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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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OPEN SESSION

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WEDNESDAY,

JULY 24, 2019

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The meeting was convened via teleconference, at 10:00 a.m., Christopher J. Palestro, ACMUI Chairman, presiding.

MEMBERS PRESENT:

CHRISTOPHER J. PALESTRO, M.D., Chairman

DARLENE F. METTER, M.D., Vice Chairman

VASKEN DILSIZIAN, M.D., Member

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

MELISSA C. MARTIN, M.D., Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

A. ROBERT SCHLEIPMAN, Ph.D., Member

MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

LAURA M. WEIL, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

MARYANN AYOADE, NMSS/MSST/MSEB

LISA DIMMICK, Designated Federal Official, NMSS/MSST/MSEB

VINCENT HOLAHAN, Ph.D., NMSS/MSST

SOPHIE HOLIDAY, NMSS/MSST/MSEB

IAN IRVIN, ESQ., OGC/GCLR/RMR

KELLEE JAMERSON, NMSS/MSST/MSEB

CYNTHIA JONES, OCM/AXC

VERED SHAFFER, RES/DSA/RPB

KATIE TAPP, Ph.D., NMSS/MSST/MSEB

JOHN TOMON, RES/DSA/RPB

KEVIN WILLIAMS, NMSS/MSST

ALEXUS WILLIS, RES/DE/CMB

MEMBERS OF THE PUBLIC:

JAMIE BARNES, Cook Children's Medical Center

MIGUEL de la GUARDIA, Cook Children's Medical Center

ARIEL DOUCET, Virtua Health

SHERRIE FLAHERTY, Minnesota Radioactive Materials Unit

STANLEY HAMPTON, Eli Lilly

RALPH LIETO, St. Joseph Mercy Health System

CAROL MARCUS, Ph.D., M.D., University of California at Los Angeles (UCLA)

ANDREW NAJJAR, Harvard Medical School, Boston Children's Hospital

MICHAEL PETERS, American College of Radiology

ARIA RAZMARIA, M.D., UCLA Medical Center

CINDY TOMLINSON, American Society of Radiation Oncology

MATTHEW WILLIAMS, Georgetown University

MELONIE WISSING, Virginia Office of Radiological Health

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

(10:06 a.m.)

MS. DIMMICK: Good morning. As the Designated Federal Officer for this meeting I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes or the ACMUI.

My name is Lisa Dimmick, I am the leader of the Medical Radiation Safety Team in the Medical Safety and Events Assessment Branch.

I have been designated as a federal officer for this Advisory Committee in accordance with 10 Code of Federal Regulations Part 7.11.

Present today, we have Kellee Jamerson, our ACMUI Coordinator as a Designated Federal Officer for the ACMUI.

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

This meeting is being transcribed by the NRC, and it may also be transcribed by or recorded by others.

The meeting was announced in the July 9th, 2019 edition of the Federal Register Volume 84, Page 32785.

The purpose of this meeting is to discuss the NRC's abnormal occurrence criteria, and two, the ACMUI subcommittee's report on a draft guidance document. The first topic of this meeting will be discussed in an open session.

However, the ACMUI's discussion regarding its report on the draft guidance document will be closed to the public. The function of the ACMUI is to advise the NRC staff on issues and questions that arise on the medical use of 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 various issues that we will discuss today, but I also recognize there may be minority or differences in 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. Christopher Palestro, Chairman --

CHAIRMAN PALESTRO: Present.

MS. DIMMICK: -- Nuclear Medicine Physician.

CHAIRMAN PALESTRO: Present.

MS. DIMMICK: Dr. Darlene Metter, Vice Chairman, Diagnostic Radiologist?

VICE CHAIR METTER: Here.

MS. DIMMICK: Dr. Vasken Dilsizian, Nuclear Cardiologist?

MEMBER DILSIZIAN: Present.

MS. DIMMICK: Dr. Ronald Ennis, Radiation Oncologist?

MS. DIMMICK: Mr. Richard Green, Nuclear Pharmacist?

MEMBER GREEN: Present.

MS. DIMMICK: Ms. Melissa Martin, Nuclear Medicine Physicist?

MEMBER MARTIN: Present.

MS. DIMMICK: Dr. Michael O'Hara, FDA Representative?

DR. O'HARA: Present.

MS. DIMMICK: Mr. Zoubir Ouhib, Radiation Therapy Physicist?

MEMBER OUHIB: Present.

MS. DIMMICK: Dr. Robert Schleipman, Health Care Administrator?

MEMBER SCHLEIPMAN: Present.

MS. DIMMICK: Mr. Michael Sheetz, Radiation Safety Officer?

MEMBER SHEETZ: Present.

MS. DIMMICK: Ms. Megan Shober, State Government Representative?

MEMBER SHOBER: Present.

MS. DIMMICK: Ms. Laura Weil, Patients' Rights Advocate?

MEMBER WEIL: Here.

MS. DIMMICK: Dr. Harvey Wolkov, Radiation Oncologist?

MEMBER WOLKOV: Present.

MS. DIMMICK: I confirm that we do have a quorum of at least six members present.

MEMBER ENNIS: This is Ron Ennis. Just letting you know I joined.

MS. DIMMICK: Okay, thank you. The second and final terms for Ms. Laura Weil and Dr. Christopher Palestro will be ending in August and September respectively. I would like to introduce Mr. Gary Bloom and Dr. Hossein Jadvar to the Committee.

Mr. Bloom has been selected as the ACMUI Patients' Rights Advocate and Dr. Jadvar has been selected as the ACMUI Nuclear Medicine Physician. Both are pending security clearance but may participate in the meeting today. However, they currently do not have voting rights.

All members of the ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes that he or she may have a conflict of interest, as that term is broadly used within Title V of the Code of Federal Regulations Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible, before the ACMUI discusses it as an agenda item.

ACMUI Members must recuse themselves from participating in any agenda item in which they may have a conflict of interest. Unless they receive a waiver or a prior authorization from the appropriate NRC official.

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

MR. TOMON: John Tomon, Office of

Research.

MR. IRVIN: Ian Irvin with the Office of General Counsel.

MS. JAMERSON: Kellee Jamerson, medical team.

DR. TAPP: Katie Tapp, medical team.

DR. HOLAHAN: Dr. Vincent Holahan, NMSS.

MR. WILLIAMS: Kevin Williams, NMSS.

MS. DIMMICK: Members of the public who notified Ms. Jamerson that they would be participating on the teleconference will be captured in the transcript.

Those of you who did not provide prior notification, please contact Ms. Jamerson at kellee.jamerson@nrc.gov. That is, K-E-L-L-E-E.J-A-M-E-R-S-O-N@NRC.gov. or 301-415-7408, at the conclusion of this meeting.

We also have our bridge line available, and that phone number is 888-469-3051. The pass code to access the bridge line is 8524437#.

This meeting is also using the GoToWebinar application to view presentation handouts in real time. You can access this by going to www.gotowebinar.com. That's www.gotowebinar.com. And searching for meeting ID 594545019.

Individuals who would like to ask a question or make a comment regarding a specific topic the Committee has discussed, should dial *1 to signal the operator that you wish to speak. Please clearly state your first and last name for the record.

Comments and questions are typically addressed by the Committee near the end of a presentation. After the Committee has fully discussed the topics. We will notify the operator when we are ready for the public comment period of the meeting.

I would also like to add that the handouts and agenda for this meeting are available on the NRC's public website.

At this time, I ask that everyone on the call who is not speaking to place your phone on mute. If you do not have the capability to mute your phone, please press *6 to utilize the conference line mute and unmute functions.

I would also ask everyone to exercise extreme care to ensure that the background noise is kept at a minimum as any stray background sounds can be very disruptive on a conference call this large.

At this point, I would like to turn the meeting over to Dr. Palestro.

CHAIRMAN PALESTRO: Thank you, Ms.

Dimmick. I want to thank everyone for joining the meeting this morning.

And the open session is going to cover the medical event abnormal occurrence criteria. And the ACMUI is being asked, and correct me if I am wrong, Dr. Tapp, is being asked to determine whether or not the criteria, as they stand now, are acceptable?

DR. TAPP: That's correct.

CHAIRMAN PALESTRO: Thank you. At this point, I'm going to turn the meeting back to you, Dr. Tapp.

DR. TAPP: Okay. Just to let you know, that was Lisa Dimmick, the Medical Team Leader who was the Designated Federal Officer.

CHAIRMAN PALESTRO: I'm sorry. Yes, I'm looking at the slide, I apologize.

DR. TAPP: That's okay. But now this is Katie Tapp. And as you guys have mentioned, I am here to talk about medical event abnormal occurrence criteria. And at the end I will be asking the ACMUI that question.

For my presentation, I will go over the abnormal occurrence background. Let the ACMUI know the current commission direction, and the question that the staff is being asked to do, give an overview

of the medical abnormal occurrence criteria that stands today, the past ACMUI recommendation and then that question for the ACMUI.

I know we have a lot of new ACMUI members who may not have had experience with the abnormal occurrence. So, I'll give a little background here but please ask questions at the end if you have more questions about what is an abnormal occurrence.

An abnormal occurrence is defined as an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety. The abnormal occurrences that the NRC determine in a year are sent to Congress in an annual report entitled, NUREG-0090.

Abnormal occurrences cover everything the NRC regulates. They include medical events, power reactors, high-level waste. It incorporates everything that the NRC regulates.

The AO criteria was changed in 2017. In the medical area, as directed by the Commission, it was only changed slightly. There were some very minor modifications.

So, when we talk about it, really looking at the whole criteria has been, has not been changed significantly, but when I go over the criteria we'll

highlight what was changed in 2017.

Today, the Commission has requested that the Staff evaluate whether the current abnormal occurrence criteria provides an appropriate threshold for determining if an incident or event is significant from a standpoint of public health or safety or whether these criteria should be revised.

This question, as the Commission has asked the Staff, and today we would like to hear the ACMUI's thoughts on this question as well. And we're not coming up with new criteria, but we're just looking at whether the current criteria are appropriate for determining an appropriate threshold.

The current abnormal criteria have three parts. First, an abnormal occurrence in medical, it must meet the medical event definition in 10 CFR 35.

Second, the event must meet a dose threshold. It can either, depending on the organ that is affected, it's either equal or greater to 1 gray to the bone marrow or lens of the eye or 2.5 grays to the gonads.

If it's other organs, it must exceed by 10 gray the expected dose to any other tissue. What is highlighted in red, which is ''exceeds the expected dose,'' is what changed in 2017. Everything else

remains the same for the past ten years.

In addition to the dose threshold, the medical event must involve one of the following. It must involve a dose that is at least 50 percent of the prescribed activity. Greater than 50 percent of what is described.

It must either be the wrong radiopharmaceutical, the wrong route of administration or the wrong treatment mode. It also could include a leaking source or a wrong patient or research subject. It just must have one of the following items.

Since 2006, over 95 percent of the abnormal occurrences have been medical related. As I stated, AOs can be, include everything the NRC regulates. But in general, the report is mostly medically related events.

In most AOs reported, that are medically related, the event description states that there is, the patient received no significant harm. The NRC does not verify this in all licensees per agreement state, we just take what there was reported in the event. And like I said, in most cases, the patient experiences no significant harm.

In 2018, since the criteria was changed, there were nine medical abnormal occurrences. Since

that change was very small, there were no events that met the old criteria that were expanded in 2018 to report.

So, all nine medical event AOs meet both the old criteria and the new criteria.

In 2015, the ACMUI recommended that the NRC change the medical AO criteria. They believe the current criteria leads to over reporting in the medical area.

They believe the current criteria, or you guys stated that the current criteria were flawed because the dose threshold can be very, it can be met with very slight changes and beam location with no consequences to patients and can result in reporting of events to Congress, which were known, which involved known inherent risks on the procedures such as yttrium-90 microsphere events.

The ACMUI recommended in 2015 that specific criteria be changed. And require that the events include dose that resulted in unintended permanent functional damage to an organ or a physiological system as determined by an independent physician deemed qualified by the NRC or agreement state staff.

As I mentioned, this was not adopted in

the 2017 change. And so, the current criteria does not include this recommendation from the ACMUI.

So today, the question I have for the ACMUI is, does the current ACMUI believe that the current medical AO criteria provides an appropriate threshold for determining if an incident or event is significant from the standpoint of public health and safety or does the ACMUI recommend that the criteria be revised?

I'll turn it over to Dr. Palestro.

CHAIRMAN PALESTRO: All right, thank you. Questions, comments from the Committee?

MEMBER DILSIZIAN: Vasken Dilsizian here. Everybody hear me?

(Chorus of ayes.)

MEMBER DILSIZIAN: Okay. I just wanted to, I wanted to ask the question, why did this come about?

What is it that changed in reporting or any event that resulted in this meeting to suggest that maybe we should review and reconsider the current medical AO criteria?

DR. TAPP: Sure. The Commission, about six months ago, just asked the Staff the question, if the AO criteria is appropriate today.

The Commission has, there are new Commissioners up there and as they review the criteria, I think periodically they ask this question of the staff. Is, are we at an appropriate threshold for determining these events and is there appropriate criteria today?

MEMBER DILSIZIAN: So, there is no specific event that occurred, that came to our attention, NRC's attention, to question whether the current criteria is adequate?

DR. TAPP: No. It was just a team --

MEMBER DILSIZIAN: Okay.

DR. TAPP: -- question, position.

MEMBER GREEN: This is Richard Green, Dr. Tapp. In 2018 we were told there were nine medical AOs, do we happen to know the value for the prior year of 2017? Was there a dramatic change with this new --

DR. TAPP: Yes. The average is about 12 medical abnormal occurrences a year. It doesn't fluctuate, and there was no difference in them.

MEMBER GREEN: Okay. So there's no real change in the frequency with the new definition?

DR. TAPP: No.

MEMBER GREEN: Thank you.

MEMBER MARTIN: This is Melissa Martin. I

was just wondering, were most of them Y-90 reports?

DR. TAPP: The last two years most have been Y-90 reports.

(Simultaneous speaking.)

CHAIRMAN PALESTRO: This is Dr. Palestro. Question. And I don't recall if in fact it's been covered in the past, the recommendations by the ACMUI regarding an independent physician and eliminating dose thresholds were not incorporated into the changes.

Is there an explanation or rationale provided as to why?

DR. TAPP: So, the Staff agreed with ACMUI's recommendation, the ACMUI's recommendation. And when we sent up the paper to the Commission in 2014, '15, we did recommend that that change be included in the AO criteria.

The Commission took that into consideration, and when they voted they chose not to make that change. They believed, looking at the vote records, the strong opposition to it was an independent physician with more resources and would be a little bit harder for the Staff to determine if an abnormal occurrence occurred. And they did not want to report less but have more resources expended.

That was one of their written votes that was on the topic. The other Commissioners, I don't know, it wasn't clear in their vote records why they voted against it.

MEMBER ENNIS: This is --

CHAIRMAN PALESTRO: And so --

(Simultaneous speaking.)

CHAIRMAN PALESTRO: Go ahead, I'm sorry.

MEMBER ENNIS: No, go ahead.

CHAIRMAN PALESTRO: So then, my other question would be, what about the reason for not eliminating the dose thresholds?

DR. TAPP: The Staff actually didn't, they capped the dose thresholds in 2015 in their recommendation because they believe there had to be a regulatory threshold to screen all medical events before we started doing independent physician, review all medical events. We felt that that would be overly burdensome.

So we thought there should be a minimum threshold to start and then go into the independent physician screening at that time.

I should remind, or say that today we're not recommending going back to that 2015 criteria. We hadn't made that call. We were just asking if today's

threshold is appropriate.

CHAIRMAN PALESTRO: Thanks.

DR. TAPP: The basic question, yes.

MEMBER ENNIS: Hi, Ron Ennis here. So, in my opinion the answer to the question is no, the threshold is not aligned with the stated goal of issues that are public health and safety. The definition that I see is basically, a slightly more serious medical event than other medical events. But it doesn't seem to be anywhere near the kind of thing that Congress meets to, or should be apprised of.

I don't know what the right definition would be. I think what the ACMUI had recommended a few years back, it sounds to me on first blush kind of a good direction to go. But in terms of answering Dr. Tapp's question, to me, the AO definition is not appropriate.

DR. TAPP: And, Dr. Ennis, that's a good point you bring up. Just to give the ACMUI an understanding of the path forward, what we will do is provide this information to the Commission.

It will be up for them to choose to vote if the Staff should go forward and then look to evaluate which criteria could be used if they agree with that. Or if they agree that it needs to be

changed.

MEMBER ENNIS: Okay.

CHAIRMAN PALESTRO: Any other comments or questions from the Committee?

MEMBER OUHIB: Yes, this is Zoubir Ouhib. I have to agree with Dr. Ennis. I think if you're talking about a dose, a dose is different it's treating different parts of the patient.

So, I don't think we can draw a general statement saying that a dose above whatever is an AO or criteria type of thing.

Just a comment, I think on the background slide, I'm just curious, it caught my attention. If we can go back to it.

Yes. An unscheduled incident, I mean, I wasn't sure that incidents are, a core event, actually scheduled. I mean, these types of things are covered that we don't anticipate. I'm not sure I understood that statement.

DR. TAPP: I will say that the definition is defined in an act or legislation. So, it's nothing we can change, but --

MEMBER OUHIB: No, I understand, it just caught my attention because, I mean, we don't schedule incidents at a medical stage, they just happen. Which

they don't.

So, anyhow, that's all I have. Thank you.

MEMBER SCHLEIPMAN: This is Robert Schleipman.

CHAIRMAN PALESTRO: Go ahead, Dr. Schleipman.

MEMBER SCHLEIPMAN: Just to answer Zoubir's point. The AO unscheduled incident is also referring to power plants and reactor issues, this is not just for medical events. And that's why that language is there I think.

MEMBER OUHIB: Ah, okay. And for reactor they do actually schedule an incident?

(Laughter.)

MEMBER SCHLEIPMAN: Not my area of expertise.

CHAIRMAN PALESTRO: Mr. Ouhib, this is Dr. Palestro.

MEMBER OUHIB: Yes.

CHAIRMAN PALESTRO: Let's not get off onto the reactors because the real question --

MEMBER OUHIB: No, I'm not. I'm not.

CHAIRMAN PALESTRO: I understand. The question that we're being asked to answer is, are we agreeable or satisfied with the AO criteria as they

stand or do we believe that they need to be revised.

MEMBER OUHIB: Very good.

CHAIRMAN PALESTRO: And I want to keep the focus on that. Other comments or questions from the Committee?

VICE CHAIR METTER: Yes, this is Darlene Metter. I have a comment.

So, let me just speak, I just want to have a clarification regarding a medical event versus a medical event abnormal occurrence criteria. Those are two different criteria, is that correct?

DR. TAPP: Yes, that is correct.

VICE CHAIR METTER: Okay. I just wanted you to clarify that because, so this is out of the ordinary.

MEMBER SHEETZ: This is Mike Sheetz.

CHAIRMAN PALESTRO: Go ahead, Mr. Sheetz.

MEMBER SHEETZ: I don't want to belabor it, but I do still have a question on the AO definition. So does the term public health and safety include an individual? Has that interpretation been made?

DR. TAPP: That is kind of how the threshold is going to be questioned. Exactly what is that threshold for public health and safety?

MEMBER MARTIN: This is Melissa Martin.

MEMBER SHEETZ: -- determination does not include a single individual?

DR. TAPP: I believe that would be up to the discretion of the Commission. But an individual is considered member of the public.

MEMBER SHEETZ: Okay.

MEMBER WEIL: This is Laura Weil, can I interject something here? We should perhaps consider that the AO is maybe a surrogate for identifying places where the policy and procedures in place don't adequately protect public health and safety.

And that can only be identified by what happens to a particular individual in some situations. But it has larger implications.

MEMBER SHEETZ: This is Mike Sheetz again. I support Dr. Ennis' opinion. I do not think the current criteria is appropriate. It's too vague.

MEMBER OUHIB: This is Zoubir Ouhib. The way I look at it probably is, if it's something that affects a lot of individuals, a lot of institutions per se, if you have a medical event here, a medical event there, those are more or less expected in a way.

But I think if there is a device or a procedure or whatever, that all of a sudden we're

seeing it happening all over the country per se, then that's an abnormal occurrence, I think, in my mind.

DR. TAPP: Yes. And if the Commission does vote for and directs the Staff to evaluate and come up with a new medical abnormal occurrence criteria, it will go back to the Commission then for more consideration and to help us develop that criteria.

MEMBER OUHIB: Okay.

DR. TAPP: And that's a good thought.

MEMBER GREEN: This is Richard Green.

CHAIRMAN PALESTRO: Other comments or questions from the Committee?

MEMBER GREEN: Yes, this is Richard Green.

MEMBER MARTIN: Yes, this is Melissa, go ahead, Richard.

MEMBER GREEN: Thank you, Melissa. So, I sense the discomfort perhaps is the fact that there were nine medical events that each said, no patient harm occurred. So we triggered the thresholds to be an AO but there's really no patient harm.

So, I think that's why I'm uncomfortable with, it meets the medical event criteria, it meets the abnormal occurrence criteria, but still, there is no patient harm. And our definition is, where

significance is a standpoint of public health or safety.

Most of these, I think, as Dr. Tapp said, were yttrium-90 sphere redistributions or locations. So I think that's the confusion. Why are these still hitting the two levels of criteria but there's no patient harm?

MEMBER OUHIB: This is Zoubir Ouhib.

CHAIRMAN PALESTRO: This is Dr. Palestro. Mr. Green, I assume that you're suggesting that the criteria be revised?

MEMBER GREEN: Yes.

CHAIRMAN PALESTRO: Thank you. Thank you. Mr. Ouhib?

MEMBER OUHIB: Yes. What I think we have to think, not just yttrium-90 today, we have to think down the road, ten years from now, 15 years from now. And there could be devices or whatever that could potentially have harm. And I think we need to be very careful and not to focus just on the yttrium-90 procedure itself.

VICE CHAIR METTER: This is Darlene again.

CHAIRMAN PALESTRO: Thank you. Dr. Metter.

VICE CHAIR METTER: To bring up again, so

as far as the medical events itself, and then a medical AO criteria event, so you're going to have one Y-90 individual be reported in both systems, is that what happens?

I'm just trying to clarify the difference between the two. And should we make a difference between radionuclide therapy and brachytherapy?

CHAIRMAN PALESTRO: Dr. Metter, I think your question goes beyond what the Committee is charged with at the moment.

MEMBER OUHIB: If I could just --

CHAIRMAN PALESTRO: So the question that we're being asked to address, and we're rapidly running out of time, is whether or not the ACMUI recommend the criteria be revised, not to suggest new criteria, new definitions, so forth, but merely to determine whether or not the criteria be revised.

MEMBER MARTIN: This is Melissa Martin.

DR. TAPP: Go ahead.

CHAIRMAN PALESTRO: Go ahead, Ms. Martin.

MEMBER MARTIN: I agree. Basically, what I was going to say, Mr. Green did an excellent job of stating exactly what I was thinking and so I would recommend that it needs to be further defined.

CHAIRMAN PALESTRO: Okay, thank you. Any

other comments or questions from the Committee?

MEMBER OUHIB: Yes, this is Zoubir Ouhib. Just to answer Dr. Metter's question.

If I understood correctly is that, it counts as a medical event but out of these medical events some of them are actually selected, so per se, based on these criteria that it's an abnormal occurrence. And that's how they basically pull those out and make a report to, and which goes to the Congress and so on and so forth. I think, if I'm correct.

DR. TAPP: That's correct.

MEMBER OUHIB: Yes.

CHAIRMAN PALESTRO: Any other comments or questions from the Committee?

Comments or questions from anyone else on the call?

THE OPERATOR: If you'd like to ask a question, please press *1.

Please unmute your phone and record your name slowly and clearly when prompted. Your name is required to introduce your question. To withdraw your request, please press *2.

One moment for the first question. And there are no questions in queue at this time.

CHAIRMAN PALESTRO: Thank you. Ms. Dimmick, I believe at this time we are ready for the Committee to address the question at hand, am I correct?

MS. DIMMICK: That's correct.

CHAIRMAN PALESTRO: All right, then I'm going to ask for a motion by a member of the Committee, to recommend that the medical AO criteria be revised.

MEMBER SCHLEIPMAN: So moved.

VICE CHAIR METTER: Can I make a little revision, that I think the medical AO occurrence criteria should be revisited and revised as needed.

MEMBER SCHLEIPMAN: I second that. Robert Schleipman.

CHAIRMAN PALESTRO: Any discussion?

MEMBER OUHIB: Would that be on an annual basis or what? Revisit it. This is Zoubir.

DR. TAPP: ACMUI can continue to look at it, but at this time, the Commission directed us to do the evaluation and answer that question. So, the question, whether the current criteria today is appropriate.

MEMBER OUHIB: Okay.

MEMBER WEIL: This is Laura Weil.

CHAIRMAN PALESTRO: Any other discussion?

MEMBER WEIL: Yes, please. This is Laura. In reconsidering the definition, I would suggest that the Committee evaluate the goal of reporting AOs and what purpose that is intended to serve and how a definition would support that goal and whether the goal is to protect NRC, institutions or patients.

CHAIRMAN PALESTRO: Ms. Weil, are you suggesting that we amend the motion to include that or is that just a comment for the record that we can look at it in the future?

MEMBER WEIL: I guess it's just a comment for consideration.

CHAIRMAN PALESTRO: Thank you.

VICE CHAIR METTER: Dr. Palestro, this is Darlene. I think if we're looking at reviewing it, I think that would include Ms. Weil's additional comment. Because if you're going to review the whole, you're going to look at what the goal is and make the criteria based on that goal.

CHAIRMAN PALESTRO: So are you suggesting that Ms. Weil's statement be incorporated into the motion?

VICE CHAIR METTER: No. No, I think --

CHAIRMAN PALESTRO: Oh, okay.

VICE CHAIR METTER: -- if we just have the statement as is, that we review the current and make changes as needed.

CHAIRMAN PALESTRO: Okay. Can I ask you then to please restate the motion, Dr. Metter?

VICE CHAIR METTER: Yes, I can do that.

CHAIRMAN PALESTRO: So that we're all clear on it.

VICE CHAIR METTER: I propose that the ACMUI form a subcommittee to review the medical abnormal occurrence criteria and revise as needed.

DR. TAPP: This is Dr. Tapp. Maybe it would be a second motion, if that is a motion from ACMUI, you're right, but that would be hard for us to write in the SECY paper today, and we are planning to respond to the Commission here in the next month or two.

We're really hoping that you guys could vote whether you believe the current criteria is appropriate or whether you would like to look at it further and to revise it.

VICE CHAIR METTER: Okay. I will make a motion that the current medical event AO criteria is not appropriate.

CHAIRMAN PALESTRO: Are you recommending

that it be revised or just that it's not appropriate?

VICE CHAIR METTER: I think Dr. Tapp just asked that question. Is that correct, Dr. Tapp?

DR. TAPP: Yes. It is not appropriate, and you would like it revised is fine.

VICE CHAIR METTER: Okay. Okay, and I would like it revised.

DR. TAPP: All right.

VICE CHAIR METTER: And revised as appropriate.

CHAIRMAN PALESTRO: All right, I'm going to ask you once again, since we've gone through several iterations, to please restate the motion so we have it clear, at least in the transcript. And for everyone listening.

VICE CHAIR METTER: I propose that the ACMUI, well, first of all, number one, the current medical event abnormal occurrence criteria needs to be reviewed, needs to be, how can I say needs to be voted on, is not appropriate and needs to be reviewed and revised as needed.

CHAIRMAN PALESTRO: All right, I'm going to ask for a second for that motion since it's a bit different than the others?

MEMBER MARTIN: Second. This is Melissa

Martin.

CHAIRMAN PALESTRO: Any further discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN PALESTRO: Any opposed? Any abstentions? Okay, then the motion is carried unanimously.

Ms. Dimmick, Dr. Tapp, at this point is there anything else that we need to address or the open session be concluded?

MS. JAMERSON: Hi, Dr. Palestro, it's Kellee. First, I'd just like to thank the ACMUI Members and our additional meeting attendees. This does conclude our open session.

I'd like for our ACMUI Members to stay on the line for the closed session, as well our court reporter. And Chris, our operator, if you could place us back into the pre-call conference. This concludes our open session.

(Whereupon, the above-entitled matter went off the record at 10:45 a.m.)