

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Meeting of the Advisory Committee on the
Medical Uses of Isotopes: Open Session

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Friday, May 9, 2014

Work Order No.: NRC-755

Pages 1-103

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
+ + + + +
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
+ + + + +
SPRING 2014 MEETING
+ + + + +
OPEN SESSION
+ + + + +
FRIDAY,
MAY 9, 2014
+ + + + +

The meeting was convened in room T-2B3 of
Two White Flint North, 11545 Rockville Pike, Rockville,
Maryland, at 1:00 p.m., Bruce R. Thomadsen, Ph.D., ACMUI
Chairman, presiding.

MEMBERS PRESENT:

BRUCE R. THOMADSEN, Ph.D., Chairman

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

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

FRANCIS M. COSTELLO, Agreement State
Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

STEVEN R. MATTMULLER, Nuclear Pharmacist

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

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

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

LAURA M. WEIL, Patients' Rights Advocate

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

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

NRC STAFF PRESENT:

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MICHAEL FULLER, Designated Federal Officer
2 SOPHIE HOLIDAY, Alternate Designated Federal
3 Officer, ACMUI Coordinator
4 DOUGLAS BOLLOCK, FSME/MSSA/RMSB
5 SUSAN CHIDAKEL, OGC/GCLR/RMR
6 JACKIE COOK, RIV/DNMS/NMSB-B
7 SAID DAIBES, Ph.D., FSME/MSSA/RMSB
8 JIM DWYER, RI/DNMS/MB
9 SARA FORSTER, RIII/DNMS/MLB
10 CASSANDRA FRAZIER, RIII/DNMS/MLB
11 SANDRA GABRIEL, Ph.D., FSME/MSSA/RMSB
12 JOE GIESSNER, RIII/DNMS
13 LATISCHA HANSON, RIV/DNMS/NMSB-A
14 MICHELLE HAMMOND, RIV/DNMS/NMSB-B
15 VINCENT HOLAHAN, Ph.D., FSME/MSSA
16 DONNA-BETH HOWE, Ph.D., FSME/MSSA/RMSB
17 KEVIN NULL, RIII/DNMS/MLB
18 DENNIS O'DOWD, RIII/DNMS/MLB
19 BRYAN PARKER, RIII/DNMS/MLB
20 PATTY PELKE, RIII/DNMS/MLB
21 WILLIAM REICHOLD, RIII/DNMS/MLB
22 GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB
23 LIZETTE ROLDAN, Ph.D., RIV/DNMS/NMSB-B
24 MOHAMMAD SABA, RES/DSA/RPB
25 TOYE SIMMONS, RIII/DNMS/MLB

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 REBECCA TADESSE, RES/DSA/RPB

2 FRANK TRAN, RIII/DNMS/MLB

3 LESTER TRIPP, RI/DNMS/MB

4
5 MEMBERS OF THE PUBLIC PRESENT:

6 DAVID ALLARD, Pennsylvania Bureau of Radiation
7 Protection

8 MAXWELL AMURAO, Columbia University Medical
9 Center

10 SARAH BENDER, Ph.D., National Nuclear Security
11 Administration

12 LISA BRUEDIGAN, Texas

13 SUE BUNNING, Society of Nuclear Medicine and
14 Molecular Imaging

15 JESSICA CLEMENTS, Texas

16 PETER CRANE, unaffiliated

17 ROBERT DANSEREAU, New York State Department of
18 Health

19 RAY DIELMAN, Florida Department of Health

20 KAREN FLANIGAN, New Jersey Department of
21 Environmental Protection

22 CINDI GILBERT, North Carolina Nuclear Medicine
23 Technologists, Inc.

24 BRIAN GORETZKI, Arizona Radiation Regulatory
25 Agency

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 GEORGIA HEARN, American Society of Nuclear
2 Cardiology
3 ANGELA HILL, Arkansas Department of Health
4 CAITLIN KUBLER, Society of Nuclear Medicine and
5 Molecular Imaging
6 RALPH LIETO, Trinity Health System
7 JOSE MORALES, MD, Hima San Pablo (Puerto Rico)
8 VICKI MORRIS, University of Cincinnati
9 ELIZABETH PEETZ, Mallinckrodt Pharmaceuticals
10 MICHAEL PETERS, American College of Radiology
11 GLORIA ROMANELLI, American College of Radiology
12 DANIEL SNYDER, Geisinger Health System
13 TOD SPEER, MD, Willmar Regional Cancer Center
14 PARRISH STAPLES, Ph.D., National Nuclear
15 Security Administration
16 MICHAEL STEPHENS, Florida Bureau of Radiation
17 Control
18 JOY STEPHENSON, Florida Bureau of Radiation
19 Control
20 GLENN STURCHIO, Mayo Clinic
21 JULIE TIMINS, MD, unaffiliated
22 CINDY TOMLINSON, American Society for Radiation
23 Oncology
24 PAUL YURKO, Veterans Health Administration
25

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

A-G-E-N-D-A

| | |
|---|--|
| 1 | |
| 2 | Research on the Release of Patients Following Iodine-131 |
| 3 | Administration 16 |
| 4 | Opportunity for Public Comment 49 |
| 5 | NNSA's Efforts on Reducing HEU in Molybdenum-99 |
| 6 | Production 56 |
| 7 | Administrative Closing 98 |

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

P R O C E E D I N G S

1:01 p.m.

CHAIRMAN THOMADSEN: Before we start with the agenda we have one item on gallium from yesterday.

We created a subcommittee to address the issues around the decommissioning plan for gallium-68 with Mr. Mattmuller as the chair. We had not established the charge. We wanted to take a little time to think about it.

And Mr. Mattmuller has developed a first draft charge if you would like to read that.

MEMBER MATTMULLER: Certainly. Yes. It would be to evaluate the cost of a decommissioning funding plan, its effect on the future clinical use of new gallium-68 grade pharmaceuticals and how appropriate regulatory relief may be gained.

CHAIRMAN THOMADSEN: Thank you. Comments. Mr. Costello.

MEMBER COSTELLO: It's a small plan. I realize the target of decommissioning --

CHAIRMAN THOMADSEN: I can't understand a word you're saying. It sounds like we're getting a lot of the echo again. At least I am.

MEMBER COSTELLO: I'll speak more slowly, does that help?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 CHAIRMAN THOMADSEN: Give it a shot.

2 MEMBER COSTELLO: I believe that this is
3 germanium-68 rather than gallium-68 that creates the
4 problem for decommissioning. So just to be clear in the
5 charge, that we're really talking about the
6 germanium-68.

7 CHAIRMAN THOMADSEN: Then why don't we make
8 that change in the charge.

9 MEMBER COSTELLO: And the other point is, and
10 I don't know how to put this in there. This is only a
11 problem because the table is wrong. Okay?

12 Regardless of what the cost may be if the tables
13 were consistent with every other isotope on the table,
14 we wouldn't even be discussing this. So I don't think
15 the burden should be that we have to show that -- how
16 expensive it is to develop a decommissioning plan for
17 gallium-68 generators because actually displacing them
18 is fairly simple.

19 But that is unnecessary from any risk-based
20 sensible approach. And the problem really comes in not
21 with the disposable generator which we have here which
22 you could give back to the manufacturer and be done with
23 it.

24 But rather that in the use of an artificially
25 low value you wind up having -- for some places it being

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 decommissioning carbon-14 labs and tritium labs, that
2 otherwise you would not have to have a decommissioning
3 plan for.

4 I would hope the NRC would not require --
5 demonstrate the tremendous burden for disposing of
6 germanium-68 generators when that's not really the heart
7 of the problem. The heart of the problem is we shouldn't
8 be talking about it at all. That make sense?

9 CHAIRMAN THOMADSEN: Yes.

10 MEMBER MATTMULLER: I fully agree.

11 CHAIRMAN THOMADSEN: And I would assume that
12 issue would be coming out of the subcommittee's work.

13 MEMBER COSTELLO: And that's -- I think the
14 staff is in agreement. I mean, technically in agreement
15 I would think.

16 MEMBER LANGHORST: Steve, would you read the
17 first part again?

18 MEMBER MATTMULLER: Just given Frank's
19 comments. Can I --

20 MEMBER LANGHORST: Yes.

21 MEMBER MATTMULLER: The cost of a DFP for the
22 use of germanium-68 come -- its effect on the future
23 clinical use of new gallium-68 radiopharmaceuticals and
24 how appropriate regulatory relief may be gained.

25 MEMBER LANGHORST: I know that Ms. Dudes asked

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 yesterday about getting cost and so on. But it's so
2 dependent on if it's just a clinic that's only going to
3 use this generator decommissioning funding plan isn't
4 going to be that big a deal.

5 But if it is an established licensee that may
6 have 3 labs, 20 labs, 100 labs, I don't know how we can
7 figure out the cost of a decommissioning funding plan.
8 I think we can give indication of the impact it would
9 have and be unfair to some licensees unnecessarily
10 because the numbers are not in the table and should be
11 in the table.

12 MEMBER COSTELLO: I would put that on the staff
13 if they've got the Appendix B value for germanium-68,
14 the lowest possible value. Considering the
15 radiological risk -- considering everything.

16 It's just an artifact of the history of the
17 regulation. If we could change regulation legally we
18 would get the regulation out and change it by hand. But
19 unfortunately that's not the way things are done.

20 CHAIRMAN THOMADSEN: Do you know what they
21 could change in there?

22 MEMBER LANGHORST: I would say that we might
23 want to evaluate the inconsistent or the unintended --
24 and I can't say it right. The unintended unfairness to
25 different licensees that this burden adds. I can't

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 write it very well for you but that's - it's not a fair
2 measure because it has different impacts for different
3 groups.

4 And I don't know how we would figure out the
5 decommissioning funding --

6 CHAIRMAN THOMADSEN: I read that first line
7 and thought it meant the cost to society in which case
8 that would be --

9 MEMBER MATTMULLER: No, that was not the
10 intention. It would be the cost to the licensee.

11 MEMBER LANGHORST: So maybe --

12 CHAIRMAN THOMADSEN: It could go both ways.

13 MEMBER LANGHORST: Maybe if we -- sense of
14 cost, the implication of decommissioning funding, the
15 need for a decommissioning funding plan at various --
16 for various licensees.

17 CHAIRMAN THOMADSEN: That sounds good.

18 MS. DUDES: I think that we have the same point.
19 And I think we asked yesterday however you want to frame
20 the question. I think we added this idea of cost just
21 because -- but not necessarily some exact quantitative
22 analysis.

23 I think Donna-Beth had suggested yesterday
24 that what we're trying to do is get a recommendation from
25 you that would actually either put us into a rulemaking,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 a direct final rule, or something to address this issue.

2 And in particular if it is the table we should
3 address the underlying cause rather than a specific
4 isotope or relief on that.

5 And so I think the suggestion was -- even if
6 it's qualitative to just get us down the road for having
7 to justify why we would do such a thing. And I wouldn't
8 spend a lot of time trying to exact the cost. But maybe
9 start us on a qualitative path for that type of analysis.

10 MR. FULLER: The only thing I would add as
11 something to consider is in situations like this when
12 it's really, really hard to quantify, to bring it down,
13 you might do some sort of bounding calculation.

14 In other words, say, you know, in the best set
15 of circumstances it would be in the range of. And in
16 the worst set of circumstances it could be as high as.
17 Something like that would be very helpful.

18 CHAIRMAN THOMADSEN: Dr. Howe.

19 DR. HOWE: It appears as that the table is the
20 problem. So if we were to change the table that would
21 go a long way to solving the problem.

22 And if we were to change the table for this
23 isotope it would be good to have a recommendation of what
24 to change into and a basis for that. And that goes into
25 the concept of what -- because the more information you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 can provide us with the more sure I will be that it will
2 be right. So I would defer to your charge...

3 MEMBER COSTELLO: I can do it now sitting here,
4 okay?

5 DR. HOWE: Say that again?

6 MEMBER COSTELLO: I can do it now, okay? I
7 don't know if you have a copy of the CFR but we have them
8 here.

9 We talk about Appendix B to Part 30, right?
10 That's where you get the numbers for decommissioning.
11 And the title of that is Quantity of Licensed Material
12 Requiring Labeling.

13 Well, it so happens that in Part 20 there's a
14 table called Quantity of Licensed Material Requiring
15 Labeling. And in fact it has a value for germanium-68.
16 There's not one in Part 30, but there's one in Part 20.

17 Well, you know, the -- if you look at the Part
18 20 one for germanium-68 it's in microcuries. If you look
19 at in Part 20 in the radionuclide it's 10 nanocuries.
20 It's a lot different.

21 So maybe if you just -- basically it's
22 essentially the same thing. Essentially.

23 Part 20 is more generous in indicating isotopes
24 than Part 30 is. Just saying. They're both from the
25 same intention. They're both the intention to be a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 risk-based frame with the number being, you know, bigger
2 numbers are associated with less risky isotopes and
3 smaller numbers, more risky isotopes.

4 Our number is truly inappropriate. It's just
5 going from one page in this book at 602 to page 435 and
6 you may find some useful information. Just a
7 consideration.

8 MS. DUDES: Mr. Chairman, if I may. It's your
9 meeting to run as you would.

10 I would suggest -- I mean part of this -- the
11 whole idea of having a subcommittee is so that you guys
12 can provide us something in writing so that we can get
13 off a dime on this. And so we have a very important topic
14 coming up to do it.

15 And we will be able to act if you can develop
16 that and provide it to us in writing.

17 CHAIRMAN THOMADSEN: Yes. But we've learned
18 you need to have these charges written carefully and
19 covering what's supposed to be in here.

20 Can you read us back the charge as you have it
21 right now?

22 MEMBER MATTMULLER: Well, I haven't changed it
23 too much. But just to clarify, because what I'm hearing
24 is we have our charge but the conversation we've had now
25 are aspects of the information we need to include in our

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 report which I've got half a dozen different items here.
2 So I don't know if that's -- if we need to put all that
3 detail into that. No.

4 So, okay, the charge as I have it now. Evaluate
5 the cost of a decommissioning funding plan for the use
6 of germanium-68, its effect on the future clinical use
7 of new gallium-68 radiopharmaceuticals and how
8 appropriate regulatory relief may be gained.

9 CHAIRMAN THOMADSEN: Sounds fine to me. Any
10 further comments?

11 MS. HOLIDAY: Dr. Thomadsen?

12 CHAIRMAN THOMADSEN: Yes.

13 MS. HOLIDAY: Just for the record I'm going to
14 repeat what we have from yesterday to today. So I have
15 on May 8 Dr. Thomadsen formed a subcommittee to provide
16 staff with background information to justify the
17 recommendation for the decommissioning funding plan
18 regulatory relief.

19 The subcommittee is specifically charged with
20 evaluating the cost of a DFP for the use of germanium-68,
21 its effect on the future clinical use of new gallium-68
22 for radiopharmaceuticals and how appropriate
23 regulatory relief may be gained.

24 Subcommittee members include Dr. Susan
25 Langhorst, Mr. Frank Costello, Dr. Palestro, Dr.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Zanzonico and Mr. Steve Mattmuller as the chair. Is that
2 correct?

3 CHAIRMAN THOMADSEN: I think so. Does that
4 charge sound like what you just said? That sounds like
5 it to me.

6 MS. HOLIDAY: Thank you.

7 CHAIRMAN THOMADSEN: I think we stand. With
8 that we'll launch into this afternoon's agenda.

9 And we have with us Mr. Saba to tell us about
10 the status of the patient release study.

11 MR. SABA: Thank you. I'm the project manager
12 for the patient release study and it's my pleasure to
13 give you an update on this subject for the next 15-20
14 minutes.

15 First, I would like to give you a short
16 background on the subject and then I think an update just
17 to refresh your memory.

18 According to the old rule the measure
19 illustrate dose from the patient on the human subject
20 is less than 5 millirems per hour at a distance of 1 meter.
21 All the activity of the returning the patient or human
22 research subject is less than 30 millicuries.

23 This rule was changed in 1997. According to
24 the current rule, the licensees should make sure that
25 the total effective dose to any member of the public is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 not likely to exceed 5 millisieverts as a result of the
2 release.

3 Of course, this rule was different. People
4 had different opinions on this. That's why the
5 Commission directed us to review publicly available data
6 on doses being received by members of the public, the
7 results of the application of 10 C.F.R. part 35.75
8 release criteria and also perform some collection of
9 data in the area where data is missing or is not enough.

10 Of course, an assessment of this rule is not
11 part of this project.

12 But basically the objective is to how well
13 these patient release practices are working and to what
14 extent that 500 millirem dose to the public is being met.

15 In this slide I give you the current status of
16 work. We have completed review of the technical
17 literature. We have completed dose calculations of
18 some situations not found in the literature that I show
19 you later. And also we have completed a contract to do
20 the field work to -- and I will talk to you about this
21 later. This work takes about 3 years after awarding the
22 contract.

23 Research staff has conducted an extensive
24 review they have done on the domestic and international
25 journals like Health Physics, Medical Physics,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Radiation Dosimetry and so on. And for medicine,
2 radiology and so on.

3 And also we have the new NCRP publications
4 related to patient release. We have reviewed ICRP, IAEA
5 and we looked at Commission's judgments that they are
6 related to patient release criteria.

7 Our review was focused more on internal and --
8 internal dose, external dose, effective dose, effective
9 half-life and dose calculation. And dose calculations
10 in Regulatory Guide 8.39.

11 NRC has conducted calculations using
12 computational phantoms with the new ICRP biokinetic
13 model and Monte Carlo calculation to reach a larger
14 patient and the target and extrapolate doses in greater
15 situations such as transportation, hotels, and nursing
16 homes.

17 I would like to say more about the slide, the
18 phantom that was used known as PMO. This phantom was
19 developed at NRC last year but it's not public yet.

20 It contains all the relevant organs and tissues
21 with dimensions and densities that conformed with the
22 recommendations in ICRP 89.

23 The phantom has capability of bending the arms
24 and legs. This permits us to model the realistic
25 situations. And also it was necessary for us to know

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the distribution of iodine in the body as a function of
2 time following administration of the therapeutic doses.

3 That's why we use the new ICRP biokinetic
4 model. This model was produced later in the Oak Ridge
5 lab for ICRP. And doing a study using phantom and
6 biokinetic model showed that dominant sources of
7 exposure from the cancer patient were the thyroid and
8 the urinary bladder.

9 So, we allowed the calculation to be performed
10 using PMO with iodine distributed in three different
11 organs, in thyroid and -- in thyroid, in the bladder and
12 the rest of the remaining tissue.

13 Two thyroid combinations were examined,
14 thyroid cancer patients and thyroid toxicosis patients.
15 Next slide.

16 I just show you the different scenarios that
17 they are missing in the literature and we did the
18 calculations by using MCNP6 and our phantom.

19 These are the situations in transportation.
20 The first slide shows a patient standing next to a member
21 of the public. I won't go through the whole thing.

22 This is also transportation. This is
23 transportation, sitting patient behind a member of the
24 public. This is next sitting beside the patient, a
25 member of the public. And also this is another situation

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 in a transportation case, another transportation case.

2 But also this is one can happen in hotel or
3 nursing home. This is a situation in nursing home and
4 a hotel where a patient is staying in one room and another
5 patient is in the other room adjacent to the patient's
6 room.

7 There is another case that we studied or we
8 calculated dose for. Okay, the last one is -- the last
9 one is also nursing home.

10 I just wanted to show you that we have done our
11 literature review and we have found what was missing.
12 And we tried to calculate what was missing in the
13 situation.

14 The field work opportunity, I can tell you that
15 these are just -- although I can give you the following
16 general information about the contract because it's not
17 public yet. The contract -- actually notice will be
18 posted in the Federal Business Opportunities website
19 within 2 weeks.

20 Basically in the first part of the contract we
21 want to know how many percentages of people went to a
22 location out of their homes or their relatives' homes,
23 i.e., like going to a hotel or a nursing home.

24 And also identify possible sites that we can
25 go and collect that data. If it is possible to go to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 any site and collect data under [inaudible] we can go
2 and collect data on doses received by the workers and
3 visitors.

4 And if it doesn't work then we have to perform
5 time and motion study to document and replicate patient
6 and member of the public exposure scenarios and
7 activities. And then combine this information with
8 what the -- replicate the calculation that we did in Oak
9 Ridge lab and come up and actually reconstruct doses for
10 members of the public. We might say members of the
11 public, the workers, you know.

12 This slide basically is a summary of the
13 project. We are looking for public exposure. Public
14 exposure can be internal, external.

15 For residents, they tell me we reviewed the
16 literature and we have an update on the patient
17 relatives. We are ready to give our recommendation to
18 the condition on that part.

19 But for hotel and nursing home as I said before
20 we don't have anything. Either we will be able to get
21 the information from the field work or a combination of
22 field work and our calculations.

23 And the general public exposures like
24 transportation, again, there was nothing in the
25 literature. And we calculated all the possible

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 scenarios that as mentioned we could.

2 The next -- this slide is basically our last
3 stage of our project. After we are done with the
4 literature review and calculations we inputted all of
5 finding into our Regulatory Guide 8.39.

6 What we do review equation use review
7 assumptions in this guide and also interact with medical
8 center. We know that it's very important to, as you
9 recommended before, it was very important to us. And
10 we get more influence on the subject. Hopefully we will
11 have a much better Reg Guide this time.

12 RES will submit the results of its review and
13 calculations in a detailed report to the ACMUI when it's
14 final. The draft report is under review. It's titled
15 "A Review of Technical Literature Dose Calculations and
16 Recommendations.

17 And once we receive the comments from the
18 offices we incorporate them and send it to -- submit it
19 to the Commission.

20 What's our next step? We have to wait for
21 direction from the Commission.

22 Thank you so much and I'm open to questions.

23 CHAIRMAN THOMADSEN: Thank you. Comments and
24 questions from the Committee?

25 I just have sort of a business-related

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 question. You do if I understood correctly a research
2 contract or a contract presumably for some entity to
3 perform field maintenance. Is that correct?

4 MR. SABA: Yes. There are two tasks. I can't
5 tell the details, but there are two tasks. The first
6 task, we find out if there is a way that we can go in
7 one of these facilities and collect data.

8 If we can do it, as I said, we have to do it
9 within days.

10 CHAIRMAN THOMADSEN: Well, the reason I ask is
11 it just seems that if this -- is this going to be a typical
12 sort of like NIH research contract type peer reviewed
13 selection process?

14 MR. SABA: We have a contract with ADM. ADM
15 qualified this contract as a small business contract.
16 So only small business companies can respond to this
17 solicitation.

18 CHAIRMAN THOMADSEN: So, universities and
19 other research institutions would not be allowed?

20 MR. SABA: I don't think universities are
21 considered small businesses.

22 CHAIRMAN THOMADSEN: It strikes me as a
23 suboptimal way. Because I think the most credible
24 entities in terms of scientific credibility would be --

25 MR. SABA: As far as businesses, they can use

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 universities. If they are affiliated with universities
2 then they can use universities.

3 MS. TADESSE: Hi. This is Rebecca Tadesse.
4 I'm the branch chief for the research group.

5 What we're doing is that the contract would be
6 coming in with the small business and we'll have a number
7 of panels that would look at it, some of them being from
8 FSME. And once that they're evaluated, if it's not the
9 correct mechanism, we'll go to --

10 MS. HOLIDAY: Sorry to interrupt you real
11 quick. Can you please identify yourself for the court
12 reporter?

13 MS. TADESSE: Hi, this is Rebecca Tadesse.
14 I'm the branch chief for the Research Division of
15 Radiation Protection.

16 So, we will look at it. If it's not the right
17 contract then we'll go to the next step. But we have
18 a panel that's going to be looking at it that are, you
19 know, Donna-Beth and others that will see whether or not
20 they're capable of doing such work.

21 CHAIRMAN THOMADSEN: Not to label [inaudible]
22 it just seems that, especially sort of doing it in the
23 holistic guidance particularly given the politically
24 sensitive nature of this, it just seems that expanded
25 research has a contract including initially

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 university-based labs or research organizations rather
2 than commercial entity will give the result, will give
3 the greatest credibility.

4 MR. SABA: It's commercial - it's commercial.
5 Only small businesses can respond.

6 CHAIRMAN THOMADSEN: Why is that?

7 MR. SABA: That's the rule in the statute.

8 CHAIRMAN THOMADSEN: Oh, okay. So it's
9 legally required. I think that's the answer.

10 MS. TADESSE: And also, we will look at what
11 their capabilities are. So it's not that just because
12 it's a small business, if they're not capable of doing
13 it, they don't have the right makeup of people, we won't
14 go to that next step of vetting. First we have to go
15 through the steps to see whether or not.

16 CHAIRMAN THOMADSEN: Thanks. Dr. Welsh.

17 MEMBER WELSH: Thank you. I think my question
18 might have been answered, but first I want to commend
19 you for taking this important step. A number of years
20 back when this issue first reared its head, I suggested
21 that we could do all the calculations in the world and
22 be 100 confident in our calculations but until it's
23 corroborated by some type of actual data there are still
24 going to be some naysayers out there.

25 And at that time I think I volunteered to design

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 a study. And so I hope that the study that you are
2 working on is very cost-efficient because this shouldn't
3 cost more than a few thousand dollars.

4 And I hope that you have consulted with members
5 of the ACMUI and medical communities to ensure that it
6 does have the scientific rigor that Dr. Zanzonico
7 alluded to and that the design will satisfy each and
8 every person in the end. Because that is our goal, to
9 make sure that we have an answer that is irrefutable in
10 the end. And I hope that --

11 MR. SABA: As far as I know we can't share the
12 statement of work or anything related to the contract
13 with ACMUI. It's our limitation and they're out of our
14 control.

15 MEMBER WELSH: It just seems -- I get it, but.

16 MS. TADESSE: Once again, we're going to get
17 the data and after that we will go through the scientific
18 process to evaluate it. We have a contract with Oak
19 Ridge which is -- they are our technical dosimetry
20 experts and will have people within NRC who probably will
21 come back to ACMUI with the results to look at.

22 But right now we're just trying to see whether
23 or not it could be done and if the data could be collected.

24 MEMBER WELSH: I guess if I could follow up.
25 I think that is my subtle point, that this should be easy.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And with all due respect to them as a DOE national
2 laboratory it probably isn't doing as much radioiodine
3 thyroid therapy as people in this room are.

4 And therefore there's tremendous expertise
5 available to the NRC for designing a study that would
6 answer the question effectively and definitively.

7 And I -- you have availed yourself of the
8 appropriate resources rather than relying on a
9 Department of Energy national laboratory which does not
10 do medical therapy.

11 CHAIRMAN THOMADSEN: Dr. Suleiman.

12 MEMBER SULEIMAN: I guess, I don't think
13 analyzing the data is going to be a problem. I think
14 the only problem will be where's the data coming from.

15 I mean, these are all licensed facilities so
16 I would assume, but I'm not sure, that all the licensed
17 facilities do all of this.

18 MR. SABA: We will go somewhere and collect
19 data. But if it is not possible we can't do anything.

20 I mean, the more I read papers the more hopeful
21 that we can get -- we can collect data.

22 CHAIRMAN THOMADSEN: Ms. Weil.

23 MEMBER WEIL: So I'm concerned about a
24 selection bias in -- with respect to the sites that would
25 be amenable to the collection of their data. It's likely

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 to be the sites with best practices rather than sites
2 that are less concerned with following the regulations
3 and the professional best practice guidelines.

4 And I don't know that you will be able to
5 collect a balanced group of data to --

6 MR. SABA: So what do you suggest?

7 MEMBER WEIL: I guess I would suggest that in
8 your queries to sites that you make sure that you have
9 a very wide range of practice standards. Universities,
10 crowded offices, Medicaid clinics. All kinds of things
11 that might be producing different kinds of data rather
12 than just best practice data.

13 CHAIRMAN THOMADSEN: Dr. Suleiman.

14 MEMBER SULEIMAN: The only suggestion I make
15 is the confidence of radiation control program
16 directors. FDA has worked with them historically to do
17 samples of X-rays across the country. The States have
18 information on their sites. A similar process could be
19 where they will give you -- you could use that to collect
20 these sites that do this sort of thing and then you can
21 select to your heart's content.

22 I'm not really sure that you're not missing
23 large sites, or all sites, or whatever. That's the
24 approach I would take.

25 MR. SABA: We will talk to CRCPD next two weeks.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 So we will get inputs from them.

2 MEMBER SULEIMAN: I would -- short of using
3 your own database which apparently you seem constrained,
4 I think the other thing would be the one. Because they
5 provide this kind of information annually for doing
6 what's known as the NEXT, or Nationwide Evaluation of
7 X-ray Trends.

8 And they provided the sites to FDA. FDA
9 randomly selects them and reassigns these sites around
10 the country. And the States - it's a voluntary program
11 but they go and conduct the surveys at each and every
12 site.

13 And it's a random selection. And our
14 experience, my experience in my other life was when we
15 had data on a much larger scale -- statistics is
16 wonderful if it's a random sample.

17 So I don't think you'd need a lot. I just see
18 this as an extremely simple study. The execution may
19 be complicated. I would use them if you can.

20 MR. SABA: We have to have a reasonable
21 distribution for field size and also for the site size
22 and also for [inaudible].

23 MEMBER SULEIMAN: Yes, it's doable. It's done
24 every year with another program.

25 MR. SABA: I can't talk about the contract.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 That's why I'm tight. I can't talk about it.

2 MEMBER SULEIMAN: Well, that's why I'm just
3 suggesting. Maybe you're already doing this so that's
4 perfectly fine.

5 MEMBER ZANZONICO: It just strikes me that the
6 details of the contract are not disclosable. I think
7 there's a little debate about the calculation of
8 results. Whether by Monte Carlo or analytically the
9 results seem to converge. And the heart of this effort
10 and what's going to be the sites is the field data
11 collection. And it would seem the input of the committee
12 in the design of the tests, in the design of the charges
13 of this contract would be invaluable.

14 Because I, you know, with all due respect I
15 could conceive this in another scenario where the charge
16 is such that insufficient or inadequate data to finally
17 address the questions on the table might help.

18 MR. SABA: First, after we are done with the
19 comments it's going to be discussed in the next ACMUI
20 meeting. So our report includes researcher reviews and
21 calculations. And you can go into details about it.

22 MEMBER ZANZONICO: Right, but I'm focusing
23 specifically this contract.

24 MS. TADESSE: Basically once the solicitation
25 is out it's in the federal website where we could share

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 that information with you and maybe then that we would
2 evaluate what your inputs are. We could look at that.

3 But right now the solicitation is not out so
4 it's difficult to discuss it because just the procedure
5 doesn't allow us to.

6 MEMBER ZANZONICO: And so there will be an
7 opportunity to modify it at that point?

8 MS. TADESSE: We could get feedback from you
9 guys at that point.

10 MEMBER ZANZONICO: Could that result in
11 modification of the contract proposal?

12 MS. TADESSE: I would expect. Yes.

13 MR. SABA: We might be able to modify, yes,
14 later.

15 MS. TADESSE: We might.

16 CHAIRMAN THOMADSEN: Dr. Welsh.

17 MEMBER WELSH: I don't mean to belabor the same
18 point over and over again, but this does strike me as
19 possibly being at odds with what I heard this morning
20 about effective communication and utilization of
21 medical expertise on the ACMUI and our connections.

22 I think each one of us in this room, maybe the
23 majority, have a great deal of experience in designing
24 clinical trials and in essence this is just a clinical
25 trial.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 It's a field study. We'll want to - I'm not
2 talking about the calculations. That's all been done
3 by the subcommittee and we hope that you come up with
4 the same results that will be addressed in the contract
5 what that amounts to.

6 But the field study is basically a clinical
7 study in essence with slight variation of that.

8 And we do have a lot of expertise in this room.
9 And it strikes me as a little bit surprising that we will
10 be reviewing this at the next ACMUI and provide our
11 comments and hope that if our comments are that we should
12 really revise this that we'll be able to heed that
13 advice.

14 It just seems a little bit unusual or
15 surprising that that expertise hasn't borne included.
16 Particularly since it's been volunteered two years ago
17 or three years ago that at least a couple of people in
18 this room could easily design this for you.

19 CHAIRMAN THOMADSEN: You're members of the
20 general public. Right. You have to keep secret things
21 secret from. Everyone in this room is not an NRC
22 employee. This is open session -- well, that can be
23 changed.

24 But the point is that in closed session, in
25 closed session, right, in closed session we'd all be NRC

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 employees like you and Rebecca and. But you get my point
2 though.

3 While there are members of the general public
4 here, though not many, you're addressing helps other NRC
5 employees whose tasks, what we are doing here is the same
6 as yours.

7 So you know, we have security training. This
8 is a measure of security information we're talking
9 about. I don't see any reason, and maybe someone does,
10 why this information should be kept. It certainly isn't
11 need to know I would suggest.

12 We all have our little devices, you know. But
13 we could do this in closed session. What do you think?
14 I mean, Dr. Welsh, can we do it that way? And if we had
15 a closed session while we're here, any reason why we
16 couldn't be hearing this stuff?

17 MEMBER WELSH: I don't know the legal answer
18 to your question but I would welcome it if it were
19 technically legally possible.

20 MS. DUDES: So it strikes me in the same way
21 that I think it strikes Dr. Welsh that we are not actually
22 living to what I think we want to live to which is really
23 an engaged advisory board.

24 And I'm looking at Sophie and OGC over there.
25 I think all -- the action that we need to take as the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 staff coming out of this is make sure that we're within
2 the FACA rules, right. And make sure that we're
3 following those rules and still achieving the results
4 that we want to achieve which is the only engagement.

5 I mean, I agree, I'm new here, but I'm sort of
6 looking at this and saying, well, we want early
7 engagement. We want early input. I think in my opening
8 remarks I said something about I don't want -- it would
9 be really helpful with this body to have you engaging
10 when we're developing products as opposed to reviewing
11 and dispositioning the products.

12 And so -- but as I'm sitting here I'm also
13 thinking that there's some FACA rules that -- not that
14 they're insurmountable. You cannot say that we're
15 going to have some rules that are going to prevent us
16 from doing things as effectively as we can. But we need
17 to just take the action to work within the system that
18 we have.

19 And for us if it's making more documents public
20 earlier, or you know, trying to get them out earlier so
21 that it is a collaborative effort as opposed to a review
22 and dispose and comment. Because that doesn't seem to
23 be the most effective use of people's time or money.

24 So I think there's an action to take here. I
25 know Rebecca wants to say something. And we're probably

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 not going to solve it. This is a process issue and
2 there's a technical issue that we need to discuss.

3 But I heard from Ms. Weil and Dr. Welsh and
4 after sitting through the morning's meetings I mean I
5 ask you for, well hey, what's an example of this. And
6 I think this is one of those -- and it's not necessarily
7 what technical expertise we have on our staff but the
8 most effective in our action as a committee.

9 MS. TADESSE: I just want to make a point that
10 this is a procurement requirement that we have to follow.
11 As the solicitation comes out we could offer to the ACMUI
12 or part of the ACMUI to be part of our panel to review
13 the solicitation. But it's -- we have to follow certain
14 rules that are put in place. So we cannot share.

15 It's not a matter of security, or national
16 security or anything like that. It's a procurement
17 requirement. We can't share information before it goes
18 through the [proper channels] out to the public.

19 MEMBER COSTELLO: I assume if this information
20 is developed by other NRC employees. I mean, it didn't
21 just appear. And those NRC employees were aware of what
22 was in the solicitation, right?

23 MS. TADESSE: Yes.

24 MEMBER COSTELLO: So couldn't we be given
25 access to this as well? Because we're NRC employees too.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. TADESSE: I have to go back to the OGC to
2 find out what the answer might be.

3 MEMBER COSTELLO: This is incredibly valuable
4 knowledge here. Arguably very expensive knowledge if
5 you had to go pay for it in the open market and have them
6 reviewing this problem for Gazillion [inaudible]. Even
7 if my job for them to go out to do it it would be a lot.

8 CHAIRMAN THOMADSEN: And depending on what
9 Bruce has said we could probably by engaging this body
10 sooner save resources on the part of the NRC going back
11 and making changes after they've made a determination
12 and then we've looked at it and it goes back. Dr.
13 Suleiman?

14 MEMBER SULEIMAN: First off, I think for
15 everybody else this process may be far enough along, but
16 we may not have much input. I mean, I think you have
17 to appreciate they have a procurement process.

18 I think some of the issues that I'm concerned
19 about, I mean honestly, is whether as a group or
20 individually there's a lot of expertise here in the whole
21 variety of areas.

22 I know this has been discussed before. I
23 forget how many meetings ago. So for you guys to go away,
24 stay away and then sort of come in and say here, the cake's
25 in the oven, you'll get to taste it when it comes out.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And I don't think we can micromanage it. I
2 think with due respect at this point it looks like the
3 ship has sailed. I think we're just going to have to
4 wait until it comes in.

5 I don't know all the details but I wouldn't want
6 us to micromanage your contract. I think you heard what
7 we wanted.

8 But I think it would have been really valuable
9 to sort of bounce some ideas off us and then take those
10 ideas and go back and bake your cake.

11 But I think I would hate for this thing to come
12 and we spend another exercise critiquing it. I mean,
13 this patient exposure thing I think goes back to when
14 I got on the committee. I mean, I guess you can drag
15 this out into the 22nd century. I mean, this thing is
16 just, it's never, never ending.

17 And I think -- I mean I have my opinions on this
18 thing but this is the sort of thing I think could it won't
19 bring a definitive end to it but it will keep it quiet
20 for maybe a couple of years until the next completely
21 new committee gets involved.

22 MS. TADESSE: We are in the earliest process
23 right now. So any input that we could get from you guys,
24 it would be helpful. And we're just at the solicitation
25 to get contract. We can change some of the statement.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 It hasn't been let out yet. So that's what I'm offering.

2 Let the solicitation go out and at that point
3 we'll go through FSME to get some input.

4 MEMBER SULEIMAN: But you've written your
5 scope of work. You've written the objectives of the --
6 right? That's way beyond.

7 MS. TADESSE: That would be my statement. And
8 we could work with you, you know, with FSME.

9 MS. DUDES: Again - I'm sorry.

10 VICE CHAIRMAN GUIBERTEAU: Again, I think the
11 point has been made by almost everybody here that we have
12 the need for information to try to determine whether or
13 not any rulemaking or any change in guidance needs to
14 be made.

15 What I heard with the Commissioners this
16 morning, particularly from the Chairman is that she is
17 not willing to tolerate information that we collect that
18 is not considered valid, that is, the methodology in
19 which it was obtained. Those are the results.

20 Once we have the data it can be interpreted in
21 numerous ways once we translate data to information.

22 But I find it incredibly untenable that we
23 should have to sit here and go through this year after
24 year after year.

25 And if we really care about the people that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 we're trying to protect we would want the best
2 information now and not in the 22nd century.

3 So, I mean I think this process is flawed. And
4 I realize we may have -- the train may have left the
5 station, but it may not be too late for us to hop on the
6 tail end of it.

7 Whatever we can do to get this going. Because
8 the results are going to come back to haunt everybody
9 including those who are collecting the information if
10 we don't do it right.

11 CHAIRMAN THOMADSEN: Any last comments on
12 this? You've heard our comments.

13 MS. DUDES: Yes and we will take that as an
14 action. And we have to, again, I think we're stuck in
15 a bit of a process but I don't think it's at all
16 insurmountable.

17 And I do want to reiterate what Rebecca was
18 saying, that although they have developed the
19 solicitation. Once that goes out we'll make sure that
20 that's accessible.

21 And if we need to make changes we'll make
22 changes. And we'll look for ways in the future to get
23 over this hurdle for early engagement.

24 MR. SABA: Also on the draft report with each
25 stage will go through a review.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. DUDES: That's in the literature.
2 Certainly.

3 MR. SABA: I'm sorry? That's -- no. Other
4 than this report that we have, the other reports, that
5 comes from the contractors. Anything -- we are supposed
6 to have a [inaudible]. All of this should go to FSME
7 and all the FSME staff.

8 MS. DUDES: Well, yes, and I agree. And I,
9 their point is that even in designing the approach,
10 again, the early engagement. That is moving in the draft
11 report is really -- if you didn't agree with the approach
12 in the beginning then that's not going to be very
13 helpful. But we'll get through this, I agree with you
14 all very much on this.

15 CHAIRMAN THOMADSEN: But thank you very much,
16 Mr. Saba. And Dr. Zanzonico.

17 MEMBER ZANZONICO: I think -- well, I don't
18 think there's consensus on the research contract so I
19 don't think there's any point even there.

20 But my reading of the current draft report on
21 the dose calculations and on the review of the literature
22 I think is very consistent with the prevailing
23 scientific consensus.

24 For example, in NCRP Report No. 155 and in
25 various papers that in fact the internal contamination

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 dose does appear to be minimal to the point of being
2 negligible. And that the doses to individuals measured
3 in a home environment with dosimeters would find uptake
4 measurements.

5 And I emphasize a normal thyroid individual has
6 radioiodine uptakes on the order of 25-40 percent. And
7 those uptakes, the activities can be measured
8 extraordinarily sensitively, the thyroid uptake,
9 probes and measurement methods.

10 And the lack of thyroid uptake that's been
11 shown in the literature studies among family members,
12 where there were a range of radiation precautions
13 recommended and observed I think are very compelling
14 data in terms of the lack of internal dose from
15 contamination.

16 Again, I think it won't be settled until
17 there's a systematic field study such as the one that's
18 being planned. But I think the data on that point, the
19 peer reviewed scientific literature are already fairly
20 compelling.

21 Likewise the estimation of external dose by
22 patient and family members wearing dosimeters, by
23 calculational methods, whether analytic or Monte Carlo,
24 also seem to converge since it's a good point where the
25 total doses are really under the 500 mg limit and often

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 on the order of 100 mg or less.

2 So beyond reiterating those points I don't
3 think there's anything new that I can contribute on this
4 issue.

5 But I think the collection of field data, of
6 properly designed, properly vetted data hopefully will
7 be decisive in convincing in a robust way the current
8 release criteria are or are not adequate.

9 MEMBER WEIL: Just a quick question about the
10 phantoms. You don't have a child phantom or an infant.

11 MR. SABA: No.

12 MEMBER WEIL: And it's my understanding that
13 the thyroid uptake in children is different than adults?

14 MR. SABA: No, for child we are not using --
15 this is for external dose.

16 MEMBER WEIL: External.

17 MR. SABA: Not internal. And for external,
18 for child dose is much better than adult.

19 MEMBER WEIL: It's lower? Is that what you're
20 saying?

21 MR. SABA: It's lower. Because the height is
22 --

23 MEMBER WEIL: Yes, children held in arms are
24 the same height as adults.

25 MR. SABA: Yes for child. But --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MEMBER WEIL: That's how children came to be
2 carried and standing. We have been in a New York City
3 subway lately.

4 DR. HOLAHAN: I'm Dr. Vince Holahan.
5 Previously I've been a senior-level advisor for health
6 effects research in the Office of Nuclear Regulatory
7 Research.

8 In the last 3 years I've been senior advisor
9 for FSME. Now, just a couple of points we'd like to
10 clarify when we're dealing with Mohammad's study here.

11 First of all, we're about to go into federal
12 acquisition space. And if you've ever seen any requests
13 for proposals it's a 30-page document. Most of it's
14 boilerplate except for about one page which is the
15 statement of task.

16 And the statement of task has some very broad,
17 general requests that we'll make from a contract offer.

18 What happens then is the potential offeror will
19 spend approximately 30 days putting together proposals
20 that would address our statement of task.

21 When we receive all of those proposals we'll
22 actually convene a board if you will to review those
23 contract proposals.

24 And it's at this point we could possibly put
25 a member of your committee on that review panel to take

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 part and look at the actual designs that come in.
2 Because quite frankly we have no idea what the designs
3 are going to be.

4 So if that sounds like it would be a good idea,
5 whether it be Dr. Welsh, Dr. Zanzonico, or some other
6 member it's very possible to have them on this.

7 Now, keep in mind because it's in federal
8 acquisition space they cannot then discuss those
9 contract proposals with this committee. There's
10 basically, you know, it's gotten very silent and there's
11 very much concerns about conflict of interest. And any
12 information given out to a proposed contractor will get
13 some sort of damage.

14 And that's why in this space we really can't
15 go into the details about that statement to ask because
16 it could give some contractor an advantage and we can't
17 have that. Otherwise the whole process could be
18 challenged.

19 CHAIRMAN THOMADSEN: Can I ask you, when
20 you're writing that one page describing what you want,
21 do you feel that that gives you some control over what
22 you would be getting back as far as the proposals?

23 DR. HOLAHAN: Yes, very much so. Whether it
24 be a contract proposal for this or going to the National
25 Academies you've got to be very explicit in what you're

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 looking for in that statement of task.

2 CHAIRMAN THOMADSEN: And I think that that's
3 the point that this committee was making. That our input
4 would be most efficacious if it were in doing the design
5 of that one page as opposed to reviewing the proposals
6 that come back.

7 Dr. Welsh.

8 MEMBER WELSH: Going back to what Dr.
9 Zanzonico has said recently regarding potential input
10 that we could be invaluable for, I think most of us in
11 this room are either journal editors, or editorial board
12 journals, or at least peer review.

13 And there's an advantage regarding approval
14 studies and field studies. A journal can keep junk out.
15 And I think that as peer reviewers and journal editors
16 we feel very strongly about that.

17 There's probably been many times when I and
18 many of you in the room have read papers and said this
19 shouldn't even be published. It's certainly not going
20 to be published in my journal.

21 And I would hope that when the study is finished
22 it's not going to be of that caliber. It's going to be
23 of the utmost caliber and it would be something that will
24 definitively answer the challenges, questions that Dr.
25 Macfarlane posed this morning in system-wide data but

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 good data.

2 Definitively and to the best -- given that we
3 can answer the important questions raised by Mr. Crane
4 over the past seven years.

5 This is an opportunity that should not be lost
6 that we should take very seriously and provide the best
7 possible data to provide the answer whether it
8 corroborates or refutes our calculations.

9 And as a constructive criticism if what I just
10 heard, that the field study might exclusively measure
11 external but not internal radiation, there's a flaw
12 there. Because Dr. Zanzonico has pointed out --

13 MR. SABA: -- to the calculation.

14 MEMBER WELSH: Well, I'm talking about field
15 studies now. So, there's input that could be done that
16 and we're happy to provide that to you.

17 CHAIRMAN THOMADSEN: Thank you. I think the
18 last comment. We've made pretty much this point.

19 MEMBER ALDERSON: All right. I haven't
20 commented before. It'll be sort of in a different
21 direction.

22 So as the administrator here I think I
23 appreciated very much, and sorry, I didn't get your name,
24 but what you just had to say.

25 So yes, it would be wonderful to have our input

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 at all points, at all times in all these projects. But
2 the government is going to issue an RFP and as a conflict
3 of interest issue, we can't do that.

4 So if any one of us happens to have stock in
5 a company that does a study a certain way and we say hey,
6 that's the way you've got to do this thing because that's
7 the right way, I mean we can't do that.

8 So in fact, there is an administrative reason
9 why we can't have all the access that we want to have.
10 I just think we have to understand that and we have to
11 know when to back off.

12 I don't think we've backed off quite far enough
13 on this one. I think we've been a little too aggressive.
14 That will be my final comment.

15 CHAIRMAN THOMADSEN: Okay. I think that --
16 and I'm sorry to cut you off, but we've had the science
17 discussion.

18 VICE CHAIRMAN GUIBERTEAU: I just want to
19 point out in our bylaws that you were all commenting on
20 there is an opportunity for each of us to declare, either
21 self-declare or it can be declared for us recusing
22 ourselves because of conflicts of interest or bias of
23 any sort.

24 So, I mean I'm not sure that what you're saying
25 would be absolutely true in this case if we all admit

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 what our biases are.

2 CHAIRMAN THOMADSEN: Right. We just have to
3 control our conflicts.

4 I believe we have on the line a member of the
5 public who would like to make a statement. Are you
6 there? Dr. Crane? Or Mr. Crane?

7 MR. CRANE: Yes, please.

8 CHAIRMAN THOMADSEN: Mr. Crane, welcome. We
9 have a statement that you have given to us. It's been
10 distributed to the Committee and it's available here for
11 the members or the general public.

12 Would you like to make a statement?

13 MR. CRANE: Thank you very much. I don't want
14 to read off what I've already submitted to you.

15 CHAIRMAN THOMADSEN: No, I don't think --

16 MR. CRANE: -- on my computer because I'm
17 getting duplicate noise.

18 CHAIRMAN THOMADSEN: Yes, Mr. Crane, if you
19 can - I'm getting some feedback now. If you can hear
20 and make the statement you have five minutes.

21 MR. CRANE: Well, thank you very much. I'd
22 like to respond to a couple of things that have been said
23 today.

24 I think that I agree with Dr. Zanzonico that's
25 important to collect field data. I think I agree with

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Dr. Welsh that this is the best way to assure that the
2 concerns that are felt by members of the patient's
3 community and others are satisfied.

4 I agree with Laura Weil that it's important
5 that we not look only at the best institutions. You
6 don't judge high school education in this country by
7 looking only at Boston Latin and Bronx Science, and you
8 can't judge simply by Sloan Kettering and Mass General.
9 You do need the range.

10 I also agree with Dr. Welsh that you have to
11 look at internal dose. Given what ICRP 94 says about
12 internal dose, it just can't be explained away.

13 I have said in the past that I think that as
14 far as patient instructions are concerned, NCRP 155 is
15 a great place to start. I've praised it in the past and
16 Dr. Zanzonico for his role as co-author.

17 But I will note a few things about that report
18 that I think are significant. That the instructions
19 include saying that the bed linens of the I-131 patient
20 ought to be laundered separately and put through the
21 rinse cycle twice which to me seems to let out sending
22 patients to hotels.

23 There's an instruction that patients should
24 flush the toilet twice after using it, rinse the shower
25 stall, tub, et cetera. Wipe up spills of urine, saliva

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 and/or mucus with tissues and flush it down the toilet.
2 All of that tells us that bathrooms are a source of
3 contamination that can be harmful to others and that's
4 why I think that you can't dismiss internal
5 contamination as negligible and you can't do a study of
6 hotel rooms that doesn't look at the bathroom.

7 I think it's also significant that NCRP says
8 that release limits are on an annual basis, not a
9 per-release basis. And I quote, "The foregoing limits
10 are annual totals and therefore do not apply to
11 individual treatments but collectively to all
12 treatments a patient may receive in a given year."

13 And that's consistent with the ICRP,
14 consistent with the NCRP that these are on an annual
15 basis, not per-release.

16 The report also says that the maximum allowable
17 radiation dose to members of the public, and that's
18 people defined as those who have no familial connections
19 to the patients and to whom there's no emotional benefit,
20 had a limit of 100 millirems per year.

21 Given that the NRC rule is five times that, I
22 see the report as calling for changing the rule to
23 conform to international and national standards maybe
24 in the direction of something like Part 20 which are the
25 split 500/100 standard.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And finally, the report makes clear that
2 through the wall exposures are problematic and has to
3 be taken into account. It says, "Other patients
4 confined in the medical facility may be unintentionally
5 exposed to patients receiving radionuclide therapy.
6 The usual source of this exposure is occupancy of the
7 room immediately adjacent to a patient receiving
8 therapy."

9 And if that's true in a hospital, it's
10 certainly true in hotels. I'm interested to see that
11 the -- Dr. Saba's presentation, that one of the scenarios
12 he takes into account is beds in adjoining rooms that
13 are head to head. And if that's the case, you've got
14 a thyroid to thyroid distance that is a lot closer than
15 the 2.2 meters estimated by Dr. Zanzonico in the 2010
16 report.

17 So on all of those points I think that NCRP 155
18 is on the right track and I hope that that right track
19 will also be adopted by the Committee. And having said
20 that I think I'm done unless anybody's got a question
21 for me.

22 CHAIRMAN THOMADSEN: Thank you very much for
23 your comments. Are there any questions for Mr. Crane
24 amongst the Committee?

25 We have a comment from a member of the general

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 public, if you could identify yourself.

2 MS. BUNNING: Sue Bunning with SNMMI. And I
3 wanted to just share that at lunch today after listening
4 to all the discussion this morning about instructions,
5 as many of you probably know, we have extensive
6 information on the SNMMI website.

7 We also have a brochure, that our conversation
8 at lunch today with AAPM, ACR, ASTRO, we all were
9 together and discussing ways in which to push the
10 information out.

11 But we would welcome the opportunity to work
12 with this group on reviewing the instructions that are
13 already out there which, you know, a lot of those of you
14 in the room have been part of creating those and working
15 with those going forward on that.

16 And take it upon ourselves to work collectively
17 at the medical societies on reviewing those instructions
18 and how we do a better job of pushing them out.

19 CHAIRMAN THOMADSEN: Thank you very much. And
20 seeing one more comment. We do have one comment. Pat
21 Zanzonico.

22 MEMBER ZANZONICO: It's Pat Zanzonico. It's
23 always a pleasure hearing from you and you're popular
24 with comments about NCRP 155.

25 I'd just like to clarify some points and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 whether your citations to 155 are correct.

2 A number of those in terms of washing bed linens
3 twice, et cetera, et cetera, are really ALARA, as low
4 as reasonably achievable. And I put the emphasis on
5 reasonable.

6 For example, one could reduce public doses
7 further, for example, by somehow confining diagnostic
8 nuclear medicine patients from leaving the hospital.
9 They contain activity; they irradiate individuals
10 around, but at very low doses, but non-zero doses. But
11 that would be completely impractical. The number of
12 patients on a daily basis undergoing diagnostic nuclear
13 medicine studies would make those sorts of measures
14 impractical.

15 And what one can and perhaps should do in their
16 own home in an environment under their own control like
17 flushing the toilet twice, so forth and so on is
18 different than what one could and should expect in a less
19 controlled environment.

20 It doesn't meant that not performing those
21 measures is significantly hazardous, it's just an
22 overabundance of caution in an environment in which it's
23 very easy to do so and doesn't otherwise impede the
24 optimum ability of healthcare.

25 The other issue I'd like to emphasize, that you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 do allude to the 100 millirem limit. And as I said when
2 I was on the NCRP scientific committee that wrote that
3 report, I do not endorse that limit. The committee was
4 bound to adhere to that limit or recommended dose because
5 that was the one promulgated by the NCRP.

6 I do not personally endorse it at all. I would
7 have opted for a 500 millirem limit. So that's neither
8 here nor there because that's what's in the report.

9 The -- and just one final item about the
10 flushing twice. That has nothing to do with
11 contamination. Many toilets in non-public buildings,
12 in homes have traps beneath the bowl where the activity
13 remains until the next flush. Often that's not the case
14 in public buildings and hotels and so forth which have
15 different kinds of plumbing. So I just wanted to make
16 that point.

17 But again, some of the precautions on the NCRP
18 155 were in the spirit of ALARA and those precautions
19 can in fact should be done at home in that spirit. That
20 does not mean they can or should be translated to other
21 environments.

22 MR. CRANE: I appreciate that. Could I say
23 just one thing more?

24 CHAIRMAN THOMADSEN: One thing.

25 MR. CRANE: That in the spirit of ALARA I think

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 that one of the productive areas for thought is are there
2 things we can do short of hospitalization that could
3 reduce dose such as keeping people in a safe room for
4 a few hours until they've had their first urination; for
5 example, something to get past the area in which vomiting
6 is most likely.

7 And I hope that we don't think solely in
8 all-or-nothing terms and can think creatively about --
9 or facilities short of a hospital that could serve as
10 a safe place. I hope we think about some of these
11 intermediate ideas.

12 CHAIRMAN THOMADSEN: Thank you very much for
13 that final comment. I think thinking outside the box
14 is possibly a good approach in this case.

15 With that I think we're closing this topic.
16 Thank you very much, Mr. Saba.

17 We have Dr. Staples and Ms. Hamilton. Please,
18 we will now have a presentation on NNSA's Efforts for
19 Reducing Highly Enriched Uranium in Molybdenum-99
20 Production.

21 DR. STAPLES: I would like to -- so we've had
22 a change in staff that's come along with me. Dr. Sarah
23 Bender from my staff is accompanying me today instead
24 of Ms. Hamilton. She also -- Sarah also works on the
25 NNSA program.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And you have our slide set that we're going to
2 go through today. And I was asked to make it different
3 from the previous presentations because I have been here
4 in front of this board before. And thank you very much
5 for bringing us back again so we can present the status
6 updates on our program.

7 I will give you a few slides that are somewhat
8 redundant from previous presentations. I don't want to
9 insult your intelligence in that respect. I do want to
10 make sure that any new entities in the room do have a
11 reasonable baseline for how we go through some of the
12 major issues that we are facing in the future
13 molybdenum-99 supply.

14 And to preface the discussion it is primarily
15 on the economic and the commercial side of the industry
16 where the major issues are now facing us, let's say, a
17 collective group to ensure a reliable supply for patient
18 needs in the future.

19 But we also achieve other international
20 commitments regarding threat reduction activities
21 which we also manage in this program.

22 So first and foremost I am the director of the
23 European and African Threat Reduction Office, who also
24 has a functional responsibility for the conversion of
25 civilian research reactors and medical isotope

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 production processes from the use of highly enriched
2 uranium to low enriched uranium to accomplish an
3 international threat reduction objective.

4 This slide indicates what the mission for the
5 Global Threat Reduction Initiative programs are which
6 is to reduce and protect the vulnerable nuclear and
7 radiological materials that are located at civilian
8 sites worldwide.

9 The leftmost box under the Convert function
10 defines the HEU minimization aspect of our program.
11 Complementing that are two other offices with the
12 functional responsibility to remove and dispose of those
13 excess nuclear radiological materials once they have
14 become available for disposition through conversion
15 activities or when they are no longer used.

16 And in the interim and while such materials are
17 being used, there are complementary physical protection
18 activities that are also implemented.

19 All of these efforts are accomplished both
20 internationally and domestically. These are
21 collectively items that we have identified as a
22 community as being at-risk materials.

23 And in the United States, we feel it's very
24 important to do what we are asking others to do. And
25 also we have identified that these materials can be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 stolen and used for illicit purposes in the United States
2 where they're co-located with population centers and/or
3 national interest objectives.

4 The best overview of the current situation and
5 our strategy for the moly-99 program. And I should point
6 out that it is a two-phased effort that we have.

7 First and foremost was our longstanding goal
8 of reaching minimization.

9 Secondly, based upon supply shortages
10 primarily that took place in the 2009 time frame of the
11 simultaneous shutdown of several major producers we were
12 tasked with the objective to develop a long-term
13 reliable supply of moly-99 for patient needs.

14 This slide shows the current status of the
15 major producers that supply the U.S. market as well as
16 actually the global market. Red indicates the use of
17 HEU, blue indicates the use of non-HEU production
18 methodologies.

19 The top-most bar which shows Australia, South
20 Africa, the Netherlands, Belgium and Canada is the
21 current status for moly-99 production of the global
22 major producers.

23 Australia is fully and has always been an
24 LEU-based supply. South Africa through NTP
25 Radioisotopes is transitioning. In fact, we understand

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 they are now approaching 50 percent of their production
2 capacity as LEU-based moly-99.

3 Mallinckrodt and IRE in the Netherlands and
4 Belgium respectively have both made commitments at
5 nuclear security summits with President Obama and
6 roughly 50 global leaders in both 2012 and 2014 to
7 accomplish HEU minimization objectives.

8 Most important is the 2012 commitment from both
9 of those entities, France as well as the United States,
10 to work towards the conversion of their facilities from
11 HEU to LEU by the 2015 time frame.

12 To date, IRE is on schedule to meet that
13 commitment. Mallinckrodt has experienced some
14 technical difficulties, not surprising given the
15 complexity of the process, and they probably won't make
16 their 2015 time frame. Regardless, they are a very
17 strong partner and making tremendous efforts in that
18 path towards conversion to LEU.

19 The very important component on this slide is
20 the Canadian production which is the only bar that is
21 shown respectively larger than the others for a reason
22 in that the global supply from Canada is roughly 40
23 percent of the global supply, roughly 50 percent of the
24 U.S. domestic supply.

25 What's very important and happening in 2016,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 they've clearly and repeatedly stated that they will
2 cease isotope production at their facility in Canada in
3 October of 2016.

4 There's going to be a significant gap in the
5 supply chain at that point in time. Our strategy that
6 we have addressed here is in that time frame we would
7 expect that Mallinckrodt and IRE could and/or should be
8 converted to LEU.

9 NTP Radioisotopes will fully be converted and
10 that conversion process is wholly dependent upon the
11 drug regulatory approval process in several of their
12 major markets, primarily in Europe.

13 To fill that gap we have a domestic program.
14 We're supporting a number of cooperative agreement
15 partners to help fill the need. Plus there is the
16 reality that the market share of the other existing
17 producers will change to address that demand need from
18 the patient side.

19 Our interest and involvement in this is not to
20 define who has what market share in the future which is
21 why we tried to indicate that all of the scale of each
22 one of these respective industries is uniform.

23 It's their commercial obligation to attract
24 whatever market share and adjust to whatever market
25 share they can capture. That is their commercial and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 economic obligation. The same is true for the
2 cooperative agreement partners we're working with.

3 And then beyond the U.S. domestic cooperative
4 agreement partners, there are other entities not
5 associated with government funding that are also working
6 towards producing new supplies of moly-99.

7 Most importantly, or not most importantly,
8 just very timely is actually a press release that came
9 out late yesterday from Northwest Medical Isotopes is
10 a new U.S. entity that was very quiet in their activities
11 but has been making significant progress in developing
12 their program to develop supplies of moly-99 in the
13 future.

14 I understand that they're having significant
15 reactions with the NRC these days regarding the process
16 and procedures that they go through for their production
17 capacity.

18 So, this slide highlights what our global
19 objective and strategy is. To be very clear it is to
20 accelerate the establishment of reliable supplies of the
21 medical isotope moly-99 produced without highly
22 enriched uranium.

23 A very important word in that statement is to
24 accelerate the establishment of reliable supplies. And
25 this is done in cooperation with commercial partners

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 both domestically as well as internationally.

2 Our strategy that we developed in the 2009 time
3 frame in particular with the entire U.S. Interagency
4 including NRC involvement, Health and Human Services
5 involvement from both Centers for Medicare and Medicaid
6 Services as well as the FDA were to address a number of
7 weaknesses in the current moly-99 supply chain.

8 The Global Threat Reduction Initiative had the
9 primary obligation and responsibility to lead this
10 simply due to our longstanding cooperation with both the
11 foreign and domestic entities that were utilizing the
12 highly enriched uranium or developing processes for the
13 production of the moly-99.

14 But the major weakness, one of the major
15 weaknesses, is that the current supply chain uses HEU
16 to produce moly-99. There have been a number of very
17 high-level wide commitments from governments and
18 leaders over the past several years especially to reduce
19 if not eliminate the use of highly enriched uranium in
20 civilian applications.

21 The second bullet is also an extremely
22 important weakness in the current supply chain that by
23 all identifications including by the Organization of
24 Economic Cooperation Development, the OECD, have
25 identified that subsidies by foreign governments has

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 undermined the ability for industry to reinvest in
2 itself to support current and/or ongoing production.

3 And this -- to be very clear, the subsidization
4 wasn't done in a malicious manner. It's simply how the
5 industry evolved from a boutique industry decades ago
6 and grew into a very important component of the medical
7 community's tools that they use to diagnose and treat
8 patients.

9 Unfortunately, the subsidies continued and in
10 many cases weren't identified that they were even taking
11 place until recently, or was not acknowledged, or the
12 governments were not cognizant that they were taking
13 place until recently. So all governments have also
14 pledged to remove those subsidies from this commercial
15 activity.

16 In everyone's best interests, the subsidies
17 are not immediately being removed. We are trying to
18 develop a transition strategy with governments and
19 industry through the next few years to remove the
20 subsidies, remove the use of HEU to transition to a
21 long-term reliable supply to ensure that patient needs
22 are met in the future.

23 In addition, the third bullet highlights
24 events that we've seen take place numerous times, once
25 again over the past several years. But to the commercial

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 industry's credit, they've learned from past mistakes
2 or just the past situation and they have been able to
3 coordinate and prepare such that patient needs are met
4 while facilities go down.

5 And I'm specifically referring to the fact that
6 both the Canadian, the Dutch and also the South African
7 facilities were down for long periods of time over the
8 past year.

9 In the past year there were some supply
10 shortages it appears, but nothing so dramatic as
11 happened in the 2009 time frame during the first outage
12 of both the Canadian and the Dutch facilities for
13 approximately a year time frame.

14 But by building enough reserve capacity into
15 the system we can assure that patient needs will be met
16 into the future as different facilities go on and offline
17 as these facilities are wont to do.

18 And the next bullet, the fourth one about the
19 current supply chain is primarily dependent on the aging
20 facilities. Also refers back to the inability of the
21 industry to reinvest in itself just simply due to the
22 economic and market structure that the current industry
23 was operating under.

24 We are also working towards trying to diversify
25 the technology that the industry works on to ensure that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 there are no single points of failure in this industry
2 so that we can be sure to achieve our long-term objective
3 of a reliable supply of moly-99 patients.

4 But this does require that the global
5 production of moly-99 transition to a full cost recovery
6 is some other verbiage that we use to define the lack
7 of subsidies in the industry, non-HEU based supply
8 chain.

9 I think there's some bullets missing. Let's
10 turn to the next page and see how your slides came out.

11 In the June 2012 time frame there was a U.S.
12 government Interagency group that is working on reliable
13 supplies of moly-99. Led by the Office of Science and
14 Technology Policy the White House released six
15 statements to encourage reliable supplies of moly-99
16 produced without highly enriched uranium.

17 A large driver in this was the suspension of
18 a cooperative agreement by -- we were partnered with
19 General Electric-Hitachi due to their assessment of the
20 business and economic situations which we were aware of
21 but not directly addressing.

22 This public statement works to address many of
23 the issues that they identified and that we identified
24 actually as the international community facing the
25 industry.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 First and foremost was that a unique product
2 code or identifier be associated with the use of non-HEU
3 based moly-99. This actually is a proxy for full-cost
4 recovery. Because we were making the assumption in this
5 labeling that anything that is produced without HEU is
6 also produced according to full-cost recovery or
7 non-subsidies.

8 And as the medical community works and I'm sure
9 you're aware, it's very appropriate and a standard
10 operating procedure that any pharmaceutical product is
11 going to be traced from cradle to grave. It's very
12 difficult to trace the financial aspect of
13 radiopharmaceuticals and how they're produced, but it
14 is very easy to identify the genesis of the material that
15 is used. So that is a reason that labeling is associated
16 with a non-HEU based moly-99.

17 But this is simply an action so that the other
18 statements could actually be effected.

19 Second, again following through the statement
20 that it is very important -- that actions speak louder
21 than words, is that U.S. government entities that do
22 procure moly-99 based products would preferentially
23 procure those products under the obligations that we
24 have with international trade agreements.

25 And the status is that the Veterans Affairs had

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 issued a policy statement recently calling for the
2 Veterans Health Administration facilities to begin
3 preferentially procuring non-HEU based moly-99 as they
4 become commercially available.

5 It's not a very large segment of the industry,
6 but it's an important segment that speaks very loudly
7 about the actions that the government will support as
8 these new products become available.

9 Third is that we will examine potential health
10 insurance payment options that might promote a
11 sustainable non-HEU supply of moly-99. In January 1 of
12 2013 Centers for Medicare and Medicaid Services issued
13 a new rule that offers a \$10 premium payment to any
14 medical procedure that uses moly-99 based
15 radiopharmaceutical products that are produced without
16 HEU.

17 This is now in its second year of
18 implementation and in a few of the other slides we'll
19 come back to address this specific aspect of the U.S.
20 government's public statement.

21 Next is that we will take steps as appropriate
22 to further reduce exports of HEU that will be used for
23 medical isotope production as sufficient supplies of
24 non-HEU produced moly-99 are available to the global
25 marketplace.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 And these exports are made on an annual basis
2 and it allows us to determine what the current non-HEU
3 based production quantity is and how we can transition
4 -- help transition the industry over to non-HEU based
5 moly-99 as the other material becomes available.

6 The last few bullets I'm going to go over
7 extremely quickly. They're just simply a reaffirmation
8 of continuing our efforts to work with both the domestic
9 partners in the United States as well as the
10 international partners to support the conversion of
11 their activities from HEU to LEU.

12 This is a slide that we used in some recent
13 meetings with radiopharmacies of trying to educate them
14 of the process that we're working through also.

15 First, that line is very important and it
16 restates what we have already discussed about the
17 subsidies have undermined the investment in the
18 infrastructure which led to reliance on aging
19 facilities, jeopardizing supply.

20 And some of the asks that we had of that segment
21 of the community to help have that segment of the
22 commercial industry also work with us towards a
23 transition to a long-term reliable supply for patient
24 needs.

25 The first to follow the lead that we have done

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 with the Veterans Administration to ask for the non-HEU
2 based moly-99 that is available today. That we
3 encourage private payers to adopt the \$10 add-on
4 payment. Surprisingly enough, they're not necessarily
5 so enthusiastic to move in that direction. That is their
6 own business decision as we best understand it.

7 We do want to ask everyone to educate customers
8 that non-HEU based moly-99 does equal long-term reliable
9 supply for their patients. It is the direction we're
10 moving in, but we do acknowledge that the transition over
11 the next several years is going to be extremely
12 difficult.

13 Where we're going is the last bullet, and we
14 can come back to that again in a little bit is to report
15 the cost of non-HEU based LEU moly-99 to CMS.

16 There's been some contention that the \$10 is
17 not sufficient to pay for the cost of the non-HEU
18 non-subsidized moly-99. However, no one is providing
19 information contrary to that \$10. So quite honestly
20 we're somewhat confused by the criticism in that
21 respect.

22 But we are always open to input to CMS. And
23 in fact we congratulate CMS that in very few
24 circumstances can they be proactive, but in this
25 circumstance they actually were proactive that they put

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the \$10 payment on the table based upon their projection
2 of what the cost would be for using that non-HEU based
3 moly-99.

4 So, the next set of slides are some of the more
5 interesting ones. Because as you can imagine there is
6 a tremendous transition in the commercial industry and
7 many different entities with their specific commercial
8 interests at risk and/or potential for adjustments in
9 market share. So there is some misinformation
10 propagated throughout the industry supporting
11 different positions and objectives.

12 So we're working to try to dispel as best we
13 can with the facts that we're aware of and/or we take
14 from the industry to offset the myths that we perceive
15 are propagating through the industry.

16 First and foremost is that patients are paying
17 for the non-proliferation effort on the conversion from
18 HEU to LEU, and that this conversion to LEU is
19 jeopardizing efforts to provide reliable supplies of
20 moly-99.

21 The fact is that the U.S. objective has and will
22 remain consistent that we are working and always say
23 first and foremost; in fact, these three sub-bullets are
24 the order in which the White House refers to the
25 objectives for this program.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 First and foremost is to ensure the reliable
2 supply of moly-99 for patients worldwide.

3 The second is to eliminate the use of HEU in
4 moly-99 production.

5 And the third is to help transition the global
6 moly-99 production to a full cost recovery to establish
7 an economically sound industry for the long term.

8 Patients are not paying for the conversion of
9 the process. The real issue here is long-term
10 reliability of moly-99 supply.

11 As conversion to LEU is considered an
12 externality on the isotope production facility
13 governments as I mentioned before about the nuclear
14 security summit objective in 2012 between Belgium, the
15 Dutch, France and the United States, we have as
16 governments pledged to commit money to support those
17 conversion efforts and in fact have provided funding
18 necessary for those conversion efforts as much as
19 commercial industry is willing to accept.

20 And under the CMS \$10 add-on reimbursement,
21 moly-99 as I stated, is a proxy for both non-HEU and most
22 importantly full cost recovery sources of moly-99.

23 The next myth that we're working to try to expel
24 is that hospitals must -- let me say it this way. I'll
25 just read it, actually. I don't mean to insult your

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 intelligence, I was trying not to do that, but it's
2 probably best and most appropriate if I do this.

3 In order to supply hospitals with LEU doses to
4 receive the CMS \$10 add-on reimbursement
5 radiopharmacies need to segregate the LEU generators,
6 thereby increasing costs.

7 The easiest way to address that is it actually
8 is a business decision of how they manage their
9 functionality. And that the overhead cost that is
10 shared by both HEU and LEU is part of their business
11 decisions.

12 And there are numerous ways to overcome this.
13 In fact, we have examples from radiopharmacies that have
14 made different business models that are being effective,
15 and they are in fact able to also utilize the \$10
16 reimbursement.

17 The second is that this is a temporary
18 situation regardless. This is going to be a fact only
19 while there are parallel lines in place. At some point
20 in time there will no longer be any HEU-based moly-99.

21 But if they do make the decision to segregate
22 the dispensing lines and incur these additional costs
23 these are obviously the operating costs that are passed
24 onto the customer and reimbursed by standard payments.
25 And this information is reportable to CMS.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 The next is somewhat associated with how the
2 facilities hospitals industry decides to operate. To
3 receive the \$10 CMS add-on reimbursement hospitals need
4 to segregate CMS patients thereby increasing costs.

5 Hospitals don't need to segregate patients.
6 It's simply a matter of tracing the material through the
7 system. And from one nuclear pharmacy we heard a very
8 interesting statement that they have these magic boxes
9 in their facility that allows them to do this. And they
10 call these magic boxes computers.

11 And I loved that analogy when they stated that,
12 that utilizing this modern technology they were able to
13 track the materials through the systems and obtain the
14 reimbursements.

15 The \$10 add-on reimbursement is a
16 reimbursement for those added costs that are
17 attributable only to Medicare beneficiaries when they
18 receive the non-HEU based technetium-99 dose.

19 We are asking private payers to adopt this same
20 \$10 add-on payment which typically is the process that
21 takes place. And that is, as I understand, the normal
22 process that private payers do adopt. There has not
23 again been a significant take-on from private payers to
24 move in that direction.

25 The \$10 add-on reimbursement has not had an

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 effect on the uptake of LEU moly-99. There was a
2 previous Society of Nuclear Medicine medical imaging and
3 CMS data that was aligned very well with levels of LEU
4 moly-99. We understand that there's some updated data
5 that does show that the uptake is somewhat smaller than
6 the amount of LEU moly-99 that's available.
7 Regardless, they are definitely in the same range.

8 But what we are observing is that the end users
9 are utilizing the \$10 add-on reimbursement at levels
10 that is consistent with the projections that we have for
11 2013-14 time frame and is consistent with current
12 availability of LEU-based moly-99 and the market.

13 MEMBER ALDERSON: What is that level now? Is
14 it 50 percent? Five percent?

15 DR. STAPLES: It's roughly 30 percent.

16 MEMBER ALDERSON: Thirty percent.

17 DR. STAPLES: Yes. And this actually goes
18 back to a few of the previous myths. Actually, this
19 might be a question that will come up later. It usually
20 does so I can address it now.

21 Part of the issue with segregating lines also
22 is in some cases some parts of the industry have decided
23 to blend the LEU and the HEU moly-99. That's not
24 something that is reimbursable through the CMS system.

25 There have been asks to incorporate that.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 That gets extremely complicated in terms of how the
2 tracking and the financials work.

3 And my personal perception in that is it's
4 asking way too much of the CMS. They've already been
5 very proactive in putting \$10 on the table for the direct
6 full LEU reimbursement.

7 To move in that direction for temporary payment
8 for a few years is probably too onerous and only that
9 much more complicated in how the system works. But
10 roughly 30 percent of the moly-99 available today is LEU
11 moly-99.

12 Roughly have of that is pure LEU moly-99. The
13 other half of that is blended as we understand it.

14 And this actually is aligned exactly with the
15 question we asked here in the myth is how much LEU moly-99
16 is available to take full advantage of it.

17 As I mentioned, there are two large-scale
18 producers that use LEU, both Australia and South Africa.
19 There's actually been a lot of discussion about the
20 distance factor associated into supply of moly-99, and
21 that material coming from Australia and South Africa is
22 going to have a significant decay take place.

23 In fact, the industry uses a unit called the
24 six-day curie. And the six-day curie takes into account
25 the difference in shipping from facilities at different

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 locations. It's how the industry has always
2 functioned.

3 The six-day curie means that you will buy what
4 is going to be on your -- six days after they ship it.
5 In no case does the shipping of any one of these
6 facilities take six days. So in many cases the
7 radiopharmacies are receiving more moly-99 in their
8 generators than what is actually labeled on the
9 generator. Just how the decay laws work out.

10 I also understand that from some of the -- for
11 some of the facilities, I'm not going to name any which
12 ones take longer, but that from some of the other
13 facilities Australia who is geographically the most
14 distant, they can actually get material to U.S.
15 pharmacies faster than some of the other producers can.
16 So, there's again no real validity in terms of the
17 distance being a direct correlation to decrease in
18 supply.

19 The significant one here is it's been
20 propagated that the \$10 add-on reimbursement is actually
21 only \$8. It is \$8 from CMS and a \$2 copay. What's
22 important is in the second bullet is that's very
23 consistent with how Medicare benefit pays across the
24 board. It's always 80 percent of the outpatient
25 procedures and 20 percent is the patient's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 responsibility.

2 By law hospitals should be collecting that \$2
3 copay from the patient unless copays are waived for
4 indigent patients based on need. What's important - \$10
5 goes into the system for the reimbursement of the medical
6 isotope.

7 This is quite important and we've been very
8 transparent about the \$10 being available exactly to
9 allow industry to manage this into their contract
10 negotiations.

11 Is it the hospitals receive the \$10 add-on
12 payment, not the rest of the moly-99 supply chain. The
13 best analogy I heard in this case is when you go to buy
14 a car you don't pay for the windshield, you don't pay
15 for the tires, you don't pay for all of the nuts and bolts
16 that are associated with it. You pay a dealership for
17 the car and all of those costs that you pay the dealership
18 propagate down through the supply chain. That's
19 exactly what we are expecting to take place in this
20 industry.

21 I don't need to go through the facts because
22 it basically gives a very similar analogy. We're
23 transparent about the \$10 being available to pay for the
24 costs of the full cost recovery non-HEU based moly-99
25 at the beginning of the supply chain and to allow the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 market dynamics and contract negotiations between
2 commercial entities take place to properly pay for their
3 costs associated with producing the material.

4 We've been asked that we should provide more
5 funding from our program to the domestic projects to
6 avoid a shortage.

7 Two points here. First and foremost, both
8 through the OECD and our own independent assessment
9 while the transition over the next several years is going
10 to be tight in terms of supply dynamics and emergencies
11 or unplanned outages can always take place we do project
12 that there will be sufficient supplies for patient needs
13 in that time frame barring any unforeseen outages and/or
14 other dramatic emergencies that take place in that
15 supply chain. But that will cause a shortage more likely
16 than not regardless of how this industry is going to be
17 transitioning.

18 What's associated with that is that according
19 to OECD guidelines and on this myth here is that the \$25
20 million that we are providing to each one of the
21 commercial products to accelerate their production does
22 not cross the identified threshold by the World Trade
23 Organization and utilized by the OECD in terms of what
24 defines a subsidy.

25 They specifically state that around the 15

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 percent level is when a subsidy is taking place from
2 government activities. Our rough figure of merit for
3 all of the different commercial projects is roughly that
4 they are \$200 million total cost. In that respect we're
5 a minor funding partner and nearer the threshold of the
6 World Trade Organization's 50 percent subsidy threshold.

7 And I think for use our list of acronyms that
8 we've used in the slide set. Hopefully I didn't use any
9 that are not defined here. So with that we're available
10 for any questions that you might have, please.

11 CHAIRMAN THOMADSEN: Thank you very much. Dr.
12 Alderson?

13 MEMBER ALDERSON: I'd like to follow up on some
14 of the new sources of moly-99. Because it turns out if
15 I've been reading the things that I've come across
16 correctly that a couple of them are right in the area
17 in which I live and in which Susan lives.

18 Out in the University of Missouri, one company
19 I believe is looking at using their big reactor to
20 produce moly-99.

21 Then there's another company that's set up shop
22 over in southern Illinois and that actually just created
23 a corporate office in St. Louis. Its name is very much
24 like a chemotherapy so I may be missing it. But the word
25 Zebulon comes into my mind. I don't know.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. BUNNING: It's not that, but yes, it begins
2 with a Z.

3 MEMBER ALDERSON: Yes, it begins with a Z.
4 Okay. So there are two of these groups that are right
5 in our home territory. And I don't really know what
6 their technologies are, whether they're high-HEU or LEU.
7 But they are claiming that they are going to be the answer
8 to this whole problem and it's going to be made right
9 here in the United States. Can you elaborate on that
10 at all?

11 DR. STAPLES: I'm happy to as much as possible
12 in that the entity -- the second entity you're referring
13 to doesn't actually ring a bell.

14 But I have to admit there are many that are not
15 associated with government activities. And for
16 business proprietary reasons they are maintaining a low
17 profile as Northwest Medical Isotopes was up until a few
18 days ago. We had some discussion with them but they
19 wanted to remain off the radar until they decided it was
20 appropriate to move forward.

21 All of the technologies in the U.S. for medical
22 isotope production are planning to use LEU or non-HEU
23 based production methodologies.

24 I do want to differentiate because there's
25 always a question that comes up regarding Missouri

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 University Research Reactor which is an HEU-fueled
2 research reactor.

3 In their station, the American Medical Isotope
4 Production Act, as well as others, it does allow the use
5 of HEU-fueled facilities for medical isotope
6 production. In the U.S. the target for production
7 methodology again is non-HEU. It's important to
8 differentiate between the reactor fuel and the targets
9 and/or processes used for production.

10 So at Missouri they have an agreement in place
11 with us and are working strongly towards converting the
12 fuel of that research reactor to LEU as a completely
13 separate program and process. Just to be very clear in
14 the distinction between those elements.

15 But at Missouri University Research Reactor
16 they have a number of activities and commercial programs
17 in place. And since this is definitely an open meeting
18 and we don't have non-disclosure agreements in place,
19 I want to be as generic as possible.

20 What I will say is that the basic methodologies
21 that we are supporting are fission-based, which there
22 is either HEU fission which is the current production
23 methodology. We're working simply to convert the HEU
24 targets that are used over to LEU. That has certain
25 technical constraints as well as other implications in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 terms of how that production takes place.

2 One part of our program under the GTRI effort
3 has been to increase the target density such that the
4 waste volumes are minimized when you transition from HEU
5 at 93 percent to LEU at 20 percent. Very simplistically
6 you can imagine that you would have roughly a 5 time
7 increase in waste volume.

8 That has caused us issues within other
9 implications. We're trying to minimize through
10 increasing the target density.

11 But then there also is other LEU-type
12 production methodologies. There's Morgridge Shine is
13 one of our cooperative agreement partners as well as B&W.
14 Babcock & Wilcox had a program where they were using a
15 solution, either reactors and/or targets of LEU material
16 to produce the moly-99.

17 The simplest analogy is that they would then
18 have similar to a swimming pool filter skimming off the
19 moly-99 out of this large solution.

20 Extremely efficient because they're able to
21 utilize all the fission taking place in their system,
22 not just in the targets versus as you would have in a
23 normal reactor where you can't access the medical
24 isotopes that are being produced in the fuel. You can
25 only use that material coming out of the targets.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 There is another entity, NorthStar, you might
2 hear some releases about. They are promoting two
3 different technologies. One was a gamma-N process
4 where moly-100 is a stable isotope. They have a
5 high-energy photon to get the moly-100 target, knock the
6 neutron out and it becomes moly-99.

7 They're also working, as are some other
8 entities, on a neutron capture process which is actually
9 how GE used to make moly-99 for the medical community.
10 Moly-98, also a stable isotope. They added a neutron
11 to that material and it becomes moly-99.

12 The difference between the neutron capture or
13 the neutron knockout process is that those are low
14 specific activity, moly-99s, and they require a
15 different generator technology than what the industry
16 currently utilizes.

17 So that is actually the one advantage that
18 NorthStar has been working through FDA approval is a
19 generator that will allow the radiopharmaceutical
20 industry to utilize the low specific activity as they
21 currently utilize it with what originally was a low
22 specific activity, moly-99, coming through a stable
23 isotope production process.

24 There is also a direct technetium production
25 that is being produced in Canada just as a reference

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 point. And that's where they will take as the PET
2 industry currently utilizes cyclotrons and take targets
3 and they will directly produce tech.

4 The difficulty there is that it is a much
5 shorter half-life material and it's not easily
6 transportable.

7 However, our position on that methodology is
8 that if it is commercially viable and usable for certain
9 segments of the international production of moly-99 be
10 it in the U.S. or in any other facility internationally
11 the commercial industry will utilize what is most
12 effective and commercially viable for their interests.

13 It might not be useful for rural farmland, but
14 in terms of large city center populations direct tech
15 production might well be an effective production
16 methodology to meet patient needs. And that's how
17 commercial industry will and should transition over the
18 next several years.

19 CHAIRMAN THOMADSEN: Good. Thank you, Dr.
20 Welsh.

21 MEMBER WELSH: This is a question for the
22 Chair. As you and the staff know, I am directly involved
23 in the radioisotope production. And through an entity
24 that has not been named here yet. I know Parrish is quite
25 familiar with this.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Is it appropriate for me to engage in
2 conversation and ask questions, or should I recuse
3 myself from any active involvement?

4 CHAIRMAN THOMADSEN: I would think that
5 discussion is okay. Can I get a ruling from somebody
6 in the NRC? I don't see a problem with discussion.

7 MR. FULLER: I don't see an attorney in the room
8 at this point so we probably need to -- I don't know how
9 we would advise at this point in time on a legal issue
10 without a lawyer.

11 CHAIRMAN THOMADSEN: Maybe just discretion
12 would be the appropriate call at the moment.

13 Any other --

14 MEMBER ZANZONICO: I have a technical
15 question. So, it's funny, you make this point that any
16 new production of moly sounds like it would less
17 efficient overall. Does that translate at some point
18 into increased costs of moly and then technetium-99m?
19 Or that has been projected far out enough to make a usable
20 estimate of cost?

21 DR. STAPLES: Yes, actually that's an
22 excellent question. And what I'll refer to is
23 information from two previous studies that were done,
24 one by the National Academy of Sciences and a more recent
25 one by the OECD reflecting to the cost of conversion

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 activities from HEU to LEU and impact on the industry.

2 And then what the OECD study got into is
3 reflecting the cost of transitioning from subsidy to
4 non-subsidy.

5 The HEU to LEU transition cost is estimated to
6 be roughly or less than 1 percent of the total cost of
7 the cost to a patient. This is -- and putting figures
8 on a table, roughly the reimbursement is about \$1,500
9 or the cost is averaged to be \$1,500 for a myocardial
10 perfusion imaging study.

11 The cost of the radiopharmaceutical I believe
12 is roughly \$30. And that's the total
13 radiopharmaceutical.

14 The cost of the isotope is estimated to be maybe
15 in the \$10 total cost range, or less than that, which
16 is again reflective on the \$10 cost of the CMS
17 reimbursement for that material.

18 The cost -- the current cost of the LEU is hard
19 to project exactly because it is mixed up in the subsidy
20 issue. The cost of the subsidies taking place, there
21 is estimated to be as much as a factor of 2 to 5 increase
22 in that.

23 And that data again is also extremely difficult
24 to come by. It's more a figure of merit and word of mouth
25 because it's proprietary sensitive from all of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 industry.

2 CHAIRMAN THOMADSEN: Thank you. Dr.
3 Suleiman?

4 MEMBER SULEIMAN: The LEU has -- the moly from
5 LEU has been being produced for a couple of years now,
6 so it's slowly been ramping up in composition.

7 And if you go to the government schedule and
8 look at what the price of a 10- or a 12-curie generator
9 is, it's only a couple of thousand dollars.

10 So, depending on the yield because you can
11 yield efficiently or you can yield less efficiently, my
12 calculations show that the entire cost, the entire cost
13 of the nuclide is on the order of \$10, let alone the
14 differential between HEU and LEU.

15 And right now, except for labeling where they
16 try to differentiate in order to get the CMS
17 reimbursement, the manufacturers really haven't
18 differentiated in terms of cost. They're pretty much
19 nominally setting about the same price. But that's
20 dynamically changing -- and the other thing seems
21 legitimate.

22 The CMS average price, \$1,200 to \$1,500 for a
23 SPECT. The radionuclidic component is just as you said,
24 a couple of dollars. So even if it were to double or
25 triple it really doesn't have that much of an impact on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the overall cost.

2 But, that's okay if you're up the line, but the
3 people down at the bottom end, you double their cost or
4 triple it, it has an impact.

5 DR. STAPLES: And what we actually have
6 observed again more just figure of merit is that as
7 different entities have supply availability and
8 depending upon long-term contracts in place or not the
9 cost of generators fluctuates tremendously, sometimes
10 by factors of 4 or 5 at the generator level dependent
11 upon how the supply chain is currently functioning,
12 where the material is coming from and total magnitude
13 of supply dependent upon facility outages.

14 So it's really a tremendously large dynamic in
15 terms of supply-demand and how that actually is
16 functioning in the industry. Much larger than any cost
17 associated to the HEU/LEU supply issue.

18 MEMBER COSTELLO: I wonder if -- my local
19 nuclear pharmacy and ask them do they have HEU or LEU.
20 Are they likely to know?

21 DR. STAPLES: We're hoping that they would
22 more so today than they would have yesterday. It's a
23 transition.

24 In all due respects what we've always heard
25 from the medical industry is they didn't care if it was

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 HEU or LEU. They wanted to know that they have it
2 available to meet patient needs.

3 And that actually reflects back to the whole
4 cost issue. When we first started in this business there
5 was actually testimony that Congress provided. And it
6 referenced basically that the cost of the isotope is
7 negligible in the process, that it really was a supply
8 reliability.

9 And this is a very important tool to the medical
10 community. And for the few dollar differential they
11 wanted the supply available. That was really the basic
12 theme of the response coming from the medical community.
13 And that really did propagate down through.

14 To make these actions effective and to really
15 develop long-term reliable supply we do need to educate
16 the entire community so they do ask those informed
17 questions in terms of making a really difficult choice.

18 Because it exactly relates to the economics.
19 These are commercial entities. They have to answer to
20 their shareholders in three months, not in three years.
21 And the activities we're asking them to implement affect
22 their industry in three years and it costs them in three
23 months. So it's against their short-term best interest
24 and the viability of how they function as a commercial
25 entity.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MEMBER COSTELLO: If you talk with them
2 they're very squeezed right now in their performance in
3 general.

4 DR. STAPLES: We recognize that. And we
5 realize that this is an incredibly difficult transition
6 period that we're working through, that we are asking
7 a lot of the entire community. It's really through
8 education.

9 In fact, being able to be in front of this group
10 and the voice and understanding that you have going out
11 through the community also just to help us address this
12 as a group to ensure this important radioisotope is
13 available for patient needs throughout the future.

14 CHAIRMAN THOMADSEN: Thank you very much.
15 Last question I think, Mr. Mattmuller.

16 MEMBER MATTMULLER: If I could go to your slide
17 3, please. Now that Northwest has announced do you have
18 a time line as to when you think their production
19 facility will be ready and will be able to supply moly-99
20 to the market?

21 DR. STAPLES: One way -- when we reference U.S.
22 domestic projects we're referencing here on this slide
23 those with which we have a cooperative agreement,
24 commercial legal agreement with. We do not with
25 Northwest.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Reading their press release I do not recollect
2 a date associated with their press release.

3 MEMBER MATTMULLER: I don't either.

4 DR. STAPLES: Yes. And it's not appropriate
5 for me to project on their behalf.

6 MEMBER MATTMULLER: I didn't know if you had
7 other information.

8 I guess my only quibble with this slide is that
9 we know that a number of these projects are in essence
10 shut down and that they're really not going to contribute
11 anything to the market.

12 And it's my understanding Babcock & Wilcox has
13 ceased. GE-Hitachi has ceased. Morgridge has -- last
14 I heard they had achieved some additional money but it
15 was for a different project not related to moly
16 production. And NorthStar is still a working project.
17 To my knowledge I have not heard or seen an announcement
18 that they have even started to dig to build their new
19 production facility in Wisconsin.

20 DR. STAPLES: Let me go through a very quick
21 assessment. I'll start with NorthStar. They're in an
22 FDA approval process for their TechnGenTM. And they
23 have a projected production in the near future with the
24 neutron capture project with Missouri.

25 So that's not at the 3,000 6 to 8 curie level

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 is all I think it's appropriate for me to say, but it
2 is well before the 2016 time frame. And it does depend
3 upon a number of factors of their commercial
4 availability.

5 I don't want to say more on their behalf in that
6 respect because it is commercial proprietary.

7 Morgridge Shine actually just signed an
8 agreement with GE-Hitachi in terms of additional
9 commercial activity in the area for this medical isotope
10 production.

11 We are -- also have a program under evaluation
12 for additional support through our cooperative
13 agreement partnership. So they actually are a strong
14 program moving forward.

15 B&W, you're absolutely correct. They have
16 ceased their program. They lost their commercial
17 partner several years ago. And knowing what their
18 projected time line was they are not viable, no longer
19 viable in the 2016 time frame.

20 Our cooperative agreement with General
21 Electric, which spurred the June 2012 Interagency public
22 statement or White House public statement, our
23 assessment and understanding and agreement with them is
24 that they were actually pausing that program due to
25 commercial status and that it was roughly on a 2-year

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 rolling window once they would resume activities.

2 So if they made the business decision that the
3 market economics are viable for resumption of their
4 activities we have the understanding that they would be
5 able to resume their program and achieve production
6 within approximately a 2-year time frame.

7 So not exactly failed and/or it is paused is
8 a very important clarification.

9 MEMBER MATTMULLER: And while I was familiar
10 with the announcement between Morgridge and GE, but it's
11 somewhat perplexing because it was to -- there wasn't
12 -- if we're reading the same announcement GE has agreed
13 to buy any amount they might produce.

14 Which is somewhat perplexing because GE does
15 not produce generators in the U.S. So I'm not quite sure
16 what they would do with moly-99 here in the U.S.

17 MEMBER SULEIMAN: They do make a generator in
18 the UK.

19 MEMBER MATTMULLER: In the UK. The UK
20 generator?

21 MEMBER SULEIMAN: It's just a --

22 DR. STAPLES: Well, I realize you advocate for
23 it. It's very important happening in that direction,
24 in that specific circumstance.

25 What we've been advocating for is the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 commercial industry needs to invest in its own future.

2 Now, governments can spur or inhibit these
3 activities. These are inherently commercial
4 activities. There is money to be made. Commercial
5 entities need to invest in their future. For how they
6 perceive the supply-demand scenario proceeding given
7 the market conditions. So I think that is a very
8 positive indicator that commercial entities are seeing
9 widely supported in terms of investing appropriately in
10 their supply future. And that's simply the way the
11 commercial activities should take place.

12 MEMBER MATTMULLER: As was mentioned before,
13 we're dying for a steady supply. And we really don't
14 care how or where it comes from.

15 I guess I'm just trying to get a handle of how
16 much hope I can put on this one, this one, or that one
17 as to whether or not our desires are going to be realized
18 in a few years.

19 DR. STAPLES: It would be inappropriate for me
20 to -- like children you cannot have a favorite child.
21 At least you can't say that you have a favorite child.

22 (Laughter)

23 DR. STAPLES: To be really honest. But let's
24 say in this case the commercial activities that are
25 associated with us, we're supportive of them. In fact,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the activities that we're putting in place for the U.S.
2 Interagency are supportive of all entities that are
3 trying to produce moly-99.

4 Those that are in the U.S. domestic cooperative
5 agreements, those we're working with internationally,
6 those that are current producers and those that are
7 intended future producers. We try to work as diligently
8 as possible to be as fair and equitable as possible for
9 all entities coming forward.

10 We remove all possible obstacles. I think the
11 complement of both the FDA and the NRC from a regulatory
12 perspective, they obviously do not bypass any of the
13 regulatory process. But they certainly make resources
14 available that these are high-priority projects and try
15 to work them through the system as rapidly as possible
16 to support the process and procedures of their
17 respective regulatory organizations.

18 CHAIRMAN THOMADSEN: Thank you very much, Mr.
19 Staples and Ms. Bender.

20 MEMBER MATTMULLER: I'm sorry, can I ask a few
21 more?

22 CHAIRMAN THOMADSEN: One minute.

23 MEMBER MATTMULLER: One minute? Okay. You
24 mentioned that private payers should match Medicare
25 payments.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 DR. STAPLES: Yes.

2 MEMBER MATTMULLER: In our experience in the
3 clinic, private payers are the most uncharitable
4 companies we've ever dealt with. We have trouble
5 getting them to pay for FDA-approved products for
6 patients who have had pre-certification taken care of.

7 And we can only surmise that they hire a lot
8 of creative writers because of the excuses they come up
9 as to why they don't want to pay for legitimate expenses
10 and procedures, is very, very frustrating on our part.

11 So, in a perfect world, yes, they probably have
12 a policy statement they do that but the reality is not
13 even close.

14 DR. STAPLES: Being an insured person I
15 commiserate with you in that respect.

16 CHAIRMAN THOMADSEN: Thank you, again. And
17 that brings us to the next topic, administrative
18 closing, and Ms. Holiday.

19 MS. HOLIDAY: Good afternoon. This is our
20 administrative closing part of the meeting where I go
21 over the recommendations and actions that were put forth
22 during our two-day meeting, that we are getting ready
23 to wrap up. And then lastly I propose our dates for the
24 fall 2014 meeting.

25 So, for item 1 this was where we talked about

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the subcommittee for medical policy statement. And
2 item 2 was where Dr. Thomadsen had added Dr. Alderson
3 to that policy statement subcommittee.

4 I was saying that we are closing these two items
5 because the subcommittee has presented their report to
6 the Committee which the Committee then endorsed.

7 Are there any objections to closing items 1 and
8 2? Okay.

9 Item 3 was where the ACMUI recommended to
10 endorse this report which includes the recommendation
11 to make no changes to the current medical policy
12 statement. That was presented on yesterday. Are there
13 any objections to that? Seeing none I go onto item 4.

14 Item 4 is where Dr. Thomadsen formed a
15 subcommittee to review the medical event reporting
16 criteria of the yttrium-90 microspheres 35.1000
17 guidance. Subcommittee members include Dr. Guiberteau
18 as the chair, Mr. Frank Costello, Dr. Susan Langhorst,
19 Dr. Christopher Palestro, Dr. Bruce Thomadsen and Dr.
20 James Welsh.

21 The subcommittee will present their
22 recommendations at the fall 2014 meeting. The NRC staff
23 resource person is Dr. Donna-Beth Howe. Are there any
24 objections to that?

25 Moving onto item 5. This is just to say that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Dr. Thomadsen added Mr. Frank Costello to the medical
2 event subcommittee.

3 Item 6. Dr. Thomadsen formed a subcommittee
4 on May 8, 2014 to provide staff with the background
5 information to justify the recommendation for the
6 regulatory relief from the decommissioning funding plan
7 of germanium-68.

8 The subcommittee is specifically charged with
9 evaluating the cost of the decommissioning funding plan
10 for the use of germanium-68, its effect on the future
11 clinical use of new gallium-68 radiopharmaceuticals and
12 how appropriate regulatory relief may be gained.

13 Subcommittee members include Mr. Steve
14 Mattmuller as the chair, Dr. Susan Langhorst, Mr. Frank
15 Costello, Dr. Christopher Palestro and Dr. Zanzonico.
16 Are there any objections to that?

17 All right. Moving onto item 7. I put this in
18 here as a staff action as Dr. Donna-Beth Howe mentioned
19 yesterday. Staff should provide the ACMUI subcommittee
20 with NRC guidelines for developing a regulatory basis.

21 If the recommendation that eventually comes
22 from the subcommittee report is that NRC revises
23 regulations, then we will have to provide a regulatory
24 basis.

25 I would provide this to the committee as a whole

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 either tonight or next week.

2 And item 8. This is where we are going to
3 propose our dates for the fall 2014 meeting. The last
4 page of your packet.

5 As we've said in the past, I've sent out the
6 meeting wizard to the committee in advance so that you
7 can indicate your availability so that this process
8 could be a little bit smoother.

9 If I am capturing it correctly I believe that
10 all committee members are available on September 29 and
11 30. Has that changed for anyone?

12 CHAIRMAN THOMADSEN: Do we have any conflicts?

13 MEMBER DILSIZIAN: I was informed that - I'm
14 on the board of directors of SNMMI. And I was informed
15 that the meeting is on the 29th.

16 I would think that if everyone can make it I
17 will attend.

18 MS. HOLIDAY: Okay. The meetings in October,
19 the dates I have highlighted, though a little bit
20 difficult to see, in green are the dates that I thought
21 were going to be our first and second choices.

22 So, the other date that we had produced was
23 October 20-21. I know that Dr. Guiberteau had indicated
24 that he has a conflict with that date.

25 MEMBER WEIL: So do I.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. HOLIDAY: So does Ms. Weil. Okay, does
2 anybody else have a conflict with those dates? Okay.

3 How about October 27 and 28? I believe there
4 are a few people that have conflicts.

5 MEMBER WEIL: I have a conflict.

6 VICE CHAIRMAN GUIBERTEAU: I have a conflict.

7 MS. HOLIDAY: Two conflicts. Are there any
8 other conflicts for October 27 and 28?

9 Okay. October 30 and 31. Do we have any other
10 conflicts? Same two.

11 Okay, so it's looking like our proposed dates
12 there will be at least one person or two persons who are
13 unavailable. So I guess I would leave it up to the
14 discretion of the Chair to choose the dates that you
15 would like to propose as your first choice.

16 So, September 29 and 30, 12 of the 13 members
17 are available with the exception of Dr. Dilsizian.
18 October 20 and 21 Dr. Guiberteau and Ms. Weil are
19 unavailable and they are also unavailable for the other
20 two dates.

21 CHAIRMAN THOMADSEN: Well, no offense to the
22 one, but it sounds like the 29th and 30th would be best.

23 MS. HOLIDAY: Okay.

24 CHAIRMAN THOMADSEN: Can you attend on the
25 30th? Are they meeting here?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MEMBER DILSIZIAN: Yes. I will try to
2 accommodate obviously to come to this meeting.

3 CHAIRMAN THOMADSEN: Dr. Welsh.

4 MEMBER WELSH: This is meeting on the 29th and
5 30th?

6 MS. DUDES: It's Sunday and Monday of the --
7 ending our day around 2.

8 MS. HOLIDAY: Okay, so it sounds like we're
9 going to have the 29th and the 30th as our first choice.
10 So, it looks like we need a date out of one of those three
11 dates as your second choice. Either way Ms. Weil and
12 Dr. Guiberteau will be unable to attend. So whichever
13 date that you would like to choose.

14 CHAIRMAN THOMADSEN: I'm not sure that it
15 makes too much difference. If the 20th and 21st sounds
16 as bad as any other date?

17 MS. HOLIDAY: Okay. So for the record we are
18 choosing September 29 and 30 for the fall 2014 ACMUI
19 meeting as our first choice. Our backup date will be
20 October 20 and 21.

21 At this time, Dr. Thomadsen, that concludes my
22 portion of the meeting. Please remove your badges.

23 MR. FULLER: I just have one point to make. I
24 just want to give you a heads up for something to think
25 about. I've looked historically at the times that we've

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 scheduled these meetings. The idea is to have two per
2 year approximately six months apart.

3 For the last few years it has went to less April
4 dates and more May dates, and less October dates and more
5 September dates. So we now have three or four month
6 between one and seven to eight, maybe nine months between
7 the next one.

8 I have not been able to find any reason why it
9 couldn't be March and September. So again, when we get
10 here in September something to be thinking about between
11 now and September is we would like to move towards moving
12 the meeting subsequent to the next one sometime around
13 March time frame.

14 So just be thinking about that when Sophie
15 sends out the wizards after the next meeting. We may
16 be asking for some folks to be looking at their calendars
17 around the March time frame. That way we get more of
18 a six-month separation between these meetings and it
19 helps the staff.

20 And again, it's not the most important thing
21 in the world but it would help the staff to better prepare
22 and plan for all of these meetings.

23 MS. HOLIDAY: So for clarification for the
24 spring we usually say let's look at our April-May
25 calendars. Instead we'll say let's look at our March

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 and April calendars.

2 MR. FULLER: Yes. Try to get a six-months
3 separate. Okay, thank you.

4 MS. DUDES: And just as a point of process I
5 just wanted to say thank you. It was nice to meet all
6 of you. I really benefitted from the discussion.

7 I look forward to trying to find ways within
8 the FACA process to continue benefit earlier and that
9 we can be contributors rather than review and
10 dispositioners.

11 And I thought the Commission meeting today was
12 very engaging. And there was some good dialogue on some
13 of the key issues. And we will continue to do that. So
14 thank you all for coming. Travel safe.

15 CHAIRMAN THOMADSEN: And thank you all for a
16 very good meeting and the support as always. Thanks to
17 the committee. Mr. Costello, are you making a comment?

18 MEMBER COSTELLO: More a question. We're
19 staffing two in-person meetings a year, but I understand
20 we have conference calls once in a while.

21 Can somebody tell me when and why and what the
22 topics are? When the next conference call will be?

23 CHAIRMAN THOMADSEN: They aren't set. They
24 always have been to address a particular issue that has
25 come up.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. FULLER: And the next one will be on the
2 bylaws it looks like.

3 MEMBER COSTELLO: So these are sort of ad hoc.

4 CHAIRMAN THOMADSEN: Yes.

5 MEMBER COSTELLO: Single issue.

6 MR. FULLER: Yes.

7 CHAIRMAN THOMADSEN: Yes. A very narrow
8 agenda.

9 MEMBER COSTELLO: But with some advance
10 warning.

11 CHAIRMAN THOMADSEN: Oh, definitely.

12 MR. FULLER: They have to be public and they
13 have to be publicly noticed and the whole thing.

14 CHAIRMAN THOMADSEN: We can't surprise
15 anything.

16 MS. HOLIDAY: That's right.

17 CHAIRMAN THOMADSEN: Any other final comments
18 from the committee? In that case thank you to everybody
19 and have a safe trip home.

20

21 (Whereupon, the foregoing matter went off
22 the record at 3:18 p.m.)

23

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701