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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

6 MEETING

7 + + + + +

8 FRIDAY, SEPTEMBER 21, 2012

9 + + + + +

10 The meeting was convened in room T-2B3 of
11 Two White Flint North, 11545 Rockville Pike, Rockville,
12 Maryland, at 8:00 a.m., Leon S. Malmud, M.D., ACMUI
13 Chairman, presiding.

14 MEMBERS PRESENT:

15 LEON MALMUD, M.D., Chairman

16 BRUCE THOMADSEN, Ph.D., Vice Chairman

17 DARICE BAILEY, Agreement State Representative

18 MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

19 SUSAN LANGHORST, Ph.D., Radiation Safety Officer

20 STEVE MATTMULLER, Nuclear Pharmacist

21 CHRISTOPHER PALESTRO, M.D., Nuclear Medicine
22 Physician

23 JOHN SUH, M.D., Radiation Oncologist

24 ORHAN SULEIMAN, Ph.D., FDA Representative

25 WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

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1 MEMBERS PRESENT (Continued):

2 LAURA M. WEIL, Patients' Rights Advocate

3 JAMES WELSH, M.D., Radiation Oncologist

4 PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

5
6 NRC HEADQUARTERS STAFF PRESENT:

7 BRIAN McDERMOTT, Director, Division of
8 Materials Safety and State Agreements

9 PAMELA HENDERSON, Deputy Director,
10 Division of Materials Safety and State
11 Agreements

12 CHRISTIAN EINBERG, Chief, Radioactive Materials
13 Safety Branch

14 MICHAEL FULLER, Alternate Designated Federal
15 Official, Team Leader, Medical Radiation
16 Safety Team

17 ASHLEY COCKERHAM, Alternate Designated Federal
18 Official, ACMUI Coordinator

19 SOPHIE HOLIDAY, Alternate ACMUI Coordinator

20 NEELAM BHALLA, FSME/DILR/RB-B

21 SUSAN CHIDAKEL, OGC/GCLR/RMR

22 JACKIE COOK (via webcast), RIV/DNMS/NMSB-B

23 DONALD A. COOL, Ph.D., FSME/DILR

24 SAID DAIBES, Ph.D., FSME/DMSSA/LISD/RMSB

25 SANDRA GABRIEL, Ph.D., FSME/DMSSA/LISD/RMSB

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1 LATISCHA HANSON (via webcast), RIV/DNMS/NMSB-A
2 VINCENT HOLAHAN, FSME/DMSSA
3 ANTHONY HUFFERT, RES/DSA/RPB
4 ANDREA KOCK, OCM/WO
5 JEFF KOWALCZIK, FSME/DMSSA/LISD/RMSB
6 ANGELA MCINTOSH, FSME/DMSSA/LISD/RMSB
7 ANDREW PESSIN (via webcast), OGC/GCLR/RMR
8 JOSEPHINE PICCONE, Ph.D., FSME/DILR
9 LIZETTE ROLDAN (via webcast), RIV/DNMS/NMSB-B
10 DUANE WHITE (via webcast), FSME/DMSSA/LISD/RMSB
11 RONALD ZELAC, Ph.D., FSME/DMSSA/LISD/RMSB

12
13 PUBLIC PARTICIPANTS:

14 ROBERT DANSEREAU (via webcast), NYS Department of Health
15 WILLIAM DAVIDSON (via webcast), University of
16 Pennsylvania
17 ROBERT GORSUCH, Johns Hopkins Hospital
18 KELLI HAYASHI, Johns Hopkins Hospital
19 KAREN LANGLEY (via webcast), University of Utah
20 RALPH LIETO (via webcast), Trinity Health
21 ANGEL MCCULLOUGH, Johns Hopkins University
22 JANETTE MERRILL, Society of Nuclear Medicine and
23 Molecular Imaging
24 MICHAEL NOSKA, U.S. Food and Drug Administration
25 MICHAEL PETERS, American College of Radiology

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1 DENNIS PHILLIPS (via webcast), U.S. Department of Energy

2 JOE RODGERS (via webcast), Theragenics

3 RUTH SCHUKMAN-DAKOTAS, University of Kansas Hospital

4 MICHAEL SHEETZ (via webcast), University of Pittsburgh

5 CINDY TOMLINSON (via webcast), American Society for
6 Radiation Oncology

7 GARY E. WILLIAMS, VA NHPP

8 NANCY YOUNG (via webcast), Xcenda

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P R O C E E D I N G S

8:07 a.m.

CHAIRMAN MALMUD: The agenda today will begin with the presentation by Angela McIntosh entitled, "Abnormal Occurrence Criteria."

Angela.

MS. McINTOSH: Thank you, Dr. Malmud. Good morning. I am back here again to present on the abnormal occurrence criteria. And I've already presented on it a couple of times, as events develop you realize you have to come back, and it is best to get it right. So, I'm back here again and maybe this will be the last time I have to bring this before you.

But to give you a little background on -- to catch everyone back up to speed on how we got to where we are today, back in 2008 the staff identified that the definition of medical event -- the staff identified rather, that too many medical events were (audio interference) AO criteria.

What I mean by that statement is that we believe that too many relatively non-significant medical events were in the AO criteria and thereby --

(Phone interruption.)

MS. McINTOSH: And so, the staff presented some draft criteria at the 2008 meeting for the ACMUI to

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1 discuss. And the ACMUI reviewed and discussed those
2 criteria and recommended that (audio interference) the
3 committee voted on it and the staff accepted that
4 recommendation.

5 Well, in the meantime, the staff had to wait
6 because per condition of the regulation, we could not
7 open up the criteria and proceed with the change, because
8 the Office of Nuclear Reactor Regulations portions of the
9 criteria needed to - it needs to have a certain amount
10 of experience with that criteria before they would
11 entertain a change to the criteria. So, the staff had to
12 wait.

13 And in the meantime while the staff was
14 waiting, the committee changed some people and the staff
15 also recognized that significant adverse effect might be
16 a little too qualitative for the staff to use to make a
17 determination whether a potential AO had occurred.

18 So, in December of 2011, the staff suggested
19 that significant adverse effect be defined, because it
20 was a little too qualitative.

21 The ACMUI again looked at criteria and what
22 they did - I can bring it up - they recommended what you
23 see on the screen right there before you. And basically,
24 the ACMUI suggested that a designated consultant
25 physician be employed to help determine whether an AO had

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1 occurred.

2 Well, the management has been contemplating
3 these particular criteria and has decided that these
4 criteria as stated, the practical application of these
5 criteria probably will be that we will have to hire a
6 medical consultant in nearly every case that we come
7 across a potential medical event - I mean a medical event,
8 rather.

9 And that would, we foresee, would put an
10 excessive burden on the AO determination process, it
11 would slow the process down quite a bit, and present an
12 excessive financial burden on NRC and the agreement
13 states as the staff tires to make this determination.

14 Does this particular medical event that
15 we're looking at - should we hire a consultant? Well,
16 probably the default would be that we would have to hire
17 one, because who would really be sure?

18 And so, criteria to screen the events seemed
19 appropriate. Some criteria for staff to screen the
20 events, to screen out events where we felt we probably
21 wouldn't need to hire a consultant.

22 And so, the following slides will present
23 an overview of some refinements that we have added to the
24 criteria for your consideration. And subsequent to those
25 slides we'll present some red line strikeouts of the

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1 precise suggested refinements that we are presenting to
2 you today. And the details of those refinements will be
3 discussed.

4 So, here's an overview of what the
5 refinements are. You will note that the title has been
6 changed and footnoted on this slide. And there's some
7 language added back to the criteria that looks
8 significantly like existing AO criteria language.

9 On this slide, and you can't see on this
10 slide, but we'll see it on another one, a phrase in bold
11 font has been - well, actually you can't see the bold font
12 part. "One or more" is the bold font, and the criteria
13 are bulleted.

14 Now, this is where we discuss the changes
15 in detail. The existing criteria says "For Medical
16 Licensees," and we suggest that that be removed and
17 replaced by "Events Involving Patients or Human Research
18 Subjects."

19 We believe this has probably always been
20 understood, but we thought it was important to make it
21 clear that these criteria actually apply to patients and
22 not to medical licensees.

23 There are other criteria in the AO criteria
24 that apply to licensees. And so, we wanted to make it
25 clear that these particular criteria do not.

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1 Our second change there that you see on the
2 bullet, "A medical event that results in," we've crossed
3 out "death" and replaced that with "a dose other than the
4 dose to the intended target."

5 Currently, the AO criteria do not specify
6 that the target organ is excluded. And so, we've had
7 instances where the target organ received a thousand rad
8 above the prescription. And we've had to capture it as
9 an AO.

10 And so, we didn't - that wasn't what we
11 intended to do. So, this suggested change makes it clear
12 that it's not the target organ that should be included
13 in the determination, but some other organ or tissue.

14 And then the third edit that is presented
15 as blue font on the screen, these criteria are
16 substantially what we're using right now.

17 There's a minor change that we added. We
18 reiterated on the third bullet that it's any other
19 unintended organ other than the treatment site. It's
20 reiterating what you see there on the - in the red line
21 text above it, just to make it clear. And then there's
22 an "and" statement.

23 So, these criteria in blue are functioning
24 as screening criteria for the NRC staff. A medical event
25 would have to at least meet these criteria before we would

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1 even consider going forward to possibly determine that
2 a medical consultant would need to be hired.

3 And then on this screen, remember there was
4 an "and" statement before. So, one of those screening
5 criteria would have to be met, and the event would have
6 to result in a significant impact on patient health that
7 would result in.

8 And then that language that the ACMUI
9 recommended before, we've crossed that out and replaced
10 that with "one or more of the following, as determined
11 by a consultant physician deemed qualified by NRC or an
12 Agreement State."

13 Then you have those four bulleted
14 statements in front of you, unintended permanent
15 functional damage to an organ, unintended permanent
16 functional damage to a physiological system, a
17 significant unexpected adverse health effect and death.

18 I want to point out a couple things about
19 this suggested change. First of all, what the ACMUI
20 already recommended is substantially there. It's
21 essentially there.

22 If you look at the stricken out text, you
23 will see "permanent functional damage." Well, that idea
24 or that phrase is below in the red line text, "Unintended
25 permanent function damage." It's there twice in two

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1 different bullets.

2 And significant unexpected adverse health
3 effect, which is part of the stricken out text has been
4 carried forward. That's still there. And death as one of
5 the criteria, is still there.

6 The reason why staff is recommending these
7 changes that you see before you, is because we wanted to
8 make it clear that only one of the criteria need be met,
9 even though that probably was sufficiently evident in
10 what the ACMUI recommended.

11 Still, this makes it very clear that only
12 one of these criteria needs to be met, and not all of them,
13 for an event to be considered a potential AO.

14 And then secondly, the staff suggests
15 adding unintended permanent functional damage to a
16 physiological system, because that criterion is
17 consistent with other AO, with another criterion
18 elsewhere in the AO criteria.

19 So, that whole idea with physiological
20 system being unintendedly damaged, it just carries
21 through the entire AO criteria whether you're speaking
22 of the medical arena, or some other arena. And so, there's
23 consistency there.

24 And then, another thing that staff did in
25 bulletizing these criteria, was rank them. Because the

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1 way the criteria had been presented before, the very
2 first item on the list was "death", followed by these
3 other things.

4 And so, the staff just believed that, you
5 know, logically we would rank these criteria from
6 relatively most severe - pardon me - relatively least
7 severe to most severe in terms of consequence to the
8 patient.

9 Footnote 17 Reference, this is where your
10 handout will probably be most useful to you. Because with
11 these slides, you know, you have to follow conventions
12 about how big the text is and you can't put all this
13 information on one slide and it might be hard to follow
14 logically. So, if you refer to your handout, that will
15 help explain Footnote 17 to you.

16 Remember that we suggest crossing out "For
17 Medical Licensees" and replacing that phrase with
18 "Events Involving Patients or Human Research Subjects"
19 and footnoting that title.

20 And the footnote as you can see on your
21 sheets there, says that criteria III.A.3 and III.A.4 also
22 apply to medical licensees. And then immediately below
23 the line there's criteria III.A.3 and III.A.4 presented
24 before you.

25 And the reason the staff recommends that

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1 this be explicitly stated in the AO criteria, is that this
2 will be a way for the staff to capture what we believe
3 should reasonably be considered an abnormal occurrence,
4 but it is referring to the management of medical events,
5 what could happen at a facility to cause a potential issue
6 at that facility.

7 To give you an example of the kind of things
8 that would be captured under these criteria, III.A.3 and
9 III.A.4 in the medical area would be the VA Philly event
10 in which the individual doses were not necessarily
11 significant in the medical arena.

12 But the fact that so many repetitive errors
13 occurred would be something that NRC would be interested
14 in knowing about and something that we feel would be
15 significant enough to report to Congress.

16 And so again, III.A.3 and III.A.4 are
17 already in NRC's abnormal occurrence criteria. They're
18 not new. But footnoting the medical arena criteria just
19 makes it a little more clear that these criteria would
20 apply at medical facilities.

21 Truthfully, we believe they would apply
22 anyway. But again, this just makes it clear. Because if
23 you read Roman numeral III there, it says "Events at
24 Facilities Other than Nuclear Power Plants." Well, that
25 would be a hospital. Just makes it more clear.

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1 And so, to summarize the refinements that
2 the staff is suggesting, we suggest that the current dose
3 criteria be retained.

4 Again, NRC staff, we're not clinicians. And
5 we can't make medical judgments. And so, it's helpful to
6 us to have criteria to help us identify what we should
7 look at a little bit more closely and screen out those
8 things that probably do not need to be looked at more
9 closely.

10 We believe that without these dose
11 criteria, both the NRC and the Agreement States would
12 probably need to hire a consultant for nearly every
13 medical event that could possibly result in an unexpected
14 adverse health effect.

15 We have clarified the criteria to make it
16 absolutely clear that minimally only one set of - only
17 one of the second set of criteria need to be met. We have
18 ranked the criteria so that the significance are ranked
19 from relatively lowest to highest. And we are proposing
20 just to clarify in the criteria, that the generic trend
21 criteria do apply to medical facilities.

22 Our next steps would be to obtain early
23 Agreement State comment. We believe that this is
24 important because the vast majority of licensees are in
25 the Agreement States. And so, this would impact the

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1 Agreement States significantly any changes made in this
2 area.

3 After obtaining early Agreement State
4 comments, we would send the criteria to the Commission
5 for review. The Commission would include publication of
6 it in the Federal Register for a 90-day comment period.

7 The staff would review those comments and
8 incorporate them, represent the criteria to the
9 Commission for a final review and approval. And then the
10 final AO criteria would be published in the Federal
11 Register.

12 And with that, I'd like to open up this item
13 for discussion, Dr. Malmud.

14 CHAIRMAN MALMUD: First, Ms. McIntosh, I'd
15 like to thank you for a very clear presentation with the
16 historical footnotes for how it evolved. I think that it
17 made it very easy for all of us to follow, because all
18 of us had not been on the Committee over the term of these
19 discussions.

20 And with that, I open the discussion for any
21 comments from members of the Committee, please.

22 MEMBER WEIL: Just a clarification, please.
23 This is only for events that do not involve the intended
24 target. And I assume that the intended treatment target
25 then is covered under the plus or minus 20 percent.

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1 MS. McINTOSH: It would be a medical event
2 to begin with to even be considered really to be an AO,
3 but, yes. But exactly the event would have resulted in
4 a differential of 20 percent in the dose. And so, yes,
5 the target organ -

6 MEMBER WEIL: So, in a comprehensive
7 definition of a medical event, should that not be
8 reiterated, or is it unnecessary? I just put that out.

9 MS. McINTOSH: In a comprehensive -

10 MEMBER WEIL: This is a comprehensive
11 definition of medical event, abnormal occurrence, right?
12 That is what this is intended to be.

13 MS. McINTOSH: Yes.

14 MEMBER WEIL: But it only talks about doses
15 to unintended organs outside the target.

16 MS. McINTOSH: Correct.

17 MEMBER WEIL: And I just wonder if it
18 wouldn't be useful to include somewhere in there what
19 constitutes a medical event that does involve the target
20 organ. I'm just putting it out there.

21 MS. McINTOSH: I don't think I really
22 understand your question. A medical event is - occurs
23 when a prescription is made for a dose to an organ and
24 that prescription is plus or minus 20 percent.

25 MEMBER WEIL: Uh-huh.

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1 MS. McINTOSH: And that's covered under Part
2 35.

3 MEMBER WEIL: Okay.

4 MS. McINTOSH: So, when a medical event
5 occurs and an additional, if you want to look at it that
6 way, an additional error has occurred to the tune of
7 unintended permanent functional damage or -

8 MEMBER WEIL: Any of these things.

9 MS. McINTOSH: - organ or system, that's an
10 AO. It is a medical event to begin with. We wouldn't even
11 look at anything that wasn't a medical event to begin
12 with, because there would be no medical error.

13 MR. EINBERG: Angela, let me try asking if
14 I understand Ms. Weil's question a little bit
15 differently. Would there ever be a case where a medical
16 event to the intended target would be an abnormal
17 occurrence?

18 MS. McINTOSH: No, there wouldn't.

19 MR. EINBERG: Okay. So, then I think that's
20 her question for discussion then.

21 MS. McINTOSH: No, there wouldn't. We are
22 looking for something - I think I see what you're getting
23 at.

24 If the target organ got so overdosed that
25 permanent functional damage occurred, if that's what

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1 you're saying -

2 MEMBER WEIL: Right, uh-huh.

3 MS. McINTOSH: - if that was not the intent
4 of the prescription -

5 MEMBER WEIL: Exactly.

6 MS. McINTOSH: So, an example I can think of
7 is a dose was prescribed to the thyroid. Maybe it was a
8 diagnostic dose and the thyroid was ablated. All the dose
9 went to the thyroid.

10 MEMBER WEIL: Or there was an error in the
11 pharmacy or there was a misadministration.

12 MR. EINBERG: Angela, can you bring up the
13 criteria?

14 MEMBER WEIL: It's your qualifying criteria
15 that excludes anything that affects the target organ.

16 MS. McINTOSH: Target organ.

17 MR. EINBERG: Can you bring up Slide 6?

18 MS. McINTOSH: I think we want Five,
19 actually.

20 MR. EINBERG: No, I was thinking about this
21 one here, the proposed refinement.

22 MS. McINTOSH: Okay.

23 MR. EINBERG: If we were to take off
24 "unintended" over the first two sub-bullets and just keep
25 it as permanent functional damage to an organ or

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1 permanent functional damage to a physiological system,
2 would that address -

3 MEMBER WEIL: No, because it's the blue
4 bullets. It's the blue bullets which have to be met first,
5 before you proceed to the red bullets.

6 MS. McINTOSH: It's page - it would be Page
7 5. She's referring to the bullet that says "A medical
8 event that results in a dose other than the dose to the
9 intended target."

10 MEMBER WEIL: You're qualifying everything
11 here to only involve things other than the target.

12 MS. McINTOSH: So, if the intended target got
13 a dose, but that dose resulted - going back to the thyroid
14 example, it was supposed to be a diagnostic, but it wound
15 up being an ablative therapy, that would not have been
16 intended, but the target, the dose did go to the target.

17 MEMBER WEIL: Uh-huh.

18 MS. HENDERSON: If we added in a dose other
19 than the prescribed dose to the intended target, would
20 that address your concern? Because then if it was more
21 than what was prescribed, it could also result in an AO.

22 In other words, if the patient got two,
23 three times what was - I see what you're saying that this
24 would not address the dose to the intended organ. So, if
25 the intended organ was overdosed, this language might

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1 exclude that from being an AO.

2 MEMBER WEIL: Yeah, but that takes you back
3 to where you were before where almost anything can be a
4 medical event, because you're not putting in any
5 thresholds there about what that target - what - the
6 magnitude of the unintended dose, either under or
7 overdosed, and you're back where you were before.

8 MS. McINTOSH: Because in that case and that
9 specific example, it would be greater than a thousand
10 rad.

11 MEMBER WEIL: Right.

12 MS. HENDERSON: Greater than or equal to a
13 thousand rad to -

14 MS. McINTOSH: And then we repeat
15 "unintended" there.

16 MS. HENDERSON: Right. So, we would have to
17 add something a thousand rad greater than the intended
18 dose and a thousand rad to any other unintended organ or
19 tissue.

20 (Discussion off the record.)

21 MS. McINTOSH: A thousand rad greater than
22 the intended dose.

23 CHAIRMAN MALMUD: Dr. Welsh.

24 MEMBER WELSH: I might suggest to address the
25 important issue that Ms. Weil has just brought up that

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1 maybe a medical event that results in a dose other than
2 a dose to the intended dose to the intended target, and
3 then to address Ms. Weil's concern. But then we also have
4 concerns about these numbers, because they are organ
5 system-dependent.

6 So, 10 gray for a thyroid is very different
7 from 10 gray to the optic chiasm, or it could be very
8 different from 10 gray to the spinal cord if given in a
9 stereotactic fashion using a gamma knife, for example.

10 So, I'm not sure that these numbers are
11 helping us, because they vary from system to system and
12 technology to technology.

13 MS. McINTOSH: But these are only screening
14 criteria though.

15 MEMBER WELSH: But there's an "and".

16 MS. McINTOSH: There's an "and", correct.
17 That's where the real errors come in. The and, in this
18 case, screening criteria to the significant things like
19 unintended permanent functional damage.

20 CHAIRMAN MALMUD: Dr. Thomadsen.

21 VICE CHAIRMAN THOMADSEN: Addressing Ms.
22 Weil's comment, isn't it caught by the term "medical
23 events" in that bullet?

24 I mean, you're already triggering this
25 because it's a medical event. So, do you need to change

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1 the wording so that you pick up medical event again by
2 referring to the target?

3 MEMBER WEIL: I don't know.

4 CHAIRMAN MALMUD: Dr. Suleiman.

5 MEMBER SULEIMAN: Yeah, I'm going down the
6 same path. Medical event picks it up. Now, you're trying
7 to determine severity. You're talking about some
8 specific organs? You're assigning some different dose
9 values.

10 I think once it's already triggered into a
11 medical event, you really need a medical professional to
12 assess it.

13 Dr. Welsh's point is you've got different
14 technologies. I thought I made the point yesterday at
15 least in terms of if you're dealing with unsealed sources
16 versus sealed sources and external beam the precision and
17 accuracy may vary. So, you've got uncertainty which
18 organs are going to - in other words, I'd almost back off
19 and say maybe use one number for all organs that would
20 say, this is serious, this is a high number.

21 And then have somebody who understands
22 whether it was a diagnostic procedure that wound up with
23 a much higher dose, whether it was a therapeutic dose that
24 wound up very, very wrong place.

25 This is a little confusing to me. And I think

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1 maybe take a step back and come up to the more simple
2 action limit with some experts analyzing what actually
3 happened.

4 CHAIRMAN MALMUD: Dr. Thomadsen.

5 VICE CHAIRMAN THOMADSEN: Can I ask where the
6 blue numbers came from?

7 MS. McINTOSH: This is what we currently use,
8 actually.

9 VICE CHAIRMAN THOMADSEN: Where did they
10 come from that you're currently using them?

11 MS. McINTOSH: Oh, where did they come - I
12 would have to - I'm going to venture a guess. I'm not sure
13 about this, but probably an NCRP or ICRP-recommended
14 number.

15 CHAIRMAN MALMUD: Dr. Welsh.

16 MEMBER WELSH: I think the question at hand
17 is do we need these numbers at all? Because I think
18 they're leading to more confusion than benefit here.
19 Because as we said, radiopharmaceutical therapy is so
20 very different from gamma knife in terms of the effects
21 of a specified dose that putting a specified dose,
22 nominal figures in here, leads to more confusion than
23 clarification.

24 CHAIRMAN MALMUD: Dr. Langhorst.

25 MEMBER LANGHORST: I like the criteria to

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1 give to the staff to screen out medical events that don't
2 need medical review.

3 I mean, it just - it helps minimize the
4 number that they have to consider for adverse occurrence.
5 And I understand that need.

6 I do think that Laura brought up a really
7 good point. Because if you have an extreme dose to the
8 target organ while this is a medical event, it's that
9 results in a dose other than to the dose of the intended
10 target. So, it rules out if you had a very substantial
11 dose to the target that didn't result in any of these
12 screening criteria. And that would not trigger that next
13 medical review.

14 So, I understand the need to kind of sort
15 out, okay, here's a medical event. Does it rise to the
16 need to review for medical purposes whether it's an
17 adverse occurrence?

18 But I'm not quite sure how to work in the
19 target organ there like what you're recommending.

20 CHAIRMAN MALMUD: Dr. Thomadsen.

21 VICE CHAIRMAN THOMADSEN: Well, the question
22 is to both - Dr. Langhorst first. I'm not sure we care
23 if the target gets a huge dose if it doesn't have any
24 physiological problems to the rest of the patient. I'm
25 not sure that -

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1 MEMBER LANGHORST: Right.

2 VICE CHAIRMAN THOMADSEN: Other than being
3 a medical event, whether we need to worry about it being
4 an abnormal occurrence.

5 To Dr. Welsh, I can understand why the staff
6 would like a screening cutoff so that there's some de
7 minimis error that they don't have to deal with.

8 Would it be possible to propose some cutoff
9 level that could be uniformly applied that could both
10 screen out the de minimis, yet be sufficient to catch both
11 the optic chiasm case and any other case?

12 MEMBER WELSH: This is Jim Welsh.

13 I suppose the answer is yes that if we put
14 in a lot of thought and effort, we would come up with
15 numbers that would satisfy that criterion.

16 But I suppose the - my question is just
17 because we've done this for so many years and staff likes
18 it because it's comfortable, doesn't mean that we should
19 continue to perpetuate this.

20 Because, you know, I guess we could come up
21 with a number that would be good for spinal cord -
22 cervical spinal cord gamma knife or optic chiasm, optic
23 nerve and come up with numbers that would also be below
24 - would be appropriate for radiopharmaceutical therapy
25 or permanent implant brachytherapy, HDR brachytherapy,

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1 et cetera.

2 But that exercise, in my opinion, is not
3 very valuable, because we are going to be coming up with
4 arbitrary numbers that I'm not sure I see the real value
5 in.

6 And as long as we have that Boolean algebra
7 there, that means that we don't - that we have to satisfy
8 those numbers, that they are very important numbers.

9 And if we're struggling to come up with
10 these numbers and some of us are questioning the real
11 merit of these numbers, I'm not so sure that this whole
12 category is worth keeping.

13 CHAIRMAN MALMUD: Dr. Langhorst, then Dr.
14 Suleiman.

15 MEMBER LANGHORST: Dr. Welsh, do you feel
16 that the numbers that are listed here would miss some
17 adverse occurrences? Is that -

18 MEMBER WELSH: Absolutely.

19 MEMBER LANGHORST: - the point? Okay. And so,
20 you're recommending that there be a medical review of all
21 medical events? Is that -

22 MEMBER WELSH: Well, my point is that if you
23 have a case of blindness that should not have happened,
24 as an example, it would not fit this definition because
25 of those numbers.

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1 And if such a case could happen, then it
2 illustrates that there is a deficiency in this proposed
3 refined definition, as a quick example of why I feel like
4 there is a deficiency.

5 CHAIRMAN MALMUD: Dr. Suleiman.

6 MEMBER SULEIMAN: Orhan Suleiman. I am also
7 very concerned with the human research subject
8 application, because - especially with radioactive
9 drugs. You don't know. You're observing.

10 And so, sometimes patients get some - some
11 of their organs get some pretty unpredictable, because
12 that's the nature of research.

13 So, I don't know what that means to the
14 research protocol, which is already under institutional
15 review board oversight and IND oversight. So, are we -
16 is it - is there double jeopardy here?

17 I mean, they have to - and during the
18 research, they're obligated to report all sorts of
19 observations. So, that would get picked up as part of the
20 research phase.

21 MS. McIntosh: Okay. So, that for human
22 research subjects there's a recognition. I think that
23 what I'm hearing from you is that there is a recognition
24 that something is unintended. But nevertheless, very
25 severe if it happened.

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1 And under the research protocols, that's
2 accounted by whatever committees or rules that are under
3 that apply to human research. So, you see it as redundant
4 to -

5 MEMBER SULEIMAN: Well, when you subject a
6 human subject to research, it involves protection not
7 only from a safety point of view, from an ethical point
8 of view. And so, the purpose of the research is to
9 document everything you see.

10 Some of it's not very serious, but document
11 everything because, you know, later on some minor side
12 effect may turn up when you expand the study size or maybe
13 it goes - the drug gets approved and you start using it
14 on hundreds of thousands of people.

15 All of a sudden you say, oh, we may have seen
16 this earlier, but now it's much more serious. But that's
17 more of a non-radiation effect, but the objective is to
18 follow all those.

19 MS. McIntosh: But does it make sense for NRC
20 to have a licensee that does this and something goes awry
21 and is significant and we know that it happened under an
22 NRC license and we don't report it to Congress?

23 MEMBER SULEIMAN: Yeah, I don't know. I mean,
24 I'm saying we should be picking it up assuming the
25 researcher is doing what they're supposed to. I mean,

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1 there's always that caveat, but we should be picking it
2 up.

3 But if it's related to the product that you
4 regulate, if it's related to the radioactive source in
5 some way, form or another, maybe you need to be aware of
6 it, you know.

7 CHAIRMAN MALMUD: Dr. Langhorst.

8 MEMBER LANGHORST: But Part 35 covers human
9 research subjects in medical events. I mean, they're
10 already in there. So, I don't think - if they're not doing
11 the administration in accordance with their own
12 procedures and they're plus or minus 20 percent whether
13 it's human subject or patient, I think it's still under
14 NRC purview and it makes sense to be included in here.

15 MEMBER SULEIMAN: You're regulated. So,
16 that's fine with me.

17 (Laughter.)

18 MEMBER LANGHORST: I'm not saying I like it.

19 MEMBER SULEIMAN: If it works, you know, if
20 it's working, that's fine.

21 CHAIRMAN MALMUD: This is Malmud. Raising
22 Dr. Welsh's point, are we trying to achieve something
23 with uniformity that's really not applicable to the use
24 of radiopharmaceuticals versus the use of external
25 radiation from a sealed source, versus implants? Are we

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1 trying to develop a single code for all when it is not
2 applicable?

3 And with respect to Dr. Suleiman's comment,
4 is any of us aware of a permanent damage from a research
5 radiopharmaceutical that was - that occurred as a result
6 of the radiation rather than the pharmaceutical implant?

7 Is there any awareness of such an episode
8 in the past? I'm not aware of any. There are
9 radiopharmaceuticals which have caused difficulties
10 because of the pharmaceutical employed which had
11 untoward effects, but I'm not aware that the radiation
12 burden was an issue.

13 Has there ever been such an example?

14 MEMBER SULEIMAN: Oh, I think that there were
15 therapy trials where, I mean, these are trials. These are
16 investigational drugs where patients get some pretty
17 serious doses.

18 CHAIRMAN MALMUD: Radiation -

19 MEMBER SULEIMAN: From the radiation.

20 CHAIRMAN MALMUD: From the radiation? In
21 diagnostics, or just therapeutics?

22 MEMBER SULEIMAN: These are oncology trials.

23 CHAIRMAN MALMUD: These are therapeutics?

24 MEMBER SULEIMAN: Yes.

25 CHAIRMAN MALMUD: Dr. Thomadsen.

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1 VICE CHAIRMAN THOMADSEN: I don't have the
2 reference. I think there was a Swedish trial quite some
3 time ago using strontium-90 for metastatic prostate bone
4 pain where the radiation did cause severe injury.

5 CHAIRMAN MALMUD: Again, that's
6 therapeutic.

7 VICE CHAIRMAN THOMADSEN: That is
8 therapeutic, yes.

9 CHAIRMAN MALMUD: I've only been involved in
10 the field for 40 some years, but I don't recall a
11 diagnostic radiopharmaceutical having untoward
12 radiation effects from the radiation associated with the
13 pharmaceutical, only from the pharmaceutical that was in
14 trial.

15 Once again I raise the question, are we
16 trying to do something that really is not achievable in
17 applying the same criteria for diagnostics,
18 therapeutics, in radiopharmaceuticals and for external
19 beam radiation and for sealed sources such as implants?

20 Dr. Welsh.

21 MEMBER WELSH: To respond immediately to
22 your question, I think that we are trying to do something
23 which is not impossible. As Dr Thomadsen pointed out, we
24 could come up with some numbers. But as I pointed out,
25 it's a difficult exercise and I question its value.

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1 But to solve this, I'm just wondering about
2 that Boolean algebra and substituting it with an "or"
3 would satisfy NRC's desire to have some numbers.

4 But by not making that an "and," it would
5 minimize the relative importance of those numbers, which
6 would be very difficult to come up with something that
7 satisfies teletherapy, HDR, et cetera, et cetera.

8 MS. McINTOSH: Dr. Welsh, that would put us
9 back to where we are currently, though. Which anything
10 greater than a thousand rad, I mean, every permanent
11 implant brachytherapy that was just off by a little bit
12 would be an AO the way it is right now. Then an AO report
13 has - we have a total of 15 AOs, and 12 of them are medical.

14 MEMBER WELSH: Then I would recommend
15 getting rid of this entire section of nominal figures
16 then. I think it's just not as valuable as we might think
17 it was in the past. And it's too difficult to apply when
18 we're trying to come up with numbers for
19 radiopharmaceutical therapies versus gamma knife,
20 versus HDR, versus permanent implant brachytherapy.

21 The numbers would be very difficult to come
22 up with that would make sense.

23 CHAIRMAN MALMUD: Mr. Einberg.

24 MR. EINBERG: Just to reiterate, our goal
25 here is to have the screening criteria so that the AO

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1 criteria is practical or implementable.

2 And if we don't have some kind of screening
3 criteria, then it puts the staff and the Agreement States
4 in a position where they have to get a medical consultant
5 or a physician to screen every medical event across the
6 country.

7 And it's not implementable unless we have
8 some kind of de minimis threshold for us to make that cut
9 and say if it meets this, whatever the criteria is, then
10 go ahead and get a medical consultant.

11 I think if we go forward without any
12 screening criteria, the Agreement States will probably
13 - or we've already, you know, we're hearing that, you
14 know, in this tight budgetary time frame, you know, to
15 get a medical consultant is, you know, very costly and
16 is it really necessary to have a medical consultant for
17 things that most likely are not significant anyway.

18 CHAIRMAN MALMUD: Well -

19 MEMBER WEIL: The purpose of a good screening
20 tool is to be overly sensitive. And if I'm hearing Dr.
21 Welsh's concern, there will be events that will not be
22 picked up using these criteria. So, it's not sensitive
23 enough; is that fair?

24 MEMBER WELSH: Yes.

25 MEMBER SULEIMAN: I think I'm speaking - I

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1 think this is confusing to me, and I get a sense it's
2 confusing to other people, but I'm going to take a step
3 back.

4 And if you want to segregate these into
5 brachytherapy, external beam, unsealed sources or
6 radiopharmaceuticals and try to apply some criteria to
7 each of those, would it make more sense and be less
8 confusing?

9 I mean, I think part of the problem is we're
10 trying to set numerical standards for very different
11 sources that behave very differently in the body and for
12 which the uncertainty in estimating those doses either
13 to the organs or the body vary greatly.

14 But if you were to segregate into these
15 three categories, would it make more sense if you came
16 up with three different sets of numbers?

17 What's going to happen here, you're going
18 to have a bunch of people look and say, what's that mean?
19 How do we evaluate this?

20 And so, you're going to have, you know, you
21 may bring in people who understand the language, but
22 don't understand the underlying science.

23 MR. EINBERG: That certainly is an approach
24 and, you know, would be implementable. But, you know,
25 what are those numbers, I guess it comes down to.

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1 MEMBER SULEIMAN: Well, I think I could come
2 up with some numbers off the top of my head, but I won't
3 use them - try it now if you were to segregate them by
4 those sources, but I'm still trying to cope with these
5 numbers that you have there.

6 CHAIRMAN MALMUD: Dr. Zanzonico.

7 MEMBER ZANZONICO: Pat Zanzonico.

8 I guess the question I have is do the
9 screening criteria need to be part of the formal
10 definition of an abnormal occurrence?

11 In other words, couldn't the - because what
12 I'm thinking is you have this and so that in order for
13 an event to be formally characterized as an abnormal
14 occurrence, it would have to meet these dose criteria,
15 as well as the subsequent clinical criteria.

16 The sense I'm getting is that it's really
17 the clinical criteria that matters. So, couldn't the
18 screening criteria be separated from the formal
19 definition of the medical event and used
20 administratively, for lack of a better term, by the NRC
21 staff to pursue it? And since they would then not be part
22 of the definition if you had an occurrence like the one
23 Dr. Welsh described where there was an inadvertent dose
24 to a particular radiosensitive part of the body that had
25 a significant clinical sequelae, that would be captured

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1 as an abnormal occurrence?

2 MR. EINBERG: I would say that, yeah, that's
3 a possibility if the screening criteria are clear enough
4 for a non-physician or, you know, to make that
5 determination.

6 CHAIRMAN MALMUD: Dr. Thomadsen.

7 VICE CHAIRMAN THOMADSEN: It sounds like you
8 would then be in the position though that you would for
9 each medical event, you'd have to hire a consultant to
10 evaluate whether there was actually permanent functional
11 damage to an organ or a system.

12 MEMBER ZANZONICO: Well -

13 VICE CHAIRMAN THOMADSEN: Or maybe death if
14 you need a consultant to establish that.

15 MEMBER ZANZONICO: Well, again, Pat
16 Zanzonico. Just getting back to the example Dr. Welsh
17 raised if, say, the dose criteria were not satisfied in
18 that instance, yet there was an overdose - an avoidable
19 overdose to the optic nerve or optic chiasm and that
20 subsequently was recognized that the patient became
21 blind in that - in the affected eye, then at that point
22 it could trigger a review.

23 It would seem that we have a cause and effect
24 relationship that would be recognized subsequently
25 between the irradiation and the clinical effect even

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1 though these particular dose criteria were not reached.

2 So, in that case, yes, you would need a
3 medical consultant, but that would be a very obvious
4 effect. But I still think you need, I mean, I sympathize
5 with the NRC staff. You need some objective criteria so
6 that you don't need to hire a medical consultant in every
7 instance.

8 MS. McINTOSH: I would just add, Dr.
9 Zanzonico, that the screening criteria wouldn't make it
10 an AO. The screening criteria would be just that. It would
11 just be a starting point for NRC to look - it's not that
12 the screening criteria and these other criteria together
13 make it an AO. It's just that the screening criteria is
14 used to segregate out those that could meet these other
15 criteria.

16 MEMBER ZANZONICO: But there is an "and".

17 MS. McINTOSH: There is an "and".

18 MEMBER ZANZONICO: So, it would have to be
19 both. So, I think Dr. Welsh's point is there were
20 instances where there are abnormal occurrences where the
21 dose criteria would not be met, yet there would be a
22 clinically significant effect. And that would not be an
23 AO according to the way this is written, because there's
24 an "and" in there.

25 CHAIRMAN MALMUD: Dr. Langhorst, then Mr.

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1 Einberg.

2 MEMBER LANGHORST: Let me suggest this,
3 because I think it may get back to Laura's point about
4 the target organ and so on. And that's the criteria
5 III.A.3, a serious safety-significant deficiency in
6 management or procedural controls.

7 And that might be the catchall that NRC
8 staff could use that if the target organ got way too much
9 dose, that would be something that that
10 safety-significant deficiency, you'd have to have a
11 physician review of that for the patient and it would
12 catch perhaps those criteria that maybe it doesn't
13 obviously meet the criteria of the dose that you're using
14 for screening.

15 I offer that up that that might be your
16 catchall there. And I don't know if you mean that to be
17 to apply to patients and human research subjects, or to
18 other aspects of the program, of the radiation safety
19 program for medical use licensee.

20 CHAIRMAN MALMUD: Mr. Einberg.

21 MR. EINBERG: To respond to Dr. Langhorst's
22 question, I'm not clear - I'm not sure I understand how
23 that would apply in -

24 MEMBER WEIL: It's too subjective.

25 MR. EINBERG: It's too subjective, as Ms.

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1 Weil said. So, the practicality of it for us would still
2 kind of get us into the position where we would have to
3 get a medical physician or consultant.

4 MEMBER LANGHORST: Right. I mean, you have
5 to have that in order to make that determination for III,
6 don't you, a safety-significant deficiency?

7 MEMBER WEIL: No.

8 MEMBER LANGHORST: If it applies to a patient
9 or a human research subject, you certainly would want
10 medical -

11 MS. McINTOSH: That is meant to apply to the
12 facility management.

13 MR. EINBERG: These are for events at
14 facilities. And this is -

15 MEMBER LANGHORST: Nothing to do with the -

16 MR. EINBERG: With the patients, yes.

17 MEMBER LANGHORST: Then you need to get rid
18 of the criteria.

19 (Laughter.)

20 MEMBER LANGHORST: Because you don't, I
21 mean, you need a catchall someplace here.

22 CHAIRMAN MALMUD: The discussion has raised
23 two important points. One by Ms. Weil, which is that she
24 reminds us that the screening procedure is a screening
25 procedure and it should be sensitive.

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1 Then Dr. Welsh's comment that even with
2 these criteria, it's possible for there to be a
3 catastrophic event in radiation oncology not covered by
4 these screening criteria.

5 So, it seems to me that we have not achieved
6 the goal, because both of those comments are valid.

7 I also keep looking at this and say we're
8 trying - it's as if the space program and commercial
9 aircraft are to be governed by the same rules. They're
10 not the same thing. They both go up in the air, but they're
11 not the same thing.

12 And these are all radiation-related issues,
13 but they are not the same thing. And, therefore, should
14 we - these criteria that have been presented to us, from
15 my perspective, are applicable to diagnostic
16 radiopharmaceuticals, clearly.

17 I can't speak to their applicability to
18 radiation oncology, but Dr. Welsh has spoken to them, and
19 they're not - they don't achieve the goal there.

20 And I'm not even certain that they would
21 have fit the issue that raised the concern at the
22 Philadelphia VA so that I think we need to look at this
23 with two separate sets of rules.

24 The staff out in the field needs criteria,
25 we all agree, that can't be too subjective. We can give

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1 them objective criteria if they were suited to the
2 particular applications. Not individual applications,
3 but the particular specialties of nuclear medicine
4 diagnostic, nuclear medicine therapeutic and the various
5 fields of radiation oncology so that there would be, I
6 think, the need to look at these as separate issues.

7 Now, what about the issue of diagnostic
8 radiology, for example, in cardiac - well, in issues
9 where the cardiologist or the radiologist exposes the
10 patient to an excessive amount of radiation during the
11 course of the procedure?

12 Is that governed by this as well, or is that
13 a separate issue?

14 MEMBER VAN DECKER: You're asking about
15 machine producing radiation, Doctor?

16 CHAIRMAN MALMUD: Beg your pardon?

17 MEMBER VAN DECKER: You're inquiring to
18 machine-produced radiation?

19 CHAIRMAN MALMUD: Yes, machine. That's
20 radiopharmaceuticals.

21 FEMALE PARTICIPANT: That apply in an
22 Agreement State.

23 MR. EINBERG: Just to go on the record, they
24 would not apply and we do not regulate that.

25 CHAIRMAN MALMUD: So, then we have a simpler

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1 issue. We simply have the nuclear medicine approaches and
2 the radiation oncology approaches. I just wanted to
3 clarify that.

4 Dr. Suleiman.

5 MEMBER SULEIMAN: Orhan Suleiman.

6 FDA has had reported incidents of serious
7 overdoses from CT, from fluoroscopy. So, those things do
8 happen from diagnostic procedures.

9 CHAIRMAN MALMUD: Are they dealt with by the
10 FDA?

11 MEMBER SULEIMAN: Yes.

12 MR. EINBERG: And the FDA has their own
13 criteria, which is -

14 MEMBER SULEIMAN: Serious adverse event,
15 serious adverse event. Let me add earlier there was an
16 incident a number of years ago and I know it was public,
17 and I forget the - it was an isotope. It was used for
18 research. And instead of the - I think the critical organ
19 was supposed to be the kidneys or it was the other - or
20 the bladder.

21 Anyway, they wound up giving a lethal dose
22 to the kidneys and they didn't find this out until, you
23 know, six to 12 months later. So, that's an example where
24 the wrong organ got the dose for a number of reasons. And
25 there was a lot of publicity and publications out of it.

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1 To be honest, I wonder if that ever got
2 reported as a medical event to the NRC. It was under
3 trials.

4 CHAIRMAN MALMUD: It was an FDA issue.

5 MEMBER SULEIMAN: Oh, definitely, but it was
6 a radioactive -

7 CHAIRMAN MALMUD: The last thing the country
8 needs is duplicative regulations. If it's handled by one
9 agency, it needn't be handled by the other as long as one
10 agency or another is dealing with it. That's just a
11 personal comment.

12 However, I still remain concerned about the
13 points that Ms. Weil made and the point that Dr. Welsh
14 made. And that is that these screening criteria will not
15 apply to certain situations in radiation oncology that
16 might result in untoward effects. And, therefore, I think
17 we need to revisit it.

18 The criteria that you've presented, I
19 believe, are perfectly applicable to diagnostic nuclear
20 medicine procedures.

21 MS. McINTOSH: So, then, do you believe it
22 would be prudent then for the Committee to come up with
23 a screening criteria for therapy and we just - we keep
24 these for diagnostics?

25 CHAIRMAN MALMUD: I would want to hear the

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1 Committee's opinion about keeping these. I personally
2 see nothing objectionable then and I see everything
3 applicable in them, but that's just one man's view on
4 nuclear medicine as it relates to this.

5 With respect to radiation oncology, we may
6 need a radiation oncology subcommittee to deal with this
7 and come up with criteria that are applicable to
8 radiation oncology.

9 If then the people in the field have one set
10 of guidelines for nuclear medicine and one set of
11 guidelines for radiation oncology, we would have met our
12 responsibility in giving them guidelines that will
13 assist in patient safety and not interfere with the
14 practice of medicine in both disciplines.

15 Dr. Welsh.

16 MEMBER WELSH: There's been a lot of valuable
17 discussion and important points raised. And I might offer
18 a suggestion just to throw down as a practical solution
19 to see if this would solve the concerns that have been
20 raised.

21 Number one, Ms. Weil has brought up the
22 question of excluding the target. So, how about if we
23 change the wording to include a dose other than the
24 intended dose to the intended target.

25 That would allow us to include erroneous

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1 doses to the intended target rather than exclude the
2 target entirely.

3 The second point was my concern about these
4 nominal figures, which I still think they're held over
5 from an era that is long gone and not necessary, but I
6 appreciate and I'm sensitive to those who like these.

7 Therefore, I might suggest like Dr.
8 Thomadsen said, come up with some numbers that are more
9 appropriate and that would be much lower and capture
10 everything that could be in this abnormal occurrence,
11 including lower doses to the optic chiasm, lower doses
12 to the gonads if we're talking about fractionated
13 teletherapy, et cetera.

14 And then finally on the next slide where we
15 have the two bullet points unintended permanent
16 functional damage to an organ or physiological system,
17 I might suggest adding the word "unexpected." So,
18 unintended and unexpected permanent functional damage.

19 Because unintended of course, but
20 unexpected means that - it means something different.
21 Because we know that radiobiologically there are
22 thresholds that make possible unintended effects
23 unlikely to have been related to the radiation itself
24 depending on the clinical circumstances.

25 Radiation sensitivity, hypertension,

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1 diabetes, these predispose individuals to more likely
2 consequences of doses of radiation, as an example, that
3 might be unexpected. Certainly they would be unintended,
4 but would they be expected?

5 So, those are just some - a first attempt
6 at a practical solution to the problem at hand.

7 CHAIRMAN MALMUD: Thank you. Dr. Guiberteau.

8 MEMBER GUIBERTEAU: Yes, I agree with most
9 of what Jim said and I think the sentiment that's going
10 around here.

11 I would really not like to see the screening
12 criteria go away, because I've had a concern for a long
13 time that this really roots this in what we're supposed
14 to be doing. And that is radiation - the medical effects
15 - adverse medical effects of radiation and I think these
16 are very helpful.

17 I do agree that they're not as sensitive as
18 they need to be. If we get rid of them, then there is,
19 you know, reporting these things is not necessarily
20 benign to those physicians who are treating patients who
21 fall accidentally, because there are effects that are not
22 covered in here that are not just unintended, but they're
23 unrelated or incidental. And I think the screening
24 criteria are a way of, you know, are a way of getting
25 around that.

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1 I agree very strongly that from a, you know,
2 whether you're talking about - and I know that it's not
3 covered, but diagnostic radiology and radiation oncology
4 or nuclear medicine that I think trying to get one set
5 that fits all will either make it too sensitive for some
6 areas, and not enough for others and I would really
7 encourage the ACMUI to ask for criteria that fit what we
8 do, the major categories.

9 And I think like Dr. Malmud, I think that
10 makes sense to me. And I think that would solve several
11 problems.

12 CHAIRMAN MALMUD: Dr. Suh.

13 MEMBER SUH: So, I think this is a complex
14 topic. And I think the two issues we have are we need the
15 screening test that's sensitive. But at the same time,
16 I agree with the sentiment around the table where that
17 we also need a specific modality.

18 So, as Dr. Welsh pointed out, this criteria
19 are greater than or equal to 10 gray, that means very
20 different things to the optic chiasm versus the spinal
21 cord.

22 And I could think of a scenario where
23 someone, lets say, has gamma neck radiosurgery the optic
24 chiasm gets nine gray. Which in some people's estimation
25 is a pretty high dose particularly if it's unintended and

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1 it caused blindness to the patient.

2 With this criteria, you know, question is
3 would it be caught or not. So, I think it does need to
4 be specific to modality. Because if you're talking about
5 brachytherapy, the dose of 10 gray over a couple of months
6 is very different than giving it in one single session
7 like in gamma neck radiosurgery. So, I agree that I think
8 it needs to be specific to modality.

9 I think these are very generic numbers and
10 I think there's a chance that you're going to miss some
11 abnormal occurrences which should be reported.

12 CHAIRMAN MALMUD: Thank you. Dr. Van Decker.

13 MEMBER VAN DECKER: Just a couple of
14 comments, if I may. I guess one reminder to all of this
15 is that every case that's going to fit into this category
16 almost by definition had to have fit medical events,
17 right?

18 So, all of these are being looked at.
19 There's a root cause being done on all of these for
20 systems errors and everything else. So, there is a
21 screen.

22 The screen is did you make medical event?
23 So, that's our screen and we have a universe out there
24 and we have people looking at it at the State level and
25 people looking at it at the NRC level.

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1 Now, we're talking about a second screen.
2 A second screen that would raise it to the level of, you
3 know, would it be reported at the Congressional level,
4 would we be taking a higher resource to look into this?

5 So, then the question is, where is that
6 second screen before we get everybody, you know, running
7 in a circle?

8 And in Orhan's point, I think this is
9 similar in clinical trial work when we talk about adverse
10 events versus serious adverse events where we raise that
11 second screen.

12 And I think as you would well point out,
13 these red bullets here, the unintended and unexpected
14 stuff is actually very similar to the wording that goes
15 into serious adverse events.

16 Now, obvious in clinical trials
17 irrespective of the radiation piece of it, which is an
18 extra piece of this to the screen, you know, I can see
19 many pragmatic reasons for why staff would like a number
20 cutoff to say, well, that's clearly in a medical event,
21 this just could be looked at, at medical - at root cause
22 they are in, you know, we may not need to be looking for
23 high enough that we definitely need a medical expert to
24 say, well, put it back into the medical event category
25 and root analysis there versus, yes, I think this is the

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1 highest level of abnormal occurrence and it stays there
2 rather than going back into the other medical event area.

3 What that number is, I think you can have
4 lots of different views on it. And I think that's going
5 to be the problem here trying to come to some consensus,
6 you know.

7 The last comment I want to make because I
8 don't want to get lost in all of this is where this
9 Paragraph Number 3 fits in, because this is making me
10 really confused here.

11 You know, I think as our State
12 representative pointed out, both III.A.3 and III.A.4 are
13 fairly subjective in nature to some degree. And, you
14 know, if you put them in as an or situation as I think
15 was proposed irrespective of the top two pieces, then you
16 bring up the question of who's making the decision
17 process on, you know, what is significant deficiency and
18 what was a procedural control or generic, you know, I
19 think that that kind of fits into the category.

20 And I think we had this conversation on the
21 teleconference call about this topic is that I think that
22 the real or at the bottom is, or under the discretion of
23 the staff and the agency. Which means it didn't fit any
24 of these and that's okay, but we think we wanted to report
25 it to do some due diligence here.

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1 But I think once you start getting into, you
2 know, subjective kind of things and the question becomes,
3 what's the adjudicating body for Three and Four, is that
4 a physician, is that a systems management person and how
5 do you really sort out that piece of the puzzle, you know,
6 those actually look more fuzzier to me than some of the
7 stuff we're talking about up above, actually.

8 So, I can see that point, but I'm not quite
9 sure how it plays in.

10 MS. McINTOSH: I would just like to remind
11 the Committee that we believe we've already actually seen
12 an example of III.A.3 or Four. And that would be the VA
13 Philly events.

14 If these new criteria were in place, they
15 wouldn't have captured the VA Philly events. But the fact
16 that there were numerous events is - makes it obvious that
17 there was some sort of programmatic breakdown.

18 And that's what this, you know, trending for
19 generic implications probably will not be that
20 complicated.

21 MR. EINBERG: And just - I'm sorry. And just
22 to add, you know, we have inspectors. The inspectors go
23 out and inspected the VA. And whenever there is a
24 significant event like this, then, you know, they bring
25 their results back and it gets a lot of discussion and

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1 management review here.

2 And if there is a determination made by NRC
3 staff that there has been significant program breakdown,
4 that's incumbent upon us to make that determination and
5 report to Congress.

6 MEMBER VAN DECKER: Discretion.

7 MR. EINBERG: Absolutely.

8 MEMBER VAN DECKER: But at the same time if
9 we looked at the top piece of this, we would say anything
10 that fits into this category. Whether we've put in a
11 radiation number, plus the clinical stuff, or clinical
12 stuff alone, the root cause of that is either going to
13 be human error or systems error or, you know.

14 So, it fits into the category. I mean, you
15 have to have a breakdown of where you came from. So, I
16 mean, this explains some of that other piece of it.

17 I'm not sure it adds other than, you know,
18 common sense root cause analysis stuff, but that's fine
19 because I understand the last piece is discretion. I got
20 that.

21 CHAIRMAN MALMUD: Dr. Thomadsen.

22 VICE CHAIRMAN THOMADSEN: I had some comments
23 on that. But, first, if you go back to Slide 5, please,
24 by inserting the green intended on the dose, that would
25 eliminate those medical events so as the target receives

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1 the correct dose, but other organs do not.

2 Such as if the prostate were to have gotten
3 its correct dose, but at the same time the rectum received
4 a dose higher than 150 percent of what was intended, the
5 dose other than the intended dose to the intended target
6 would not be triggered.

7 So, this whole thing would not - it could
8 never be an abnormal event. So, I don't think we want the
9 green test there.

10 And going back to III.A.3, I agree with Dr.
11 Van Decker here that how this would be used is a definite
12 problem.

13 Back in the days when there was the QMP rule
14 and we had a misadministration with no other violations,
15 we were cited as violating the QMP only because the - if
16 we had a misadministration, we therefore could not have
17 had a QMP that would have prevented the
18 misadministration. So, we were in violation.

19 And one could say if you had an abnormal
20 event, therefore you obviously fail in III.A.3 where you
21 could not possibly have had an abnormal event.

22 CHAIRMAN MALMUD: I have a question. I
23 thought that III.A.3 applies to situations that don't
24 necessarily involve patients at all. For example, having
25 a one curie technetium generator in a room which is

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1 unlocked. That would be a III.A.3, wouldn't it? A serious
2 safety-significant deficiency in management -

3 (Simultaneous speaking.)

4 CHAIRMAN MALMUD: Beg your pardon?

5 MS. McINTOSH: No, I don't believe so.

6 CHAIRMAN MALMUD: That wouldn't be covered
7 by this?

8 MS. McINTOSH: We have a process called the
9 agency action review meeting in which we look at
10 procedural issues at licensees facilities. Because even
11 though an individual event may not be significant, the
12 fact that there is a procedural issue, a repetitive
13 problem which could lead to a bigger issue is something
14 that the Agency has always been concerned about, has
15 always looked at.

16 So, it's not necessarily that a significant
17 error occurred. It's a precursor kind of - it's the
18 identification of a precursor to a possible significant
19 error. That's all this is looking at. It wouldn't - again,
20 going back to the - I keep using this example, but back
21 to the VA Philly example. I think most people would agree
22 that the individual cases there were not significant
23 relative to, you know, a very serious event at a medical
24 facility.

25 But the fact that there was one incident

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1 involving one specific physician, an incident involving
2 a specific physician which so many patients got the wrong
3 dose, is something that NRC would be interested in, is
4 something that we do believe Congress will be interested
5 in.

6 They would be interested to know that at
7 Hospital X in the year, you know, 2008 there were, you
8 know, 118 errors in this one procedure.

9 We believe that they would be interested in
10 knowing that. And that's all this kind - that's all these
11 criteria are intended to capture. It's programmatic
12 generic - programmatic things with generic information.

13 CHAIRMAN MALMUD: There already is a system
14 to capture the department that has a moly generator for
15 technetium production with a curie in it in a room with
16 no safety controls on the door so that anybody could walk
17 in.

18 Reading this, it seems to me that that is
19 included here. May be included elsewhere, but it's also
20 inclusive here.

21 Isn't that a serious safety-significant
22 deficiency in management or control?

23 MS. McINTOSH: I don't believe that one
24 incident of deficiency in management or procedural
25 control would be what we would capture to report to

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1 Congress necessarily.

2 MR. EINBERG: But it possibly could though.

3 CHAIRMAN MALMUD: It possibly could.

4 MR. EINBERG: Yeah.

5 CHAIRMAN MALMUD: Homeland Security would be
6 interested to have a curie sitting around unprotected.
7 All right. Just a question.

8 Dr. Thomadsen.

9 VICE CHAIRMAN THOMADSEN: Just a question
10 also in the title on Three, are those events at facilities
11 other than nuclear power plants and other than all
12 transportation events, or is it other than nuclear power
13 plants and now including all transportation events?

14 What are the limits on the other as far as
15 what is modifying we're referring to?

16 MS. McINTOSH: It's referring to events -

17 MR. EINBERG: The way I would read it, Dr.
18 Thomadsen, and we have somebody from research here also
19 who is responsible AO criteria and he can correct me if
20 I'm wrong, but the way I would read this is it's events
21 at all facilities other than nuclear power plants. And
22 then, also, all transportation events.

23 VICE CHAIRMAN THOMADSEN: I would suggest
24 clarifying that now.

25 MEMBER WELSH: Jim Welsh.

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1 To follow up on Dr. Thomadsen's point, I
2 would agree that perhaps clarifying that sentence is
3 worthwhile. But similarly as Bruce pointed out a few
4 minutes ago, my suggested wording perhaps needs to be
5 wordsmithed also so as to not cause confusion as Bruce
6 has pointed out, but also capture the spirit of what Ms.
7 Weil's point was that you could still overdose the
8 intended organ and have an abnormal occurrence.

9 So, I don't know how to wordsmith it other
10 than perhaps putting in "or" in there and having intended
11 dose - other than the intended dose to the intended
12 target, or a dose other than the dose to the intended
13 target.

14 CHAIRMAN MALMUD: May I try to bring the
15 question forward in the following fashion? The first one
16 to the Committee is does the Committee feel that it's
17 realistic to have a single standard applicable to both
18 nuclear medicine procedures and to radiation oncology
19 procedures?

20 Dr. Langhorst.

21 MEMBER LANGHORST: The criteria that NRC
22 staff is wanting to have put in place helps them to decide
23 this medical event really doesn't need any more medical
24 review by a physician because we know it wouldn't meet
25 these unintended or unexpected consequences.

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1 If we have something low enough that
2 triggers it to catch anything, I mean, to catch what Dr.
3 Welsh is talking about as far as the potential blindness,
4 I would suggest that maybe for the intended target that
5 doses greater than 50 percent more or something like that
6 as far as what was intended and it's greater than a
7 hundred rad to any other tissue. And that's a really
8 sensitive criteria that then you have a physician come
9 in and review for the red items of the
10 unintended/unexpected results.

11 It's always disappointing to me that we're
12 trying to save so much money and not having the NRC hire
13 a lot of physicians to do these reviews when we have a
14 lot of people who review things in a power plant
15 situation.

16 I mean, I think we should have a lot of
17 physicians looking at these particular events to see if
18 they are of significance to report to Congress.

19 So, I think you can have a very sensitive
20 number that may lead to a lot of physicians having to -
21 consultants having to review these things, but I think
22 that's what's needed and could be very simple and trigger
23 that additional review by a medical professional.

24 CHAIRMAN MALMUD: So, you believe that it
25 could be a single standard applicable to both nuclear

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1 medicine procedures and radiation oncology procedures?

2 MEMBER LANGHORST: Yes.

3 MEMBER MATTMULLER: Steve Mattmuller.

4 I'm really struggling with the direction of
5 our discussion today. Because as I remember past
6 discussions on this issue, using the blue criteria and
7 evaluating existing medical events and then taking them
8 to the level of an AO that goes to Congress, I thought
9 we had a pretty uniform agreement that these were too
10 sensitive.

11 That if you look back at some of the past
12 reports that go to Congress, there are really incidents
13 that don't need to go to Congress. And, hence, that's why
14 we try to come up with the unintended.

15 So, now I'm really struggling with now we're
16 saying it's still not sensitive enough. I mean, I thought
17 we were already in agreement that they were too
18 sensitive.

19 CHAIRMAN MALMUD: Well, that was my point,
20 Steve. You are correct. We were trying to eliminate
21 unnecessary reports to Congress which created issues
22 that really were trivial.

23 My question is, can we have such a sensitive
24 screening that is applicable to both radiation oncology
25 and nuclear medicine?

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1 They're two different techniques. And
2 within radiation oncology, there are a variety of
3 techniques.

4 When people in the field have to evaluate
5 these, they are not sophisticated - they are not
6 necessarily sophisticated Ph.D. physicists. And,
7 therefore, they will go by the book. And if the book says
8 X, they're going to do X even though it may be trivial.

9 So, the trick is to find the standards that
10 are a reasonable cutoff, and I'm questioning whether or
11 not such a standard could be applied across these various
12 disciplines. And that's the question I'm addressing and
13 that Dr. Langhorst wants to comment on again.

14 MEMBER LANGHORST: Thank you. So, really the
15 new criteria are the red listed bullets. That is the new
16 criteria to make that an adverse occurrence.

17 What was used in the past, the blue bullets,
18 NRC is asking, staff is asking this is what we want to
19 check to see do we need to bring a medical consultant on
20 board to then review the red bullets.

21 I think we need to have a low threshold for
22 that criteria on when to bring in a medical professional
23 to judge the red criteria that would be
24 unintended/unexpected permanent functional damage,
25 those criteria.

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1 And I am sensitive to the need to save money,
2 but I think it would be good to have medical professionals
3 judge these criteria and have a very sensitive trigger
4 point for staff to choose or to have exceeded to then
5 bring in that medical professional.

6 CHAIRMAN MALMUD: Mr. Einberg.

7 MR. EINBERG: Thank you, Dr. Langhorst.

8 And to your point and to Dr. Welsh's point
9 as far as that the criteria were too sensitive previously
10 and we were trying to fix that, part of the criteria if
11 you look - actually, can you bring up the blue criteria,
12 the third bullet there, greater than or equal to a
13 thousand rad to any other unintended organ, that
14 previously we've clarified that.

15 It previously stated to any organ. And that
16 was, you know, whenever you had a medical event because
17 of the therapeutic doses, you would automatically have
18 an AO. So, we put in "unintended organ" to clarify that
19 to raise the threshold there. However, as per this
20 discussion, that's had unintended consequences as well.

21 CHAIRMAN MALMUD: Dr. Welsh.

22 MEMBER WELSH: To answer your question, Dr.
23 Malmud, I personally think that we could come up with one
24 set of criteria that would be appropriate for both
25 nuclear medicine, diagnostic procedures and all forms of

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1 therapy if the nominal figures are adjusted
2 appropriately. They would have to be decreased to
3 capture everything, but I do think that it's possible.

4 I think the question, a big question,
5 big-picture question might be which is going to be an
6 easier task to come up with criteria for nuclear
7 medicine, diagnostic, HDR brachytherapy, permanent
8 implant brachytherapy, gamma knife, et cetera, et
9 cetera, versus the solution that's currently proposed in
10 addressing the numbers.

11 I personally think that we could use the
12 proposed suggestion up on the board now and adjust the
13 numbers far easier than the alternative of coming up with
14 criteria for all the different modalities.

15 And for that reason as well as the other I
16 have mentioned, I'm in favor of one set of criteria for
17 both nuclear medicine and therapy.

18 CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

19 MEMBER SULEIMAN: I think some systems
20 analyst somewhere is saying, gee, this would be so easy.
21 I think you need a systems approach to this.

22 This is a - you want a sensitive indicator.
23 So, let's say the medical event criteria is adequate, but
24 then you want to triage and pick up the really serious
25 ones.

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1 I don't think based on my own experience and
2 I can give you examples, unless you get exam-specific,
3 you're not going to be able to apply criteria across the
4 board.

5 And even if you try to somehow translate
6 that into a risk number, I wouldn't go there, I mean, to
7 sort of standardize or normalize, because risk varies for
8 individual.

9 If you've got cancer patients that all have
10 expected lifetimes of a year, their risk of harm versus
11 their risk of living is very different than a
12 four-year-old child. So, risk varies, but that's, I
13 think, what we're trying to drive here.

14 You're trying to come up with a dose number
15 that sort of says, this is serious, we need to report
16 this.

17 I think at triage, somehow you're using the
18 medical event criteria. And then at that point, a
19 decision has got to be made. I think experts in the
20 appropriate modality have to say, this is standard of
21 practice, this is normal, and whereas the same number may
22 be serious for another modality.

23 So, I'm uncomfortable with trying to make
24 it apply across the board to everything. I think you need
25 to segregate somehow by modality or source.

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1 CHAIRMAN MALMUD: Dr. Welsh.

2 MEMBER WELSH: Jim Welsh.

3 If I might reply to Dr. Suleiman's points,
4 yes, you are correct, but I think that the red bullet
5 points that have been added help clarify this. Because
6 when we say permanent functional damage or significant
7 unexpected adverse effect or death, I don't think that
8 you have to be a health professional to recognize such
9 severe consequences.

10 So, the numbers on the previous part of the
11 boolean and, I think, are irrelevant, but could we come
12 up with - we could come up with some numbers.

13 It's the important second component of this
14 boolean and, the red bulleted added points that are the
15 real meat of all this and permanent functional damage or
16 death satisfies those concerns. And I don't think that
17 you need to bring in medical experts for each and every
18 one of these things that is more than 250 rad to the
19 gonads, because they're not going to satisfy the other
20 criteria in the boolean and of death or unexpected
21 permanent functional damage.

22 So, I think that the added red bullet points
23 answer that concern.

24 CHAIRMAN MALMUD: So, Dr. Welsh, you're in
25 favor of the current proposal with the exception of the

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1 doses that are stated?

2 MEMBER WELSH: Yes, those nominal figures
3 are inappropriate.

4 CHAIRMAN MALMUD: Dr. Guiberteau.

5 MEMBER GUIBERTEAU: You know, I think there
6 are two things in the screening that we deal with in
7 diagnostic radiology. And one is the sensitivity of the
8 study, but the other major area is the appropriateness
9 of the screening criteria.

10 I think we go to great pains in the NRC and
11 the ACMUI to address our stakeholders based on the
12 modalities that they deal - that they use.

13 The medical event criteria as the initial
14 screening criteria, apply to everyone. So, it's very
15 general.

16 I think we owe it to our stakeholders and
17 I think we need these screening criterias because unlike
18 Jim I think once it gets to these medical issues that only
19 a physician is qualified to deem whether they are
20 significant or not, that puts that clearly where it
21 belongs in the practice of medicine.

22 In the interim screening criteria between
23 medical events and abnormal events based on dose if they
24 are category-specific, would basically put this - put
25 that part of it back where it belongs in the NRC. So, it

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1 would tie these two together and I'm very uncomfortable
2 trying to get not only medical event as generic criteria,
3 and then we're trying to parse it out by another set of
4 general criteria.

5 I think what will happen is that in nuclear
6 medicine, some things will, you know, we're going to have
7 to have them pretty low to catch some of our things. And
8 the same is true with radiation oncology.

9 And what I don't want to deal with is, for
10 instance, in my case, the nuclear radiology, you know,
11 stakeholders saying, well, you know, all of these things
12 are being captured because we have one set of criteria.
13 And it's, you know, it's too low for really - it's
14 capturing a lot of things we don't need.

15 So, I mean, I do understand it would be nice
16 to do that, but I think the process here is winnowing out.
17 And in order to winnow out, we go from the general
18 criteria of a medical event and parse this out based on
19 the secondary criteria, and then get to the medical
20 issues. To me, that makes perfect sense.

21 MS. McINTOSH: Dr. Malmud.

22 CHAIRMAN MALMUD: Thank you, Ms. McIntosh.

23 MS. McINTOSH: I appreciate that comment,
24 Dr. Guiberteau. And I realize that this committee is here
25 to help us, you know, with regard to identifying what is

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1 - or that the medical aspect of it is your - is primarily
2 what will always be your focus.

3 But I do want to also reiterate along with
4 Dr. Guiberteau's comment, that we are in an environment
5 where we're trying to be open as possible, because we are
6 told we have to be. And part of that openness is reporting
7 things as promptly as we possibly can and in a timely,
8 you know, in a timely manner.

9 So, from the staff's perspective, it would
10 be helpful for us to have some common sense kind of
11 criteria that will help us to relatively quickly identify
12 things for screening so that they are promptly reported
13 to Congress, you know, unless the NRC is accused of, you
14 know, withholding information and that sort of thing.

15 And also we recognize that we are not
16 physicians and we don't want to be put in a position where
17 the criteria are so general that we're sort of making
18 these medical judgments.

19 We would prefer that, you know, things be
20 parsed out for us enough that just with our HP and
21 engineering backgrounds we can decipher that event
22 enough to say it makes sense for this event to be sent
23 to a consultant. And we get that done in, like I was
24 saying, a timely manner to satisfy our stakeholders'
25 concerns of being informed promptly of things.

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1 So, I'm just throwing out for consideration
2 as well.

3 CHAIRMAN MALMUD: Thank you. We understand
4 the goal. We're trying to assist you in achieving it, and
5 obviously we have differing opinions within the
6 Committee at the moment.

7 Dr. Langhorst.

8 MEMBER LANGHORST: I wanted to ask a question
9 of you. So, you feel with this openness, that you really
10 do need to have your screening criteria as part of this
11 whole description and how NRC staff decides to go seek
12 medical professional opinion; is that correct?

13 MS. McINTOSH: We believe it's an approach
14 to helping us to meet that goal.

15 MEMBER LANGHORST: And it needs to be part
16 of this definition and not part of this is the screening
17 we do.

18 MS. McINTOSH: Well, no. I guess what I'm -
19 the point that I was trying to make with the openness
20 comment is that NRC is not perceived as unduly
21 withholding information just because it's taken us so
22 long to get these events reported to Congress.

23 I mean, we do have a time frame to get them,
24 you know, an event that happens this year, maybe it kind
25 of looks odd if it's not reported to Congress until three

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1 years later because we had to always hire a medical
2 consultant.

3 I just throw that out for consideration.

4 MEMBER LANGHORST: And so, I'm still not
5 clear. Does it need to be part of the AO definition, or
6 can it be these are the criteria that NRC staff have
7 established to then seek medical - a medical consultant
8 to judge the red bulleted items that are the definition
9 for an adverse occurrence?

10 MR. EINBERG: To answer your question, Dr.
11 Langhorst, I'm not sure whether it will need to be out
12 in the open or if this is more of a procedural issue that
13 we use to get a medical consultant to further that
14 threshold.

15 My personal belief is that I'd rather have
16 more things out in the open than, you know, have it
17 transparent and we have people comment on it. But having
18 said that, I'm not sure whether, you know, it's a
19 requirement or not.

20 MEMBER LANGHORST: Okay. Well, I guess my
21 point is, is, I mean, it still can be out in the open.
22 It sounds like this definition is difficult to change
23 because of all the logistics of doing what you've
24 described in your next steps. And it's kind of tied to
25 all adverse occurrences.

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1 You have to time it with the reactor adverse
2 occurrences when you make those changes. Am I correct in
3 that?

4 MR. EINBERG: The abnormal occurrence of
5 definitions or the policies, yeah, there's a paper. It's
6 for the entire agency where -

7 MEMBER LANGHORST: Okay. So, I might suggest
8 that NRC can still remain open by having its guidance on
9 its criteria that they know needs more medical review on
10 judging the red bulleted items, that then gives you some
11 flexibility of adjusting those criteria as you learn more
12 going through what is a true abnormal occurrence or what
13 is a significant abnormal occurrence. And that might be
14 easier to change going forward rather than being part of
15 the actual definition of adverse occurrence.

16 CHAIRMAN MALMUD: You wish to comment on
17 that, Mr. Einberg?

18 MR. EINBERG: I think that's certainly an
19 approach. I would have to explore it with our different
20 offices and our Office of General Counsel to see whether
21 that's achievable or not.

22 The one thought I do have in those regards
23 is that, you know, the NRC would have their screening
24 criteria, but then each Agreement State would have to
25 have a separate screening criteria or they would have

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1 their own screening criteria. Which, you know, there
2 could be all these different screening criteria out
3 there, and so that's - from a practical standpoint, it
4 would be better to have one and have that all discussed.

5 CHAIRMAN MALMUD: Ms. Bailey.

6 MEMBER BAILEY: I may be confused, but I
7 think when we get to abnormal occurrences there is the
8 report to Congress; NRC has that role with the states.
9 I mean, we've entered our medical events and, yes, we're
10 going to communicate, well, here's what happened and we
11 may come to the decision, it would be NRC's criteria that
12 develop the report to Congress.

13 MR. EINBERG: Well, if -

14 MEMBER BAILEY: - it went into the report to
15 Congress.

16 MR. EINBERG: The criteria that is being
17 proposed now is just to have the criteria that's in the
18 red then.

19 MEMBER BAILEY: Right.

20 MR. EINBERG: But as far as making that
21 determination, then I guess we're discussing whose role
22 would it be to make that determination whether it's
23 significant or, yeah.

24 MEMBER BAILEY: And I think routinely we
25 would all work - we and NRC would come together. Because

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1 routinely, NRC has come into our space at that point and
2 go on and why do you think this is not an abnormal
3 occurrence or why do you think it is.

4 So, I don't know that we would necessarily
5 have different screening criteria.

6 MR. EINBERG: Okay.

7 MEMBER BAILEY: I believe you would have a
8 role and say, yeah.

9 MR. EINBERG: Okay.

10 MEMBER BAILEY: I think, at that point.

11 MR. EINBERG: Okay. Thank you, Ms. Bailey.

12 CHAIRMAN MALMUD: Another issue which hasn't
13 been discussed is that - it's been alluded to is that our
14 responsibility to our stakeholders, including the
15 providers of these services, the requirement for a
16 physician or physicist to review a case will create
17 anxiety within the department that's being looked at.

18 And if the criteria are too sensitive,
19 that's going to create an atmosphere in which there may
20 be given human behavior, a desire not to reveal events.

21 Once again I come back to the issue which
22 I won't give up on mentioning, although I may be defeated
23 on it in the Committee, and that is I don't believe that
24 these criteria are uniformly applicable across the
25 various specialties in radiology in the use of

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1 radioactive material.

2 And to make them too sensitive so that they
3 are fair to one specialty and unfair to another is a
4 mistake. Whereas if they are defined in a handbook and
5 guidance to our people out in the field, they'll know what
6 to do.

7 When I was in the military, they used to say
8 the best training manuals were written by geniuses for
9 the Navy to be used by less than geniuses. And I would
10 make an analogy here in that it's the responsibility of
11 NRC and this committee in its consulting role, to devise
12 the best criterion possible so that they can be applied
13 by people who are not as highly trained as members of this
14 committee are.

15 And we miss that point when we assume that
16 they're going to have the same ability to make a wise
17 decision as some of you, and that they have the ability
18 to do that. They need guidelines.

19 I don't see a uniform guideline. Dr. Welsh
20 does, and he and I differ on this point, because he comes
21 from one specialty, and I from another.

22 Dr. Welsh.

23 MEMBER WELSH: Jim Welsh.

24 If I might respond to continue the debate
25 with your perspective and with Dr. Guiberteau's, I would

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1 go back to the question that you raised earlier about how
2 often does a diagnostic nuclear medicine procedure ever
3 get elevated to the point of abnormal occurrence.

4 And I think I heard earlier the answer is
5 screen the rarely, if not zero, and that might be in part
6 because of those new red bulleted items such as death and
7 permanent damage.

8 And if I'm correct in this interpretation,
9 it doesn't matter what the previous component of that
10 boolean and is. Those numbers could be anything. It
11 doesn't matter if they were - the numbers were zero,
12 because if you don't get death and unintended permanent
13 damage from a diagnostic procedure, you will never have
14 inappropriately low or an unduly sensitive definition
15 for abnormal occurrence that would adversely affect the
16 nuclear medicine diagnostic community.

17 CHAIRMAN MALMUD: I accept your point.

18 Dr. Suleiman.

19 MEMBER SULEIMAN: Really, I don't want to say
20 what I'm going to say, but I will, okay.

21 (Laughter.)

22 MEMBER SULEIMAN: I don't want to introduce
23 risk. I told everybody we shouldn't be discussing it. But
24 if you administer a diagnostic dose that's a thousand
25 times what they should have got, you may not see

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1 short-term deterministic harm, but you've clearly
2 increased the risk of that individual.

3 How do you weigh that? I mean, I'm asking
4 you. So, is that any less important than maybe giving an
5 extra several gray to a therapy patient?

6 So, I wouldn't - the problem is we consider
7 diagnostics so safe that the community sometimes gets
8 pretty flippant and sloppy about how they use diagnostic
9 procedures. I mean, that's my perspective.

10 The community they are diagnostic, we don't
11 worry about that, but we've seen at least with
12 machine-produced equipment where you actually get skin
13 burns or necrosis and you get hair loss. And so, it's
14 capable.

15 So, sorry, Dr. Malmud, I agree with you a
16 hundred percent. You have all these guidelines for
17 different diseases and you look at it and you find out
18 what the state of the practice is, and medicine is fuzzy.

19 So, what's pretty precise and limiting in
20 one area and I'm going to use external radiation therapy,
21 may be completely inappropriate for some of the other
22 things.

23 So, trying to have one size fits all, one
24 number fits all, is why we're dealing with this thing
25 right now.

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1 I think you need a triage. I don't think you
2 need medical analysis earlier on. I think the final
3 analysis will be when you've got this very specific
4 procedure and the hospital as the institutions, the site
5 should be evaluating these errors or mistakes on a case
6 by case.

7 But the purpose of the NRC just like the
8 purpose of the FDA is, are we seeing a trend here? Is this
9 broader than just this isolated incident? Should we do
10 something?

11 I mean, aside from reporting to Congress
12 whatever, you know, all statutes have that requirement.
13 So, when I first started government I said, wow. Then I
14 find out that every statute says you have to let us know
15 what's going on, but I think clearly you can't just be
16 collecting information and not passing it on.

17 But at some point you may not need expensive
18 review early on, but only if it's simple so you can do
19 the analysis. But as I said, I look at this thing and I
20 get confused. How am I going to interpret this? How am
21 I going to apply it?

22 But if it was different modalities, you
23 could probably come up with some pretty simple numbers
24 that you could have cutoffs for.

25 And then finally the physicians will weight

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1 in and say this is appropriate or this is not appropriate.

2 CHAIRMAN MALMUD: Thank you. Dr. Langhorst.

3 MEMBER LANGHORST: I think you can have one
4 criteria for all if it has to be part of this formal
5 definition that can only be changed every so often.

6 I'm uncomfortable with trying to do
7 specific therapy numbers in a definition that can't
8 change often.

9 So, really, adverse occurrence are the red
10 bulleted items. And I think that if NRC needs some
11 criteria on who, when to bring in that medical
12 professional, I think that should be as you've been
13 calling it, Dr. Malmud, guidance. It shouldn't be part
14 of this definition.

15 But if we have to have criteria to be part
16 of this definition, I think we want a very sensitive one,
17 very simple one that then brings in the medical
18 professional to decide the red bulleted items.

19 CHAIRMAN MALMUD: Thank you. Dr. Welsh.

20 MEMBER WELSH: Jim Welsh.

21 If I might respond to Dr. Suleiman's point,
22 I think that even if we try to come up with separate
23 criteria for each one of the modalities or diagnostic
24 procedures, we're still going to wind up pretty much
25 where we are now, but maybe with different numbers.

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1 Because I think Orhan's point was maybe
2 stochastic events from a nuclear medicine procedure in
3 which the dose was via the administered activity, was a
4 thousand times off, could result in an adverse health
5 effect such as a stochastic rather than these
6 deterministic effects that we're classically thinking
7 of.

8 However, bullet point Number 3 is
9 significant unexpected adverse health effect, which I
10 believe would include any of these stochastic events
11 also.

12 So, there is inherently going to be some
13 medical judgment in this whole process of abnormal
14 occurrence definition, but I don't believe that the extra
15 - and I think significant extra effort of trying to come
16 up with different categories for each one of the
17 different modalities is an exercise that's really
18 worthwhile in the long run because we're going to come
19 up with the same solution in the end, I think, for
20 everything.

21 CHAIRMAN MALMUD: Thank you. I also thought
22 that Dr. Langhorst's point that these numbers will change
23 with time as new procedures are introduced and,
24 therefore, these numbers will need to be reevaluated
25 periodically is a very valid one.

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1 And we'll need to back off of my point based
2 upon the argument presented by Dr. Langhorst and the -
3 your willingness to apply the current criteria to
4 radiation oncology procedures.

5 Mr. Einberg.

6 MR. EINBERG: One possibility, if I may
7 suggest, is to have a subcommittee formed to decide what
8 those numbers should be. And then we'll take the action
9 from our standpoint to determine whether we can point,
10 you know, use that screening criteria from an
11 administrator's standpoint or whether it has to be in a
12 more formal abnormal occurrence process.

13 We'll still need some kind of screening for
14 everything - we're still - I think what I'm hearing is
15 we're going in the direction that we need some kind of
16 screening criteria whether it be modality specific or
17 not. But perhaps a subcommittee could hash that and then
18 provide something to the NRC staff.

19 And then we'll take that and either put it
20 into the formal abnormal occurrence process, or we'll put
21 it into some kind of a handbook or into one of our
22 administrative procedures for using that to screen
23 whether we get a medical consultant or not.

24 CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

25 MEMBER SULEIMAN: Let me ask a question that

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1 we, both agencies, have dealt with the last year. But when
2 a patient gets a radiopharmaceutical and the amount of
3 activity that they've received, the dose that they've
4 received may be 40 or 50 times that which they were
5 supposed to receive, and in some cases some of these
6 patients, this is number of patients are subject - there
7 are some issues there whether it's with the user or
8 manufacturing or both, but some of them, in fact, may have
9 received more than, you know, five millisieverts, five
10 rads or higher, because the dose estimates by experts say
11 we could be off by two or three in either direction. So,
12 they could be getting much more than five or 10 rads or
13 lower.

14 Would that qualify as an abnormal
15 occurrence, or is that just a product mislabeling - is
16 that serious enough to -

17 CHAIRMAN MALMUD: To whom is your question
18 addressed?

19 MEMBER SULEIMAN: Anybody. To NRC.

20 MR. EINBERG: That's under the existing
21 abnormal occurrence, or the new proposed AO criteria?

22 MEMBER SULEIMAN: Both. Would it fall under
23 one, and not the other?

24 MS. McINTOSH: Under the current criteria if
25 it's not one of these listed organs, bone marrow, gonads,

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1 so on and so forth, it has to be at least a thousand above
2 what was prescribed.

3 If it's one of those targets, it has to be
4 what the target specifies there, a hundred rad to the bone
5 marrow or lens of the eye or 250 to the gonads.

6 Under the new criteria, it wouldn't - it
7 would have to be unintended permanent functional damage
8 would have one of those unintended statements or
9 significant adverse health effect things would have to
10 have occurred.

11 MS. HENDERSON: Under either of the criteria
12 it would not be an AO, because it's not triggering the
13 doses.

14 CHAIRMAN MALMUD: Okay, thank you. I think
15 Dr. Welsh had his hand up next.

16 MEMBER WELSH: And my point is that, yes,
17 that that's correct. It would not be an abnormal
18 occurrence, and it should not be.

19 Because in my understanding, the abnormal
20 occurrence is way at the top of the list as the worst
21 possible scenario, and this does not qualify for that.
22 And I don't think too many diagnostic procedures ever are
23 elevated to that severity that they would or should meet
24 any existing or proposed definition.

25 MS. HENDERSON: I mean, that doesn't mean we

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1 wouldn't capture it under medical event and that there
2 could be a big programmatic problem that caused the
3 medical event. So, it would still be looked at.

4 MEMBER SULEIMAN: I mean, that's sort of how
5 it's played out.

6 MS. HENDERSON: Yes, yes, uh-huh.

7 CHAIRMAN MALMUD: Mr. Mattmuller.

8 MEMBER MATTMULLER: This would be to the
9 staff. Was it your intention with retaining the blue
10 criteria, that that would be the trigger point as to when
11 you would have a physician review the case to see if then
12 the red points apply?

13 MR. EINBERG: That's correct.

14 MEMBER MATTMULLER: Okay.

15 CHAIRMAN MALMUD: Thank you. Now, is the
16 Committee prepared to vote on this document as amended
17 at the current time?

18 Ms. Weil.

19 MEMBER WEIL: In the interest of
20 wordsmithing, I would just like to suggest that
21 unintended and unexpected might be better unintended or
22 unexpected.

23 Dr. Welsh, is that what you were after when
24 you suggested that? Does it need to -

25 MEMBER WELSH: Yes, yes.

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1 MEMBER WEIL: Okay. So, it should be an "or".
2 Okay.

3 And then if we could go back one to the first
4 statement, a medical event that results in - this is back
5 in my original point. Could we say an unintended dose to
6 the intended target - that's ugly - or then the phrase
7 that is there, a dose other than the dose to the intended
8 target that is.

9 That's not particularly elegant, but I
10 think it needs to be an "or". I think we need to have one
11 statement that refers to the intended target, and one
12 statement that refers to unintended target.

13 CHAIRMAN MALMUD: Dr. Thomadsen.

14 VICE CHAIRMAN THOMADSEN: I'm still unclear
15 as to why.

16 MEMBER WEIL: Because you think it's a
17 medical event and - it just seems to me that this language
18 is so exclusive of intended targets that it is
19 misleading.

20 VICE CHAIRMAN THOMADSEN: Yes, but why do we
21 care if the target gets more dose? We had a medical event
22 with Zevalin where the patient received - I think it was
23 50 percent more dose than they should have, according to
24 the description. Actually, the disease disappeared. They
25 had no other problems to any other organs in their body,

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1 because the doses would not have triggered any of that.
2 But that would have been an abnormal event, but actually
3 was a beneficial event.

4 Why do we care?

5 CHAIRMAN MALMUD: Dr. Welsh.

6 MEMBER WELSH: I'm going to contradict
7 myself because thanks to your question or comment I've
8 come up with the example in nuclear medicine diagnostics
9 where you can have possibly an abnormal occurrence. And
10 that is diagnostic procedure for thyroid cancer, in which
11 case you would want to diagnose - make a - with thyroid
12 disease. A diagnostic procedure for thyroid disease in
13 which the dose was so off that you ablated the entire
14 thyroid inadvertently.

15 And for that reason, I think that Ms. Weil's
16 point is important that it can be the intended target.
17 But if the intended dose is way, way off, you can have
18 an abnormal occurrence.

19 That's why as inelegant or ugly as that
20 wording is, it's to the point that I think that it's worth
21 rewording it.

22 CHAIRMAN MALMUD: Except that one of the
23 risks of I-131 therapy to the thyroid is ablation.
24 Unintentional ablation is a risk, because the thyroid has
25 variable radiosensitivity.

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1 So, even though the dose may be very
2 carefully calculated, in a particular patient it may
3 result in ablation.

4 Dr. Welsh.

5 MEMBER WELSH: If the isotope was I-123 for
6 diagnostic procedure and the isotope was I-131 and it was
7 the incorrect activity, you could have -

8 CHAIRMAN MALMUD: That's clearly a
9 misadministration. It's the wrong radiopharmaceutical.

10 MEMBER WELSH: It's a medical event
11 misadministration and it would perhaps fall into this
12 category.

13 CHAIRMAN MALMUD: Yeah, I agree. Dr.
14 Suleiman.

15 MEMBER SULEIMAN: All right. I remember a
16 couple of years ago at a Society of Nuclear Medicine
17 meeting where one of the physicians gave a talk. And the
18 first thing he says, I don't want to disappoint you all,
19 but we give every patient 150 millicuries per thyroid
20 ablation. End of discussion.

21 And so, ever since then I sort of ask my
22 nuclear medicine colleagues, what do you use? Some do the
23 dosimetry, and some don't.

24 That tells me that the practice of medicine,
25 of therapeutic, there may be some that are doing it one

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1 way, and there may be others that are doing it another
2 way, but I think that's still being sorted out among the
3 medical community. So, it's medical practice until the
4 professionals all decide you should be doing it, you
5 know, this way.

6 Which gets back to the fuzzy standards.
7 What's acceptable for one group? I mean, at some point
8 you have to kick it over to the medical community and say,
9 this is standard of care, this is standard of practice.
10 And so, we're going to have this fuzzy line as to what's
11 appropriate or not.

12 With the therapeutic I think especially
13 with the particulates maybe if you overdose, there's
14 nothing wrong with it. So, you give it up, so, as long
15 as you're making sure you're not falling below that
16 threshold.

17 There are just so many complex issues that
18 one number - and then you've got the uncertainty, you
19 know. You have one person say, well, we've exceeded the
20 limit, and some other person will say, no, it's up by a
21 factor of two.

22 FEMALE PARTICIPANT: See if this works.

23 CHAIRMAN MALMUD: Ms. Weil.

24 MEMBER WEIL: To the point that was made
25 earlier that thyroids are radiosensitive in different

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1 ways, an unintended dose to the target, not the intended
2 dose that behaved peculiarly, but an unintended dose to
3 the target, or take out the - actually the green intended.

4 So, it's just adding that small phrase to
5 the beginning, which then would be inclusive of
6 unintended doses to the target organ, not eliminating
7 them and saying only doses that are other than the
8 intended target.

9 Does that make sense?

10 CHAIRMAN MALMUD: Dr. Thomadsen.

11 VICE CHAIRMAN THOMADSEN: Well, according to
12 that, then, all medical events in which there is an
13 unintended dose to the target, that is the target
14 receiving more than 20 percent, would be an abnormal
15 event.

16 MEMBER WEIL: Only if it met the other red
17 criteria at the bottom.

18 VICE CHAIRMAN THOMADSEN: That doesn't seem
19 to be what that was saying.

20 (Discussion off the record.)

21 MS. McINTOSH: We do intend that the
22 unintended permanent functional damage, one of those
23 statements, also be met.

24 VICE CHAIRMAN THOMADSEN: In that case, the
25 or after the target maybe should be an "and".

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1 (Simultaneous speaking.)

2 VICE CHAIRMAN THOMADSEN: Right.

3 MS. McINTOSH: This was screened for us, and
4 then we would look at this.

5 VICE CHAIRMAN THOMADSEN: Yeah, and I'm not
6 sure that that's actually capturing that.

7 CHAIRMAN MALMUD: Ms. Henderson.

8 MS. HENDERSON: May I suggest that this
9 really does need to be addressed by a subcommittee. That
10 we're doing a workshop here and wordsmithing and that we
11 really need to take the time to look at this very closely
12 and it's not going to happen in the time frame we have
13 today.

14 CHAIRMAN MALMUD: I think most of us agree
15 that there's clearly a lack of consensus here with regard
16 to the current document. We understand the goal, but we
17 haven't achieved it yet and it should go back to a
18 subcommittee.

19 I motion for further clarification and then
20 representation to this. Do we all agree that we can do
21 that? There is agreement. Thank you for the
22 recommendation.

23 And, Angela, than you for putting together
24 a very difficult document, but a very sound one in terms
25 of where we need to go from here. Thank you.

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1 MS. McINTOSH: Thank you, Dr. Malmud.

2 CHAIRMAN MALMUD: Mr. Einberg.

3 MR. EINBERG: I assume that you'll form a
4 subcommittee at this point then?

5 CHAIRMAN MALMUD: Yes. Does anyone wish to
6 volunteer to chair this subcommittee?

7 (No response.)

8 (Laughter.)

9 CHAIRMAN MALMUD: I think Dr. Langhorst, Dr.
10 Welsh and Dr. Thomadsen have demonstrated intense
11 interest in this, as has Dr. Suleiman. But I'm standing
12 on the left side of the table, and Dr. Palestro's silence
13 has been deafening.

14 (Laughter.)

15 CHAIRMAN MALMUD: And I know that you have
16 something to say.

17 MEMBER PALESTRO: I'll be happy to work on
18 the subcommittee.

19 CHAIRMAN MALMUD: Thank you. And Ms. Weil.
20 Okay. So, that's the committee. Dr. Langhorst is the
21 chair, Ms. Weil, Dr. Palestro, Dr. Thomadsen. And then
22 on this side of the table we have with Dr. Langhorst, we
23 have Dr. Welsh.

24 MR. EINBERG: Dr. Malmud, I'd like to also
25 offer an NRC staff resource to the committee, and that

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1 would be Angela.

2 CHAIRMAN MALMUD: Thank you.

3 MR. EINBERG: I think that is - in previous
4 subcommittees, that's been very useful to have a staff
5 resource who can answer questions on various aspects.

6 I would also perhaps recommend that Ms.
7 Bailey be considered for the subcommittee, because it
8 does have implications for the states.

9 CHAIRMAN MALMUD: All right, thank you. Oh,
10 Dr. Langhorst.

11 MEMBER LANGHORST: I would ask one more
12 thing. I would definitely ask the NRC staff to give the
13 subcommittee their conclusion on whether criteria needs
14 to be part of the definition, or whether it can be removed
15 from that and obviously publicly shared, but not be part
16 of the definition of adverse occurrence. That would be
17 greatly helpful to our subcommittee.

18 MR. EINBERG: Okay, absolutely we'll do
19 that. And then also, Ashley, if you could send Dr.
20 Langhorst the wordsmith edits as a starting point, you
21 know, we've done some work on those and that might be a
22 good place to start with.

23 CHAIRMAN MALMUD: And with that, we will take
24 a break. Can we get back at 10:30? Thank you.

25 (Whereupon, the above-entitled matter went

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1 off the record at 10:12 a.m. and resumed at 10:31 a.m.)

2 CHAIRMAN MALMUD: We'll begin with a
3 presentation by Mr. Cool, "Reducing Occupational Dose
4 Limits." And he will discuss the potential changes to 10
5 CFR Parts 20 and 50. Thank you - excuse me, I stand
6 corrected. Dr. Cool.

7 DR. COOL: Good morning, ladies and
8 gentlemen. It's good to be back and see a number of you
9 that I have known for many years and appreciated the
10 relationship.

11 It turns out that the last time we talked
12 about this subject was actually October of 2010. So, it's
13 been a little while.

14 So, what I intend to do today is to give you
15 just a very quick, full update for those who haven't
16 touched this subject of late, and then to review the
17 information that is in the staff's SECY paper.

18 So, by way of background, the NRC
19 regulations for radiation protection derive their bases
20 from national and international recommendations, use as
21 points of reference for its international standards, use
22 both national and international analyses of health
23 effects, radiation risks, as well as reflect an ongoing
24 coordination with various federal and the state
25 agencies.

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1 The last time 10 CFR Part 20, which is
2 referred to as "Part 20" most of the time, was
3 significantly revised was 1991. That was the culmination
4 of a 12-year process of revision, substantial revision,
5 and actually had its basis in the then new ICRP
6 recommendations, Publication 26 from 1977.

7 Other portions of the regulations which
8 were not cross-references as in they contained their own
9 explicit dose criteria or references, were not updated
10 at that time. So, in fact, part of the issue that we have
11 is that you have within the NRC regulation guidance
12 structure three new generations of recommendations and
13 scientific information going all the way back to 1958 and
14 '59.

15 ICRP completed their latest revision update
16 of their recommendations in December of 2007. ICRP
17 Publication 103.

18 The staff as we had committed to our
19 commission did an analysis, which we presented to them
20 in December of 2008 indicating that there were some areas
21 that certainly warranted an examination for possible
22 updates.

23 The Commission approved us going off and
24 beginning to engage the stakeholders and initiating for
25 development of technical basis information in April

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1 2009. We have been busy doing that since that point.

2 A set of recommendations in a staff paper
3 was provided to the Commission on April 25th of this year,
4 and that's what I will be reviewing for you.

5 Over the last three years we have done a lot
6 of different things to try and reach out to various
7 stakeholder organizations. We've had interactions with
8 this committee on at least three occasions, with the
9 Advisory Committee on Reactor Safeguards, with a wide
10 variety of organizations, professional societies,
11 groups and otherwise the organization of agreement
12 states, conference of radiation control program
13 directors.

14 Federal Register Notices put out there. We
15 all know that everyone reads the FR, but that's the way
16 in which we can actually formally develop a docket and
17 keep track of all the things for nice, legal purposes.

18 We ran a series of three more formal
19 facilitated roundtable workshops where if you take this
20 table and make it about three times as large, you put 30
21 something people around it representing every kind of
22 licensed use that we have, plus some other stakeholders
23 and get them all to talk about this subject, you have sort
24 of a rough idea of what those two to three days worth of
25 activities were. They were quite enlightening.

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1 The workshop in Los Angeles was
2 specifically aimed towards medical uses. More than half
3 the participants were from the wide variety of different
4 medial uses. Several of you here participated in those
5 workshops.

6 In addition to that, there was a called
7 third phase after the ICRP put out a separate new
8 recommendation related to protection for lens of the eye,
9 which was last year.

10 We had a total of 59 formal comments on the
11 docket. From the 500,000-foot level there was general
12 support for the idea of doing some updates, updating
13 methodologies and terminologies.

14 There was also equally a generalized view
15 that we should just say "no" to changes to the actual
16 regulations, dose limits, ALARA, those sorts of things.
17 A view, unfortunately, not substantiated by detailed
18 discussions despite our attempts to elicit them with
19 regards to the risks, generalized statements that the
20 impact would be unacceptable that you would no longer be
21 able to practice medicine, you'd no longer be able to do
22 industrial radiography, et cetera, and the number of
23 times where there was a view expressed that the kinds of
24 sources that are used in the United States as in typically
25 somewhat higher activities than that used in Europe,

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1 meant that we should have different dose limits
2 applicable to us. That's a view.

3 So, to briefly review where some of the
4 pieces are, radiation risk. The current basis for the
5 regulations, as I said, is a mixture from 1958 to 1990.
6 Part 20 itself in basis, is based on what was known in
7 the late 1970s as in one times 10 to the minus four per
8 rem cancer mortality and risk of heritable disease.

9 Now, that's not the number that we are all
10 familiarity with. Because by the time the rule was
11 finalized in 1991, there had been updates to the
12 dosimetry in Hiroshima/Nagasaki, there were
13 considerable additional follow-ups with that cohort and
14 other cohorts and the general presumptive risk for
15 radiation was more like five times to the minus four per
16 rem.

17 In addition, there was a broadening
18 consideration of not just cancer mortality, but
19 morbidity, years of life lost and other things as they
20 looked at the risk. And that's all discussed in a moment
21 in the methodology.

22 The most recent analysis is actually from
23 EPA, EPA's radiogenic cancer risk models and projections
24 for the US population, which was published in April of
25 2011. Their value for incidence, 1.2 time 10 to the minus

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1 three per rem of radiation. Cancer mortality, 5.8 times
2 10 to the minus four with the range on that latter number
3 being 2.8 times 10 to the minus four to one times 10 to
4 the minus three.

5 And so, while if you look at the risk
6 estimates and you look at the ranges of risk that are
7 associated with each of those, those uncertainty bands
8 clearly overlap. In fact, the current uncertainty band
9 does not include the central estimate of the previous
10 band.

11 Methodological basis, again, we have a wide
12 variety of things. You've got some parts such as Part 50,
13 Appendix I, which is the ALARA effluent for reactors,
14 some of the things related to sources in Part 30 and other
15 things, which go all the way back to '58 and '59, critical
16 organ concept, a system which did not allow the summation
17 for internal and external exposures.

18 Part 20 generally based on Publication 26
19 and 30, total effect of dose equivalent approach, some
20 also now use the ICRP 60 methodology. The Commission has
21 by specific license amendment, authorized the licensee
22 to use the new set of methodologies that came out in the
23 early '90s for a licensee so long as they use that entire
24 set. And so, they couldn't cherry pick new and old
25 numbers, whichever they thought would be more

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1 advantageous for them.

2 The public exposure limits in Part 20
3 actually reflect the new risk estimates, because the
4 proposals at the time that rule was a proposed rule
5 included within the range of options, the current
6 recommendation for a public dose limit of 100 millirem
7 a year.

8 The occupational numbers do not, because
9 the proposals that were out at that time did not include
10 the recommendations for lowering the occupational dose
11 limit in light of the revised radiation risks. And there
12 was nothing upon which we could base a change.

13 The staff, in fact, in the statement of
14 considerations noted the publication, the ICRP
15 recommendations, and noted that at that time that the
16 change was not substantial enough to warrant stopping the
17 presses, those aren't actually the words used, but that's
18 an easier way to express it, because of the significant
19 changes and reductions that were already being made and
20 the importance of getting that out and getting it
21 implemented and would be revisited later.

22 So, in addition to that, something which
23 actually becomes fairly important in some of the medical
24 modalities at the time in 1991 that the rule was
25 published, the external dose was measured by the mean

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1 dose equivalent as in the badge at the point of highest
2 exposure on the body.

3 The modeling in approaches and
4 considerations have of course continued to improve. And
5 the NRC regulation today now recognizes effective dose
6 from external exposure allowing for several different
7 standard methodologies for calculating an effective dose
8 from one or more badges when there is known geometries
9 shielding to the body such as the leaded aprons in
10 interventional radiology and cardiology, which
11 substantially reduces the effective dose on an
12 individual vis-a-vis that which would be the badge on the
13 collar up above the lead apron.

14 The basis for the occupational dose limits
15 in 1977 wanted to have protection be roughly equivalent
16 to that which was generally accepted for a safe working
17 environment. Roughly, 1.3 to the minus four risk.

18 That risk actually corresponded not to the
19 limit selected, but to the limits and the assumption that
20 the application of the as low as reasonably achievable
21 principle would result in essentially everyone getting
22 a fraction of that as in one rem.

23 So, the actual numeric equivalence to
24 generally accepted working environment was one rem, not
25 five rem.

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1 ICRP's recommendations in 1990 adopted a
2 considerably more complex multi-attribute approach. I
3 won't attempt to describe to you all of the
4 considerations that went into that, but you can enjoy
5 reading the first appendix of ICRP Publication 60 if
6 you're having a little bit of insomnia and wish to go into
7 those details from that time. That has essentially not
8 changed since that point.

9 ICRP's new recommendations did not change
10 the occupational dose limits. They still recommend an
11 average of two rem per year over a five-year period, or
12 sometimes expressed as 10 rem over five years, with a
13 maximum of five in any one year.

14 Underlying that, the basis is a basis that
15 it is not acceptable to have a cumulative exposure over
16 the working lifetime of an individual to be greater than
17 one sievert, or 100 rem. That is actually the same
18 underlying basis which is the support for the NCRP, the
19 National Council on Radiation Protection and
20 Measurement's recommendation.

21 NCRP chose a slightly different recommended
22 approach. They said five in any one year, but that an
23 individual's cumulative should be limited to one times
24 N their age in years.

25 And you can see that that has different

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1 implications over the course of time depending on how you
2 might accumulate exposure.

3 I should also note that the Commission in
4 putting out the revision of Part 20 in 1991, explicitly
5 stated that it considered and had rejected the concept
6 of imposing a lifetime dose limit because of a number of
7 complications associated with the tracking follow-up and
8 the implications for individuals.

9 So, to quickly now walk you through some of
10 the pieces in the SECY paper, you will find that this
11 tracks fairly well to different paragraphs in the SECY
12 paper.

13 First, a discussion of the updated dose
14 assessment methodology. There was general support for
15 incorporating the latest scientific information and
16 modeling. We've gotten a lot more refined in how we model
17 the intake and movement of radioactive material on the
18 body, how do you calculate the doses. We are well beyond
19 the old phantoms, which were the nice geometric cylinders
20 and cones, to now the voxel phantoms with more critical
21 detail and transfer back and forth.

22 Those are in the process of being utilized
23 along with the most recent revisions to nuclear decay
24 data to prepare a new set of dose coefficients, which
25 would be the information necessary to calculate the

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1 annual limits of intake and derived air concentrations
2 that would be part of Appendix B.

3 So, the stakeholders said, yes, we think you
4 should go ahead and use those. Yes, we think you should
5 go ahead and take the time necessary to have the new
6 information, do it once, leapfrog the generation in the
7 middle, and bring everything up to date.

8 And, oh, by the way, Don, can NRC see if you
9 can get the other federal agencies to come along with you?
10 The difficult takes a bit longer.

11 Terminology. With the changes in the
12 calculation approaches came a change in how the dose was
13 described as the new term. Current rule talks about total
14 effective dose equivalent.

15 Actually, that phase was something we
16 created, because the ICRP including their
17 recommendation, dah, dah, dah, used the entire long
18 sentence of the sum of dah, dah, dah, dah, dah, dah, dah,
19 dah. And you can't do that when you write a rule and write
20 that long paragraph every single time.

21 Our friends in the General Counsel's Office
22 suggested to us, I think quite rightly, you need to have
23 a term and stick with it so there's a definition. So, we
24 created that.

25 Interestingly, everybody picked it all up.

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1 Even ICRP now uses the phrase with the newer terminology,
2 which is effective dose.

3 So, often times you will see in ICRP
4 documents now, the reference to the limit as the limit
5 to total effective dose. The sum of the internal and the
6 external component.

7 They drop the equivalent when the
8 calculation changed from using quality factors to
9 describe the effects of different types of radiation,
10 gamma, beta, to the use of the radiation weighting
11 factor. So, there was a change in the methodological
12 calculation with the terminology.

13 Everyone said, yeah, it's correct you
14 should probably do it so that we're all using the same
15 language. Although, it's going to be really hard to
16 explain to all the people we've trained all the years,
17 that total effective dose really is sort of the same thing
18 as total effective dose equivalent and we're changing all
19 of this and we're changing all the procedures because
20 it's the correct term.

21 Okay. What we suggested to the Commission
22 is that that should be updated and that we should look
23 at ways to provide some flexibility so that instead of
24 making everybody just, snap, change a bunch of things,
25 that we allow for time so that as people update procedures

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1 and activities, they can incorporate this into it and,
2 therefore, reduce the burdens of moving forward.

3 The occupational dose limits, the one that
4 everyone seems to focus on, the occupational dose limit
5 does not have its basis in the current radiation risk
6 projections.

7 In fact, from a legal perspective, you can
8 accumulate doses at five rem per year every single year
9 and be within the regulation.

10 Now, the total framework which also
11 requires that exposures be reduced as low as reasonably
12 achievable, additional words on that, means we would be
13 really unhappy with that. But, in fact, it allows a
14 situation in which individuals could accumulate
15 exposures in 20 years, which would exceed the recommended
16 cumulative level.

17 And, therefore, cause them to question
18 whether or not some change should be made in order to
19 provide a more explicit assurance that each individual
20 would be provided protection in addition to the fact that
21 the application of ALARA provides protection and moves
22 the majority of the population to well below that dose
23 limit.

24 The recommendations of both ICRP and NCRP
25 have flexibility built in, because this is not a precise

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1 number. Nothing dramatically changes at 99.9 versus a
2 hundred in accumulation, or at two rem a year versus 2.1
3 or 2.2 rem a year. They are all dots on the regulatory
4 straight line that is drawn for purposes of constructing
5 regulation.

6 For the more we know there are differences
7 in population, differences in each of us, my risk is
8 different from Dr. Zanzonico's risk, et cetera, et
9 cetera, et cetera. We're all different.

10 When I was talking with Dr. Mike Lang the
11 other day, he's six-foot-five. A very large individual.
12 Substantially different organ geometries and otherwise.

13 So, we know that this is a population
14 average that has to be used for radiation protection
15 purposes. This is not an estimate of an actual
16 individual's risk associated with it.

17 Occupational exposure in the United States
18 comes from a lot of places. That yellow, big piece of the
19 pie is something that no one takes direct control over.
20 That's the doses that airline crews, stewardesses and
21 other folks get as a result of flying to and fro about
22 the earth at 30,000 feet in the cosmic radiation field
23 the whole time.

24 Medical is the second largest component,
25 almost all of which is not reportable to the NRC under

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1 the current regulations. Well, that's interesting.

2 In addition to what you have, other types
3 of activities, commercial, industrial, government,
4 education, some of those things.

5 So, I put you up only one chart for interest
6 of discussions. This is from NCRP's Report Number 160
7 from two years ago looking at occupational exposure. This
8 data was derived from data received from dosimetry
9 processors.

10 So, it is uncorrected data in the sense that
11 this information may have been used to calculate an
12 effective dose, which might well have been less than the
13 actual badge dose.

14 In that circle up there on the right-hand
15 side, you'll see doses that are greater than the
16 currently recommended average value by ICRP of two rem
17 per year. You'll, in fact, see values in each year that
18 are greater than five rem per year.

19 Again, I can't tell you the extent to which
20 those actually represent occupational overexposures or
21 that which may represent badge readings which, in fact,
22 are not a total effective number for purposes of
23 demonstrating compliance.

24 If you'd like to do the math on that, you'll
25 see that 99.57 percent of the folks in that distribution

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1 in 2006 are less than the two rem per year average. ALARA
2 works almost all of the time. Does a good job. And that's
3 really where protection comes from in an operational
4 setting.

5 So, stakeholder feedback. We don't like the
6 idea of changing the regulation. We think there will be
7 significant impacts on licensed activities and delivery
8 of healthcare and other sorts of things.

9 There were numerous suggestions that
10 changing these numbers or changing ALARA or anything else
11 would increase the weight of noncompliance, which was
12 intimated. Not quite allegations that we actually could
13 follow up on, but intimated that there is noncompliance
14 in various categories with people leaving their badges
15 and doing other things so as not to nudge up against that
16 occupational dose number.

17 And again, the statements that sources and
18 uses are different, our sources are higher, we should
19 have a different dose limit.

20 I will tell you that the staff rejects the
21 last argument. A health and safety limit that provides
22 adequate protection in public health and safety should
23 have no basis in what size source you use. It should be
24 providing protection for whatever you use.

25 In looking at all of this and giving you a

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1 brief preview of the discussion I'll talk about in a
2 minute, which is the discussions on the lowest reasonably
3 achievable approach, the staff concluded that there
4 would be a technical basis for considering or exploring
5 in greater detail, I believe that's the exact words used
6 in the recommendation of that particular section, to
7 reduce the dose limit perhaps to two rem per year.

8 Within this, one of the significant
9 discussions was stakeholders in our initial activities
10 said, please do not impose averaging. Make us look at
11 multiple years of exposure, go back and get people's dose
12 histories over multiple years, keep track of it, do all
13 of that in calculating where they can be in this
14 particular year with all of the variables associated with
15 it. We really don't want you to go there.

16 Now, I suspect that as we would go forward,
17 we might hear some modifications of that view and they
18 see what the alternatives might be.

19 In the staff paper, we have suggested to the
20 Commission that a single number might be a more
21 straightforward approach, but that there certainly
22 needed to be flexibility.

23 One of those approaches might be the same
24 approach which is already in place for public exposure,
25 or in place for planned exposure situations, which is to

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1 allow for application and approval of an additional dose
2 amount with whatever specific conditions and go over
3 whatever period of time might be appropriate so that you
4 can deal with the particulars of the case as need be
5 without imposing the burden of additional record
6 keeping, recording and transferring things upon the
7 entire license community.

8 That would tend to work pretty well for a
9 lot of materials users who usually have no difficulty in
10 applying for and looking at exactly what they need. And
11 the states in discussing the proposal with them were in
12 agreement with that. It matches their approach of liking
13 to work with the individual licensees which they have
14 when they have issues in order to figure out the best way
15 to move forward and have protection.

16 I will tell you that the folks in our reactor
17 community are not so enamored in this approach for a very
18 simple reason. No chief nuclear officer of a reactor is
19 ever going to allow his reactor to apply for an additional
20 dose limit. That would look very bad on his INPO rating.

21 So, the discussion will have to continue,
22 because there are implications on both sides of the
23 equation.

24 Let's move on to some of the other issues,
25 because we have not all that much time and I want to engage

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1 in some discussion with you.

2 The lens of the eye was the most recent
3 recommendation. The ICRP recommended a reduction from
4 the current value which was 15 rem, 150 millisieverts in
5 any one year, to an average maximum value.

6 This was based on considerable evidence
7 that has been accumulating that the threshold for
8 cataract induction was more on the order of 50 rem
9 accumulated dose in the lens of the eye. Substantially
10 less than the several hundred that had been previously
11 estimated.

12 Numerically, that would mean with the
13 ICRP's recommendation of using two rem lens dose
14 equivalent average over a five-year period and five rem
15 maximum, that the numeric number is exactly the same as
16 the numeric numbers for effective dose of a whole body.

17 Now, in many circumstances or most
18 generalized circumstances, the effective dose and the
19 lens dose will be similar. Not exactly the same, because
20 there are differences in the criteria. But you will also
21 recognize that if there are situations in which there is
22 shielding to portions of the body such as the leaded
23 aprons, or you have lower energy beta/gammas or very
24 specific things or fields, that you can have substantial
25 differences.

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1 And that, in fact, in some cases that would
2 make the lens of the eye the limiting dose limit for the
3 circumstance, which it essentially has never been in the
4 regulations to date.

5 I will tell you that this recommendation
6 from ICRP has already been incorporated by the
7 International Atomic Energy Agency and the International
8 Basic Safety Standards, which was approved by IAE's board
9 of governors just a year ago.

10 IAEA will in two weeks have a technical
11 meeting in Vienna to start looking at developing
12 implement guidance for how they're going to do that.

13 We intend to have staff participate. We
14 expect to have a couple of US dosimetry processors be
15 present to help discuss those sorts of issues.

16 Certainly information that is discussed
17 there will be useful in an ongoing dialog for ourselves.

18 The feedback when we put this out was
19 actually sort of a mixture of things. There was some
20 question to the scientific information. There was a whole
21 bunch of questioning about whether a cataract should be
22 considered an equivalent effect as a cancer. And there
23 was concern about the implication of the numbers and that
24 would be a controlling dose in certain situations.

25 So, the staff has actually recommended at

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1 this point, that we explore for purposes of trying to
2 develop a detailed technical basis, a reduction in
3 limits, but we have not recommended a particular value.

4 If you look at the comments received, those
5 would point towards a single number value at five rem
6 suggested by several of the commenters. So, that's what's
7 on this particular slide.

8 There needs to be continued dialog, because
9 there are a lot of open questions of how you do this. The
10 dosimetry for lens of the eye, the dosimetry when you have
11 leaded glasses, if you have leaded glasses with side
12 shields and a variety of other circumstances which
13 heretofore have not been crucial in the analysis process
14 become more so now.

15 Embryo/fetus, this is an application to the
16 occupational limit for a declared pregnant individual.
17 This is the only limit in the regulations which only
18 applies if the individual chooses to declare it. So, it
19 is a variable situation.

20 As we discussed the recommendations, there
21 was some mixed feedback. Much of what we heard from
22 licensees and groups were that they were able to
23 accommodate the individuals. So, there was no
24 substantial impact to the activities.

25 There were concerns expressed about the

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1 lower value whether that might cause individuals to not
2 declare, because they wanted to complete residency
3 programs or otherwise. A variety of dose possibilities
4 not unlike some of the things we've heard with the
5 occupational dose limit itself.

6 We've recommended to the Commission that we
7 continue to develop a detailed regulatory basis for
8 reducing the limit to the 100 millirem level, which is
9 the ICRP recommendation.

10 The ICRP recommendation is stated to apply
11 only to the period after the declaration, which again is
12 a variable highly dependent upon when the individual
13 would choose to declare it.

14 And, in fact, if you construct a whole
15 series of scenarios, in some cases would be more
16 restrictive than the present NRC regulation, which is 500
17 millirem over the entire gestation period.

18 It could be more restrictive? It, in fact,
19 could be less restrictive under some circumstances if she
20 declared later, or if a fairly substantial portion of
21 that dose had already been received before the choice to
22 declare it.

23 So, there are some things that still need
24 to be discussed and elaborated and which will directly
25 impact what the implications would be for different

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1 groups of licensees.

2 ALARA planning. ICRP's recommendations
3 provided a significant new emphasis on a consistent use
4 of optimization there were for the whole process of
5 improving protection and the use of constraint.

6 Their term for values that are used in
7 planning or delimiting a set of options for consideration
8 to try and get the best achievable protection.

9 We had a number of proposals to add
10 requirements to the ALARA program. In fact, I'll be quite
11 frank with you. We started off just thinking this might
12 well be attacked better by adding strength to ALARA,
13 which at the moment is a generalized statement that you
14 should reduce exposures and, in fact, is hardly ever
15 cited against. Citations are usually against licensee's
16 procedures or commitments rather than to the regulation.

17 That also has some downsides to it. First
18 is an opposition to determine constraints. In fact,
19 there's an opposition to any specification of a planning
20 value in the regulation.

21 Quite frankly, people said, Don, if you make
22 that a number that is de facto a limit, you might call
23 it by some other name. But if you require us to do specific
24 things and if we have to take actions to return to
25 compliance, it sounds and looks and quacks just like a

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1 limit.

2 So, having gone back and forth and looked
3 at the implications, having examined some things, we
4 actually received some specific proposals from state
5 commenters on how to construct this, which focused on the
6 approach that's typically in reactors, a very detailed,
7 proceduralized process and reviews and approvals and
8 information, all of which pretty much guarantees they're
9 never going to be anywhere close to the limit, or the DOE
10 approach which is a limit of five and an administrative
11 control level in their radiation protection guide, which
12 requires the deputy under secretary approval to exceed,
13 meaning it doesn't happen, and concluded that we could
14 do that. We could impose a lot of procedural burden and
15 detail, lots and lots and check boxes. And that when it
16 got all said and done, it would not change at all the
17 possibility that an individual could get over whatever
18 the planning value might be, because you could go through
19 all of the little box - you could check all the little
20 boxes, you could do the approval, somebody could approve
21 it and you could happily go right through it. Because
22 unless you require a change in the doses, you could still
23 have the higher doses.

24 So, in the end, the view was that it was
25 probably simpler and more straightforward, more

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1 performance-based if you want to provide the protection
2 for that small group of individuals to high dose end, you
3 move the limit and you work with people to figure out the
4 right way to do it.

5 Some of the other things out there, one
6 that's a favored subject for the Health Physics Society,
7 isn't it time to use SI?

8 Well, certainly there are a lot of people
9 who feel that way. The scientific literature is all that
10 way.

11 There is the Health Physics Physician
12 Statement now which is just do it. Just chop it off, end
13 of discussion. Just make everybody go ahead and do it,
14 for which I would quietly reflect it's not nearly that
15 simple. If it were that simple, the US would have all of
16 our speed signs in kilometers long ago.

17 So, we have recommended to the Commission
18 that this is certainly an issue that requires some
19 additional exploration.

20 There is a step that would already be
21 consistent with the NRC's metrication policy which came
22 out in the mid-`90s, which would be to list the SI first
23 one step in the direction.

24 There needs to be considerable discussion
25 with our federal partners in the states and others who

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1 would do this. I have heard a number of people in the
2 states who have said, oh, we after I am dead, okay.

3 On the other hand, we also have
4 observations, for example, following the Fukushima event
5 and the incredible press coverage and interest for months
6 and months and all the reporters going over there. All
7 of that discussion being in millisieverts and
8 becquerels.

9 A whole new viewpoint of what people are
10 using and a real question of so, why are you still doing
11 this and what's a rem?

12 So, it's time to look at it, but we are not
13 at all convinced that it actually passes the threshold
14 where we should actually demand a change, continued
15 exploration needed.

16 Reporting of occupational exposure,
17 another one that gets stuck sideways in lots of people's
18 thinking.

19 Currently today there are seven categories
20 of licensed activities that are required to report. That
21 does not include any of the medical categories. Nuclear
22 pharmacy is one of the categories, but none of the medical
23 physician categories, et cetera, is required to report.

24 Further, in terms of agreement states, it's
25 a D. They do not have to include it in terms of the

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1 compatibility.

2 So, in fact, very few of the states require
3 any reporting of occupational exposure to their
4 organizations.

5 So, when you look at the data that we have
6 available for doing this analysis and if you go looking
7 for something that would help us understand if some
8 individual were working in Virginia and in D.C. and in
9 Maryland, three different regulatory jurisdictions, you
10 would discover that you've got nothing to rely upon.

11 So, it certainly begs the question of
12 whether there is a value and whether there should be a
13 reexamination of the implications.

14 Now, I will be very frank with you. The
15 energy necessary to get to a national database of
16 anything is very substantial. It has been done in source
17 security in tracking of sources with the money and
18 associated focus on that post-September 11, 2001, but not
19 without extreme handwringing.

20 So, this again is something that will
21 require a lot of discussion in what are the possible ways
22 to make progress.

23 So, we've suggested to the Commission we
24 explore the options, they explore the mechanisms. We
25 don't have a viewpoint at the moment. It's pretty clear

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1 to us that it's not simply make everybody report their
2 occupational exposure to the regulatory authority.

3 Obviously there are some categories which
4 have such low occupational exposures that that doesn't
5 make sense. Why should I make small gauge uses otherwise
6 report when they can't possibly get anywhere as close to
7 this.

8 On the other hand, there are a number of
9 categories including much of what's represented by this
10 group around this table for which there is no data unless
11 we go licensee by licensee to mine it in terms of getting
12 information.

13 In terms of the other portions of the
14 regulations, we have recommended to the Commission that
15 in parallel with the revision of Part 20, that we step
16 up and move forward with the development of the revision
17 for Part 50, Appendix I. Move that out of the really old
18 maximal permissible concentration approach. Have it
19 parallel to current recommendations.

20 And that, in fact, as we pursue rulemaking
21 in other areas where the older dosimetry and standards
22 occur to look to bring those forward as a policy direction
23 to move forward. We think that's an appropriate approach.
24 It will take some time, of course.

25 As I said, much of the scientific

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1 information for calculating internal exposures is not
2 yet available. In fact, the complete set of revised dose
3 coefficients from ICRP is not expected to be done until
4 the end of 2015. So, there is still some time.

5 Now, while it doesn't apply to medical, Part
6 20 applies to everything and, thus, is subject to the
7 backfit requirements for reactors and for fuel cycle and
8 for several other types of facilities that have that
9 requirement put in place.

10 The previous revision was justified as a
11 substantial increase to public health and safety on both
12 quantitative and qualitative grounds.

13 I think you can readily see that there are
14 some things where you cannot do a dollar per person rem
15 improvement to justify making a change, but that there
16 are a variety of other reasons which may make that the
17 right thing to do. Those are the qualitative grounds that
18 we put in place.

19 Things such as a change in dose limit could
20 be argued under the grounds of a redefinition of adequate
21 protection. That would have to be worked through in each
22 of the individual basis to put together the particular
23 case once we know what the proposal might be.

24 So, don't let my statement here suggest that
25 that would or would not be used, or how it would be

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1 constructed. It very much depends on the details of the
2 proposal.

3 So, that means that we need a lot of
4 additional information. It's really hard to generate
5 specifics of the regulatory analysis, cost benefit
6 analysis when you're discussing concepts. It only works
7 if you actually are talking about the specifics of the
8 impacts, what might the language actually look like. What
9 might be the approach for compliance as in the general
10 approach to the guidance.

11 The staff has recommended to the Commission
12 that we believe that there's a sufficient basis to
13 warrant the continued expenditure of our resources to
14 develop the details to work through with the stakeholders
15 the possible implications so as to develop that
16 regulatory basis, the technical basis for each of these
17 areas and bring it back to the Commission.

18 We have not recommended to the Commission
19 that this is the final decision on any of those things.
20 Details to follow. Clearly we expect some renewed
21 discussion on what's the right kind of flexibility,
22 because one size does not fit all.

23 And we're recommended to them that they
24 approve that the staff continue to move forward in
25 parallel that with the regulatory basis for doing Part

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1 50, Appendix I.

2 With that, ladies and gentlemen, I am
3 concluded with this walk-through of that and I will be
4 pleased to answer your questions. Thank you very much.

5 CHAIRMAN MALMUD: Thank you, Dr. Cool.

6 Are there questions for Dr. Cool? Very
7 thorough presentation.

8 Dr. Zanzonico.

9 MEMBER ZANZONICO: Pat Zanzonico. That was
10 terrific. Really very thorough and clear presentation.

11 You know, now is not the time and place if
12 there ever is a time and place to pursue linear
13 non-threshold, et cetera, et cetera, that show a basis
14 for a lot of these recommendations, but - and this is not
15 a rhetorical question: Are you aware of any
16 epidemiological studies which indicate that among NRC
17 licensees, whether medical or non-medical, a
18 statistically significant increase in cancer which mean
19 compliant with the five rem limit?

20 In other words, is there any data other than
21 the linear non-threshold theorizing, so forth, support
22 dose reduction of any sort from the five rem limit.

23 DR. COOL: From an epidemiological
24 standpoint, there have been several studies that have
25 been done looking at various occupational databases.

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1 Some of them have shown slight differences depending on
2 data which is included or excluded.

3 In fact, right now there is underway - it's
4 gotten nicknamed the million man study, to take the
5 databases that are available in the United States in DOE,
6 in NRC, and do a more detailed analysis on those looking
7 particularly at the earlier years.

8 Now, we are fairly far removed where; one,
9 doses were higher and; two, there has now been a fairly
10 significant time period for a follow-up to see if there
11 is anything that can be drawn from those studies. So, that
12 information is not available now.

13 You have in addition to that, I'm sure
14 you're aware, the ongoing work that the NRC contracted
15 with a national academy to look at doses in populations
16 round nuclear facilities and do a refresh of the study
17 that was done in 1990 or so to look at whether there was
18 any evidence of statistical differences for those
19 populations at the very low environmental dose rates.

20 That is also in an ongoing process. The
21 National Academy gave Phase 1 of its report with some
22 recommendations for a pilot which the staff is currently
23 considering.

24 There's the DOE low dose study program and
25 other things looking at the cellular, molecular other

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1 side of things and trying to work through the
2 information. Low dose for them is 10 rem, but that work
3 continues.

4 And you see a wide variation in things that
5 are found depending upon single cells, small groups of
6 cells or something which comes closer to tissue levels.

7 All of that information helps to contribute
8 to our understanding. At this point, it does not provide
9 information that would suggest that from a regulation
10 development basis that we would have a basis to move away
11 from a linear model.

12 Now, quite frankly, if I took off my NRC hat
13 and said just Don Cool, do I think the radiobiological
14 response of a human to radiation is linear? No. I don't
15 know of any response that we have that's linear to
16 anything.

17 On the other hand, I only know two
18 reasonably effective regulatory structures. They're
19 either lines, or they're a switch.

20 And so, within the construct of what we have
21 while we certainly need to continue to look at what we
22 know and refine that and apply what we know if we're
23 looking at a particular case in point for the regulatory
24 structure, I think we still need to be in a position of
25 using this in order to have a consistent, predictable,

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1 transparent process.

2 CHAIRMAN MALMUD: Thank you.

3 MEMBER ZANZONICO: Can I just make an
4 editorial comment? Pat Zanzonico.

5 As much as I would like to say otherwise,
6 because I just have this visceral suspicion - linear
7 non-threshold model. I think given the available data and
8 given the applicable risk assessment algorithms, it's
9 really hard to argue against a reduction of either the
10 occupational MPD to two rem per year, or in particular
11 the lens dose MPD.

12 The one point I would make is, and I agree
13 completely that certainly for medical work is the
14 overwhelming majority, essentially a hundred percent,
15 are less than two rem per year.

16 There is a practical and cost implication
17 for reducing that dose limit nonetheless, because most
18 sites use an action level of ten percent of the MPD. It's
19 as reasonable as any in terms of triggering some
20 reduction.

21 And so, by reducing the MPD from five rem
22 to two rem, then obviously the action level for many sites
23 will be reduced from 0.5 to 0.2 rem. And there may be
24 practical and economic implications of that that are
25 real, nonetheless, even though all of their workers are

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1 below the two rem proposed limit.

2 DR. COOL: That's very correct. The question
3 that Marge, although I didn't mention today, is a key
4 question in terms of how you demonstrate compliance and
5 your confidence that you will stay in compliance. I would
6 agree.

7 CHAIRMAN MALMUD: Thank you. Dr. Van Decker.

8 MEMBER VAN DECKER: Thanks. A small handful
9 of questions, if I could. Number one, help me understand
10 where you are process-wise.

11 So, a SECY paper has gone and it says you
12 want to continue where you're heading. And the ask to come
13 back is continue to find a technical basis for rulemaking
14 or what's going to come back is go ahead with rulemaking
15 and establish stakeholders and your timeline for
16 rulemaking.

17 DR. COOL: Thank you. I realized as you
18 started to ask that, that I didn't actually tell you where
19 we were.

20 The staff has given the paper to the
21 Commission. The Commission is still in the voting
22 process.

23 What the staff has requested is permission
24 to continue to develop the regulatory basis over the next
25 three years at least to the point in which technical

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1 information like the dust coefficients would be
2 available to have a regulatory basis upon which to write
3 a rule.

4 Now, we have told them that we would like
5 to go beyond what might typically be a regulatory basis
6 development and actually look at the specifics of
7 possible rule language in order to be able to check the
8 implications. Normally, that's done after the basis is
9 developed.

10 But in terms of process, this is a
11 regulatory basis development, complete a regulatory
12 basis roughly at the end of 2015.

13 With agreement to then work a proposed rule,
14 there would be public comment on the proposed rule after
15 Commission, there would have to be analysis, comments,
16 agreement on the final rule, publication and an
17 implementation period.

18 When you start to do the math on that, a
19 possible effective date is 2020 or perhaps further.

20 MEMBER VAN DECKER: Okay. I understand the
21 shrewdness of your answer. I like that very much,
22 actually.

23 So, my second comment here is, you know, on
24 an ALARA program basis, you know, most of the time raw
25 data is being used to, you know, work internally and not

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1 always, you know, effective dose is being calculated on
2 all of this.

3 You need to recognize that internally we
4 need to be doing something so that we're not chasing our
5 tail on a large variety of things. And I'm not sure what
6 can be done to help that out, but we'd have to think about
7 it some.

8 And I guess my last comment on this is just
9 the general comment, you know. There's nobody here that's
10 going to say we're not against trying to provide the most
11 safe and effective environment possible for occupational
12 workers, as well as our patients and everything else.

13 And obviously, you know, the lower, you can
14 go lower. It's always better than higher. And then the
15 question comes, it comes at what cost and where does that
16 cost go.

17 So, you know, what's in the purview of the
18 practitioner or the occupational worker, which is
19 obviously time, distance, shielding, right? But
20 recognize that that pressure point which comes by this
21 may not be the only pressure point that gets us as a
22 society where we want to be.

23 Because as you pointed out, the majority of
24 your five percent outliers are not the regulation within
25 this room per se. It's mostly machine-produced, right?

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1 Fluoroscopy, fluoroscopy, fluoroscopy.

2 DR. COOL: There is a substantial
3 contribution out there, but I will also reflect that in
4 our interactions with the states, one of the things that
5 has been quite clear is that there can be only one set
6 of requirements.

7 There are 37 agreement states. The adequacy
8 and compatibility would apply. They will have a single
9 set of standards.

10 MEMBER VAN DECKER: Yeah, okay. Well, we
11 know I believe that. But my question and my comment is,
12 obviously, you know, a pressure point on the machine on
13 the production on what can be done technology-wise in
14 addition to just the pressure point on the individual,
15 obviously, so that there are really more stakeholders in
16 this in a broader sense than just, you know, what you're
17 there in and how they become a percentage of what can be
18 done to help improve the environment rather than just the
19 pressurization of time distance shielding.

20 So, and, you know, reference defaults on
21 machine-produce may help, but some concept that this is
22 a broader discussion needs to at least be recognized.

23 CHAIRMAN MALMUD: Thank you. Any other
24 comments?

25 MEMBER LANGHORST: Dr. Cool.

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1 CHAIRMAN MALMUD: Oh, Dr. Langhorst.

2 MEMBER LANGHORST: Dr. Cool, thank you.
3 That was a very thorough talk on that, but you did not
4 come back to other agencies and their implementation or
5 evaluation of these dose limits.

6 And so, for agreement states I would
7 understand that if they have to meet the NRC requirement,
8 that they would apply that to all radiation sources, I
9 would assume, but what is the - and you may not have
10 answers, but what is OSHA doing in regard to their
11 regulation on radiation control programs?

12 And another question I have is, would this
13 impact the FDA's limit for human research subjects, which
14 is currently five rem whole body or three rem to organs?

15 So, kind of a question for you, question for
16 Dr. Suleiman, too.

17 DR. COOL: The U.S. interagency has this as
18 an ongoing discussion. We have an Interagency Steering
19 Committee on Radiation Standards that talks about it
20 almost constantly.

21 The Environmental Protection Agency is
22 looking at a number of things. And, in fact, has in
23 preparations advance notice of proposed rulemaking to
24 move - to propose or to discuss moving to this methodology
25 in some of the general applicable environment standards

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1 for the fuel cycle, 40 CFR 190, 192 and other parts.

2 On Monday will be the first formal meeting
3 of an interagency subcommittee that will look at
4 questions of whether there should be an update to the
5 formal federal guidance on occupational exposure last
6 revised in 1987.

7 OSHA put out a request for information some
8 several years ago earlier on before we actually started
9 this process, and is watching to see what we will do.

10 It's not active at this moment, but they are
11 engaged in following the discussion and the process.

12 The Department of Energy completed just in
13 the last year a couple of rulemaking, which moved the
14 scientific information to the 1990 approach. They are
15 also interacting with us, but at this point have not
16 indicated an active consideration of any other changes
17 to the system.

18 FDA is also represented on that committee,
19 and we have two individuals from the states who are
20 observers and actively participate in that discussion.

21 So, we're trying to keep tabs on it.

22 CHAIRMAN MALMUD: Thank you.

23 MEMBER LANGHORST: Thank you.

24 CHAIRMAN MALMUD: Dr. Suleiman.

25 MEMBER SULEIMAN: I have comments for you,

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1 but I'll answer that question.

2 MEMBER LANGHORST: Thank you.

3 MEMBER SULEIMAN: The Radioactive Drug
4 Research Committee writes those are independent. They
5 apply to the research subject. So, right now they stand
6 as they are.

7 MEMBER LANGHORST: Okay, thank you.

8 MEMBER SULEIMAN: I will share with you that
9 we've been wanting - I've been wanting to readjust those,
10 you know, because I think research is risk based unlike
11 occupational protection, I mean, the way the standards
12 - standards are protected, you know, you have like a 55
13 mile an hour speed limit so all of society is safe You
14 don't have a speed limit for each car and each person or
15 whatever. But with research, you've got people with
16 different ages and whatever. I mean, I'm just sharing
17 with you what's going through some of our minds.

18 The questions to you, Don, or at least just
19 to let you know what I think, my observation is that ALARA
20 more so is appropriate, it seems to be working in
21 occupational.

22 I think in medicine it's not - and probably
23 that's not relevant here, but it's not practice. People
24 don't often even know the doses they are giving.

25 So, I always argue that the first step in

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1 practicing ALARA is knowing what you have in the first
2 place. So, how can you make sure you're reducing the doses
3 if you don't know what you have?

4 A little anecdotal story that I think is
5 important in sharing, we had a poster to be presented in
6 some meetings a couple of years ago on RDRC. And we had
7 the RDRC limits and other dose numbers up there from a
8 variety of radiation sources, including background.

9 And I found it really, really interesting
10 to me that some of our - we have a lot of smart, educated
11 people at the agency. Obviously a lot of them don't have
12 radiation background, but they picked up on the general
13 population limit of one millisievert and similarly with
14 you were talking about the fetal limit, and they said,
15 why would you have a limit that's less than background
16 radiation? Because we had the background level there.

17 Can I just share that with you? I think -
18 I also feel that if the two millisievert limit is
19 attainable because you've got data that shows that and
20 I've heard from colleagues in New York who say people seem
21 to be complying with it.

22 But as long as we at some point we say this
23 is fine, we can't keep - just because we can detect lower,
24 we don't want to keep on lowering things where it becomes
25 impractical, but I share that one millisievert

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1 observation both regarding the limit to the fetus and to
2 the general population.

3 So, I'm comfortable with what's being
4 proposed. I just wouldn't want to get ridiculously lower
5 here.

6 CHAIRMAN MALMUD: Thank you. Other comments
7 or questions? Dr. Welsh.

8 MEMBER WELSH: Jim Welsh. Appreciate the
9 presentation and the perspectives, but I have to say that
10 I, as an individual, am not in favor of lowering the dose
11 limits. And I would call your attention to the ASTRO paper
12 that was submitted to the NRC in January 2011 addressing
13 this issue in which that organization also posed
14 reduction in annual limits.

15 And I would ask if stakeholder
16 representation has been provided by ASTRO, AAPM, ACR and
17 the other really large players which have a large
18 population of radiation biologists to provide input to
19 perhaps balance the perspective of the ICRP, the NCRP and
20 their reports.

21 Because as we all know, there are extremely
22 differing opinions on this subject and I, for one, do not
23 feel that the ICRP report accurately reflects the
24 reality.

25 So, I just ask if AAPM, ACR, ASTRO has

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1 continued to weigh in as we proceed and make these
2 recommendations.

3 DR. COOL: I believe all of those societies
4 were present seats at the table in Los Angeles. I'm not
5 sure that all of them actually formally submitted
6 comments on the work group.

7 Our intention if the Commission agrees that
8 we should continue this dialog and start to look at
9 specifics and details, is that we would be both welcoming
10 and trying very hard to get all of those players to the
11 table and interacting to try and have the best
12 understanding of the various implications.

13 CHAIRMAN MALMUD: Thank you.

14 DR. COOL: Thank you, sir.

15 CHAIRMAN MALMUD: We'll move on to the next
16 presentation. Mr. Mattmuller.

17 DR. COOL: Before we do, can I make a request
18 that I can also join the subcommittee on the AO events?

19 CHAIRMAN MALMUD: The subcommittee we just
20 formed, absolutely.

21 DR. COOL: Thank you.

22 CHAIRMAN MALMUD: You are hereby appointed,
23 unless the chair objects.

24 MEMBER LANGHORST: Not at all.

25 (Pause in the proceedings.)

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1 MEMBER MATTMULLER: Good morning. I'll give
2 you an update on where we are with molybdenum-99, an
3 update on the progress we're trying to make for a safe,
4 robust and affordable supply of moly-99. And of course
5 it's very important to us because that's the parent to
6 technetium-99m, the most commonly used nuclear medicine
7 diagnostic radionuclide.

8 And for the test of my talk instead of
9 stumbling over molybdenum-99 each time, I'll refer to it
10 as moly, and technetium-99 as technetium.

11 And technetium is used in about 80 percent
12 of all procedures and worldwide. And the majority of the
13 moly used with technetium comes from highly-enriched
14 uranium which is defined as greater than 20 percent. But
15 typically the targets that are used for moly production
16 are around 95 percent.

17 And, unfortunately, there are countries in
18 the world that have a strong desire for HEU and are
19 interested in its use for, shall we say, non-constructive
20 uses.

21 And so, there's a coordinated
22 multi-national effort to - sorry - to phase out the use
23 of HEU in the world, but our need for moly right now for
24 our technetium is about 12,068 curies per week, which is
25 somewhat of a bizarre unit.

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1 But that's defined as a unit of measure for
2 moly producers present in a shipment six days after it
3 leaves the producer's facility. And in the US alone, we
4 use up about half of the world's need for moly-99.

5 So, let's take a look at our supply chain
6 and why it's often characterized as being fragile. On the
7 left we have the reactors around the world. None are in
8 the US. And some have multiple supply lines to the
9 producers in the middle. And then to the far right are
10 the two US generator manufacturers.

11 All these reactors currently right now are
12 using HEU for moly production, except the two exceptions
13 here at the bottom, or at least OPALs at the bottom.
14 that's the Australian reactor. And they're 100 percent
15 LEU. And the SAFARI reactor in the yellow is about -
16 they're in the progress of changing over and they're
17 about 50/50 right now. They use LEU to HEU for targets.

18 Complicating this supply line are the large
19 distances between reactors to producers, to generator
20 manufacturers. International borders have to be crossed.

21 You're talking about radioactive packages
22 that are in Type B packages as opposed to the Type A that
23 we're most familiar with which can be a robust cardboard
24 box. Type B is usually a steel and concrete-type
25 structure that has to also withstand accidents. So, it's

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1 a substantial, expensive and difficult package.

2 One of the other bigger concerns for our
3 fragile supply is the age of the reactors. Most of these
4 you could say are baby boomer reactors. They were
5 commissioned in the `50s and `60s.

6 Two exceptions. The Maria, you could say,
7 is a Generation Y in that it was rebuilt in 1993. And the
8 newest is Generation Z, the OPAL reactor down in
9 Australia, but unfortunately for us it's halfway around
10 the world.

11 So, as some - and also contributing to this
12 issue is some reactors supply more than one producer. As
13 you can see the lines crossing from reactors to different
14 producers.

15 But even in this process of converting to
16 LEU, the producers can be a bottleneck in that not just
17 do they have to redesign LEU targets that work in the
18 reactors, the producers now have to redesign their
19 processes to handle the LEU targets and which usually
20 means they need more hot cells, which are very expensive.
21 And they have to deal with more waste than what they
22 typically use or typically are accustomed to.

23 And as an example, well, it used to be an
24 example, is the OPAL reactor. The OPAL reactor can
25 actually produce a lot more moly than it does right now.

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1 And my talk is now out of date as of two days ago.

2 They didn't have the processing capability
3 to handle the additional moly. But if you're a real moly
4 junky, you may have seen the new story that came out two
5 days ago where the Australians are going to invest about
6 \$170 million into a new processing line so they can, in
7 essence, double their production capabilities of moly to
8 the world, which is great news. I just wish they were a
9 little bit closer to us.

10 So, that's probably the best news we've had
11 in a real long with regards to moly, and that just came
12 out two days ago.

13 This is also a partial diagram of the supply
14 chain which missing to the right of the manufacturers are
15 the hundreds of nuclear pharmacies around the country
16 that take the technetium generators and prepared the
17 technetium kits and then send out to the thousands of
18 nuclear medicine departments around the country.

19 And this is all with the clock ticking with
20 moly with that half life of two and a half days and
21 technetium with six hours.

22 So, it's why we always say this is fragile,
23 because it's a time sensitive product, complex in distant
24 supply chain, reactors near the end of their lifetime,
25 the need to convert to LEU and also the need for

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1 processors to convert their systems to LEU.

2 Here's an older slide from 2010 of where
3 moly comes from. It doesn't have the contributions of
4 the newer reactors that have been added lately such as
5 the Maria reactor in Poland or the LVR15 in the Czech
6 Republic, but - and their contributions are important,
7 but that's still a relatively small percentage, but still
8 the big five on this diagram are responsible for 95
9 percent of the moly.

10 The NRU being the oldest in Canada, and
11 unfortunately whose breakdowns over the years have sort
12 of made it our poster child for our fragile moly supply.
13 And it's scheduled to be shut down in four years in 2016.
14 It's handling 31 percent of our supply right now.

15 In 2016 when the NRU shuts down, this is what
16 - well, somewhat our slide is going to look like, because
17 hopefully by then the Australians will be into this.

18 But in Canada, they have no plans to update
19 the - to replace the NRU. In Canada, they have a two-prong
20 program for producing moly or technetium for just Canada.
21 They're going to have a network of cyclotrons to produce
22 technetium directly and to distribute it quickly, of
23 course, within metropolitan areas.

24 And then they also have a second program
25 where they're going to use linear accelerators to produce

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1 moly versus a gamma neutron reaction on stable moly-100
2 much in the same way as NorthStar here in the US plants
3 produce moly. And I'll be talking about them later.

4 Also in the news recently has been the Maple
5 reactors. There is some legal wrangling going on between
6 AECL - or what's going to operate the Maples versus
7 Nordion, but I think it's just a business legal dispute
8 of course involving money.

9 Because if you look at the Maples, they were
10 originally designed for HEU fuel and HEU targets long
11 before the moly issues came to light.

12 And they're having trouble - well, they
13 can't get it to operate properly now as it was originally
14 designed. To get it to operate with LEU targets and LEU
15 fuel would practically require redesigning the whole
16 reactor from the ground up.

17 So, I think personally it's very, very
18 unlikely that we'll ever - they'll ever be
19 recommissioned. I think, unfortunately, especially in
20 terms of moly, we'll never receive any from the Maples.

21 So, there are plans, fortunately, to update
22 some of the big five reactors around the world. The first
23 one I'll talk about is the BR2 in Belgium. And this is
24 a design for the replacement reactor, the MYRRHA. And
25 it's actually going to be more of a two-in-one facility.

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1 Their plans for it are to be called Europe's
2 fast spectrum irradiation research facility with a
3 secondary aspect for radionuclide production.

4 And they do plan to use LEU fuel and targets
5 for this. This is some of the different reactors though
6 that you may have seen and that there's a standard
7 research reactor to the right, but also they are going
8 to have an accelerator produce protons directed into the
9 targets within the reactor so they can have, I mean,
10 usually test reactors just irradiate neutrons. This one
11 will be able to irradiate with neutrons and protons. So,
12 quite the hybrid.

13 Their plan is to have this operational in
14 about 11 years. So, it's still some time away and they've
15 not even started to dig for it yet.

16 The next one would be the HFR in the
17 Netherlands. The replacement is called PALLAS. And they,
18 too, plan to use LEU fuel and targets for the new reactor.
19 And I should back up a little bit in that one of the
20 efforts currently going on right now is Covidien. It's
21 working to develop LEU targets that would work in both
22 reactors on both the BR2 and the HFR right now, which is
23 somewhat a bit of a challenge to get one target to fit
24 and work in both reactors.

25 So, Covidien is actively working on that now

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1 as part of this process to phase out HEU now rather than
2 later. But certainly when these new reactors come online,
3 that will also take care of the issue in that both fuel
4 and targets use LEU.

5 This one also in on what I would call a slow
6 timeline. It's about 11 years away before they commission
7 it.

8 Here's one I can get excited about. From the
9 donut, the OSIRIS French reactor is going to be replaced
10 with the Jules Horowitz reactor. And this is a national
11 image from about a year ago of their construction site.

12 So, its plans are approved, construction is
13 underway, they're making great progress and their hope
14 is to have this operational in about three years.

15 But some like the Belgium reactor, the
16 problem with this reactor is that it's really designed
17 only for irradiation testing. They weren't really
18 interested in radionuclide production. So, now it's sort
19 of being added as an afterthought and here's a diagram
20 of their reactor core and test pools and such in that now
21 they figure they can squeeze in moly targets that would
22 maybe be 500 targets a year.

23 They think it can maybe squeeze in a
24 thousand targets a year. But if they put in a thousand,
25 then it starts competing with other targets that they had

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1 originally planned the reactor for. So, it's not an
2 automatic.

3 500 targets a year they estimate would
4 produce about 2,000 six-day curies per week. So, about
5 one-sixth of what we need in the world.

6 So, back to our donut of moly. If we add in
7 the French reactor in three years, their old reactor is
8 eight percent on the right, the new one gets to 25 percent
9 of the world's supply is 17 percent. Some crude drawing
10 skills, and this is what our moly looks like. Still
11 missing 14 percent.

12 At this point, it's too soon to know how soon
13 the Australians will be up and working, but I'd like to
14 think they'd be up and operating far sooner than the other
15 reactors who are a good 11 years away.

16 So, we still have a need for more moly
17 especially here in the US. And hopefully it will come from
18 one of the four projects that currently are underway here
19 in the states that are through the Global Threat
20 Reduction Initiative. That's Department of Energy's
21 national - or security agency or administration, but
22 they're GTRI to get civilian - to reduce civilian use of
23 HEU and replace it with LEU where possible.

24 The GTRI program is providing technical
25 support for these groups through Los Alamos, Argonne

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1 National Laboratories. And they're also providing
2 multi-million dollar grants. And they're also, you know,
3 to date moly production has been in a lot of reactors that
4 have other functions and other support from the
5 governments and there's really not been a true commercial
6 market model for moly.

7 Well, the GTRI is now saying you have to do
8 it with LEU and you have to have full cost recovery. So,
9 it's like get rid of all the fuzzy economics that exist
10 today.

11 And the big issue with that is waste
12 management especially here in the US since there is -
13 well, the waste is an issue. I won't comment any further.

14 So, the first of these projects is with GE.
15 And they were going to redo an old process of neutron
16 activation of the moly-98 cold nuclide to produce
17 moly-99. And this is the way moly used to be produced
18 years ago before fission took over in popularity.

19 The biggest issue with this is that moly
20 produced in this method typically is two to four orders
21 of magnitude less than a fission moly that we produce now.
22 And the problem is, is that then you need to use a bigger
23 column in your generator.

24 The column for an approximate comparison
25 for a fission moly used in the generator today, is about

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1 the size of a piece of chalk from - hopefully you all
2 remember what a chalkboard looks like - versus a column
3 for neutron capture moly is maybe about nine, ten inches
4 tall and about the thickness of a broom handle.

5 So, a much bigger column which produces -
6 which the biggest issue was that it limited the amount
7 of moly that you put on the column. So, the generator
8 should not nearly be as big as what we're accustomed to
9 today.

10 So, GE was trying to address this issue by
11 looking at a technology called gel generator technology
12 that I believe in India they are using, but they've only
13 been - in India, they're only successful with it with very
14 small generators. I don't even think they exceeded one
15 curie in size. So, completely ineffective for our uses.

16 And so, sadly at this point in time, GE has
17 put their program on hold. So, they're no longer an active
18 participant.

19 Another group that's looking is Morgridge
20 Institute of Research. And they've partnered with a group
21 called SHINE Medical Technologies. And they too have
22 gotten awards from - through the GTRI program, but
23 they're working on a brand new program - or process, I
24 should say, for producing moly.

25 And instead of using neutrons from a

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1 reactor, they're trying to use a process of using
2 neutrons that are made from the reactions of two
3 different isotopes of hydrogen, of deuterium, or heavy
4 hydrogen, and tritium.

5 And so, in their proposed accelerator,
6 they'll be pushing ions towards the target chamber - or
7 the deuteron ions, excuse me, the gas flow is
8 accelerated. And the accelerating deuterons strike the
9 tritium gas in the target chamber creating neutrons.

10 And then the neutrons are multiplied by the
11 beryllium multiplier. And then these neutrons strike in
12 the blue segment there, the aqueous LEU target. So, it
13 starts a subcritical fission of the LEU uranium to
14 produce moly.

15 Their projected production rate for a
16 single unit like this that's about six feet tall, would
17 be about 500 six-day curies per week.

18 It is an interesting new process because it
19 doesn't involve a research reactor. However, one of their
20 big challenges will be dealing with the waste, because
21 they still have fission of LEU uranium.

22 A third company is Babcock & Wilcox and they
23 too are pursuing a different technology using what they
24 call a MIPS or a modular isotope production system, where
25 the fuel and the targets are one in the same liquid and

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1 fission occurs.

2 And then at some point in time when they feel
3 there's enough moly has built up in the fission process,
4 they remove the solution, separate out the moly.

5 And of course whenever there's fission of
6 uranium like this with either process, neither process,
7 most processes, only a small percentage can actually
8 fission occurs to produce moly.

9 So, there's substantial cost savings to
10 putting the solution back into the reactor to let it
11 continue to build up its moly production.

12 They've been at this probably the longest
13 of the groups. And as they put it, they have completed
14 Phase 1 which included conceptual design,
15 bioengineering. They've completed research projects
16 with Argonne, Los Alamos, Purdue University. They've got
17 their QA plan in place with the NRC, but then the other
18 challenge is market conditions.

19 And so, actually, they've put their project
20 on hold right now, too. They are not going further yet.
21 So, unfortunately, it too is on hold.

22 So, the fourth group in the US is NorthStar.
23 And they too are proposing a nontraditional method for
24 moly production.

25 Like the Canadians, they are using a

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1 high-power electron beam generated by a linear
2 accelerator. The beam strikes a solid tungsten window and
3 this creates a bremsstrahlung radiation or breaking
4 radiation.

5 And for a quick Physics lesson,
6 bremsstrahlung radiation is electromagnetic radiation
7 produced by deceleration of an electron and deflected by
8 another charged particle. Typically an electron.

9 The electron uses its kinetic energy and
10 it's converted into a photon because as all the
11 physicists will tell you here in this room, energy is
12 conservative.

13 So, and this reaction has a big - again,
14 we're starting - the GE reaction, we're starting with a
15 cold, stable moly-100 in this case. And the photon
16 interacting with the nucleus causes the ejection of the
17 neutron and it's converted to moly-99.

18 So, a huge upside to this process is that
19 there's no fission of LEU. There's no uranium, plutonium
20 or fission waste that they have to deal with.

21 The one downside they do have similar to the
22 GE process, is that it will be low-specific activity. So,
23 that is the challenge, but then they're also working on
24 new technology that I'll explain later to address that
25 issue.

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1 So, I hitchhiked up to Argonne to see their
2 linear accelerator that they're using for their test. And
3 the accelerator they have there, they're using - the beam
4 is - actually from the diagram on the left, the
5 accelerator sits about where it says "Argonne." And the
6 first unit you see is actually the beam splitter.

7 And part of the beam goes to the alpha
8 magnet, which in the photograph above it is the green
9 magnet structure or what I would call a U-turn magnet,
10 but I'm not a physicist. So, then this from one beam,
11 they're able to split it and irradiate the target on both
12 sides. Also in the inset, there's a smaller beam magnet
13 about - like bends at about ten degrees.

14 They have completed some tests on their
15 targets, but right now they're in the process of
16 upgrading the energy of their linear accelerator so they
17 can perform higher energy tests.

18 Now, they're also still moving forward for
19 their production plans and they're going to be building
20 a plant in Beloit, Wisconsin with about 12 or 14 sets of
21 linear accelerators.

22 And in the production plant, they'll have
23 two linear accelerators on each side of the target using
24 - they won't be directly aligned with each other. They'll
25 be offset with using a magnet very similar to the red

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1 10-degree bending magnet.

2 To me, personally, once they're fully
3 operational for the number of linear accelerators
4 they're going to be using, they're going to use the
5 electricity equivalent not to one, but three auto
6 assembly plants.

7 So, instead of having three large auto
8 assembly plants, there's just going to be this one plant
9 drawing the same amount of electricity. That's a lot of
10 electrons.

11 So, the target in moly production, this is
12 the actual target that they're using up at Argonne. In
13 the inset, this is a blown up image of the target holder
14 that has 25 slots in it. Currently they're using little
15 wafers - not wafers, but slugs for an inelegant
16 description, that's about a millimeter to 12 millimeters
17 in diameter. It's about the size of a dime of the
18 moly-100.

19 Now, if you've got two high-energy electron
20 beams on you, you're going to get warmed up. So, to remove
21 the heat from this, they're using helium gas to
22 recirculate through the target. And that's why you can
23 see the two big ports on either side. That's for the
24 helium and flow of cooling system.

25 For their actual production linear

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1 accelerator system, they are planning on using a bigger
2 version of this target where the disc of moly will
3 actually be about 25 millimeters in diameter or about a
4 little bit bigger than a quarter.

5 So, no more physics, but hopefully you're
6 up for a little bit of chemistry here. As I've mentioned
7 before with the GE process and with the NorthStar
8 process, it's low-specific activity moly.

9 So, for a conventional generator system,
10 low conventional - or excuse me - low-specific activity
11 moly would require the larger column reducing the amount
12 of moly they could put on it. So, how to solve this
13 problem.

14 One way is the brand new generator
15 technology that involves what they call ABEC
16 chromatography, which is aqueous biphasic extraction
17 chromatography.

18 In this system, the first generator column
19 is an ABEC column. Or a little bit less of a mouthful would
20 be a primary separating column, or PSC is how we refer
21 to it.

22 The PSC is a polymer, a polyethylene glycol,
23 which is the static chain to the right on a base molecule
24 of polystyrene divinylbenzene. Like I said, the PSC.

25 And it's suitable for a two-phase system of

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1 separating out liquid, separation of metal ions such as
2 moly and technetium.

3 And the first big difference with this type
4 of generator system is that the current generator is the
5 moly on a solid phase aluminum column. In this generator
6 system, the moly is going to be in a liquid solution
7 adjacent to the generator.

8 The first step then would be to pass the moly
9 technetium mixture through the PSC column where the moly
10 has very little affinity for it, but great affinity for
11 the technetium. So, the technetium is going to be
12 extracted and adhere to the PSC while the moly passes
13 through and goes back to the vial.

14 So, this has an advantage in that since the
15 moly is all off or out of the mixture, you just have
16 technetium on your column. You can then pass saline
17 through your PSC to cool off your technetium.

18 And regardless of your low-specific
19 activity moly that you started with, you can get
20 high-specific activity technetium in your collection now
21 which is great for nuclear pharmacies for producing kits
22 as they do now.

23 So, this is a little bit better schematic
24 how the generator will operate. As I said before, the big
25 difference is the moly and the technetium in a mixture

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1 in a solution in a vial separate from the generator.

2 It's pushed through the ABEC PSC column, and
3 this actually shows it going to a separate vial. But in
4 essence, the moly would continue back to the original
5 solution vial.

6 the technetium is then alluded off of the
7 ABEC by saline running through the ABEC through the
8 aluminum guard column. And this is an additional
9 purification step just in case there is any additional
10 - or I shouldn't say additional, I should say residual
11 moly that's on the PSC. It will be trapped by the aluminum
12 on the guard column so to ensure that our final product
13 of technetium is equivalent to what we get now.

14 If you split this diagram in half, you
15 basically have a diagram for the technetium generator
16 that we have now where the moly is on the aluminum column
17 already and we just pass saline through it to pull off
18 the technetium.

19 the other advantage for this system is that
20 once the moly-99 has decayed away, the residual solution
21 can actually be returned to NorthStar and they plan to
22 recover the residual moly-100 that's in the solution that
23 was never irradiated.

24 So, there is of course an expense to having
25 moly-100. So, they're able - part of their economic

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1 market plan is dependent on recycling the unused
2 moly-100.

3 So, this is the current plan they have - or
4 I shouldn't say - version of what they call their
5 TechneGen generator. And this is up at Argonne right now.

6 In it, you can see the two - but at the bottom
7 there at the vertical, those are two syringes that are
8 used for pulling and moving the solutions from the
9 different vials through the different columns.

10 Above them are multi-valve systems with
11 different lines going to the vials or the reagent vials
12 that are on top.

13 To the left you can see a stainless steel
14 and a lead-shielded vial. The one would be for the
15 moly-100 - or excuse me - the moly-99/technetium-99m
16 mixture. The other one is a waste vial.

17 The PSC column would sit - you can see the
18 four vials on top and there's a square lid there. That's
19 where the PSC column actually fits in this unit.

20 Different solutions fit on top, and the
21 technetium collection vial, shielded collection vial,
22 would fit on the far right of this unit.

23 This is - they've gotten to the point where
24 they are - actually, they've been active in talking to
25 the FDA and they're actually very close to submitting

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1 this to the FDA. So, they do have a prototype what they
2 call their moly-technetium reagent kit, which is good for
3 five elutions using this system.

4 In it is the primary separation column which
5 is difficult to see in the bottom right and a clear
6 plastic back. Behind that are the four different reagents
7 that will be used for the elutions.

8 Actually, one of the vials has hydrogen
9 peroxide in it that they'll use to clean and sanitize the
10 pathway of the tubing from the PSC to the collection vial.

11 There's a sodium hydroxide in it, which is
12 the solution used to move the moly-technetium mixture
13 through the PSC to the waste vial.

14 There's also - I forgot to mention this
15 earlier. There's also a vial of sodium acetate that once
16 the moly-technetium mixture has gone through the PSC
17 once, they use sodium acetate to run through it also again
18 as a purification step to pick up any residual moly that's
19 still on the PSC before they elude it to the guard column.

20 Also in this picture on the bottom left you
21 see blue that are small filters, adapters that in this
22 current kit attach to the vials before they put it on top
23 of the TechneGen. And all this right here is good for five
24 allusions.

25 The next part to this process is the

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1 technetium collection kit. And this is what they have
2 with their current version.

3 You have the guard column which is, sadly,
4 difficult to see to the left. In the middle is a new -
5 is a needle that they've worked on. It's actually a
6 two-in-one needle in that one puncture of the septum as
7 a port for flow of the technetium into it. And the other
8 port is used for venting the vial so there's equalization
9 of pressure and it flows easily.

10 The collection vial you see, and also from
11 a nuclear pharmacy perspective our old friend the blue
12 millipore sterilizing filter with a 0.22 pore. And this
13 is actually the same type of filter that's used in current
14 generators right now and its flow pathway.

15 So, this is assembling the collection kit
16 here and it's also showing the two-part lead shielding
17 that's used.

18 The collection vial of course goes in the
19 bottom half on the right. What the picture in the inset
20 is trying to show is this two-part needed. It's there if
21 you strain. I could have used a bigger, better picture,
22 but someone on the staff made a complaint about that, but
23 we won't go there.

24 What you can see just above the inset is the
25 guard column, the blue millipore filter, the dual

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1 two-in-one needle adapter all assembled. And then
2 there's a core plastic shield that goes over that.

3 That whole assembly then goes in the top
4 half of the lead shield that then is put together on the
5 bottom half holding the collection vial. And there's
6 little notches that fit into - or tabs that fit into
7 notches to lock it together securely.

8 This is then put on the right side of the
9 generator. So, you have - it's all set up. Your PSC's in
10 place, your vials, your solutions are in place, the
11 collection vial is there.

12 Then to lift the generator, you hit "Start"
13 on a computer. And the computer controls the vials, the
14 movement of the liquids through the different vials
15 through columns and whatnot. It's a completely automatic
16 process.

17 So, to borrow a line from - ad line from
18 Oldsmobile, this is not your father's generator. So,
19 completely different.

20 You can almost think of this more as a hybrid
21 between what we have for a standard technetium generator
22 now and what we use in PET for F18 and FDG synthesis with
23 the chemical synthesis unit. And likewise with the PET
24 module we add our reagents to it, put our vials, our
25 sterilizing filter in place. Close up the box between the

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1 hot cell and then hit Start on the computer.

2 So, there's been a couple different
3 variations in the FDG modules. More of a second
4 generation module. It would be set up similar to this to
5 where you have individual vials of solutions.

6 Current generations of FDG synthesis
7 modules now have a cassette where each individual vial
8 is already fixed in place into this plastic cassette that
9 can only go in one way into the module.

10 And so, that's a nice difference in that you
11 can imagine at 0 dark hundred in the middle of the night
12 a pharmacist trying to set this up where he might get the
13 vials in the wrong order. If you have this cassette, then
14 it eliminates that possibility.

15 So, and NorthStar is now working on that
16 cassette system. So, they plan to have that with our next
17 generation.

18 So, they have already done some testing with
19 this generation of TechneGen. And they've already tested
20 up solutions up to two curies of moly. And the technetium
21 elutions have passed all QC tests in regards to
22 sterility, pH, moly breakthrough.

23 And then they've also taken these elutions
24 and they've prepared technetium kits with them. And
25 quality control in the kits has also passed all quality

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1 control tests. So, it's a system that's working very,
2 very well.

3 So, this represents Part 2 of their plan.
4 Part 1, of course, is the production of moly. With their
5 process will be a problem with standard generator. But
6 this new technology, it's a very elegant solution.

7 In fact, they plan to go to market using moly
8 produced by the MURR reactor in Missouri using the same
9 process that GE was going to use. That is the neutron
10 bombardment of moly-98 to produce moly-99.

11 So, they're not waiting for their Beloit,
12 Wisconsin facility to be constructed. They're planning
13 then to market, sooner rather than later, using moly from
14 Missouri.

15 And then once their production facility is
16 up and running, they then plan to use just the moly from
17 Wisconsin.

18 Now, the other interesting thing about this
19 generator is that conceptually it can be used for other
20 separations of different parent-daughter radionuclides.

21 And they've already tested it for
22 separating the alpha emitter bismuth-213 from its parent
23 actinium-225. And it's also been used for separating
24 gallium-68 from its parent of germanium-68.

25 So, the ABEC chemistry has other

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1 applications besides technetium and moly that we may see
2 in the future.

3 So, we're making slow progress on new
4 reactors and new LEU targets. We do have some very
5 promising US producers for moly. And we have exciting
6 generator technology on the horizon and soon a new source
7 of moly from the MURR reactor here in Missouri using end
8 gamma reaction stable moly-98, but so far we still don't
9 have a solid and fair - fair plan yet and just how to pay
10 for all this.

11 Perhaps the biggest challenge in this whole
12 process will be obtaining adequate reimbursement, which
13 is of course likely to be for much more expensive moly
14 in the future.

15 So, metaphorically I would say we're
16 between the rock of the GTRI saying no more cheap HEU
17 fission moly for our field, and the hard place of limited
18 additional reimbursement from CMS for more expensive
19 moly. Thank you.

20 CHAIRMAN MALMUD: Thank you, Mr. Mattmuller.
21 Oh, I see we have some questions. Dr. Welsh.

22 MEMBER WELSH: Yes, thank you. Thank you,
23 Steve, for that wonderful presentation. And I can't help
24 but believe that it's not by accident that you omitted
25 one of the major players in this whole arena.

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1 And just in the way of disclosure and
2 fairness, you all know I've been on this committee for
3 about six years and I've given presentations very similar
4 to what Steve has just given.

5 And I think it was Dr. Malmud who said at
6 the conclusion of my presentation that it looks like I'm
7 calling for a very large Manhattan Project scale US
8 effort. And I was, but I've grown tired of holding my
9 breath waiting for that to happen.

10 So, I am on the board of directors for a
11 company that does plan to make moly in the United States.
12 And the name is Co-Key, in the way of disclosure.

13 Just in way of information, this is - the
14 plan is for twin 20 megawatt research reactors to be
15 housed in Gainesville, Florida using in-depth designed
16 LEU fuel, LEU targets just like the OPAL reactor of ANSTO.
17 The projected output is 7,000 six-day curies per week,
18 365 days a year, which is very favorable compared to
19 anything else that's been proposed.

20 And also unlike some of the other innovative
21 technologies mentioned such as neutron capture and
22 photonuclear reactors, this technology makes moly-99 and
23 the therapeutic isotopes that are important to me as a
24 radiation oncologist.

25 Also, unlike some of the other innovative

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1 concepts with low-specific activity moly, this approach
2 uses an FDA-approved extraction method for its moly which
3 is identical to the Australian OPAL reactor.

4 There was a presentation to the NRC on June
5 8th of this year. The environmental report gets submitted
6 in December of this year. So, just a little addition to
7 Steve's otherwise excellent and thorough presentation.

8 CHAIRMAN MALMUD: Thank you, Dr. Welsh. Dr.
9 Van Decker, I believe, was next.

10 MEMBER VAN DECKER: Well, first of all, I
11 want to thank both my colleagues. I thought it was great
12 scientific discussions and it's good to see activities
13 going on, because I think everyone in the clinical realm
14 is worried about the age of the reactors we're working
15 with and the HEU, LEU mandate. And so, you know, concerns
16 about, you know, what's available in the future.

17 I guess my question to both of you, and it
18 has to do with something else going on in parallel, is,
19 "Where do you see the cost of technetium rising to
20 percentage-wise to where it currently is given any of
21 these methodologies and the hoops and the hassles and the
22 push buttons and - because access, I mean, access to the
23 patient is obviously the bottom line of this, right? So,
24 ballpark?"

25 MEMBER MATTMULLER: Ballpark, easily double

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1 the cost of moly is what I've read and seen, but that's
2 for moly.

3 And so, in a good, efficient nuclear
4 pharmacy for every atom of moly or every millicurie of
5 moly, you can get five millicuries of technetium out in
6 a dose.

7 So, if there's a hundred percent increase
8 in moly, then there's a 20 percent increase in technetium
9 to the patient.

10 So, and this gets to be very contentious in
11 different economic models of the different groups.
12 There is the OECD, which is a European group mostly the
13 US is participating in. And they're looking at it and
14 they're just starting - or have just started a more
15 in-depth analysis of trying to get a better handle on
16 this.

17 It's hard to get good data from the
18 different manufacturers, different reactors. Some of
19 this is market sensitive data that they don't like
20 sharing. Some of the reactors get different levels of
21 government support. So, it's hard to figure out what it
22 really costs to make the moly.

23 Some of these reactors have other functions
24 as far as test facilities that generate income in that
25 regard as opposed to a reactor dedicated just to moly

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1 production.

2 MEMBER VAN DECKER: So, the business model
3 concern of this is obviously you well alluded to, you
4 know, the CMS draft rule starting January 1st has put into
5 place a tiny incentive -

6 MEMBER MATTMULLER: Yes.

7 MEMBER VAN DECKER: - to the end producer.

8 MEMBER MATTMULLER: Yes.

9 MEMBER VAN DECKER: A tiny incentive to the
10 end user -

11 MEMBER MATTMULLER: Yes.

12 MEMBER VAN DECKER: - to purchase
13 LEU-produced moly.

14 MEMBER MATTMULLER: Right.

15 MEMBER VAN DECKER: Buy a new coding system
16 and add on the administrative cost in order to
17 incentivize the use of LEU from overseas rather than HEU.

18 MEMBER MATTMULLER: Right.

19 MEMBER VAN DECKER: The odds of that going
20 up the supply chain to all the people you just put there
21 to really making LEU-produced moly easily available -

22 MEMBER MATTMULLER: Right.

23 MEMBER VAN DECKER: - is, unfortunately,
24 unlikely to be the case by any stretch of the imagination
25 although it's kind of an interesting concept. And

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1 obviously it is an investment of money that's going up
2 the chain and then going overseas.

3 So, you know, the concept of having an
4 investment at home that pushes science and technology and
5 may have other pieces to it, obviously, is attractive so
6 long as, obviously, the cost containment - and the
7 healthcare cost containment era also is a piece of the
8 puzzle.

9 MEMBER MATTMULLER: That's a great summary
10 as to why I put "fair," because - into my last statement
11 about fair reimbursement. Because what CMS is proposing
12 in a perfect world would work if everyone switch from LEU
13 to HEU moly at once and everything was then HEU, but this
14 is a gradual phase-in process for drop of HEU, increase
15 of LEU.

16 And so, how does a producer keep track of
17 this moly came from HEU, this came from LEU, this is
18 eligible for the additional payment, and then the
19 generator manufacturer has to keep track of it, and these
20 reactors don't operate every day of the week throughout
21 the year, you know, they have to shut down for maintenance
22 and such.

23 So, the pharmacy could have a generator with
24 LEU-produced moly in it this week. The same generator
25 next week would be HEU. So, then how do you keep track

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1 of that with your different customers and they keep track
2 of it to say, okay, I can charge \$10 more for this.

3 It's very, very cumbersome and complicated
4 and impractical.

5 CHAIRMAN MALMUD: Dr. Suleiman.

6 MEMBER SULEIMAN: Nice presentation. I've
7 been involved with the OECD group and typical technetium,
8 it depends on the drug, which costs differently, run
9 around four to \$700 for the entire procedure.

10 The cost of the technetium-99 component
11 depending on the size of generator you buy, whatever, has
12 been estimated to be in the several dollar range.

13 When CMS made the decision to go with a \$10
14 - July 6th they proposed in a Federal Register document
15 to reimburse preferentially an additional \$10 for
16 LEU-manufactured technetium-99. And the intent of that
17 was to stimulate, because you now have all the molybdenum
18 coming from Australia and from - South Africa also sends
19 a pure LEU-based moly. It's not all being sold.

20 Because right now even though at some point
21 the NRU, the Canadian reactor is going to go offline, they
22 are online right now and they're producing a significant
23 amount of HEU-produced moly. So, you have a financial
24 disparity.

25 So, the intention was to sort of stimulate

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1 and get people to start buying the LEU-produced moly-99
2 and give them a \$10 out of a \$700 - one of the companies
3 has actually stated that they will be producing 100
4 percent LEU-based moly effective next year.

5 And the other question is, will there be
6 people who are willing to buy? You know, is that, or isn't
7 it? I mean, I've raised the question where I've heard the
8 critics and I said, it's just an experiment. If there are
9 no takers, then it will fail.

10 This is just intended to make the transition
11 smoother. CMS shouldn't have bothered with the \$10
12 simulation and wait for the reactor in 2016 to shut down.
13 The transition will happen. It will just be much more
14 bumpy.

15 So, I think CMS over and above their usual
16 work, you know, made an effort to try to help stimulate
17 this transfer. So, that's the intent there.

18 The comment was published July 6th. So, I
19 guess they'll come out - they do this annually. So, you
20 talk about getting rulemaking. It's always fascinating
21 for the regulatory agencies, but every year they
22 apparently do this to set the prices for Medicare
23 reimbursement on an annual basis.

24 So, they say this is what we're going to pay
25 for next year, and we publish it and they allow people

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1 to comment for 60 days. And they do this every, you know,
2 every year. So, I assume there will be some sort of final
3 decision on this.

4 But right now there's actually a large
5 supply of molybdenum out there. And the firms that have
6 invested in the LEU production were sort of saying, we're
7 there, but there aren't any buyers.

8 Now, clearly that will shift dramatically
9 in 2016. So, I think things are moving in the right
10 direction, but the cost, the technetium component of the
11 total procedure, including the drug, is extremely,
12 extremely small, you know.

13 CHAIRMAN MALMUD: I think the encouraging
14 news is that there are many different groups working on
15 this. And, therefore, the marketplace will dictate which
16 are or which one is successful.

17 Hopefully it will be more than one
18 successful one and try and keep the cost as low as
19 possible in the open marketplace.

20 So, it's encouraging because only last year
21 there was gloom and doom with regard to the supply of moly
22 for the production of technetium, and now it's much more
23 optimistic. So, we thank you for a very thorough
24 presentation and I think we're all encouraged by it.

25 If we may, we'll move on to the next item

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1 on the agenda, which is NRC staff. And I think - is Sophie
2 Holiday going to do the work? Yes, Ms. Holiday.

3 MS. HOLIDAY: Hello, everyone. All right.
4 This is our favorite part where we pull out our calendars.
5 We're going to pick our tentative dates for the spring
6 2013 meeting.

7 As you may recall, I sent out a Meeting
8 Wizard scheduler where everybody gave feedback for their
9 possible open dates.

10 One thing I want to mention before I give
11 these dates is the Committee has brought up that they
12 would like to meet with the Commission. I have tentative
13 dates that are possible for us to meet with the
14 Commission, and then I have a separate set of dates where
15 if you would like to plan it without having a Commission
16 meeting.

17 CHAIRMAN MALMUD: What are the possible
18 dates for the Commission?

19 MS. HOLIDAY: Okay. The number one choice for
20 a possible Commission meeting would be April 22nd and
21 April 23rd. That would be a Monday and a Tuesday.

22 CHAIRMAN MALMUD: Well, what about choosing
23 that one preferably if we can get a group together since
24 that would be able to reduce the number of travels.

25 MS. HOLIDAY: Okay.

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1 CHAIRMAN MALMUD: How about the 22nd and
2 23rd?

3 MS. HOLIDAY: Okay.

4 CHAIRMAN MALMUD: Is anyone not available
5 the 22nd and 23rd of April?

6 MEMBER PALESTRO: I'm not.

7 CHAIRMAN MALMUD: Chris, you're not.

8 MEMBER PALESTRO: No, I'm not.

9 CHAIRMAN MALMUD: How about April 15th and
10 16th?

11 MS. HOLIDAY: The only other date that would
12 be available for the Commission would be May 13th and May
13 14th.

14 CHAIRMAN MALMUD: May 13 and 14?

15 MS. HOLIDAY: Yes, and that's another Monday
16 and Tuesday.

17 CHAIRMAN MALMUD: May 13, 14, anyone not
18 available then?

19 MEMBER PALESTRO: Me again.

20 CHAIRMAN MALMUD: Well, if that's not
21 possible, then we would have to have a small group come
22 down and meet with the commissioners on a separate day.

23 So, it looks like April is shot if Dr.
24 Palestro can't make the 13th and 14th. There are no other
25 two other days available that don't conflict with the

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1 National meeting.

2 So, let's go back to March.

3 MS. HOLIDAY: So, if we were to consider days
4 where we know the Commission is not available, it seems
5 like the best date for everybody where I did not see
6 conflict was April 15th and 16th. That's also another
7 Monday and Tuesday.

8 CHAIRMAN MALMUD: Is everyone available
9 April 15th and 16th?

10 MEMBER MATTMULLER: Can we bring our tax
11 accountants with us?

12 (Laughter.)

13 CHAIRMAN MALMUD: April 15th, 16th sold.

14 MS. HOLIDAY: Okay. So, I'll put that as our
15 first choice.

16 Now, we actually have a couple of choices
17 as our backup dates. I have Thursday, April 18th, and
18 Friday, April 19th.

19 CHAIRMAN MALMUD: Is everyone available for
20 that date?

21 MEMBER PALESTRO: That's the ABS meeting.

22 MS. HOLIDAY: ABS?

23 CHAIRMAN MALMUD: 18th and 19th, so that's
24 out.

25 How about April 22, 23? Not available, all

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1 right.

2 April 29, 30 as the backup date.

3 MS. HOLIDAY: Dr. Palestro, are you
4 available at that date?

5 MEMBER PALESTRO: Yes.

6 MS. HOLIDAY: Okay.

7 CHAIRMAN MALMUD: Looks like we have no
8 indication of unavailability on that date. So, that could
9 be our backup, 29, 30.

10 MS. HOLIDAY: Okay. So, then I have our
11 first choice is April 15th and 16th, and our backup date
12 would be April 29th and 30th.

13 And then, if it helps, then we could arrange
14 a separate meeting with the Commission with a smaller
15 group.

16 CHAIRMAN MALMUD: Yes.

17 MS. HOLIDAY: Do we have a problem with
18 meeting those dates or those proposed - no, okay. And,
19 actually, I have a handout to pass out.

20 (Pause in the proceedings.)

21 MS. HOLIDAY: Just one sheet. This is the
22 portion where we go over our recommendations and our
23 action items that were brought forth during these two
24 days.

25 (Pause in the proceedings.)

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1 MS. HOLIDAY: Okay. Item Number 6, Dr. Malmud
2 asked NRC staff to find data on events in which the
3 radiopharmacy has dispensed the incorrect amount of a
4 radiopharmaceutical. That is an NRC action item.

5 Are there any questions, comments or
6 concerns with that item?

7 MEMBER WEIL: Did we ask for a broader range
8 of incorrect administrations or dispensing? Was it just
9 incorrect amount? Was it incorrect isotope? I mean, it
10 was a request for error.

11 CHAIRMAN MALMUD: Yes, the issue was the
12 usefulness of the dose calibrators.

13 MEMBER WEIL: Right.

14 CHAIRMAN MALMUD: And, therefore, it was
15 specific to the dosage.

16 MEMBER WEIL: Just to dosage.

17 CHAIRMAN MALMUD: The dose calibrator would
18 not be intended to detect the wrong isotope, although it
19 -

20 MEMBER WEIL: But it would.

21 CHAIRMAN MALMUD: - would by accident, yes.
22 We discussed that, but we did ask for - do you want to
23 broaden the request to incorrect pharmaceutical -

24 MEMBER WEIL: If that's feasible.

25 MR. EINBERG: It is feasible.

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1 MS. HOLIDAY: Okay.

2 MR. EINBERG: We're already doing this
3 preliminary -

4 CHAIRMAN MALMUD: Might as well.

5 MR. EINBERG: We're already looking at some
6 preliminary numbers, but we don't have the capability
7 in-house to do a detailed search. So, we're going to -
8 but in the past 10 years there has been 650 human errors.

9 And so, from that we need to refine the
10 dosage in isotopes.

11 MEMBER WEIL: Ten years?

12 MR. EINBERG: Ten years. And that's a
13 preliminary number.

14 MS. COCKERHAM: Dr. Malmud?

15 CHAIRMAN MALMUD: Yes.

16 MS. COCKERHAM: Could I just ask Ms. Weil if
17 their revision on the screen reflects what you - the
18 clarification now?

19 MR. EINBERG: Can you read it for us?

20 MS. COCKERHAM: Sure. It says Dr. Malmud
21 asked NRC staff to find data on events in which the
22 radiopharmacy has dispensed the incorrect amounts of a
23 radiopharmaceutical or the incorrect
24 radiopharmaceutical.

25 CHAIRMAN MALMUD: Thank you.

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1 MS. HOLIDAY: Okay. Moving on to Item 7, the
2 ACMUI recommends licensing radium-223 dichloride under
3 10 CFR 35.300 and recommends, but does not recommend
4 requiring direct measurement of activity before and
5 after administration.

6 CHAIRMAN MALMUD: Correct.

7 MS. HOLIDAY: Okay. Moving on to Item 8, the
8 ACMUI endorses the Committee report that was submitted
9 on July 16th, 2012 with the following changes. We just
10 wanted to make sure we captured this in open form directly
11 what we wanted to change in the report.

12 Number 1 was recommend licensing of
13 radium-223 dichloride under 10 CFR 300 and recommend, but
14 not require, direct measurement of activity before and
15 after administration.

16 Number 2, remove statement regarding
17 applicability of report for all future alpha-emitting
18 particles.

19 And Number 3, remove the statement
20 regarding radium-223 dichloride significantly
21 prolonging survival. The ACMUI will submit a report to
22 the NRC staff with the aforementioned changes.

23 CHAIRMAN MALMUD: We all agree.

24 MS. HOLIDAY: Okay. Moving on to Item 9, the
25 ACMUI requested that the reporting structure reviews

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1 remain on an annual basis.

2 CHAIRMAN MALMUD: Correct.

3 MS. HOLIDAY: Okay. Moving on to Item 10,
4 today Dr. Malmud created a subcommittee to review the
5 refined abnormal occurrence criteria and provide
6 recommendations to NRC staff.

7 The subcommittee members include Dr.
8 Langhorst as the chair - oh, I'm sorry, that's supposed
9 to be Ms. Bailey, Ms. Weil, Drs. Palestro, Dr. Welsh, Dr.
10 Thomadsen and Mr. Mattmuller. The NRC staff resource
11 person will be Ms. Angela McIntosh.

12 CHAIRMAN MALMUD: That is correct.

13 MS. HOLIDAY: Okay. And our last item is Dr.
14 Langhorst asked NRC staff to provide direction as to
15 whether or not the trigger criteria needs to be a part
16 of the abnormal occurrence criteria, or if the trigger
17 criteria could be used separately.

18 Did I capture that correctly?

19 CHAIRMAN MALMUD: That's correct.

20 MEMBER LANGHORST: Yes.

21 MS. HOLIDAY: Okay. And then of course the
22 last item which has not been entered yet is that we have
23 proposed that the spring 2013 meeting date will be April
24 15th and 16th, with a backup date of April 29th and 30th.

25 CHAIRMAN MALMUD: Correct.

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1 MS. HOLIDAY: Okay. So, now I just want to
2 touch upon the last bit of administrative items. For
3 those of you who did not submit a financial disclosure
4 form, I will send you the address via email.

5 At this time, could you remove your name
6 tags? I will need those for the next meeting. And, also,
7 could you write down your hours for the pay period so that
8 I can submit that as well? And that concludes my
9 presentation.

10 (Discussion off the record.)

11 CHAIRMAN MALMUD: If there are no other items
12 for presentation, we will adjourn the meeting to meet
13 again in April on the dates we have determined to be dates
14 set, and the backup date as well. Thank you all. I thank
15 you all for your participation and presentations. Thank
16 you, and have a safe trip home. Look forward to seeing
17 you at the next meeting.

18 (Whereupon, the above-entitled matter went
19 off the record at 12:36 p.m.)

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