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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION MEETING

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TUESDAY, APRIL 16th, 2013

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The Open Session portion of the meeting was convened in Room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

DARICE G. BAILEY, Agreement State Representative

MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

SUSAN LANGHORST, Ph.D., Radiation Safety Officer

STEVEN MATTMULLER, Nuclear Pharmacist

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

JOHN SUH, M.D., Radiation Oncologist

ORHAN SULEIMAN, Ph.D., FDA Representative

WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

LAURA WEIL, Patients' Rights Advocate

JAMES WELSH, M.D., Radiation Oncologist

NRC STAFF PRESENT:

BRIAN MCDERMOTT, Director, Division of Materials Safety and State Agreements

CHRIS EINBERG, Chief, Radioactive Materials Safety Branch, Designated Federal Officer

SANDRA GABRIEL, Ph.D., Acting Medical Radiation Safety Team Leader

ASHLEY COCKERHAM, ACMUI Co-Coordinator, Alternate Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Co-Coordinator

NEELAM BHALLA, FSME/DILR/RPMB

STEPHANIE BUSH-GODDARD, Ph.D, RES/DSA/RPB

SUSAN CHIDAKEL, OGC/GCLR/RMR

JIM DWYER, RI/DNMS/MB

SARA FORSTER, RIII/DNMS/MLB

CASSANDRA FRAZIER, RIII/DNMS/MLB

MICHAEL FULLER, COMM/OCM

LATISCHA HANSON, RIV/DNMS/NMSB-A

VINCENT HOLAHAN, Ph.D., FSME

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

DEBORAH JACKSON, FSME/DILR

ED LOHR, FSME/DILR/RMPB

KEVIN NULL, RIII/DNMS/MLB

PATTY PELKE, RIII/DNMS/MLB

GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB

MOHAMMAD SABA, RES/DSA/RPB

SAMI SHERBINI, Ph.D., RES/DSA

RONALD ZELAC, Ph.D, FSME/MSSA/RMSB

MEMBERS OF THE PUBLIC:

PAUL BESSETTE, VIEWRAY

DAVID BREUNING, VIEWRAY

ROBERT DANSEREAU, NY STATE DEPT OF HEALTH

WILLIAM DAVIDSON, UNIV OF PENNSYLVANIA

JAMES DEMPSEY, Ph.D., VIEWRAY

DANIEL DUVALL, M.D., CMS

LYNNE FAIROBENT, AAPM

RILLA HAMILTON, NNSA

KAREN LANGLEY, UNIV OF UTAH

ANDREW MCKINLEY, ASNC

MICHAEL PETERS, ACR

JOE RODGERS, THERAGENICS CORPORATION

MICHAEL SHEETZ, UNIV OF PITTSBURGH

PARRISH STAPLES, NNSA

MICHAEL STEPHENS, FL BUREAU OF RADIATION CONTROL

CINDY TOMLINSON, ASTRO

NANCY WERSTO, FDA

PAUL YURKO, VETERANS HEALTH ADMINISTRATION

TABLE OF CONTENTS

		PAGE
11.	10 CFR Part 35 Rulemaking Update	5
12.	Status of Data Collection on Patient Release	8
13.	The NNSA's Efforts to Minimize the Use of Highly Enriched Uranium in Molybdenum-99 Production	33
14.	The Federal Government's Center for Medicare And Medicaid Service's (CMS) 2013 Reimbursement Policy for non-HEU Produced Medical Isotopes	62
15.	Status of Licensing Guidance for ViewRayTM	92
16.	Thyroid Cancer Survivors' Conference	100
17.	Germanium-68/Gallium-68 Generator, Clinical Uses and Regulatory Relief	137
18.	Administrative Closing	159

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

2 CHAIRMAN MALMUD: Good morning, everyone, and
3 today's session will be on the new agenda that was
4 distributed yesterday so that the first item on the agenda
5 is being presented by Ms. Bhalla and Mr. Lohr, which is 10
6 CFR Part 35 rulemaking update.

7 MS. BHALLA: Good morning, Dr. Malmud, and members
8 of the committee. This is Ed Lohr and me, Neelam Bhalla,
9 and we are from the rulemaking group from FSME. We don't
10 have a lot here to say today except for -- give you and
11 update for this proposed Part 35 rule making. Next slide.
12 Okay.

13 I'm just going to, as I said, provide the
14 rulemaking update. Basically we have had, as you all know,
15 the ACMUI review of the proposed draft and then we had also
16 said the proposed draft to the agreement states for their
17 preliminary review. These -- as you know, the draft has
18 just now gone to the Commission, but you did have the
19 opportunity to review and provide your comments. So we have
20 received the comments from the agreement states as well.
21 Besides that, we have our internal process where we send to
22 -- within the agency to different groups for their reviews.
23 So now we have all the comments and the working group has
24 started to resolve those comments.

25 The next step that's going to happen is a comment
26 resolution, how we convey this proposal to the Commission is
27 -- we call it a SECY paper. So in this SECY paper, so as
28 far as ACMUI goes, so we would be providing your report that

1 you provided to us the last -- the final report came last
2 week, April 9th, and we do want to thank the committee and
3 Dr. Zanzonico on that for the very thorough review and the
4 comments.
5 So what will go to the Commission is that report,
6 the way it is, as an enclosure, and along with that will be
7 another enclosure which will provide to the Commission how
8 the staff resolved ACMUI's comments and the comments that we
9 did take, and perhaps there may be some comments that the
10 staff perhaps did not accept. But we would have to give a
11 pretty good reason as to why the staff did not take those
12 comments.
13 So the scheduled proposal -- rule is still on
14 schedule to go to the Commission mid-2013. That's this
15 year, in a few months. And then final rule is due to the
16 Commission late 2014 because as you know once we -- once the
17 rule goes to the Commission, the pending Commission
18 approval, the rule will be published in February 2014 for
19 certain time period, and for this one we proposing 90 days,
20 but that's again up to the Commission. May extend it for a
21 little bit longer or make it shorter. And then that same
22 process will start for the final rule. We will be going
23 over the comments, resolve the comments, and again the final
24 rule would come to the committee as well. And then we do
25 the comment resolution and eventually the final rule would
26 go to the Commission and that plan is late 2014. Ed, do you
27 want to add anything?
28 MR. LOHR: I think you've covered it very well,

1 Neelam. And of course we want to entertain any questions
2 that the committee may have on the process and know where we
3 are.
4 CHAIRMAN Malmud: Are there any other questions
5 from members of the committee? Dr. Langhorst.
6 MEMBER LANGHORST: I would just request that at
7 least 90 days be given for a comment period, if not a little
8 bit longer, because I think the length of our discussions on
9 teleconferences gives you an idea that this is a pretty
10 expansive change and we want to make sure that the licensees
11 have plenty of time, and others, to comment on the many
12 changes that are being proposed, so I would hope it is at
13 least 90 days.
14 CHAIRMAN MALMUD: Any other comments? If not,
15 thank you. Ms. Bhalla, Mr. Lohr, thank you very much. I'll
16 say personally that it's been a pleasure working with you
17 over these years. You've been very helpful to us in
18 clarifying issues, patient with us, and understanding our
19 perspective, and we're very supportive of the effort. Thank
20 you both.
21 The next item on the agenda is the status on data
22 collection on patient release. And we're a bit ahead of
23 schedule. Is Mr. Saba here?
24 MR. SABA: Good morning, Dr. Malmud and members of
25 the committee. I'm Mohammad Saba, the project manager for
26 the patient release study, and it's my pleasure to give you
27 an update on the project this morning.
28 Basically, in the first few slides -- oh, it's not

1 this -- this picture shows how difficult it is, the job for
2 balancing the situation if it needs two groups. There are
3 two groups. One group that believes we are too conservative
4 in assumptions, methods, calculations in Reg Guide 839, and
5 we should revisit that objective. And the other group
6 thinks we are too relaxed -- oh, and we have to relax that.
7 We should change the regulation to what it was before, the
8 old rules that was more conservative.
9 Basically, for the next few slides I give you an
10 update. I'll give you a brief background, and history of
11 the subject, just to refresh your memory, and then give you
12 updates on what we have done and what we are going to do on
13 the project. Previous rule -- the current rule was -- it
14 became effective in 1997. And before 1997 patient release
15 was based on the following. I just extracted it from the
16 old regulation. The licensee authorized release from
17 confinement for medical care and patient and all human
18 research subjects, administered a radio pharmaceutical unit
19 until the measure dose surveyed of the patient or the human
20 research subject is less than five millirems per hour at a
21 distance of one meter, or the activity in the patient is --
22 or in the human subject is less than 30 millicuries.
23 A major advantage of the old rule was the release
24 was based on directly measurable criteria, i.e. the activity
25 of volume at the time of release, or the dose rate of one
26 meter from the patient. A significant disadvantage of the
27 previous rule was that it was not flexible. It didn't allow
28 for the specific conditions of patients fall and release.

1 If we knew the patient -- was not -- is not going to be in
2 contact with anybody after release, we couldn't release her
3 yet.
4 On the other hand, the current rule is the same.
5 A licensee may authorize the release of control of any
6 individual who has been administered radioactive material or
7 implant containing radioactive materials if the total
8 effective dose to any other individual is not likely to
9 exceed five millirem. The current rule is based on the --
10 goes to members of the public. It does not provide the
11 licensee with a measurable quantity to be used for releasing
12 the patient. Therefore, a model is required to translate
13 the release criterion into an operational quantity. That's
14 why NRC came up with guidance. The model suggests that --
15 by NRC by use of licensee to determine the release criterion
16 is described in Regulatory Guide 8.39. Release of patient
17 administered radioactive material.
18 The model provides two options for the licensees.
19 The first option is to use the old parameters. The second
20 option is to use specific parameters. So it's more
21 flexible.
22 The other parameters include effective half-life
23 of radioisotopes, duration of exposure of the member of the
24 public, attenuation of radiation in the patient, and the
25 target, et cetera. It is very interesting to note that the
26 use of the default parameters in the model leads to a
27 release criterion that is nearly identical to the 30
28 millicuries retained activity criterion in the old rule, and

1 of course this is not coincidental -- we didn't push.
2 As you know, the Commission last year directed the
3 NRC staff to review publicly available data and see if any
4 data is missing. Either reproduce the data or -- and so we
5 had to do some collection of data if you need to do.
6 Assessment of the rule is not within the scope of
7 this work. Basically, the objective of this work is to see
8 how well a patient release practices are working, and to
9 what extent the 500 millirem limit is met. In addition, the
10 Commission directed the staff to examine the methods and use
11 in Regulatory Guide 8.39 to calculate the dose to members of
12 the public and to recommend this as appropriate. The items
13 to be reviewed include use of point source and point target,
14 use of gamma ray constant. No credit for self-absorption in
15 the patient or target. No credit for biological
16 elimination, occupancy factor .25.
17 Now, I give you an update on the project. So far
18 we have reviewed so many papers including the guidance from
19 ICRP, NCRP, and IAEA. There appears to be sufficient data
20 in the literature to reach reliable conclusions on exposure
21 of the member of the public, both for external and
22 internals. But we didn't find enough data for one area: the
23 exposure to workers in nursing homes and hotels. As you
24 know, some of the patients decide to go to hotels after
25 release from the hospital. NRC is -- and we found it very
26 difficult because of different reasons to go through these
27 facilities and collect data, and so the NRC staff came up
28 with another approach to stipulate the situation. The NRC

1 staff is conducting calculation using state of the art
2 phantoms and Monte Carlo calculations to represent the
3 patient and the target, and to calculate doses.
4 We are -- currently we are doing some QA tests on
5 our patient -- on our phantom, and we are confident that the
6 results are close, very close to what experimental data is.
7 Calculations are designed to assess doses in various
8 situations such as public transportation, hotels, at home,
9 et cetera. After this point, it is unclear if any NRC
10 initiative measurements will be needed. This will be clear
11 at the end of our literature review. The NRC staff has been
12 in contact with so many medical centers to get more
13 information to -- about the patient release practices and
14 calculations, and any data that they have concerning
15 exposure of members of the public. This will really help us
16 to come up with a good quality reg guide in the future.
17 The work is scheduled to be completed by the end
18 of 2016, but maybe we can finish it earlier. Our first
19 report would be a draft NUREG. We are going to send it to
20 FSME and ACMUI for your comments at the end of this year.
21 And the last slide, I provide this flow chart
22 which is a summary of the project. As you can see, for both
23 internal and external data for family members, we think we
24 have enough data in the literature for the family members,
25 how much exposure they get. But for hotel and nursing home
26 workers, we may need to perform calculations, time and
27 motion studies, and also get some information about
28 procedure of data from medical centers. And for general

1 public we still will need -- we may need to perform some
2 calculations and time and motion of studies. Once we are
3 done with this first phase, we use the information we have
4 from the first phase to develop Reg Guide 8.39. We use the
5 information from our literature review and we use those
6 calculations that we do with MCNP [spelled phonetically],
7 and we also use information that we get as a result with
8 interaction with medical centers. Okay, that's the end of
9 it. Thank you so much.
10 CHAIRMAN MALMUD: Thank you, Mr. Saba. Are there
11 questions?
12 VICE CHAIRMAN THOMADSEN: Mr. Saba, the time and
13 motion information you're getting for nursing homes and
14 hotels, how are you gathering that data?
15 MR. SABA: We should contract it out --
16 VICE CHAIRMAN THOMADSEN: Okay, that's not --
17 MR. SABA: It's not our --
18 VICE CHAIRMAN THOMADSEN: -- not set yet?
19 MR. SABA: No, not yet. It's -- there are
20 questionable -- there are some questions about funding. We
21 are not clear on that yet. And we don't know that we need
22 it if we have enough data. We might not need it at all.
23 CHAIRMAN THOMADSEN: What sort of data would --
24 MR. SABA: Oh, for nursing home we might get some
25 permission from the licensees, or maybe we are hoping that
26 we might get some papers still in that area, but if we don't
27 find it we have to do it.
28 CHAIRMAN MALMUD: Dr. Suleiman, you had a

1 question?

2 MEMBER SULEIMAN: Yes. Orhan Suleiman. Why not
3 just badge some of these sites with all their personnel in a
4 prospective study, including maybe the carts they carry
5 around, including themselves, just to do a pretty
6 comprehensive sweep and collect some real data? I think
7 it'd be easier

8 MR. SABA: Yeah. That's what we were going to do,
9 but there will be some legal issues. It should not be done
10 by NRC, it will be done by contractors. But that's what we
11 are going to do it with, yeah. I just wanted to tell you
12 that there are -- we think that there are lots of difficulty
13 in doing that.

14 MEMBER SULEIMAN: In a former life I remember
15 having to tell sites to go ahead and badge employees that we
16 suspected were getting below minimal. I did just for legal
17 purposes. Go ahead, document it, and then you can feel
18 safer later. So, yes, why couldn't anybody take that kind
19 of approach?

20 CHAIRMAN MALMUD: Yes?

21 MEMBER MATTMULLER: Steve Mattmuller. I'm
22 curious. Parts of 1997, when patients were hospitalized, I
23 know, at least at our facility, we badged the nursing staff
24 that took care of those patients, albeit the care was
25 minimal. But have you considered use -- or maybe trying to
26 find some of that old exposure data to nursing staff for
27 those hospitalized patients as part of assimilation to what
28 a hotel worker would get?

1 MR. SABA: We have been contacting with the
2 medical centers. Yes, eventually, if we can't do any -- if
3 we can't go to nursing homes, yes, or hotels, we can't do it
4 that way and we -- yeah, most of the hospitals they have
5 some data, but the only problem is we give instructions to
6 the patient in the hospital, but when they go home, they are
7 not instructed as much as they are in the hospital, so it's
8 not the real case. That's...
9 CHAIRMAN MALMUD: Dr. Langhorst?
10 MEMBER LANGHORST: Mr. Saba, you did not mention
11 whether you were looking at ACMUI's paper on this topic.
12 MR. SABA: Yes, we actually read that.
13 MEMBER LANGHORST: Okay. And looking at our
14 calculational method --
15 MR. SABA: Yes.
16 MEMBER LANGHORST: Okay, so you -- I did want to
17 note on your comment concerning the 30 millicuries as far as
18 the old rule versus current, you really should say that's
19 only limited to I-131 and it does not necessarily apply to
20 any other --
21 MR. SABA: Yes.
22 MEMBER LANGHORST: -- isotope.
23 MR. SABA: Yes, thanks.
24 MEMBER LANGHORST: Thank you.
25 CHAIRMAN MALMUD: Thank you. Yes?
26 MEMBER ZANZONICO: Pat Zanzonico. Hi, one
27 question. When you say that the work of your group is
28 outside the scope or addressing the rules outside the scope

1 of the work, can you just clarify what that means?
2 MR. SABA: Oh, I'm sorry.
3 MEMBER ZANZONICO: You said that the assessment of
4 the rule itself is not within the scope of this work.
5 MR. SABA: Yes, yes.
6 MEMBER ZANZONICO: What exactly does that mean?
7 MR. SABA: Clearly they told us don't touch
8 regulations.
9 MEMBER ZANZONICO: Does that mean that the .5 rem
10 dose is not in play?
11 MR. SABA: Yeah. It's not that.
12 MEMBER ZANZONICO: So now these are a couple of
13 comments. One is I'm sure you're familiar with NCRP Report
14 155 --
15 MR. SABA: Yes.
16 MEMBER ZANZONICO: -- which dealt in depth with
17 this whole issue, and among the components of that report
18 were occupancy factors other than the .25 value for
19 different cohorts of exposed individuals. I still think
20 that's the most comprehensive treatment of this subject. I
21 have a biased view of it since I was on the committee that
22 wrote the report. The -- and just to follow up Dr.
23 Langhorst's comments, it's the 30 millicurie conformity
24 between the old and new rule is not just for I-131, it's
25 really just for I-131 hyper thyroid patients who have a very
26 long biological half-life; it really doesn't apply -- you
27 would at least apply the effective half-life to thyroid
28 cancer patients in whom the biological half-life is much,

1 much shorter. So for .5 rem dose individuals, when needed,
2 you'll get a much higher releasable activity.
3 Just one final point. Wes Bolt at University of
4 Florida has really has been developing, publishing state of
5 the art models, anthropomorphic models that are remarkably
6 realistic and are very adaptable to all sorts of situations.
7 And I know he's aware of this ongoing effort by NRC because
8 I told him about it. And he would be very willing and
9 certainly able to assist in adapting some of his models to
10 this sort of calculation, and I can give you his contact
11 information and so forth. But those I think really are
12 considered state of the art anthropomorphic models for these
13 sorts and other sorts of the dosimetric analyses.
14 MR. SABA: Thank you. Again, I told them that
15 benchmarks are phantom against ICRP data and other
16 experimental data, and we came really close to what they
17 had. But thank you so much.
18 CHAIRMAN MALMUD: Ms. Weil?
19 MEMBER WEIL: The common motion studies and the
20 other use of phantoms presupposes, I assume, that patients
21 are being given good discharge -- will be using -- the model
22 will use discharge instructions that are given to patients
23 about keeping certain distances from certain members of
24 their family and certain member of the public and other more
25 vulnerable populations. And I question whether that's a
26 good assumption to base this research on.
27 MR. SABA: Based on the --
28 MEMBER WEIL: Based on the understanding and

1 following of those instructions.
2 MR. SABA: Yeah, but we wanted to see what's in
3 reality because the committee directed us to see how -- to
4 what extent the 500 millirem has been met?
5 MEMBER WEIL: If people follow instructions.
6 MR. SABA: Yes --
7 MEMBER WEIL: But there's a large cohort of people
8 --
9 MR. SABA: Yes.
10 MEMBER WEIL: -- who don't follow instructions.
11 MR. SABA: Yes
12 MEMBER WEIL: So you won't be capturing that
13 information? About the people who don't follow those
14 instructions.
15 MR. SABA: No.
16 MEMBER WEIL: So you're looking at a best case
17 scenario as opposed to realistic scenario?
18 CHAIRMAN MALMUD: Perhaps it should be
19 characterized as a compliant scenario versus a non-compliant
20 scenario on the part of the patient.
21 MEMBER WEIL: No, I disagree with you, Dr. Malmud,
22 because there's a question as to whether good instructions
23 are being provided by the licensees in a way that patients
24 can understand in a language that they understand with the
25 time to discuss at a time when the patient is perceptive to
26 instructions. I wouldn't put this off on the patient.
27 CHAIRMAN MALMUD: Well, I'm projecting, perhaps,
28 to the general physician group, my experience since I treat

1 patients with I-131, and I go through great detail of what
2 they should be doing and what they should not be doing, but
3 noncompliance patients in the old days, when we treated them
4 as inpatients, we found noncompliant inpatients as well who
5 leave the room, walk down the hallway, urinate on the floor.
6 So there's always a possibility of noncompliance whether in
7 the hospital, to the hospital staff, and other members of
8 the public, or at home. That risk always exists. Under any
9 circumstances the risks exist.
10 I do agree with you, though, that part of the
11 treatment plan includes detailed radiation safety
12 precautions. My own personal feeling about it is that when
13 the patient goes home, he or she understands the risks to
14 the family and tends to be very, very compliant. Even
15 asking questions about what they could and could not do, how
16 close they can be, et cetera. The risk is always that the
17 patient will not go home and check in to a hotel without
18 calling us that they're doing it. That risk exists. In the
19 hospital the risk is that treating patients on an inpatient
20 basis will give to the nursing staff and to the ancillary
21 staff in the hospital radiation burdens over the course of a
22 period of time, which are greater than anyone in the public,
23 including the medical staff, would receive exposure casual
24 exposure through the individual patient. And this was all
25 discussed at length by this committee prior to my joining
26 the committee, more than 10 years ago, and that's how the
27 current rules came to be. So what's being asked for now is
28 actual calculations and numbers for the models that are

1 shown there. So we will see the data. The data should be
2 interesting. And as one of my colleagues here pointed out,
3 the 30 millicurie rule is generally for patients who are
4 being treated for hyperthyroidism, with just smaller dose
5 compared to 100 millicuries for cancer, but the half-life --
6 the biologic half-life in the patient's body is longer.
7 Whereas, with a high dose, 100 millicuries of I-131 given
8 orally, for thyroid cancer the biologic half-life was quite
9 brief. Most of the dose doesn't go to the thyroid tissue,
10 or other target organs of the body is urinated out with 24
11 hours.
12 The situations are quite variable and there is no
13 single perfect solution to the problem, but hopefully the
14 data will help this committee to come up with a deliberation
15 which results in the least risk to members of the public
16 including nurses and other ancillaries, and try to achieve
17 what you are pointing out to us which is not giving an
18 unknown member of the public radiation exposure which could
19 be prevented. We're sensitive to it.
20 SUSAN LANGHORST: Dr. Malmud?
21 CHAIRMAN MALMUD: Dr. Langhorst.
22 MEMBER LANGHORST: I wanted to just clarify one
23 thing that you said. You mentioned occupational staff
24 getting radiation burns and I wanted to ask you if you meant
25 radiation exposure?
26 [talking simultaneously]
27 [laughter]
28 MEMBER MATTMULLER: I heard that too.

1 MEMBER LANGHORST: Sorry, I heard -- I apologize.
2 I heard that incorrectly.
3 CHAIRMAN MALMUD: Apologize for my pronunciation,
4 but the word was "burden."
5 MEMBER LANGHORST: Thank you.
6 [laughter]
7 CHAIRMAN MALMUD: I'm glad you were listening.
8 [laughter]
9 MEMBER LANGHORST: I was.
10 CHAIRMAN MALMUD: Any other comments? If not,
11 thank you very much. Mr. Saba, the committee will look
12 forward to seeing the results of these studies --
13 MR. SABA: Thank you so much.
14 CHAIRMAN MALMUD: -- and coming up with a solution
15 which meets the needs of not only the patient but members of
16 the public, and as soon as possible. Thank you. We're a
17 bit ahead of schedule. May we go on with the next item?
18 MS. HOLIDAY: Dr. Malmud, this is Sophie. I don't
19 believe the next two presenters have arrived yet, so if
20 possible could we hold off until they arrive?
21 CHAIRMAN MALMUD: In that case, Sophie, may we
22 used these next 15 minutes for you to deal with us with some
23 issues that you'd normally bring up at the end of the
24 meeting such as travel and time?
25 MS. HOLIDAY: Certainly. Okay, so I guess I will
26 flip to the very back of our big handout here, which is when
27 we start looking at dates for the fall meeting. So I know
28 that early on I sent out a MeetingWizard request to poll the

1 committee members as to their availability for a fall
2 meeting. Initially, we had offered up both September and
3 October dates, but I think it was a couple weeks ago staff
4 came to the conclusion that an October meeting was not
5 feasible with all of our schedules here, so I think we are
6 going to look at September dates. I believe out of all the
7 responses that I've got -- correct me if I'm wrong -- but I
8 believe September 9th and September 10th, that's a Monday
9 and a Tuesday, worked for everybody. Dr. Langhorst, correct
10 me. I think that was the date I asked you for or --
11 MEMBER LANGHORST: Yeah, it's only a Radiation
12 Safety Committee for me so -- maybe mid meeting for my own
13 RSC, so I will have someone else cover it.
14 MS. HOLIDAY: So I would like to thank Dr.
15 Langhorst for bending her schedule for us. I guess I would
16 like to reconfirm with everybody that September 9th and the
17 10th work for everybody for a fall meeting date. Hopefully
18 there are no objections, or I should wait another minute so
19 everyone can check their calendars?
20 MEMBER SULEIMAN: I have a conflict that's
21 resolvable, so that's fine.
22 MS. HOLIDAY: Sure. Okay.
23 CHAIRMAN MALMUD: It's looks as if it's acceptable
24 to everyone. Is there a conflict for anyone? Dr. Welsh?
25 MEMBER WELSH: I don't anticipate any conflict,
26 but I do need to clear it with my medical colleagues that I
27 would have coverage. So I'm anticipating this will be okay.
28 I will let you know as soon as I get a reply.

1 MS. HOLIDAY: Sure. Okay. So I will tentatively
2 pencil September 9th and 10th as our first choice and then I
3 believe the next set of dates that worked for everyone, and
4 Dr. Welsh, thank you for already bending for the second set
5 of dates, is Monday, September 16th and Tuesday, September
6 17th. So if I could just get a confirmation that those sets
7 of dates works for everyone as well.
8 CHAIRMAN MALMUD: Has everyone had a chance to
9 check his or her calendar?
10 VICE CHAIRMAN THOMADSEN: Much less well for me,
11 but there are possibilities.
12 CHAIRMAN MALMUD: Looks as if that's an acceptable
13 alternate.
14 MS. HOLIDAY: Okay. So for the record I have
15 September 9th and 10th as our first choice for the fall
16 meeting and September 16th and 17th as our second choice,
17 our backup meeting.
18 We are still a little bit ahead of schedule. I
19 guess at this time I could just as the committee members,
20 during the presentation I gave yesterday, if you'd like to
21 go ahead and write down the hours that you would like to
22 submit for this pay period. Your pay period ends on this
23 Saturday and then I'll just collect those and I'll enter
24 them in for you. And also, if you have not turned in your
25 biennial evaluations, please do that also. Thank you.
26 [break]
27 CHAIRMAN MALMUD: Please introduce yourself.
28 MR. CRANE: Yes, please. My name is Peter Crane.

1 I am NRC's Counsel for Special Projects in the Office of
2 General Counsel, now retired.
3 CHAIRMAN MALMUD: Thank you.
4 MR. CRANE: And thank you. And I'd like to have
5 to opportunity to make some comments on a Mr. Saba's
6 presentation.
7 CHAIRMAN MALMUD: You're invited to do so.
8 MR. CRANE: Thank you. First, I'd like to say
9 that I'm indebted to Dr. Malmud for having so cogently
10 described in 2007 the practical effects of the current rule
11 and the reasons that hospitals are unwilling to hold
12 radioactive I-131 patients. It's never been expressed more
13 concisely or forcefully.
14 I'd like a few points. Mr. Saba says that, "We're
15 torn between those that think we're too conservative and
16 those who think we should go back to the old rule." Well,
17 there's things to be said on both sides of that. The one
18 thing the pressure that says that it's too conservative is
19 come in large part from The Society of Nuclear Medicine.
20 There's a paper by Carol Marcus and I think Stabin on
21 licensee over-conversatisms. Well, on January 31st I got a
22 letter from Chairman Macfarlane responding to a letter from
23 me, and it is clear that for the last nine years, The
24 Society of Nuclear Medicine has been advertising its
25 guidance as having NRC's blessing to be used in place of
26 NRC's and licensees are encouraged, although it's far more
27 liberal.
28 A quotation is attributed to the NRC that the NRC

1 never made. The result is that if people have been
2 operating under the false belief that this document can be
3 used by licensees in place of NRC's, they may have been
4 sending patients out the door with as much as 457
5 millicuries of I-131 in them; which is a pretty daunting
6 idea. It turns out that the statements attributed to it by
7 SNM were not true, the NRC intervened with SNM to find out
8 where these statements supposedly came from, and the SNM has
9 now altered its advertising. I think it's important to get
10 the word out to the licensee community that you cannot rely
11 on this SNM guidance from 2004 and be confident that you're
12 in compliance with Reg. Guide 8.39.
13 Secondly, as to whether the whether my argument is
14 for going back to the 30 millicurie rule, that was what my
15 initial petition asked for, to be sure. But that was a
16 rulemaking conduct -- petition being handled under rule
17 forum, which was a brainchild of the late Bill Olmstead of
18 OTC. And the idea was that petitioners, participants, et
19 cetera, could interact, modify their views in time. And
20 after talking with their Ernie Mazzaferri, the then head of
21 The American Thyroid Association, I modified that because I
22 think that there is room for greater flexibility about
23 sending people home, for one, thing in accordance with NCRP
24 number 37 from 1970. And it's also true, and this is a
25 point often made, that the athyreotic patients getting 100
26 millicuries may be less of a radiation hazard than the
27 Graves' patient getting 15 millicuries because that patient
28 -- the Graves' patient got an intact thyroid that is

1 retaining I-131 longer. So, I'm willing to see flexibility
2 and I would not want to be caricatured as simply a
3 reactionary asking to go back to pre-1997 days.
4 Another point is that I think it's important to
5 note that our 500 millirem standard, which is not being
6 touched, is five times what the NCRP and the ICRP recommend
7 and it's very much out of step with the world community.
8 I have a question for Dr. Saba. I mean, I'm quite
9 sure he's right in his major point. And I applaud that in
10 saying that we don't have enough data on hotels and nursing
11 homes. I guess my question would be, "Are you considering
12 collective doses?" This is a point that Jim Luehman of the
13 staff made in an ACMUI meeting in October 2010, that
14 although the individual dose to the house keeper who cleans
15 the room may be small, we don't know if they are, perhaps,
16 getting many treatments in a year. If you are working in the
17 hotel down the street from the Mayo Clinic or associated
18 with the Mayo Clinic, or if you're working in one of the
19 eight hotels to which Sloan-Kettering feeds patients because
20 it has preferential rates arranged with them, you might be
21 cleaning a number of radioactive hotel rooms in a year and
22 accumulating a dose from each one.
23 So my question would be, "Was he considering collective
24 dose?"
25 I'd also say, the question was asked, and it's a
26 very reasonable one, "Why not badge people?" The problem
27 with badging people is that when you do that you put them on
28 notice that there's a radiation hazard. Our problem in the

1 hotel context is that they don't know. And how do people
2 behave when they are unaware of the hazard altogether? Our
3 problem is that we do not have informed consent; we've got
4 ignorant people being exposed, and the creation of dangerous
5 working environments. I'm told that there are hospitals
6 that are hospitals where radioactive rooms are left vacant
7 for a week before anybody even goes in there to clean in
8 order to let them cool down. And Dr. Malmud made a point in
9 his -- at the ACMUI meeting in October 2007 that hospitals
10 leave the rooms on either side empty because of the
11 radiation coming through the walls. And, you know, yet
12 we're having people going in there and cleaning right away.
13 We've also got hotel guests moving in in a matter of hours,
14 which I think should be a source of concern. I don't know
15 whether the charter of the committee goes to the possible
16 dose that could be absorbed by the subsequent hotel guest.
17 We've seen at the Braidwood Hotel incident -- motel incident
18 a hotel guest who needed to be decontaminated.
19 Finally, to Dr. Weil's point of questioning of
20 whether patients are getting instructions, I made a
21 suggestion at a meeting a couple of years ago, and Dr. Welsh
22 expressed the thought that it was a positive idea, which is
23 that the industry and the NRC could collaborate on preparing
24 information for patients contained on a compact disc or DVD.
25 It could be in different languages which could be played for
26 the patient before they ever consulted with a doctor. It
27 would give them preparatory information. They could take it
28 home. They could play it over again if they had any doubts,

1 because frequently patients are in a kind of upset state
2 when they are given instructions. They don't always
3 remember it, especially if they're hypo-thyroid.
4 I think Jim Luehman came back reporting from a
5 psych conference that sometimes the safety instructions are
6 simply one piece of paper in a stack of pieces of paper that
7 are handed to the patient on discharge. I'm sure Dr. Malmud
8 is as conscientious as he says in going through these issues
9 with patients. But again, that's a best-case scenario and
10 not, necessarily a realistic scenario. But, that's
11 essentially what I wanted to say.
12 CHAIRMAN MALMUD: Thank you, Mr. Crane. You made
13 a number of points, and we will ask Mr. Saba's committee --
14 team, excuse me, to consider these, and when the data is
15 collected regarding exposure of members of the public, that
16 these issues be revisited.
17 MR. CRANE: Very good, I appreciate it.
18 CHAIRMAN MALMUD: Your comments are appreciated
19 and will not be ignored.
20 MR. CRANE: Thank you, and if I could ask one more
21 thing, it used to be that there was a Federal Register
22 Notice -- or not a Federal Register Notice, an NRC news
23 release announcing upcoming ACMUI meetings, which was quite
24 helpful in -- to the public in knowing in being put on
25 notice. Those seem to have been discontinued more than a
26 year ago. I think it would be a benefit from the standpoint
27 of public participation if that practice were resumed, and I
28 want to thank you all for your patience and receptivity,

1 willingness to listen to me this morning. And to you, Dr.
2 Malmud, as you leave the committee I wish you everything
3 good in private life.
4 CHAIRMAN MALMUD: Thank you. And we discussed
5 your concern earlier and Ashley Cockerham has a response for
6 you with regard to that concern. Ashley?
7 MS. COCKERHAM: This is Ashley Cockerham. We were
8 advised --
9 MR. CRANE: Hi, Ashley.
10 MS. COCKERHAM: -- last year that NRC press
11 releases are issued at the discretion of the NRC Chairman
12 and they were -- regular meeting notices are not typically
13 done in press releases. I would note that that is standard
14 practice also for the Advisory Committee on Reactor
15 Safeguards; they do not regularly issue public notices for
16 meetings --
17 MS. CRANE: So, was that --
18 MS. COCKERHAM: -- press releases for meetings.
19 We do issue notices in the Federal Register per FACA
20 regulations.
21 MR. EINBERG: Ashley, can you also point out that
22 where else this was noticed so that members of the public
23 can access the meeting notices.
24 MS. COCKERHAM: Yes, this was noticed on March 6th
25 in the Federal Register notice. This was also noticed on
26 the ACMUI medical list -- or not the ACMUI -- just the NRC
27 medical list server on March 11th, I believe. It was also
28 noticed -- the ACMUI public agenda was posted on the ACMUI

1 public website on March 11th. And it was also published on
2 the NRC public meeting notification page, where all public
3 meetings of the NRC are posted --
4 MR. CRANE: [affirmative]
5 MS. COCKERHAM: -- and it was posted on March 11th
6 on that website, as well.
7 MR. CRANE: Well, thank you, Ashley. I'm not one
8 of those who spends his days thumbing through the Federal
9 Register, and I gather it was a decision the previous
10 chairman's. It dates from then. I don't think that that
11 was a change for the better, but I realize that it's not --
12 I appreciate being told that this was not an ACMUI decision
13 but a chairman decision. So, thank you very much.
14 CHAIRMAN MALMUD: Thank you, Peter.
15 MR. CRANE: And good morning to you.
16 CHAIRMAN MALMUD: Thank you for your
17 participation, Mr. Crane.
18 MR. CRANE: Thank you, goodbye.
19 CHAIRMAN MALMUD: Goodbye. And if we may, we'll
20 move on to the next item on the agenda, which is the NNSA's
21 efforts to minimize the use of highly enriched uranium in
22 molybdenum-99 production. And that will be presented by Dr.
23 Staples and Ms. Hamilton.
24 DR. STAPLES: Thank you very much. I apologize
25 for coming in a few minutes late, but it appears you had
26 some questions going anyway.
27 So, I would like to thank you very much for
28 presenting -- or allowing us to present this information to

1 you on our efforts on moly-99 production associated with
2 efforts on HEU minimization. The title slide, as you can
3 see, we're part of The Department of Energy, the National
4 Nuclear Security Administration, with the Defense Nuclear
5 Nonproliferation Branch, the Office of the Global Threat
6 Reduction Initiative.
7 We've gotten involved in this mission, to begin
8 with, to reduce and protect vulnerable nuclear and
9 radiological materials that are located at civilian sites
10 worldwide. There are three technical polars within our
11 office. First, to convert research reactors on isotope
12 production facilities from the use of highly enriched
13 uranium to low enriched uranium, to achieve a threat
14 reduction perspective; to complement the conversion of these
15 facilities to LEU; and to ensure permanent threat reduction
16 we also provide services to remove and dispose of access
17 nuclear and radiological materials.
18 There's a U.S. origin disposal program. There's a
19 Russian origin disposal program. And, in fact, just about a
20 week ago there was a lot of publicity associated with the
21 disposition and the significant quantity of nuclear material
22 from the Czech Republic back to the Russian Federation. I
23 think it was even on the Rachel Maddow show that this was
24 associated with that effort.
25 Until these permanent threat reduction activities
26 can take place, or in circumstances where these materials
27 continue -- is continuously utilized, we also provide
28 physical protection support, internationally, for these type

1 materials to protect them from theft and/or sabotage.
2 The focus of this presentation today is on moly-
3 99. Historically, HEU has been utilized to produce moly-99,
4 one of the most widely used medical isotopes in the
5 industry. And I think, looking at your titles at the table
6 here, I have a feeling that you're much more familiar with
7 this utilization than I am. So I'm not going to try to bore
8 you with those details.
9 But our efforts are to work to achieve the
10 production capability of the industry while at the same time
11 achieving our HEU minimization missions. Medical isotope
12 production -- this is something that we've been doing,
13 roughly now, for about 15 to 20 years. We've been making
14 significant progress, lately, in due to the failures of
15 several parts of the industry for regular, reliable
16 production. So we have actually assumed the mission, in
17 addition to the HEU minimization, of working to establish a
18 reliable U.S domestic supply of moly-99 that is produced
19 without the use of HEU. And this is the complement of two
20 efforts, both internationally and domestically. And due to
21 the fact that we are, for lack of a better term, interfering
22 in commercial activities, we have to keep very careful
23 balance or how we work with our international partners, how
24 we support domestic efforts. All the while, we work with
25 the international community to provide this important
26 medical isotope for patient needs that I think are used,
27 roughly, 50,000 times a day here in the United States alone.
28 In our international efforts, we only assist with

1 converting their facilities from LEU targets or to LEU
2 targets from HEU targets to achieve our HEU minimization
3 objective. It is their obligation as existing commercial
4 entities to increase their production capacity or update
5 their facilities.
6 In addition, there are some new entrants coming in
7 in the international market. We simply work to make sure
8 that they adhere to their nonproliferation goal statements
9 and priorities of utilizing a non-HEU based production
10 process to implement their technologies. Domestically,
11 where there's currently no commercial HEU or non-HEU based
12 production, we're working with a number of cooperative
13 agreement partners and working with the industry, in
14 general, to support all activities that are taking place to
15 produce moly-99 for the needs of patients. And that is part
16 of our objective to establish a reliable supply of moly-99
17 produced without HEU.
18 The current situation of the industry shown below
19 -- and this is certainly a very simplified cartoon
20 schematic. Each one of the rows of the bar chart represents
21 some time in the current, or projected future history.
22 Today, we're at the top bar chart where Australia produces
23 solely using LEU. NTP Radioisotopes in South Africa is in
24 the transition process and they've recently advertised
25 significant progress towards the conversion of their isotope
26 production towards LEU. Covidien, IRE, and AECL Nordion all
27 continue to produce with HEU.
28 At some point in the near future, we know that NTP

1 will fully transition to LEU-based production. And we have
2 from a recent nuclear summit, led by President Obama, and
3 from the United States, with approximately 50 international
4 leaders, we've received a pledge from both the Netherlands
5 and Belgium that they will work with us and France, who is
6 the target producer, to convert the processes to LEU-based
7 production by the 2015 to '16 timeframe.
8 The most significant issue, and the bar in any --
9 in no cases to these bars represent market share, other than
10 the implication that the Nordion -- AECL Nordion bar is
11 significantly larger than the others. They are the current
12 largest producer of medical radioisotopes. They have made
13 continuous and regular statements that they will cease
14 medical isotope production in the 2016 timeframe. That's
15 the one very important issue that we're facing. Part of
16 that is due to the fact that they were not able to get their
17 projected future production process, the Naples facility,
18 operational. And the current facility that they utilized,
19 the NRU reactor is a very aged facility and has had numerous
20 operational issues over the past several years. So in 2016,
21 there's going to be a significant gap in medical isotope
22 production, unless the international community can step up
23 their efforts to produce isotope, or we're successful with
24 U.S. domestic moly-99 projects.
25 We have four current cooperative agreement
26 partners that we're working with to develop that replacement
27 capacity. In addition, there are other commercial entities
28 that are not associated with funding with our program that

1 are also working towards domestic production.
2 So the support that we have both for
3 internationally, as I've mentioned, is for conversion from
4 HEU targets to LEU targets. We developed the technology and
5 we provide that at no cost to entities that are interested
6 in implementing them.
7 I've already stated about the four-party joint
8 statement at the 2012 Nuclear Securities Summit, which was a
9 very significant accomplishment and a pledge at the highest
10 levels to support this effort. In addition, we have
11 provided South Africa with a significant amount of support
12 for their conversion process, from HEU to LEU targets, and
13 they're making significant progress; as indicated here's the
14 June 2010 timeframe when they first had LEU based production
15 and was received commercially in the United States later
16 that year.
17 In addition, we are providing some support to
18 Belgium and towards their conversion commitment by 2015.
19 Netherlands and Covidian, they're leading their own effort
20 towards the conversion project to LEU targets in that same
21 timeframe. And as mentioned, Canadian reactor -- and we
22 can't state that more often -- cannot state that enough
23 about their cessation of isotope production in 2016.
24 To develop our cooperative agreements and to try
25 to avoid a single point of failure, we looked at the
26 straightforward or the most straightforward production
27 technologies, methodologies for production of moly-99. And
28 to ensure that there is no single point of failure, I've

1 developed our cooperative agreements to support each one of
2 these pathways towards production. First, there is the
3 traditional fission based methodology showing in the top
4 chart. In the middle is neutron capture, which is
5 historically how moly-99 was made in the industry when this
6 first started 30, or so, years ago. And then the last one,
7 the bottom, is an accelerator-based production which has
8 received attention also for the production of moly-99. Each
9 of them have their benefits, and each of them have their
10 impediments towards production.
11 The four cooperative agreements that we have with
12 domestic partners in the United States are shown on this
13 slide. In no particular order, first and foremost, is the
14 NorthStar Medical Radioisotopes Program, which we have
15 awarded a total of $25 million to NorthStar Medical
16 Radioisotopes to pursue the accelerator-based technology.
17 Before I go further, I should point out that each of these
18 cooperative agreements are limited to a $25 million cost
19 share arrangement and a 50/50 percentage basis with the U.S.
20 government.
21 Second, is the Morgridge Institute for Research,
22 also known as SHINE Medical Technologies, or associated with
23 SHINE Medical Technologies. We've thus far awarded a total
24 $10.7 million to Morgridge to pursue their accelerator based
25 LEU fission technology.
26 Third, is Babcock and Wilcox, which we've awarded
27 thus far $9.1 million to pursue their LEU solution reactor
28 technology. Currently, they are looking for a commercial

1 partner to continue that process towards the implementation.
2 And last, is the General Electric Hitachi process.
3 We've awarded them $2.3 million to pursue their neutron
4 capture technology. However, what was a significant issue
5 to us is that on February 7th of 2012, they announced a
6 business decision to suspend progress on the project
7 indefinitely due to the market conditions. And this is
8 something that we identified for a long period of time of
9 how the industry operates and the imposition the current
10 market practices have on reliable, long-term projection.
11 It's one of the things we're working with the -- I
12 apologize, I'm staying on this slide. It's one of the
13 things we're working with the international community
14 through the Organization for Economic Cooperative
15 Development to, at a high level working group, to address
16 that situation both from an economic standpoint and a
17 technology standpoint to ensure the long-term, reliable
18 production, not just for patients here in the United States,
19 but globally, for patients that require this very important
20 medical radio isotope.
21 To further support the program, and going back, as
22 I've mentioned, several decades, is the significant amount
23 of U.S national laboratory technical support that has been
24 developed for the production of moly-99. And we make that
25 expertise from the national laboratories available to all of
26 the different moly-99 technical pathways. And we ensure
27 that this expertise at the national laboratories is
28 available for any commercial projects that are utilizing

1 non-HEU technologies, both domestically and internationally.
2 These work packages are funded by NNSA, our program, through
3 strong support from Congress for these technologies.
4 Recently, and in very close cooperation through
5 the entire U.S. interagency, the White House issued a
6 statement on encouraging reliable supplies of moly-99 are
7 produced without highly enriched uranium. And there were
8 several significant statements, one of which I think we're
9 going to spend a lot of time on in the next presentation by
10 Dr. Duvall. But first, we are calling upon the moly-99
11 industry to voluntarily establish unique product code or
12 identifying marker for moly-99 based radiopharmaceutical
13 products that are produced without the produced without the
14 use of HEU.
15 And it's as much a marker for LEU or non-HEU based
16 moly-99 as it is for what we refer to as full cost recovery
17 moly-99, which is something that we're working has helped
18 working to address the impact of subsidies on the industry.
19 And we're working to transition the entire industry towards
20 full cost recovery from the beginning of the supply chain to
21 the end.
22 As from your perspective, you're probably aware on
23 the downstream side of the supply chain, full cost
24 recovery's probably, you know, has to be the way that you
25 operate. Unfortunately, the early part of this supply chain
26 does not operate that way and that has significant impacts
27 on how the industry produces the isotope that you receive
28 for production and it's something that we need to address.

1 It's slowly being addressed throughout the industry. But the
2 rate of uptake is certainly not as rapid as we had hoped,
3 and it does have impacts for how we will achieve the 2006
4 scheme success of the program.
5 The second bullet is the U.S. government has
6 decided it is very important not just to ask others to do
7 things that we are not willing to do our self. So, we want
8 to lead by example. And so, we're working through the
9 interagency, and it will probably be through the Veterans
10 Administration. We'll start the process hopefully in the
11 next several months, and this is preferentially procuring
12 moly-99 based products that are produced without the use of
13 HEU whenever they are available, and this will be in a
14 manner that are consistent with our U.S. obligations under
15 international trade agreements. You can imagine that's
16 something that's very difficult to do, but at the same time,
17 it's work that we are undertaking to ensure that we lead by
18 example to help transition this industry for long-term,
19 reliable supply.
20 The third bullet is something that Dr. Duvall will
21 talk about, which is -- at the time the statement came out,
22 was worded as such, and it's that examining potential health
23 insurant payment options that might promote sustainable,
24 non-HEU supply to moly-99. And last is something that we
25 are going in close cooperation with the interagency, and in
26 particular with the NRC, and it's about how we can take
27 steps to further reduce exports of HEU that will be used for
28 medical isotope production when sufficient supplies of non-

1 HEU produced moly-99 are available to the global
2 marketplace. To provide further clarification on that, the
3 U.S. exports HEUs -- the international producers. We have
4 legislation in place that authorizes and directs us to do
5 such. However, there are significant limitations, and
6 obligations, and requirements on the export of that
7 material, and we work with the international commercial
8 community to ensure that all of their obligations and
9 requirements are met while we do provide for the regular
10 reliable supply of HEU while they are transitioning their
11 industry to LEU materials.
12 The last two bullets on the U.S. government Public
13 Statement -- I've already mentioned to some extent, is that
14 we are continuing to encourage domestic commercial entities
15 in their efforts to produce moly-99 without HEU during the
16 transition of the moly-99 industry. It's a full-cost
17 recovery, and some cases, if you're aware, right now the HFR
18 reactor, the second-largest producer in the Netherlands, has
19 experienced a prolonged outage, and it has significant
20 implications on the supply. We are monitoring that closely
21 and working throughout the entire interagency to determine
22 at what point in time we might need to take extraordinary
23 steps to support production to ensure that patients receive
24 medical isotope in timely and reliable fashion.
25 And lastly, we are working with the international
26 producers to assist their projects however they request
27 within certain conditions towards the conversion of moly-99
28 production facilities from HEU to LEU.

1 We were in meetings earlier this morning in some
2 part coordinating with our NRC colleagues here, and we're
3 going to be in a variety of meetings throughout the rest of
4 the week with other colleagues throughout the interagency to
5 understand how to implement the requirements therein
6 recently passed, American Medical Isotope Production Act of
7 2012. It was a very good New Year's for us; there's been a
8 number of parties that were involved in the passage of this
9 act. It goes back starting first as H.R. 3276 from
10 approximately three or four years ago if I remember
11 correctly, through Senate Bill 99. But recently
12 incorporated into the National Defense Authorization Act on
13 January 2nd, 2013 is the American Medical Isotope Production
14 Act. First and foremost, it requires the secretary of
15 Energy to establish a technology neutral program to provide
16 assistance for production of moly-99 in the United Sates
17 without HEU. We obviously knew this was happening; this was
18 developed in close concert with our existing program. So,
19 that box is already checked off, and we've made significant
20 progress in that direction over the past number of years,
21 but we now have a law that helps to authorize us to
22 implement this program.
23 It does require public participation in review of
24 the program. In some part, it will be through a large
25 topical meeting similar to what we just had a week ago --
26 two weeks ago in the Chicago area with many members of the
27 community and stakeholders. The Office of Science and
28 Technology Policy of the Executive Office of the White House

1 has significant involvement in the program. They're also
2 bringing together stakeholders on a quarterly basis -- or
3 roughly a quarterly basis to review the program. We're also
4 working with the National Science Advisory Committee through
5 the Department of Energy's Office of Science program to
6 review the program.
7 The third bullet is it requires the development
8 assistant for fuels, targets, and processes. Again, this is
9 a long-standing part of our program that we've been
10 implementing through the national labs.
11 Establishing a Uranium Lease and Take-back
12 program: This is probably the newest part of the program, is
13 similar to what we've implemented in terms of disposition of
14 research reactor fuels, both U.S. and international origin,
15 but this bullet is for domestic utilization only, and it
16 enables the department to provide uranium, for production
17 of, and if a commercial disposition pathway does not exist
18 for the material after production, the U.S. government will
19 provide adequate cost recovery disposition pathways for that
20 material after production of the medical isotope. It does
21 require the Department of Energy and NRC to coordinate our
22 NEPA, our environmental reviews where practicable, and that
23 is something that, if you're familiar with government
24 process and procedure, can be difficult and onerous, but it
25 is part of the process that we go through, and we're closely
26 coordinating and have also been coordinating with our NRC
27 colleagues to implement these requirements.
28 To support the program -- does provide a cutoff in

1 exports of HEU for isotope production in seven years with
2 the possibility for extension in the event of a short
3 supply. And this is something I have to say: I think with
4 close coordination of the interagency, everyone recognizes
5 the importance of supply, and there are no actions that we
6 are taking in any of these activities that will actually
7 impinge upon the ability of the industry to provide isotope.
8 We understand first and foremost is the supply of isotope to
9 the patients, and then we will achieve our threat-reduction
10 objectives. We are very optimistic with the pledges we have
11 from the international partners, and the commitment from
12 Canada -- or the statements from Canada that they'll cease
13 isotope production in 2016, that we will achieve the
14 minimization of HEU in this industry within the next several
15 years. It's simply a direction that we have to go in, and I
16 think everyone in the industry recognizes that the more
17 important issue is the transition of the industry to full-
18 cost recovery so that it operates as a true commercial
19 industry rather than with government subsidies at the
20 initial parts of the supply chain, which have actually
21 impinged upon the ability of the industry to provide
22 maintenance and replacement capacity for production.
23 And last and not least on that is it does require
24 reports to be submitted to Congress on an annual basis,
25 which -- very honestly, those are very complicated and
26 require a lot of interagency coordination with all of these
27 activities taking place, and literally as soon as we
28 complete one report to Congress, we start the annual process

1 to submit the next one; we're on an annual basis.
2 Here are some documents that were used in the
3 presentation, and I hope that I did not go too fast, but I
4 think I got back about five minutes on your schedule, and I
5 believe the process is that we are very happy to take any
6 questions. Also, at this point in time, I would like to
7 introduce my colleague Rilla Hamilton. She actually is the
8 project manager for the moly-99 program. And for domestic
9 activities, Joanie Dix, who was not able to attend with us
10 today. She is providing her civil service by attending jury
11 duty. Thank you very much for your attention.
12 CHAIRMAN MALMUD: Thank you, Dr. Staples. Did you
13 wish to make any comments [unintelligible]?
14 MS. HAMILTON: Oh, actually I'll defer to Dr.
15 Staples, so -- I have nothing further.
16 CHAIRMAN MALMUD: Thank you. So if I may
17 summarize Dr. Staples on -- a very complete presentation on
18 your part. Number one: The Department of Energy recognizes
19 the importance of molybdenum-99 to the medical community and
20 to the patients whom we serve. Number two: The program is
21 looking forward to converting the source of molybdenum-99
22 from highly-enriched uranium to low-enriched uranium for
23 reasons of homeland security. Number three: that there will
24 be costs associated with this transition, and the Department
25 of Energy is aware of them. Number four: that there's
26 encouragement to put this in the hands of private industry
27 without government participating, other than in regulation
28 of issues with safety. Number five: this is an

1 international effort, and that the government is
2 coordinating that. Number six: that if the timeline cannot
3 be met, that there will be flexibility with regard to
4 continuing recurrent sources molybdenum-99 so that the
5 medical practices will not be interfered with. Does that
6 summarize it?
7 DR. STAPLES: That's an excellent summary, and I
8 don't think I could state that better myself.
9 CHAIRMAN MALMUD: Well, you did state it better.
10 [laughter]
11 You stated it much more completely, but I was just
12 trying to summarize it. Well, thank you very much. Thank
13 you, both. Are there questions now? Yes, Dr. Van Decker?
14 MEMBER VAN DECKER: A couple of questions if I
15 might, just I've heard it from different sources. From your
16 perspective right now in the current timeline, what
17 percentage of moly's being produced from LEU?
18 DR. STAPLES: It's a difficult number because it's
19 somewhat variable, but I would assume it's roughly and
20 probably about the 10 to 15 percent range.
21 MEMBER VAN DECKER: Okay, so we have a significant
22 way to go?
23 DR. STAPLES: A significant way to go.
24 MEMBER VAN DECKER: Second question is if we need
25 to fill a hole by 2016, and there needs to be a lead time
26 for a manufacturing process to be in place and get all of
27 the regulatory blessings, what do you think that lead time
28 is to have a source ready to go in 2016?

1 DR. STAPLES: That lead-time is consistent with
2 the stage of our current production projects, to some
3 extent. There are some projects that are obviously ahead in
4 the race versus others, and there are also projects that are
5 not associated with our funding that are also making
6 significant progress where we have much less insight because
7 of our lack of contractual insight and association with
8 those programs. But at our recent moly-99 topical meeting
9 we held in Chicago two weeks ago, we got some indicators of
10 progress being made by both those entities that are
11 associated with our programs, those that are not associated
12 with our programs domestically, and also the status of
13 international production. I don't want to be overly
14 optimistic about the status, but at the same time I think we
15 can be realistic that, given the current rate of progress,
16 and if we maintain the intention and focus of the entire
17 interagency from the regulatory and approval standpoint, we
18 should have regular, reliable supplies of moly-99 in the
19 2016 timeframe to replace those that we will lose when the
20 Canadian reactor ceases production.
21 MS. HAMILTON: And to add that a little bit, if I
22 may. Each of the technical pathways has been selected
23 because of that lead-time consideration. Some of them don't
24 require as much as others, and that's why we have
25 diversified the types of technologies that we're supporting
26 to consider how much lead-time that takes.
27 CHAIRMAN MALMUD: Dr. Van Decker?
28 MEMBER VAN DECKER: So the follow up to that would

1 be diversification and a race to good, solid technology is
2 always a good thing, and as you pointed out, industry
3 feeling that there's a government partner in this aiding to
4 them still being in this race is an important piece of
5 keeping things going, and there is a timeline. And so, will
6 there come a point in time, will you help create a winner
7 and a loser? I mean, if one is clearly ahead on a funding
8 basis, will you shift priorities to create patient access,
9 as opposed to -- what did you call it? The marketplace
10 model, or something like that?
11 DR. STAPLES: Just in terms of full cost recovery
12 continuing to operate. Obviously, if we have to take
13 extraordinary actions because the current industry collapses
14 prior to 2016, it won't necessarily be picking a winner and
15 a loser. It will be developing a reliable supply in the
16 near term. Regardless, our long-term intention is to ensure
17 the transition of this industry to full commercial
18 activities that's operated under full cost recovery
19 principles in accordance to international trade obligations.
20 It's why we work closely with the OECD to implement this.
21 The amount of funding that were currently providing is not
22 considered a subsidy by the OECD. We've had careful
23 discussions about the amount, the type, the duration, the
24 quantity of funding that's provided; but at the same time,
25 we do realize a significant government intervention is
26 required at this stage of the industry to ensure the
27 transition in the next two to three year time period.
28 MEMBER VAN DECKER: Thank you.

1 CHAIRMAN MALMUD: Thank you, Dr. Staples. Any
2 other comments? Dr. Zanzonico?
3 MEMBER ZANZONICO: Question, from a preventative
4 point of view, it looks like lead technology is the
5 accelerator producers, based on the dollars awarded to the
6 respected companies. So, it's frightening then that it's no
7 longer a byproduct issue, what's become accelerator
8 produced. So, who's the -- who has the regulatory
9 responsibility for overseeing that? Is it still NRC?
10 DR. STAPLES: I believe that the -- for NorthStar
11 is the project that you're referring to, their regulatory
12 requirements are handled because they're an agreement
13 stakeholder, of how it works through the regulatory process
14 from a nuclear aspect.
15 MEMBER ZANZONICO: So, it would still -- but it
16 would still be regulated essentially as byproduct material?
17 In most cases, the agreement states that are overseeing it,
18 who are not NRC states.
19 MS. HAMILTON: There are some NRC actions that are
20 involved in the NorthStar project as well, that from the
21 operation standpoint, that's all handled through the state
22 regulator.
23 CHAIRMAN MALMUD: Dr. Howe?
24 DR. HOWE: If I could clarify. As long as the
25 producer is using an accelerator and not using uranium as a
26 target, that would be regulated by whatever state they are
27 located in. If they are using an accelerator, but uranium
28 is the target material, then that would bring it under NRC

1 jurisdiction, because it would be a -- we're looking at it
2 as a Part 50 production facility. And so, that would be
3 NRC, regardless of what state it's located in.
4 MEMBER ZANZONICO: Right, so -- but even if it
5 were a non-agreement state, if it were not using uranium, it
6 would be under state regulation, not NRC?
7 DR. HOWE: Okay, a non-agreement state is a state
8 NRC regulates.
9 MEMBER ZANZONICO: Right, correct.
10 DR. HOWE: Okay, so if it's in a state that NRC
11 regulates and it is accelerator produced, we would regulate
12 the production of that isotope under the Energy Policy Act,
13 because we now regulate byproduct material which can be
14 produced by either reactors or by accelerators. But we
15 would not regulate the accelerator. Once the material is
16 made, we would regulate, but we would not register or
17 regulate the accelerator.
18 MEMBER BAILEY: And if I may add, the states do
19 register the accelerators -- the machine-produced.
20 CHAIRMAN MALMUD: Other questions? Dr. Palestro?
21 MEMBER PALESTRO: Yeah, Chris Palestro. I have a
22 question. You may have already partially answered it, but
23 GE has dropped out, and my sense is, from what you've said,
24 is only due to the -- it really didn't make a lot of
25 financial sense for them to continue. Is that something
26 unique, say, to GE because of its massive size and this
27 comprises such a very small component of GE health care? Or
28 is it possible that other companies, corporations also will

1 look at this as being not finically viable and drop out as
2 well?
3 DR. STAPLES: Well, that's actually -- that's a
4 very good question. They each have their own different
5 perspectives on how they develop their business model, and
6 part of the evaluation we go through when we develop the
7 agreements is we evaluate what their business models are.
8 But it's their own independent evaluation for the risks
9 versus the benefits that they want to assume of how the
10 market will transition. What I would simply take is that
11 they looked at the current market conditions and realized
12 that, if they remained as they were, that it would not be
13 economically viable. We have expectations that the market
14 conditions will change in the future based upon the
15 transition of full cost recovery. I do want to also ease
16 any concerns when we're talking about transition to full
17 cost recovery and the actual costs that are associated with
18 it.
19 At the consumer side, we're estimating the cost is
20 going to be less than a 1 percent change at the patient
21 level. However, as you go through -- you know, back through
22 the supply chain, you know, similar to the, you know -- the
23 farmer can experience a doubling in costs for producing his
24 material, but when it ultimately ends up at the store
25 shelves, it's a fractional change of the final cost, because
26 much of the costs were associated in the distribution and
27 the transportation, or the finishing of the product, which
28 that won't change as we address the full cost recovery

issue. So, I don't want to, you know -- I don't want to cause any undue alarm that the costs are going to significantly change, if we fix the downstream side. That's the one caution -- or response I hopefully provided some clarification on with that answer.

CHAIRMAN MALMUD: Other comments or questions? Dr. Welsh, and then --

MEMBER WELSH: Yes, thank you. I'd like some clarification on one of the slides -- or two of the slides that you presented regarding the U.S. domestic cooperative agreement partnership, and the slide afterwards, which was the National Laboratory Support. My understanding is that those are independent of each other. Is that correct?

DR. STAPLES: Correct, yes.

MEMBER WELSH: Thank you, and the associated question is regarding that second slide; the statement that all work pack -- at the bottom -- all work packages funded are open source, prior caring, non-critical path activities. I didn't fully comprehend what you said. What does that mean?

MS. HAMILTON: To clarify, all of the work packages that NNSA funds the National Laboratories to do are for the greater common good, if you can conceptualize it as what we're intending to do. We're supporting the development of technologies, and those technologies that we're supporting with the commercial cooperative agreement partners, a lot of that work is on those particular technologies. However, the NNSA direct-funded work packages

are also something that can be open source and shared to any commercial entity that wishes to develop these types of technologies. We don't get into that proprietary space for that particular purpose. We also don't do anything that's on the critical path of our cooperative agreement partners because we want these projects to be fully commercially viable.

We don't want to be any reason for any kind of a stall on their project, or any technical reason, or any financial reason. If our budget does not allow for continued progress on critical path activities, that's a risk, and we want these cooperative agreement partners to be fully viable. So, for those reasons that's why we put this on the slide: to invite others that are interested in understanding what the National Labs are doing in this technology development to ask. We are happy to share who is working on these and what they're doing in case there are any other entities out there that are looking to develop these technologies:

CHAIRMAN MALMUD: Thank you. Mr. Mattmuller

MEMBER MATTMULLER: Hi, Steve Mattmuller. A couple questions. The first one, in regards to the NorthStar project, it's my understanding that their production facility is under construction in Wisconsin, that the meeting -- no, not yet -- or can you comment on that? Or maybe I should be asking NorthStar how far along they are with that.

MS. HAMILTON: Yeah, NorthStar is the best one to

1 ask about that, but their site has been announced in Beloit,
2 Wisconsin, and the groundbreaking has not officially taken
3 place yet, if that's what you're asking.
4 MEMBER MATTMULLER: Sure, yes, okay. And then, my
5 other comment -- questions would be in regards to cost, and
6 I agree with your farmer analogy as far as initial cost
7 versus downstream cost, and also looking at the next talk
8 and how CMS intends to help with all of this, and I would
9 agree with all that if right now everything was non-HEU
10 moly. But during this transition phase it's going to be
11 difficult and complicated, and there's not going to be that
12 quick, easy transition -- or, not transition, but efficiency
13 in keeping despite the higher cost here from non-HEU having
14 minimal -- minimizing the cost increase to the patient.
15 So, looking at all of your activities on your
16 website, and looking at your success stories with the Czech
17 Republic, and even locally with the blood irradiator of
18 [unintelligible] in Philadelphia, you're paying for those
19 activities. Why not pay for the additional costs of the
20 non-HEU moly that goes to two generator manufacturers here
21 in the U.S., and then -- I mean, because you deal with the
22 audit that easily to see what the difference is, and then,
23 you know, wean the, you know, the industry off of that
24 subsidy over time, but during this transition phase.
25 DR. STAPLES: I think actually you touch on -- a
26 very common topic of conversation we have is about the
27 difficulty during the transition phase, and then the non-
28 equity among the different players in the market, and I

1 think that's actually a very good lead-in for what Dr.
2 Duvall's going to talk about next, of how, again, as the
3 U.S. government is trying to lead by example of providing
4 this additional payment available to the industry. I don't
5 want to speak too much for Dr. Duvall, but, you know, we can
6 only work with the CMS process. We're hoping that private
7 insurers will follow that lead. That's what we understand
8 that they will do. We also realize, as we gather financial
9 data on an annual basis that the reimbursement process will
10 be adjusted. There is some lag time, we recognize that, but
11 as also how we expect the system -- the reimbursement system
12 will catch up with the costs. Honestly, where we see the
13 larger cost differentials are associated, as you can
14 imagine, when there are shortages.
15 Any cost that we've projected is going to be
16 associated with either the conversion cost or full cost
17 recovery is swamped by the cost differentials that take
18 place when there are shortages and the charges that are
19 applied when there's lack of material or not. It goes all
20 over the map, as you can imagine. So, we realize there is a
21 certain amount of flexibility within the system, but we also
22 do recognize very much the position that we're in to not
23 just impose traditional costs on patients when these type of
24 things are always, you know, scrutinized heavily. But we
25 are trying also to educate the entire community about the
26 two benefits that are being provided by this transition.
27 One is taking dangerous materials that could be within reach
28 of terrorists out of their reach, and two is really

1 transitioning this industry for reliable supply. What gave
2 this program a tremendous amount of momentum, in some part,
3 was the, you know, September 11th, which is what caused the
4 formation of GTRI and other activities, you know, from a
5 threat reduction perspective. But what really gave them
6 momentum was the kind of concurrent outages of the HFR and
7 the Canadian reactor about three years ago. That's when we
8 really got momentum to start to implement this program, and
9 we realized the impact that the subsidies had on the ability
10 of the industry to reinvest, and it is not operating as a
11 true commercial industry. And that is also why we have, you
12 know, limited support over a period of time to help
13 transition the industry. We also take very seriously the
14 cautions from the OECD about the amount of subsidies that we
15 are providing -- or if I want to say it carefully, about the
16 amount of support that we are providing, that it's not
17 actually subsidies. We don't want to propagate the problem.
18 You know, we don't want to transition this to the next
19 generation. We want to try to fix it and step out of it
20 such that this industry can operate as other parts of any
21 industry do; you know, minimal government intervention. But
22 unfortunately, were not there yet, and it's not anything
23 that was set up maliciously by any one government. It's
24 just the way the industry evolved, and it's the way it's
25 produced. So, we recognize that, and we're simply trying to
26 undo what was not a good situation for the medical
27 community.
28 CHAIRMAN MALMUD: Thank you, Dr. Staples. Your

1 statement in response to Mr. Mattmuller's question serves as
2 a perfect segue to our next speaker who will be Dr. Duvall.
3 I thank both of you, and Ms. Hamilton, for your
4 participation today with us, and I will introduce Dr.
5 Duvall, who will discuss the federal government Center for
6 Medicare and Medicaid services, and the 2013 reimbursement
7 policy for non-HEU produced medical isotopes.
8 DR. DUVALL: Thank you very much. I am actually
9 really thrilled to see the PhD after my name, but I have to
10 confess that I don't own one. I'm just a medical doctor,
11 but I'm going to keep this and look at it periodically and
12 think of what I could be.
13 [laughter]
14 Okay, I'm Dan Duvall. I'm one of the medical
15 officers in the CMS Hospital and Ambulatory Policy Group,
16 and our job is actually to look at payment policy for a
17 large part of the really half a trillion dollars that CMS is
18 paying out. I guess our area -- my area only deals with
19 about a quarter of a trillion dollars. So, it's maybe not
20 quite as big, but we do deal with quite a good bit. And I'm
21 going to talk a little bit about our reimbursement policy as
22 far as technetium-99m goes. The -- as Parrish mentioned,
23 the United States is part of the high-level group from the
24 Organization of Economic Cooperation Development. That's
25 the international group that's been trying to coordinate an
26 international response to creating a stable supply. They
27 have a number of principles -- six principles, and three of
28 those were particularly applicable to CMS. Those were

1 promoting full cost recovery, encouraging a marketplace that
2 would be amenable to a stable supply to moly-99, and
3 promoting this conversion to non-HEU sources. Specifically,
4 the U.S. made a commitment to examine health insurance
5 payment options, and that's where CMS came in.
6 So, the U.S. goal is a stable supply of moly-99
7 based on non-HEU sources, and one of the main functions, or
8 one of the main components of that is this marketplace
9 protection. We don't, in the U.S., intervene in the market
10 as much as other countries -- you know, some other countries
11 do. We tend to take a very hands-off approach, and health
12 care is no different than any other aspect of the market.
13 So, from CMS's standpoint, we looked at it more as
14 encouraging the market.
15 Specifically, with CMS we have something called
16 the Triple Aim that is trying to promote an improvement of
17 health care population in the United States, improve the
18 health of the individual, and do this at an affordable cost.
19 So, we have these three things that we have to consider.
20 Specifically in respect to moly-99, two of those come in to
21 place. On the one hand, you need to encourage the market to
22 make sure that we have the tests available for patients as
23 they need them, but on the other hand we need to promote
24 efficiency, and efficiency from our standpoint means
25 providing services at the lowest cost. That means that, in
26 this particular environment we're creating kind of a balance
27 of making sure that enough money is flowing from CMS into
28 this particular segment of the health care environment that

1 the industry will be able to stay healthy. On the other
2 hand, we don't want to drop any penny that we don't
3 absolutely have to. And we do support presidential
4 initiatives; the Global Threat Reduction Initiative is one
5 of them. But have to note that things like this are only to
6 the extent allowed by law, and that comes into play as I
7 start to discuss a little bit of our constraints.
8 First off, there's a lot of discussion about a CMS
9 incentive, and so it's very important to bring up over and
10 over the difference between a reimbursement and an
11 incentive. I would look at an incentive as some sort of
12 bonus to create a new behavior; reimbursement on the other
13 hand is compensation for existing behavior. Because
14 anything that we do must be consistent with our statutory
15 authority, we can get into reimbursement. We don't have any
16 statutory authority for incentives. So, if there's any
17 incentive in our payments, it's an incidental benefit. The
18 other things is, and this gets into a comment that was made
19 in a question to Parrish, is that we can only pay the kind
20 of the end users of the health care delivery system. So, we
21 can pay hospitals; we can pay physicians; we can't pay
22 pharmacies, at least other than Part D, which is a little
23 different entity; we certainly can't pay manufacturers,
24 processors, and reactors.
25 And then the last thing is that CMS is a large
26 payer. We are the largest payer and the largest user in
27 terms of the dollars that are coming out from moly-99
28 towards health care uses -- or actually, I guess towards all

1 its uses. On the other hand, our market share is still on
2 the order of 20 percent or so. Depending upon how you
3 calculate it, it's some fairly wide ranges, but we're not
4 talking about a majority of the market; we're talking about
5 being a large player in a very diversified market.
6 In terms of economic constraints in addition to
7 our statutory constraints, in looking at payment options, we
8 also considered a number of things. One important point was
9 that full cost recovery is something that is not easily
10 audited and not easily tracked; in fact, it's also very
11 difficult to define. If you have a company that has fully
12 amortized a capital expense -- its reactor. We're now past,
13 let's say, the 40 years that they paid for the reactor. Are
14 the additional costs of that capital expense something that
15 needs to be in its pricing? Various arguments of full cost
16 recovery would say no, but yet that creates a disparity in
17 the market of the sorts that exist right now. So, what is
18 full cost recovery? How can audit it? How can you track
19 it? That was something that we really could not find the
20 solution for, and we had to deal with that in a different
21 way that I'll discuss.
22 Another thing is that one of the proposals that's
23 been made over and over to us has been that we could solve
24 this problem -- create additional stability by unbundling
25 the radiopharmaceutical. Now, in terms of cost, it's
26 important to know that the cost of the isotope in terms of
27 the final test per person is on the order of $10. Is it $2?
28 Is it $20? Again, it depends upon your accounting

1 principles, but it's on the order of $10. The cost of the
2 radiopharmaceutical varies considerably depending upon the
3 pharmaceutical-specific drug that's being attached to the
4 radioisotope, but it's on the order of $50. Again, $30,
5 $130, wide variation, but on the order of $50. The cost of
6 the overall test: on the order of $500. So, we're looking
7 at something that, for the isotope, a very small part of
8 this very large expense for the test. Now, even unbundling
9 that relatively -- or approximately $50 radiopharmaceutical
10 doesn't really create a factor that can differentiate
11 between non-HEU or HU moly, or full cost recovery/non-full
12 cost recovery moly. In fact, even unbundling the
13 radioisotope itself doesn't. If we paid for the average
14 cost of the radioisotope separately, it would still be
15 cheaper for someone that was not using full cost recovery;
16 they could underbid someone else, and if there's additional
17 costs -- and there are additional costs of using non-HEU
18 sources, that would be a competitive disadvantage for those
19 producers.
20 So, these unbundling proposals don't really get to
21 the root of the problem. The other thing from our
22 standpoint is that unbundling is not really consistent with
23 our general reimbursement models. Our approach is that --
24 really going back to the DRGs, or Diagnostic Related Groups
25 of the 19 -- introduced in the 1980s is that if we pay large
26 bundles, large packages to care of someone who's had a heart
27 attack, then the individual hospitals and physicians can
28 make choices about what they want to include, what they want

1 to provide, and that's where the efficiencies come in the
2 health care system, as opposed to the government saying,
3 "Thou shalt provide this, and we will pay that."
4 So, the solution -- the approach that we took was
5 a couple of things. First off, we determined that we would
6 link this non-HEU conversion to full cost recovery at the
7 consumer level, the way that we're looking at our payments.
8 And part of the reason for that is that there's a very
9 strong correlation between full cost recovery and non-HEU
10 sources. The non-HEU production facilities are newer, and
11 generally being implemented without the support of the
12 government; certainly without the legacy reactor instead of
13 already -- are kind of into their twilight periods where
14 capital cost has been accounted for. Second is that: non-
15 HEU sourcing is something that is much more easily tracked,
16 thanks to the Food and Drug Administration, which keeps
17 really detailed records on everything that goes into the
18 drugs that you put in your body, and really anything else
19 that we use in the health care world for patient purposes.
20 There is a record that says, "This particular dose came from
21 this source, and that was a non-HEU source." And then the
22 last thing is that because of both of those and one other
23 factor, that's non-HEU sourcing creates an artificial
24 benefit that we can use as a proxy. If you -- I talk about
25 it sort of like dolphin-free tuna. It's something that you
26 can -- in talking to hospitals, and in talking to
27 physicians, and in talking to patients, you can say that
28 this is safer source of your medical test. This has

1 implications for the safety of the world, which is not
2 something you can do at full cost recovery. That's --
3 patients really have no interest in that kind of discussion.
4 So, by packaging these two things together -- linking these
5 two things together, we felt that we could have a benefit
6 when we were creating our payment options. So, this is now
7 a defined and visible payment differential, and we can
8 reimburse hospitals for that differential. The weakness is
9 that we pay hospitals, as I mentioned before. Only the
10 industry can take that payment differential and move it back
11 through the supply chain to the reactors and the processors
12 where the real cost differential occurs. So, our intent
13 with our payment option was to create a payment to cover the
14 increase cost -- so, increased cost holding, not incentive -
15 - of the Medicare portion of full cost recovery non-HEU
16 sources. We can't pay for non-Medicare patients.
17 In addition to paying for this increased cost, we
18 wanted to create a signal, and I think that in many ways
19 that's the most important factor, is sending a clear signal
20 that Medicare backs a sustainable pricing model. That is,
21 our belief that increases in cost due to either movement to
22 full cost recovery or movement to non-HEU sources is
23 something that can be easily absorbed by the industry, and
24 will not, from the end-user perspective, create
25 significantly higher costs that would cause problems with
26 the health care industry. We also wanted to make sure that
27 we minimized the hospital administrative burden. We're
28 talking about a benefit that's going back up the supply

1 chain to producers and processors, not to hospitals. On the
2 other hand, our payments go to the hospitals, so we wanted
3 something that would not create a significant amount of
4 effort for the hospitals.
5 And then the last thing was that: we realize that
6 during the transition process, there are going to be a
7 number of administrative issues that won't be in place once
8 this transition is continued -- is complete. Looking at
9 this transition as happening over a four- or five-year
10 period, it was our expectation that there may some
11 administrative costs of, for example, keeping track of non-
12 HEU doses versus your HEU doses. We did not feel that that
13 was something that needed to be built into our model,
14 because we were targeting the model towards the difference
15 in total cost to the end user of the conversion, not of the
16 process that converted them. So, in explaining the amounts
17 that we came up with, we were not looking at pharmacy costs
18 for paying one source versus the other, keeping their doses
19 separate, or anything like that. We're only saying, "What's
20 the additional cost of the non-HEU sourcing at full cost
21 recovery?"
22 The payment that we introduced -- we used HCPCS
23 [spelled phonetically] to -- which is a kind of coding that
24 hospitals use to report procedures and pay on the basis of
25 those. So, we created a code effective 1/1/2013, this Q9969
26 code, and this is a payment -- allows a payment of $10 per
27 dose for any dose -- for any diagnostic test using
28 technetium-99 that was produced from a non-HEU source using

1 full cost recover principles. So, again, we're trying to
2 package this together.
3 As a practical matter, this is an outpatient
4 payment. The inpatient system that has huge diagnostic
5 related groups, or a single payment for your entire hospital
6 stay, really isn't conducive to a $10 payment addition. If
7 you've got a $9,000 payment, $10 one way of another doesn't
8 make a whole lot of difference. Additionally, the legal
9 authority for this payment has to do with the difference
10 between the costs to one hospital versus the costs to
11 another hospital. So, we did not have legal authority to
12 extend that -- this particular payment to a physician
13 office. That limits the environment.
14 And so, as I've said, we really are paying for
15 some increased costs, but in a much larger fashion, this is
16 a signal to the industry more than it is real dollars
17 flowing into the pipeline, because we only control one small
18 part of the pipeline. On the other hand, where CMS goes a
19 lot of the health care industry follows. We create a code;
20 other people use the codes. So, it is not -- would not be
21 unexpected to find that many, if not most, Medicaid programs
22 would follow the Medicare lead. Commercial programs are
23 perhaps slightly less likely, but having previously worked
24 for a large commercial insurer, I know that we, in general,
25 tend to import payments and make payments. It depends upon
26 the individual contracts with hospitals, but there should
27 still be a significant trickledown effect among private
28 insurers.

1 The impact of the individual payment. Looking at
2 the added cost of a conversion as being something on the
3 order of $3 or so up to a high end of about $10, we felt
4 reasonably confident that this $10 per dose payment was
5 covering the added cost of full cost recovery -- of
6 additional conversion of full cost recovery, and of
7 conversion to non-HEU sources.
8 Looked at another way, if you multiply this by the
9 number of doses that can come out of a generator, and you
10 looked at expected increases based on some generators that
11 are already out there, of generator cost, this type of level
12 of payment would allow radio pharmacy to absorb a doubling
13 of the generator costs. Now, that's assuming that the
14 payment was made for all doses in the generator, which is
15 not the case. But one way or another -- again, this is a
16 signal that, at least from Medicare standpoint, we believe
17 that the health care industry can absorb whatever cost
18 increases are necessary. And the final point is, again,
19 this is targeted at reimbursing real costs; not at creating
20 an incentive to induce people to create a conversion. Our
21 feeling is that this conversion is going to happen. We want
22 to make sure that we can remove roadblocks to that
23 conversion. In creating this payment we did a fairly
24 comprehensive analysis of the industry, of the models, of
25 the supply chain, and we based a lot of this on both prior
26 National Academy study and then a more recent OECD analysis.
27 The OECD analysis was very detailed; carried out
28 over a couple of years. There are actually a number of

1 different components to it. And a lot of what we did was
2 apply that analysis to the United States, and determined
3 that really, we have not found any particular reason to feel
4 that the United States is any -- in any way unique relative
5 to the rest of the world; that it is basically a world
6 market, and that the information that was provided to the
7 OECD and went into their models really is equally applicable
8 to the United States.
9 Another thing that we came up with is in looking
10 at the model of both past payments and past production, and
11 future payments and production is that unfortunately, a
12 competitive advantage for subsidized production, whether
13 we're talking about HEU or non-HEU production, is going to
14 continue in the supply chain in the future. Putting more
15 money in at the end of the chain doesn't address that --
16 those potential inequalities at the beginning of the chain.
17 We think that there will be modest increases in payments
18 that will cover the costs. Again, significant increases in
19 cost at the reactor and the processor translate to very
20 small increases in cost -- percentage increases in cost at
21 the user end.
22 So, we see no problem with the payments increasing
23 as costs increase, but there's no guarantee, and in fact
24 little economic pressure, to ensure that those increased
25 payments are actually going to translate back to the
26 producers and the processors. And that leads to the
27 conclusion that the payment initiatives, whether it's ours
28 or any payment initiatives, really cannot promote full cost

1 recovery. We can promote an industry-wide movement to full
2 cost recovery, but we actually can't do anything other than
3 really make sure that there's money at that -- the table at
4 the end of the line.
5 Since there's no difference in benefit between
6 full cost recovery doses to a patient, it doesn't matter
7 where the moly-99 or where the technetium came from. It's
8 really -- market reforms that are going to promote a stable
9 environment for production are going to depend on equalizing
10 user costs. So, we're talking about taxes, subsidies, or
11 some sorts of passthrough payments that we don't haven
12 statutory authority to do. And that's because of the cost
13 differentials at the reactor level, and so any payment
14 differentials have to be passed up to the reactor. But that
15 can't happen, because in the middle of the supply chain is
16 this generator, and the generator is a step where one
17 generator creates many, many doses, and there is not a one-
18 to-one or one-to-x relationship. So, there's a break in the
19 relationship between cost and dose, and cost and supply of
20 moly-99.
21 What that means is that: a payment differential --
22 and our payment differential in specific -- can provide a
23 tool, but it doesn't really directly use the tool. Any
24 benefit for a stable supply really depends on the way the
25 tool is used. And again, there's the acronym [inaudible],
26 and at this point, if there's any questions, anything that I
27 could clarify further, I would be happy to answer them.
28 CHAIRMAN MALMUD: Thank you, Dr. Duvall. Are

1 there questions for Dr. Duvall? Dr. Van Decker?
2 MEMBER VAN DECKER: Thank you, Sir. I have a
3 handful of questions, if I might. First of all, Dr. Malmud
4 is always the greatest summarizer of someone's presentation,
5 but I would look at this presentation as, I am a reluctant
6 participant in this process, because I'm not sure how far
7 what I'm doing gets back to the initial part, but I'm
8 willing to try to be helpful.
9 DR. DUVALL: I wouldn't say reluctant. I would
10 say our eyes are wide open; that we can't control how far it
11 goes back. We'll put the money on the table or, as I was
12 telling Orhan a few minutes ago, we can put the food down on
13 the table. Whether people eat and who eats, we can't
14 control that.
15 MEMBER VAN DECKER: Okay, so a couple of comments,
16 if I might. You now have one quarter's worth of high
17 computer data on this queue code. Can you give us some
18 sense for what percentage of times it's being hit so far?
19 Are there pockets that are hitting it? Are the pockets
20 related to their access to LEU? How do you see that playing
21 out in its early stages so far, just epidemiologically?
22 DR. DUVALL: Our data at best lags by about a
23 month. So, the most that I could see would be January and
24 February data. I haven't actually looked, because we're
25 actually looking at some different sets of data right now
26 for other purposes. Our expectation was, and from what I've
27 heard in talking to people, is that they're -- the code is
28 being used some; very little, and that was actually

1 according to our model. Because we're introducing
2 additional costs a year at a time and then balancing in
3 future years, if we had expected a very rapid adoption of
4 this side and a, you know -- a -- let's say a 25/50 percent
5 utilization, I would have head some really heavy-duty
6 explaining to do OMB, and this wouldn't have happened.
7 So, keeping in mind that, as Parrish, maybe 10
8 percent of the supply is eligible for this payment, you then
9 cut that down to, say, half to look at what's being provided
10 in a pure form as opposed to being blended, because we had
11 to look at a payment differential for hospitals, and paying
12 for blending really wouldn't work. We're now down to two or
13 three percent, and adoption is probably on the order of 10
14 percent of that. So, we're talking a few handfuls of doses,
15 but they are out there, and as near as we can tell,
16 scattered around.
17 MEMBER VAN DECKER: Okay, so we know the
18 commercial industry hasn't picked up the queue code at all.
19 So, what's your sense for Medicaid as a partial partner of
20 yours at the state level for picking it up right now?
21 DR. DUVALL: The -- there's a difference between
22 adoption of the code as a payment mechanism and utilization
23 of the code to actually achieve payments. I actually don't
24 know -- I don't know whether any Medicaid plans have or have
25 not. It depends on the specific plans. One of the ones
26 that I was associated would have adopted it by now just as
27 an automatic one because it's out there.
28 MEMBER VAN DECKER: Okay, it's not like a CD

1 [unintelligible] answer. That's good; I like it. Code
2 difficulties, obviously. You know, you recognize that, you
3 know, your point of not paying for the administrative burden
4 of the transition point -- you know, $10 for somebody
5 changing a charge master in the hospital setting, actually
6 tracking all these codes, is not a small number. And so, I
7 would just put out on the table that, you know, as we look
8 what goes back the food chain, you know, the administrative
9 burden is, unfortunately, about a small percentage of this.
10 And hitting on two more, if I could: Number one, hitting on
11 the crux of this issue being a trust but verified kind of
12 guy, you know, in a complicated model of where things are
13 coming down where the generator obviously is the big catch
14 point, you know, how do you see we should look to be sure
15 that this current policy has actually had an effect? Once
16 you put a policy into effect with a trial to see if
17 something happens, how are you sure -- what parameters do
18 you use to see how it affected things?
19 DR. DUVALL: Which affect are you speaking of?
20 MEMBER VAN DECKER: For cost recovery, or shifting
21 of the LEU, I guess, towards full cost recovery.
22 DR. DUVALL: Okay, from our standpoint, remember
23 that our particular requirements -- authorization from
24 Congress doesn't allow us to promote full cost recovery.
25 That would be -- gets into that incentive world. So, from
26 our standpoint it is making sure that the reimbursement is
27 there. I think the way that we would measure that, and the
28 way that I expect that we will continue to measure because

1 we will be monitoring the utilization of the code over the
2 next five years, we're looking at it, again, as a five-year
3 time horizon. And what our expectation is, is that over the
4 course of the five years, we will see the utilization of the
5 code go from very small to very large, and essentially,
6 that's tracking industry conversion.
7 MEMBER VAN DECKER: And then my last question, if
8 I could. Now, obviously, from your seat it's pressure-
9 control -- pressure price controls, and bundling is a key
10 word in life. How do you see transition ending? You see
11 the queue code just being added in at its base cost to the
12 base reimbursement? You see a percentage of it being added
13 back in? You see a percentage of the utilization of the
14 code being added just to the total codes? How do you see
15 that playing out?
16 DR. DUVALL: From the way that the payment systems
17 work, if the industry decided today that it expected its
18 cost to increase by, say, $10 a dose in two years, and the
19 industry as a whole, you know, without collusion and
20 monopoly collusion and things like that, decided that it
21 wanted to proactively raise its prices by $10, those costs
22 would pass down, and we would pay them. So, what this is
23 actually doing is, assuming that costs are going to go up,
24 and, in a sense, prepaying costs -- we're saying that we
25 expect the industry cost to go up, so we're going to earmark
26 some money right here and put it on -- out in front. Now,
27 as the costs actually do go up, then within five years, the
28 full cost of conversion will be part of the system. At that

1 point, the queue code goes away.
2 MEMBER VAN DECKER: Right, but the statutory
3 requirement of HOPs is based on hospital claims data from
4 two years prior. If the percentage of the cost hit the
5 hospital level is only half a percent, or one percent,
6 because it's not at the farmer level, then the amount that
7 that cost had seen the claims data to recover back along the
8 line is going to be much harder to get to.
9 DR. DUVALL: The -- if it's -- if the cost is
10 being passed to the hospital even though it's only 1 percent
11 of the total hospital payment, that full 1 percent of --
12 that full 1 percent goes in. So, the entire cost is going
13 to be accounted for. Now, in terms of this --
14 MEMBER VAN DECKER: Saying that the hospital finds
15 it and does it appropriately, yes.
16 DR. DUVALL: Assume -- that's the whole supply
17 chain thing, and that's actually the market forces that
18 create problems for someone who has full cost recovery
19 compared to somebody who can offer a lower cost product
20 without full cost recovery.
21 MEMBER VAN DECKER: I thank you for your time,
22 sir, and I thank you for your patience.
23 CHAIRMAN MALMUD: Thank you, Dr. Duvall. Are
24 there any other questions? Now, thank you for the --
25 MEMBER WELSH: Yes.
26 CHAIRMAN MALMUD: Oh, excuse me. Dr. Welsh?
27 MEMBER WELSH: Thank you. At the risk of sounding
28 like a broken record, having said this many times at the

1 ACMUI and various other meetings, I do have a bias as a
2 radiation oncologist who appreciates the challenges that my
3 diagnostic brethren are experiencing with this moly-99
4 shortage. But as a radiation oncologist involved in
5 radiotherapy, I have a vision-based bias, number one,
6 because I don't want to see the isotopes that I need
7 disappear, and therefore, I'm an advocate of diversifying
8 technology. But my question might be, is this exclusively
9 for technetium-99m? I think from the discussions it sounds
10 like it is. And would it be possible for this concept that
11 you're developing to apply not just to the diagnostic
12 isotope, but to any isotope that is used for diagnostic or
13 therapeutic purposes that is produced without the use of HEU
14 when non-HEU alternatives may present themselves. So, I
15 suppose it's a question that is, can we use the idea for
16 therapeutic isotopes in addition to the moly-99 isotope?
17 DR. DUVALL: The answer is that it is possible.
18 It was extremely difficult to find authority to actually
19 create this payment in the first place. We had to base it
20 on the fact that some hospitals would have -- could have a
21 non-HEU source at higher cost than another hospital, but
22 have a different source, you know, through different
23 suppliers, and had HEU sources. We had an authority
24 equalize payments to hospitals. The biggest reason for
25 limiting it to Tc-99 was that this is a -- really, the
26 biggest elephant in the room. Expanding it further gets
27 into services that are used much less frequently, and as
28 you're aware of, the administrative difficulty for the

1 hospital, even with the frequency that this is used and even
2 at $10 dollar amount there's a lot of hospital resistance
3 to, you know, why do we want to get into this. So, it was a
4 balance, it could've been done, but it was felt that getting
5 that through Office of General Counsel and getting
6 acceptance by the hospital industry probably was not
7 something that would happen. There was achievable, so we
8 limited it this year. In terms of comments to future rules
9 and things like that, you know, that's always something that
10 we could consider further.
11 CHAIRMAN MALMUD: Thank you. Dr. Welsh?
12 MEMBER WELSH: If I might add a follow-up comment.
13 I think one of your points was that patients might not
14 really be too concerned about where their isotope is
15 produced. I might challenge that simply because as a
16 radiation oncologist all my patients must provide informed
17 consent, and with the therapeutic isotopes I could envision
18 in the future asking the patients that if there is an
19 alternative that uses non-HEU-produced isotope, would you
20 check the box in this consent form; if not, don't bother
21 with it. It's just a comment. I suppose I would challenge
22 that assumption that patients wouldn't prefer the dolphin-
23 free tuna.
24 DR. DUVALL: Clarification: that was actually our
25 assumption as well. We felt that patients would prefer the
26 dolphin-free tuna; Patients would not prefer full-cost
27 recovery tuna. That was something that would not resonate
28 with them.

1 CHAIRMAN MALMUD: Thank you, and there's a
2 question from Mr. Mattmuller.
3 MEMBER MATTMULLER: Hi, Steve Mattmuller. In
4 regards to the OECD analysis of, I guess, I would challenge
5 the assumption that the European market is identical to the
6 U.S. market given the huge differences in health care being
7 government-sponsored over there versus our system here. So
8 there's a huge difference in payers. And also in regards to
9 the previous comment that right now they have like 10, 15
10 percent reduction of non-HEU Moly in the world. The U.S.
11 could really only expect to see about half of that, so we're
12 really dealing with 5 to 7 percent of our total moly now
13 potentially non-HEU.
14 In regards to your analysis conclusions that in
15 the -- I've heard this a few times and I don't understand
16 where -- the concern seems to be that the hospital gets the
17 patient. How is that additional money going to work its way
18 back up the supply chain? And I can assure you right now in
19 our current state with our -- it's still a fragile moly
20 supply, as we all know, with the one big reactor down and
21 actually they want to shut the Navy reactors over Duke --
22 being shut down for routine maintenance. So we're really in
23 a very perilous situation right now. And everything the
24 manufacturers have had to do to bring additional moly into
25 the market has raised their cost already, and I can assure
26 you they're not shy about raising our prices. I mean,
27 because we've already experienced significant increases for
28 our technetium generator at the hospital; already in the

1 past few years, despite our national price contracts that
2 say, you know the price will stay the same for three or four
3 years. That's just been blown away. So we're already
4 getting substantial price increases now just for HEU moly
5 because the supply is so unreliable. And so I do have a
6 question for you, in regards to your model, when you look at
7 -- and this goes back to the farmer analogy, that price
8 increases for the farmer because of the efficiencies of the
9 distribution. If it's a 50 percent increase in moly cost
10 it's not a 50 percent increase at the consumer level or
11 patient dose. So in your model if you look at a technetium
12 generator, say for every curie that's in a generator, how
13 many doses come from that curie?
14 DR. DUVALL: The answer to that one is that -- one
15 clarification first, and that is we did not assume that the
16 U.S. market was identical to the European market, rather our
17 assumption -- or, not our assumption -- our conclusion was
18 that the elements going into the model that OECD used as a
19 world model were not significantly different when applied to
20 the United States. So, yes, there are differences, but the
21 fundamental assumptions and conclusions did not
22 significantly change when we looked at the U.S. market.
23 Now with respect to the dosing, one of the
24 differences between the U.S. market and European market is
25 that we -- at least our evidence is that on the average we
26 tend to have larger generators and a wider distribution for
27 our regional radial pharmacies which actually creates some
28 efficiencies. The range in generators, as you know, is

1 extremely wide, so for the purposes of a model we used a
2 standardized 10-curie generator. However, the model that we
3 used is actually a spreadsheet model with hundreds of cells
4 in it and various distributions for each element so that the
5 model can -- you can change any particular assumption within
6 the model. And one of the things we can do is vary the
7 generator size to see what happens if you assume five curies
8 or 15 curies. In terms of doses per generator, that depends
9 on the efficiency of the generator. On the order of, I
10 think, several hundred doses, I believe on the order of
11 about 300 doses from a 10 curie generator; however, the
12 range is extremely broad and that actually shows the biggest
13 problem that we have in the model is the -- not just the
14 reliability of the data but the variability of the data.
15 The first thing that we can measure, the one thing we can
16 measure directly is the costs to a hospital by looking at
17 the hospital charges, reducing it to cost on the basis of
18 the cost reports that we have full access to. And what we
19 find is that the costs for the tests, this basic -- let's
20 say it's about a $600 to $700 for one of the particular
21 versions of the test. Hospitals report that as costing them
22 between $200 and $1,200. It's that much of a range
23 depending on the accounting systems of the hospital. Well,
24 clearly if they were all using the same accounting systems,
25 their salaries and things like that don't create that much
26 difference. So it's an accounting impact. That same
27 variability hits at things like the doses per generator, and
28 the only way there we're able to do it was to take the

1 model, look for midpoints, and then vary the model to see as
2 we varied it what would be the impact on the final dose.
3 And the main thing was that you could have wide variations
4 at any individual step that tend to have the buffers by
5 other steps.
6 CHAIRMAN MALMUD: Thank you. A follow-up, please.
7 MEMBER MATTMULLER: Yes. Just a comment, then --
8 I think at our hospital I think our financial system was
9 approved by Congress so that may explain why you have these
10 wide variations.
11 [laughter]
12 Because at times we don't even understand it. So
13 I can appreciate the wide numbers that you get. And I guess
14 I made this comment with a previous speaker. The problem as
15 I see it is the transition because if every dose we were
16 giving, coming into the hospital, was from a non-HEU source,
17 that makes using this code so much easier. And even if we
18 do have a relatively steady supply of non-HEU coming into
19 the hospital, it's relatively easy -- once we go through all
20 the work of setting it up the billing ought to be automatic,
21 just about. Now then -- but you do have to take a step back
22 which is going to make us reluctant participants, is not
23 knowing what the cost -- as soon as we find out what the
24 cost increase is -- because cost increase applies to all of
25 our patient doses, not just the hospital outpatient patients
26 who are then needing to take all the doses, hospital out-
27 patient doses, Medicare-covered hospital out-patient doses.
28 So this additional $10 per dose is going to be needed for

1 our perspective, the hospital, need to cover the cost -- the
2 additional cost -- at all the other doses. So that's going
3 to be a hurdle to jump over.
4 But if and when we do get past that and do try
5 this -- as you know with our -- and it's just fragile, our
6 whole supply, and even with the newer sources coming out
7 it'll still be fragile. It's entirely possible that we'll
8 be using non-HEU moly or technetium, but then there'll be
9 some interruptions, and then that's when it really gets kind
10 of scary. It's like, okay, we've been using non-HEU, we've
11 been charging an extra $10, now we're not, so now we have to
12 go into our system -- and basically it's like a manual
13 system -- say, no, don't charge the extra $10. And in
14 talking with several people from my department who are far
15 more knowledgeable about this than I am, and they said, you
16 know what, our lawyers -- we have lawyers in the hospital,
17 too, say, it's not worth the risk of billing for something
18 that we didn't actually incur the extra cost to because of
19 the additional penalties that can be applied to the hospital
20 that our legal staff, and accounting staff, and billing
21 staff are very, very aware of; so that's the real risk we
22 have at our level during the transition phase.
23 DR. DUVALL: One of the downsides, I think, of
24 being a government employee now as opposed to one of my
25 prior hats is that in response to issues like that I used to
26 be able to go sit down with the individual financial
27 managers of the hospitals, the CFOs and their staff, and
28 actually work with them on how they could configure their

1 systems easily. My prior job at the -- before CMS was
2 actually systems efficiency expert and so I did system
3 configuration, things like that. I can say that it is not
4 as difficult as some hospitals believe and sometimes it's
5 knowing just the one or two facts that allow you to say,
6 "Oh, that's how you can do it." But we didn't – in
7 determining this, I mean we produced the thousands of codes
8 every year that the hospitals have to put in their systems,
9 so we try to stay pretty close in touch with how you have to
10 use the codes. And it was our determination after looking
11 into it and talking to people and things like that, that
12 actually this is not that difficult to implement and to
13 implement safely and absolutely in a way that you would not
14 overbill the government because we definitely get very upset
15 when you do that. So I would urge those of you that are in
16 the industry that are hearing that to have hospitals that
17 are having difficulties with this talk to other hospitals
18 because there are hospitals that have found ways of
19 implementing it fairly easily, and I think that as that
20 knowledge spreads it's not a lot of discussion among CFOs
21 for a $10 payment that they are not using that often. But
22 again, as more LEU comes into the system the costs go up,
23 then the pressure is going to be on the hospital that, oh,
24 we really do need that payment, and I think they'll then
25 find that it's actually not so difficult to implement.
26 CHAIRMAN MALMUD: Dr. Suleiman, did you want to
27 comment?
28 MEMBER SULEIMAN: Yeah, just a quick one. I want

1 to compliment CMS for what they did. The whole purpose of
2 this exercise was to encourage professional procurement of
3 the LEU-produced moly. Not during a shortage, because
4 during a shortage you should pocket the 10 and not give it
5 to the community. But it's during the period of time when
6 there's ample supply of moly that people start buying the
7 cheaper HEU, and the infrastructure that's now in place for
8 the non-HEU production is standing there not being used.
9 And so that component of the supply chain has been
10 complaining, we went to all this trouble and now there's a
11 moly glut because right now the supply is not short, and so
12 to encourage that I think the White House policies said we
13 really want to preferentially procured guarantee that the
14 LEU producers are not disenfranchised once we go through one
15 of these surges where we actually have more moly. And so
16 the whole purpose there was to give a little bit of
17 encouragement to differentially repay the higher cost of the
18 non-HEU moly.
19 This is so simple I've just been fascinated; I'll
20 be honest with you, how difficult the community has reacted
21 to this. I've talked to radiopharmacies where they've
22 implemented it, and they said it's not a big deal. The
23 people who have implemented it have been quiet, they've
24 succeeded, and it's really pretty low at this time just
25 because of the numbers. But if it's so complicated, and
26 I've argued this before, don't use it. Just go ahead and
27 pay your regular rate. This was not meant to be forced on
28 the community. If you think this extra $10 is not worth it,

1 don’t bother with it. And it’s going to go away when the
2 HEU production goes away. So it’s just to help in
3 translation over this period of time. I think you guys have
4 done a phenomenal job and I wish people would try to take
5 advantage of this.
6 CHAIRMAN MALMUD: Thank you. As a retired hospital
7 CEO, I am impressed with the fact that you’re introducing
8 new billing code. Makes it easy to add it on as an add-on
9 to the procedure and get reimbursed. I’m sure the hospitals
10 that will enjoy this in the future are appreciative of it.
11 And we very much appreciate your presentation here today.
12 Thank you.
13 DR. DUVALL: Thank you very much.
14 CHAIRMAN MALMUD: We now have a schedule to take a
15 break. We’re running about a half-hour behind. What would
16 you recommend for the length of the time for the break, Mr.
17 Einberg?
18 MR. EINBERG: Should we take the half-hour break
19 or run an abbreviated break of 15 minutes?
20 CHAIRMAN MALMUD: Is 15 minutes sufficient for the
21 group?
22 MR. EINBERG: Before we go to break, I would
23 suggest that maybe we change the agenda a little bit because
24 there are some more interest in Ms. Weil’s presentation from
25 the members of the public, perhaps, so when we come back
26 from the break if we could perhaps start with Ms. Weil’s
27 presentation.
28 MS. COCKERMAN: Actually, that was assuming we

1 were going to come back at 11:15, so if we're going to come
2 back at 11:00 maybe we should proceed with Sophie and Dr.
3 Gabriel's presentation on ViewRay. Use that 15 minutes, and
4 then move onto Ms. Weil's presentation at 11:15 to keep that
5 on schedule.
6 MR. EINBERG: That sounds like a good plan if it's
7 acceptable to the Committee?
8 CHAIRMAN MALMUD: Yes. So that will allow Ms.
9 Weil's presentation to be exactly on schedule. Thank you.
10 [break] [resume at 11:00AM]
11 MS. HOLIDAY: So, good morning, everybody. As you
12 know, my name is Sophie Holiday, and Dr. Gabriel and I are
13 listed to give this presentation because we were both part
14 of the working group that worked to develop the licensing
15 guidance document for the ViewRay. We are both members of
16 medical radiation safety team, and we have the pleasure of
17 presenting to you today the status of our licensing guidance
18 document. Today, I just want to give you a brief
19 description of the device, touch on with the sealed source
20 and device registry, talk about the working group, give you
21 our progress and current status, share with you our
22 communications plan, and then wrap it up with a summary.
23 CHAIRMAN MALMUD: Thank you.
24 MS. HOLIDAY: You're welcome. The ViewRay device.
25 This device -- is a unique device. It's a new device. It
26 just hit the market not too long ago. The device in
27 particular is very unique because of its a rotating gantry -
28 - it has a rotating gantry with three Cobalt-60 radiation

1 therapy heads and three multi-leaf collimators. This device
2 also has a MRI system that's integrated with it so you get
3 real-time imaging while you're treating the patient. In
4 addition to this, you also have an integrated treatment
5 planning and delivery software so all of the dose
6 calculations are merged, essentially, so there's no
7 transferring of the parameters for treatment as the patient
8 is being treated. This information -- basic information can
9 be found on the ViewRay website at www.viewray.com. It was
10 understanding that there may have been some representatives
11 that were going to join us from ViewRay, but I believe since
12 our presentation got switched around that perhaps they were
13 unable to accommodate this change in agenda.
14 Also, I would like to share before I go further
15 into my presentation that due to the nature of this work --
16 guidance document, in particular, and due to the proprietary
17 nature of the device, we are strictly limited to how much
18 information we can disclose with members of the public. And
19 since the licensing guidance decision or how we want to
20 license this device is considered pre-decisional
21 information, so at this time, I'm afraid I will not be able
22 to tell you which particular category we will be licensing
23 this device.
24 Sealed source and device registry. This device --
25 the sealed source and device registry was created by Ohio
26 and approved on August 17, 2012. On your screen if you're
27 interested in looking up the sealed source device and
28 registration -- if you have access to that database, you can

1 find it here.
2 The working group. This is the main component of
3 my presentation. A working group was requested to the NRC
4 from the state of Ohio; Ohio being the state that submitted
5 the sealed source and device registration. And since they
6 requested a working group to look at this licensing guidance
7 document development, we had to send that solicitation
8 through the OAS Board. Per NRC's management directive 8.3,
9 Agreement State Participation in Working Groups, there's a
10 whole process and procedure about how NRC has to go about
11 developing a working group with agreement state
12 participation. Among these procedures include things as a
13 working group charter that outlines your tentative
14 deadlines, your objectives, who is involved, and the roles
15 that they play.
16 There were a total of six members on this working
17 group evenly split between NRC and the agreement states.
18 There were two individuals from headquarters. That's myself
19 and Dr. Sandy Gabriel. The Region III representative was
20 Ms. Frazier, who is one of the co-chairs on the working
21 group. The other representatives were from agreement
22 states; there was an individual from California, an
23 individual from Ohio, and an individual from Wisconsin. The
24 individual from Wisconsin was the OAS co-chair of the
25 working group. As you will note that we have three
26 individuals from agreement states, and the other individual
27 from Region III. The reason why these individuals were
28 chosen is because Ohio has an interest in that ViewRay is

1 based in Ohio, and they were the individuals who created the
2 sealed source device registration. Region III is involved
3 because they have a licensee who has the device. Wisconsin
4 also has the device. For those of you who may not know, Dr.
5 Langhorst and Dr. Thomadsen's facilities currently house
6 those devices. And California is a expecting an application
7 quite soon. So all of the individuals that were on the
8 working group were familiar with the device and were the
9 knowledgeable people to be involved in the development of
10 this licensing guidance document.
11 Onto the progress and the current status. So, we
12 formed the working group a couple months ago, and a charter
13 was drafted and concurred upon -- concurred by both the NRC
14 and the OAS Board. So both parties were aware of the
15 procedures and objectives of the group and how the
16 proceedings were supposed to go forward. The working group
17 recently completed their initial draft of the licensing
18 guidance document, and this is currently undergoing review.
19 We just received comments from Regions I, III, and IV, and
20 the OAS board; so the working group will be meeting later on
21 this week to go over the comments to hopefully resolve the
22 comments. After the document has gone under review, it will
23 go through our management, and then it will also go through
24 legal to make sure we're not doing anything we're not
25 supposed to. And then that brings me to our next slide,
26 communication.
27 There are several methods which NRC may use to
28 communicate with members of the public and the agreements

1 state stakeholders on the licensing decision for particular
2 devices. One of the methods is the medical listserver. I
3 believe everyone here on the committee is a part of that.
4 If you are not, you can simply send an email to the email
5 address that's listed here and request that you be added to
6 the medical listserver. Gretchen Rivera-Capella is actually
7 the project manager over that medical listserver. An
8 additional step that we would take is to issue a memo to the
9 NRC regions and the OAS board to inform them of our decision
10 of how we chosen to license this device. Another method
11 that is available is the medical toolkit. The medical
12 toolkit amongst other things has such things as 35.1000
13 guidance, FSME newsletters, other regulations, and
14 references.
15 So, in summary, the working group completed its
16 initial draft, and it is undergoing review. The working
17 group will meet this week to hopefully resolve all the
18 comments. And then upon approval, the guidance will be
19 shared via multiple routes so that we can reach as many
20 stakeholders as possible, as many agreement states,
21 stakeholders, and members of the public that may be
22 interested in this device licensing.
23 So, here are some acronyms. And that completes my
24 presentation. Do you have any questions?
25 CHAIRMAN MALMUD: Thank you. Questions or
26 comments for Ms. Holiday? Please.
27 MEMBER WELSH: Jim Welsh. So I heard you say, I
28 believe, that you wouldn't be disclosing where in 10 CFR 35

1 this will be licensed, but from my perspective as a
2 potential user, the radiation oncologist, I can't understand
3 any reason for in not being in the clearly defined 690
4 teletherapy section. Is anybody aware of any reason why it
5 wouldn't fit well in that section right now? To me, it
6 seems like a teletherapy unit that has modernized image
7 guidance.
8 CHAIRMAN MALMUD: Perhaps someone from NRC staff
9 can answer.
10 MS. HOLIDAY: There's a limitation on how much we
11 can share as far as our licensing decision without actually
12 announcing what it is, but I do understand your concerns.
13 When staff looks at devices, what we do is we evaluate it
14 against our regulations, and that device has to meet all
15 those regulations. If for some reason it can't, then we
16 consider another category. I'm not saying of course that it
17 would be 600, but this is how we evaluate every device that
18 we get. So we evaluate it against the current regulations
19 and see how it fits, and then if there are certain
20 components that don't fit, then it gets moved to another
21 category.
22 MEMBER WELSH: My question here might be just as
23 last year with Dr. Zanzonico and we had our radium-223
24 dichloride subcommittee to ultimately provide some advice or
25 recommendations about licensing. Why would there be no need
26 for ACMUI input ahead of time for you to make this decision?
27 MS. HOLIDAY: Sure. One of the reasons why we
28 didn't necessarily go through ACMUI this time is because we

1 didn't want to delay the use of the device. As I've been
2 told, some licensees are trying to use this device as early
3 as this summer. And duly noted, it may have not been
4 sufficient time to form a subcommittee and get a report and
5 get adequate feedback in order to make this licensing
6 guidance document. However, I will say that a guidance
7 document is simply a guidance document, and there's always
8 opportunity for comments to be provided on licensing
9 guidance documents.
10 CHAIRMAN MALMUD: Thank you. Dr. Langhorst.
11 MEMBER LANGHORST: As Ms. Holiday said, my
12 institution, my organization does have a ViewRay device with
13 sources at this point in time that the ViewRay Incorporated
14 is still testing and getting to that point to where our
15 medical physicists will then be doing acceptance
16 measurements and testing. We have applied to Region III for
17 medical use of the device last September and did make the
18 argument of why it should be considered under 35.600. And I
19 know that Region III is considering that, and that was
20 probably one of the driving forces also to put together this
21 group to review it. I do want to make mention, too, that at
22 the May CRCPD meeting, the AAPM is sponsoring a training in
23 ViewRay licensing and some of the challenges involved in
24 that, too. So there's a lot of discussion going on on it
25 and a lot of excitement about this new device, and we agree
26 that it's teletherapy heads, and an MRI system is just an
27 additional thing to help with giving effective teletherapy
28 doses to patients.

1 CHAIRMAN MALMUD: Thank you. Other comments? If
2 not, we'll move on to the next item on the agenda. It's
3 Laura Weil, and we'll invite you to the front of the table.
4 MEMBER WEIL: Thank you, Dr. Malmud. Thank you
5 for the opportunity to share with you my experiences at the
6 2012 Thyroid Cancer Survivors' Association annual meeting.
7 I'd like to give you a little background history. Which
8 one?
9 MS. HOLIDAY: The one on the right.
10 MEMBER WEIL: The one on the right. Really?
11 MS. HOLIDAY: Point it this way.
12 CHAIRMAN MALMUD: You did.
13 MS. WEIL: There we go. We'll see how it works
14 next time. So, ThyCa is a non-profit organization, really
15 grass-roots association that provides support and
16 information for people with thyroid cancer. It has IRS
17 501(c)(3) status, and it's predominantly a volunteer
18 organization. It has one full-time executive director.
19 So, the services that it provides. You can see
20 here it's got 14,000 participants in email support groups.
21 It's got a lot of local in-person support networks, free
22 online newspapers. It does low-iodine cookbooks in several
23 languages. They're working on the Chinese version. And it
24 has periodic local workshops for informational purposes as
25 well as this annual conference. Supports research, has --
26 here's a partial list of its grantees. So you can see these
27 are prestigious institutions that receive funds from ThyCa.
28 And the annual meeting has over 500 attendees on multiple

1 days. A thousand -- a hundred separate sessions, speakers,
2 predominantly physicians from leading cancer centers
3 including Cleveland Clinic, MD Anderson, Mayo, Memorial
4 Sloan-Kettering, Yale, Johns Hopkins, and also other health
5 care providers and attorneys are represented.
6 So ThyCa decided to survey its members in 2010.
7 It had over 2,400 respondents, and this is some of the
8 information that it captured. Sixty-seven percent of the
9 patients who responded to the survey were released from the
10 treating facility within 30 minutes, 17 percent within an
11 hour, 8 percent within two hours. So you can see that the
12 predominant majority of patients are released very, very
13 quickly from the treating facility. Ninety-four percent
14 went home or to a relative's home, and 5 percent reported
15 going to a hotel or motel. Ninety-four percent said they
16 received oral instructions. Only 87 percent stated they
17 received written instructions on reducing radiation exposure
18 to others. The treatment settings were 89 percent hospital
19 and 11 percent out-patient, non-hospital settings.
20 So, I had the opportunity to attend the 2012 ThyCa
21 conference. And I went with the intention of surveying
22 attendees about which were family members of patients and
23 patients, former patients mostly, to interview folks about
24 their experience with outpatient iodine 131 therapy. I
25 talked to more than 25 people. They are a highly motivated
26 and highly activated patient population. These are folks
27 who are very intelligent, very well informed about their
28 disease, and very interested in becoming more informed.

1 My underlying concern, and this is the, you know,
2 the soft counterpoint to Dr. Saba's presentation. My
3 underlying concern is that patients who are given discharge
4 instructions at the time of treatment have trouble
5 understanding and following those instructions. And I
6 backed that by comparing them to emergency department
7 patients. It's been fairly well documented that emergency
8 department patients don't understand discharge instructions,
9 don't know they don't understand discharge instructions, and
10 therefore don't reliably follow discharge instructions in
11 large numbers. It's been postulated 75 to 78 percent of
12 emergency department patients have problems following
13 discharge instructions. Well, when release instructions are
14 given to radioiodine therapy patients at the time of
15 discharge, they are compromised the same way emergency
16 department patients are compromised. They're frightened,
17 they're not feeling well, they may be extremely hypothyroid.
18 I think I get to this. Here we go, on the next slide. They
19 are not at their best, and therefore, it's a difficult time
20 to be giving instructions. Some centers provide them
21 instruction well ahead of time, and some providers don't.
22 And to assume that everybody gets their release instructions
23 when they're feeling well and able to integrate them and
24 with the person accompanying them perhaps who can assist
25 them in understanding discharge instructions is a
26 problematic assumption. Some of the barriers to
27 understanding are fairly obvious. They may not have
28 adequate time to integrate the information. The written

1 instructions are often, you know, in that stack of papers
2 which, you know, can be this big with the important message
3 from Medicare, and the bill, and information about not, you
4 know, not bringing valuables with you to the institutions.
5 It's a bunch of stuff that people get when they are
6 receiving treatment, and those instructions are not always
7 pointed out. And then a big problem that we really don't
8 address well in any medical care is that the patient's
9 primary language may not be used in providing this
10 information to him.
11 So, I interviewed a lot of people, and I would
12 like to share with you what I think is a representative
13 sample of the stuff that people told me. So, I met a young
14 woman who was treated at a small community hospital. She
15 was given her final discharge instructions at the time of
16 treatment stating she was completely hypothyroid. She felt
17 cognitively compromised at the time. She remembers that she
18 receives conflicting instructions from different members of
19 the clinical team. She was feeling nauseated after
20 treatment, but no antiemetics were offered. She wasn't
21 offered instructions about travel home. She was not told to
22 actively hydrate in the post-treatment period. And she
23 learned about these concerns at the ThyCa conference. At a
24 major university center, the interviewee told me that she
25 received contradictory discharge information. She states
26 she received no information about how to mitigate damage to
27 salivary glands. She remained at the treatment site for 15
28 minutes post administration of her iodine 131. She traveled

1 home alone. She was totally unaware of any precautions that
2 might relate to trash disposal, eating utensils. She
3 learned this again at the conference, and she stated, "that
4 stresses you out, not knowing what to do."
5 I met the mom of a 10-year-old who was treated at
6 a university hospital. The mother was given no instructions
7 for post treatment period other than she was told to bring
8 the big car so that she could stay as far away from the
9 patient as possible during the long drive home. She had
10 another child at home, a 6-year-old, and she was given no
11 instructions to isolate the patient from her sibling. She
12 got no information about solitary sleeping or bathroom use,
13 or eating utensils, laundry. She was suspicious about this
14 and being that highly activated, typical ThyCa member, she
15 accessed the ThyCa website for information. She called the
16 hotline, and she got more information about what she ought
17 to do, and she sent the younger child with -- to stay with
18 relatives for three days.
19 Another conference attendee told me she was sent
20 to a hotel. This is her word, after her therapy. She
21 states she was given no other opportunities or
22 recommendations. She's now a ThyCa volunteer who staffs the
23 hotline, and she says she receives a lot of calls about
24 hotel stays after treatment. Many patients tell her they
25 get instructions only on the day of treatment, and she
26 reports that many patients state that the instructions are
27 included in a stack of discharge papers not specifically
28 identified or verbally reviewed.

1 I met a young mom who has a 6-month-old. She's
2 now two months status post breastfeeding cessation in
3 anticipation of her iodine-131 treatment. She was expecting
4 to get her treatment in the next month or month and a half.
5 She thought she had excellent instructions from a major
6 medical center. She showed me an email that she'd received
7 from the center which was listed the specifics of her post-
8 treatment period. She was very, very happy with the
9 instructions that she received. I have to say that this is,
10 among the 25, the only person I spoke to who was really,
11 really happy with the way the instructions were presented
12 ahead of time and with the access that she had for -- to
13 people to ask questions. She said she'd gotten some
14 conflicting information from other clinical presentations at
15 the conference, but she was perfectly confident that she
16 would be able to call her provider and get her questions
17 answered. This was a happy thing.
18 So a summary of the concerns that I heard
19 repeatedly expressed involved conflicting instructions from
20 members of the team even at the same institution, cursory to
21 minimal discussion of precautions, missing information, no
22 effective contact information given for information after
23 release. People told me that they went home and vomited on
24 the shag rug and couldn't reach anybody at the institution
25 to get information about what they should do to clean up a
26 spill. A lack of information, uniform information in the
27 medical community about appropriate precautions is another
28 thing that was raised repeatedly. So my informal conclusion

1 based on very soft anecdotal data is that people at this
2 conference felt that they had not received consistent,
3 understandable discharge instructions that would enable them
4 to maximize safety to themselves and minimize harms to
5 others. Any questions?
6 CHAIRMAN MALMUD: Are there question for Ms. Weil?
7 Or comments? Dr. Zanzonico.
8 MEMBER ZANZONICO: It's very interesting data.
9 MEMBER WEIL: Well --
10 MEMBER ZANZONICO: Information. It's very
11 distressing.
12 MEMBER WEIL: Yes, I agree.
13 MEMBER ZANZONICO: It's -- I have to. It's
14 nothing like what we do at --
15 MEMBER WEIL: Of course not.
16 MEMBER ZANZONICO: And I'll take this opportunity
17 to again applaud NCRP Report number 155, which virtually
18 states all of the issues that you address in terms of the
19 immediate hopes in the period, hour so forth, people should
20 remain under medical observation, report to discharge --
21 this is for out-patient -- instructions and information upon
22 the trip home, written instructions, contact information, so
23 forth and so on. All of these are included in detail in
24 that report, and it's what we follow at Memorial and a
25 number of other sites follow it as well. But I'd just like
26 to take this opportunity to plug this report once again
27 because I think it reinforces the problems that do occur
28 obviously at a number of places where there's conflicting

1 information even among the medical and professional staff,
2 and I think this provides a systematic comprehensive
3 resolution to a lot of those issues. Thank you for that.
4 CHAIRMAN MALMUD: Dr. Suleiman.
5 MEMBER SULEIMAN: I want to compliment you on a
6 nice presentation.
7 MEMBER WEIL: Thank you.
8 MEMBER SULEIMAN: There is nothing like real
9 information. Maybe this is not a formal, large scale,
10 random collection of data but it's always like the first
11 step in maybe considering that. That's why I still would
12 urge Mr. Saba and the NRC to collect some actual dosimetry
13 data. I'm not a big fan of modeling when it's very easy to
14 come up with an alternative, relatively inexpensive way to
15 collect real data because no matter what model you select, I
16 guarantee you, it's going to be challenged. And even real
17 data will sometimes be challenged, but there's no substitute
18 for it. And the dilemma I think we as a committee we have
19 always got to consider, it's not what we do at our
20 respective institutions with highly qualified individuals.
21 MEMBER WEIL: Right.
22 MEMBER SULEIMAN: The people that need to be --
23 whose safety has to be protected are nowhere near here. And
24 so, what sort of safeguards are necessary to ensure that
25 this situation doesn't exist out there. And again, if the
26 magnitude is -- I've had some experience extrapolating from
27 very tiny, little information to larger scale. And usually
28 what you see here is probably much more representative that

1 we would like to admit. So, if this kind of superficial
2 process exists out there, I would be concerned.
3 CHAIRMAN MALMUD: Mr. Einberg.
4 MR. EINBERG: Thank you, Ms. Weil, for this
5 excellent presentation. It really does bring home, the
6 personal nature of what we're dealing with, and emphasizes
7 how these are real patients, real families that we're trying
8 to protect.
9 One thing that comes to mind is that the ThyCa
10 organization or the members of the ThyCa were surveyed by
11 the Health Physics Society and basically to see whether the
12 instructions were able to be followed. And there's a
13 discrepancy in what you're reporting and what the -- what
14 that survey indicated. And that survey indicated 97 percent
15 of the members of ThyCa thought that the instructions were
16 understandable. Now, however, having said that, I think
17 that there is room for improvement. So, I just make that
18 statement.
19 MEMBER WEIL: No, it's true, and I've discussed
20 that discrepancy with Gary Bloom, who's the president of
21 ThyCa. And he had some question about the accuracy of that
22 97 percent finding about the way the question was asked or
23 about -- just about the way that information might have been
24 presented.
25 MEMBER ZANZONICO: Can I just say something? How
26 did you solicit interviews at the meetings?
27 MEMBER WEIL: I just walked around and said, "Hi,
28 can I ask you about your iodine therapy -- acquisition

1 iodine therapy. Did you -- ” I mean I tried to be as
2 neutral as possible. Now one is never totally neutral. And
3 my bias of course is that I believe there’s a problem out
4 there with the way patients are understanding and following
5 their discharge instructions in this particular instance,
6 because in the broader medical world, patients have trouble
7 following discharge instructions or understanding them and
8 following them. And I’m not using the word compliance
9 because I don’t think it’s a question of choice. I think
10 it’s that we don’t a good job in general in providing people
11 with the information they need so they can protect
12 themselves and others. But I tried to be as neutral as I
13 could. And except for that one woman who had a very
14 positive experience with her provider, the other people I
15 spoke to all had concerns about their ability to understand
16 the discrepancies in the information that they received, to
17 make reasonable choices or that they learned later on at the
18 conference of things that they should have done that they
19 weren’t aware that they were supposed to be doing. So,
20 that’s how I presented it. I just said I’d like to, you
21 know, if I could, just ask you how you felt about your post-
22 treatment experience and the instructions that you were
23 given.
24 MEMBER ZANZONICO: I don’t know. Maybe some of
25 the physician members can comment on this but I’m struck by
26 the relatively large portion of those patients who said they
27 were nauseas and vomited, because when I speak to physicians
28 at Memorial, and I think we treat more patients with

1 radioactive iodine for thyroid cancer than anyone in the
2 world. To their knowledge, at least what they're willing to
3 admit, they say it's almost undetectable proportion that
4 they're aware of -- Dr. Malmud, what is your experience in
5 terms of immediate, post-treatment nausea among the I-131 --
6 CHAIRMAN MALMUD: I've been doing -- I've been
7 treating patients for 40 years. I've had two that have
8 vomited. One vomited while in the department. We were able
9 to handle that with radiation safety cleanup. Another one
10 vomited on the street but only blocks from the hospital.
11 And we sent a team out there from our own radiation safety
12 to clean it up. Those are the only two that have reported
13 to me that they vomited, because when I see them in follow-
14 up, I ask them about what happened after I treated them. I
15 don't doubt that the people that you interviewed said the
16 things that they said. Some of the things, for example,
17 frankly are illegal in our state. It's illegal to treat a
18 patient who doesn't speak English without having a
19 translator there; either a live translator, which slows down
20 the process but we have them there. Or, in the absence of a
21 translator, a telephone translation system. So, that's
22 actually a breach of practice not to do that to someone who
23 doesn't speak English. The other issues I can believe
24 occurred. They would occur when we hospitalize the patient
25 and then discharge the patient after several days or whether
26 they were discharged from the laboratory. These are issues
27 which are not related to the issue we discussed before, not
28 directly related. And I don't doubt that; the patients are

1 very anxious when they're hyperthyroid and very slow when
2 they're hypothyroid as any of us would be. And we give
3 written instructions, and I go into detail with patients
4 about situations that they may be facing or experiencing.
5 And -- but I never -- we never at our institution direct the
6 patient to go to a hotel. In fact, I tell them specifically
7 not to go to a hotel or a motel.
8 MEMBER WEIL: That's unusual, I think, Dr. Malmud.
9 I think it's an option that is broadly offered.
10 CHAIRMAN MALMUD: It may be unusual, and that's
11 why I don't doubt what you said, because I've known the
12 patients who have gone to hotels.
13 MEMBER WEIL: To comment on your statement about
14 the use of interpreters, when a person speaks no English,
15 it's usual that a medical provider, if not turning to a
16 family member, which is a very questionable practice, will
17 access either phone interpretation or call a staff
18 interpreter or arrange for an independent interpreting
19 service. It's when the patient speaks English, but it's not
20 their primary language, and it's impossible to ascertain how
21 much of that information is actually being understood
22 because people want -- people will -- "Do you understand?"
23 "Yes, of course, I understand." But it's difficult to
24 assess what degree of the information is being absorbed when
25 English is -- English proficiency is questionable.
26 CHAIRMAN MALMUD: You're absolutely correct, but
27 the same thing is true for the patient who's fluent in
28 English.

1 [laughter]
2 And doesn't absorb the information that the doctor
3 transmitted.
4 MEMBER WEIL: True. It's just a double whammy for
5 the person with limited English proficiency.
6 CHAIRMAN MALMUD: Just dealing with when they're
7 on a medication, when the capsule should be taken. Is it
8 before breakfast or after breakfast or in the evening? And
9 you tell the patient, and it's written on the prescription
10 bottle. And yet they don't follow the direction. So we
11 find frequent non-compliance in that sense, not to mention
12 the fact that in prescribing medications there are national
13 figures for non-compliance for patients taking their
14 medication, not radioactive, but medications in general. So
15 I don't doubt that you gained that information from this
16 number of patients. Though I think that it may be that you
17 randomly had astute population of people who were more
18 dissatisfied than usual, or more poorly informed than usual.
19 But I don't doubt that there's a significant number of them,
20 and we're concerned if there's only one. Dr. Guiberteau.
21 MEMBER GUIBERTEAU: I also want to compliment
22 Laura Weil for her proactive and enthusiastic approach to
23 her role as our public representative. I think it brings us
24 back to what we're all here about, and that's for our
25 patients and their providers. I have two questions. One,
26 do you have any idea how recently these 25 people had been
27 treated?
28 MEMBER WEIL: Oh, some of it goes back 20 years.

1 Some of these folks -- although the ones who had been
2 treated a long time ago have been re-treated since. This
3 would -- they would have been describing a secondary
4 treatment, generally speaking, because they wouldn't have
5 been discharged from the hospital long ago. So because this
6 was all out-patient therapy that I was inquiring about, it's
7 probably since '97.
8 MEMBER GUIBERTEAU: Well, I mean, I think that's
9 important to consider. One, given the fact that about 90
10 percent of these people were treated in a hospital and the
11 trend recently has been the reverse. And also, I think
12 education and through the Society of Nuclear Medicine and
13 other organizations where treating physicians is probably
14 better, more recently than perhaps it was 20 years ago.
15 MEMBER WEIL: I hope you're right.
16 MEMBER GUIBERTEAU: Well, I'm just suggesting that
17 we understand that this is anecdotal, but this is what makes
18 it so interesting. But -- my second question is has any of
19 this data from the surveys from ThyCa, has any of that --
20 have any of the data been published? And if so, can we get
21 a reference because it would be interesting to read more
22 about this.
23 MEMBER WEIL: I have a copy of the survey which
24 was unpublished but perhaps you have accessed it from a --
25 in a published form.
26 MR. EINBERG: There's an abstract here and as such
27 I believe it has been published by the Health Physics
28 Society. We can get you that abstract.

1 MEMBER GUIBERTEAU: I think if you could send the
2 references maybe to anyone here who is interested. Maybe
3 I'll --
4 CHAIRMAN MALMUD: We'll send it to the whole
5 committee.
6 MEMBER GUIBERTEAU: I think that would be
7 interesting for us to read. Thank you.
8 CHAIRMAN MALMUD: Dr. Welsh.
9 MEMBER WELSH: Well, I too would like to
10 compliment you on this effort.
11 MEMBER WEIL: Thank you.
12 MEMBER WELSH: I know it's a bit of a challenge,
13 and it was outside the expected role. But nonetheless, I
14 have to say that I'm skeptical. And I'm not skeptical about
15 what you have here as far as what these people said, but I
16 am skeptical about what might -- I have questions about what
17 truly transpired. And to me, it's the three Cs of out-
18 patient radio iodine therapy: comprehension question,
19 conveyance question from the caregivers, and compliance
20 concerns. We'll never know which one of those three Cs
21 contributed to this -- these surprising anecdotes. But one
22 explanation might be that, as Dr. Guiberteau explained, some
23 of these patients were from a while back. Perhaps memory is
24 failing. Perhaps standards were less stringent then than as
25 they are compared to today. But for patients who were
26 recently treated, one internal control might be to ask them.
27 I don't know if you did. If you asked them, did you provide
28 written consent, and I think that 100 percent should say

1 yes. If you got a number other than 100 percent, you would
2 know that there is some human memory possible failure there.
3 We'll never be able to know the true explanation for why
4 these patients were not as happy as I would expect them to
5 be, because these stories are deplorable and entirely
6 unacceptable to my personal practice or any institution I've
7 ever been with. And I believe that these responses would be
8 unacceptable to any professional society that I'm aware of,
9 namely the radiation oncology professional societies or the
10 nuclear medicine societies. It raises the question in my
11 mind that, is it possible that there is another group of
12 practitioner authorized users, the endocrinologists who have
13 standards that are slightly different from what I would
14 expect the radiation oncology or nuclear medicine. I don't
15 know if it's possible to ever tease out that data, but given
16 the anecdotes, not true data, but the anecdotes that you
17 presented, it raises this questioning in my mind because
18 these are deplorable situations that I find so unacceptable
19 that it makes me want to look into this further.
20 CHAIRMAN MALMUD: Dr. Suleiman.
21 MEMBER SULEIMAN: Did you collect information on
22 where they had their procedures or the date? That would
23 answer Dr. Welsh's one question.
24 MEMBER WEIL: Yeah, and frankly, I mean in the
25 anecdotes that I've selected, I think I stated where they
26 got their treatment. I think it was mostly hospital
27 patients, but I can look back at my -- the other notes that
28 I took. I don't remember the preponderance of whether it

1 was endocrinologists or others.
2 MEMBER SULEIMAN: I'm not questioning the
3 credibility of what's been reported. I truly believe these
4 people didn't dream this up, okay. And I fully expect that
5 this occurs out there. My concern is how widespread is it.
6 Could somehow we get a -- would there be some way to find
7 out if there's a particular group or a particular
8 circumstance or a -- you know, particular type of
9 institution. I mean there are all sorts of hospitals. But,
10 this sort of thing, having been a patient myself on several
11 occasions, you know, when you sign those consent forms, who
12 really has the time to read them, because you're about to
13 undergo a procedure that's going to impact on your health;
14 so maybe I'll look at them later after the fact. So, having
15 been on both sides of the informed consent -- this consent
16 issue, we really -- it's almost -- it's just a legal
17 document. It's more to make sure the patient's been
18 informed somehow, and we've got their signature but in terms
19 of communicating across. Sometimes you almost need a lawyer
20 to figure out what the informed consent means. So aside
21 from that act, I just think this is worth some follow-up
22 with some real data.
23 CHAIRMAN MALMUD: Dr. Guiberteau?
24 MEMBER GUIBERTEAU: I just want to make a
25 distinction here between informed consent and the safety
26 items that are instructions given to patients. They're
27 usually distinct. At least in our state, they must be
28 distinct. And so informed consent basically are the risks

1 and benefits of the treatment for the patient. The other is
2 for the benefit of the caretakers of the patient, and we
3 have to make that very clear so we don't like to confuse
4 those items. We do, at our institution and many others,
5 have the patients sign off that --
6 MEMBER WEIL: That they have received --
7 MEMBER GUIBERTEAU: -- they have read and have had
8 a chance to ask questions and discussion. We give them our
9 phone numbers. And that's pretty standard from the people
10 that I know who treat these patients. Now of course I'm --
11 that's in itself is an anecdote. But I just want to make
12 sure in the minutes here that we make a decision between
13 informed consent and radiation safety instructions for the
14 patients.
15 CHAIRMAN MALMUD: Dr. Palestro?
16 MEMBER PALESTRO: Yeah, a couple of comments.
17 Number one in response to Pat Zanzonico's question about
18 post-treatment vomiting, we treat about 200 thyroid
19 carcinoma patients a year. And that's between North Shore
20 University and Long Island Jewish Medical Centers. And I
21 can only remember one instance of that happening, and that
22 happens to be an in-patient some years ago. I do not recall
23 it ever happening with any of the out-patients that we
24 treat. In terms of language difficulties, as Leon noted,
25 when we have someone who does not speak English or who we're
26 concerned may not understand, we use the telephone
27 translator. We don't have onsite translators. It was my
28 assumption as it is yours that it was a law. I don't know

1 if it's a state law or federal law --
2 MEMBER WEIL: It is the office of civil rights.
3 MEMBER PALESTRO: -- but we do use that. A couple
4 of other comments in terms of patients being hypothyroid and
5 feeling quite poorly. While that's certainly true, I think
6 the incidence of that happening is decreasing with the
7 increasing use of recombinant human TSH, thyroid stimulating
8 hormone --
9 MEMBER WEIL: Absolutely.
10 MEMBER PALESTRO: -- which is the vast majority of
11 patients that we treat now. And I'm also not surprised that
12 some of the information that they're given at the conference
13 and by some of the medical speakers is conflicting, because
14 the literature are conflicting. And the one thing that
15 caught my eye is something that we grapple with all the time
16 is what do you do about minimizing damage to the salivary
17 glands. And over the years, we've told people to use sour
18 candy, to chew gum, use lemon juice, but there's actually at
19 least one -- excuse me, one paper published that says that's
20 the worst thing you can do because the patients who've done
21 that have actually had worse results in terms of increased
22 salivary gland damage. So I think we're kind of at a loss
23 now and are very -- from our own practice are reluctant to
24 make any recommendations regarding how to protect the
25 salivary glands.
26 MEMBER WEIL: Right, and you know, at the
27 conference, there was conflicting information from speakers;
28 some said use the lemon candy immediately. Some said wait a

1 day. Some said -- it was difficult for patients to
2 understand what they should do given the lack of consistent
3 recommendation out there from the medical community, and
4 that's part of this dissatisfaction that patients have
5 expressed about the instructions that they've been given.
6 It's because they get conflicting information. That's
7 nobody's fault, necessarily. That's that there isn't
8 consensus in the medical community about what protects
9 patients best.
10 CHAIRMAN MALMUD: So, very useful information. If
11 you -- we also give our patients the ThyCa folder. ThyCa
12 produces a folder --
13 MEMBER WEIL: It does.
14 CHAIRMAN MALMUD: -- and suggest to them that they
15 can use that resource if they wish to, but that's separate
16 from the behaviors that you described, and there is concern.
17 Did I see a hand over here? Dr. Welsh?
18 MEMBER WELSH: Yes, just a quick comment.
19 Although it seems appropriate to compare patient
20 comprehension of directions in the emergency department to
21 this population, it probably is not really a good analogy
22 because this is an out-patient scheduled procedure, and
23 there is consultation and there is a follow-up discussion,
24 in most cases right before the treatment. So there would be
25 ample opportunities for interpreters and for questions to be
26 asked and answered under normal circumstances. So I don't
27 think that the analogy to the emergency department is truly
28 a valid one.

1 If it turns out that that is not happening and
2 there is not a consultation and there is not a pre-
3 administration follow-up visit for immediate questions and
4 answers with the physician, it again raises my concerns that
5 somewhere along the line our standards are not being met.
6 And perhaps I might recommend that we revisit the question
7 of whether or not physicians who are not nuclear medicine
8 physicians or radiation oncologists should be allowed to
9 administer this, because to my understanding and experience,
10 I've never encountered a radiation oncologist or nuclear
11 medicine physician or practice that doesn't vastly exceed
12 these minimum standards from these anecdotes. So I don't
13 have any reason to disbelieve what you've said, but it
14 raises a question, that maybe there is a group of physicians
15 out there that I'm not aware of that are not complying by
16 our standards. So I might suggest that we revisit the
17 question of who should be an authorized user.
18 CHAIRMAN MALMUD: Dr. Guiberteau.
19 MEMBER GUIBERTEAU: I'd just like to add, while
20 we're putting patients who should or should not be doing
21 certain procedures, which I do not think is the purpose of
22 this committee, that most radioiodine 131 therapy in this
23 country is performed by diagnostic radiologists with
24 training in nuclear medicine. So I would not want that to
25 leave here without putting that in our documents here. I
26 think one -- I don't think that's the purview of this
27 committee about who should and who should not be doing
28 these, but also the fact that it's not just radiation

1 oncologists who actually perform the least number of the
2 three groups we're talking about, and nuclear medicine
3 physicians and diagnostic radiologists.
4 CHAIRMAN MALMUD: I think it might be useful just
5 to give a brief description of how patients wind up being
6 treated with radioiodine, because I don't think the
7 committee is necessarily aware of it, all the members of the
8 committee. A patient is diagnosed with thyroid cancer.
9 Surgery is performed. Then, post-op, the patient is staged
10 with iodine, usually I-123, a gamma emitter, in order to see
11 if the residual thyroid tissue is considerable in the
12 thyroid, in the neck, or elsewhere in the body. That
13 requires whole body imaging. And the patient is prepared
14 for that by withdrawal of the thyroid hormone which is
15 autologous THA stimulation or with thyrogen stimulation. We
16 use the thyroid withdrawal one. Then after the withdrawal
17 of the hormone, then the patient is imaged with the I-123.
18 A determination of the dose is then made. The dose is
19 administered for the I-131, and there are three office
20 visits associated with these three different -- well, at our
21 institution. There are at least -- there are three office
22 visits associated with this process, during which the
23 patient is told what will be done, what the relevant risks
24 are, and the patient is asked about their living
25 arrangements, because it's essential that we understand
26 those before we treat them. And once -- and then the
27 patient's treated, obviously, and seen in follow-up after
28 treatment. One week is the standard after treatment so that

1 we can image the patient after having received the I-131,
2 which sometimes will disclose metasteses which were not
3 evident previously.
4 So in all that process, there's more than one
5 patient contact with the physician, and it's unlikely that
6 the patient would be denied the information. In addition,
7 we have handouts both in English and our second most
8 frequent language at our institution is Spanish, so we have
9 Spanish printouts as well. The -- it's disturbing to learn
10 that this group of patients feels that they were not
11 adequately informed, but that's very useful information to
12 us, very useful. And I'm glad that you have collected it,
13 because even if it doesn't represent a statistical, valid
14 evaluation of these patients, the fact that it's happening
15 at all is a concern. And probably is something that should
16 be discussed either at the American College of Radiology or
17 the Society of Nuclear Medicine with respect to
18 reestablishing the guidelines of regular intervals for -- in
19 our practitioner. What do you use at Sloan-Kettering? You
20 say you have a regular handout?
21 MEMBER ZANZONICO: Yeah, basically, it's modeled
22 on the NCRP -- it's the model you see here. It's pretty
23 standard among most academic places.
24 CHAIRMAN MALMUD: And that's the same thing.
25 Sure, anyway thank you. It's been a very useful
26 presentation. If we may -- oh, excuse me, I'll get to you.
27 MEMBER MATTMULLER: I'm sorry, keep going. Yes,
28 Steve Mattmuller. And, Laura, you talked -- you mention --

1 touched on this issue during Dr. Saba's presentation, but
2 I'm not sure if he fully grasped -- and I think the issue
3 is, maybe before the NRC goes and does research on how to do
4 more effective guidelines, the issue -- to me what your
5 presentation cites, how can we make the current guidelines
6 implement it better? I mean, because if you look at that
7 tug of rope I'm pretty much right in the middle. I'm
8 leaning to the left now because it's like we've got good
9 guidelines, appropriate guidelines. But from this data and
10 this experience it's not being shared properly with patients
11 who need to know it. So how do you solve that problem?
12 MEMBER WEIL: It's not -- you know, obviously,
13 it's done very, very well in many institutions. Obviously
14 it is. But what worries me is that if one looks at that
15 best-case scenario and measures how well the guidelines are
16 being followed, or how well they're being implemented, then
17 you're missing this other shadowy world where it's not so
18 well done.
19 CHAIRMAN MALMUD: Thank you. If I may, we have
20 two more items on the agenda. The first one is that the
21 representatives from ViewRay are here. They were not
22 present for the earlier discussion because the schedule was
23 changed. So may we invite them to first make any comments
24 if they wish to? And that would be relating to the
25 presentation that Sophie made. Sophie, would you just give
26 us the intro?
27 MS. HOLIDAY: Sure.
28 CHAIRMAN MALMUD: Thank you.

1 MS. HOLIDAY: So the representatives that we have
2 present here today from ViewRay are Mr. David Breuning, Dr.
3 James Dempsey, and Mr. Paul Besette. So if you guys would
4 like to present any comments on behalf of ViewRay, we will
5 just ask that you come to the microphone and identify
6 yourself.
7 DR. DEMPSEY: My name is Jim Dempsey -- is this
8 on? My name is Jim Dempsey; I'm the inventor, founder,
9 chief scientific officer, member of the board of directors
10 of ViewRay Incorporated. I'm sorry we missed the
11 presentation. You know, I guess we are keenly watching for
12 the clinical guidance to come out for this product. The
13 history of isotope use in external beam radiotherapy to the
14 NRC is comprised mostly of teletherapy, which started back
15 in the '50s. And in the mid-'70s to late '80s, developments
16 in teletherapy sort of ground to a halt because the linear
17 accelerator started demonstrating great efficacy in treating
18 head and neck cancer and then breast cancer. And so, most
19 companies that were producing teletherapy equipment stopped
20 producing teletherapy equipment, started producing linear
21 accelerators.
22 There's also the gamma knife, which is a device
23 for treating disease in the brain. Dr. John Suh is an
24 expert in this area of stereotactic radiosurgery. The
25 ViewRay system is sort of a resurrection and modernization
26 of the teletherapy device to the current standards of the
27 linear accelerator. In fact, for the FDA our predicate
28 device was not a cobalt machine, and it was not a gamma

1 knife, it was the CT guided linear accelerator. And so it
2 represents a very broad spectrum of indications and use, all
3 the way from palliative therapy, which may not need image
4 guidance, simple therapies, to image-guided stereotactic
5 body radiotherapy, and stereotactic use. And so we just, I
6 guess, are keenly watching our clinical guidance to make
7 sure that the broad spectrum of indications and uses are
8 covered by the considerations of the clinical guidance. So
9 I think our concern, as a company, is that that's
10 appreciated as the guidance is produced.
11 And I guess we missed the presentation. There was
12 a nice set of slides, they were a little terse. I don't
13 know what transpired or was discussed. We'd be happy to
14 answer any questions about it, and I think that's just the
15 statement we'd like to say is that, "The clinical guidance
16 considers the broad spectrum of indications and uses of the
17 device and its practice. And just to be aware that there is
18 this spectrum of treatment being performed in radiation
19 oncology departments with devices like the Varian map and CT
20 guidance, and that's really, sort of, the work flow we use -
21 - that our device is entering into.
22 CHAIRMAN MALMUD: Thank you. Are there questions
23 for Mr. Dempsey? Mr. Einberg.
24 MR. EINBERG: Yeah, Chris Einberg with the NRC. I
25 don't have any questions; however, I just wanted to kind of
26 summarize what was discussed at the meeting. We didn't
27 indicate which way that our licensing decision was going to
28 be going because that information right now is pre-

1 decisional and it will be inappropriate. So, the focus of
2 the discussion was more process than status as to where we
3 are, and I think you probably could get that from the
4 presentation -- from the slide packet. So, from that
5 standpoint I don't think you've really missed anything.
6 I would also point out that afterwards, this
7 meeting is being transcribed so there will meeting minutes
8 and transcription. So, and that will be posted on our
9 website and you can see, word for word, what was said.
10 CHAIRMAN MALMUD: Thank you. Does either of the
11 other two gentlemen accompanying you wish to make a
12 statement? They're invited to do so. Please introduce
13 yourself first.
14 MR. BESETTE: Good afternoon, my name is Paul
15 Doucette; I'm with Morgan Lewis Law Firm here in D.C. And,
16 I guess I would be interested, obviously, the process for
17 the public having input on the clinical guidance. I
18 understand it's pre-decisional, but I also understand the
19 guidance is supposed to take into account the practicalities
20 of the users. So we're just trying to understand how folks
21 could have in input to the guidance before it's finalized.
22 CHAIRMAN MALMUD: That question should go to --
23 MR. EINBERG: Dr. Howe.
24 CHAIRMAN MALMUD: Dr. Howe. Dr. Howe.
25 DR. HOWE: Depending on how the final
26 determination comes out, I think I can answer best for a
27 case in which guidance status was 35.1000 because that
28 guidance was different than the guidance that's currently in

1 the NUREGs 1556 series. So if you're talking about guidance
2 for a 35.1000 device, the guidance is published on our
3 public website at our medical toolkit for everyone to look
4 at.
5 The guidance is always considered to be draft. In
6 other words, anyone can make a comment on the guidance at
7 any time; it's not the same as a regulatory position that's
8 in our regulations where you can make a comment but you got
9 to wait for NRC to go into rulemaking to make a change. So
10 the 35.1000's very flexible in how -- and when we develop
11 the guides, we develop them, generally, fairly quickly and
12 it's very flexible in that we will take comments at any time
13 on the guidance and then we will make a decision if we need
14 to change it. And I think you can use the example of the
15 yttrium-90 microspheres to show that the guidance has
16 evolved over time with additional use and that we have been
17 pretty responsive to requests for changes to it. So, the
18 guidance is always considered draft and not final and you
19 can also comment, if we were to decide to go 35.1000.
20 MR. BESETTE: Just one final question, Is there an
21 opportunity to provide written comments on ViewRay currently
22 before you publish that guidance?
23 DR. HOWE: Sophie, answer that.
24 MR. EINBERG: This is Chris Einberg, NRC. Your
25 office proceeds right to the NRC, and I think Sophie laid
26 out -- we're moving with our licensing decision right now.
27 So if you are going to be providing any comments please
28 provide them to the staff or -- as soon as possible.

1 MR. BESSETTE: I appreciate that.
2 CHAIRMAN MALMUD: Ashley.
3 MS. COCKERHAM: Just to follow up on what Donna-
4 Beth was talking about, a decision with basically, something
5 like 35.1000 as another example, radium-223 dichloride is
6 another product that came before us, and we made the same
7 type of considerations. We didn't publish guidance because
8 we decided it was not 1000. And so we just issued a memo to
9 our regional offices, and we did mailings on our medical
10 listservers, and as much kind of public outreach as we could
11 to convey what our licensing decision was and that it fit
12 within the existing regulations. So those are kind of the
13 two pathways that we've used as models before it goes to
14 1000 to be on the website, and follows guidance, and it goes
15 in the regulations, we would use communications -- just to
16 communicate that decision with the public.
17 MR. MCDERMOTT: Dr. Malmud. I'd just like to point
18 out for clarification --
19 CHAIRMAN MALMUD: Mr. McDermott.
20 MR. MCDERMOTT: Thank you. The gentlemen
21 mentioned clinical guidance, and I don't know if it's just
22 the terminology of if you're actually looking for something
23 different, but NRC would issue licensing guidance, okay. So
24 in terms of the use the material, as the founder of the
25 device brought up the wide variety of uses, NRC is focused
26 on how the product is licensed in NRC space and not
27 necessarily the different clinical uses.
28 CHAIRMAN MALMUD: Dr. Suleiman.

1 DR. SULEIMAN: Yes, I have some questions, also
2 clarification. Radium- 223 has not yet been approved by the
3 FDA, but it is under investigational research right now. So
4 clearly, there's a licensing requirement as well.
5 You got cleared by FDA. What about your label, your
6 instruction manual? That's already out there?
7 DR. DEMPSEY: So we have --
8 CHAIRMAN MALMUD: Please come to the microphone
9 and reintroduce yourself.
10 DR. DEMPSEY: So yes, labeling was part of the
11 submission to the 510(k) for the FDA. So all of that was
12 complete. We also did complete IEC testing for the FDA
13 before they granted us the 510(k).
14 MEMBER SULEIMAN: So your instruction manual is
15 available.
16 DR. DEMPSEY: Yes.
17 MR. EINBERG: Excuse me, can you please restate
18 your name.
19 DR. DEMPSEY: My name is James F. Dempsey PhD,
20 DABR, formerly medical physicist, now purveyor of fine
21 medical instruments.
22 MEMBER SULEIMAN: He answered my question.
23 CHAIRMAN MALMUD: Dr. Welsh.
24 MEMBER WELSH: Yesterday, during one of our
25 discussions, Dr. Suh and I addressed the concern or issues
26 surrounding the fact that cobalt must be -- cobalt-using
27 units must be thoroughly evaluated, investigated every
28 certain number of years, and perhaps for the older

1 teletherapy units, these inspections can be done without
2 complete dismantling and replacement to the sources. But
3 for the gamma knife, it appears that for these inspections
4 to be done, it must be accompanied by the very costly
5 exchange of sources. So, I'm just wondering, in your
6 particular unit, where will that fall, just so we can get an
7 understanding ahead of time whether inspections are going to
8 cost maybe a million dollars.
9 DR. DEMPSEY: Okay, so the pricing model and the
10 cost is one thing, I can tell you on the servicing, on the
11 source exchange. So for us, we can change the sources in
12 about a weekend. It does use the old source drawer and
13 source technology. It's in a shuttle that doesn't have any
14 friction or touch any parts, so everything in our system
15 that has moving parts are newly designed. We do capture the
16 old source drawer. The source mechanism and the pneumatics
17 are all external and accessible. And so you can completely
18 do inspections, preventive maintenance, service on the
19 system without having to remove the sources. So the source
20 exchange is quite efficient. You know, the cost of cobalt
21 is quite high these days so there's not a lot of use cobalt
22 teletherapy, so I can't promise you that it won't cost a
23 million dollars. But the answer is, in terms of preventive
24 maintenance and servicing, it's all quite accessible without
25 any exposure. And our heads are very thick. So you very
26 quickly get the outside of the head even with a 15,000 curie
27 source or down to about 2 mR an hour or less.
28 CHAIRMAN MALMUD: Any other questions for the

1 representatives from ViewRay? If not -- Mr. McDermott.
2 MR. MCDERMOTT: Just one question, is that -- your
3 about the serviceability without removing the source, does
4 that include that variable collimator?
5 DR. DEMPSEY: No so too -- you can service -- the
6 motors are accessible. If there's a problem with the
7 mechanics or the linkage, you will have to remove that. And
8 so -- but we do have toolings and mechanisms where a head
9 can have its source mechanism removed, it's bolted and
10 locked. We do have a locking mechanism on the source
11 drawer. And so that can be bolted and locked, removed from
12 the machine, and then the MLC can be extracted. And again,
13 it's a procedure that just takes on the order of six to
14 eight hours.
15 CHAIRMAN MALMUD: Does that answer your question?
16 MR. MCDERMOTT: Yes, thank you.
17 CHAIRMAN MALMUD: It's Dr. Dempsey, right? You're
18 a PhD.
19 DR. DEMPSEY: Yes, technically.
20 CHAIRMAN MALMUD: Do you have any other statements
21 that you want to make to us?
22 DR. DEMPSEY: Just thank you for allowing us the
23 time.
24 CHAIRMAN MALMUD: Thank you for being here.
25 DR. DEMPSEY: Thank you.
26 CHAIRMAN MALMUD: Thank you all. If we may, we'll
27 move on to the next item on the agenda, which is Mr.
28 Mattmuller.

1 MEMBER WEIL: Dr. Malmud?
2 CHAIRMAN MALMUD: Yes.
3 MEMBER WEIL: Can I offer a clarification on my
4 presentation? There was a question about nausea and
5 vomiting.
6 CHAIRMAN MALMUD: Yes.
7 MEMBER WEIL: According to the Annals of Nuclear
8 Medicine, June 2004, the incidence of nausea is 40.2 percent
9 and vomiting is 7.6 percent for those that tried that
10 therapy of I-131, iodine 131.
11 MEMBER MATTMULLER: Good morning. Ms. Holiday,
12 how much time do I have?
13 CHAIRMAN MALMUD: Thirty minutes.
14 MEMBER MATTMULLER: Thirty minutes, really? I was
15 warned beforehand that some people are on a tight flight
16 schedule. So, I'll try to abbreviate some of my slides in
17 the interest of time. Let's get this guy to work here.
18 Here we -- all right.
19 So today I'd like to talk about gallium-68 and the
20 germanium generator that comes from. And in regards to
21 this, four areas I need to cover are receptor imaging and
22 why this this is such an important strategy for rating
23 pharmaceuticals for diagnosis and therapy. Why gallium-68
24 is such an important radionuclide, it's available via a
25 generator, so sites do not need to have an expensive,
26 complicated cyclotron on-site. And personally, I tell you
27 because it has a half-life of 68 minutes, so it's one of the
28 few that's easy to remember.

1 I'd also like to talk a little bit about the
2 different radiopharmaceuticals that are being developed in
3 the U.S right now. And of course, since this is an ACMUI
4 meeting, we've got some regulatory issues to discuss. And
5 as a side note, to avoid getting tongue tied with all the
6 long names, whenever I refer to gallium, it'll be gallium-
7 68, indium, indium-111. The slides will have the right
8 radionuclide.
9 This is a schematic representation of the
10 somatostatin receptor in a cell wall. And then the yellow
11 insert is the actual pathological somatostatin peptide
12 hormone. And you can see the four dark critical amino acids
13 that interact with this receptor that gives this molecule,
14 this peptide hormone, its great specificity. And it's
15 important for the regulation in the endocrine system, it
16 affects neurotransmission, and for cell proliferation in
17 certain tissues.
18 The issues -- or the problems when the SSJR at the
19 somatostatin receptor go awry is that it's expressed in
20 neuroendocrine tumors, excuse me, such as those that would
21 include carcinoma, growth hormones creating pituitary
22 tumors, paraganglioma tumors, fetal proctomas, and
23 neuroblastoma.
24 We're actually doing receptor imaging right now,
25 in nuclear medicine, with Altria scan which is an indium
26 radiopharmaceutical, it's a SPECT imaging agent. And at the
27 top you can see the somatostatin peptide hormone; at the
28 bottom is the Altria scan molecule. And if you can read it,

1 it has the exact same four important amino acids in a
2 critical order so it interacts with the receptor. In the
3 middle of the Altria scan is a DTPA molecule which is a
4 chelator, derived from Greek, which means like a crab claw.
5 So the chelator is like a crab claw that can hole the metal
6 atom. And in this case, it's indium.
7 Now this is a gallium version of the same molecule. In this
8 case, the amino acids are expanded out in their complete
9 chemical structure, so -- but it is the exact same four
10 amino acids.
11 Instead of using DTPA because the chemistry is a
12 little bit different between gallium and indium, this is
13 called -- instead of DTPA, we're using DODA. And in the
14 literature you may see there's like three versions of DODA
15 that's in use, DODATOT, DODANOT and DODATATE. But
16 essentially, they all have the crab claw aspect going to
17 hold the metal atom.
18 So if we already have a good receptor imaging
19 agent, why change? And I think this image clearly
20 demonstrates -- this is the same patient image with the
21 indium SPECT agent versus gallium-68 DODATOT version. And
22 so, it's quite apparent with the greater resolution and
23 clarity. There's also advantages for the patient in that
24 indium version takes three visits to the clinic in two days,
25 whereas the gallium because of its - to back up. The indium
26 has a half-life of 68 hours versus the gallium that has 68
27 minutes. So it's imaging -- the injection imaging is all
28 much faster so it takes one visit in one day.

1 So to have gallium-68, you've got to have
2 germanium-68 for the generator. And I'm going to skip over
3 most of this. This is about the chart tree and how they
4 produce germanium. But it is done here in the U.S. at the
5 two national laboratories. It takes a much bigger machine
6 than what we typically have at commercial grade pharmacies
7 that produce F-18. But this is the generator. Here's the
8 schematic of our -- of the germanium generator -- gallium
9 generator. It looks a lot like a moly generator with
10 technetium. You have your -- where you're eluent goes in,
11 your column, your shielded column. As it passes through it
12 goes through a sterilizing filter, your 0.22-micrometer
13 filter, into your collection vial.
14 There are differences, of course: the technetium,
15 it's an aluminum column. There's actually three different
16 gallium generators available right now and they use
17 different column materials: titanium dioxide, tin dioxide,
18 one actually has an organic material in its column. The LE1
19 is different: technetium, of course is 0.9 percent sodium
20 chloride. The gallium generator uses dilute hydrochloric
21 acid to loop the generator. Lifespan: Technetium
22 generator is good for 14 days. The gallium generator can be
23 used for about nine months, so another big advantage for
24 this radionuclide.
25 The sizes: Technetium generators can range in size
26 from one to 20 curies. And there's a wide range of gallium
27 generates, but those used for human use typically range from
28 40 to 100 millicuries. Or a way of looking at it, the

largest gallium generator is about one-tenth the size of the smallest technetium generator.

I'm going too fast, sorry. Shielding, with the technetium generator up to about 10 curies, they'll use lead. And they get larger, they'll use depleted uranium versus the gallium generators; lead is sufficient. And disposal's an important difference. Technetium generator, you can hold on to and let the moly decay, and you can disassemble the generator yourself, and dispose of it yourself safely. Whereas, with the gallium generator because the germanium -- apparent half-life of 270 days, it's rather impractical to do that. Plus, most manufacturers, I can't say all, but one's I contacted, do require that if they sell you a gallium generator, they expect you to send it back to them. So the site has no disposal issues, in a sense, for germanium.

This is one example of one of the commercially available generators. And this is from Eckert & Ziegler. I picked it to make our FDA representative the most comfortable. Because it is -- it has recently received pharmaceutical grade approval from the German regulatory there --

MEMBER SULEIMAN: It's not approved by -- it has not been approved by --

MEMBER MATTMULLER: It's not approved by FDA, but it's the closest one getting to that status.

So since we have a generator, we have to be concerned about breakthrough. And breakthrough testing with

1 this type generator requires some outside of the box
2 thinking. Especially since the germanium decays 100 percent
3 by electron capture, so there's no measureable gamma or x-
4 ray emissions to measure. So you have to do it as we do it
5 now with a strontium rubidium generator, in that you elute
6 the generator, you assay for the rubidium generator --
7 rubidium activity so then you hold it for decay to let the
8 rubidium decay away, and with its 75 second half-life, it
9 does that pretty quickly and typically you do it for one
10 hour. So that's about 48 half-lives of your rubidium. So
11 then you assay it again. So then your -- any activity you
12 measure is -- you'll be measuring rubidium, but you'll be
13 measuring strontium indirectly because, at that point, if
14 there's any rubidium activity it has to be there only
15 because there's strontium activity. So you measure the
16 strontium indirectly.
17 Likewise, you have to do it the same way for the
18 gallium generator. With the difference -- the big
19 difference, and this will be unusual for anything else we've
20 used, is that you have to hold it for two days because of
21 the long half -- because of the relatively longer half-life
22 of gallium-68, we have to let it decay away sufficiently so
23 that you have high confidence that any activity that you're
24 measuring at that point is due to germanium breakthrough.
25 Again, it's not approved in the U.S. but there is
26 -- it hasn't got official approval in Europe either but they
27 -- Europe is ahead of us with use of this radionuclide.
28 They have a proposed limit in the European Pharmacopoeia

1 that the activity needs to be 99.9 percent pure.
2 Another important difference with this generator
3 versus current generators we're using now is that the eluent
4 from a technetium generator or a rubidium generator can be
5 used directly into a patient, that as it comes out of the
6 generator, it's safe and good to use on a patient for
7 various studies. With this generator, you can't. It's in a
8 dilute hydrochloric solution, so it's not useful for any
9 imaging procedure at that point. You have to do some
10 chemistry with it. And the best way to do chemistry with a
11 68-minute half-life radionuclide is quickly. And the best
12 way to do something quickly is with a radiochemical
13 synthesis module.
14 Here's an example of three different versions that
15 are commercially available and they're computer control
16 pumps to elute the generator so you never have to touch the
17 gallium-68; it goes right to the generator to the reaction
18 vessel. Different reagents come in for repairing your
19 radiopharmaceutical. You can then push it through
20 purification columns, and then finally into your final
21 collection vial.
22 These are actually very, very similar to what we
23 use in PET now for FDG synthesis. So they're constructed
24 and operated very much the same way. And these mark the
25 images such that you'll never see one like this sitting on a
26 bench some place in a lab. It'll be in a hot cell, behind a
27 lot of lead.
28 The other important difference from technetium,

1 but similar to FDG, is that the quality control testing
2 would be a lot more extensive. I have to test the pH, for
3 pyrogens, for sterility. And chemical and radiochemical
4 purity testing would be a lot more involved for a gallium
5 radiopharmaceutical versus the relatively simple
6 radiochemist -- radiochromatography that we do for a
7 technetium rated pharmaceuticals.
8 Here's another example of gallium imaging. This
9 is with DODATOT, and this also shows where they're at with
10 this imaging modality now, in that there's a fused MR image
11 with the patient. And again, it was acquired quickly, one
12 hour after administration. And they're able to fuse the
13 anatomical information from the MR with the physiological
14 information from the DODATOT.
15 Dosimetry -- there's another important advantage
16 with gallium versus indium because dosimetry roughly is
17 about one half of the indium radiopharmaceutical.
18 So gallium-68 is also being used for other
19 receptors besides the somatostatin receptor, although that's
20 the biggest class that's being looked at right now. Here
21 are three other examples of -- for melanoma, patients for
22 angiogenesis, patients with the RGB version, and for
23 prostate for the bombesin.
24 Now another important advantage, or let me --
25 advantages for this agent, it's PET, so you have the
26 advantages of coincidence imaging from PET, the convenience
27 of a generator; so you have a long source for your gallium-
28 68, one that can last up to nine months. Plus another

1 reason these agents have a lot of interest right now is that
2 the chemistry is relatively simple to convert it from a
3 diagnostic agent to a therapeutic agent, and that's what we
4 have here. Here we have the same DOTO type agent, only the
5 only difference is now you have a therapeutic radionuclide,
6 the beta emitter, yttrium-90 in place instead of the
7 gallium-68. So it's the same receptor agent, same amino
8 acid sequence, so it's going to the same receptor, same
9 bifunctional chelator, just a different radionuclide. In
10 fact, this strategy's been in use now in Europe for well
11 over 10 years, so currently U.S. patients who can take
12 advantage of this, if they have the means, are going to
13 Europe for this diagnosis and therapy. It'd be nice to
14 treat those patients here. So, I tell you it's hard to
15 read, it's better up here.
16 So, this is our issue with our gallium generator,
17 with its parent germanium, is that a DFP -- or excuse me, a
18 decommissioning financial plan gets triggered. And the DFP
19 gets triggered because of the germanium unsealed, has half-
20 life greater than 120 days, and then you have to go to
21 Appendix B to figure it out, your limit, which is this:
22 Appendix B when the limits are in the first column, your
23 microcuries, for some commonly used radionuclides that we
24 use now, and then if you do the math in the appendix, you
25 take that limit, multiply it by 10^5, and then I've converted
26 that to curies so it's a little bit easier to read; so
27 that's the next column, that's the quantity to limit in
28 Appendix B, for the top four radionuclides in curies.

1 Now the problem with germanium is that it's not
2 listed in Appendix B, and when a radionuclide's not listed
3 in appendix B you go to a default value of 0.1 microcuries,
4 so after you do the math, convert to curies, your limit is
5 10 millicuries if you want to avoid a DFP; and that's a
6 problem in a lab because our generators need to be from, you
7 know, anywhere from 40 to 100 millicuries, so we can't -- we
8 can't escape that.
9 Here's another slide that I never intended you to
10 read, but it just gets into the difficulty and complexity of
11 a DFP. And the highlights are they're not cheap, you have
12 to have an independent contractor, that's mandated, and from
13 sites I talked to can run $15,000 to $20,000, you have to
14 revise it, renew it every time you resubmit your license,
15 and the cost for germanium. People were saying you have to
16 have a bond up to $1.1 million.
17 So the DFPs are costly and burdensome and a real
18 barrier right now. I'll skip through this one pretty quick.
19 Except that to point out they've got some wiggle room to try
20 to make it more palatable, but these tests are difficult for
21 a lot of places to meet; in this case a centralized radio
22 pharmacy would be an ideal place to have this, but then they
23 have to have a net tangible worth of $21million. And that's
24 just to get them away from part of the expense. Hospitals,
25 nonprofit colleges can get a little relief if their bonds
26 are sufficiently high grade, in the A's, but then this is a
27 Moody evaluation of their ratings versus all other public
28 health care finance rating, and it's probably hard to read,

1 but basically if you draw a line behind where the A's stop,
2 just a little more than one half of all health care
3 facilities have bonds that meet this test.
4 So the current regulatory status of germanium is
5 hampering its use. I think it's unintentional. I think
6 germanium fell through the regulatory cracks in 2005 when
7 byproduct material was redefined; it's missing from appendix
8 B part 30. DFP is a very onerous and expensive process. It
9 is being used in the states now though, but there's a wide
10 range of experiences by licenses. And most who have had
11 success are at large institutions who have already had a DFP
12 in place. So it was a seamless addition to their program.
13 But for those who don't have a DFP or can't meet the
14 financial test, this is a real barrier to being licensed for
15 germanium. And this is the really tragic part in my mind.
16 I talked to two licenses that were using the
17 gallium generator before 2005 and then when the new rules
18 and the DFP requirements came into place they had to stop
19 using them, because they couldn't afford to use them
20 anymore.
21 So my interpretation of how it got lost, how we
22 got into this predicament, and I would suggest perhaps it
23 got lost in translation. I think the scene from Tokyo works
24 well. It's a nice metaphor for the regulatory process.
25 There are a lot of people jostling you around on the
26 streets, bright lights vying for your attention, it's easy
27 to get distracted, with even an occasional dinosaur walking
28 around. For the record, I'm not suggesting anyone here is a

1 dinosaur, but I have heard comments that late at night in
2 this building you can hear heavy footsteps, but --
3 [laughter]
4 We'll move on. So this is collection of three
5 schedules appendices from the regs, and I think we have to
6 dig into this a little bit to try and figure out how or
7 where this went awry. I've said before, starting in 2005
8 when byproduct material was redefined to basically include
9 everything that's radioactive including, and at that time,
10 you know, an important category was added that of, in
11 essence, material made radioactive by a particle
12 accelerator, which then incorporated the PET radionuclides
13 and germanium. And it was a good change, because prior to
14 that there was a big dichotomy of how the different
15 radioactive material in different labs was handled or
16 regulated. So it was a good change. And it brought all of
17 our material under the purview of the NRC, and so now
18 they're covering everything from U238 with a half-life of
19 4.4 billion years to rubidium-82 with a half-life of 75
20 seconds. So they're pretty versatile.
21 So that was 2005. The first column 30.71 Schedule
22 B to Part 30, this is for exempt quantities of byproduct
23 material. Basically stay under these limits in microcuries
24 and you don't need an NRC license. The next column,
25 Appendix C to Part 20, quantities of licensed material
26 requiring labeling. Again this is in microcuries. Stay
27 under these limits if you've got a 100-microcurie source of
28 -- in a test tube in your lab, if it's 95 microcuries, I

1 don’t have to label it. And then, let’s see, let me back up
2 a little bit, Schedule B 30.71, it was last -- if you dig
3 into its history, last amended October 2007, Appendix C last
4 amended April of ’95, our problem child, Appendix B -- and
5 again, it has the same title as Appendix C, Quantities of
6 Licensed Material Requiring Labeling; same title, but they
7 are of course referring to different sections of the
8 regulations. And you can look into its history. It was
9 last re-designated in 1993, but last amended in 1980. And I
10 don’t want to quibble over re-designation versus amendments,
11 but still, even with 1993, that was a good 12 years before
12 byproduct material was redefined in 2005. I think what’s
13 really interesting from this chart is that regardless of the
14 schedule or appendix, you’ve got the same limits for all the
15 radionuclides, and in fact, if that had just continued into
16 the last one I wouldn’t be here, but.
17 So, I think from a regulatory perspective, I would
18 suggest that maybe it got lost in the translation. So
19 hopefully I’ve been able to demonstrate quickly the three
20 important points here: vast potential receptor
21 radionuclides; gallium in particular, in that it can create
22 smooth transition from diagnostic radio pharmaceutical, and
23 if you get a diagnostic pharmaceutical to work well, you’re
24 going to have a high probability that a therapeutic radio
25 pharmaceutical is going to work, be very effective because
26 of the specificity of the receptor aspect of it.
27 But we’re kind of stuck now; the nuclear medicine
28 community needs relief in the DFP requirements so its use

1 can grow throughout the U.S. So I'd like to indulge on the
2 committee and put forth a recommendation for the committee
3 to consider regardless of how germanium was or wasn't
4 considered in these appendices. I don't think the NRC ever
5 intended to create such a barrier for this important PET
6 radionuclide. So I'd like to recommend that -- ACMUI
7 recommends that the NRC provide regulatory relief for the
8 DFP requirements for the use of germanium-68/gallium-68
9 generator, given that there's a good possibility that all
10 this was unintentional, given that the licensees return
11 their generators back to the manufacturer if they're not
12 dispensing any germanium, and given that the burden of the
13 DFP is stifling the use of the radionuclide in nuclear
14 medicine. So what type of relief could this come in the
15 form of? There's the regulatory process, but we all know
16 that that takes many, many years. But would it not be
17 possible for quicker relief through something like an RIS, a
18 regulatory issue summary; and it could contain, you know,
19 restrictive statements such as a site gets a generator, they
20 have to send it back to the manufacturer. If they comply
21 with that the DFP requirement would be waived. Thank you.
22 CHAIRMAN MALMUD: Thank you. Are their questions
23 for Mr. Mattmuller? Dr. Langhorst.
24 MEMBER LANGHORST: I have a question first for NRC
25 staff. And are you able to grant an exemption in this case
26 for licensees that would put forth this is the number we
27 think for the germanium-68 generator? Is that a possibility
28 or is that not a possibility in licensing?

1 MR. EINBERG: I'm going to ask Dr. Howe to address
2 that and see what our options are for regulatory relief.
3 DR. HOWE: The NRC can grant exemptions. However,
4 the Commission set a policy a number of years ago that we
5 can't regulate by exemptions. So it's easy to grant one --
6 two exemptions, but if you're talking about a whole
7 industry, then you've got to go through rulemaking. With
8 regards to -- Mr. Mattmuller suggested perhaps a RIS
9 regulatory issue summary would be -- a RIS cannot be used to
10 change policy. It can only be used to explain the
11 regulations. So I don't think that's a viable route. I
12 would think that you would need rulemaking to address the
13 issue permanently. And the question that I have is how
14 common is this right now in the U.S.?
15 MEMBER MATTMULLER: In the U.S. it's, I believe
16 there's about four or five sites who are using the gallium
17 generator.
18 DR. HOWE: Under investigational --
19 MEMBER MATTMULLER: Yes. All under INDs. Yes.
20 But there're -- I do know, my institution and others at this
21 table are also interested in using it. So -- and I breezed
22 over one of the other -- as far as the expense of this,
23 these two sites that I talked to, one's in an NRC state,
24 one's in an agreement state. They both -- their cost
25 estimates were remarkably close. Fifteen to 24 that --
26 consultant, and then another 20 to 25 for the surety bond to
27 verify that they had the financial assurance, to cover the
28 DFP. So, very expensive for these sites.

1 MEMBER LANGHORST: Dr. Malmud, I had a second
2 question.
3 CHAIRMAN MALMUD: Please, Dr. Langhorst.
4 MEMBER LANGHORST: Thank you. And I don't know if
5 NRC staff can answer, maybe Ms. Bailey can answer. Are
6 there -- do agreement states maybe have this isotope
7 identified in their comparable tables, given that this was
8 always state regulated --
9 MEMBER BAILEY: They had known before.
10 MEMBER LANGHORST: Yeah
11 MEMBER BAILEY: It's possible, but I don't know
12 the compatibility of the chart once NRC -- if it's a
13 compatibility A or B now, that would have --
14 DR. HOWE: I can answer that, I believe. When we
15 were involved in the rulemaking, we went through and looked
16 very carefully at the state-proposed regulations, especially
17 for the norm side of things, to see if it was something we
18 needed bring into the NRC regulations that it was already
19 over in the agreement state, suggested regulations. And it
20 was nothing identified here.
21 MEMBER LANGHORST: Okay, thank you.
22 MEMBER MATTMULLER: I can tell you the Ohio
23 experience is that when you look at that last -- or look at
24 the schedule, instead of multiplying your limit by 10^5, in
25 Ohio it gets multiplied by 10^4. So actually our limit in
26 Ohio is 10 times more restrictive right now.
27 CHAIRMAN MALMUD: Dr. Suleiman.
28 MEMBER SULEIMAN: Clarification. So, if the NRC

1 or anybody would go back and recalculate, that would involve
2 rulemaking, to see if it fell under this category?
3 DR. HOWE: Right now NRC considers it's covered in
4 this other category.
5 MEMBER SULEIMAN: Under the default.
6 DR. HOWE: And so in order to bring it out of the
7 other category, you would probably have to go through
8 rulemaking, and you'd need a regulatory basis and a lot of
9 information to support it. So it's not -- this is a nice
10 thing to do, you need some more information to support it.
11 MEMBER SULEIMAN: Another quick question just for
12 Steve. Has anybody labeled it with gallium-67? Which is
13 not as heavy as --
14 MEMBER MATTMULLER: I'm not aware of, although I
15 don't know if that would give you any more advantages over
16 indium-111, since they're both PET agents.
17 MEMBER SULEIMAN: I was curious because it's the
18 same, I mean, the same isotope, so...
19 CHAIRMAN MALMUD: Any questions for Mr.
20 Mattmuller? What would you -- what are you proposing as a
21 result of your presentation, other than --
22 MEMBER MATTMULLER: I would still like a put
23 forward this recommendation to the NRC staff that --
24 CHAIRMAN MALMUD: And what is the recommendation
25 precisely?
26 MEMBER MATTMULLER: That as stated on the screen,
27 ACMUI recommends that the NRC provide regulatory relief for
28 the DFP requirements for the use of the -- excuse me,

1 germanium-68, gallium-68 generator.
2 CHAIRMAN MALMUD: That's a motion. Is there a
3 second to that motion?
4 MEMBER ZANZONICO: Second.
5 CHAIRMAN MALMUD: Seconded by Dr. Zanzonico.
6 Further comment or discussion? Dr. Suleiman.
7 MEMBER SULEIMAN: Would it -- rather than provide
8 regulatory relief just address about getting this
9 incorporated into the existing regulatory mechanism. I mean
10 --
11 MEMBER MATTMULLER: I mean add it into the current
12 35 revision?
13 MEMBER LANGHORST: So it's not 35. It's not that.
14 CHAIRMAN MALMUD: Yeah, yeah.
15 MEMBER LANGHORST: Separate rule making.
16 CHAIRMAN MALMUD: Dr. Thomadsen.
17 VICE CHAIRMAN THOMADSEN: I think that Mr.
18 Mattmuller has made a very good case for this, although I
19 don't feel that just at the end of this presentation that I
20 understand the issues well enough to vote on this, so...
21 CHAIRMAN MALMUD: Other comments? Mr. McDermott.
22 MR. MCDERMOTT: As for clarification, when you're
23 interested in regulatory relief and the decommissioning
24 funding plan requirements, are you speaking licensees who
25 would use the unit and would return it to the manufacturer -
26 - the manufacturer would still have their decommissioning
27 requirements. You're just talking about people through
28 licensing or other mechanisms won't actually have to

1 decommission.
2 MR. EINBERG: Right.
3 MEMBER MATTMULLER: Right, and I'd like to think
4 that further research given how the original index was set
5 up, that they had no idea this even existed or would be used
6 in this manner. But there could be a way to find relief.
7 CHAIRMAN MALMUD: Dr. Suleiman.
8 MEMBER SULEIMAN: I agree with Dr. Thomadsen's
9 first comment. I think I don't have enough information for
10 myself, but number two, could they lease it? You know, you
11 get the lawyers and the economists. Could they lease it --
12 would than mean, if a site is leasing it from the
13 manufacturer, does that relieve some of the responsibility
14 for meeting that?
15 MEMBER BAILEY: It's authorization requirements.
16 If it's authorized on their license then they have the go
17 through the decommissioning.
18 MEMBER SULEIMAN: So they're still licensed.
19 MEMBER BAILEY: Yes.
20 DR. HOWE: NRC and the agreement states regulate
21 the possessions, but we don't get into who owns it.
22 CHAIRMAN MALMUD: That was Dr. Howe answering Dr.
23 Suleiman's question. Any further discussion? There's a
24 motion on the floor. All in favor?
25 MULTIPLE SPEAKERS: Aye.
26 CHAIRMAN MALMUD: One, two, four, six, seven,
27 eight. Any abstentions?
28 MEMBER SULEIMAN: I abstain.

1 CHAIRMAN MALMUD: Two, three, four abstentions.
2 And any opposed? It's eight for, four abstentions, no
3 opposition. Thank you, Dr. Mattmuller -- I'm sorry, Mr.
4 Mattmuller. The next item on the agenda was already covered
5 by Sophie. You may have a few other points that you may
6 want to make to us.
7 MS. HOLIDAY: Yes, sir. I'd like to go over
8 changes to the recommendation chart.
9 CHAIRMAN MALMUD: Okay, please do.
10 MS. HOLIDAY: Okay, so I didn't have time to print
11 this just yet, since I just got a final recommendation from
12 Mr. Mattmuller. But I will start with item number 15, from
13 our closed session, we recommended to table the discussion
14 of the amendments to the bylaws the fall 2013 ACMUI meeting,
15 when there's adequate time to review the changes.
16 The next recommendation was Dr. Langhorst
17 requested NRC staff could add the draft guidance for the
18 draft expanded Part 35 rulemaking into the same docket
19 number as the rule making document, and that if this is not
20 possible she requests that the location or the docket number
21 of the draft guidance be clearly identified in the draft
22 that is the Part 35 rulemaking docket. Ms. Bhalla, of
23 course, did indicate that she's going to check if that's an
24 option for us.
25 MEMBER LANGHORST: May I add, and you can say vice
26 versa. So if you know the guidance, you want to be able to
27 be pointed to the docket number through the rulemaking too.
28 MS. HOLIDAY: Certainly. Okay, item 17, ACMUI

1 plans to hold a summer teleconference to discuss the medical
2 subcommittee analysis of the yttrium-90 microspheres medical
3 events. The dates proposed are June 18th, 2013, from 2:00
4 to 4:00 p.m. Eastern or backup date of June 20th, 2013 from
5 2:00 to 4:00 Eastern. Yes, Dr. Welsh.
6 MEMBER WELSH: Well, for clarification can you who
7 remind us who is on this subcommittee?
8 MS. HOLIDAY: I believe the members of the
9 subcommittee are yourself, Dr. Langhorst, Dr. Thomadsen, Dr.
10 Suh, I believe is on the medical event subcommittee. We're
11 going to pull up that list for you.
12 So moving on to item 18, that ACMUI endorsed the
13 Abnormal Occurrence Subcommittee report that was up for
14 approval. Item 19, that ACMUI had planned to hold the fall
15 2013 ACMUI meeting here at headquarters on September 9th and
16 10th, 2013, or backup date of the 16th and 17th -- [coughs]
17 -- excuse me. Item 20, and I may not have gotten this right
18 because I was coming in between. I believe Dr. Guiberteau
19 requested that NRC staff provide a link to the abstract that
20 was cited in Ms. Weil's presentation, and so it's --
21 MR. EINBERG: We will provide that.
22 MS. HOLIDAY: We will provide that to the full
23 ACMUI. And our last recommendation is that the ACMUI
24 recommended that NRC provide regulatory relief from the
25 decommissioning funding plan requirements for the use of the
26 germanium-68 gallium-68 generator. That was approved on an
27 eight approval basis and four abstentions. Are there any
28 comments?

1 CHAIRMAN MALMUD: Are there any comments? There
2 are none.
3 MS. HOLIDAY: Okay. I'd also like to add one
4 clarification. During my presentation for the ViewRay, one
5 of my communication resources I mentioned was the medical
6 listserver. I had the incorrect email address on there. So
7 for the record, if you would like to subscribe to the
8 medical listserver you can send an email to medical, M-E-D-
9 I-C-A-L, dash G-C dot resource at NRC.gov. Dr. Thomadsen.
10 VICE CHAIRMAN THOMADSEN: In any -- in just some
11 future email to us, would you just include that?
12 MS. HOLIDAY: Sure. Dr. Malmud, at this time I
13 would like to turn this over to Mr. McDermott.
14 CHAIRMAN MALMUD: Mr. McDermott.
15 MR. MCDERMOTT: And one final thing for Dr. Malmud
16 on his departure from the committee as chair, I have a
17 certificate of appreciation here for Dr. Malmud. In
18 recognition of 11 years of service and leadership, the
19 Advisory Committee on the Medical Uses of Isotopes, which
20 resulted in significant contributions to the work of the
21 U.S. Nuclear Regulatory Commission, we greatly appreciate
22 your service and advice.
23 CHAIRMAN MALMUD: Thank you Mr. McDermott --
24 [applause]
25 CHAIRMAN MALMUD: Thank you all. I will be very
26 brief and just say that I've been practicing for 40 years,
27 and this has been one of the most enjoyable experiences that
28 I've had in working with such a diverse group of talented

1 individuals, both those who have been on the committee and
2 rotated through and those who are here today. It's unusual
3 to be able to exchange information with other disciplines in
4 a collegial fashion. I also want to thank the individuals
5 who served as the communicator between the NRC and this
6 committee, and that dates back Angela McIntosh, Mohammad
7 Saba, and then of course Ashley Cockerham and Sophie
8 Holiday; they have all been a tremendous asset to us. And I
9 want to thank the NRC staff who really are most helpful,
10 most knowledgeable, and really have worked to try to assist
11 us in working within the regulations in order to effect the
12 changes that we think are necessary with implementations for
13 optimal patient care and the public safety. And sometimes
14 it's very frustrating working within the framework, but the
15 staff here has been very, very helpful. And even legal,
16 which usually is a roadblock --
17 [laughter]
18 -- has offered constructive advice to us. And we
19 thank NRC legal as well for being most collaborative in
20 circumstances which are always almost confrontational and
21 yet we manage to resolve them between the NRC staff, the
22 legal advice, and the desire of this committee with respect
23 to the patient and public welfare. So it's just been a
24 wonderful experience for me, and I appreciate very much and
25 I thank all of you.
26 [applause]
27 And I will turn the leadership over to Dr.
28 Thomadsen, who has graciously accepted the chairmanship, and

1 complementing him will be Dr. Guiberteau as the vice chair.
2 And you're in good hands. Thank you all. Have a safe trip
3 home.
4 [applause]
5 [whereupon, the proceedings were concluded at 12:30pm]