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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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6 TELECONFERENCE

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8 THURSDAY,

9 DECEMBER 15, 2011

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11 The meeting was convened via
12 teleconference at 2:00 p.m., Leon S. Malmud, M.D.,
13 ACMUI Chairman, presiding.

14 MEMBERS PRESENT:

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

16 BRUCE R. THOMADSEN, Ph.D., Vice Chairman

17 MILTON J. GUIBERTEAU, M.D., Member

18 SUSAN M. LANGHORST, Ph.D., Member

19 STEVEN R. MATTMULLER, Member

20 CHRISTOPHER J. PALESTRO, M.D., Member

21 JOHN H. SUH, M.D., Member

22 ORHAN H. SULEIMAN, Ph.D., Member

23 WILLIAM VAN DECKER, M.D., Member

24 LAURA M. WEIL, Member

25

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1 MEMBERS PRESENT (CONTINUED) :

2 JAMES S. WELSH, M.D., Member

3 PAT B. ZANZONICO, Ph.D., Member

4
5 NRC STAFF PRESENT:

6 CHRISTIAN EINBERG - Designated Federal Officer

7 MICHAEL FULLER - Alternate Designated Federal
8 Officer

9 ASHLEY COCKERHAM - Alternate Designated

10 Federal Officer/ACMUI Coordinator

11 SUSAN CHIDAKEL

12 SAID DAIBES, Ph.D.

13 SARA FORSTER

14 WILLIAM MAIER

15 ANGELA MCINTOSH

16 JOE NICK

17 GRETCHEN RIVERA-CAPELLA

18 JOHN TOMON

19 RONALD ZELAC, Ph.D.

20
21 ALSO PRESENT:

22 WILLIAM DAVIDSON, University of Pennsylvania

23 LYNNE FAIROBENT, American Association of
24 Physicists in Medicine

25 DR. JAMES HARVEY, Northstar

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1 ALSO PRESENT (CONTINUED):

2 DR. THOMAS HUSTON, Veterans Health

3 Administration

4 KAREN LANGLEY, University of Utah

5 LARRY LANGRILL, MidMichigan Medical Center

6 RALPH LIETO, St. Joseph Mercy Hospital

7 JANETTE MERILL, Society of Nuclear Medicine

8 JOSEPH RODGERS, Theragenics Corporation

9 MICHAEL SHEETZ, University of Pittsburgh

10 CINDY TOMLINSON, American Society for Radiation

11 Oncology

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P R O C E E D I N G S

(2:03 p.m.)

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

My name is Chris Einberg. I'm the Chief of the Medical Radiation Safety -- I'm Chief of the Radioactive Materials Safety Branch. And I have been designated as the Federal Officer for this Advisory Committee in accordance 10 CFR Part 7.11.

Present today as the alternate Designated Federal Officer are Mike Fuller, the Team Leader for the Medical Radiation Safety Team, and Ashley Cockerham, who is the HMEY.

This is an announced meeting of the Committee. It is being held in accordance with Rules and Regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the November 30th, 2011 edition of the Federal Register, Volume 76, page 74077.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use byproduct material. The Committee provides counsel to the staff but does not determine

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1 or direct the actual decisions of the staff or the
2 Commission.

3 The NRC solicits the views of the
4 Committee and values their opinions. I request that
5 whenever possible, we try to reach a consensus on the
6 procedural issues that we will discuss today. But I
7 also recognize that there may be minority or
8 dissenting opinions. If you have such opinions,
9 please allow them to be read into the record.

10 At this point, I would like to perform a
11 roll call of the ACMUI members participating today.

12 Dr. Leon S. Malmud?

13 CHAIRMAN MALMUD: Present.

14 MR. EINBERG: ACMUI Chairman and hospital
15 administrator.

16 Dr. Bruce Thomadsen, Vice Chairman,
17 therapy medical physicist.

18 VICE CHAIRMAN THOMADSEN: And present.

19 MR. EINBERG: Dr. Micky Guiberteau,
20 diagnostic radiologist.

21 MEMBER GUIBERTEAU: I'm present. Thank
22 you.

23 MR. EINBERG: Dr. Sue Langhorst, radiation
24 safety officer.

25 MEMBER LANGHORST: Present.

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1 MR. EINBERG: Mr. Steve Mattmuller,
2 nuclear pharmacist.

3 MEMBER MATTMULLER: Present.

4 MR. EINBERG: Dr. Christopher Palestro,
5 nuclear medicine physician.

6 MEMBER PALESTRO: Present.

7 MR. EINBERG: Dr. John Suh, radiation
8 oncologist.

9 MEMBER SUH: Present.

10 MR. EINBERG: Dr. Orhan Suleiman, FDA
11 representative.

12 MEMBER SUH: Present.

13 MR. EINBERG: Dr. William Van Decker,
14 nuclear cardiologist.

15 (No response.)

16 MR. EINBERG: Okay. Ms. Laura Weil,
17 patients' rights advocate.

18 MEMBER WEIL: Present.

19 MR. EINBERG: Dr. James Welsh, radiation
20 oncologist.

21 MEMBER WELSH: Present.

22 MR. EINBERG: And Dr. Pat Zanzonico,
23 nuclear medicine physicist.

24 MEMBER ZANZONICO: Present.

25 MR. EINBERG: Okay. We do have a quorum.

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1 I now ask the NRC staff members who are
2 present to identify themselves. And I'll start with
3 the individuals in the room here.

4 MR. FULLER: This is Mike Fuller. I am
5 the team leader for the Medical Radiation Safety Team
6 at the NRC.

7 MS. CHIDAKEL: This is Susan Chidakel.
8 I'm a senior attorney with the Office of General
9 Counsel.

10 DR. DAIBES: This is Said Daibes with the
11 Medical Radiation Team.

12 MS. RIVERA-CAPELLA: And this is Gretchen
13 Rivera-Capella with the Medical Team as well.

14 MR. EINBERG: Okay. And, Ashley, would
15 you like to identify yourself?

16 MS. COCKERHAM: This is Ashley Cockerham.

17 MR. EINBERG: Okay. Do we have anybody
18 else from the NRC on the line?

19 MR. TOMON: John Tomon from the Office of
20 Research.

21 DR. ZELAC: Ron Zelac, senior health
22 physicist, Medical Radiation Safety Team.

23 MS. McINTOSH: Angela McIntosh.

24 MS. FORSTER: Sara Forster, Region III.

25 MR. MAIER: Bill Maier --

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1 MR. EINBERG: Okay. And Region IV go
2 again please?

3 MR. MAIER: Bill Maier, Regional State
4 Liaison Officer.

5 MR. EINBERG: Okay. And there was another
6 person who was talking at the same time. If you could
7 please identify yourself.

8 MR. NICK: Sorry, Chris, it was Joe Nick
9 in Region I.

10 MR. EINBERG: Okay.

11 MS. MCINTOSH: Also that was Angela
12 McIntosh, NRC Headquarters just to identify my
13 location.

14 MR. EINBERG: Thank you.

15 Okay, Ashley Cockerham, could you please
16 perform a roll call of the participants who planned on
17 participating?

18 MS. COCKERHAM: Sure. Beverly Anderson
19 with the Massachusetts Department of Public Health.

20 (No response.)

21 MS. COCKERHAM: Keith Brown, University of
22 Pennsylvania.

23 (No response.)

24 MS. COCKERHAM: Chris Cossin, Jeppesen
25 Radiation Oncology.

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1 (No response.)

2 MS. COCKERHAM: Lynne Fairobent, American
3 Association of Physicists in Medicine.

4 MS. FAIROBENT: Here.

5 MS. COCKERHAM: Will Davidson, University
6 of Pennsylvania.

7 MR. DAVIDSON: Here.

8 MS. COCKERHAM: Ike Hall, Emory
9 University.

10 (No response.)

11 MS. COCKERHAM: Dr. James Harvey,
12 Northstar.

13 DR. HARVEY: Present.

14 MS. COCKERHAM: Dr. Thomas Huston,
15 Veterans Health Administration.

16 DR. HUSTON: Present.

17 MS. COCKERHAM: Karen Langley, University
18 of Utah.

19 MS. LANGLEY: Present.

20 MS. COCKERHAM: Larry Langrill,
21 MidMichigan Medical Center.

22 MR. LANGRILL: Present, present.

23 MS. COCKERHAM: Dr. Gary Levine, U.S. Food
24 and Drug Administration.

25 (No response.)

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1 MS. COCKERHAM: Ralph Lieto, St. Joseph
2 Mercy Hospital.

3 MR. LIETO: Present.

4 MS. COCKERHAM: Janette Merrill, Society of
5 Nuclear Medicine.

6 MS. MERILL: Present.

7 MS. COCKERHAM: Joseph Rodgers,
8 Theragenics Corporation.

9 MR. RODGERS: Present.

10 MS. COCKERHAM: Karen Sheehan, Fox Chase
11 Cancer Center.

12 (No response.)

13 MS. COCKERHAM: Michael Sheetz, University
14 of Pittsburgh.

15 MR. SHEETZ: Present.

16 MS. COCKERHAM: Cindy Tomlinson, American
17 Society of Radiation Oncology.

18 MS. TOMLINSON: Present.

19 MS. COCKERHAM: Michael Whalen,
20 Massachusetts Department of Public Health.

21 (No response.)

22 MS. COCKERHAM: Is there anyone else that
23 is a member of the public whose name was not called?

24 (No response.)

25 MR. EINBERG: Thank you, Ashley.

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1 Following a discussion of the agenda item
2 today, the ACMUI Chairperson, Dr. Leon Malmud, at his
3 option may entertain comments or questions from
4 members of the public who are participating with us
5 today.

6 At this point, I'd like to turn the
7 meeting over to Dr. Malmud.

8 CHAIRMAN MALMUD: Thank you. We have a
9 one-item agenda. And it is the 2008 ACMUI
10 Recommendation to the Medical Abnormal Occurrence
11 Criteria. And it is a re-examination.

12 I assume that everyone has received the
13 handout, which was available. And if so, I would
14 begin with page 1, which is the 2008 AO Discussion
15 Summary.

16 MR. EINBERG: If there is anybody who did
17 not receive the handout, they are available on our
18 public website at [http://www.nrc.gov/reading-](http://www.nrc.gov/reading-rm/doc/collections/ACMUI/meeting-slides)
19 [rm/doc/collections/ACMUI/meeting-slides](http://www.nrc.gov/reading-rm/doc/collections/ACMUI/meeting-slides). And I'll
20 turn this, if it is okay, Dr. Malmud, I'll turn this
21 over to Angela McIntosh, who will be making the -- or
22 giving the presentation.

23 CHAIRMAN MALMUD: Thank you.

24 Angela?

25 MS. McINTOSH: Good morning, Dr. Malmud

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1 and the rest of the Committee and members of the
2 public -- well, actually good afternoon, I should say.

3 I'm sorry. Good afternoon to everyone.

4 This is a re-examination of the 2008 ACMUI
5 recommendation to the medical AO criteria. And
6 beginning with the second slide, I'd like to begin
7 with a brief discussion summary of the 2008 meeting on
8 this topic.

9 I think I have -- I believe I've captured
10 four general ideas that were discussed at the 2008
11 meeting. And beginning with the first bullet, the
12 ACMUI at that time believe that the AO should be
13 events which result in death or threaten life. Of
14 course the point of the staff's presentation was to
15 refine the criteria because we felt that it may be a
16 little too low and it was capturing too many things.

17 And so the ACMUI agreed that AOs should be
18 events which result in death or threaten life. And
19 that they should not capture errors that are a typical
20 function of the treatment. That was another thought
21 captured back then.

22 The Committee believed that AOs should be
23 of significant adverse effect. But during discussions
24 realized that adverse effect was difficult to define.

25 Therefore, the Committee suggested that the criteria

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1 be qualitative rather than quantitative.

2 The staff put out several variations of
3 proposed criteria. And after discussion, I'm on slide
4 number three, after discussion of those different
5 proposals, the Committee agreed that Option 4 best
6 optimized the qualitative criterion they thought was
7 appropriate.

8 And Option 4, basically it is right there
9 in front of everyone. But to get it on record, Option
10 4 is a medical event that results in death or a
11 significant impact on patient health that would result
12 in permanent functional damage or a significant
13 adverse health effect that would not have been
14 expected from the normal treatment regimens as
15 determined by an NRC or Agreement State's designated
16 consultant physician.

17 Moving on to slide number four, this is
18 where we begin the 2011 AO discussion of the proposed
19 criteria. Just to fill in the gaps there, the staff
20 had very recently proposed the criteria that we are
21 now using. And we were directed by the Commission to
22 get some experience with that criteria before possibly
23 changing it. And so even though we presented to the
24 Committee some proposed criteria in 2008, we could not
25 yet open up the criteria for any change.

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1 So we came back to the Committee in 2011
2 and the discussion summary there for the same Option 4
3 that had been discussed in '08 was that staff should
4 consider adding a criterion that captures significant
5 adverse effects that are not permanent. For example,
6 a fistula that healed.

7 Then another general thought was that we
8 need to exercise caution against making the criteria
9 too stringent. In other words, the criteria should
10 not be so high that a significant event would go
11 unreported to NRC and then Congress learns of it
12 initially from the media. But that was -- these are
13 both ACMUI considerations at the 2011 meeting that we
14 had very recently.

15 After the meeting, the NRC staff got
16 together and discussed the meeting and discussed this
17 particular agenda topic from the meeting. And we
18 identified a couple of additional considerations that
19 we would like to put before the Committee today. And
20 one of those considerations is should significant
21 adverse event be defined -- I'm on slide number five.

22 Should it be defined -- the staff believes
23 that it may be helpful to define significant adverse
24 event because as the proposed criteria states, an AO
25 for significant adverse health effect would have to be

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1 determined by an NRC or Agreement State consultant
2 physician. And so we believe it may be useful and
3 prudent to define what significant adverse health
4 event means.

5 First of all, it will help the consultant
6 physician more easily identify one. And secondly, it
7 may help to eliminate the appearance of any
8 arbitrariness if that term is defined. The physician
9 would be defining it in accordance with NRC
10 guidelines. And it wouldn't strictly be someone's
11 professional opinion, although that opinion might be a
12 very good one.

13 So we put that out there for the Committee
14 to consider. And we also wanted to mention that there
15 is always this option to capture events under other
16 events of interest. But we have to be careful with
17 the other events of interest option.

18 And what I mean by that is that other
19 events of interest have to be events that do not meet
20 the AO criteria. But there is a perception by
21 Congress or the public that this particular event has
22 a high health and safety significance associated with
23 it or the event has simply received significant media
24 coverage or it has caused NRC to increase its
25 attention, its oversight of a program area.

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1 But we can't use other events of interest
2 as a kind of work around to keep from designating and
3 event as an AO. So as we look at an event, if it
4 appropriately would seem to be an AO, then as the
5 Committee moves forward with coming up with or sending
6 the AO criteria to us, they should make sure that the
7 definition would capture an event that under
8 reasonable circumstances, most people might consider
9 that to be an abnormal occurrence.

10 We're going to discuss a little bit more -
11 - or have a little more discussion on other events of
12 interest. In fact, it will be on the next slide there
13 -- slide six. Just to give you an idea of what these
14 look like, in 2010, in the nuclear power plant arena,
15 there were some leaks in underground pipes at nuclear
16 power plants.

17 Nuclear power plants normally release
18 authorized radioactive effluence under our discharge -
19 - under NRC discharge limits, including tritium. And
20 the leaks of the tritium are typically a very small
21 fraction of the authorized release limits that NRC
22 puts in place.

23 Nevertheless, this received a lot of
24 significant public attention. So we decided to put
25 that in the other events of interest AO report in

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1 2010.

2 To give you a material example, in 2008
3 there was a plutonium contamination event at the
4 National Institute of Standards and Technology at the
5 Boulder, Colorado Laboratory. And what happened there
6 was a junior researcher and other individuals that
7 were working both inside and outside of the lab were
8 contaminated with low levels of plutonium after the
9 researcher broke a vial.

10 Well, NRC, of course, did a reactive
11 inspection, verified that the laboratory had been
12 acceptably isolated. There was no immediate threat to
13 anyone. And in addition to that, sent another five
14 member inspection team to dispatch -- or the team was
15 dispatched rather and they determined that no member
16 of the public or any radiations worker exceeded any
17 radiation dose limits.

18 Nevertheless, this event received a lot of
19 public attention. In fact, I remember our office
20 director having to go to Congress to testify on this
21 particular event. So it received significant
22 Congressional and public and media attention. And for
23 that reason, we put it in the 2008 AO report.

24 And then another example is the security
25 officer's inattention to duty at the Peach Bottom

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1 Atomic Power Station. Basically there was some
2 evidence that the security officers were sleeping on
3 the job.

4 There is no AO criteria for that. But it
5 received a lot of significant attention. So it wound
6 up in the 2007 AO report.

7 So if we were to give an example of an
8 existing materials event that could have been captured
9 as another event of interest if the proposed criteria
10 we are now discussing were currently in place, and it
11 wouldn't meet those criteria but might be an event of
12 interest, then the one that we could give you as an
13 example would be the 2008 Veterans Affairs prostate
14 brachytherapy event where several patients --
15 multiples of patients were overdosed.

16 But clearly that event would not have met
17 -- we don't believe it could have met even the
18 significant adverse health effect criterion but it
19 would have been a good candidate for other events of
20 interest if the current proposed criteria were in
21 place when it happened.

22 On page seven, there is a discussion of
23 the review of existing AOs against proposed criteria.

24 We wanted to see where we would come out in AO space
25 if we reviewed existing AOs, documented AOs against

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1 the new proposed criteria. How many would we get?

2 So the date range of the event search was
3 between fiscal '07 and fiscal year 2012, the current
4 fiscal year that we're in. And we identified 43 AOs,
5 43 events that have been designated AOs. And out of
6 those, reviewed 19 of them, or 40 percent.

7 The number that appear to meet the
8 proposed criteria are three. And what those three are
9 -- one is a prostate mis-implant which resulted in a
10 dose to the penile bulb that could result in scarring,
11 fibrosis, erectile dysfunction, impotency. That looks
12 like it could be a significant adverse health effect.

13 The other was another prostate mis-
14 implant, which resulted in rectal bleeding. Again,
15 maybe that could be considered a possible adverse
16 health effect.

17 Then the third one that was identified
18 involved the use of iodine-131. And it was an
19 overdose resulting in an inadvertent thyroid ablation.

20 And that seems to, without question, meet the
21 permanent functional damage criterion in the current
22 proposed criteria.

23 So not many would have met our current
24 criteria. And, of course, these three examples didn't
25 all happen in the same year. So our suspicion that

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1 many would be met in any one given year seems to bear
2 out when we examine the current AOs against the new
3 proposed criteria.

4 And with that, I have concluded my
5 presentation, Dr. Malmud.

6 CHAIRMAN MALMUD: Thank you.

7 We'll open the discussion. Now before we
8 do, the 2008 discussion summary on page one, which
9 concludes -- which continues on, excuse me, onto the
10 next page, gives the background. The questions arise
11 on page three, the NRC staff considerations.

12 So if I may, should we begin with the
13 first question there? And that is should "significant
14 adverse event" be defined? Who wishes to address
15 that question?

16 MEMBER GUIBERTEAU: Oh, this is Micky
17 Guiberteau. I would like to address that.

18 CHAIRMAN MALMUD: Please do.

19 MEMBER GUIBERTEAU: Okay. It seems to me
20 that, you know, the crux of this is a definition that
21 will be helpful not only to the mission of the NRC but
22 also the licensees. And without defining that, you
23 know, I'm not certain that this has enough substance
24 or enough form really to be useful in terms of
25 correcting errors.

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1 And I think it is also confusing to our
2 licensees, in terms of the medical licensees, in terms
3 of determining what they should report and what they,
4 you know, should not report. Now I realize this is
5 sort of a subset of medical events in terms of our
6 Option 4. But, you know, I just find this to be --
7 without a definition, this to be too vague to be
8 useful and could be very confusing.

9 CHAIRMAN MALMUD: Thank you, Dr.
10 Guiberteau.

11 There's obviously concern about this being
12 too vague. And bringing in items which an individual
13 may think is a significant adverse event but which the
14 majority does not. So that's one risk.

15 MEMBER WELSH: This is Jim Welsh, if I
16 might offer --

17 CHAIRMAN MALMUD: Dr. Welsh, please.

18 MEMBER WELSH: -- my opinion. I'm going
19 to differ slightly with what Dr. Guiberteau has said
20 in that as I reviewed the -- slide number three --
21 2008 adverse occurrence -- abnormal occurrence
22 discussion summary Option 4, Option 4 has two bullet
23 points. The second one is a significant impact on
24 patient health that would result in permanent
25 functional damage or a significant adverse health

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1 effect that would not have been expected from the
2 normal treatment regimen as determined by an NRC or
3 Agreement State designated consultant physician.

4 So in that aspect, there is a definition
5 right there. There is a definition that says this is
6 something that would not have been expected from the
7 normal treatment regimen.

8 And herein is my main concern. That if we
9 try to generate a definition today, that definition
10 would have to vary from one procedure to another to
11 another and it would be extremely difficult to
12 encompass all potential abnormal occurrences with a
13 worded definition that would be any better than what
14 we already have.

15 And the crux is that only an expert in
16 that particular area of medical treatment can really
17 determine whether or not this is something that would
18 have been expected or not.

19 CHAIRMAN MALMUD: Thank you.

20 MEMBER GUIBERTEAU: Well -- this is Micky
21 Guiberteau. I appreciate what you are saying but it
22 does -- you know, in medicine there are things that
23 happen that we don't expect from a normal treatment in
24 a patient with no complicating diseases and no
25 complicating situations.

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1 But, you know, there are things that occur
2 in patients who have the, you know, the correct
3 regimen and the usual regimen but they are higher risk
4 for certain side effects. But they would not have
5 been expected in the majority of people.

6 And I think there needs to be some
7 differential between what do we mean when we say,
8 "would not have been expected?" And this would be a
9 difference between the treating physician and a
10 consulting physician.

11 And to me this sort of comes to he said
12 she said. It could be very confusing. And I'm a
13 little bit concerned about this, the way this is
14 worded.

15 And I also think, you know, with the
16 comment that was made in the 2011 discussion, which
17 says -- that's on slide four, that exercise caution
18 against making criteria too stringent. And that was
19 interpreted as meaning it would be too high so that it
20 wouldn't include a lot of other things.

21 But I think too stringent can also be
22 interpreted as meaning that it is too stringent on
23 those being regulated in that you have to report just
24 about anything that you didn't expect. And personally
25 I think this is very confusing.

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1 MEMBER WELSH: If I might reply.

2 CHAIRMAN MALMUD: Please do.

3 MEMBER WELSH: And Dr. Guiberteau brings
4 up some excellent points but perhaps a concrete
5 example of what I was thinking about may help clarify
6 my perspective.

7 For example, of the three identified
8 abnormal occurrences, two were prostate brachytherapy.

9 One was described as a mis-implant that resulted in
10 rectal bleeding. Well, I would say that this would be
11 very difficult to quantify and very difficult to
12 encompass within an acceptable abnormal occurrence
13 definition because we know and we accept as
14 practitioners of prostate brachytherapy that there is
15 a small but real possibility of rectal bleeding as one
16 of the anticipated consequences of any form of
17 radiation therapy for prostate cancer, external beam
18 or brachytherapy.

19 Additionally, there are certain medical
20 conditions that would predispose an individual to this
21 particular complication, if they have a bleeding
22 diaphysis or if they have diabetes, if they have
23 underlying uncontrolled hypertension, they might be at
24 greater risk.

25 So just because a patient has developed

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1 rectal bleeding does not necessarily, in my opinion,
2 qualify that particular case as an abnormal
3 occurrence. Even if it did meet the medical events
4 definition, it would be very difficult to directly
5 prove that this was not a fluke event and that it was
6 related to a patients inherent biological
7 predisposition as opposed to something that seriously
8 went wrong with the medical use of byproduct material.

9 And I believe that abnormal occurrence
10 should be reserved for something that has seriously
11 gone wrong directly because of the inappropriate use
12 of byproduct material.

13 VICE CHAIRMAN THOMADSEN: This is Bruce
14 Thomadsen. I would like to second what Dr. Welsh
15 said. As an example, gynecological intracavitary
16 brachytherapy carries with it a known and inevitable
17 probability of delivering dose to the superior bowel
18 unknowingly and the development of fistula some
19 decades later.

20 These aren't due to anything anybody did
21 wrong. It's just part of the toxicity of the
22 treatment in some patients.

23 And they should not be considered abnormal
24 events because they are definitely normal events,
25 unfortunate for the fraction of the patients to whom

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1 they occur but they aren't due to anything that
2 anybody did wrong.

3 And I think as an abnormal event, they
4 should be keyed to that, something that was abnormal
5 about the way the procedure was done, not just in the
6 outcome.

7 MEMBER WEIL: This is Laura Weil, the
8 patients' rights advocate. It seems to me that when
9 one consents the patient for any procedure, one
10 discusses the likelihood of risk and anticipated
11 benefit. If these are risks that are raised in the
12 individual discussions with individual patients about
13 individual medical conditions or co-morbidities that
14 might predispose patients to a higher risk of rectal
15 bleeding or fistula or whatever, then these are not
16 abnormal events because they are anticipated in the
17 informed consent discussion. And hopefully documented
18 as such.

19 Abnormal events, it strikes me, are things
20 that were not anticipated in that consideration of
21 whether the procedure is appropriate for a particular
22 patient or not. And perhaps that upstream discussion
23 and evaluation of risks and benefits can be used to
24 guide our definition of what an abnormal event is.

25 MEMBER ZANZONICO: This is Pat Zanzonico.

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1 I think what the other Committee members have said
2 all makes a lot of sense. Certainly you don't want a
3 possible, though rare, sequella of a procedure to be
4 categorized as an event of any sort.

5 But I imagine there are instances, for
6 example, in brachytherapy, where things such as
7 fistulas or rectal bleeds might be related to an
8 inappropriate treatment so that even though they are
9 expected consequences or possible consequences --
10 perhaps not expected but possible consequences of a
11 properly-performed procedure, there can be instances,
12 I imagine, where if the procedure were not properly
13 performed, where there was a mistake made, too much
14 activity implanted inadvertently or whatever, that
15 sort of consequence would become much more likely.

16 So I guess what I'm trying to say -- not
17 very well -- is that just because an event is an
18 understood and known possible consequence of a
19 treatment performed properly doesn't exclude it from
20 also being a consequence of an improperly-performed
21 procedure. And so that's what I'm trying -- that's
22 what I'm grappling with. How does one capture events
23 that may be a consequence of routine, properly-
24 performed treatment but also can be a consequence of
25 an improperly-performed treatment or use of byproduct

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1 material?

2 So that you don't want to capture all of
3 those events which are an understood and unavoidable
4 consequence of a properly-performed treatment but nor
5 do you want to ignore those identical events that did
6 result from an improperly-performed treatment and do
7 represent a true abnormal occurrence.

8 So I don't have an answer but that's the
9 issue I'm grappling with. It suggests that there
10 should be some additional criterion introduced, not
11 just that there is some significant adverse health
12 event but that there's also some identifiable misstep
13 in the application of a treatment or the use of
14 byproduct material.

15 It just seems that the criterion, as
16 proposed, are necessary but not sufficient. But,
17 again, how does one avoid capturing medically-
18 insignificant events in the process?

19 CHAIRMAN MALMUD: Thank you, Dr.
20 Zanzonico.

21 Other comments please?

22 MEMBER WELSH: This is Jim Welsh, again,
23 if I might reply to some of my colleagues points.

24 First what Dr. Zanzonico has just brought
25 up, I think that's a critically-important concept.

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1 That it is difficult to ascertain whether the medical
2 consequence, say rectal bleeding to continue with that
3 particular example, is due to a normal procedure or
4 due to the improper use of byproduct material.

5 And that is why I submit that having a
6 clinician that is too prescriptive is going to be very
7 challenging and perhaps impractical. And is why I'm
8 in favor of the original wording, which basically
9 stated that there was need for an expert consultant to
10 help ascertain in these very difficult situations
11 whether this was an unfortunate one-out-a-thousand
12 consequence that just happens to happen or whether
13 this example of rectal bleeding was indeed most likely
14 attributable to improper use of iodine-131 during a
15 prostate brachytherapy procedure.

16 This is where an NRC- or state-appointed
17 expert, provided he or she truly is an expert in the
18 field, can be critically helpful. Only an individual
19 with such expertise and background would be able to
20 ascertain the difference. And that's why I like the
21 idea of the original definition, which was admittedly
22 vague but it does say that the adverse event must be
23 determined by an NRC- or Agreement State-designated
24 consultant.

25 CHAIRMAN MALMUD: So -- yes?

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1 MEMBER WELSH: If I could just finish up
2 with the other point that I was going to make.

3 Laura brought up the point about consent.

4 And I think that that is critically important because
5 to use the examples that are in our slide set, we tell
6 our patients that yes, rectal bleeding, yes, erectile
7 dysfunction, are potential adverse effects of prostate
8 brachytherapy. And the patients will sign that
9 consent form understanding that the risk may be small
10 but it is not zero.

11 But if you are administering iodine-131
12 for a diagnostic procedure, the consent will probably
13 not say thyroid ablation is a possible consequence of
14 this diagnostic procedure. And, therefore, in the
15 examples that we have here today, the prostate
16 brachytherapy might not meet the definition of --
17 might fall into a different category compared to the
18 iodine-131 overdose, which clearly is not something
19 that would be included in the patient consent form, if
20 that was a diagnostic procedure that lead to permanent
21 thyroid ablation.

22 CHAIRMAN MALMUD: Thank you, Dr. Welsh.

23 I have a question as a non-radiation
24 oncologist. And that is as follows:

25 Under the current 2008 recommendations,

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1 how would an oversight body become aware that there
2 are too many -- I'll just use one example -- too many
3 fistulae resulting from radiation oncology in a
4 particular department. We know that that is a risk.
5 We accept that known risk.

6 But how would it come to the attention of
7 the NRC that out of the last 12, there were eight
8 fistulae when it is not reportable? And if it doesn't
9 come to the attention of the NRC, what oversight body
10 would do this with adequate protection of the public?

11 We know that in a large institution such
12 as a hospital that these kinds of incidents are
13 reviewed. But what would happen in a freestanding
14 radiation oncology unit? That's a question to the
15 radiation oncologists.

16 MEMBER WELSH: This is Jim Welsh. I'll
17 take a stab at answering this.

18 CHAIRMAN MALMUD: Okay.

19 MEMBER WELSH: I'll kick off the
20 conversation. I would submit that these most likely
21 would automatically have been reported if they were
22 indeed due to the radiation and not just a spontaneous
23 event that happened to occur because the patient has
24 uncontrolled cancer or has a biological or clinical
25 tendency to develop this particular complication that

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1 we might be talking about here.

2 They would be reported because they
3 probably would have fallen into the medical event
4 criteria. And then I suppose the question at hand is
5 how far beyond that have they gone. And do they
6 deserve this abnormal occurrence.

7 CHAIRMAN MALMUD: If I may, I'm trying to
8 be as concrete as possible. And that is, let's say,
9 that there is a freestanding radiation oncology unit.

10 And let's say that eight of the last 12 patients
11 treated for prostate cancer have developed fistulae,
12 which is a high incidence. And that there is no
13 requirement that this be reported because, in any
14 case, it may happen; but here we have eight out of 12.

15 Who would pick that up? Who reviews the
16 work that's done in a freestanding unit without the
17 kind of oversight committees that we have within large
18 organizations such as hospitals?

19 MEMBER WELSH: Wouldn't they have been
20 picked up because they would have been identified as
21 medical events, which would initiate further
22 investigation right off the start?

23 CHAIRMAN MALMUD: I don't know. That's
24 the question that I'm asking. Is someone from NRC
25 staff able to answer the question?

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1 Under the current guidelines, let's say
2 there was a unit which had eight out of the last 12
3 complications of fistulae, would you become aware of
4 that at the NRC under current guidelines?

5 MS. McINTOSH: Dr. Malmud, this is Angela
6 McIntosh. We are made aware of any medical event
7 regardless of the consequences if the definition in
8 35.3045 is met. So, you know, the fact that fistulae
9 occurred, you know, that may or may not be evident.
10 But if the event meets that definition, then we would
11 be made aware of it.

12 And another thing to consider though is
13 that the licensees wouldn't necessarily be required to
14 tell us a fistula developed. They would just need to
15 tell us that this was the dose intended and the
16 written directive. This was the dose that was given
17 that was 50 percent greater.

18 And I'll let one of the other staff speak
19 in and correct me if I'm wrong on this. But I don't
20 think that they would be required to tell us a fistula
21 developed. So I don't think that would be an
22 automatic thing that we would know.

23 VICE CHAIRMAN THOMADSEN: And this is
24 Bruce Thomadsen again. I think that the likelihood
25 that you would be ending up with a situation like that

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1 in the absence of a medical event or a series of
2 medical events is quite low, which is one of the
3 reasons that the medical event criteria are set where
4 they are.

5 So I don't think you would need to look
6 for additional reporting here. You already have the
7 screening for what might be causing something like
8 that to happen.

9 CHAIRMAN MALMUD: So that -- Bruce, you're
10 saying that from your understanding, current reporting
11 of medical events would cover that unlikely
12 possibility of eight out of the last 12 therapies
13 resulting in fistulae?

14 VICE CHAIRMAN THOMADSEN: I would -- well,
15 yes, given -- and the problem with saying that though,
16 is if there is some built in systematic problem with
17 say a facility's dosimetry, which they just aren't
18 seeing that they are having medical events, that would
19 be missed. That's true.

20 CHAIRMAN MALMUD: I'm sorry. I didn't
21 understand.

22 VICE CHAIRMAN THOMADSEN: For example, if
23 they had entered into their computer incorrect values
24 for dosimetry parameters that would lead them to
25 calculate doses inappropriately so they might be

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1 giving too high a dose to patients, they might never
2 know that they were having medical events.

3 CHAIRMAN MALMUD: But they would know that
4 they had eight fistulae out of 12.

5 VICE CHAIRMAN THOMADSEN: They would.
6 That's right.

7 CHAIRMAN MALMUD: And my question is,
8 again, who would or what body currently, NRC or other
9 Agency, would be alerted to this so that there
10 wouldn't be a ninth, which is, after all, what we're
11 worried about?

12 VICE CHAIRMAN THOMADSEN: Right.

13 CHAIRMAN MALMUD: It isn't the NRC
14 currently, am I correct?

15 VICE CHAIRMAN THOMADSEN: I believe that's
16 correct.

17 MR. FULLER: Dr. Malmud -- oh, I'm sorry.
18 Yes, Dr. Malmud, this is Mike Fuller. You are
19 correct.

20 The fact that there has been some effect,
21 some adverse effect is not a criteria for a medical
22 event. That's what we find out after the fact.

23 Those -- the effect or the adverse medical
24 effect or the adverse health effect are things that we
25 rely upon our consulting physicians or medical

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1 consultants to provide us with that information. And
2 that plays -- it has a part to play in any subsequent
3 enforcement action that might be taken. But it is not
4 part of the medical event criterion.

5 CHAIRMAN MALMUD: So how would the
6 consultant know to even look at this organization when
7 that organization is not required to report the
8 fistulae to the NRC? That's my question. Because I
9 think that's what the --

10 MR. FULLER: I don't have an answer to
11 that because our medical event criteria are not based
12 upon -- necessarily based upon health effects. They
13 are either dose based or have other criteria. As you
14 are fully aware, I'm sure, if you use the wrong
15 radionuclide, if you treat the wrong tray patient, if
16 you exceed certain dose criteria, then those become
17 medical events that has to be reported to us.

18 CHAIRMAN MALMUD: I understand that, yes.
19 I do understand that.

20 MR. FULLER: Yes, and one thing --

21 CHAIRMAN MALMUD: Again, I'm asking the
22 question that I believe the public and members of
23 Congress are asking, which is how do we find out about
24 a series of events that are not considered occurrences
25 rather than events when it isn't necessary to report

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1 them under the current guidelines?

2 MR. FULLER: Well, I don't know. And
3 perhaps there are other ways that these sorts of
4 things could be reported to the appropriate
5 authorities. But I don't think the NRC's role is for
6 oversight of medical practice. And I know that's been
7 a matter of discussion and a lot of things.

8 I know there are licensing boards. There
9 is -- there's all sorts of other things, I guess, that
10 could become involved. I'm not certain.

11 But one thing I do want to clarify,
12 though, for those who are asking questions about how
13 you would end up with an abnormal occurrence being
14 reported and yet they were expected to be a normal.
15 There seemed to be some confusion during that
16 discussion.

17 I want to make sure everybody understands
18 that what we're talking about here is a subset of
19 medical events. So before you can have an abnormal
20 occurrence and have this -- and be concerned about
21 whether or not something that would be reported as an
22 abnormal occurrence that might have been expected, the
23 very basis of a medical event is that what you gave
24 the patient was unintended. In other words not in
25 accordance with the written directive.

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1 So you have to start from the fact that we
2 already have a medical event. And what we're
3 discussing now is that those that are of the subset,
4 those -- whatever percentage or what number of medical
5 events would meet certain criteria to be reported to
6 Congress as an abnormal occurrence.

7 So I don't know if that helped or --

8 CHAIRMAN MALMUD: Yes, it does.

9 MR. FULLER: -- I don't think I answered
10 your question, Dr. Malmud, but --

11 CHAIRMAN MALMUD: It does because I think
12 that it clarifies two things. First of all, we've
13 been fastidious, I believe, about separating our role
14 in the NRC from clinical -- from guiding clinical
15 practice. Our concerns are radiation and not the
16 practice of medicine unless it involves the misuse or
17 radiation or the faulty use of radiation. So that's
18 clear.

19 And I think in bullet two on page one,
20 what you just stated is stated clearly. And that is
21 the AOs should not capture errors that are a typical
22 function of treatment. It says should not capture
23 errors that are a typical function of treatment, which
24 means sometimes things go wrong.

25 MEMBER WELSH: Dr. Malmud?

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1 CHAIRMAN MALMUD: Yes, who is speaking?

2 MEMBER WELSH: This is Jim Welsh.

3 CHAIRMAN MALMUD: Yes?

4 MEMBER WELSH: If I might follow up on a
5 reply to your initial question and example of eight
6 out of ten procedures that have lead to fistulas?

7 CHAIRMAN MALMUD: Thank you.

8 MEMBER WELSH: I would submit that all
9 hospitals that are permitted to do procedures of this
10 sort would have a radiation safety committee. So this
11 would most likely have been discussed at the radiation
12 safety committee.

13 And as we have mentioned -- Mike Fuller
14 has mentioned, these would be medical events because
15 if the occurrences are indeed a set of medical events,
16 so we would have to discuss the medical events at the
17 radiation safety committee meeting. That would be
18 perhaps one means that this could ultimately get down
19 the pipeline and to the appropriate authorities like
20 the NRC or the state.

21 But secondly --

22 CHAIRMAN MALMUD: But, if I may interrupt,
23 yes, Jim, I agree. But my example was not in a large
24 institution which has a medical radiation
25 subcommittee. It was in a freestanding unit where

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1 this might happen. But go ahead.

2 MEMBER WELSH: Okay. So in that
3 particular setting, radiation oncologists who are
4 Board certified understand from the published
5 literature and from guidelines from ASRO and ACR and
6 other professional organizations what the statistics
7 would be in terms of frequency of fistulas.

8 So if the published literature says that
9 maybe one out of ten patients undergoing a particular
10 procedure might experience a fistula but upon our
11 review we learn that eight out of the last ten have
12 developed fistulas, you would know that there is
13 something out of the ordinary.

14 The first possibility would be that there
15 could be a series of patients who were genetically
16 susceptible to developing fistulas. But, you know,
17 maybe two out of ten, three out of ten that could be
18 plausible. But eight out of ten would be beyond
19 credibility.

20 So these would have to be related to the
21 radiation treatment itself. Upon review, these would
22 have been ascertained -- would be determined to be
23 medical events and a particular subset of medical
24 events that have led to these complication of fistula
25 would have to qualify as abnormal occurrences. And,

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1 therefore, be reported as medical events first of all.

2 But then I suppose it would be up to NRC and the
3 expert to have determined whether or not it meets the
4 definition of abnormal occurrence-type of medical
5 event as opposed to just a medical event.

6 CHAIRMAN MALMUD: Thank you for that
7 clarification.

8 MEMBER LANGHORST: Dr. Malmud? This is
9 Sue Langhorst.

10 CHAIRMAN MALMUD: Dr. Langhorst?

11 MEMBER LANGHORST: As I was preparing for
12 this teleconference, I was looking at our discussion
13 on this topic in September this year. And it came
14 down in my mind to a balance of a couple different
15 points. Abnormal occurrences are reported to
16 Congress. And so as we said, they are a subset of
17 medical events in the case of the medical use of
18 radioactive material that NRC reports to Congress.

19 And so I know the staff is concerned about
20 there is a higher number that are reported -- that
21 meet the criteria as it stands right now and they
22 don't necessarily have that medical significance that
23 we think they should. So there was a balance of not
24 having overwhelming numbers that are reported to
25 Congress that mask those real significant occurrences

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1 that need to be discussed. And giving an incorrect
2 perception that more problems -- that there are more
3 problems in the medical arena than there are in other
4 NRC licenses.

5 But there is also the desire of -- and I
6 think you voiced this very well at our meeting in
7 September -- that you don't want to have Congress
8 blind sided by events that maybe don't meet the
9 abnormal occurrence but are, you know, in the press.

10 So I like the definition that we have in
11 the 2008 adverse occurrence -- the slide number three
12 in the presentation. And also then that if there are
13 things that don't meet that criteria, they can be
14 events of interest that NRC can bring up with
15 Congress.

16 And then my understanding is that Congress
17 always has access to the whole list of medical events
18 where they can, you know, delve into what all have
19 been reported in the past year.

20 So like I said, I like that 2008
21 definition. And I like the inclusion of events of
22 interest. I think it can only be qualitative in
23 trying to meet that balance which is not always a
24 quantitative thing you can define.

25 Thank you.

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1 CHAIRMAN MALMUD: Thank you, Dr.
2 Langhorst. Your recollections are identical to mine.

3 MEMBER VAN DECKER: Dr. Malmud?

4 CHAIRMAN MALMUD: Oh, excuse me, who is
5 speaking?

6 MEMBER VAN DECKER: This is Bill Van
7 Decker, Dr. Malmud.

8 I just wanted to cut in to say that I
9 would strongly agree with and reemphasize what Sue
10 just said. You know I think that the goal here was to
11 put a clinical significance on the medical event
12 database such that when it was reported, we felt that
13 it wasn't just a physics finding but it was something
14 of import that needed to be shared. I think once you
15 do that you can only do that by having a clinical
16 evaluation of your already-reported medical events to
17 find out what subset you're looking for.

18 I would point out that the definition
19 under Option 4 of the 2008 discussion has corollaries
20 in general medical practice already, right? So if you
21 are performing a clinical trial under good clinical
22 practice guidelines, you report adverse events and you
23 report that's called AEs. And then out of that, you
24 report a subset that are known as SAEs or significant
25 adverse events, which are usually defined as death or

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1 significant permanent functional damage or a
2 significant adverse health effect that is not expected
3 from where you are.

4 You know obviously those reports are then
5 adjudicated by monitoring and safety boards, which in
6 this case, to the NRC, is a designated consultant
7 physician. So the only difference per se in that is
8 whether you actually need two consultant or three
9 consultants to come to a decision rather than one and
10 the monetary piece of that.

11 But I think that the process is similar to
12 how we handle this in other places. And I don't think
13 that that process is that much different than the
14 sentinel event process that goes on in health
15 organizations that are frequently defined as death or
16 significant permanent impairment or unexpected ta-da,
17 ta-da, de-da.

18 So I think that this definition, although
19 I admit that Dr. Guiberteau is right, has some
20 clinical subjectivity to it, you know, there is no
21 other way to get around that. And I think that the
22 definition builds in those kinds of safeguards for
23 trying to make sure that we have a clinical piece to
24 what's going on.

25 So, you know, I still stand by the fact

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1 that I think that that was a reasonable discussion.
2 Like Sue, I am intrigued by this concept of other
3 events of interest as a reporting mechanism to say
4 other things may show up. And, you know, we may need
5 a reporting mechanism to hear about or know what we
6 think about them that doesn't fit under we guarantee
7 that this has been a major clinical significance
8 outside of the usual practice of medicine.

9 I guess my question in that regard would
10 only be what is the adjudication process to put
11 something into that category? And if there is an
12 adjudication person or an adjudication process to go
13 into that category, what would then become the
14 reporting requirements of that category to say well,
15 we've kind of looked at but we don't think it fits
16 there.

17 And I guess I was just looking for some
18 comments on that. But I think Sue hit this pretty
19 much where I would be coming from.

20 CHAIRMAN MALMUD: So you speak in favor of
21 the current --

22 MEMBER VAN DECKER: I speak in favor of
23 the '08 discussion of the definition. I also speak in
24 favor of the fact that this other events of interest
25 is possibly a useful modality for some of the other

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1 concerns here so long as we kind of understand a
2 little bit more about it.

3 MS. McINTOSH: Dr. Malmud, if I may speak
4 to the other events?

5 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

6 MS. McINTOSH: This is Angela McIntosh.

7 CHAIRMAN MALMUD: Oh, I'm sorry.

8 MS. McINTOSH: That's okay. For other
9 events of interest, it is really basically NRC
10 management decision. There aren't really any defined
11 criteria other than the definition itself, which says,
12 you know, it has received significant Congressional
13 attention or significant public attention or it has
14 caused us to increase our oversight.

15 Other than the definition itself, there's
16 no other criteria for us to determine what should go
17 there. So it also is a little bit subjective. Do we
18 think this event that happened -- it did receive some
19 attention -- did it receive enough that we think we
20 ought to make it another event of interest.

21 So if, you know, fistulas weren't making
22 the news, for instance, they may not be included. But
23 I mean we could anyway if we just happen to have that
24 information. But basically the definition helps guide
25 us as to what to include under that category. And NRC

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1 management can decide one way or the other, we'll
2 include this one or we won't. That is basically the
3 answer to that.

4 MR. FULLER: Angela, this is Mike Fuller.

5 Isn't it true though that we have an AO
6 working group that considers all of these and then
7 there is a fairly -- I don't want to say formal
8 process but there is a process that we follow each and
9 every year to determine what would be included in that
10 other category.

11 It would go through the AO working group
12 and then through both the program office and the
13 Office of Research's management and so forth and so
14 on. In other words, this would be a fairly
15 deliberative process, is that not true?

16 MS. McINTOSH: That is correct, yes.

17 MR. TOMON: This is John Tomon from
18 Research. I'm the person that pens and authors the
19 report that goes to Congress.

20 And you are right, Mike. That's how it
21 is. We have a working group and it is representative
22 of every office in the Agency plus all of the regional
23 offices. And everybody has an input.

24 And part of the agenda when we meet -- we
25 meet quarterly at the working group to discuss what is

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1 in the report -- events in the report -- and what's,
2 you know, and all of the appendices.

3 And in that report, we go back -- we all
4 realize, as everybody here has already come to that
5 conclusion, that Appendix C is subjective. So we'll
6 have back and forth with the regions, the program
7 offices. Most of the AO coordinators for the program
8 offices and regions will also -- before they come to
9 the meeting to discuss about it -- to discuss an
10 event, they will run it through their management, too.

11 So usually there is a good back and forth
12 over them. But, again, it is subjective. So there is
13 no hard and fast rule. And my case in point, it says
14 significant media attention. And, you know, in light
15 of what happened in Japan this year, there has always
16 been a lot of -- there has been significant media
17 attention.

18 So, you know, it's kind of -- and that
19 adds to the subjectivity. So -- but we do have OPA
20 and OCA on the group of representatives from each of
21 those offices to help us make the determination as a
22 group what we want to submit forward.

23 And, again, you are right. My management
24 reviews it. We also do a brief with Mike Weber in the
25 EDO's office to get an alignment before that actually

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1 goes out for office concurrence so that they know
2 what is in Appendix C, what we've talked about, what,
3 as a group, a working group, we decided didn't meet
4 the criteria and didn't put in there. And so we can
5 kind of have alignment and they know what is going to
6 pretty much be coming their way.

7 CHAIRMAN MALMUD: Thank you.

8 This is Malmud again. I have a question
9 for you.

10 MR. TOMON: Yes.

11 CHAIRMAN MALMUD: In reviewing, for
12 example, a radiation oncology AO, do you ever ask a
13 radiation oncologist for his opinion about whether he
14 or she believes that this really was an AO and a
15 significant one?

16 MR. TOMON: Not specifically. I mean I'll
17 work with the FSME's representative on the working
18 group, Angela, and we'll -- but typically when we do
19 medical events because of the way the current AO
20 criteria is written, they are dose related and then
21 there's a two step criteria they have to meet.

22 So it is very, very prescriptive. So it's
23 a medical event. And then if it goes a little bit
24 further in the dose ranges, it is an AO event. So
25 that's how it makes it in there.

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1 And so we don't really have a lot that --
2 at least in my two, two-and-a-half years of doing the
3 report, we haven't had anything that has gone to
4 Appendix C as a medical event. So -- but no, we've
5 never -- I've never specifically spoken to an
6 oncologist about it.

7 CHAIRMAN MALMUD: Should that be something
8 that you consider within the NRC, that if there is an
9 issue in, let's say in vascular radiology or in
10 cardiology or in nuclear medicine or in radiation
11 oncology, that you get some advice as to whether or
12 not that person, whose opinion you value in that
13 specialty, feels that it is an issue?

14 I have the feeling we're discussing
15 something analogous to what either a member of the
16 court or a member of Congress once described as
17 pornography. And you know it when you see it.

18 And the question that we're trying to
19 resolve is how do we make certain that we don't over
20 report issues to Congress and make things seem worse
21 than they are. And at the same time, make certain
22 that we do capture important issues that do need to be
23 reported.

24 That's what our task is. And that's what
25 we're trying to work toward without having suppression

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1 of therapy for fear of things being reported that are
2 not really worthy of reporting.

3 MR. TOMON: I guess that through the
4 working group members, I mean there is a channel that,
5 you know, whether it is the program office or the
6 regional office, if they know of an event, they can
7 propose it. So that would be a mechanism by which we
8 could have interaction with -- you know, outside of
9 the working group or before the working group meeting
10 with an oncologist to talk about it.

11 But I don't -- I mean have never thought
12 about that specific -- going that specific route. I
13 guess it is because of the way the current criteria
14 are established. I mean they are very prescriptive
15 right now.

16 And what we're talking about is a little -
17 - I mean they're kind of still -- the proposed 2008
18 changes are prescriptive. But they have that --
19 again, that area of ambiguity in there. So -- or what
20 could be interpreted as what is a significant adverse
21 health effect.

22 So I don't know. I don't know the answer
23 to that to be quite honest with you.

24 MR. EINBERG: This is Chris Einberg. Let
25 me interject here. I think the definition already

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1 covers, as designated by a consultant physician. So
2 the significant adverse health effect would have to be
3 determined or designated by a consultant physician.
4 And so that's already in the definition. So I think
5 we have it here.

6 CHAIRMAN MALMUD: Thank you, Chris, for
7 putting that in the record. Thank you. You've
8 answered the question.

9 All right. So it appears that we have
10 several options here. One is to reaffirm the 2008 and
11 the other is to alter it with 2011. Is there further
12 input from members of the ACMUI?

13 MEMBER MATTMULLER: Dr. Malmud, this is
14 Steve Mattmuller.

15 CHAIRMAN MALMUD: Yes, Steve?

16 MEMBER MATTMULLER: And the one comment I
17 would like to put in is I actually went back to the
18 last meeting's transcripts and just -- and this
19 comment is really in trying to further put in context
20 of how I think this discussion should be focused.

21 And to build on what Mike Fuller and
22 Angela McIntosh have already said in that we're
23 talking about a subset of medical events. So anything
24 that has happened has already been captured by the
25 medical events definition. And so we're looking at a

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1 smaller subset.

2 But I was intrigued by a comment that
3 Angela McIntosh made at the last meeting where she
4 read the opinion of NRC attorneys that from the
5 minutes, the AO criteria are trying to capture things
6 in which the level of protection of public health and
7 safety has been impacted. And to go further, did
8 something go awry to the degree that it can be stated
9 that the level of protection of the public health and
10 safety has been negatively impacted?

11 So as I reread this and listen to this
12 discussion, I mean we're really talking about
13 something big as evidence -- as some of the examples
14 of nuclear power plants examples in the same
15 presentation today. So stepping back from that
16 statement, I think the 2008 definition fully captures
17 that intent and focus of what ought to be reported to
18 Congress.

19 Thank you.

20 CHAIRMAN MALMUD: Thank you. Thank you,
21 Steve.

22 Other comments from members of ACMUI?

23 MEMBER ZANZONICO: Hi, this is Pat
24 Zanzonico again.

25 CHAIRMAN MALMUD: Yes, Dr. Zanzonico?

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1 MEMBER ZANZONICO: Yes, listening to the
2 discussion and bearing in mind what Mike Fuller and
3 others have said, that the AOs really are a subset of
4 MEs, which capture untoward events, you know, based on
5 quantitative criteria, I would endorse the 2008
6 criteria as well, even with its ambiguities.

7 I mean I think a certain amount of that, a
8 certain amount of vagueness and subjectivity is
9 inevitable. But in terms of what the intent of
10 defining an AO is, in terms of reportability to
11 Congress and so forth and so on, I think recognizing
12 that they are a subset of MEs, I think the proposed
13 2008 definition captures that intent probably as well
14 as one can do.

15 CHAIRMAN MALMUD: Thank you.

16 MEMBER SUH: Dr. Malmud, this is John Suh.
17 So I also agree with the discussion. I think that
18 although the current definition does -- the 2008
19 definition does have its limitations, I would favor
20 going ahead with the 2008 definition rather than the
21 2011 definition.

22 CHAIRMAN MALMUD: Thank you.

23 Any other comments from members of ACMUI?

24 MEMBER WELSH: This is Jim Welsh.

25 CHAIRMAN MALMUD: Oh, excuse me, Dr.

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1 Welsh?

2 MEMBER WELSH: I also agree that the 2008
3 definition or criteria is fine. I do not think that
4 we need to specifically define significant adverse
5 effect provided we adhere to what is written about
6 determination by an NRC or Agreement State-designated
7 consultant physician.

8 And finally, I would say that I like the
9 idea of events that do not meet the AO criteria being
10 listed in this other category of other events of
11 interest. And I don't think that we need to
12 specifically define that particular category.

13 But my recommendation might be to drop the
14 word "other" and just create the category "events of
15 interest" so that it is understood that it doesn't
16 meet AO, it doesn't meet the definition of other
17 particular categories. But by including the word
18 other, it might demean it in the public interpretation
19 as something that is a work-around. And to avoid
20 that, I suggest just the category "events of
21 interest."

22 MEMBER LANGHORST: Dr. Malmud, this is Sue
23 Langhorst.

24 CHAIRMAN MALMUD: Dr. Langhorst?

25 MEMBER LANGHORST: Jim, if you do that, I

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1 mean NRC's adverse occurrence reports already have
2 other events of interest. So, you know, you are
3 impacting a broader definition there than just medical
4 use. So they already use that phrase other events of
5 interest.

6 MEMBER WELSH: My question is whether or
7 not the word "other" is possibly lessening the value
8 of this particular important category.

9 CHAIRMAN MALMUD: I recognize the question
10 that you are asking. In my mind, it doesn't. But
11 that's only one man's opinion.

12 What do the other members of the ACMUI
13 feel?

14 VICE CHAIRMAN THOMADSEN: This is Bruce.
15 And I also don't feel that other is demeaning at all.
16 It just means it isn't designated by one of the
17 terms. And if you just delete other, it still isn't
18 designated. So I don't see the difference.

19 CHAIRMAN MALMUD: Thank you.

20 Any other comments?

21 MEMBER ZANZONICO: Yes, this is Pat
22 Zanzonico. I would tend to agree with that sentiment.

23 I don't have a visceral reaction to the word other as
24 demeaning in any sense what those events mean. It is
25 just a different category of events.

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1 CHAIRMAN MALMUD: Thank you.

2 Any other comments from members of the
3 committee?

4 MEMBER SULEIMAN: This is Orhan. I
5 concur. I don't interpret other as that much
6 different --

7 CHAIRMAN MALMUD: thank you.

8 MEMBER SULEIMAN: -- if that decision was
9 made at the time of interpretation.

10 CHAIRMAN MALMUD: Now having -- thank you,
11 Orhan, thank you.

12 Now having heard from members of the
13 committee, may we expand the discussion to members of
14 the public who wish to make comments? Are there any?

15 DR. HUSTON: This is Tom Huston,
16 Department of Veterans Affairs.

17 I guess I have a question. With these
18 criteria -- or with this, you know, view on abnormal
19 occurrence for medical events, would this take away
20 any further evaluation of dose? So dose is used to
21 determine if it is a medical event. But beyond that,
22 it wouldn't factor into determining an abnormal
23 occurrence.

24 And I'm not sure if there is an answer but
25 --

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1 CHAIRMAN MALMUD: I would ask a member of
2 NRC staff that question. Dr. Zelac? Or --

3 MR. FULLER: This is Mike Fuller.

4 CHAIRMAN MALMUD: Mike?

5 MR. FULLER: I think I can address that.

6 CHAIRMAN MALMUD: Thank you.

7 MR. FULLER: Currently -- under the
8 current definition for abnormal occurrence, and Angela
9 and Tom, keep me straight here, it is basically an
10 escalation of the medical event criteria. So if the
11 criteria is based upon dose -- and not all of them are
12 but many of them are -- but typically under the
13 current rules or the current guidelines -- again,
14 they're not rules -- under the current guidelines, it
15 would be an escalation. So, therefore, a subset.

16 But what we're talking about doing here --
17 or proposing -- or what was proposed by the ACMUI in
18 2008 and what we're discussing here is that that AO
19 criteria be more qualitative and less quantitative.
20 So in that sense it would not be simply an escalation
21 of the dose but rather be based upon, as it is stated
22 here, you know, resulting in things that are quite
23 definitive, death or significant impact on patient's
24 health and so forth.

25 So hopefully that answers the question.

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1 DR. HUSTON: Yes, it does. Thanks.

2 CHAIRMAN MALMUD: Thank you.

3 Other questions from NRC staff? Comments
4 from NRC staff? Or members of the public?

5 DR. ZELAC: This is Dr. Zelac. I have a
6 question.

7 CHAIRMAN MALMUD: Yes, Dr. Zelac?

8 DR. ZELAC: If I understand what Mike
9 Fuller said just moments ago, the intent is for this
10 statement to replace the current criteria in any AO-
11 deciding factors now, which do involve dose at
12 particular levels. Is that correct?

13 CHAIRMAN MALMUD: That's a question to Dr.
14 Welsh?

15 DR. ZELAC: Well, it is a question
16 actually to either Angela or Mike Fuller. Just for
17 clarification.

18 MS. McINTOSH: That's correct, Dr. Zelac.

19 DR. ZELAC: Thank you.

20 CHAIRMAN MALMUD: I am not sure I
21 understood the question or the significance of the
22 answer. Could you just clarify that for the record?

23 DR. ZELAC: I will try. If memory serves
24 me correctly, the current AO criteria do, in fact,
25 involve levels of dose --

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1 CHAIRMAN MALMUD: Yes.

2 DR. ZELAC: -- that have to be exceeded
3 before a particular event -- a particular medical
4 event can be considered as an AO. And if it does
5 exceed those dose limits, then it is automatically an
6 AO.

7 I understood from this discussion and I'm
8 simply asking to be clear about this, that what is
9 being proposed and discussed now would replace those
10 dose-based criteria for abnormal occurrence.

11 MS. McINTOSH: That is correct because the
12 current -- the proposed criteria are focused on the
13 results of a medical treatment whereas what we are
14 dealing with right now is strictly dose sort of
15 regardless of result. So I would say, yes, your
16 understanding is correct, Dr. Zelac.

17 DR. ZELAC: Thank you.

18 CHAIRMAN MALMUD: Was that the
19 understanding of the members of the committee? Dr.
20 Langhorst?

21 MEMBER LANGHORST: Yes, that's my
22 understanding.

23 CHAIRMAN MALMUD: Dr. Welsh?

24 MEMBER WELSH: Yes and no, understanding
25 that for certain treatments it's clear. But for

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1 others that are not as dose-based, for example,
2 thyroid I-131 therapy, it might not be as clear to me
3 how you would use dose for that. But for some,
4 clearly it is.

5 CHAIRMAN MALMUD: Dr. Suh?

6 MEMBER SUH: That's also my understanding
7 as well, what Sue Langhorst mentioned in terms of
8 dose.

9 CHAIRMAN MALMUD: Thank you.

10 Dr. Thomadsen?

11 VICE CHAIRMAN THOMADSEN: Yes, it seems
12 like it, yes.

13 CHAIRMAN MALMUD: Okay. All right.

14 So is there any further discussion?

15 MEMBER SULEIMAN: Yes, Dr. Malmud. This
16 is Orhan Suleiman.

17 CHAIRMAN MALMUD: Dr. Suleiman?

18 MEMBER SULEIMAN: Yes. Would this -- and
19 this is addressed to the NRC, we have an ongoing
20 voluntary recall of the CardioGen rubidium product,
21 which involved a number of patients in an ongoing
22 investigation. And some of the preliminary dose
23 estimates -- and I use that term very loosely -- fell
24 under the medical event criteria.

25 It has now become apparent that more

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1 patients have received dose estimates that very well
2 may exceed the medical event criteria. Early on in
3 this investigation, it appeared that there was some
4 regulatory paralysis among a number of agencies
5 because this appeared to be a potentially larger
6 problem.

7 But because there were no individual
8 examples of somebody exceeding the 5 rem, people were
9 waiting to see more information whereas the potential
10 for more contamination clearly existed. Would this be
11 an abnormal occurrence or not? I interpret that this
12 would qualify under the new criteria but would not
13 necessarily have previously.

14 MR. EINBERG: This is Chris Einberg. I
15 would say that this would qualify under the other
16 events of interest.

17 CHAIRMAN MALMUD: Thank you.

18 MEMBER SULEIMAN: And this is a case where
19 it would serve -- giving the NRC some flexibility in
20 handling situations that fall -- don't get defined
21 very clearly.

22 CHAIRMAN MALMUD: Yes. I would agree with
23 you, Dr. Suleiman.

24 And thanks for clarifying it, Chris.

25 All right. So is there a motion to be

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1 made? Who did I hear?

2 MR. LIETO: This is Ralph Lieto. Are you
3 still accepting comments from the public?

4 CHAIRMAN MALMUD: Absolutely.

5 MR. LIETO: I would like to support the
6 2008 ACMUI recommendation for addressing abnormal
7 occurrences. We'd like the committee to consider
8 maybe in the second bullet there where it is being
9 asked that the determination be made by a designated
10 consultant physician, of making maybe that
11 parenthetically a plural.

12 So it says designated consultant
13 physicians. So that there is the option of more than
14 one. And that maybe a consideration by either ACMUI
15 or NRC staff be that the physicians on the ACMUI be
16 the ones that review this very small subset of
17 potential AOs that may be, you know, going into this
18 report for the core of medical significance. That was
19 comment one.

20 My second comment has to do with this
21 other designation. It's really a follow up, I think,
22 on to Dr. Malmud's question about medical involvement
23 in this.

24 And it sounds like if this is somewhat of
25 a subjective determination as to what goes into these,

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1 I would think that anything that is medically related
2 be brought before the ACMUI or maybe even a
3 subcommittee of the ACMUI for some type of guidance
4 with the working group in determination of whether
5 this really has medical significance to go into an AO
6 report.

7 And those are my two comments. Thank
8 you.

9 CHAIRMAN MALMUD: Thank you, Mr. Lieto.

10 MS. McINTOSH: Dr. Malmud, may I respond
11 to that? This is Angela McIntosh.

12 CHAIRMAN MALMUD: Yes, Angela?

13 MS. McINTOSH: The purpose of the other
14 event of interest category is to capture things that
15 don't necessary have any, you know, particular
16 significance but are perceived to be significant. If
17 you look at those examples that I gave, in all three
18 of those examples -- well, particularly the 2010 and
19 the 2008 where actual radiation was involved, NRC
20 determined that there was no safety significance in
21 any of those.

22 But it was the heightened awareness of
23 them and the public sensitivity to them is what caused
24 us to put them -- to report them in the other events
25 of interest category. So the other events of interest

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1 category is somewhat of a catchall, you know, for
2 something that is perceived to be an issue, whether or
3 not there is any -- well, let me put it this way, if
4 there is safety significance involved, ideally it
5 would be captured as an AO. That's the purpose of
6 capturing and identifying AOs.

7 But there is not that consideration yet
8 there is this heightened perception and awareness and
9 sensitivity to it, then the other events of interest
10 category would be the appropriate place for us to
11 report it.

12 CHAIRMAN MALMUD: Thank you, Angela. So
13 what you're saying is that even if it didn't meet the
14 dose criteria, if it was still considered a risk, that
15 would enter into the other category.

16 MS. McINTOSH: Exactly.

17 CHAIRMAN MALMUD: Thank you for clarifying
18 that.

19 I heard another comment?

20 MR. LIETO: This is Ralph Lieto. If I may
21 make a follow-up comment or question. If sounds --
22 but I mean the fact that you are putting these in as
23 an attachment to an AO report, an abnormal occurrence
24 report, by virtue of that, it is indicating that this
25 has some significance.

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1 I think if you are going to capture events
2 that you determine are of interest but have no
3 significance, I think those should go into some other
4 reporting mechanism and shouldn't be included in an AO
5 report.

6 CHAIRMAN MALMUD: Is there a reply to that
7 from NRC staff?

8 MS. McINTOSH: I believe the other events
9 of interest category is actually built into -- I might
10 need John Tomon to correct me on this, but I believe
11 it is built into the idea of AO reporting.

12 MR. TOMON: This is John Tomon. Yes, from
13 what I understand, about six or seven years ago, we
14 were given direction, meaning the AO working group and
15 the people doing the AO reports at that time were
16 given direction to -- by the Commission to add this
17 category "other events of interest."

18 And I'd have to go back and look at the
19 SRM from it but it was something that the Commission
20 wanted at the time. And has not moved to remove. So
21 it is something that they still want.

22 And, again, it goes back to what Angela
23 said, it's the perception. It gives the Commission a
24 way of reporting -- a venue of reporting to Congress
25 things that do not meet the criteria that have been

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1 approved for specific events but because of for
2 whatever reason, there has been Congressional
3 interest, media interest, or we've caused increased
4 oversight but it is not deemed to be a safety-
5 significant issue. But it gives the Commission a
6 chance to identify those events to Congress and report
7 them to Congress.

8 So it was something specifically driven by
9 the Commission about -- I think it was about seven,
10 eight years ago.

11 CHAIRMAN MALMUD: Thank you for that
12 clarification.

13 Does that answer your question, Mr. Lieto?

14 MR. LIETO: Partially. Just a follow-up
15 question. So in these other reported events of
16 interest, there is a conclusion then reported by NRC
17 staff that one is deemed not be of safety significance
18 or something to that effect?

19 CHAIRMAN MALMUD: This is Malmud. I would
20 imagine, and I'll ask the NRC to clarify it, I would
21 imagine it is something that either is not of safety
22 or is of uncertain safety. And that will require some
23 oversight without penalty until it is determined that
24 it really is risky.

25 MR. TOMON: This is John Tomon again.

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1 What the attempt had been is when we write
2 -- when we do the descriptive write up for the items
3 that go in the other events of interest, we try to put
4 in the first few sentences or paragraphs why, based
5 upon that paragraph you have -- I can't remember what
6 slide it is for Appendix C items -- why it is being
7 included in the report because of media interest,
8 Congressional interest.

9 And we also go on -- and typically if they
10 are reactor events, that's what they've pretty much
11 been. There's been a fuel cycle one. We do speak of
12 the safety significance of it and whether it was a
13 safety significant or a public health or issue.

14 And so we do put that in there in the
15 writeup. We're careful about that in the writeup.

16 CHAIRMAN MALMUD: Thank you.

17 May we have a motion? Or do we have any
18 more comments?

19 MEMBER WELSH: This is Jim Welsh.

20 CHAIRMAN MALMUD: Dr. Welsh?

21 MEMBER WELSH: A quick question and
22 comment. My question is how many things wind up in
23 the AO or other category per year? And the reason I
24 ask it is because if it is a small number and it is
25 something that could be discussed in 15 minutes or a

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1 half hour, I might suggest that the ACMUI discuss this
2 at our meetings once, twice a year, just so that we
3 can continue -- we can be aware of these abnormal
4 occurrences. And if we have anything of interest or
5 value to NRC staff, as far as our input, we can go on
6 the record for it.

7 CHAIRMAN MALMUD: All right.

8 Dr. Welsh's first question is how many AOs
9 are there in the medical world annually? Does anyone
10 have any idea of the order of magnitude?

11 MS. McINTOSH: How many AOs or how many
12 other events of interest?

13 CHAIRMAN MALMUD: How many other events of
14 interest.

15 MR. TOMON: This is John Tomon again from
16 the NRC. Typically I would say the average is about
17 three to four goes in Appendix C every year. And
18 that's based on the highest being four and I think the
19 lowest I've ever seen is one event. So that's at
20 least since 2006, the last time we changed the AO
21 criteria.

22 CHAIRMAN MALMUD: Thank you. So what do
23 you think about Dr. Welsh's suggestion that this might
24 come before ACMUI for a brief discussion as these
25 events arise?

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1 MR. TOMON: I don't see any -- I don't see
2 a problem with that. I mean it sounds like a good
3 idea. I don't know how many events would actually --
4 I guess the criteria, the 2008 criteria, if that is
5 what is proposed then there could be more events that
6 we would want to at least bring to the attention based
7 upon the definition of Appendix C, other events of
8 interest.

9 So I wouldn't think there would be more
10 than two or three that it could be discussed. I don't
11 know all -- I have never attended any of your other
12 meetings so I don't know if that is feasible in the
13 time frame of your meetings to discuss those items.
14 So -- but it sounds like a good idea to me.

15 CHAIRMAN MALMUD: It is feasible for us to
16 do that. We meet physically twice a year but we also
17 have telephone conference calls and could deal with an
18 issue that was of concern promptly. It would not take
19 15 minutes. I think Dr. Welsh is a little optimistic
20 about the time frame. But it would take longer than
21 that to discuss most issues.

22 However, it is possible to do that. One
23 of the issues that was of concern of some members of
24 the Committee in the past was that we didn't have an
25 adequate role in dealing with some of these issues

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1 early on. And that some issues which rise to a level
2 of concern which need not have risen to that level
3 could have been avoided had they been discussed at
4 ACMUI. And that may be behind the suggestion.

5 So as the Chair, I'll say that a member of
6 the Committee has asked if this is possible. Is it
7 possible?

8 MR. EINBERG: Dr. Malmud, this is Chris
9 Einberg.

10 CHAIRMAN MALMUD: Yes.

11 MR. EINBERG: And I'll direct this
12 question to John Tomon.

13 The annual report to Congress is on a
14 certain schedule within the Agency. My concern here
15 is that, you know, the ACMUI meets twice a year. And
16 if the ACMUI has to make a determination on whether
17 these are abnormal occurrences or not, it could stymie
18 or severely restrict the schedule of the --

19 CHAIRMAN MALMUD: Time when it is reported
20 to Congress.

21 MR. EINBERG: Yes.

22 CHAIRMAN MALMUD: Well, that's why I said
23 we also have conference calls. Now if it is a
24 subcommittee of the Committee, it wouldn't require a
25 public announcement. If it were a full Committee

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1 conference call, it would.

2 Do these things occur with frequency
3 enough that the timeliness is an issue?

4 MR. FULLER: This is Mike Fuller. I want
5 to make sure people are really clear here on this.
6 When they talked about three or four per year --

7 CHAIRMAN MALMUD: Yes?

8 MR. FULLER: -- those are all of the other
9 events of interest including nuclear power plants,
10 fuel facilities. I mean does the ACMUI want to hear
11 about all the nuclear power plant other events of
12 interest?

13 CHAIRMAN MALMUD: No. In fact I said
14 medical. When I asked the question --

15 MR. FULLER: Right. And we don't have
16 any. We have not had any. We may have some going
17 forward. We may have some going forward if we change
18 the AO criteria to such that it is no longer based
19 upon the current criteria.

20 CHAIRMAN MALMUD: I see.

21 MR. FULLER: So we can't really predict
22 what other events of interest -- there may be some and
23 we've given a couple of examples that we think that
24 might have been considered that were AOs in the past
25 that would not AOs going forward under the new

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1 definition.

2 CHAIRMAN MALMUD: Thank you for clarifying
3 that. But I was very specific in raising my question
4 saying I limited it to medical, as you recall.

5 MR. LIETO: Comment please?

6 CHAIRMAN MALMUD: Yes, who is speaking?

7 MR. LIETO: This is Ralph Lieto. I want
8 to clarify. In the last AO report that was published
9 in the Federal Register of June of this year, okay,
10 there were, I think 11 events that were reported that
11 were medically related -- ten or 11.

12 So I, you know, I want to be sure that
13 we're talking about apples and oranges here, okay?
14 Now if we're talking about under the new criteria,
15 this may go down to two or three a year. Then, you
16 know, I agree that that would be something that I
17 think the ACMUI could definitely manage an appropriate
18 review by some subcommittee.

19 MS. McINTOSH: Dr. Malmud, this is Angela
20 McIntosh. I think, again, I need to, if I may, make a
21 comment.

22 CHAIRMAN MALMUD: Please do.

23 MS. McINTOSH: I want to underscore to the
24 Committee that what drives other event of interest
25 reporting is perception. It is the perception of

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1 something being an issue. It does not at all have to
2 be safety significant, not one iota. It's just that
3 the media gets wind of it, they take it and run with
4 it, and people are concerned.

5 Of the one medical event that I gave as an
6 example that I believe would -- if the current
7 proposed criteria were in place, I don't think this
8 event would meet this new proposed criteria but
9 probably would have met other events of interest were
10 the VA prostate implant events back in 2008 because
11 they received significant media attention. Not
12 because they were necessarily health and safety
13 significant.

14 So if the Committee wants to discuss other
15 events of interest, you know, maybe that's doable, you
16 know, maybe, maybe not. But let's suppose it is
17 doable. You would be discussing things that are not
18 safety significant because if they were, they should
19 be AOs.

20 As I was saying earlier in the
21 presentation, other events of interest is not a work
22 around to keep from designating an event as an
23 abnormal occurrence. So it is to capture other things
24 that are just perceived to be significant in the eyes
25 of Congress or the public.

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1 MEMBER WELSH: This is Jim Welsh if I
2 might.

3 CHAIRMAN MALMUD: Please, Dr. Welsh.

4 MEMBER WELSH: I would just submit -- I
5 can't speak for everybody but I suspect that if there
6 are medically-related events of interest to the public
7 or to Congress, that they would be of interest to the
8 ACMUI. And I certainly would cast my vote for a brief
9 discussion or presentation on the annual abnormal
10 occurrences in the medical field if there were any.

11 I would love to be aware of it. And I
12 would love to put my two cents either proactively or
13 retrospectively just to comment on them and be aware.

14 And see how we can go forward in preventing them in
15 the future. Just advice, not discussing it ahead of
16 time in determining whether or not it is truly
17 deserving of the title.

18 CHAIRMAN MALMUD: Dr. Welsh, I agree with
19 you. And yet I have a question.

20 If you recall when the issues arose at the
21 VA in Philadelphia, we were told that -- we inquired
22 of the NRC about it and were told that it was under
23 investigation. But that they had no details to share
24 with us at that point since the investigation had not
25 been completed sufficiently.

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1 And I concur that we could probably be of
2 use. And certainly we do have interest.

3 Would that create a problem that doesn't
4 exist currently for NRC staff?

5 MR. FULLER: Yes, this is Mike. And,
6 again, I'm sorry to have to keep going back and
7 harping on this point.

8 What we're talking about here, and I think
9 what people still are confusing, is the difference
10 between an abnormal occurrence and an event -- an
11 other event of interest. It is true that year in and
12 year out -- and that's one of the reasons we're having
13 this discussion -- we have numerous abnormal
14 occurrences that are medically related reported to
15 Congress.

16 What we don't have are other events of
17 interest. Now abnormal occurrences are -- you know,
18 we have that process. We have twice annually -- or
19 every meeting we have a report, either by staff or by
20 the ACMUI member on medical events. And which of
21 those meet the AO criteria under the current criteria.

22 So yes, Dr. Malmud, to answer your
23 question, if we're talking about other events of
24 interest, then yes, of course, there will be
25 opportunities to have discussions, presentations by

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1 the staff and so forth. And we would very much be
2 interested in the ACMUI's perspective on that.

3 CHAIRMAN MALMUD: Thank you.

4 Any other comments?

5 (No response.)

6 CHAIRMAN MALMUD: All right. Is there a
7 motion? Does anyone care to make a motion?

8 MEMBER ZANZONICO: This is Pat Zanzonico.
9 I would make a motion to endorse the recommended 2008
10 criterion for an AO as stated in the handout.

11 CHAIRMAN MALMUD: Thank you, Dr.
12 Zanzonico.

13 Is there a second to that motion?

14 MEMBER MATTMULLER: I second it.

15 CHAIRMAN MALMUD: I'm sorry. I didn't
16 hear who seconded it.

17 MEMBER MATTMULLER: Steve Mattmuller.

18 CHAIRMAN MALMUD: Thank you, Mr.
19 Mattmuller.

20 It's been moved and seconded.

21 MEMBER GUIBERTEAU: Dr. Malmud?

22 CHAIRMAN MALMUD: I'm sorry. Who is
23 speaking?

24 MEMBER GUIBERTEAU: This is Micky
25 Guiberteau.

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1 CHAIRMAN MALMUD: Yes, Dr. Guiberteau?

2 MEMBER GUIBERTEAU: You know, while I'm
3 not a fan of ambiguity in regulations, it does appear
4 that there isn't a better way to do this. But I would
5 -- you know, my feeling is, since we are getting
6 somewhat precariously close to the practice of
7 medicine in this definition, that in terms of
8 adjudicating the classifications of whether an event
9 falls within an abnormal occurrence or not, I would
10 like to propose as a friendly amendment that we add to
11 "consulting physician" to "physicians" in parenthesis
12 just so that there would be an option in cases that
13 are not clear cut to have more than one adjudicating
14 consultant physician.

15 CHAIRMAN MALMUD: A motion has been made
16 to amend the motion to make physicians plural. By the
17 way, does that mean physicians or does that also mean
18 physicians and physicists? Dr. Guiberteau?

19 MEMBER GUIBERTEAU: Well, the definition
20 doesn't have physicists in it, as I recall.

21 CHAIRMAN MALMUD: You are correct.

22 MEMBER GUIBERTEAU: So I mean, that's not
23 what I am proposing but --

24 CHAIRMAN MALMUD: Thank you. All right.

25 MEMBER GUIBERTEAU: -- if others feel that

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1 --

2 CHAIRMAN MALMUD: So it is recommended
3 that physician be made plural.

4 MEMBER GUIBERTEAU: Well, in parenthesis.
5 So there is an option of physician parenthesis S
6 parenthesis closed.

7 CHAIRMAN MALMUD: Okay. Thank you.

8 Is there a second to that motion -- to the
9 amendment?

10 MEMBER WELSH: This is Jim Welsh here.

11 I would agree with that amendment. But I
12 also like your point, Dr. Malmud, that maybe it
13 doesn't necessarily have to be restricted to
14 physician. And perhaps the term could be appropriate
15 expert with the S in parenthesis.

16 CHAIRMAN MALMUD: I was not trying to make
17 the motion. I was just trying to make certain that we
18 covered the option if it was necessary. How about --

19 VICE CHAIRMAN THOMADSEN: This is Bruce
20 Thomadsen.

21 CHAIRMAN MALMUD: Dr. Thomadsen?

22 VICE CHAIRMAN THOMADSEN: I think that the
23 point of having the physician there is to assess
24 whether it is medically significant, in which case I
25 think only the physician would be doing that.

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1 CHAIRMAN MALMUD: Thank you.

2 VICE CHAIRMAN THOMADSEN: Whether it was -
3 - if it was a physics-related issue, I think that
4 would be more in the realm of a medical event.

5 CHAIRMAN MALMUD: Thank you.

6 MEMBER ZANZONICO: This is Pat Zanzonico.
7 I agree as well. The proposed definition of an AO is
8 in terms of medical significance. And that really is
9 in the purview exclusively of physicians.

10 CHAIRMAN MALMUD: Thank you.

11 So the amendment is to make the physician
12 plural, physicians, with the S in parenthesis. And is
13 there a second to that motion? That motion of the
14 amendment?

15 MEMBER MATTMULLER: This is Steve
16 Mattmuller. I'll second it.

17 CHAIRMAN MALMUD: Thank you.

18 Any further discussion?

19 MEMBER LANGHORST: Dr. Malmud, this is Sue
20 Langhorst.

21 CHAIRMAN MALMUD: Dr. Langhorst?

22 MEMBER LANGHORST: I wanted to ask about
23 the motion, whether it purposely left out other events
24 of interest or would we be discussing that in a
25 separate motion?

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1 CHAIRMAN MALMUD: It was not included in
2 the motion. Am I correct?

3 MEMBER VAN DECKER: Separate motion, Dr.
4 Malmud. You can bring it up next.

5 CHAIRMAN MALMUD: That was Dr. Van Decker?

6 MEMBER VAN DECKER: Yes. I'm looking for
7 an action point here.

8 CHAIRMAN MALMUD: Dr. Van Decker says it
9 is a separate motion.

10 MR. FULLER: Excuse me, this is Mike
11 Fuller.

12 MEMBER LANGHORST: This is Sue Langhorst.
13 That sounds good to me.

14 CHAIRMAN MALMUD: Mike Fuller?

15 MR. FULLER: Yes, just to clarify again.
16 The other events of interest is already there. And
17 used by the NRC for lots and lots of things.

18 All we're saying is is under this current
19 definition, the option -- or under this new proposed
20 definition, the option will always be available to
21 capture other things. I don't think we need for the
22 ACMUI to provide us with recommendations on how to
23 define it. It already exists. And it is just an
24 option that would be available to capture --

25 CHAIRMAN MALMUD: Thank you for --

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1 MR. FULLER: -- things that might not be
2 captured as we move from one set of criteria to the
3 new set of criteria.

4 CHAIRMAN MALMUD: Thank you for clarifying
5 that and for your patience in dealing with us.

6 MEMBER VAN DECKER: But this is Van
7 Decker.

8 CHAIRMAN MALMUD: Dr. Van Decker?

9 MEMBER VAN DECKER: It is the second
10 action point. The second motion could be the ACMUI
11 recommends that events of interest be utilized as a
12 useful medical category as it has in other forms of
13 NRC whatever as it is stated.

14 CHAIRMAN MALMUD: Right. But we haven't
15 moved on this motion yet, Dr. Van Decker.

16 MEMBER VAN DECKER: That's correct. So
17 let's do that.

18 CHAIRMAN MALMUD: Let's do what?

19 MEMBER SULEIMAN: This is Orhan. I am
20 confused. What is the motion on the floor?

21 CHAIRMAN MALMUD: To reaffirm the 2008
22 recommendation, altering the one word which is
23 physician becomes physicians with the S in
24 parenthesis.

25 MEMBER SULEIMAN: So we're going to be

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1 discussing that motion?

2 CHAIRMAN MALMUD: Yes -- no, we're going
3 to be voting on it. The motion is before us now.
4 We're discussing and voting on it, yes.

5 MEMBER SULEIMAN: Okay. I want to make a
6 comment. I would expect that the NRC would discuss
7 with any and all appropriate professionals. That
8 would vary depending on the incident.

9 So I lean a little bit toward what Bruce
10 was suggesting earlier. It could be nothing more than
11 a dosimetry calculation or it could be something where
12 -- it's not like -- I don't think the NRC would render
13 a decision without consulting a physician.

14 So I'm not against the motion. But I
15 think it adds an element that may cause a situation
16 where you don't need to talk to a physician, but they
17 are going to be obligated to.

18 CHAIRMAN MALMUD: Well, the word physician
19 appears there --

20 MEMBER SULEIMAN: Yes.

21 CHAIRMAN MALMUD: -- in the motion. The
22 amendment was to make physician plural in some cases.

23 MEMBER SULEIMAN: Well, in that case, I
24 guess they would -- if a physician wasn't necessary,
25 they could still discuss -- talk with one and say give

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1 us your opinion and then move on. So --

2 CHAIRMAN MALMUD: Yes, thank you.

3 MEMBER SULEIMAN: -- fine.

4 CHAIRMAN MALMUD: Are we ready to vote?

5 All right. All in favor?

6 (Chorus of ayes.)

7 CHAIRMAN MALMUD: Any opposed?

8 MEMBER SULEIMAN: I oppose -- Orhan.

9 CHAIRMAN MALMUD: I'm sorry? Who said --

10 MEMBER SULEIMAN: Orhan -- oh, Dr.

11 Suleiman.

12 CHAIRMAN MALMUD: Dr. Suleiman opposes.

13 MEMBER SULEIMAN: Right.

14 CHAIRMAN MALMUD: Any abstentions?

15 (No response.)

16 CHAIRMAN MALMUD: It carries with one
17 opposition.

18 All right. So we reaffirmed the 2008.

19 We've really accomplished what we wanted
20 to at this conference. Are there any other issues
21 that you wish to raise with regard to this subject?

22 (No response.)

23 CHAIRMAN MALMUD: Hearing none, I will ask
24 once again if each of you feels that he has had an
25 opportunity to express himself in this?

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1 (No response.)

2 CHAIRMAN MALMUD: And hearing none, I
3 would like to thank the members of the ACMUI for their
4 participation, members of the public for their
5 participation, and, of course, the members of the NRC
6 for their participation.

7 We've achieved the goal, which was to
8 reaffirm -- to make a motion and approve it. And I
9 thank you all for your participation. And wish you
10 all a very happy holiday season and a healthy new
11 year.

12 (Whereupon, the above-entitled Advisory
13 Committee on the Medical Uses of Isotopes
14 teleconference was concluded at 3:53 p.m.)

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