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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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THURSDAY,

DECEMBER 15, 2011

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

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

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

MILTON J. GUIBERTEAU, M.D., Member

SUSAN M. LANGHORST, Ph.D., Member

STEVEN R. MATTMULLER, Member

CHRISTOPHER J. PALESTRO, M.D., Member

JOHN H. SUH, M.D., Member

ORHAN H. SULEIMAN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

LAURA M. WEIL, Member

MEMBERS PRESENT (CONTINUED):

JAMES S. WELSH, M.D., Member

PAT B. ZANZONICO, Ph.D., Member

NRC STAFF PRESENT:

CHRISTIAN EINBERG - Designated Federal Officer

MICHAEL FULLER - Alternate Designated Federal Officer

ASHLEY COCKERHAM - Alternate Designated Federal Officer/ACMUI Coordinator

SUSAN CHIDAKEL

SAID DAIBES, Ph.D.

SARA FORSTER

WILLIAM MAIER

ANGELA MCINTOSH

JOE NICK

GRETCHEN RIVERA-CAPELLA

JOHN TOMON

RONALD ZELAC, Ph.D.

ALSO PRESENT:

WILLIAM DAVIDSON, University of Pennsylvania

LYNNE FAIROBENT, American Association of Physicists in Medicine

DR. JAMES HARVEY, Northstar

ALSO PRESENT (CONTINUED):

DR. THOMAS HUSTON, Veterans Health Administration

KAREN LANGLEY, University of Utah

LARRY LANGRILL, MidMichigan Medical Center

RALPH LIETO, St. Joseph Mercy Hospital

JANETTE MERILL, Society of Nuclear Medicine

JOSEPH RODGERS, Theragenics Corporation

MICHAEL SHEETZ, University of Pittsburgh

CINDY TOMLINSON, American Society for Radiation 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

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

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

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

Dr. Leon S. Malmud?

CHAIRMAN MALMUD: Present.

MR. EINBERG: ACMUI Chairman and hospital administrator.

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

VICE CHAIRMAN THOMADSEN: And present.

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

MEMBER GUIBERTEAU: I'm present. Thank you.

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

MEMBER LANGHORST: Present.

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

MEMBER MATTMULLER: Present.

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

MEMBER PALESTRO: Present.

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

MEMBER SUH: Present.

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

MEMBER SUH: Present.

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

(No response.)

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

MEMBER WEIL: Present.

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

MEMBER WELSH: Present.

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

MEMBER ZANZONICO: Present.

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

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

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

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

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

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

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

MS. COCKERHAM: This is Ashley Cockerham.

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

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

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

MS. McINTOSH: Angela McIntosh.

MS. FORSTER: Sara Forster, Region III.

MR. MAIER: Bill Maier --

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

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

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

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

MR. EINBERG: Okay.

MS. McINTOSH: Also that was Angela McIntosh, NRC Headquarters just to identify my location.

MR. EINBERG: Thank you.

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

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

(No response.)

MS. COCKERHAM: Keith Brown, University of Pennsylvania.

(No response.)

MS. COCKERHAM: Chris Cossin, Jeppesen Radiation Oncology.

(No response.)

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

MS. FAIROBENT: Here.

MS. COCKERHAM: Will Davidson, University of Pennsylvania.

MR. DAVIDSON: Here.

MS. COCKERHAM: Ike Hall, Emory University.

(No response.)

MS. COCKERHAM: Dr. James Harvey, Northstar.

DR. HARVEY: Present.

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

DR. HUSTON: Present.

MS. COCKERHAM: Karen Langley, University of Utah.

MS. LANGLEY: Present.

MS. COCKERHAM: Larry Langrill, MidMichigan Medical Center.

MR. LANGRILL: Present, present.

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

(No response.)

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

MR. LIETO: Present.

MS. COCKERHAM: Janette Merill, Society of Nuclear Medicine.

MS. MERILL: Present.

MS. COCKERHAM: Joseph Rodgers, Theragenics Corporation.

MR. RODGERS: Present.

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

(No response.)

MS. COCKERHAM: Michael Sheetz, University of Pittsburgh.

MR. SHEETZ: Present.

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

MS. TOMLINSON: Present.

MS. COCKERHAM: Michael Whalen, Massachusetts Department of Public Heath.

(No response.)

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

(No response.)

MR. EINBERG: Thank you, Ashley.

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

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

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

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

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

CHAIRMAN MALMUD: Thank you.

Angela?

MS. McINTOSH: Good morning, Dr. Malmud

and the rest of the Committee and members of the public -- well, actually good afternoon, I should say. I'm sorry. Good afternoon to everyone.

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

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

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

The Committee believed that AOs should be of significant adverse effect. But during discussions realized that adverse effect was difficult to define. Therefore, the Committee suggested that the criteria

be qualitative rather than quantitative.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2010.

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

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

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

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

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

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

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

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

On page seven, there is a discussion of the review of existing AOs against proposed criteria. We wanted to see where we would come out in AO space if we reviewed existing AOs, documented AOs against

the new proposed criteria. How many would we get?

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

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

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

Then the third one that was identified involved the use of iodine-131. And it was an overdose resulting in an inadvertent thyroid ablation. And that seems to, without question, meet the permanent functional damage criterion in the current proposed criteria.

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

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

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

CHAIRMAN MALMUD: Thank you.

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

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

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

CHAIRMAN MALMUD: Please do.

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

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

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau.

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

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

CHAIRMAN MALMUD: Dr. Welsh, please.

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

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

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

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

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

CHAIRMAN MALMUD: Thank you.

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

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

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

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

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

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

MEMBER WELSH: If I might reply.

CHAIRMAN MALMUD: Please do.

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

For example, of the three identified abnormal occurrences, two were prostate brachytherapy. One was described as a mis-implant that resulted in rectal bleeding. Well, I would say that this would be very difficult to quantify and very difficult to encompass within an acceptable abnormal occurrence definition because we know and we accept as practitioners of prostate brachytherapy that there is a small but real possibility of rectal bleeding as one of the anticipated consequences of any form of radiation therapy for prostate cancer, external beam or brachytherapy.

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

So just because a patient has developed

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

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

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

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

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

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

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

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

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

MEMBER ZANZONICO: This is Pat Zanzonico.

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

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

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

material?

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

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

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

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.

Other comments please?

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

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

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

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

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

CHAIRMAN MALMUD: So -- yes?

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

Laura brought up the point about consent. And I think that that is critically important because to use the examples that are in our slide set, we tell our patients that yes, rectal bleeding, yes, erectile dysfunction, are potential adverse effects of prostate brachytherapy. And the patients will sign that consent form understanding that the risk may be small but it is not zero.

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

CHAIRMAN MALMUD: Thank you, Dr. Welsh.

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

Under the current 2008 recommendations,

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

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

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

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

CHAIRMAN MALMUD: Okay.

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

we might be talking about here.

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

CHAIRMAN MALMUD: If I may, I'm trying to be as concrete as possible. And that is, let's say, that there is a freestanding radiation oncology unit. And let's say that eight of the last 12 patients treated for prostate cancer have developed fistulae, which is a high incidence. And that there is no requirement that this be reported because, in any case, it may happen; but here we have eight out of 12.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VICE CHAIRMAN THOMADSEN: Right.

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

VICE CHAIRMAN THOMADSEN: I believe that's correct.

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

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

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

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

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

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

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

MR. FULLER: Yes, and one thing --

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

them under the current guidelines?

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

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

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

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

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

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

CHAIRMAN MALMUD: Yes, it does.

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

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

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

MEMBER WELSH: Dr. Malmud?

CHAIRMAN MALMUD: Yes, who is speaking?

MEMBER WELSH: This is Jim Welsh.

CHAIRMAN MALMUD: Yes?

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

CHAIRMAN MALMUD: Thank you.

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

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

But secondly --

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

this might happen. But go ahead.

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

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

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

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

therefore, be reported as medical events first of all. But then I suppose it would be up to NRC and the expert to have determined whether or not it meets the definition of abnormal occurrence-type of medical event as opposed to just a medical event.

CHAIRMAN MALMUD: Thank you for that clarification.

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

CHAIRMAN MALMUD: Dr. Langhorst?

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

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

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

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

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

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

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

Thank you.

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

MEMBER VAN DECKER: Dr. Malmud?

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

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

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

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

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

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

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

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

So, you know, I still stand by the fact

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Yes, Dr. Langhorst.

MS. McINTOSH: This is Angela McIntosh.

CHAIRMAN MALMUD: Oh, I'm sorry.

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

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

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

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

MR. FULLER: Angela, this is Mike Fuller.

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

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

MS. McINTOSH: That is correct, yes.

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

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

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Thank you.

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

MR. TOMON: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Yes, Steve?

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

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

smaller subset.

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

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

Thank you.

CHAIRMAN MALMUD: Thank you. Thank you, Steve.

Other comments from members of ACMUI?

MEMBER ZANZONICO: Hi, this is Pat Zanzonico again.

CHAIRMAN MALMUD: Yes, Dr. Zanzonico?

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

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

CHAIRMAN MALMUD: Thank you.

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

CHAIRMAN MALMUD: Thank you.

Any other comments from members of ACMUI?

MEMBER WELSH: This is Jim Welsh.

CHAIRMAN MALMUD: Oh, excuse me, Dr.

Welsh?

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

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

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

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

CHAIRMAN MALMUD: Dr. Langhorst?

MEMBER LANGHORST: Jim, if you do that, I

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

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

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

What do the other members of the ACMUI feel?

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

CHAIRMAN MALMUD: Thank you.

Any other comments?

MEMBER ZANZONICO: Yes, this is Pat Zanzonico. I would tend to agree with that sentiment. I don't have a visceral reaction to the word other as demeaning in any sense what those events mean. It is just a different category of events.

CHAIRMAN MALMUD: Thank you.

Any other comments from members of the committee?

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

CHAIRMAN MALMUD: thank you.

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

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

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

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

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

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

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

MR. FULLER: This is Mike Fuller.

CHAIRMAN MALMUD: Mike?

MR. FULLER: I think I can address that.

CHAIRMAN MALMUD: Thank you.

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

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

So hopefully that answers the question.

DR. HUSTON: Yes, it does. Thanks.

CHAIRMAN MALMUD: Thank you.

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

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

CHAIRMAN MALMUD: Yes, Dr. Zelac?

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

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

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

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

DR. ZELAC: Thank you.

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

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

CHAIRMAN MALMUD: Yes.

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

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

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

DR. ZELAC: Thank you.

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

MEMBER LANGHORST: Yes, that's my understanding.

CHAIRMAN MALMUD: Dr. Welsh?

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

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

CHAIRMAN MALMUD: Dr. Suh?

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

CHAIRMAN MALMUD: Thank you.

Dr. Thomadsen?

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

CHAIRMAN MALMUD: Okay. All right.

So is there any further discussion?

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

CHAIRMAN MALMUD: Dr. Suleiman?

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

It has now become apparent that more

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

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

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

CHAIRMAN MALMUD: Thank you.

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

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

And thanks for clarifying it, Chris.

All right. So is there a motion to be

made? Who did I hear?

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

CHAIRMAN MALMUD: Absolutely.

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

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

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

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

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

And those are my two comments. Thank you.

CHAIRMAN MALMUD: Thank you, Mr. Lieto.

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

CHAIRMAN MALMUD: Yes, Angela?

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

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

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

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

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

MS. McINTOSH: Exactly.

CHAIRMAN MALMUD: Thank you for clarifying that.

I heard another comment?

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

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

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Thank you for that clarification.

Does that answer your question, Mr. Lieto?

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

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

MR. TOMON: This is John Tomon again.

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

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

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

CHAIRMAN MALMUD: Thank you.

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

MEMBER WELSH: This is Jim Welsh.

CHAIRMAN MALMUD: Dr. Welsh?

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

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

CHAIRMAN MALMUD: All right.

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

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

CHAIRMAN MALMUD: How many other events of interest.

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

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

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Yes.

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

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

CHAIRMAN MALMUD: Time when it is reported to Congress.

MR. EINBERG: Yes.

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

conference call, it would.

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

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

CHAIRMAN MALMUD: Yes?

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

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

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

CHAIRMAN MALMUD: I see.

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

definition.

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

MR. LIETO: Comment please?

CHAIRMAN MALMUD: Yes, who is speaking?

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

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

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

CHAIRMAN MALMUD: Please do.

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

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

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

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

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

MEMBER WELSH: This is Jim Welsh if I might.

CHAIRMAN MALMUD: Please, Dr. Welsh.

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

I would love to be aware of it. And I would love to put my two cents either proactively or retrospectively just to comment on them and be aware. And see how we can go forward in preventing them in the future. Just advice, not discussing it ahead of time in determining whether or not it is truly deserving of the title.

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

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

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Thank you.

Any other comments?

(No response.)

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

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

CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.

Is there a second to that motion?

MEMBER MATTMULLER: I second it.

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

MEMBER MATTMULLER: Steve Mattmuller.

CHAIRMAN MALMUD: Thank you, Mr. Mattmuller.

It's been moved and seconded.

MEMBER GUIBERTEAU: Dr. Malmud?

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

MEMBER GUIBERTEAU: This is Micky Guiberteau.

CHAIRMAN MALMUD: Yes, Dr. Guiberteau?

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

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

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

CHAIRMAN MALMUD: You are correct.

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

CHAIRMAN MALMUD: Thank you. All right.

MEMBER GUIBERTEAU: -- if others feel that

--

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

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

CHAIRMAN MALMUD: Okay. Thank you.

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

MEMBER WELSH: This is Jim Welsh here.

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

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

VICE CHAIRMAN THOMADSEN: This is Bruce Thomadsen.

CHAIRMAN MALMUD: Dr. Thomadsen?

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

CHAIRMAN MALMUD: Thank you.

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

CHAIRMAN MALMUD: Thank you.

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

CHAIRMAN MALMUD: Thank you.

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

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

CHAIRMAN MALMUD: Thank you.

Any further discussion?

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

CHAIRMAN MALMUD: Dr. Langhorst?

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

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

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

CHAIRMAN MALMUD: That was Dr. Van Decker?

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

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

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

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

CHAIRMAN MALMUD: Mike Fuller?

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

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

CHAIRMAN MALMUD: Thank you for --

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

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

MEMBER VAN DECKER: But this is Van Decker.

CHAIRMAN MALMUD: Dr. Van Decker?

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

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

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

CHAIRMAN MALMUD: Let's do what?

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

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

MEMBER SULEIMAN: So we're going to be

discussing that motion?

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

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

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

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

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

MEMBER SULEIMAN: Yes.

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

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

us your opinion and then move on. So --

CHAIRMAN MALMUD: Yes, thank you.

MEMBER SULEIMAN: -- fine.

CHAIRMAN MALMUD: Are we ready to vote? All right. All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed?

MEMBER SULEIMAN: I oppose -- Orhan.

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

MEMBER SULEIMAN: Orhan -- oh, Dr. Suleiman.

CHAIRMAN MALMUD: Dr. Suleiman opposes.

MEMBER SULEIMAN: Right.

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: It carries with one opposition.

All right. So we reaffirmed the 2008.

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

(No response.)

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

(No response.)

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

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

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