CHAIRMAN MALMUD: Ths is a motion.

25 DR. VETTER: The consequences of that

1 would be that a practitioner would not be allowed to
2 do imaging 48 hours later to confirm placement of the
3 sources. He has to do within one working day.

4 MS. SCHWARZ: Is that a problem?

5 DR. WILLIAMSON: I think many
6 practitioners would consider it so.

7 MS. SCHWARZ: Can it then be changed to
8 "within 48 hours"?

9 DR. NAG: No, but you don't want the
10 practitioner to do the imaging, do a dosimetry and
11 then change his prescription. The prescription or his
12 intent has to be stated before he's implanting and he
13 should be allowed to change it while he's implanting,
14 but not after. I mean if you wait until he's done the
15 dosimetry then he has the ability to change the
16 prescription to show what the dosimetry came out to.

17 DR. WILLIAMSON: Well, I mean there may be
18 legitimate reasons for doing that actually.

19 MR. LIETO: This is Ralph. I think
20 basically what we want to do is establish a time line
21 when the treatment has been done as far as the written
22 directive state and I think within one working day is
23 totally acceptable. I think we're going to end up
24 pushing this time period back farther and we're going
25 to be into this is it two days or 30 days. I think we

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1 should leave it right where it's at as already
2 approved.

3 DR. NAG: The only difference being taking
4 out that phrase "based on written directive specify
5 total source strength."

6 CHAIRMAN MALMUD: Is that acceptable?

7 DR. WILLIAMSON: Are you asking for a
8 vote?

9 CHAIRMAN MALMUD: Yes. This is Malmud.
10 I'm asking for a vote.

11 DR. VETTER: May I express just one
12 concern?

13 CHAIRMAN MALMUD: Yes.

14 DR. VETTER: I don't feel adequately
15 informed about this relative to if you specify the
16 prescription in terms of dose and then while you're
17 doing the procedure, you recognize that something
18 isn't quite as you expected. The motion as stated
19 would require that you do imaging within one working
20 day.

21 DR. NAG: No, it doesn't require you to do
22 any imaging, what you wanted to -- Imaging is not
23 going to give you the dose. The only way to get the
24 dose is from the imaging to do calculation and do a
25 dosimetry.

1 DR. VETTER: Right. Yes, I understand
2 that. What I'm saying is if you implant your sources
3 in a pattern other than what you originally intended,
4 then don't you have to re-image or can you with your
5 dose --

6 DR. NAG: No, basically you need to know
7 your intent, what did you intend to, what dose did you
8 intend to give and basically, that's why from the
9 beginning I have been saying that we should get away
10 from dose and say the medical implant and so on could
11 be defined in terms of the implanted activity.

12 DR. SULEIMAN: Yes, I agree. The purpose
13 of the imaging in this context is to validate that the
14 number of seeds or whatever is where they were
15 intended.

16 CHAIRMAN MALMUD: May I ask who just said
17 that?

18 DR. SULEIMAN: That's Orhan.

19 CHAIRMAN MALMUD: Thank you, Orhan.

20 DR. WILLIAMSON: Well, it's not it's only
21 intent. It's other intent is to quantify the absorbed
22 dose you've given the target and the critical anatomy
23 and it's a very important number. The numbers derived
24 from that are very important and they are used in
25 clinical study to rule data from different

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1 institutions.

2 DR. SULEIMAN: Isn't that a slightly -- I
3 agree but isn't that a slightly different intent?
4 That's where whether it's an unsealed source or a
5 sealed source. You want to valid somehow that the
6 activity is, that the counts that you're seeing with
7 your imager are in fact correlating with the
8 administered radioactivity.

9 DR. WILLIAMSON: No, I don't think you
10 have the right idea. One doesn't use a radioactivity
11 counting method when a transmission x-ray CT imaging
12 finds where the seeds are, one finds where the
13 prostate and one calculates the 3-D dose distribution.

14 DR. SULEIMAN: But do you have consensus
15 on your imaging? I just heard ultrasound is used to
16 validate. Are you doing x-ray? Are you doing CT?
17 Are we clear on the imaging modality and how accurate
18 it is in the first place?

19 DR. WILLIAMSON: Within certain limits,
20 yes. I mean there's a variation among practitioners.
21 Some practitioners do it right away with ultrasound
22 imaging if they are doing intra (Beeping sound)
23 planning. Others would use x-ray, CT day of
24 procedures. Others prefer to wait 30 days and
25 legitimate arguments can be made for all three

1 methods. Whatever we agree on has to not constrain
2 the practitioner because that's constraining the
3 practice of medicine.

4 DR. VETTER: This is Dick Vetter. If Dr.
5 Nag who made the motion can live with it, I can
6 certainly support it.

7 DR. WILLIAMSON: As it's stated, I'm going
8 to vote against it because it's simply inconsistent.
9 I think there are other and more consistent ways of
10 achieving the same goal Dr. Nag wants to achieve which
11 I sympathize with.

12 MS. SCHWARZ: What other ways, Jeff?

13 DR. WILLIAMSON: I would suggest go back
14 to issue 3 and revise the written directive to require
15 the written directive to be specified in terms of
16 activity and then the 24 hour rule works and it
17 doesn't punish anybody for doing their imaging at 30
18 days or one day or anything else. It would be a
19 consistent approach to the problem. Wrong site, wrong
20 dose, written revisions all would be a consistent
21 package. That is I think the virtue of Dr. Nag's
22 original proposal and what we have now is a mishmash
23 of inconsistent dose-based and activity-based
24 prescriptions which I'm uncomfortable with.

25 DR. VETTER: I agree. I'm actually

1 uncomfortable with that as well.

2 DR. SULEIMAN: I'm confused. Why would
3 you validate 30 days after the fact? Why wouldn't you
4 want to do it sooner?

5 DR. WILLIAMSON: Because many
6 practitioners believe that you can't get an accurate
7 dose plan right after the implant because prostate
8 edema is at its maximum and you need to wait for that
9 to resolve in order to get a better feel for what the
10 average dose is to the prostate.

11 DR. SULEIMAN: What if there's been a
12 gross migration of the seeds during the implant? What
13 if it hasn't been done properly at all? Or are you
14 saying the ultrasound would solve that initially?

15 DR. NAG: No, that is the drawback of
16 doing it at 30 days.

17 DR. SULEIMAN: I mean inherently that just
18 bothers me. I'm not going to lie to you.

19 DR. WILLIAMSON: The majority of the field
20 I think does it that way. That's my feeling. A lot
21 of people do it at 30 days.

22 MR. LIETO: Mr. Chair.

23 CHAIRMAN MALMUD: Yes.

24 MR. LIETO: This is Ralph. It seems like
25 we have two issues here. One has to do with

1 validating treatment planning and so forth and the
2 other is to basically establish a QA indicator that
3 what was in the written directive most likely occurred
4 and I think what we've done already has established
5 that.

6 I'm getting a little confused also because
7 we're making so many changes as we go along. I'm not
8 sure if we're even being consistent with some of the
9 other things that we've done already. And looking at
10 the clock and I know we're going to be hearing
11 somebody pretty soon --

12 DR. NAG: Two minutes.

13 MR. LIETO: -- I'm wondering if maybe what
14 we should do is take what we've done so far,
15 distribute it to the committee as a whole and redraft
16 this and try to resolve it, either come up with a
17 final before the April meeting or maybe we might just
18 have to take that long to get all these pieces
19 together. It seems like as we've been digging, the
20 deeper we get the more difficult we're running into
21 other issues like for example what we just had before
22 regarding wrong site. Just a suggestion.

23 DR. SULEIMAN: I would propose we table
24 this for exactly as Ralph suggested for the April
25 meeting.

1 CHAIRMAN MALMUD: Dr. Suleiman suggested
2 we table this for the April meeting. Is there a
3 second to that?

4 DR. VETTER: Second.

5 CHAIRMAN MALMUD: Any further discussion
6 on tabling this item to the next meeting?

7 MR. LIETO: This is Ralph again. I would
8 like that we continue to work on this and not wait for
9 our next draft until then because it sounds like
10 there's a lot of other input that might be need from
11 other members for clarity that I think would be very,
12 very valuable, to make this maybe an entire committee
13 project to complete.

14 DR. NAG: This is Dr. Nag. My strong
15 suggestion would be that we involve at least two or
16 three radiation oncologists who do a lot of permanent
17 seed implants because otherwise the discussion will be
18 between people who are not practically doing the
19 implant. Right now, the only member of the team who
20 is doing this every day is myself.

21 (Meeting ended due to termination of
22 telephone conference.)

23 (Whereupon, at 3:00 p.m., the above-
24 entitled matter concluded.)

25