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Open Session

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

OPEN SESSION

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MEETING

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TUESDAY,

SEPTEMBER 30, 2014

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The meeting was convened in room T2-B3 of
Two White Flint North, 11545 Rockville Pike, Rockville,
Maryland, at 8:00 a.m., Bruce R. Thomadsen, Ph.D., ACMUI
Chairman, presiding.

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1 MEMBERS PRESENT:

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

3 MILTON J. GUIBERTEAU, M.D., Vice Chairman

4 PHILIP O. ALDERSON, M.D., Health Care
5 Administrator

6 FRANCIS M. COSTELLO, Agreement State
7 Representative

8 VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

9 SUSAN M. LANGHORST, Ph.D., Radiation Safety
10 Officer

11 STEVEN R. MATTMULLER, Nuclear Pharmacist

12 CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine
13 Physician

14 JOHN J. SUH, M.D., Radiation Oncologist

15 ORHAN H. SULEIMAN, Ph.D., FDA Representative

16 LAURA M. WEIL, Patients' Rights Advocate

17 JAMES S. WELSH, M.D., Radiation Oncologist

18 PAT B. ZANZONICO, Ph.D., Nuclear Medicine
19 Physicist

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1 NRC STAFF PRESENT:

2 RAYMOND LORSON, Acting Deputy Director, Office of
3 Federal and State Materials and Environmental
4 Management Programs

5 LAURA DUDES, Director, Division of Materials
6 Safety and State Agreements

7 SUSAN ABRAHAM, Acting Deputy Director, Division
8 of Materials Safety and State Agreements

9 MICHAEL FULLER, Designated Federal Officer

10 SOPHIE HOLIDAY, Alternate Designated Federal
11 Officer, ACMUI Coordinator

12 MARYANN ABOGUNDE, FSME/MSSA/RMSB

13 LUIS BENEVIDES, Ph.D., RES/DSA/RPB

14 DOUGLAS BOLLOCK, FSME/MSSA/RMSB

15 SUSAN CHIDAKEL, OGC/GCLR/RMR

16 JACKIE COOK, RIV/DNMS/NMSB-B

17 SAID DAIBES, Ph.D., FSME/MSSA/RMSB

18 GINA DAVIS, FSME/MSSA/RMSB

19 SARA FORSTER, RIII/DNMS/MLB

20 CASSANDRA FRAZIER, RIII/DNMS/MLB

21 SANDRA GABRIEL, Ph.D., FSME/MSSA/RMSB

22 LATISCHA HANSON, RIV/DNMS/NMSB-A

23 MICHELLE HAMMOND, RIV/DNMS/NMSB-B

24 VINCENT HOLAHAN, Ph.D, FSME/MSSA

25 DONNA-BETH HOWE, Ph.D., FSME/MSSA/RMSB

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1 ANGELA McINTOSH, FMSE/MSSA/RMSB
2 KEVIN NULL, RIII/DNMS/MLB
3 PATTY PELKE, RIII/DNMS/MLB
4 GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB
5 KATIE TAPP, Ph.D, RES/DSA/RPB
6

7 ALSO PRESENT:

8 JENNIFER ELEE, Conference for Radiation Control
9 Program Directors
10 RONALD ENNIS, M.D., American Society for
11 Radiation Oncology
12 LYNNE FAIROBENT, American Association for
13 Physicists in Medicine
14 DEBBIE GILLEY, *presenting on behalf of*
15 *International Atomic Energy Agency **
16 STEVEN J. GOETSCH, Ph.D., Dade Moeller Health
17 CAITLIN KUBLER, Society of Nuclear Medicine and
18 Molecular Imaging
19 MICHAEL PETERS, American College of Radiology
20 GLORIA ROMANELLI, American College of Radiology
21 CINDY TOMLINSON, American Society for Radiation
22 Oncology
23 C. GIBB VINSON, Illinois Emergency Management
24 Agency
25 MARK WILLIAMS, Tripler Army Medical Center

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PAUL YURKO, Veterans Health Administration

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3

* Present by teleconference

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P R O C E E D I N G S

8:01 a.m.

1
2
3 CHAIRMAN THOMADSEN: Good morning and
4 welcome to the second day. We're going to be starting
5 off this morning talking about reporting mechanisms for
6 events. We have presentations from four organizations
7 that we'll be listening to, and then we will have
8 discussions after all four of the -- after the
9 presentations.

10 We will have first a description of the
11 RO-ILS system that's run by ASTRO and AAPM. That will
12 be given by our member-to-be soon, Ron Ennis. Then we'll
13 be having the CRCPD by Jennifer Elee. We'll be having
14 the SAFRON system by Debbie Gilley, and somewhere in
15 there, I guess between the CRCPD and SAFRON, I will be
16 giving a presentation on the CARS system. With that,
17 we'll start with Dr. Ennis.

18 DR. ENNIS: Good morning, everyone.
19 Certainly it's a little easier, having met everyone
20 yesterday, but I'm now wearing an ASTRO hat, if you
21 would, and presenting on something I'm actually very
22 excited about, and the Society is very excited about.
23 And it is a new initiative for the Society but dovetails
24 very well with the interests of this Committee in terms
25 of radiation safety. And it is a systemwide -- a

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1 specialty-wide national system for reporting medical
2 events or near medical events going by the acronym
3 RO-ILS. And the mission of this is to help facilitate
4 safer and high quality care, while providing a mechanism
5 for shared learning in a secure and non-punitive
6 environment. And of the two ranges there, the most
7 important is shared learning and secure and
8 non-punitive environment.

9 Shared learning, obviously, has tremendous
10 value, instead of each department discovering errors on
11 their own, and not being able to share with others, this
12 will allow us to learn from group events, and some of
13 the prior events that have occurred that have gotten
14 some note may have been able to be prevented based on
15 anecdotes if we had had a system which had been able to
16 share information back in the '90s and early 2000s.

17 And to get information that is complete and
18 honest, the secure non-punitive environment is
19 essential.

20 So, this is the only medical specialty
21 sponsor incident learning system radiation oncology,
22 and as you heard sponsored both by ASTRO and AAPM. It's
23 web-based, and it's collecting information about actual
24 errors and also near misses. And it's, like I said
25 before, also a national system where each institution

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1 will enter their information.

2 There's a diagram here at the local
3 facility that joins the system will have their own
4 database, and then send it on to the patient safety
5 organization; and they could do what they want with
6 their own local data, but the national data will be
7 analyzed by a committee and reports will be generated,
8 and information will be shared with everyone.

9 It's to collect incidents, meaning some
10 type of harm, even the minor, the vast majority of
11 incidents are really extremely minor as well, but
12 nevertheless are incidents that could have been worse.
13 Even near misses are encouraged to be included. In fact,
14 it's really crucial that they're included because there
15 are more of them, and they could translate into
16 incidents, if not something else after them, and then
17 the unsafe condition also that increases the
18 possibility of an event.

19 So, the local data is seen only by their own
20 institution, and then it's uploaded to the national
21 system it's anonymized so no one will know that it was
22 Roosevelt Hospital that had that event, for example, it
23 will be anonymized which, again, encourages people to
24 be able to send in the data and contribute in an honest
25 way.

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1 And this is kind of -- it's a web-based
2 entry system, and what it looks like. You will be able
3 to pick the event type, so it could external beam, it
4 could be brachytherapy, it could be radiopharmacy,
5 whatever the options are, and various information about
6 the event, who's reporting it, so there's the options,
7 for example, what type of event it was. And, obviously,
8 for this Committee particularly interested in the
9 brachytherapy, radiopharmaceutical, although external
10 beam would also be of interest to this Committee. And
11 just, again, more information. It's just a bunch of, you
12 know, so I'll try to make it easy and straightforward,
13 but also just for text because there are certain things
14 about any event that are not easily clickable because
15 they are unique to that event and require some free text.

16 But the particular things that are going to
17 be asked for in the different pages are, you know, what
18 kind of dose deviation there was, how much under/over
19 dose, whatever the issue was, what kind of technique was
20 used, the patterns and techniques, especially the newer
21 techniques as they come out, are we seeing something in
22 this new technique that is, you know, an issue. And,
23 again, having the national view will be really helpful.
24 Imaging is crucial now, radiation oncology in terms of
25 using -- so, obviously, it's something in the type of

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1 imaging that's being done, the kind of equipment that's
2 being done, and then some kind of measure of how bad this
3 is in terms of likelihood to perform, severity scales,
4 toxicity scales, it was a toxicity, and whatever the
5 people entering it think might have been contributing
6 factors.

7 So, it was beta tested beginning about a
8 year ago, and open for more general -- for general
9 people to sign up as of June 19th. Already, 19 contracts
10 were signed covering 46 treatment sites with another 29
11 contracts and more sites working their way through their
12 respective processes within their institutions,
13 getting them to sign a contract with the vendor, who has
14 been contracted, Clarity, there are 120 reports in
15 there. That'll give you a snapshot of what that looks
16 like. It's not meaningful data yet, all 120 reports. I
17 don't think there is anything that has jumped out in
18 these reports, and the committee is starting to kind of
19 figure out how they're going to analyze this data.

20 Just to give you a flavor, so 42 percent of
21 what's been reported so far were actually incidents, and
22 31 percent were near misses, and 26 percent unsafe
23 conditions, so that's kind of a nice spread, and kind
24 of justifies looking at all three of these aspects,
25 being recorded by the physicist or the therapist, but

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1 even by administrators occasionally, as well, which is
2 also I think a positive that within the institutions
3 that are doing this, people from a variety of places,
4 if you will, people are comfortable entering the data
5 which is part of the idea that anyone can be able to enter
6 the data, or anyone at least the institution designates.

7 The vast majority are external beam so far,
8 which I guess is maybe a little less interesting to this
9 Committee. Although I'm thinking about ViewRay™ and
10 other things like that, some of that comes under the
11 purview of this Committee, a couple of brachytherapy,
12 no radiopharmaceutical events yet. And this is kind of
13 more to the -- you know, what type of treatments, so most
14 of it is 3D reflecting practiced, IMRT, again in terms
15 of issues that the Committee will look at, when they
16 share them, wanting to capture events. I don't know how
17 there's no brachy, so some data entry issues there. But,
18 basically, a big spread in terms of what we do.

19 And this is an interesting question,
20 whether the event that's being reported had occurred to
21 anyone else, so what is a single patient event and, you
22 know, vast majority is a single patient, as I think you'd
23 expect, but there were a few that are multiple, so
24 already raising the flag that this is a significant
25 issue, potentially.

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1 And that's the overview of the system. As
2 we get more data and we make more findings I suspect
3 we'll be able to share that, as well. You probably all
4 know Cindy who is in the back, and if you want to find
5 out more, she's our ASTRO native analyst.

6 VICE CHAIRMAN GUIBERTEAU: Okay. Are there
7 any questions at the moment? Yes?

8 MEMBER ZANZONICO: Just looking through the
9 handouts of the slides and these four topics, these four
10 presentations, including this one, they seem to be
11 external therapy, and to a lesser extent brachytherapy
12 centric. And I'm just wondering what kind of outreach,
13 if that's the right word, to say nuclear medicine and
14 radiopharmaceutical diagnosis or therapy, because it
15 just doesn't seem -- these sort of databases don't seem
16 to be as high profile an issue say than SNM and the
17 Molecular Imaging Society as they are in the therapy
18 societies. I'm just wondering what kind of outreach
19 there is to those disciplines.

20 DR. ENNIS: All right. So, I can't --

21 CHAIRMAN THOMADSEN: I can answer that, in
22 that one of the frequent questions we get when we're
23 talking with potential clients is will we also log
24 imaging events. And the problems with doing that is for
25 the therapy, the AAPM led an effort which was joined by

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1 ASTRO, all of the professional radiotherapy societies,
2 several government agencies to come up with a data set
3 that would capture the essence of radiotherapy events.
4 And both the AAPM and we use that data set.

5 There is no data set for imaging events, and
6 the AAPM is in the process of trying to establish a task
7 group to do exactly the same thing for imaging right now.
8 But at the moment, there is no agreed upon data set, so
9 we couldn't capture the events officially.

10 VICE CHAIRMAN GUIBERTEAU: Dr. Suleiman.

11 MEMBER SULEIMAN: This is an area, I'm
12 really glad you brought it up, Pat, because it's an area
13 that I've had concern with in nuclear medicine events.
14 Mainly, you've seen hair loss, and you've seen erythema,
15 and you've seen skin necrosis, and the reason for that
16 is the skin gets the highest dose. With nuclear
17 medicine, the source is internal.

18 I've seen in clinical trials, but these are
19 public events, but there have been cases in clinical
20 trials where the wrong organ has been destroyed because
21 of -- for a number of reasons and faults that the
22 investigators admitted to after the fact. But what you
23 don't see, you're not going to report. And then there's
24 the inherent bias of not reporting it in the first place.

25 Most of my experience with x-ray

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1 fluoroscopy years ago was when people were getting
2 erythema, the dermatologist gave them some cream. I
3 mean, they didn't recognize that as a radiation event.
4 And I'm going to share this story with you, because I've
5 raised this question.

6 If you go through the numbers and you see
7 -- I'm not saying you're going to see a single nuclear
8 medicine event that's going to cause a serious
9 biological event, but there have been lots of
10 presentations where some people in health care systems
11 have undergone 10 to 15 imaging systems.

12 Let's say for cardiac, if these people are
13 ill, they undergo multiple procedures, they may be
14 nuclear, they may be fluoro, they may be whatever. Well,
15 the body doesn't care where it's getting the radiation,
16 so I've always wondered how is that -- you know, is that
17 a hidden concern that we haven't -- that hasn't really
18 surfaced, though some people have raised that.

19 But I raised this question in a meeting at
20 the Agency, and somebody who headed up a major
21 institutional nuclear medicine clinic said we've seen
22 it. I said what are you talking about? We've seen
23 patients after a procedure where the skin gets red, but
24 it goes away. So, that was the extent of our
25 communication, so in the back of my mind I'm saying well,

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1 did this patient possibly receive some radiation from
2 other procedures, and then along comes the cardiac scan
3 and puts it over some conceptual threshold, and then it
4 resulted in a mild erythema and it went away, but it's
5 suggestive. And I'm concerned, and I -- but how would
6 you capture that? How would you capture that? You don't
7 want to start calling false alarms if you have a lot of
8 other skin diseases or reactions that basically are not
9 attributable to radiation.

10 VICE CHAIRMAN GUIBERTEAU: Dr. Dilsizian.

11 MEMBER DILSIZIAN: You know I'm clinically
12 doing nuclear medicine to cardiology. There are a lot
13 of patients that have CT scans followed up with nuclear
14 medicine diagnostic studies and therapeutics. If you
15 really do the accumulated dose, it's never going to be
16 what you are proposing. It's really not that concerning.

17 And, again, what we're trying to do here is
18 make sure the patients get proper clinical care and
19 benefit versus risk. And this comes up all the time. I
20 think that the concern of radiation is important if it's
21 done in all volunteers and some research protocol. If
22 someone has a brain tumor, or would have breast cancer
23 and we need to CT scans, or PET imaging, and appropriate
24 brain scans, and you're talking about accumulated dose,
25 it's really insignificant compared to the patient care.

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1 So, I wouldn't want to minimize what you're saying. I
2 think that whatever you're saying is very rare, it's not
3 the common, and I don't think that's a real concern.

4 If it's a misadministration, that's fine,
5 but for patients who are getting multiple studies it's
6 always clinically indicated. No one is doing it just for
7 fun.

8 MEMBER SULEIMAN: I'll agree with you on the
9 one hand, and I'll disagree with you on the other. I'm
10 not saying -- the risk from any single exam is never
11 justification to not do that exam. These are all
12 patients, I understand that. But by being aware that
13 these doses can add up, it ought to put pressure on the
14 entire community to get the doses as low as reasonably
15 achievable. So, I think from that point of view maybe
16 -- and when mistakes happen it's not the mainstream
17 people, it's the tail end of the distribution, so if
18 those are occurring we can't just say they're not really
19 occurring, or they're infrequent. It's just that maybe
20 they are occurring, but it would be nice to find some
21 and then sort of trace the case history. Why did this
22 person --

23 MEMBER DILSIZIAN: But none of us -- I mean,
24 all of the things that we do are FDA-approved package
25 insert guidelines. The doses we use are as low as

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1 possible. We've been all very sensitive to image wisely.
2 We are giving the lowest doses possible, and I don't
3 think can avoid patients having multiple studies,
4 patients, not volunteers, who are going to have several
5 nuclear studies, plus CT, plus contrast. And that's
6 always going to be for the patient care.

7 And I can tell you that there was a
8 particular occasion that was being referred to a sixth
9 PET-CT within three months, and the patient brought up
10 the concern "am I getting a lot of radiation", which was
11 a reasonable question. So, the oncologist came to me and
12 said what will I tell the patient? So, I said very nicely
13 that you give 10 millicurie dose of FDG. The incremental
14 risk over what naturally would occur for cancerous is
15 25 percent. It would be 25.0027, so is that really a
16 concern for patient management in three months for
17 breast cancer, or is this something that we should be
18 worried about? See, so we have to put this in context
19 of what is incremental risk for any procedure given what
20 the disease condition is.

21 MEMBER SULEIMAN: I didn't mean to drag us
22 off into that area. I mean --

23 VICE CHAIRMAN GUIBERTEAU: Dr. Palestro.

24 MEMBER PALESTRO: Yes, just really two
25 comments. One, in response to what Orhan just said. The

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1 fact that someone's skin turns red in a particular area
2 and someone has seen it after an injection of a
3 radionuclide doesn't necessary apply cause and effect.
4 That could be due to any one of a number of things. It
5 could be due to an allergy to a compound that has nothing
6 to do with radioactivity, to the materials that we just
7 to inject and so forth. So, I think these sorts of
8 anecdotal observations sometimes create more problems
9 than they solve. So, that's my comment on that.

10 And then, Ron, I have a question for you.
11 In terms of this system, which actually seems very
12 intriguing, you either said or I understood that there's
13 a cost involved to participate in this. Am I correct?

14 DR. ENNIS: No.

15 MEMBER PALESTRO: No, it's free. Okay.
16 There's a contract then, it's a contract.

17 DR. ENNIS: Right. You agree to the
18 liability.

19 MEMBER PALESTRO: Okay.

20 VICE CHAIRMAN GUIBERTEAU: Ms. Elee.

21 MS. ELEE: I was going to comment, and I'm
22 digging way back in my brain, but when we first at CRCPD
23 started our venture, which we'll go into in just a
24 minute, on the diagnostic side because we are the only
25 ones that really kind of tried to tackle that animal.

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1 And it did come up about patients who have multiple
2 exams, and then had an effect, but it doesn't really fit
3 into what we're looking at, because all of those exams
4 individually are fine and warranted. That's the risk
5 versus benefit, but then in the end you may have an
6 effect. And there's -- how do you capture that, you
7 know. It's not an event, it's not a -- you know what I
8 mean? It just didn't fit into what we were looking at
9 the time.

10 MEMBER SULEIMAN: And it's no different than
11 the cancer patient --

12 DR. ENNIS: And that would include -- yes.

13 MEMBER SULEIMAN: It's no different than a
14 cancer patient who undergoes multiple therapies. They
15 know they're getting higher risk from --

16 DR. ENNIS: Right. And the second thing,
17 it's hard to track. I mean, it's really -- if they're
18 having them all done at one facility, then you are
19 probably aware that they're having all of those
20 procedures done. But today they may be having them at
21 multiple sites which makes it even more difficult to
22 correlate.

23 VICE CHAIRMAN GUIBERTEAU: I think there's
24 a very interesting discussion, just to put a brief
25 perspective on it, because I know this is a side issue,

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1 is that with the advent of electronic medical records
2 and PACS systems, the Arsinay Consortium of
3 Radiological Organizations is putting together
4 programs by which institutions may share patient
5 information. Because you are correct, I mean, in our
6 city, Houston, we have patients going to multiple
7 institutions, and we find out -- last year we had a
8 patient over two years had 16 cardiac studies of various
9 types because she had various doctors. And if the
10 patients share their -- give you permission, then in the
11 future we hope, just like they have in the French system,
12 you can go online and find out not where they've had
13 -- not what they've had but where they've had it, and
14 be able to make some kind of rational decision on that.
15 That is down the line, but that's a very important
16 consideration. And, in fact, the ABR has submitted some
17 PQRS measures to CMS, and they're very interested in
18 following the issue when the technology becomes
19 available.

20 But now I'll focus on Jennifer Elee from
21 CRCPD who's going to speak to us on CRCPD's medical
22 radiation database.

23 MS. ELEE: I'm Jennifer Elee, for most of you
24 all I've met several of you over the years. For those
25 of you don't know, I've been an inspector with the State

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1 of Louisiana for over 20 years, and an active CRCPD
2 member. I was a board member and the chair of several
3 committees, so I've been involved with that
4 organization for a long time. And I'm currently chairing
5 the H-38 Committee on Medical Events.

6 Just a little bit of background. In 2010,
7 we formed a committee. That was, as you all know, an
8 active year in terms of events and publicity, and at that
9 time we surveyed all the States, and we found that 23
10 had some type of reporting requirements for diagnostic
11 or therapy machines, one or the other; we didn't
12 specify.

13 We currently are conducting an updated
14 survey, and as of August we've just sent the survey out,
15 we have 26 responses, and 20 at that time of the 26 have
16 requirements, six do not, of the States that responded
17 so far. I don't think three have dropped their
18 requirements, they just probably have not responded to
19 us at this time.

20 In 2011, we conducted a pilot and all of our
21 State program directors were sent reporting forms,
22 definitions, and instructions on how to report events
23 to CRCPD. Now, we -- in the time span from 2010 to 2011
24 spent a lot of time developing a definition, and the
25 reporting forms, and all of this information, and we

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1 collected all events for the first time. And I'm going
2 to go into what our definition is.

3 We can accept events from any State or local
4 agency that has reporting requirements in place, so if
5 the State already has requirements for you to report to
6 the State, the State would then send the information to
7 us. It's no burden on the facility to further send the
8 information; it comes from the State agency. And in
9 2013, we did enter into a Memorandum of Understanding
10 with AAPM to further analyze some of our data that we
11 felt would be better analyzed on their end.

12 Our committee provides an annual summary of
13 our data to the Board of Directors, and we present this
14 summary at the conference every year that we hold in May.
15 Our current definitions include events resulting from
16 the use of therapeutic radiation machines and from
17 diagnostic radiation machines. When we developed these
18 definitions they were not intended to be regulatory. Our
19 H-38 Committee is not a regulatory committee.

20 I will preface that and say now both the
21 diagnostic and the therapeutic definitions have been
22 incorporated into our suggested State regulations, so
23 if they choose to incorporate those into regulations for
24 reporting requirements, they can, and they are. Well,
25 for diagnostic they're in the current version that's

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1 being worked up right now. We're updating our diagnostic
2 x-ray regulation so it will be in there.

3 Our therapeutic definition we involve
4 wrong patient, wrong site, wrong modality, weekly
5 administered dose differs by more than 30 percent, total
6 dose by more than 50 percent, or single fraction
7 -- total dose by more than 20 percent, or single
8 fraction by 50 percent. And any equipment failure,
9 error, accident, anything that might be of interest that
10 could cause an unusual harm to a patient, or significant
11 harm.

12 Our diagnostic definition which we really
13 ran around with a lot because we started from scratch
14 here, and it's been a work in progress, but it is
15 anything that results in an unintended dose to the skin
16 greater than 2 gray or 200 rads for the same area,
17 procedure, or series. An unintended dose greater than
18 five times the facility's protocol, and exceeds 50 rads
19 to an organ, or 5 rads total dose.

20 Wrong patient or wrong site for the entire
21 exam and exceeds 50 rads in organ or 5 rads total dose.
22 In this instance, we were trying -- for diagnostic we
23 run into so many exams, and we were trying not to collect
24 every time somebody even in a dental office x-rayed the
25 wrong tooth. So, that's why we went with the -- we were

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1 trying to collect only the significant events, every
2 time a wrong hand or that sort of thing. Involves any
3 equipment failure, or other accident or mishap, or
4 unusual occurrence which exceeds the 5 rads total
5 effective dose.

6 In 2011, this was our pilot year. We
7 actually had 29 events reported, 48 in 2012. We had 10
8 States that were in our pilot study, and in 2012 we
9 collected events from 26 States. In 2013, we had 30
10 events, 26 therapy, and four diagnostic. 2013 was the
11 first time we actually did see some diagnostic events
12 come in. And we received information from 19 of the 50
13 States.

14 And when I say that, about half that have
15 reporting requirements at all, so we know that. So we've
16 received from 19 of the about 23 to 25 States that we
17 know have reporting requirements.

18 And this just kind of gives you some of the
19 information we collect. This is from our 2013 data that
20 tells you who the event was discovered by. It's very
21 similar to what you've already seen. How it was
22 discovered.

23 The other category is very interesting in
24 that it stays fairly high. And this is something that
25 we plan to work on and get AAPM's input on, as to is there

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1 a category we need to add to the drop-down menu, or are
2 these just isolated other events? It's hard to say
3 really when you look at them. And some of them actually
4 may fit into one of the other categories that were
5 reported as other.

6 Causes and contributing factors. That can
7 indicate more than one cause or contributing factor per
8 event, so those numbers can go up.

9 In our 2013 summary, we had 15 minor
10 consequences, 10 events with no consequence, and one
11 with moderate. This is pretty consistent from year to
12 year. On our diagnostic we had four events, three were
13 CT, and one fluoroscopy, one was an equipment failure
14 where the disk drive failed and they could not
15 reconstruct -- although they already scanned the
16 patient, the image could not be reconstructed so the
17 patient had to be redone. Two wrong patients that were
18 identified by the technologist, one wrong patient that
19 was ordered by the referring nurse practitioner. When
20 she received the report back she said that wasn't what
21 she ordered. She accidentally ordered the wrong thing.
22 It was interesting that we even got this one reported,
23 because by definition, by our -- at least my State and
24 most States there was an order when the exam was
25 performed, therefore, it's not a medical event. Even

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1 though it was the wrong exam, it was ordered.

2 This is how you can get our reporting forms.
3 They're on the website, and to the facility you don't
4 have to -- you shouldn't need to access these. Like the
5 states actually complete these and submit them to Bruce
6 at our agency, and he puts them into our system. And if
7 you have any questions, that is my contact number as
8 committee chair. Okay.

9 VICE CHAIRMAN GUIBERTEAU: Thank you very
10 much. Any questions?

11 MEMBER ZANZONICO: I just have a question.
12 I was a little confused on the data flow. So, events are
13 reported per the standard regulations on a State by
14 State basis.

15 MS. ELEE: Right.

16 MEMBER ZANZONICO: And then the State
17 agencies forward that information. In what form is that
18 done?

19 MS. ELEE: It's very similar to your
20 reporting --

21 MEMBER ZANZONICO: It's another web-based
22 tool that someone at the agency --

23 MS. ELEE: Yes, it's a web-based tool with
24 drop-down boxes.

25 MEMBER ZANZONICO: -- will extract data

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1 from the licensee's report, or the user's report.

2 MS. ELEE: Right.

3 MEMBER ZANZONICO: And enter it into --

4 MS. ELEE: Right. Right. Now, we don't
5 collect facility information that is available to -- I
6 mean, the address and all of that.

7 MEMBER PALESTRO: In your event
8 definitions, it says diagnostic radiation machines. I
9 assume, though it's not clear to me, that that excludes
10 nuclear medicine studies, or not? And I didn't see any
11 radionuclides --

12 MS. ELEE: We did not -- when we started all
13 of this, and still, we have a representative from the
14 NRC that serves on our Committee, and if it intended to
15 only be -- was not nuclear medicine at the time, we
16 intended for it to be separate because of the difficulty
17 with merging the systems. But we didn't want to exclude
18 that in the future.

19 MEMBER PALESTRO: So, at the present time
20 you did not exclude it --

21 MS. ELEE: At the present time --

22 MEMBER PALESTRO: Not include it.

23 MS. ELEE: Not included, but that doesn't
24 mean --

25 MEMBER PALESTRO: You won't.

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1 MS. ELEE: Right.

2 VICE CHAIRMAN GUIBERTEAU: I have a question
3 in terms of your overall system. I read through these
4 last night and one thing struck me, and that was the
5 sense that perhaps there's being the creation of
6 multiple silos of collecting information. And I know the
7 CRCPD is a large organization, and I wondered what your
8 thoughts are in terms of sharing this information, and
9 also preventing the collecting of the same information,
10 such as happens in meta analyses every time, is that the
11 radiation oncologist reports to ASTRO, and the RSO
12 reports to you, et cetera, et cetera. So, I mean, have
13 you gotten that far? I guess that's a question for any
14 of the presenters; that's a concern.

15 MS. ELEE: I think our system was probably
16 up and going early on, and in setting up our system we
17 did not want to be a burden, an additional burden to the
18 facility. There are a couple of other reasons, too, FOIA
19 requests and that kind of thing, but we can take the
20 information from the states themselves. So, our
21 information is only events that have been reported to
22 the states, and it's reported to us by the State agency,
23 not the facility.

24 So, I guess no longer that way. The way
25 we're collecting the information, if a facility is

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1 reporting it to another agency, we're not making them
2 report it twice to us, because we're collecting it from
3 the state agency. And they would have had to have
4 reported it to the state, anyway, if it was a reportable
5 event.

6 VICE CHAIRMAN GUIBERTEAU: And you're
7 insuring that the reporting requirements from the State
8 match your reporting requirements.

9 MS. ELEE: Those are different. We only ask
10 them to report the events that meet our requirements.
11 And, in fact, in my State, we collect -- any and all
12 patient that's imaged is reported. We get a lot of, you
13 know, they got the wrong chest, portable chest, you
14 know, the wrong patient had a portable chest. Well, that
15 is not reportable in this system because it doesn't meet
16 the dose requirement. It's an event, but it's not -- it
17 doesn't go into the CRCPD database, so we ask the States
18 to kind of --

19 VICE CHAIRMAN GUIBERTEAU: Dr. Thomadsen.

20 CHAIRMAN THOMADSEN: You have -- yes?

21 MS. TOMLINSON: Cindy Tomlinson from ASTRO.
22 I think one of the other differences that I think you're
23 getting at is that the RO-IL system is completely
24 voluntary, so it's not -- there are State requirements
25 that you still need to report to your State, or NRC, or

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1 FDA. You still need to do that even if you are reporting
2 to the RO-IL system, so it is a voluntary system. So,
3 I think that that's kind of where the difference lies
4 that CRCPD is collecting data that's already being
5 reported to the States because it has to be. Whereas,
6 our system is collecting other things that -- and it's
7 voluntary. So, I think that that's where the difference
8 -- does that answer your question?

9 VICE CHAIRMAN GUIBERTEAU: Well, it
10 highlights a difference, and so the motivations are
11 maybe different in terms of reporting.

12 MS. TOMLINSON: Right.

13 VICE CHAIRMAN GUIBERTEAU: Although,
14 self-reporting in a sense is somewhat voluntary
15 depending on the understanding of the reporting
16 requirements. But I do appreciate that, and I think that
17 somewhere in terms of overall safety culture we're
18 getting, and that is being able to report things --

19 MS. TOMLINSON: Right.

20 VICE CHAIRMAN GUIBERTEAU: - without you
21 know, in terms of understanding and correcting rather
22 than have your hand slapped.

23 MS. TOMLINSON: Absolutely. And that's the
24 whole purpose of the RO-IL system.

25 VICE CHAIRMAN GUIBERTEAU: I appreciate

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1 that. Thank you.

2 MS. ELEE: And I think States have been very
3 proactive in letting people know that if it's a
4 reportable event in your State, putting it in the RO-IL
5 system does not preclude reporting it.

6 MS. TOMLINSON: You've still got to report
7 it. We make that very clear in all of our educational
8 materials you still have to report to the State. You
9 still have to report to FDA, you still have to report
10 to NRC. But thanks for reporting to us, too.

11 VICE CHAIRMAN GUIBERTEAU: Sue.

12 MEMBER LANGHORST: I'm sorry if I missed
13 this, but has this data been available to everyone or
14 just to CRCPD?

15 MS. ELEE: No, our summary is -- I actually
16 don't know. I will have to look at the website to see
17 if they actually post the summary to the website. I know
18 it's available through the annual meeting documents,
19 the ones included in there because we present every year
20 with our annual.

21 MEMBER LANGHORST: So, it might be if you're
22 a member of CRCPD you can access it, or --

23 MS. ELEE: I think you can access the
24 proceedings online.

25 MEMBER LANGHORST: Okay.

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1 MS. ELEE: Yes.

2 MEMBER LANGHORST: Thank you.

3 MS. ELEE: And if not, let me know and I'll
4 be happy to send it to you.

5 MEMBER LANGHORST: Okay.

6 MEMBER COSTELLO: In your diagnostic
7 definition, it says results in unintended dose greater
8 than 5 times the facility's established protocol. Is the
9 expectation that the facility will have established
10 protocol in terms of dose for diagnostic x-ray?

11 MS. ELEE: At the time that we wrote this,
12 that we listed that definition there was a lot about
13 protocols and facilities looking at establishing
14 protocols for exams and all of that. I don't know that
15 that has come to fruition as much as we would have liked
16 to have seen it. But, yes, to answer your question --

17 (Simultaneous speaking)

18 MS. ELEE: -- but most do.

19 MEMBER COSTELLO: I don't think
20 Pennsylvania would require that.

21 VICE CHAIRMAN GUIBERTEAU: Any other
22 questions? Thank you very much. Our next speaker is
23 Bruce Thomadsen, who we all know on the Committee as our
24 Chair, but wearing a different hat this time for the
25 Center for Assessment of Radiological Sciences.

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1 CHAIRMAN THOMADSEN: And as a disclaimer, I
2 am the President of the Center and the Director of its
3 reporting system.

4 Just a bit about CARS. We developed this
5 system in 2012. CARS is a patient safety organization
6 listed with the Agency for Health Care Research and
7 Quality. We went live for reporting September of 2013.
8 This is the same reporting software that's used by the
9 Veterans Administration. I don't think that we've been
10 having the problems that the Veterans Administration
11 has been having.

12 Our philosophy is to help improve
13 radiotherapy quality and safety. We do this by working
14 with the clients doing the reporting and the analysis
15 events. And I'll talk about that in just a moment. We
16 also work with clients to develop corrective actions
17 that will work in their setting, and prospective quality
18 management tools.

19 Our methodology of reporting is a little
20 bit different from the RO-ILS, when a facility has an
21 event or a near event, or just wants to report a
22 hazardous condition, they go on line and fill out a very
23 brief form just like their initial form. We put the
24 questions on the form, sort of two things. One is just
25 to let the people feel that they're doing something,

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1 that they're answering some questions, and they're
2 questions that are very easy for them to answer. And the
3 second thing is once they submit it, we get an email
4 saying that an event has been reported, and we call back.
5 And we'll call back either the person who filed the
6 report, or a contact person at the facility depending
7 on how the facility wants to handle that. And we'll work
8 that out with the facility beforehand.

9 And once we're talking with that person
10 we'll go through, get a description of the event, and
11 we complete the rest of the questionnaire. The AAPM data
12 set is actually quite long, and asking the facility to
13 fill in the questions leads a lot of times to the problem
14 that you have with any facility questionnaire of an
15 event, a lot of data is not entered just because either
16 they don't know the answer, they don't understand the
17 question, or they get tired along the way. So, we fill
18 it in to assure that we capture all the data that's in
19 the data set, and that helps avoid omissions of data.
20 But it also gives us a better idea of what happened in
21 the event, so that we understand the event better.

22 And after talking with them about the event
23 we will then go off line, do a root cause analysis, try
24 and figure out what happened and what we might recommend
25 for rectification of problems, not just to prevent that

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1 event from happening again. That's not too likely,
2 anyway, but to try to address some of the latent
3 conditions in the institution that led to the events in
4 the first place.

5 And then we will complete the form, we'll
6 send it back along with our analysis and
7 recommendations, and talk again with our contact in the
8 facility about our recommendations and our analysis.
9 And we'll see how they feel that our recommendations
10 could be enacted in their setting. A lot of times what
11 we might recommend may not be practical at a given
12 facility, in which case we'll work with them and come
13 up with solutions that could be workable for them.

14 The advantages to this approach is all the
15 incidents go into the database as opposed to waiting for
16 the facility to decide to upload the event into the
17 database. All incidents go in automatically. All the
18 fields are completed, at least if they're applicable,
19 so we aren't plagued by data missing in the analyses.
20 The root cause analysis is done by professionals who
21 understand the analysis and radiotherapy. And working
22 with root cause analyses with different facilities, one
23 thing we found back in the '90s when we started working
24 with radiotherapy root cause analyses was that most
25 people do them wrong if they don't have a lot of

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1 experience doing them. So, rather than leaving the
2 facility to do it themselves, we would help -- either
3 we would do it for them and bring our results back to
4 see if they think we've got it right, or we would be very
5 happy to work with their root cause analysis team to try
6 to help guide them through the process. We like to think
7 that our clients are supportive in this way.

8 We also have an equipment reporting
9 -- equipment problem reporting section of our reporting
10 system. If somebody has a problem with equipment they
11 can report it. When we get that report, or if the
12 incident involved equipment we'll fill that in
13 ourselves. We will take any of these reports to the
14 manufacturer and try to work with them to see if there's
15 solutions to the problems people have had with the
16 equipment, and bring this back to the community. People
17 can use the equipment section to look up if other
18 people have had problems with equipment that they're
19 interested in, see if there are any solutions posted for
20 those.

21 CARS is run by radiotherapy physicists who
22 are experienced in system engineering, and system
23 engineers who are experienced in analyzing radiotherapy
24 problems; that is, we are definitely a radiotherapy
25 centric company that does this database.

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1 We also have a panel of experts, other physicians, other
2 physicists, other engineers that we would bring in to
3 help in any type of an analysis.

4 Just like with RO-ILS, this system can
5 serve as the local database for any facility because
6 they always can look up their own data, and all that data
7 is there. Somebody outside their facility is looking at
8 their data, it's all anonymized. We do accept anonymous
9 reports. If the reporter will give us contact
10 information, we will follow-up with the reporter. We
11 will not disclose who the reporter is to the facility,
12 if we know who the facility is, if they give us that.
13 We will let the facility know that there is a problem,
14 and what the problem may be. We try to follow-up on the
15 problem, and take care of whatever is being reported
16 while keeping the reporter anonymous.

17 Our vision is we would like data sharing
18 amongst all radiotherapy databases. As a PSO, our data
19 is automatically periodically sent to AHRQ. They have
20 a super database of all events in health care.
21 Unfortunately, radiotherapy events don't get captured
22 very well in their super database. They do periodically
23 update their database for different specialties, and I
24 talked to them about trying to update their database
25 including the radiotherapy data set that AAPM

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1 generated. They were very interested, except they said,
2 and how many facilities do you have nationally? And we
3 said it was 2,000 some, and they sort of laughed at it
4 and said we'll do this, but the priority is going to be
5 very, very low, so it's going to be a long time before
6 we will have a super database that all of us can upload
7 radiotherapy information to.

8 We do want to try to work with the
9 regulatory databases, and I have talked with Ms. Elee,
10 and with NMED, with the permission of the client, if
11 there is an event, uploading data from our database into
12 their database. We like to think that this would help
13 complete the data that might be missing -- which we find
14 a lot of data is missing in NMED, when we go through the
15 annual medical event reporting system.

16 The information that we have would be
17 disseminated to the community either in alerts, which
18 would be immediate announcements we feel should go out
19 to the community if there's some hazard that we've
20 noted. Bulletins, which are important notices, periodic
21 reports of our findings, and these would all be sent,
22 emails to our clients, message to listservs, letters to
23 the professional newsletters. And we have two slides
24 with acronyms, since there are too many to fit on one
25 slide.

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1 VICE CHAIRMAN GUIBERTEAU: Well, thank you,
2 Dr. Thomadsen. That was very interesting. Any
3 questions? Yes?

4 MEMBER ZANZONICO: I have several
5 questions. One is -- I mean, I've heard the acronym
6 CARS, and roughly aware of what it does, but it's an
7 entity within what, within AAPM?

8 CHAIRMAN THOMADSEN: No. It's a standalone,
9 patient safety organization.

10 MEMBER ZANZONICO: And how is it supported?

11 CHAIRMAN THOMADSEN: We are not free.
12 We're a not-for-profit, so we charge fees. And I can tell
13 you the costing structure is: the first accelerator is
14 \$1,000 a year, the second is, I think, \$850, the third
15 is like \$600. We don't charge for brachytherapy,
16 simulators, anything like that, and it's just meant to
17 cover the cost. That's how we fund it. You can also make
18 donations. We will -- we know we're not-for-profit, but
19 we're not a nonprofit.

20 (Simultaneous speaking)

21 MEMBER ZANZONICO: -- especially with all of
22 these -- non-regulatory databases like RO-ILS and so
23 forth, what's their, for lack of a better word,
24 standing, or policy with respect to mitigation? I mean,
25 these are data that potentially -- for events that could

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1 potentially be litigated by a patient, and how is that
2 handled?

3 CHAIRMAN THOMADSEN: By the Patient Safety
4 Act of 2005, patient safety organizations that are
5 listed with the Agency for Health Care Research and
6 Quality can interact with their clients, those who have
7 a contract, and that's why the contract is so important,
8 so that data that is given to us, data that we give back,
9 analyses we give back to our clients is protected from
10 discovery. It cannot be -- we can't be subpoenaed. They
11 can't get that data.

12 The client is responsible for keeping that
13 data separate in their own -- and it has a fancy name,
14 according to the Act. They have to keep that data
15 separate so that it doesn't -- it can't be subpoenaed
16 from their side, either. That does not mean that
17 anything in the patient's chart is not discoverable. It
18 is, it's completely discoverable, but anything -- any
19 discussion we have with the patient, with the client is
20 excluded.

21 MEMBER ZANZONICO: And that's true of
22 RO-ILS, as well?

23 CHAIRMAN THOMADSEN: Yes. That is the carrot
24 that Congress gave to try to get people to contribute
25 data to a Patient Safety Organization.

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1 VICE CHAIRMAN GUIBERTEAU: Dr. Suh, do you
2 have a question?

3 MEMBER SUH: Yes. So, actually, the first
4 question is the cost of it, but how many centers have
5 you signed up for this system right now?

6 CHAIRMAN THOMADSEN: We have several
7 contracts out that we're negotiating right now. We don't
8 have any active. The VA has been using our system for
9 a while, so at the moment that's where the data is coming
10 in [from].

11 MEMBER SUH: In terms of root cause
12 analysis, like what is your timeline, for instance, for
13 turning data over, like if a client were to submit
14 something, we had an incident on a machine, how do you
15 envision it in the turnover --

16 CHAIRMAN THOMADSEN: We would get back to
17 you to complete the data gathering as soon as we got the
18 email and could make contact with whoever we're supposed
19 to make contact with. The root cause analysis we would
20 start right away, but we'd probably have to be talking
21 with some of the people who were involved, and how long
22 it takes depends on how accessible those people would
23 be to discuss. The root cause analysis probably doesn't
24 take very long once you get the interviews with all the
25 people, so it's hard to say. It's hard to give a

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1 deadline, but we try to do that very quickly once we get
2 to talk with people.

3 VICE CHAIRMAN GUIBERTEAU: Dr. Palestro.

4 MEMBER PALESTRO: Yes, I have a question
5 about this. This has been a session on event reporting
6 mechanisms, and so far we've heard three different
7 approaches to the event reporting mechanisms. And,
8 presumably, as you acquire accrued data, we'll get to
9 look at reports with the ultimate goal being able to
10 improve patient care.

11 But given that you're three separate
12 organizations, and there's no mandatory requirement for
13 participating in any one of them, it seems to be that
14 potentially, not saying it's going to happen, but
15 potentially each of the organizations could wind up with
16 different conclusions. So, for myself as a practicing
17 clinician, if you will, radiation oncologist, who's
18 right? Who do I follow?

19 CHAIRMAN THOMADSEN: I think the answer to
20 that would simply be if they find that there's some
21 hazards that you have to look out for, those are hazards
22 you should look out for. If we find there's different
23 sets of hazards that you should look out for, you should
24 probably look out for those hazards, too. I don't think
25 that there's a right or wrong. We're just all trying to

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1 highlight things that you should be aware of, and watch
2 out for in your own practice. We're trying to uncover
3 the traps that you might fall into.

4 VICE CHAIRMAN GUIBERTEAU: Dr. Langhorst.

5 MEMBER LANGHORST: I think it's very
6 important, as Dr. Thomadsen had said, to learn from
7 others mistakes or problems, and so wherever you can
8 gather that kind of data, I think it's very helpful. It
9 would be nice to have one place to go to and you know,
10 boy, they're really on top of it, but I think you have
11 a lot of different sources to --

12 CHAIRMAN THOMADSEN: And our database is
13 open to any researcher that wants access; they just have
14 to register and they can look at all the anonymized data.

15 VICE CHAIRMAN GUIBERTEAU: Dr. Suleiman.

16 MEMBER SULEIMAN: I think it's a noble
17 effort. I think we're moving in the right direction. I
18 don't know how many years it's going to take, but I think
19 part of it has to do with the whole error concept where
20 people have to learn that reporting errors is not
21 -- shouldn't be taken personally. And I think we realize
22 that, if you collect data on a large scale you may see
23 things that you're not going to pick up anecdotally,
24 individually and say -- and I would want to know, if I
25 made a mistake, did others make the same mistake because

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1 of some underlying circumstance?

2 And, yes, I think this database sharing,
3 even at FDA we have -- our experience, at least how I've
4 seen how we handled things, because consumers can report
5 through a pretty comprehensive way of reporting
6 mistakes, but the companies are supposed to
7 -- mandatory, they're legally required to report to us.
8 And, of course, companies say this was a user mistake,
9 or the consumer made a mistake, and vice versa, so you're
10 never going to get that issue completely resolved. But
11 when there's a problem you have to have all these
12 databases, and surprisingly when you investigate
13 something specific, they do coincide. We start to see
14 trends, so they can be helpful. It would be nice; we all
15 want a uniform one-size-fits-all. We're just never
16 going to get it.

17 MS. ELEE: On our end, that was one of our
18 main goals, was to look at if something is happening in
19 one State, is it happening in another State. Does that
20 State know it's happening? And the brain perfusion is
21 a prime example where it happened in California and then
22 it popped up in Alabama. Now, would Alabama and
23 California have ever correlated the two had it not been
24 so publicized and we'd known about it? Maybe, maybe not.
25 It wasn't a large number of patients, but it was an event

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1 in both States.

2 In ours, we don't give recommendations
3 back to individual facilities on our end. We're looking
4 at trends, we're looking at is something happening more
5 than once? And, you know, is there -- if there's
6 something that comes in and it's an immediate risk to
7 health which we haven't, since the brain perfusion, we
8 haven't had any of those. But if we did, what we would
9 do is immediately siphon it off to our committees, our
10 committee on CT, or mammography, whatever committee
11 would deal with it, and have them issue a guidance.

12 VICE CHAIRMAN GUIBERTEAU: Dr. Palestro.

13 MEMBER PALESTRO: Yes. I understand what
14 you're saying, and perhaps I used the wrong phrase when
15 I asked who's right, but I think let me go back and
16 rephrase it and say that with multiple different
17 organizations, I think the potential exists for
18 conflicting conclusions, if you will. Even if you're not
19 making a recommendation, I may be reviewing the data and
20 forming my own conclusion, saying Conclusion A based on
21 your data, looking at your data maybe Conclusion B. I'm
22 not saying that that's going to happen. I'm merely
23 pointing out that when you have X number of
24 organizations, and the more organizations you have
25 approaching this, the more likely you are to wind up with

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1 conflicting results.

2 VICE CHAIRMAN GUIBERTEAU: Yes, Dr. Ennis?

3 DR. ENNIS: I think since we're pretty early
4 in this kind of self-reporting space, it would be
5 natural for people to go to different solutions, and
6 each one is going to have their strengths and
7 weaknesses. And generally that's a good thing because
8 over time you end up seeing what's working, what's not
9 working, what are the strengths and weaknesses, and go
10 down the road towards a time where we kind of converge
11 on one solution. But I think it would be, probably, less
12 than ideal if at the start we only had one way of doing
13 things.

14 VICE CHAIRMAN GUIBERTEAU: Dr. Alderson.

15 MEMBER ALDERSON: I just want a
16 clarification. Bruce, one of your slides says that CARS
17 would like to provide information to NMED. And I heard
18 you now said something different. Are you providing
19 information to NMED?

20 CHAIRMAN THOMADSEN: Not yet, not yet. I had
21 discussions with them about that, and it's something
22 that we're looking forward to, if we can work things out.

23 MEMBER ALDERSON: Okay.

24 MS. ELEE: We discussed that early on, too,
25 and I guess technically there's just some data talking

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1 back and forth issues.

2 (Simultaneous speaking.)

3 VICE CHAIRMAN GUIBERTEAU: Mr. Costello.

4 MEMBER COSTELLO: Dr. Thomadsen, I was
5 intrigued by what you had to say about root cause, that
6 you probe a little deeper in your root cause, because
7 having investigated a whole bunch of incidents and
8 having root cause training, operator error is rarely the
9 root cause, almost never. Yet, I think when things are
10 reported, these are -- this is often the first and
11 easiest thing to say, the therapists made a mistake, or
12 what have you.

13 And if you're filling out the data and
14 you're going to enter something like that, it'll look
15 like that. But if you pursue that, okay, I think the real
16 model comes from -- and what does anybody learn from
17 operator error, you know, that means you're fallible.
18 But if you pursue the real root cause, I think you may
19 get information that may be far more valuable for other
20 organizations. It came from ergonomics, the
21 relationship between person and equipment; it can come
22 from training; it even comes from safety culture. And
23 I've certainly seen, and not just in the medical arena,
24 where safety culture has played a critical role in
25 events, and I can talk to people about that off line.

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1 I mean, of all the ones I've heard, I think
2 that is very, very important to do, is not just to stop
3 at operator error and say well, what is the root cause
4 of this event, because it almost certainly isn't.

5 MS. ELEE: And I'd say that most of ours that
6 come in, even those a lot of them list the technologists
7 as one of the causes, they always have more than one
8 cause. In most all of our events there's multiple
9 causes.

10 MEMBER COSTELLO: Sure.

11 MS. ELEE: Because like you said, that may
12 be the initial cause, but it's not always the --

13 MEMBER COSTELLO: It's rarely the true root
14 cause.

15 VICE CHAIRMAN GUIBERTEAU: I would like to
16 go back to this issue of data sharing, because that has
17 become extremely important in the safety culture,
18 particularly in radiological procedures. And just in my
19 own experience, as well as that as a number of
20 organizations, the word anonymize means different
21 things. Certainly, at a minimum the patient information
22 is anonymized as per the HIPAA law. But, for instance,
23 if we were going through an analysis of a certain type
24 of safety infraction, taking each of your databases, is
25 there going to be any information?

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1 I think Ms. Elee talked about the regions,
2 so you know if it came from a particular State, and
3 perhaps city, but is there any information that would
4 be helpful to the other persons- to a researcher, for
5 instance, in wanting to put this data together?

6 MS. ELEE: I guess, I -- if you wanted to
7 individually look at where an event occurred, we would
8 require you to go to the State. We will tell you, you
9 know, you have to go to them because it's the State's
10 information. And they have all of that information, and
11 if you requested it through the right channels, you
12 would get that information I'm assuming from the State
13 --

14 VICE CHAIRMAN GUIBERTEAU: -- It's very
15 difficult to obtain this information.

16 MS. ELEE: It's difficult, but we don't want
17 to be the easy way out to release the information so that
18 you don't have to go through the State. That would be
19 counteractive to what our whole purpose is, and what the
20 organization is, since we're a collection of States
21 speaking as one. But it could because -- I've had
22 concerns, too, if we were to combine databases in some
23 way, how to tell you're not double counting the same
24 event, because ours are coming from the State, yours are
25 coming from facilities. You would think that some of

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1 those are going to be the same, so how do you make sure
2 that you're not counting it twice?

3 CHAIRMAN THOMADSEN: Yes, anonymized data
4 is just removing the name or anything that would
5 identify the patient or the facility. Basically,
6 anything else is up online, with the exception that if
7 there's something about the procedure that would
8 identify the facility, for example, were it a ViewRay™
9 event, seeing these only two facilities, we probably
10 wouldn't put that up, because it would be hard not to
11 be able to identify the facility from the description,
12 given the few number of practitioners. So, we would look
13 at the data and see if there was something identifiable,
14 but otherwise it would all go on the database. And you
15 have, I think, ASTRO's [inaudible]- but I want to hear
16 from them.

17 VICE CHAIRMAN GUIBERTEAU: Well, I'll hear
18 from you, too.

19 MS. TOMLINSON: Cindy Tomlinson, ASTRO. So,
20 in terms of our making it anonymous, we ask for no
21 patient information. There is a form; there is a
22 section, or a slot on the website that does ask for a
23 patient identifier. That is really for the facility when
24 they go back and do their analysis, because if you're
25 a big facility and you've got hundreds or even thousands

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1 of patients, and you've got to go back and look at a
2 patient record, if you're not intimately familiar with
3 that case, with what had happened, you need some way of
4 going back and figuring it out. So, we do ask for that,
5 but it is not required. That is the only patient
6 identifier that is in our data set.

7 In terms of facility information, as Dr.
8 Thomadsen said, there are cases where it would be very
9 easy to figure out which facility this was coming from
10 based on equipment, or there are some proprietary
11 software that some folks use; we strip all of that. We
12 know because when our contractor, which is Clarity PSO,
13 goes in and talks to facilities- when they're signing
14 the contract they ask for specific information, such as
15 do you have proprietary software, or is there something
16 that you use that nobody else uses? So, we strip all that
17 out, as well, so it is -- we try to keep it as anonymous
18 as possible.

19 And I think as we all start collecting more
20 and more data, because remember the PSO program is very
21 young. The regulations only went into effect in 2009,
22 so this is a very young program in general, for general
23 medicine, not just for radiation oncology or anybody
24 else. As we get more and more data it'll be easier to
25 make it more anonymous, because we'll have more and more

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1 data, and more and more people participating.

2 VICE CHAIRMAN GUIBERTEAU: Thank you. I
3 think we'd like to proceed, if that's okay. Do you have
4 a short question?

5 MEMBER SULEIMAN: No, that's fine.

6 VICE CHAIRMAN GUIBERTEAU: All right. I
7 think Debbie has been very patient. I hope you're still
8 on the line. Debbie Gilley.

9 MS. GILLEY: Good morning.

10 VICE CHAIRMAN GUIBERTEAU: Good morning,
11 welcome. Debbie is a former member of this Committee,
12 and it's always a delight to hear from you. Today she's
13 representing the IAEA going to tell us about the SAFRON
14 reporting system from IAEA, and at this time is yours,
15 Debbie.

16 MS. GILLEY: Great. Could I have the first
17 slide, Sophie?

18 MS. HOLIDAY: It's up, Debbie.

19 MS. GILLEY: Okay, it's not up on the
20 webcast.

21 VICE CHAIRMAN GUIBERTEAU: Is there any
22 slide up on the webcast?

23 MS. GILLEY: Yes. Okay, we're ready to go.
24 Well, thank you first for letting me have the
25 opportunity to talk to you today about the incident

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1 learning system that's been developed by the
2 International Atomic Energy Agency. It is the SAFRON
3 system, and it is a user-based system that's identified.
4 Our purpose: it's to improve safety and quality of care
5 in radiation therapy, and its goal is to share knowledge
6 that we collect from near misses and from incidences
7 that are reported around the world. Next slide, please.
8 Next slide.

9 MS. HOLIDAY: It's there.

10 MS. GILLEY: Oh, there's a delay between the
11 webcast and the telephone. Please bear with me in the
12 technology challenges we have in giving this
13 presentation.

14 SAFRON is designed to be a clearinghouse of
15 multiple reporting systems, and it contains information
16 that's gathered by IAEA reported events, the ROSIS
17 system out of Ireland that many of you are familiar with
18 and the French Nuclear Regulatory Authority also
19 participates and provides any medical events that
20 happen in France directly into the SAFRON system.

21 In addition to that, there are about 35
22 individual clinics throughout the world that have no
23 other options for an incident learning system that are
24 using SAFRON as a base to do individual learning in their
25 facilities. There's about 1,200 incidents in the

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1 database system. It covers both actual events and near
2 misses. It's designed to be non-punitive. It is
3 anonymous not only by patient, facility, but also by
4 country, and it is voluntary. You have to register to
5 participate in the SAFRON system.

6 It tries to provide the most comprehensive
7 source of information on radiation safety. It not only
8 includes actual near misses and events, but we've also
9 tried to include information and links to published
10 scientific journals, so if somebody was looking at a
11 particular event or near miss that happened at their
12 institution, there would be a wide variety of resources
13 that might be available to you to go in and look at maybe
14 a failure mode effect analysis that's been performed by
15 some other institution and they published that
16 information. Next slide, please.

17 This is a really busy slide, but this is
18 kind of to demonstrate the complexity of radiotherapy,
19 or radiation oncology as we say here in the United
20 States. And in external beam radiation therapy, IAEA has
21 identified 92 different process steps from the time the
22 patient is identified as needing radiation therapy
23 until they complete their course of radiation therapy.

24 This is just for external beam. It could
25 also look at the process steps for brachytherapy and

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1 radiopharmaceutical therapy, and at every process step
2 along the way there is an opportunity for error to
3 happen. In treatment planning it may be that they pull
4 up the wrong CT plan when doing the treatment planning
5 and it's not caught, so the basis for SAFRON is to
6 identify errors that occur at each individual process
7 step along the way. Next slide, please.

8 This is the web page for the SAFRON system.
9 As you can see, you can look at all 92 process steps along
10 the way. You can actually do your own search for errors
11 in the process. There's a place for you to look at any
12 kind of reports, or scientific journals, or instant
13 reports that might be out there. I hope your screen is
14 not nearly as blurry as my screen is.

15 Every couple of weeks the website- or every
16 couple of months they change the featured cases, and in
17 this particular screen, when I took this screen shot,
18 we were looking at calibration. And we also try to
19 provide some documents and links to assist the
20 participant in identifying some learning material that
21 might be available. And in this case, we were
22 referencing some of the task group reports that are
23 published by the American Association of Physicists in
24 Medicine. Next screen, please.

25 In this particular one, we're looking at

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1 how to do a search. And you can see we can search on
2 different process steps, we can look at how individuals
3 who discovered the event, we can also look at how the
4 event was discovered, and we can also use a free text
5 search where we'd be looking at things like some of the
6 newer modalities to identify any type of near misses or
7 events that were reported.

8 I want to give you a little bit of -- next
9 slide, please -- information on what we can do with this
10 data. And I think it's important that we look at what
11 the learning component is of collecting this
12 information. In this particular case, we're looking at
13 near misses and incidences that occur with setting up
14 a patient with ISOCENTER set ups. And that seems to be
15 an area where we could do some improvement in our
16 processes and procedures, so that we don't have
17 ISOCENTER near misses or incidences that happen that
18 have impact to the patient.

19 There are many areas where the ISOCENTER
20 issue is identified as a problem. It can be in the
21 pre-treatment phase when we're doing the treatment
22 planning, or even in the simulation, or it can actually
23 occur in the treatment phase.

24 We also can look at who is identifying those
25 particular incidences along the way. And as you would

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1 expect, therapists at the treatment unit are actually
2 the ones that are most likely to identify an incident
3 that's associated with wrong ISOCENTER, or wrong shift
4 from ISOCENTER in some instances. Next slide, please.

5 The way SAFRON is set up, we have the
6 ability to look at what kind of safety barriers could
7 be put in place at each process step along the way, in
8 order to try to prevent those errors from ever reaching
9 the patient. And in this particular case, we're looking
10 at portal imaging as a safety barrier. We are also
11 looking at chart checks as a safety barrier.

12 And one of the features of the SAFRON system
13 -- next slide, please -- is the identification of the
14 appropriate safety barrier within the safety system of
15 radiation oncology. So, we try to capture that
16 information from individuals reporting in, as to
17 whether or not the safety barrier that they used that
18 identified the error or the near miss was adequate, was
19 not available, or if there was a better safety barrier
20 that should have been used for that.

21 And this is one of the unique
22 characteristics about the SAFRON system, and safety
23 barriers are good, but if they're not appropriate for
24 that particular area, we would like to be able to
25 identify that so that we could put the appropriate

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1 safety barrier in. There are situations where
2 checklists work very well as a safety barrier. There are
3 other instances where checklists are not the best choice
4 in safety barriers for the safety systems. Next slide,
5 please.

6 This is just a little bit further breakdown
7 of looking at ISOCENTER, and whether the types of events
8 that happen in the pre-treatment phase. As you can see,
9 the common issues are treatment planning, is where the
10 near misses incidents happen, and also with simulation.

11 In the SAFRON system in the questions that
12 were asked of the participant bringing the information
13 in is causality of those type of events. And I agree very
14 much with the rest of you that human error is probably
15 not an appropriate assessment in all cases, so we give
16 them a list of options, a menu of potential items that
17 might be causes for this particular near miss or event.
18 And from the data that we've collected, we've seen that
19 communication issues are problems, particularly with
20 handoff and verbal instructions.

21 We have an issue where there are a lack of
22 procedures that have been developed for a particular
23 type activity. We see that there is a lack of positive
24 safety culture, and that individuals aren't following
25 the procedures that are in place. And we see that

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1 sometimes with the newer technology, employees are not
2 appropriately trained in how to do those procedures.
3 Next slide, please. This set comes from the "Safety Is
4 No Accident" document; and this is kind of where we are
5 on the hierarchy of effectiveness. At IAEA... oh,
6 excuse me. Sorry, wrong slide. This slide.

7 We talked about the sharing of information.
8 We talked about sharing the information domestically.
9 Well, at IAEA we feel that there is value in sharing this
10 information internationally, and this is one of the
11 cases that was reported. Sophie, would you hit the
12 button for the popup box to show up, please?

13 There have been similar accidents between
14 the other developing countries and the United States,
15 and this, in particular, is one where commissioning of
16 a stereotactic unit was done using the wrong size
17 detector. This event happened in France in 2007. It
18 happened in the United States in 2009. And as a result
19 of using the wrong size detector for measuring the
20 field, over 200 patients were adversely affected by
21 that. So, there is value in an international global
22 system and sharing information with others. Next slide,
23 please.

24 SAFRON's goal and objective in setting up
25 this program and gathering information of incidences

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1 and near misses, are to start working on trying to
2 improve the effectiveness of the activities that we do.
3 And we start that with the training and education
4 policies and procedures, developing checklist
5 reminders, double checks, deciding what safety barriers
6 work within the safety system.

7 Ultimately, as much as we can standardize
8 about radiation oncology will reduce errors along the
9 way and simplify. Realizing that we work with patients,
10 and standardization is difficult sometimes in radiation
11 oncology, when we are going off protocol or off
12 standardized procedures, effective communication
13 becomes very important. And, ultimately, we'd like to
14 work with manufacturers out there to come up with ways
15 to automate as much of this activity as we can, knowing
16 that we will never ever, ever reduce the human element
17 that's involved in radiation oncology.

18 There may be some other equipment or
19 support that we can get through engineering
20 capabilities with our equipment that can reduce some of
21 the errors. Next slide, please. So, just to kind of go
22 back over a little bit of about SAFRON. It is
23 menu-driven. We use a lot of drop-down menus. There are
24 some text boxes that are involved in adding information
25 there. We have mapped systems to the SAFRON system from

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1 other countries, so that we would be able to share that
2 data and capabilities of doing that.

3 If you would like to look at the SAFRON
4 system, it is open access to review any of the data. You
5 would just be required to go to the RPOP website, access
6 the SAFRON logo at the bottom. You do have to register
7 with the gateway with IAEA, but then you can have access
8 to review any of the data that is there, so it is publicly
9 available.

10 Individual facilities can actually use
11 SAFRON as their own internal local reporting system.
12 There is a capability of doing that within the system.
13 They can also compare data coming out of their system
14 to whatever else is available in the SAFRON system.

15 One of the unique features is trying to
16 identify the appropriate safety barrier for the type of
17 event or near miss that occurs at different process
18 steps along the way. And there's issues in continuously
19 enhancing and upgrading the current system. Right now
20 SAFRON is set up to do external beam. In 2015, they'll
21 be adding brachytherapy, and hopefully
22 radiopharmaceutical therapy to their system.

23 Their method of communicating issues that
24 are going on with radiation oncology and results doing
25 the queries are through RPOP website, and I'll give you

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1 that address at the end. So, any communication on best
2 practices, changes, identification of errors would be
3 carried out, communicated through that website, which
4 also happens to be the most popular website at IAEA.

5 IAEA has historically supported the safe
6 use of radiation benefitting mankind, and draws on a lot
7 of experience they have with other applications for
8 improving safety in medical applications of radiation.
9 If you're not aware, more accidents have happened in
10 medical use of radiation than any other beneficial use
11 of radiation in society, and this also includes any
12 accidents that have occurred at nuclear facilities,
13 including Chernobyl.

14 We also realized that having this
15 information available and not sharing it is of little
16 value, so it is geared toward sharing that information
17 with the public. Next slide, please.

18 So, some of the things that we're doing to
19 improve patient safety is education and training
20 programs, capabilities, both providing that training to
21 institutions as well as updating training curriculum on
22 our website, supporting the development of policies and
23 procedures as they become available and apparent that
24 these are active; evaluating safety barriers and how
25 well they work within a safety system, and if they are

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1 appropriate to respond to the type of events that
2 happen; promoting standardization as much as we can on
3 treatment practices; working with manufacturers who we
4 believe can help identify technology solutions to
5 reduce errors. Next slide.

6 And with that, I would thank you and
7 entertain any questions. And I have provided you the
8 RPOP website at the bottom of the slide. Thank you.

9 VICE CHAIRMAN GUIBERTEAU: Thank you, Ms.
10 Gilley, very much. Are there any questions specifically
11 for Debbie Gilley from members of the Committee? I have
12 a question in terms of your -- on one of your first
13 slides when you're giving a definition here about SAFRON
14 collecting information from various clearinghouses,
15 and including individual clinics. Do you anticipate
16 information collection from any of the organizations
17 speaking today, or any other organizations in the United
18 States?

19 MS. GILLEY: Well, I think we've talked both
20 with Bruce and with Cindy Tomlinson about an opportunity
21 to share information along the way to an international
22 reporting system, so the conversation has been carried
23 on. There are a few clinics within the United States that
24 actually participate in SAFRON.

25 VICE CHAIRMAN GUIBERTEAU: Any other

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1 questions? Dr. Langhorst.

2 MEMBER LANGHORST: I just want to commend
3 all of the organizations for this attempt because it's
4 not easy, and I'll be very interested. I know it's not
5 easy to figure out what the questions should be, how you
6 categorize things, and then how you grow a database like
7 this, because it's a lot of care and feeding kind of
8 issues that you have to do in order to build this bank
9 of data.

10 So, I'll also be very interested to see how
11 Dr. Thomadsen's group with -- how you approach it, and
12 have someone who knows how to do these analyses ask the
13 questions so that you can glean the most information
14 with the person who knows how to look at these things,
15 knows how to investigate, I guess. So, I just really
16 appreciate what you're doing, and I appreciate that you
17 shared it with us today.

18 VICE CHAIRMAN GUIBERTEAU: Thank you for
19 your comment. Dr. Alderson.

20 MEMBER ALDERSON: Well, I'll just make a
21 generic comment. I also compliment all of you on what
22 you're doing. This, to me, resonates with what I see in
23 so many other places. This is the big data problem, and
24 in other agencies and in the private sector people are
25 struggling about how to handle this problem. And I think

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1 the answer they're coming up with is that the old method
2 was let's form a new committee, and several committees,
3 and that's the wrong way to handle this.

4 The way you have to handle big data is with
5 computers, and some other agencies. The NIH, where I
6 serve on a committee now also, they are now starting to
7 create a group that's going to deal with all sorts of
8 computerized data. And you need big computers to analyze
9 big data, to put it into parts that are understandable.
10 And then you've got to solve these privacy problems, and
11 other things you're dealing with to ever get anything
12 back out that can have any impact at all, or else we'll
13 all just be spinning our wheels. And the private sector
14 is going after this. There are companies out there in
15 the private sector right now who are developing this
16 technology- this is their business to take big data and
17 reduce it relatively quickly to data that can be
18 understandable, and then make an impact in the real
19 world. So, I just hope that government agencies don't
20 wind up getting left behind by that because it,
21 unfortunately, costs a lot of money to do that. That's
22 my comment.

23 VICE CHAIRMAN GUIBERTEAU: Ms. Weil.

24 MEMBER WEIL: I'd like to echo Sue's comment
25 about the importance of this work for patient safety.

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1 I think, though, that greater synchronicity in the kinds
2 of data that is being collected would facilitate the
3 aggregation of that data, and it would sense for these
4 organizations to be collaborative in the way that the
5 queries are formed, and the responses gathered.

6 CHAIRMAN THOMADSEN: Well, as I said,
7 between -- we use the same data set which is the official
8 AAPM-generated taxonomy.

9 MS. GILLEY: Ours is very similar.

10 CHAIRMAN THOMADSEN: Yes. Right.

11 VICE CHAIRMAN GUIBERTEAU: Mr. Fuller.

12 MR. FULLER: Thank you. Mike Fuller with the
13 NRC. As I was listening to these presentations, I had
14 a thought that kept coming to mind, and I don't have an
15 answer... obviously, don't have an answer, more
16 questions than answers, but as the regulator, you know,
17 we have, Jennifer, I guess, could echo this
18 ... traditionally had our role in wanting to have
19 events, things reported to us that met certain
20 thresholds.

21 And this is an entirely different set of
22 circumstances, so my question, the thing that's kind of
23 rolling in my head is we've had these four presentations
24 to this particular body, to the ACMUI. It would be
25 interesting to see as time goes on, and as we learn more

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1 and more about this, what sort of recommendations or
2 ideas that might come from the ACMUI on how the regulator
3 could utilize this data for trending and so forth,
4 because that's a big reason why we have this
5 requirement- you know, if you look at the Statements of
6 Considerations, a big reason that it is an underlying
7 requirement -- or a big reason underlying our
8 requirements for having to report these not only to, you
9 know, look at it from our traditional role as the
10 regulator, but also to aggregate data and so forth, and
11 understand where trends are. It's always been a part of
12 that, and we know it's an imperfect system.

13 So, it would be interesting to see what the
14 ACMUI thinks that we, as the regulator, or the
15 regulators, there's a lot of us, out to think about and
16 maybe, perhaps, how we might utilize some of the things
17 that are learned from these various systems,
18 recognizing that that's not the main purpose.

19 MS. ELEE: I was going to say, I know just
20 in the short period of time we've been doing this and
21 just in talks with other States and other inspectors,
22 I think we're seeing more questions asked at inspections
23 regarding events. And I don't mean are you reporting
24 your events, but what would you do if you had one, or
25 do you know what to do, or what do you call an event on

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1 the inspector side, just through education in this field
2 who may not have... a lot of the inspectors probably did
3 not know how to phrase the questions before.

4 MR. FULLER: Yes. I hope they'd be more along
5 the lines of, you know, we're an agency that's committed
6 to risk-informing our regulations. So as we learn more,
7 and more, and more about where some of the higher risk
8 incidents, or risks based upon higher incidents of
9 occurrence, those sorts of things, maybe we could then,
10 you know, focus our attention, as well. So, I just see
11 this as something that has the potential to help us
12 actually be better, as well. So, again, I'd like to just
13 request that folks kind of think in those terms of what
14 -- how the regulator might best utilize some of this in
15 the appropriate ways.

16 But I have a question for all four, because
17 one of the things that I also thought about as I was
18 listening to all the presentations is that I think,
19 especially when you're starting off, there has to be
20 some difficulty, some learning curve on the part of the
21 folks who are participating in these various systems for
22 understanding how to recognize something that ought to
23 be reported.

24 Because, again, if you have imperfect
25 knowledge-- but not imperfect, but if there was a lack

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1 of knowledge, a lack of understanding of exactly what
2 could be identified, and collected, and reported, that
3 goes a long towards validating the data, ultimately. So,
4 anybody take a go, whoever wants to go first, help me
5 understand a little bit about what sort of training goes
6 in to use, how much training goes into the up front for
7 folks, say it's the therapist, or the physicist, or the
8 physician, or the administrator?

9 DR. ENNIS: I mean, ASTRO ran a whole bunch
10 of seminars at its annual meeting, which was a couple
11 of weeks ago about these concepts to help start
12 educating the membership. But you're right, I mean, it's
13 just the beginning of that process, and as people sign
14 up and see what is happening, they will continue to
15 learn. There may be some specific training when you
16 actually sign a contract --

17 MS. TOMLINSON: Yes. So, there's a couple of
18 things that ASTRO has been doing. One is we do have a
19 lot of educational materials that are available to
20 anybody on our website, so if you want to go to
21 astro.org/ro-ils, you all can download them. They're --
22 the elements are public. It's not completely open- you
23 do have to sign a form- you do need to register- you
24 don't need to be an ASTRO member to download our guide,
25 but you do have to actually sign in because we are

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1 tracking who's downloading our guide for marketing and
2 other purposes.

3 But in there are the data elements, there
4 is a sample contract that has to be signed with Clarity
5 PSO, and that contract, as I think we mentioned before,
6 is what gives you the protections that are afforded to
7 you under the Patient Safety Act. And I can certainly,
8 off line, go into more detail than anybody probably
9 needs to know about that. But once you do sign that
10 contract with Clarity, they do training on how to use
11 the system, but we also have a guide that walks you
12 through each of the data elements, explains sort of the
13 purpose of the data elements.

14 We're toying with the idea of maybe doing
15 sort of a good/bad, like what's good data, what's bad
16 data, but we're not quite there yet because we need to
17 see what people are entering in. It is sort of our
18 experience in talking to -- especially our beta testers,
19 a lot of them are already collecting this type of
20 information within their clinics. And one of the big
21 impetuses for this program was because yes, each
22 individual institution is collecting their own data,
23 but they're not talking to each other. So, something
24 might happen in one institution, and it might also be
25 happening across the country, and the only way you're

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1 going to know about it, and know what each other did to
2 solve that problem is if you happen to be colleagues and
3 talking about it. So, this is one of the things that
4 we're trying- that we want to try to do, is to bring
5 everything sort of nationally so that people know that
6 you're not alone, that this is happening in other
7 places, and here's a suggestion on how to avoid it in
8 the future. So, there is a lot of education that goes
9 on with that.

10 We will continue to do education at our
11 annual meetings. And I know AAPM is also doing a program
12 in February on incident learning, not just RO-ILS, but
13 on this idea of reporting and tracking these kinds of
14 things.

15 VICE CHAIRMAN GUIBERTEAU: Thank you.

16 MS. ELEE: I would just say on the therapy
17 side, I think we're a lot more educated in terms of
18 events, and the therapists, and the medical physicists,
19 and the physicians knowing when something occurs.

20 On the diagnostic side, I think we have a
21 very steep learning curve because it's just -- it's not
22 been done before, a method - we're just seeing events
23 start to trickle in. And I think a lot of that is
24 facilities say, well, I didn't know that was an event,
25 or I didn't realize I had to report that. And we're

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1 getting the education out there but it's a slow, slow
2 process on the diagnostic side at least.

3 MR. FULLER: And I have one last question for
4 everyone. And as we talked yesterday, we were talking
5 about the medical groups reporting to us. It's very
6 helpful, and it's only been in the last few years that
7 we've been able to actually collect data about the
8 denominator. It's always been, I think, a little
9 misleading to talk about the number of incidents, or the
10 number of medical events, or whatever the case may be.
11 And once we were able to get our hands on some reliable
12 data about the denominators, how many of these actual
13 procedures are done each year, it became very helpful
14 for us, and also for the Commission to understand as we
15 report these things, to understand that we're talking
16 about extremely low numbers. Again, we're only talking
17 about medical events, those things that rise to some
18 level of concern, but I'm wondering if any of these
19 systems that we've heard about today as a matter of
20 routine, or as a matter of when someone reports an
21 incident or a near miss, and so forth, that they also
22 have an opportunity to say how many of those procedures
23 they did that month, or how many procedures did they do
24 annually and so forth.

25 CHAIRMAN THOMADSEN: That is data that we

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1 collect if we have an incident, the questions is how many
2 of these procedures are you doing per unit of time? How
3 many patients are you seeing a month, a year? So, we do
4 try to capture some of that data, but it's not giving
5 you a denominator, it's only giving you the denominator
6 for that facility.

7 MR. FULLER: Right.

8 MS. GILLEY: Hello.

9 VICE CHAIRMAN GUIBERTEAU: Yes, Debbie.

10 MR. FULLER: Hi, Debbie.

11 MS. GILLEY: With SAFRON systems they do
12 fill out a registration that identifies the number of
13 patients that they treat, approximate number of
14 patients they treat per year, as well as some of the
15 demographics of the type of procedures they're
16 performing, and the equipment that they have on hand.
17 And that's updated when they choose to update it, or
18 annually when a notice to update that particular
19 information goes out to them.

20 MEMBER ALDERSON: I'd like to echo what I
21 said just a few minutes ago but in a different way. This
22 detection and prioritization of low frequency events is
23 the heart of informatics. So, what you all need is an
24 informaticist. You ought to be talking to
25 informaticists; you ought to be setting up programs so

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1 that the computer analyzes these complex data for you,
2 in addition to people, and then you'll start, I think,
3 making some progress.

4 VICE CHAIRMAN GUIBERTEAU: Mr. Costello.

5 MEMBER COSTELLO: I would like to comment on
6 something that you said in your opening statement there,
7 Mike. You said regulator, and then you thought, you said
8 regulators. I'd like to bring it back to regulator
9 again. Okay? Because really, I don't think you expect
10 individual States to do a whole lot with this data. I
11 mean, at least not the State that I live in, anyway.
12 However, I think you could expect the National Materials
13 Program, that's why I think it's singular again -- this
14 National Materials Program, the NRC and the States
15 working collectively, that that's probably where it's
16 best to be done. Not the NRC by itself, the National
17 Materials Program reviewing events and getting
18 information out of it.

19 MR. FULLER: And that's why I said it that
20 way because I was sensitive to the fact that we all do
21 work together, or we're working very, very hard to work
22 together, and I didn't want anybody to think that I was
23 just speaking only for NRC.

24 MEMBER COSTELLO: Ideally we're the
25 National Materials Program- ideally. We're not there

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1 yet, but we're moving in that direction, I think.

2 MR. FULLER: I agree.

3 MEMBER COSTELLO: Having a program with
4 infrastructure and sharing data in which you'll have a
5 much bigger denominator of people looking at this data.

6 VICE CHAIRMAN GUIBERTEAU: Dr. Langhorst.

7 MEMBER LANGHORST: And I would say that one
8 of the things that hopefully, at least in my mind this
9 allows NRC to do and NRC staff is to look at the bigger
10 picture, not just radioactive materials, because
11 there's a lot to learn from all of the medical
12 applications of radiation. And I'll tell you, I get so
13 frustrated when I talk to some NRC folks that say, oh
14 I'm only allowed to look at the materials, and I can't
15 consider anything else. I hope this allows NRC to be a
16 player in the bigger picture as far as considering what
17 is safety culture, what are lessons learned, how the
18 risk compares across these modalities. My little cheer
19 lead here, sorry.

20 VICE CHAIRMAN GUIBERTEAU: Dr. Suleiman.

21 MEMBER SULEIMAN: I'll take that and I'll
22 raise you, because I [inaudible].

23 (Laughter)

24 MEMBER SULEIMAN: We have to look at it from
25 an even larger perspective, because a chemotherapy

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1 patient is ... may not have been exposed to radiation,
2 and so medical errors transcend just radiation. I've got
3 to remind you, this entire field has been based on
4 safety. We've all been trained on how to deal with
5 radiation. It's a level of concern that I don't think
6 you see in other specialties. In a lot of the other
7 medical procedures they learn how to treat the patient,
8 and then they find out afterward there may be side
9 effects with some of the things. Here we all learned
10 about the hazards, or the risks of radiation, and then
11 proceeded, so I think it's inherent -- it's intuitively
12 obvious that we probably should have a lower rate of
13 incidents, but just like doing a project, I think you've
14 got to do a literature review. I think there's probably
15 a whole lot of other organizations out there that are
16 doing this on a broader, maybe better scale, and before
17 everybody reinvents the wheel. Now, we've got to do it
18 uniquely for regulation, but I think you have to sort
19 of jump onto the bigger bandwagon. I think this whole
20 medical records initiative [inaudible] I mean, I get
21 shocked by the whole privacy issue. Private folks know
22 so much about us, yet we get obsessed and [inaudible]

23 (Laughter)

24 MEMBER SULEIMAN: You know, it's like
25 throwing the proverbial monkey wrench into the engine,

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1 but there are easy ways to link things up by date, by
2 height and weight. I mean, there are easy ways to link
3 the data because these things don't happen hundreds and
4 hundreds every single day at every institution that you
5 could easily duplicate -- identify duplicates, you
6 know.

7 So, I think a lot of these issues are all
8 soluble, they're all solvable. But yes, rather than
9 reinvent, I think the effort is to find and integrate
10 it all. I think it's -- what you guys have done has been
11 a step in that direction.

12 MS. ELEE: I agree with you, and I'll say
13 that one of our CRCPD member's call this the radiation
14 medical events database because when we started this we
15 were looking at the big picture. And, in fact, talked
16 to NRC at the time at the possibility of maybe taking
17 the nuclear medicine events that are in NMED and putting
18 them somehow, data dumping, if you will into the CRCPD
19 database or vice versa. It became so large that we
20 decided, hey, we've got to start somewhere. So we
21 started with the machine side, because at the time there
22 wasn't anything on the machine side. It may be that we're
23 getting to the point now maybe it's time to bring that
24 back around and see where we are, and if that's doable,
25 or what is doable. I don't know.

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1 VICE CHAIRMAN GUIBERTEAU: Mr. Costello.

2 MEMBER COSTELLO: Since I'm wearing two
3 badges today, I'll talk on both perspectives
4 separately. For my NRC badge, and I expect Mike will
5 agree with me, you can't expect NRC inspectors to look
6 at the machine-produced radiation. It's not going to
7 happen. Okay? It's [inaudible] and generally the
8 greatest risk, I mean almost always the greatest risk
9 is from machine-produced radiation. Certainly have
10 LINACs and proton machines and, you know, CTs and so
11 forth. However, the regulations are the way they are and
12 the people wearing this badge are not going to be looking
13 into your notch.

14 If I could continue, wearing this badge,
15 okay, I have inspected accelerators, you know. That's
16 the advantage of the Agreement State Program, is that
17 we can regulate all- we don't look at chemotherapy but
18 we can regulate all uses of radiation. Okay? So, your
19 friends from Region III, I think you're probably in,
20 when they come wearing this badge, they're not going to
21 look at your LINAC, they're not going to look at your
22 CTs. Okay? They're not.

23 They may look at safety culture which
24 spreads over, but they have got to tread very lightly.
25 But the people with these badges can look at everything

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1 in depth.

2 MEMBER LANGHORST: I just wanted to clarify,
3 I wasn't saying NRC needs to inspect on linear
4 accelerators. What the question is, I can't even talk
5 to them about that perspective, so I hope that is
6 something that- I hope we can get into that discussion
7 of what it means on a bigger picture, even as Orhan says
8 in the more medical, wider field of cancer therapy. So,
9 that's my only thing. I wasn't saying NRC should do it.

10 MEMBER COSTELLO: As an inspector, okay,
11 I'll talk to whatever it is, about whatever people want
12 to talk about. Okay? And someone actually had a concern
13 about the chemotherapy program. It is after all, we are
14 State Department of Health. Okay? I'd like to get the
15 phone number and give them a call. I'll talk to anybody
16 about anything that appears to be a real safety issue.
17 I won't step over dead bodies, as they say. But you
18 really have to be aware that I play within the lines,
19 you know, and not to do anything if I'm an NRC inspector,
20 if you have a problem with your LINAC. But I've listened
21 to you, and maybe passed on to the State of Missouri,
22 or wherever.

23 VICE CHAIRMAN GUIBERTEAU: I want to thank
24 the Committee for your comments and questions. I'm
25 getting off-stage direction here. And I certainly want

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1 to thank the speakers, Dr. Ennis, Dr. Thomadsen,
2 Jennifer Elee, and Debbie Gilley for this very
3 interesting bit of information on what's happening in
4 our communities because it's something, and I think Mr.
5 Fuller hit it correctly, I think the NRC needs to track
6 this very carefully and decide how we can take advantage
7 of it particularly, as you pointed out, disparate
8 databases, and how to make some sense of that. But I
9 think since this is rather fledgling as we move on maybe
10 things will somewhat sort themselves out, but thank you
11 very much.

12 Ms. Angela McIntosh is going to speak to us
13 now as soon Dr. Thomadsen takes his seat. Here she is.

14 MS. McINTOSH: Good morning, everyone. I
15 know we're running a little bit behind schedule. I'll
16 try to make this brief, and yet informative for you. I'm
17 here this morning to discuss -- we probably should call
18 that the announcement for a public nuclear materials
19 events database rather than proposal because I believe
20 it's a foregone conclusion that it will happen, but I
21 wanted to introduce this to you and let you know what
22 we're planning on doing with respect to this effort. So,
23 let's go on ahead and begin.

24 I have three more discussion points I'd
25 like to cover, and they are the top three Agreement

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1 States comments, NRC's response to those comments, and
2 the proposed path forward. So, beginning with the top
3 three comments.

4 One of those comments is that the State's
5 law and/or policy prevents the release of the identity
6 of licensees or the State believes the release of this
7 information is inappropriate for the public version of
8 the NMED.

9 Another one is that the State's law and/or
10 policy prevents the release of the isotope's identity
11 for those isotopes that are Category 1 through 3 IAEA
12 sources, or the State believes that the release of any
13 activity level is in conflict with Part 37 in the
14 National Security Posture.

15 And then the other, or the third of the top
16 three comments, is that the States will need to review
17 the event narratives in order to ensure that
18 inappropriate information errors are not inadvertently
19 released on the public NMED, which would create an
20 unacceptable burden on the States. So, let's go on ahead
21 and review FSME's response to those comments.

22 To the first one that the State law and/or
23 policy prevents the release of the identity of
24 licensees. Basically, our comment to that is that the
25 States can elect to not release this information, but

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1 there is an asterisk to that statement. And the
2 statement is that the non-inclusion of basic
3 information such as this may lead to a lot of questions
4 from members of the public who are looking at the
5 information in the public NMED. And the NRC believes
6 that any questions should be answered, or any questions
7 along these lines should be answered by the State in
8 question if the State is withholding that information.

9 With respect to the comment that the
10 State's law and/or policy prevents the release of the
11 identity of Category 1 through 3 sources, again States
12 may elect not to release this information. And I should
13 probably take just a moment to explain our internal
14 guidance with respect to the release of this
15 information.

16 We have internal guidance on the protection
17 of what we call sensitive unclassified non-safeguards.
18 We abbreviate that to SUNSI, the SUNSI information. Our
19 internal guidance does prohibit the release of the
20 activity of Category 1 through 3 sources in event
21 reports. It does not prohibit the release of the isotope
22 identity or activity of below Category 3 sources. So,
23 we will release that information for below Category 3
24 sources, and we don't believe that that is in conflict
25 with Part 37 or the National Security Posture.

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1 Nevertheless, States that aren't comfortable with
2 releasing that information can elect to not release this
3 information in the public NMED.

4 Once again, it may generate questions. If
5 some States choose to release it and other States choose
6 not to release it, it may generate some questions from
7 the members of the public why certain States are not
8 releasing that information. And, again, we believe that
9 the State in question is in the best position for
10 answering that question to a member of the public.

11 With respect to the State's comment that
12 they'll need to review the event narratives in order to
13 ensure that NRC does not inappropriately release
14 information on the public NMED and thereby wind up
15 creating an unacceptable burden on the States. Our
16 response to that is that we plan to have a 90-day hold
17 on these events. So, to give you a for instance, an event
18 occurred on October 1 would not be eligible for release
19 to the public NMED until January 1. And we believe that
20 the States should also supply the event narrative.

21 Now, what is the advantage that we see in
22 this approach? We see basically four advantages. First
23 of all, no historical information will be included, will
24 need to be processed for release to the public NMED. So
25 we're not going back retroactively and asking States to

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1 supply events back from a year ago, or back from 10 years
2 ago, but we will go forward in this effort.

3 And then the 90-day hold we believe will
4 provide ample time for States to do their event
5 follow-up, and they won't be rushed to do it. They'll
6 be able to get the information that they need to make
7 an informative public NMED record.

8 Also, we believe that if the State supplied
9 the event narrative, that obviously will mean that NRC
10 doesn't -- won't be providing the event narrative and,
11 therefore, the State won't have to review what NRC has
12 supplied to make sure that we have not inappropriately
13 included information in the event narrative.

14 And along those lines, the likelihood of
15 inadvertent release of inappropriate information means
16 that the -- in most cases the States won't have to --
17 to do any sort of corrective action, because they are
18 the ones who supplied the event narrative, and we
19 didn't. So, that's what we believe is the best, for
20 those four basic reasons, we believe that this approach
21 for including events in the public NMED is the best
22 approach.

23 And there were some other significant
24 Agreement State comments that we received that are
25 probably worth mentioning. And I'll go on ahead and read

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1 -- there's three of them. One of them is that the reason
2 for this is not clear. People are thinking why do we care
3 if we do this now? What's the point?

4 Some States wanted there to be a disclaimer
5 on the public NMED stating that State participation in
6 this effort is voluntary. And some States were concerned
7 that patients may wind up being identifiable in the
8 public NMED.

9 And so, to address the first point that's
10 listed there, the reason. Well, the reason for the
11 public NMED, it's basically stakeholder-driven. And we
12 did communicate this in a communication plan that was
13 shared with the Agreement States in a letter that FSME
14 sent out to the Agreement States on June the 9th. And
15 so, we're trying to satisfy the stakeholders' desire for
16 direct access to information contained within the NMED
17 while remaining responsive to the Agreement States'
18 concerns, and that's the general reason for this.

19 With respect to the disclaimer, the
20 Agreement State can elect to not participate in the
21 public NMED if they choose not to. Once again, this will
22 probably generate questions, and maybe a lot of
23 questions if as a member of the public approaches public
24 NMED and they see that State A, B, and C, you know, or
25 20 States- you know, most States are participating but

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1 three or four are not, they'll probably wonder why they
2 can get event information from some States or most
3 states and not from others. So, that's something to
4 remain sensitive to.

5 And with respect to patients being
6 identified- perhaps being identifiable, once again the
7 State- if the State supplies the event narrative, we
8 think the State supplying the event narrative is a root
9 answer to a lot of concerns here.

10 The States can provide- they have the
11 flexibility of supplying information in a way that would
12 minimize the ability for the patients to be identified.
13 And as we'll explore a little bit later in a slide coming
14 up very soon, a release of the city where the event
15 occurred will be optional. So, that would make it more
16 difficult to identify a specific patient, which we do
17 understand that in a small town where there's just no
18 one clinic or something of that nature. It would be
19 pretty easy to piece together information to figure out
20 if you're from that area well, that's my neighbor that
21 that happened to. So, we understand that, but we believe
22 that for those reasons that the release of the city being
23 optional is appropriate to help to protect the patient's
24 identity.

25 And then another comment that we received

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1 that we thought was significant is that if we release
2 a publicly available version of the NMED, it could
3 damage trust between the Agreement State and its
4 licensee. And, basically, the sentiment being expressed
5 there is that the States have the relationship, they've
6 developed trust with their licensee, and have assured
7 their licensee that they're not going to release
8 information that is sensitive, and so they don't want
9 to ruin, the States don't want to damage that trust, and
10 we understand that. And yet, again, we would argue that
11 this is one more reason that it's best for the States
12 to supply the event narrative.

13 Each State understands their own licensee.
14 They have that relationship with the licensee,
15 understands the licensee's concerns, and therefore can
16 determine... the State is most sensitive to how to frame
17 the event so that sensitive information is not
18 inadvertently released.

19 So, now we're at the point where we're
20 discussing the path forward. We had a meeting with the
21 Organization of Agreement States Board on July 24th of
22 this year to discuss issues and a proposed path forward.
23 And this is what was discussed at that time, ideas that
24 were proposed.

25 It was proposed that in the public NMED that

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1 there not be an event narrative included. And, also, to
2 withhold the licensee's name, street address and city,
3 but release the identity of the State. So, basically,
4 if this option were adopted, as you go to the public NMED
5 all you would see, and I'll just pick on Maryland since
6 that's where we are. You go to Maryland and we adopted
7 this option, all that you would see for Maryland is that
8 a medical event happened on such and such a date in
9 Maryland. That's all you would see.

10 The other option is to include the event
11 narrative, but still withhold the licensee's name,
12 street address and city, and release the identity of the
13 State. And we are more comfortable with this option. We
14 believe that it will best serve the public's interest.
15 It'll be maybe a little hard to defend and/or explain
16 why we would have a database that didn't even
17 characterize with any detail at all what happened, just
18 said it happened. We don't think that that would be very
19 useful to most people, so we are again... we believe
20 that the second option to include the narrative, which
21 again the Agreement State and/or NRC for all our
22 licensees we would supply, but release the State so that
23 people know the State that it happened, but they
24 wouldn't know the city, and they wouldn't be able to- it
25 wouldn't be easy to piece together information to figure

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1 out sensitive information about the event.

2 I think it skipped. It skipped on me. Okay.
3 So, yes, there we go. Thank you. It was discussed at that
4 July 24th meeting that the Agreement State should
5 provide the event narratives, so the Agreement States
6 were on board with that idea.

7 It was also discussed that the Agreement
8 State should respond to any public inquiries. We
9 recognize that we are not in the best position to respond
10 to an inquiry about a state that's not our jurisdiction,
11 so everyone agreed that the state in question should
12 reply to inquiries about events that happened in that
13 state.

14 The State will assist OAS to distribute a
15 survey to the Agreement States. That has actually
16 happened, and we're having a follow-up meeting on
17 October 14th with OAS to discuss the results of that
18 survey, to see if they've come to any consensus about
19 the issues that were raised. And there's also going to
20 be an October 22nd meeting, a public meeting here at NRC
21 Headquarters in the Commissioner's Hearing Room from 1
22 to 2:30 to introduce the public NMED to the members of
23 the public. So, I'll be glad to take any questions anyone
24 might have.

25 CHAIRMAN THOMADSEN: Thank you very much.

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1 Mr. Costello.

2 MEMBER COSTELLO: Angela, the Agreement
3 States were concerned- had a lot of questions when we
4 were at the OAS meeting. And you've characterized them
5 very accurately up there. And I'll be interested to see
6 the results of the survey. But my question is- I have
7 a different kind of question.

8 When the States report events like this,
9 they initially report them to the HOO, right? And in it
10 they include all this information that we want to
11 withhold, you know. They report the name of the
12 licensee, and the patient information, the location,
13 and an event description, et cetera.

14 MS. McINTOSH: Per SA-300.

15 MEMBER COSTELLO: Yes. And we follow that
16 faithfully, sometimes. However, all this information is
17 posted very quickly on the NRC's website, right? I mean,
18 you know, very frequently I'll check on the website to
19 see what other States are reporting, and any member of
20 the public, if they want to know what events are being
21 reported by the States, can go on there. It's
22 searchable, you can search it, and get the narrative,
23 and where it happened, and so forth, and so on. And it's
24 there, and it works fine, you know. I'm a regular
25 customer. That being the case, what does the public NMED

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1 add in addition to that that we already have?

2 MS. McINTOSH: The current NMED is not
3 publicly available. In AASB though, the stakeholder
4 request was that we make the NMED available to the
5 members of the public so that anyone can go to the NMED
6 and look up events.

7 As we proposed that idea to the States, and
8 the States came back and said well, there's certain
9 information that we prefer not be released in the public
10 NMED, and we recognize that the information that they
11 said that they don't want to release, we recognize that
12 if that information was available in the event
13 notifications that are on our public website, so it is
14 difficult to argue just from a logic point of view to
15 not include that information in the public NMED.

16 MEMBER COSTELLO: My question is a little
17 different. It's that any member of the public can mine
18 the NRC's website now...

19 MS. McINTOSH: Yes.

20 MEMBER COSTELLO: ... to get all the events
21 that have been reported by let's say Pennsylvania, or
22 pick whatever. And it works very well, I think. And I
23 review the NRC's posting events almost every day because
24 there's fascinating stuff there. I'd encourage you all
25 to read it. I just don't know that NMED is going to

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1 provide the public a whole lot more information than it
2 already has. In fact, it will probably provide less
3 information than it already has.

4 MS. McINTOSH: NMED provides, it will
5 provide information that is right. You know, the event
6 notifications, it's preliminary information, so that's
7 probably the biggest improvement over...

8 CHAIRMAN THOMADSEN: Ms. Weil.

9 MEMBER WEIL: The purpose of public NMED is
10 to provide greater access for information to members of
11 the public. The fact that the information is already
12 available on the NRC's website may or may not indicate
13 how easy it is to navigate, how do you find that stuff?
14 I haven't tried, so I can't comment on Mr. Costello's
15 comment that it's there already. It's simple to find.
16 Why reproduce it?

17 It doesn't make sense to me that NRC would
18 provide this, you know, watered down source of
19 information without making it -- without providing a
20 direct link to where you could get more information, or
21 providing -- making it easy to access the additional
22 information. I don't see a point. I know you're trying
23 to meet the needs of the Agreement States, which is
24 reasonable, but if that information is publicly
25 available, what obligation does NRC have to make it more

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1 difficult for the public to find this stuff?

2 MS. McINTOSH: I preface the answer to that
3 by saying now you see another reason why we want the
4 States to answer the public's questions, because it is
5 difficult to explain.

6 CHAIRMAN THOMADSEN: Dr. Langhorst.

7 MEMBER LANGHORST: For those of us who don't
8 know the system as well as you two do, would you explain
9 the process of States putting in event notification
10 information?

11 MS. McINTOSH: Sure. What happens is if an
12 event is required to be reported within 24 hours. It's
13 not necessarily what happens with events required for
14 30-day reports, but if the event is required to be
15 reported immediately, which is within four hours or 24
16 hours according to our regulations, then the event has
17 to be called into the headquarters operations center.
18 The event initially -- in an Agreement State the event
19 is to be reported to the State regulator, and then the
20 State regulator makes the commensurate report or a
21 report within a commensurate time frame to NRC. So, our
22 staff at the headquarters operations center makes a
23 report that we refer to as an Event Notification and it
24 includes the licensee's name, the date, the city and the
25 State, and of course an event narrative explaining what

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1 happened. And that gets put on our website- after a
2 5-day hold, I should say, after a 5-day hold on the event
3 that gets put on the NRC's public website.

4 MEMBER LANGHORST: Okay. So, the Agreement
5 States do not have a choice whether they report an event
6 or not to NRC. They have to- that's a requirement by the
7 Agreement State.

8 MS. McINTOSH: Correct. It's a requirement
9 per our regulations and we communicate the requirement
10 in the document called SA-300.

11 MEMBER LANGHORST: Okay. So, in my
12 opinion, one of the wonderful benefits of being on this
13 Committee is to be able to see the database. And I know
14 in looking at the event notifications that has been a
15 way for me as a licensee to look at what are lessons
16 learned, and it's not easy to find additional
17 information on how it all turned out, even if it's an
18 NRC licensee. But it is impossible to learn anything
19 more if it's an Agreement State. I've never learned how
20 to mine that information.

21 Having looked at NMED data, it's not always
22 satisfying either, because my understanding is NMED is
23 voluntary for the Agreement States to participate.

24 MS. McINTOSH: But it's not.

25 MEMBER LANGHORST: It's not. Okay. It seems

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1 like there's a dearth of events in the NMED from certain
2 Agreement States, like they never have a problem, so
3 that's why I was curious whether it was voluntary or not.
4 So, then NMED you're saying is Agreement States are
5 supposed to be putting their information in there.

6 MS. McINTOSH: Yes, if they have a
7 reportable event, if it's a non-reportable incident
8 it's not required.

9 MEMBER LANGHORST: And then on this public
10 part, that's where they have the choice to participate
11 or not participate.

12 MS. McINTOSH: Correct.

13 MEMBER LANGHORST: Okay.

14 MS. McINTOSH: And we're thinking also of
15 making that -- for those who do participate, the data
16 would be limited in quantity.

17 MEMBER LANGHORST: Right. Thank you.

18 CHAIRMAN THOMADSEN: Ms. Weil.

19 MEMBER WEIL: So, this request that the
20 disclaimer for the voluntary participation be public,
21 if that disclaimer is not on the public NMED website,
22 then that leads the public to believe that this is
23 comprehensive information when, in fact, it isn't. So,
24 what does NRC- what do you plan to do with that request
25 from the States? The States want it to be there, I think,

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1 for a different reason than I as a member of the public
2 would want it to be there.

3 MS. McINTOSH: I'm not sure I understand the
4 question.

5 MEMBER WEIL: Well, if you add the
6 disclaimer that participation in the public NMED site
7 is voluntary for States --

8 MS. McINTOSH: And we do plan to have that.

9 MEMBER WEIL: You do plan to have that.

10 MS. McINTOSH: We do.

11 MEMBER WEIL: Okay.

12 CHAIRMAN THOMADSEN: Mr. Costello.

13 MEMBER COSTELLO: Going back to Sue's
14 comment that some States report more than other States,
15 and often times- and there are reasons for that. You
16 know, the reports don't originate in States, the reports
17 originate with the licensees. And oftentimes if there's
18 a well-known event, let's say the prostate cases for a
19 number of years ago. The States who were associated with
20 that from their inspections might put event reporting
21 high on the list of the things they may look at
22 inspecting. So, those cases that were so famous that
23 occurred in Pennsylvania, and were associated with one
24 of our licensee's, and we put a lot of emphasis when we
25 did the inspections, and not surprisingly we have a fair

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1 number of reports. Other States such as Wisconsin did
2 the same thing. Wisconsin put a big emphasis on that,
3 and they have a great number of reports, which I think
4 was mentioned in somebody's presentation.

5 Sometimes I talk about events, you know, at
6 meetings which you've been to, I think, of CRCPD, and
7 OAS and such, and I will note because that some States
8 do not have as many reports as you might expect
9 considering their size. Why that's happening, I don't
10 know. I mean, it may be just the amount of emphasis
11 on-- maybe the inspectors don't emphasize event
12 reporting, perhaps they're emphasizing other parts of
13 the safety program. I think the States themselves,
14 though, are pretty good about passing on the NRC reports
15 they hear about.

16 CHAIRMAN THOMADSEN: Dr. Zanzonico.

17 MEMBER ZANZONICO: Is it possible, this
18 issue of the disclaimer, is it possible to share some
19 draft wording of the disclaimer that you're
20 proposing- that will be on NMED, public NMED?

21 MS. McINTOSH: We haven't discussed the
22 language of the disclaimer with the States yet, so what
23 I can do- to offer you some draft language, it would just
24 be my rendering of some language. It wouldn't be the
25 actual- have been anything that had been discussed and

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1 vetted. But it would say something along the lines of
2 certain States have elected to not participate, or State
3 X, name of the State, has elected to not participate in
4 the public NMED. Please contact, and we'd probably have
5 the Radiation Control Program Director's information
6 there, some information, something along those lines.

7 CHAIRMAN THOMADSEN: Dr. Langhorst.

8 MEMBER LANGHORST: I want for our newer
9 members to make one clarification, that always confused
10 me, because NMED sounds very medical, doesn't it? But
11 it's not just medical, it's Nuclear Material Event
12 Database.

13 MS. McINTOSH: Yes.

14 MEMBER LANGHORST: So, it's not just
15 medical, so I just wanted to pass that along.

16 CHAIRMAN THOMADSEN: The acronym is NMED,
17 nuclear materials events database.

18 MEMBER LANGHORST: Yes, so that confused me
19 for a long time. I just thought that might be helpful
20 to others.

21 CHAIRMAN THOMADSEN: Any other comments or
22 questions? In that case, thank you very much.

23 MS. McINTOSH: Thank you.

24 CHAIRMAN THOMADSEN: And with that we have
25 a break. It's just a 15-minute break. We are running a

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1 little behind schedule, so try to be back by 10:30. Thank
2 you.

3 (Whereupon, the above-entitled matter
4 went off the record at 10:15 a.m. and resumed at 10:28
5 a.m.)

6 CHAIRMAN THOMADSEN: Welcome back again,
7 and our order of business this afternoon will be a
8 little bit special. And to start this off, we have Mr.
9 Holian to make a special presentation.

10 MR. LORSON: Well, thank you. Just a
11 clarification. I'm actually not Mr. Holian. I'm
12 filling in for Mr. Holian.

13 (Laughter)

14 And I'm sure that the resemblance gives you
15 --

16 (Laughter)

17 I'm actually a few years younger than him,
18 maybe like 20. So I understand the mistake.

19 I'm Ray Lorson. I'm the Acting Deputy
20 Office Director for the Office of Federal and State
21 Materials and Environmental Management Programs, and
22 I'm pleased to be here this morning to recognize three
23 individual members of the Committee for their strong
24 commitment to public safety and to help further the NRC
25 mission.

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1 And having said that, I would like to ask
2 Dr. Welsh to please join me. Dr. Welsh has been a
3 member of the ACMUI since February of 2007. He was
4 nominated for a second term in February of 2011. He
5 has briefed the Commission on multiple occasions, has
6 been a member of several of the subcommittees,
7 including the very important subcommittee related to
8 permanent implant brachytherapy, which, as we all know,
9 has been a very strong policy issue that we have
10 wrestled with over the last several years.

11 So we do have a couple of gifts for Dr.
12 Welsh, first being a flag that was flown over the U.S.
13 Capitol at the request of Chris Van Hollen, a
14 representative from the State of Maryland. This is one
15 gifts that we'll provide you.

16 MEMBER WELSH: Thank you.

17 MR. LORSON: Secondly, we have a
18 certificate of appreciation from our Chairman
19 Macfarlane in recognition of eight years of service and
20 leadership on the Advisory Committee on the Medical
21 Uses of Isotopes, which resulted in significant
22 contributions to the work of the U.S. Nuclear
23 Regulatory Commission. Congratulations.

24 MEMBER WELSH: Thank you.

25 (Applause)

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1 MR. LORSON: We have more. We have more.
2 And, last, we have a gold pin commemorating Dr. Welsh's
3 service.

4 MEMBER WELSH: Thank you so much.

5 (Applause)

6 MR. LORSON: Okay. I would like to thank
7 Dr. Welsh for having the easiest name to pronounce, and
8 the difficulty is starting to increase here.

9 But I would like to request that Dr.
10 Suleiman please join me. How was that? Was that
11 close?

12 MEMBER SULEIMAN: Enough.

13 MR. LORSON: Dr. Suleiman has been the
14 second-longest serving member of the ACMUI. He began
15 his service here in 2004, has also been a representative
16 of the Commission -- or has made several presentations
17 to the Commission, has been involved with many
18 subcommittees, and including the very contentious
19 issue of substantive patient release. So he has
20 provided his valuable insights to help us in that policy
21 endeavor. Thank you, Dr. Suleiman.

22 We also have some gifts for you. First
23 off, with respect to the flag, the flag has been
24 ordered, but it has not yet arrived. So in lieu of that
25 we gave you a certificate for a flag.

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1 (Laughter)

2 MEMBER SULEIMAN: Anything over \$35, I
3 can't accept gifts, you know.

4 MR. LORSON: Well, rest assured, the flag
5 will arrive here, and then we will send it to you via
6 an appropriate transportation method and you will
7 receive it.

8 We also have a certificate of appreciation
9 honoring Dr. Suleiman, in recognition of 10 years of
10 service and leadership to the Advisory Committee on the
11 Medical Uses of Isotopes, which resulted in significant
12 contributions to the work of the U.S. Nuclear
13 Regulatory Commission.

14 (Applause)

15 And we also have a gold pin.

16 MEMBER SULEIMAN: Thank you.

17 MR. LORSON: Thank you very much.

18 (Applause)

19 And the difficult names continue with Dr.
20 Guiberteau.

21 (Applause)

22 Dr. Guiberteau is actually unique in the
23 sense that he is the first diagnostic radiologist to
24 this Committee. And I think what's striking is that
25 he recognized the need to have a diagnostic radiologist

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1 to this Committee and began as a volunteer. Later, I
2 think, we recognized the need to have someone with that
3 skillset and made him a term member of the Committee.
4 So thank you very much.

5 We also, because of the late notice, and
6 in lieu of a flag, have a paper that has a flag picture
7 on it.

8 (Laughter)

9 That will be soon replaced by a real flag.

10 VICE CHAIRMAN GUIBERTEAU: I will fly this
11 over my home.

12 (Laughter)

13 MR. LORSON: We also have a certificate of
14 appreciation for Dr. Guiberteau, in recognition of six
15 years of service and leadership to the Advisory
16 Committee on the Medical Uses of Isotopes, which
17 resulted in significant contributions to the work of
18 the U.S. Nuclear Regulatory Commission. Thank you.

19 (Applause)

20 And can anybody guess what comes next?
21 Congratulations.

22 VICE CHAIRMAN GUIBERTEAU: Thank you.

23 (Applause)

24 MR. LORSON: With that, I will turn the
25 meeting back over to Dr. Thomadsen. If you liked what

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1 you heard, then my name is Lorson. If you didn't like
2 what you heard, my name is Holian.

3 (Laughter)

4 CHAIRMAN THOMADSEN: Dr. Welsh, would you
5 care to grace us with some words?

6 MEMBER WELSH: Should I sit over there or
7 right from here?

8 CHAIRMAN THOMADSEN: Sure. Come on up.

9 MEMBER WELSH: Thank you, Dr. Thomadsen,
10 for reminding me last night that this was going to
11 happen, because it's kind of a surprise to me, and I
12 apologize to those who assume that I read each and every
13 word of all the documents that are sent to me months
14 in advance. But it wasn't until last night that I
15 learned that on that second page that had allegations
16 and ethics training, that I quickly closed it, that
17 there was more than just that this morning. So this
18 is a surprise.

19 The second surprise is I'm very pleased to
20 see Dr. Ron Ennis returned after his first experience
21 yesterday.

22 (Laughter)

23 But I have to admit that my departure
24 today, the expiration of my term, comes with some
25 bittersweet emotions. And seven years ago I don't

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1 think I would have said that. This was hard work back
2 then, and it certainly felt like hard work. It still
3 is hard work, but it's very different today.

4 The somewhat adversarial interactions and
5 the antagonism have undoubtedly, unequivocally, and
6 palpably yielded to a sense of cooperation and
7 constructive collegial interaction. So it's still a
8 lot of work, but it's actually a lot of fun. And I mean
9 that.

10 In the past year or two, I have grown to
11 look forward to the emails from Frank.

12 (Laughter)

13 There is something of interest there. I
14 don't agree with that. I'm going to change it, type
15 this in, and I'm going to send out the email and -- oh,
16 Bruce doesn't agree with this. Oh, but I'm going to
17 hold my ground, you know, type another email. And now
18 what have I done? Maybe I should assign you more
19 homework because --

20 (Laughter)

21 But it has been very beneficial, and it has
22 been constructive, and I have enjoyed it. I have had
23 the pleasure of participating in numerous
24 subcommittees, including the short list I see here of
25 Medical Event Subcommittee, the Patient Release

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1 Subcommittee, the Radium-223 Chloride Subcommittee,
2 numerous Y-90 Microspheres Subcommittees over the
3 years, and most -- most intensively, Permanent Implant
4 Brachytherapy Subcommittee, which has been going on for
5 I guess seven years, maybe many years before that.

6 And these subcommittee interactions have
7 recently been very enjoyable. I will look forward to
8 comments from Dr. Zanzonico and Steve and Sue, and then
9 I'll respond to these emails. And then I'll start
10 putting together my presentation or summary, and then
11 I'll look back and say, "Why didn't I concur with Orhan
12 to begin with? I should have concurred. If I had only
13 concurred, I wouldn't have to do this whole thing over
14 again."

15 But I have learned an awful lot by being
16 on this committee, and I have enjoyed it a lot. I have
17 had the pleasure of introducing some things to the staff
18 and this Committee, including the SHINE technology of
19 hybrid fusion fission methodology for producing
20 medical isotopes, which was something new and
21 interesting to me.

22 I also recall giving a presentation on
23 variations in half-lives of radionuclides as a function
24 of solar activity, which, after giving the
25 presentation, I found Dr. Zanzonico commenting that

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1 this has elevated us to an all-time high in terms of
2 nerdiness of the Committee.

3 (Laughter)

4 I think that he is quite right, that being
5 on the ACMUI has certainly changed me. Preparing for
6 being on the ACMUI was quite a change for me in the first
7 place. I remember asking one of my ASTRO colleagues
8 how to prepare myself for this, and I heeded his advice.
9 I proceeded to buy and read cover to cover three
10 textbooks of nuclear and particle physics only to learn
11 afterwards that it was a joke. I didn't get it. I
12 wasn't laughing.

13 (Laughter)

14 But I was quite nervous. I was anxious and
15 actually filled with trepidation as I was joining this
16 Committee, and I did prepare myself quite thoroughly
17 well in advance. But I do recall people asking me, how
18 did they pick you? What happened? So in addition to
19 reading my textbooks, I started reading about the
20 history of this.

21 And I learned that this was once called the
22 Advisory Subcommittee on Human Applications of the
23 Interim Advisory Committee on the Isotope Distribution
24 Policy of the Manhattan Project. It's quite a
25 mouthful. When the Atomic Energy Commission took

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1 over, it became the Advisory Commission with the
2 Subcommittee on Human Applications of the Committee on
3 Isotope Distributions within the Atomic Energy
4 Commission. Still quite a mouthful.

5 So I learned that it was shortened to the
6 Sub-Human. And when I explained this to my colleagues,
7 they all said, "Yeah, now it makes sense. We do have
8 the right person."

9 (Laughter)

10 It has been a lot of fun. And being on the
11 ACMUI has had a lot of beneficial effects for me
12 personally and professionally. I've gotten to work
13 with Cindy and many others from ASTRO over the past four
14 to eight years, and these positions have been of
15 increasing importance and relevance.

16 I am going to become the President of ACRO
17 next year. I have had the opportunity to lead the
18 clinical neutron program, fast neutron program and BNCT
19 program at Fermi National Accelerator Laboratory. I
20 have worked with the American Nuclear Society and the
21 International Conference on Isotopes. These are
22 things that I doubt would have happened in my career
23 had I not had the privilege of being on the ACMUI, and
24 certainly the NRC.

25 Additionally, I am on the Board of the

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1 Society of Brain Mapping and Therapeutics, SBMT. And
2 this also stems from my tenure here, because before Dr.
3 Suh joined us I realized and I was told that there was
4 a void in our experience and expertise on gamma knife.
5 So I would go to -- every week I would go to another
6 hospital, a rival hospital, to observe and learn about
7 gamma knife.

8 And they were gracious enough to allow me
9 to do that, because they wanted me to be capable, if
10 called upon, to provide useful, meaningful,
11 intelligent advice to the Nuclear Regulatory
12 Commission on gamma knife. I took that to an extreme,
13 whatever Dr. Suh -- read his review articles and a whole
14 lot more, and actually sat for the Neuro-Oncology
15 Boards and became one of the few people who is dual
16 certified in radiation and neuro-oncology. But it was
17 because of my compulsion to be capable of serving the
18 Nuclear Regulatory Commission to the best of my
19 ability.

20 Another very clear example of how being on
21 the ACMUI has affected me, stems from one of the
22 meetings that we had here where we were talking about
23 the medical isotope crisis. And I don't remember
24 exactly what my comments were -- I was probably running
25 my mouth as usual -- but Dr. Malmud said, "So, Dr. Welsh,

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1 what it sounds like you're calling on is perhaps a large
2 scale, perhaps a Manhattan Project scale governmental
3 effort to solve this isotope problem."

4 I wasn't truly expecting that. I wasn't
5 holding my breath. But it gave me an opportunity to
6 put those nuclear physics and engineering books to good
7 use, and so I helped establish Coqui Radioisotopes and
8 Radiopharmaceuticals. And if we get the funding, I
9 would look forward to continuing to work with Nuclear
10 Regulatory Commission colleagues down the road.

11 So, clearly, the ACMUI has benefited me
12 personally and professionally, but I certainly hope
13 that my participation here has benefited the
14 radioisotope community at large, the medical user more
15 specifically, and ASTRO and radiation oncology in
16 particular.

17 I, most importantly, hope that my
18 contributions here have benefited the Nuclear
19 Regulatory Commission during some trying times where
20 there were rough times with a lot of tough questions,
21 particularly in 2009, 2010, with the permanent implant
22 brachytherapy challenges, the prostate implant
23 situation.

24 And I recall my maybe weekly telephone
25 calls with Mike, with Ashley, and certainly with Dr.

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1 Ron Zelac in particular during those times. And I
2 don't want to get into that, because it feels too much
3 like hard work again.

4 I will just conclude by saying that this
5 has indeed been a bittersweet moment for me to depart
6 from the ACMUI. I truly enjoyed my tenure here, and
7 I have made a lot of excellent professional contacts
8 and colleagues and a lot of good friends. And I think
9 that those friendships and contacts and collaborations
10 will endure.

11 Thank you very much for the opportunity to
12 have served on the ACMUI. Thank you, everybody.

13 (Applause)

14 CHAIRMAN THOMADSEN: Thank you very much,
15 Dr. Welsh. And on behalf of the Committee, I would like
16 to thank you for all of your contributions. You always
17 kept bringing us back to science, a lot of it arcane.
18 You always kept in mind the calculations that
19 authorized users should have and tried to keep us to
20 task to make sure we recognized that.

21 You brought a lot of your experience -- it
22 has been varied -- and practicality to what we do. I'm
23 sure from what you just said you were the best prepared
24 ACMUI member to come on board, and probably the only
25 one who owns a tortoise.

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1 MEMBER WELSH: I thought that was a
2 prerequisite.

3 (Laughter)

4 CHAIRMAN THOMADSEN: But thank you again.
5 We will miss you, and we hope that you will enjoy what
6 you do next.

7 MEMBER WELSH: Thank you.

8 (Applause)

9 CHAIRMAN THOMADSEN: And while Jim should
10 have had some warning about this, Orhan, you weren't
11 listed on here, but would you care to give us some
12 parting words?

13 MEMBER SULEIMAN: Yes. I have
14 appreciated working with all of you, including your
15 predecessors. I am getting off the Committee because
16 I am basically retiring from federal service, so I'll
17 have put in 39 years in another month, and I'll be
18 retiring Halloween. So I will be on call for another,
19 you know, 30 days.

20 This was another one of those other duties
21 as assigned. "Orhan, we'd like you to represent the
22 agency," you know. And I've been following, you know,
23 I mean, my -- my career started with a local health
24 department where I established, in the State of
25 Florida, and interacted with the NRC way back then.

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1 And so I sort of followed, you know, NRC
2 rulemaking over the years, and I knew they were revising
3 [Part] 35. And I'd hear about it and I said, "Boy, am
4 I just glad I'm away from that kind of stuff." And this
5 is like a decade or so ago.

6 So a few years later when I moved from the
7 Center for Radiological Center for Devices and
8 Radiological Health, where most of my FDA career early
9 on was with X-ray, mammography, CT, and so on, when I
10 did my master's thesis in graduate school with nuclear
11 medicine, it was sort of like riding a bicycle, sort
12 of getting back up to speed.

13 And I haven't answered the one question I
14 remember was, are they more bureaucratic than the FDA,
15 you know. And even to this day, it's sort of like one
16 week I -- I get pretty depressed when I interact with
17 you guys, and I'm never sure which group is more
18 bureaucratic. Okay?

19 But I learned from -- collectively, but
20 looking at a bigger picture, I think we have come a long
21 way historically in terms of radiation safety. I think
22 back, again, relating to my personal experience, we
23 were advocating quality control test procedures in the
24 '70s, because Ford and Benning and all of these people
25 that -- it hadn't been done in this field. And here

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1 we are several decades later and some of those concepts
2 are still, you know, gaining traction or coming back
3 as a new, improved, you know, version.

4 I beg to differ with Frank, but that's not
5 difficult. I think human error is almost always at the
6 root cause, because humans design the equipment, humans
7 program the equipment, and, if you want to blame
8 technology, you'll probably find out that something was
9 done wrong with the technology. And that has been one
10 of my biggest beefs.

11 And this is something that a technologist
12 told me 40 years ago. She said, "We are getting these
13 photon timers, so the X-ray equipment will
14 automatically terminate exposure. The skill of
15 measuring the patient and selecting the right energy
16 and MAS is going to go away. They are going to start
17 relying more and more on the technology, and I'm afraid
18 people are going to lose their skills."

19 And I'll fast-forward it. When the
20 medical events were -- with the radiation therapy
21 devices were proliferating, some therapy physicist
22 told me, "Orhan, I can't calculate the dose like I used
23 to. It's all done by the computer." And that's good
24 news because it has allowed us to do more sophisticated
25 things. It is bad news because we have become

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1 inherently more reliant on the technology.

2 And to me, when the rubidium incident
3 occurred, I was furious because we have qualified
4 people onsite, we have supposedly knowledgeable people
5 at the company, and what really was a breakdown in my
6 opinion is, if you've got automation taking care of a
7 lot of your issues, but you don't know how it works,
8 then you ought to be replaced by somebody off the
9 street, because some of the people, some of the
10 so-called qualified personnel onsite abrogated their
11 responsibility and didn't understand what the
12 technology was doing.

13 So just because it gets automated, and just
14 because it gets easier to perform the tasks, I think
15 it's going to be tough in the future. But for us to
16 -- the humans are going to have to make sure that the
17 technology is doing what it is supposed to be doing,
18 which means they have to understand what it's doing.

19 And we see this in -- so I don't know how
20 we address that, but it doesn't mean we rely more and
21 more on technology and at the same time cut back on our
22 responsibility. So good luck. I think that's an area
23 that we will have to somehow address.

24 That's it. I don't want to really say much
25 more. It has been fun. There is -- I think the

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1 committees that I've been on have been much more civil
2 than some of our predecessors. I mean, there was a time
3 historically -- and some of these people are still
4 alive, but --

5 (Laughter)

6 I mean, that this Committee had some very,
7 very ugly, you know, chemistry. And I have learned
8 this with my own experience at FDA with some of our
9 advisory committees. I think one of the most important
10 characteristics to serve on a committee is to be able
11 to communicate and respect other people's opinions.

12 And I think sometimes we just get too
13 defensive, you know, in terms of we think we've got to
14 protect our profession when in fact it's a collective
15 problem that we sort of -- you know, you've got a
16 wonderful group here with some real understanding of
17 the subject matter. And so you need to tap into each
18 other's experiences.

19 Otherwise, thanks so very much.

20 (Applause)

21 CHAIRMAN THOMADSEN: And, Dr. Suleiman,
22 on behalf of the Committee, I want to thank you for your
23 years of service, which predated mine. It's amazing,
24 your longevity here, that you've been able to put up
25 with it that long. Maybe coming from the FDA,

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1 sometimes this might be a breath of fresh air. It's
2 hard to tell.

3 But we have really appreciated your views
4 on things, the deep experience that you have brought
5 from various corners of your history, your idealistic
6 caring for what's right, the passion with which you try
7 to see that done, the standard for quality and for the
8 patients has always been something that we respect and
9 need, and the vision that you have helped to bring to
10 this Committee for all of that.

11 Thank you very much.

12 (Applause)

13 Now you shouldn't be surprised.

14 (Laughter)

15 Would you care to give us some wisdom as
16 your --

17 VICE CHAIRMAN GUIBERTEAU: I would like to
18 make some comments.

19 CHAIRMAN THOMADSEN: Please do so.

20 VICE CHAIRMAN GUIBERTEAU: Well --

21 CHAIRMAN THOMADSEN: Do you want to do it
22 from there or --

23 VICE CHAIRMAN GUIBERTEAU: I'll do it from
24 here. You know, I have been very honored to be the
25 first diagnostic radiologist to actually be a member

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1 of the Committee. A number of years ago when I was
2 President of the American College of Radiology, it was
3 my goal, also as Chair of the Commission on Nuclear
4 Radiology, Nuclear Medicine, it was my goal to have the
5 diagnostic portion of radiology recognized by the NRC
6 for the depth and breadth of its involvement in
7 radiation-producing devices, but also in terms of
8 radiopharmaceuticals and radioisotopes, understanding
9 that in terms of diagnostic isotopes, diagnostic
10 radiologists perform the largest number of procedures
11 in the country, non-cardiac procedures.

12 The point of this, really, is just that the
13 training and the acceptance of the NRC of that training
14 has been -- has always been with us. But I think as
15 we have evolved it has become even more necessary,
16 particularly PET being a primary example, which started
17 as a research tool many years ago. It really didn't
18 go anywhere until FDG came along and fluorine-18, and
19 it has mushroomed. I mean, it is virtually everywhere.

20 And I think to the NRC's credit they have
21 recognized the importance of expanding the purview of
22 this Committee with the expansion of the -- of the use
23 of radioisotopes in diagnostic radiology.

24 In terms of my own interests, I have always
25 been fascinated by negotiations and consensus, and I

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1 think, as Orhan said, I have been at this Committee as
2 a guest many, many -- many times in the past, I mean,
3 before your times, and it wasn't always like this. But
4 this has been really a sheer pleasure, and just chairing
5 the committee/subcommittee I just did, it was amazing
6 how the more we talked -- we didn't start out
7 altogether, but the more we talked and the more we took
8 the various perspectives together, the easier it was
9 for us to come up with what surprisingly was a unanimous
10 recommendation.

11 And so I think -- I think everyone who has
12 spoken has said this, but I think it is really true that
13 the advice you are getting from this Committee now is
14 -- should be very useful to you in making decisions on
15 how we think regulations should evolve, particularly,
16 in my case, in terms of the new procedures that have
17 come in diagnostic and interventional radiology.

18 In terms of the current Committee, I want
19 to thank you all, because I have enjoyed working with
20 each and every one of you. And in terms of the staff,
21 I think the staff has been more responsive to this group
22 as a committee than I have ever seen. I think -- I
23 haven't worked with Laura Dudes much yet, but I hear
24 very good things about you.

25 Mike Fuller has been tremendous.

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1 Donna-Beth Howe is a treasure. She keeps us from
2 getting in trouble when we want to go down the wrong
3 path.

4 (Laughter)

5 But she has already been down many times,
6 and that has been a real -- of course, Sophie, and Ashley
7 before her, have been excellent in providing us the
8 support that we need in terms of being members.

9 So I want to thank everyone here, and I want
10 to -- I really appreciate having been here for my last
11 six years. Thank you.

12 (Applause)

13 CHAIRMAN THOMADSEN: And, Mickey, you too
14 I want to thank on behalf of this Committee. And
15 personally, as to the Vice Chair, thank you for your
16 support and back up all the time. You are --

17 (Laughter)

18 -- very secure about that, particularly
19 noticing things around, such as people who want to
20 speak. And you noticed things about the issues, and
21 you always bring us back to the issues at hand as we
22 start straying into strange territories. You
23 understand reality, and you bring that perspective to
24 the discussions when we start thinking too globally
25 possibly.

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1 You distilled the discussions often into
2 their essence, and we really appreciate that. You see
3 things very clearly, even when you don't have your right
4 glasses with you.

5 (Laughter)

6 And for all of that, I think everybody here
7 has appreciated your contributions, and we thank you
8 very much.

9 (Applause)

10 Before we get to the administrative
11 closing, we have a couple of issues to take care of.
12 And the first is taking care of the Water and Energy
13 Bill, which I hope somebody is going to pay.

14 The Committee has seen a copy of the
15 proposed legislation. ASTRO has been addressing this,
16 and I'd like to ask Cindy Tomlinson from ASTRO to tell
17 us what ASTRO has done so far.

18 MS. TOMLINSON: Hi. Cindy Tomlinson.
19 It has been a long time since I've gotten to speak with
20 you all.

21 So we obviously are very concerned about
22 this Bill. We have talked with Hill staff, and our
23 biggest concern was that it likely could really impact
24 patient access to treatments, not just therapy but
25 likely diagnostics as well. And they told us that the

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1 intent was not that, not to impede patient access, but,
2 rather, to curb our reliance on materials made from
3 highly enriched uranium. And we were a little shocked
4 by that.

5 So we are right now working to revise this
6 language to send back to the Hill in the hopes that they
7 will accept it. We think that our revisions hopefully
8 capture what their intentions were. It -- also, we are
9 striking -- just to give a little taste, we are going
10 to strike the language specific to gamma knife and
11 teletherapy and well water.

12 So, but we are still in the process of
13 revising that language. We are working with our
14 leadership, with our committees, to revise that
15 language, and we I think are certainly happy to share
16 it with you when we get to that point.

17 CHAIRMAN THOMADSEN: Thank you. Thank
18 you very much. And what I think might be an effective
19 use of this Committee is to have the -- well, maybe our
20 incoming therapy physician and the current mid-career
21 physician on our committee work with ASTRO to keep in
22 touch with what sort of comments they are making in this
23 Bill, which I have seen it and maybe we should send to
24 the rest of the Committee.

25 And I think the recommended language that

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1 they are coming up with would address our concerns about
2 this also, and have the members who are working with
3 ASTRO keep this Committee apprised of where things
4 stand with that proposal, in which case we may want to
5 endorse their comments, or, if we want to say something
6 else, we might make recommendations for changes in
7 that.

8 But at the moment, I would ask Dr. Suh and
9 -- Sophie, can I ask Dr. Ennis to look at that
10 unofficially or something at the moment? When does he
11 come on board?

12 MS. HOLIDAY: He actually does not
13 officially come on board until Dr. Welsh's term ends
14 in February. However, if you are just asking for Dr.
15 Ennis in the capacity to work with ASTRO, he could kind
16 of serve like how Dr. Guiberteau did in the past, as
17 a consultant before an official member. So he can
18 certainly do that.

19 CHAIRMAN THOMADSEN: I would like to ask
20 him to do that. And if Dr. Welsh is still here until
21 February, why let him get off so easily?

22 (Laughter)

23 You've got to give the flag back.

24 (Laughter)

25 Is the Committee comfortable with that

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1 action on that? Mr. Costello?

2 MR. COSTELLO: I'm comfortable, but I want
3 to make a comment. I have also read the Bill and it
4 has many, many problems. But it doesn't just affect
5 isotopes used in therapy in medical institutions. It
6 affects blood irradiators and it affects research
7 irradiators. In fact, in terms of numbers, there
8 probably are way more of those than there aren't.

9 So when you think of the scope of what our
10 comments would be, ASTRO may not address those. I
11 suspect ASTRO would not be addressing blood irradiators
12 or research irradiators.

13 But the Bill is as bad there as it is for
14 gamma knife. So this can certainly -- I would expect
15 this -- these do affect medical institutions. I would
16 expand the scope to include other areas.

17 CHAIRMAN THOMADSEN: I think that's an
18 excellent point. I think that most of the changes that
19 they are making would probably catch that in the net.
20 And, if not, we have to make sure that we do in what
21 we do. Thank you for keeping that in our sights.

22 If everybody is comfortable with that, I
23 think we will just proceed at the moment with those
24 actions.

25 The other item of business is that the NRC

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1 has questions out dealing with proposed changes in Part
2 20. Some of these issues we have dealt with in the
3 past, such as maximum permissible doses based on
4 international standards. But I would like to name a
5 subcommittee to take a look at the questions that are
6 out and make a proposal of what the ACMUI response to
7 these questions should be. And I would ask Dr.
8 Langhorst to chair that committee, and Dr. Zanzonico
9 and Mr. Mattmuller and Mr. Costello to also sit on that
10 subcommittee and come back to this body at our next
11 meeting with what we -- what you propose our response
12 to this should be.

13 Everybody agrees with that?

14 MEMBER LANGHORST: Yes.

15 CHAIRMAN THOMADSEN: Very fine.

16 MS. HOLIDAY: Dr. Thomadsen?

17 CHAIRMAN THOMADSEN: Yes, please.

18 MS. HOLIDAY: I'd just like to add that the
19 ANPR that Dr. Thomadsen is referring to was published
20 in the Federal Register I think July 18th or somewhere
21 around there, right around the time that the Part 35
22 proposed rulemaking was published.

23 Now, it is officially out there for comment
24 until November 24th. However, I did speak with staff
25 internally, and they are -- they will gladly welcome

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1 ACMUI's comments and feedback at any time. But just
2 to kind of explain our regulatory rulemaking process,
3 the ANPR is kind of put out there for comments to kind
4 of get a feel for things. And then from that, staff
5 drafts a regulatory basis. And then the regulatory
6 basis has to be sent up to the Commission, and then the
7 Commission makes a decision whether or not to pursue
8 rulemaking.

9 So this is the very preliminary stages.
10 So similar to the Part 35, when we do actually go into
11 the rulemaking phases, ACMUI will get that official
12 60-day minimum comment period to provide their
13 officials remarks.

14 CHAIRMAN THOMADSEN: Should we up the
15 deadline? And, I mean, it's not that hard of -- the
16 questions aren't that hard.

17 MS. HOLIDAY: I would request that.

18 CHAIRMAN THOMADSEN: What's that?

19 MS. HOLIDAY: I said I would request that.

20 CHAIRMAN THOMADSEN: Yes. What is the
21 deadline for --

22 MS. HOLIDAY: It's actually
23 November 24th, but I can take it, you know, maybe by
24 the end of the calendar year.

25 CHAIRMAN THOMADSEN: Do you think by

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1 Thanksgiving you could get the response in?

2 MEMBER LANGHORST: This is Sue Langhorst.
3 Yes. You would expect an ACMUI teleconference for
4 this.

5 CHAIRMAN THOMADSEN: I would think that we
6 would need to do that.

7 MEMBER LANGHORST: Yes.

8 CHAIRMAN THOMADSEN: In which case,
9 Sophie, can you set a time and --

10 MS. HOLIDAY: Sure.

11 CHAIRMAN THOMADSEN: -- a conference
12 line.

13 MS. HOLIDAY: I'll set it up similar to how
14 we did for our planning.

15 CHAIRMAN THOMADSEN: Yes.

16 MS. HOLIDAY: I'll do a meeting wizard and
17 we can try to figure out which day works, and then we'll
18 announce it in the Federal Register Notice.

19 CHAIRMAN THOMADSEN: Great. Good.
20 Thank you very much.

21 MS. DUDES: Excuse me.

22 CHAIRMAN THOMADSEN: Yes.

23 MS. DUDES: I just wanted to comment. I
24 really appreciate you moving that up -- the date, and
25 the work that you are going to do. This Committee is

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1 so important to be advising NRC on their rulemakings.
2 And although it is a long process in drafting the
3 regulatory basis -- and we talked about this I think
4 at the meeting in the spring -- the -- to the extent
5 that we can engage the Committee as early as possible
6 in the development of the thinking, is where we will
7 reap maximum benefit in making sure that the
8 regulations, as they are drafted, are reflective of the
9 views of this community. So I do appreciate very much
10 you moving up your deadline and working that.

11 CHAIRMAN THOMADSEN: My pleasure.

12 And with that, I think we are ready to
13 adjourn for lunch. Oh, no, the administrative
14 closing.

15 MS. HOLIDAY: You're just rushing because
16 you know what's upstairs.

17 CHAIRMAN THOMADSEN: I know.

18 (Laughter)

19 And it's all your fault for showing me the
20 pictures.

21 MS. HOLIDAY: I know. I tempted Dr.
22 Thomadsen this morning by showing him the picture.

23 CHAIRMAN THOMADSEN: Of a brownie, but
24 that's --

25 (Laughter)

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1 Are we still live?

2 MS. HOLIDAY: A picture of brownies.

3 CHAIRMAN THOMADSEN: Please, Ms. Holiday?

4 MS. HOLIDAY: Okay. So during the May
5 meeting, we discussed moving the spring meeting to the
6 March/April timeframe, so that there is actually six
7 months in between the spring and the fall meeting. So
8 we looked at the March and April calendars. And so
9 similar to all of our other meeting plannings, I sent
10 out a meeting wizard, and so everyone indicated their
11 availability.

12 And when I sent this out, I was also
13 informed that if the ACMUI wishes -- and I'm sure the
14 ACMUI does wish to have a meeting with the Commission,
15 so that we can get back on the annual Commission
16 briefing, the days that they are available is March 24th
17 or March 26th.

18 So with that in mind, on the 23rd and the
19 24th, it appears that only one person had a conflict
20 and that was Ms. Weil. And we did speak about that,
21 so I think we have solved that issue.

22 And then, of course, for the alternative
23 Commission meeting date of the 26th, that would mean
24 the ACMUI meeting would be the 26th and the 27th. There
25 are three members who have conflicts, or actually two

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1 since Dr. Guiberteau will not be joining us. So that
2 is another possibility.

3 And then, when you look at other dates, say
4 we say that our first choice is the 23rd and 24th,
5 because that appears to have no conflicts with anybody,
6 then you would just need a tentative backup date. If
7 that's the case, then there are a few days where there
8 is just one person or two people that have conflicts.

9 Dr. Ennis?

10 DR. ENNIS: I have a conflict with the 23rd
11 and 24th.

12 MS. HOLIDAY: Oh, no. Okay. Well, then
13 my question, Dr. Ennis, is do you have a conflict --
14 well, do you have a conflict with the 26th and 27th?

15 DR. ENNIS: I don't. I think those dates
16 would be okay.

17 MS. HOLIDAY: Okay. So then my --

18 MEMBER MATTMULLER: Excuse me. Sophie, I
19 actually have a conflict on the 27th.

20 MS. HOLIDAY: On the 27th. So it's
21 looking like, if we want to meet with the Commission,
22 if we do it on the 23rd and the 24th, our newest member
23 will not be able to join us. If we plan it for the 26th
24 and 27th, we will have three members who will not be
25 able to join us. Or if we pick a different date where

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1 all of the Committee members can be here, or one or two
2 are not here, then we will not be able to have the
3 Commission meeting on the 24th or the 26th.

4 CHAIRMAN THOMADSEN: Do we have a date
5 that all the members could attend?

6 MS. HOLIDAY: I think Dr. Langhorst has a
7 --

8 MEMBER LANGHORST: On the 13th and 14th of
9 April, that is not ideal for me, but I can make it --

10 MS. HOLIDAY: Okay.

11 MEMBER LANGHORST: -- here, if that works
12 for everybody.

13 MEMBER SUH: Also, Sophie, the 19th and
14 the 20th I am not sure why I am shown out. I am actually
15 available those days.

16 MS. HOLIDAY: Okay. So then the days --
17 well, then, the days that everyone was available is
18 March 19th and 20th. Does that work for you, Dr. Ennis?

19 DR. ENNIS: March?

20 MS. HOLIDAY: March 19th and 20th.

21 DR. ENNIS: Yes.

22 MS. HOLIDAY: Yes. Okay.

23 CHAIRMAN THOMADSEN: What about Dr. Suh?

24 MEMBER SUH: I'm checking my Outlook.
25 It's okay, actually.

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1 MS. HOLIDAY: Okay. And then -- so then
2 it appears that the next set of dates where everyone
3 is available, although not ideal for Dr. Langhorst, is
4 April 13th and 14th. Is that correct?

5 So, then, would we want our first choice
6 for a meeting to be March 19th and 20th, with the backup
7 date of April 13th and 14th? And we can work with the
8 Commissioner's staff to see if we could possibly move
9 dates.

10 CHAIRMAN THOMADSEN: Yes. But it sounds
11 agreeable. Yes.

12 DR. ENNIS: Could you give the dates
13 again?

14 MS. HOLIDAY: Sure. The second set of
15 dates, Dr. Ennis, is April 13th and 14th.

16 DR. ENNIS: April 13th and 14th?

17 MS. HOLIDAY: Not good?

18 DR. ENNIS: Not good.

19 MS. HOLIDAY: Okay.

20 DR. ENNIS: I apologize.

21 MS. HOLIDAY: That's okay. Well, what we
22 can do is we can either pick our backup date to be either
23 March 23rd and 24th or April 13th and 14th. And what
24 I can do is I can ask the Commissioners' staff to see,
25 first, if we can do a Commission meeting either on March

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1 19th or 20th. And if they say no, we can see if they
2 can do it the 13th or the 14th.

3 We already know that there is going to be
4 a conflict for the 13th and 14th of April and the 23rd
5 and 24th of March for Dr. Ennis. But as backup, because
6 that will be our backup date. Our primary date will
7 be March 19th and 20th, with the backup dates of either
8 March 23rd and 24th or April 13th and 14th. Does that
9 sound like a plan?

10 CHAIRMAN THOMADSEN: Sounds like as good
11 as we can do at the moment.

12 MS. HOLIDAY: Right.

13 CHAIRMAN THOMADSEN: When do you think you
14 will have this --

15 MS. HOLIDAY: I will reach out to staff
16 maybe this week or next week. Hopefully, I can have
17 a response to you guys, because they do Commission
18 agenda planning at a specific date and time. So I have
19 to work around their schedules. I think you have a
20 comment.

21 CHAIRMAN THOMADSEN: Oh, I'm sorry.

22 MS. FAIROBENT: Yes. Lynne Fairobent.
23 Just to point out, the NCRP meeting is the 16th and 17th.
24 I don't know if it would be more beneficial for members
25 to be able to meet on the 18th and 19th and not -- for

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1 those who would be attending the NCRP meeting, which
2 is on radiation regulation this year.

3 CHAIRMAN THOMADSEN: Dr. Langhorst?

4 MEMBER LANGHORST: I have a commitment
5 already on the 18th for a subcommittee then, so, no,
6 it wouldn't for me, but --

7 MS. HOLIDAY: Okay. So I will proceed
8 with March 19th and 20th as our first date. Our backup
9 dates are March 23rd and 24th or April 13th and 14th.

10 Okay? So now that brings us to our updated
11 recommendations and actions chart for 2014. So I'll
12 start off by saying for Item 4, which is the
13 Subcommittee on the Y-90 Microspheres Medical Event
14 Reporting Criteria, I can officially close this
15 subcommittee and remove it off of our list as we have
16 committed to do in removing all subcommittees off of
17 our list because that subcommittee has already
18 presented their report.

19 And then if you move down to Item 10 -- just
20 a little bit up, Gretchen. Right there. Item 10 --
21 Items 10, 11, 12, and 13 have to do with the
22 recommendations that came out of the Y-90 Microspheres
23 Medical Event Reporting Criteria Subcommittee.

24 The ACMUI endorsed all three of the
25 recommendations, and then endorsed the overall

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1 subcommittee report, which means that the report will
2 be published on the NRC reports website as the
3 Committee's report, final report.

4 Item 14 refers to the ACMUI bylaws. The
5 ACMUI endorsed all of the changes to the bylaws,
6 including the proposed changes or proposed language in
7 Section 1.3.5 and 3.1 and also the changes that Ms. Dudes
8 recommended, being the main change for the office and
9 the division.

10 Item 15 is where the Committee requested
11 that staff provide them with a contact list for the NRC
12 Commissioners. I am compiling all of the information
13 of all of the staff contacts that I think you should
14 have, including Commissioners, the new NMSS management,
15 and the medical team members. So I will send that out
16 to you all either this afternoon or tomorrow.

17 Item 16 refers to the memorandum that I sent
18 to the Commission regarding to the international
19 practices of patient release. I did commit to provide
20 that to the Committee, and I sent that out last night.
21 So I hope everyone received that. Not sure if you would
22 have read it, but I sent that out last night. So I
23 consider that item closed.

24 Item 17, Dr. Thomadsen tasked Dr. Langhorst
25 and Mr. Costello with creating a proposal to present to

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1 the Committee and staff regarding the costs and
2 logistics for an additional face-to-face meeting and/or
3 a medical regulatory information conference.

4 Dr. Langhorst?

5 MEMBER LANGHORST: Can we clarify yet that
6 that -- we will have a staff member to work with?

7 MS. HOLIDAY: You will. We just --

8 MEMBER LANGHORST: I mean, it's --

9 MS. HOLIDAY: As soon as management has
10 identified who the staff person will be, I will update
11 this chart and inform the both of you.

12 MEMBER LANGHORST: Just because I don't
13 know that Frank and I can do this on our own.

14 MS. DUDES: We will provide that, and I
15 think, you know, part of the discussion -- so I'm glad,
16 Frank, that you're doing that, is to see if -- you know,
17 to take a step by trying to see what we can add on a day
18 at OAS and how we would fund that. So I will get you
19 a contact person shortly and see what topics the
20 committee would like to include.

21 I think Boston is a good location. We get
22 a lot of -- should get some places to --

23 MR. COSTELLO: That's a great location.

24 MS. DUDES: Yes. I just --

25 MS. HOLIDAY: Okay? Item 18 is where we

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1 have tentatively scheduled the meeting. I won't repeat
2 the dates again, because we just said it.

3 And then another item that I did not add,
4 the last two items that I did not add because we just
5 discussed them, was that Dr. Thomadsen has tasked the
6 existing radiation oncologists on the ACMUI -- and he
7 requested the assistance of Dr. Ennis -- to work with
8 ASTRO for their proposed language changes to the FY15
9 water and energy bill.

10 These individuals will then present this
11 information to the Committee for their endorsement.
12 Are there any issues with that recommendation or action?
13 Okay.

14 And then, the very last action that I have
15 is that Dr. Thomadsen created a subcommittee to review
16 the ANPR for the Part 20 that was published in the
17 Federal Register. They will have their
18 recommendations around the Thanksgiving timeframe, and
19 we will tentatively set a teleconference sometime after
20 that report comes out.

21 The members on that subcommittee are Dr.
22 Langhorst as the Chair, Dr. Pat Zanzonico, Mr. Frank
23 Costello, and Mr. Steve Mattmuller.

24 Are there any questions or comments on any
25 of these recommendations or actions?

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1 CHAIRMAN THOMADSEN: Mr. Mattmuller?

2 MEMBER MATTMULLER: Yes. I'm pleased to
3 see the subcommittee for gallium-68 made it to this
4 list. But, also, should not the subcommittee on
5 addressing Part 35 rulemaking make it to this list, or
6 it's okay that it's on an older list?

7 MS. HOLIDAY: It's on an older list,
8 because that subcommittee did all of their work on 2013.

9 MEMBER MATTMULLER: Okay.

10 MS. HOLIDAY: So until further actions
11 come from the rulemaking subcommittee, they don't make
12 it back onto the chart, so we don't, like, carry over.
13 It is just whenever the next action comes up, then you
14 are added on the list.

15 MEMBER MATTMULLER: Just didn't want it to
16 be forgotten.

17 MS. HOLIDAY: So I'm sure that there will
18 be a flurry of activity in 2015. I'm sure there will be
19 quite a lot of activity from that subcommittee. So have
20 no fear.

21 CHAIRMAN THOMADSEN: Thank you. Mr.
22 Costello?

23 MR. COSTELLO: Yes. I'd like to comment
24 on -- thank you -- something that initially came out
25 during Dr. Welsh's presentation on medical events that

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1 I would like us to at least consider having the
2 subcommittee look into, and that is the interpretation
3 of patient intervention.

4 And during our discussions about Y-90
5 microspheres, at least it was clear to me I think that
6 the interpretation of patient intervention by the
7 medical -- most members, not all of the members of the
8 -- of our subcommittee, was different than what I
9 understand the interpretation of patient intervention
10 to be from my time at the NRC and my time in Pennsylvania.

11 I believe that -- and the NRC can correct
12 me or not -- that the traditional interpretation
13 basically is intentional or unintentional action by the
14 patient that changes the course of the treatment. So
15 if a patient gets off the -- up off the table from
16 external beam, or the patient pulls tubes out during
17 HDR, or something like that, it could be while they are
18 sleeping or it's unintentional or they become
19 uncomfortable and they stand up, or what have you.

20 But I think what came out during discussion
21 is, well, one what I would call passive patient
22 intervention, where the physiology of the patient --
23 remember you talked about the pubic arch when you were
24 talking about the prostate. And it came up when we were
25 discussing the Y-90.

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1 Now, the physiology of the patient is such
2 that despite the physician doing everything properly,
3 and the medical staff doing everything properly, the
4 outcome of the treatment is that an unintended organ
5 gets a dose beyond what the limits would be, or the
6 intended organ gets a dose under what it would be.

7 I think there is a big difference in
8 understanding what patient intervention means.
9 Patient intervention can include what I would call this
10 passive intervention. And so I think it might be
11 worthwhile for some members of the Committee to get
12 together.

13 And now the rule -- I don't think this
14 requires a rulemaking, really. The rule I think is what
15 it is; it's a matter of interpreting what is meant by
16 "patient intervention. Should that include passive
17 interventions, physiology of the patient, the pubic
18 arch, or is it only limited to things the patient
19 actually does?

20 So I think it might be worthwhile for us to
21 talk back to -- give the NRC some recommendations.

22 CHAIRMAN THOMADSEN: I agree fully. And
23 the -- I had planned on having a discussion of that at
24 our next meeting.

25 MR. COSTELLO: Okay.

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1 CHAIRMAN THOMADSEN: And naming a
2 subcommittee to come up with a proposed interpretation
3 at that time. If waiting until the next meeting is
4 acceptable--

5 MR. COSTELLO: I think that's fine.

6 CHAIRMAN THOMADSEN: It's fine.

7 MR. COSTELLO: Excellent.

8 CHAIRMAN THOMADSEN: So -- I see Sophie is
9 writing down already, so I think we have - you've got
10 it on the agenda.

11 Any other comments from the Committee on
12 where we are or what we need to do? And hearing none,
13 thank you very much, Ms. Holiday.

14 At this point, I'll ask, is there anything
15 else that you would like to bring up before we break for
16 lunch?

17 MS. DUDES: No. I know everybody wants to
18 go to lunch. I will talk to you during lunch. But I
19 just wanted to thank you again. I appreciate all of the
20 participation. I thought the discussions yesterday
21 were fascinating and very rich, both topically and the
22 sharing of information. So I look forward to comments
23 on Part 20, ANPR, and our next meeting.

24 Thank you.

25 CHAIRMAN THOMADSEN: Thank you. So we

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1 stand adjourned for lunch.

2 (Whereupon, the above-entitled matter went
3 off the record at 11:30 a.m. and resumed at 12:41 p.m.
4 in Closed Session.)

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