Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

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

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Friday, May 9, 2014

Work Order No.: NRC-755 Pages 1-106

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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

SPRING 2014 MEETING

+ + + + +

OPEN SESSION

+ + + + +

FRIDAY,

MAY 9, 2014

+ + + + +

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

MEMBERS PRESENT:

BRUCE R. THOMADSEN, Ph.D., Chairman

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

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

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

STEVEN R. MATTMULLER, Nuclear Pharmacist

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

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

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

LAURA M. WEIL, Patients' Rights Advocate

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

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

NRC STAFF PRESENT:

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

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

MICHAEL FULLER, Designated Federal Officer

SOPHIE HOLIDAY, Alternate Designated Federal Officer, ACMUI Coordinator

DOUGLAS BOLLOCK, FSME/MSSA/RMSB

SUSAN CHIDAKEL, OGC/GCLR/RMR

JACKIE COOK, RIV/DNMS/NMSB-B

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

JIM DWYER, RI/DNMS/MB

SARA FORSTER, RIII/DNMS/MLB

CASSANDRA FRAZIER, RIII/DNMS/MLB

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

JOE GIESSNER, RIII/DNMS

LATISCHA HANSON, RIV/DNMS/NMSB-A

MICHELLE HAMMOND, RIV/DNMS/NMSB-B

VINCENT HOLAHAN, Ph.D., FSME/MSSA

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

KEVIN NULL, RIII/DNMS/MLB

DENNIS O'DOWD, RIII/DNMS/MLB

BRYAN PARKER, RIII/DNMS/MLB

PATTY PELKE, RIII/DNMS/MLB

WILLIAM REICHHOLD, RIII/DNMS/MLB

GRETCHEN RIVERA-CAPELLA, FSME/MSSA/RMSB

LIZETTE ROLDAN, Ph.D., RIV/DNMS/NMSB-B

MOHAMMAD SABA, RES/DSA/RPB

TOYE SIMMONS, RIII/DNMS/MLB

REBECCA TADESSE, RES/DSA/RPB

FRANK TRAN, RIII/DNMS/MLB

LESTER TRIPP, RI/DNMS/MB

MEMBERS OF THE PUBLIC PRESENT:

DAVID ALLARD, Pennsylvania Bureau of Radiation Protection

MAXWELL AMURAO, Columbia University Medical Center

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

LISA BRUEDIGAN, Texas

SUE BUNNING, Society of Nuclear Medicine and Molecular Imaging

JESSICA CLEMENTS, Texas

PETER CRANE, unaffiliated

ROBERT DANSEREAU, New York State Department of Health

RAY DIELMAN, Florida Department of Health

KAREN FLANIGAN, New Jersey Department of Environmental Protection

CINDI GILBERT, North Carolina Nuclear Medicine Technologists, Inc.

BRIAN GORETZKI, Arizona Radiation Regulatory Agency

GEORGIA HEARN, American Society of Nuclear Cardiology

ANGELA HILL, Arkansas Department of Health

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

RALPH LIETO, Trinity Health System

JOSE MORALES, MD, Hima San Pablo (Puerto Rico)

VICKI MORRIS, University of Cincinnati

ELIZABETH PEETZ, Mallincrokdt Pharmaceuticals

MICHAEL PETERS, American College of Radiology

GLORIA ROMANELLI, American College of Radiology

DANIEL SNYDER, Geisinger Health System

TOD SPEER, MD, Willmar Regional Cancer Center

PARRISH STAPLES, Ph.D., National Nuclear Security Administration

MICHAEL STEPHENS, Florida Bureau of Radiation Control

JOY STEPHENSON, Florida Bureau of Radiation Control

GLENN STURCHIO, Mayo Clinic

JULIE TIMINS, MD, unaffiliated

CINDY TOMLINSON, American Society for Radiation Oncology

PAUL YURKO, Veterans Health Administration

A-G-E-N-D-A

P R O C E E D I N G S

1:01 p.m.

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

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

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

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

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

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

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

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

CHAIRMAN THOMADSEN: Give it a shot.

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

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

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

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

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

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

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

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

CHAIRMAN THOMADSEN: Yes.

MEMBER MATTMULLER: I fully agree.

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

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

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

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

MEMBER LANGHORST: Yes.

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

MEMBER LANGHORST: I know that Ms. Dudes asked

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

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

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

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

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

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

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

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

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

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

MEMBER LANGHORST: So maybe --

CHAIRMAN THOMADSEN: It could go both ways.

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

CHAIRMAN THOMADSEN: That sounds good.

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

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

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

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

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

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

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

CHAIRMAN THOMADSEN: Dr. Howe.

DR. HOWE: It appears an [inaudible] the table is the problem. So if we were to change the table that would go [inaudible].

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

can provide us with the more sure I will be [inaudible]. So I would defer to your charge…

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

DR. HOWE: Say that again?

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

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

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

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

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

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

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

Our number is truly [inaudible]. It's just going from one page in this book at 602 to page 435 and you may find some useful information. Just a consideration.

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

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

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

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

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

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

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

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

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

MS. HOLIDAY: Dr. Thomadsen?

CHAIRMAN THOMADSEN: Yes.

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

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

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

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

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

MS. HOLIDAY: Thank you.

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

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

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

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

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

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

not likely to exceed 5 millisieverts as a result of the [inaudible].

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

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

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

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

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

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

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

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

NRC also has contacted [inaudible] computational * with the new ICRP biokinetic model and Monte Carlo calculation to reach a larger patient and the target and extrapolate doses in greater situations such as transportation, hotels, and nursing homes.

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

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

The phantom has capability of bending the arms and legs. This permits us to model the realistic situations. And also it was necessary for us to know the distribution of iodine in the body as a function of

time following administration of the therapeutic doses.

That's why we use the new ICRP biokinetic model. This model was produced later in the Oak Ridge lab for ICRP. And doing a study using phantom and biokinetic model showed that dominance [inaudible] was some exposure from the patient, the thyroid and the bladder.

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

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

I just show you the different scenarios that they are missing in the literature and we did the calculations by using ICM v6 [inaudible] and our phantom.

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

This is also transportation. This is transportation, sitting patient behind a member of the public. This is next sitting beside the patient, a member of the public. And also this is another

situation in a transportation case, another transportation case.

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

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

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

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

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

And also identify possible sites that we can

go and collect that data. If it is possible to go to any site and collect data under [inaudible] we can go and collect data on doses received by the workers and visitors.

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

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

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

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

And the general public exposures like transportation, again, there was nothing in the

literature. And we calculated all the possible scenarios that as mentioned we could.

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

What we do review equation use review assumptions, these two plots. We have all the [inaudible] and also interact with medical center. We know that it's very important to, as you recommended before, it was very important to us. And we get more influence on the subject. Hopefully we will have a much better Reg Guide this time.

If I'm [inaudible] NRC submit the results of its review on calculation in the detailed report. The draft report is under review. It's titled "A Review of Technical Literature Dose Calculations and Recommendations.

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

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

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

CHAIRMAN THOMADSEN: Thank you. Comments

and questions from the Committee?

I just have sort of a business-related question. You do if I understood correctly a research contract or a contract presumably for some entity to perform field maintenance. Is that correct?

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

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

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

MR. SABA: This is contract that are happening with the offices that are responsible for contract. They [inaudible] because it's small business, so only small business companies can respond to this solicitation.

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

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

CHAIRMAN THOMADSEN: It strikes me as a

suboptimal way. Because I think the most credible entities in terms of scientific credibility would be --

MR. SABA: As far as businesses, they can use universities. If they are affiliated with universities then they can use universities.

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

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

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

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

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

CHAIRMAN THOMADSEN: Not to label [inaudible] it just seems that especially sort of doing it in the

holistic guidance [inaudible] politically sensitive nature of this it just seems that expanded research has a contract including initially university-based labs or research organizations rather than commercial entity will give the result, will give the greatest credibility.

MR. SABA: It's commercial – it's commercial. Only small businesses can respond.

CHAIRMAN THOMADSEN: Why is that?

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

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

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

CHAIRMAN THOMADSEN: Thanks. Dr. Welsh.

MEMBER WELSH: Thank you. I think my question might have been answered, but first I want to commend you for taking this important step. A number of years back when this issue first reared its head, I suggested that we could do all the calculations in the world and be 100 confident in our calculations but until

it's corroborated by some type of actual data there are still going to be some naysayers out there.

And at that time I think I volunteered to design a study. And so I hope that the study that you are working on is very cost-efficient because this shouldn't cost more than a few thousand dollars.

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

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

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

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

But right now we're just trying to see whether

or not it could be done and if the data could be collected.

MEMBER WELSH: I guess if I could follow up. I think that is my subtle point, that this should be easy. And with all due respect to them as a DOE national laboratory it probably isn't doing as much radioiodine thyroid therapy as people in this room are.

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

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

CHAIRMAN THOMADSEN: Dr. Suleiman.

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

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

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

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

CHAIRMAN THOMADSEN: Ms. Weil.

MEMBER WEIL: So I'm concerned about a selection bias in -- with respect to the sites that would be amenable to the collection of their data. It's likely to be the sites with best practices rather than sites that are less concerned with following the regulations and the professional best practice guidelines.

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

MR. SABA: So what do you suggest?

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

CHAIRMAN THOMADSEN: Dr. Suleiman.

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

select to your heart's content.

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

MR. SABA: We will talk to CRCPD next two weeks. So we will get inputs from them.

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

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

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

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

MR. SABA: We have to have a reasonable

distribution for field size and also for the site size and also for [inaudible].

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

MR. SABA: I can't talk about the contract. That's why I'm tight. I can't talk about it.

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

MEMBER ZANZONICO: It just strikes me that the details of the contract are not disclosable. I think there's a little debate about the calculation of results. Whether by Monte Carlo or analytically the results seem to converge. And the heart of this effort and what's going to be the sites is the field data collection. And it would seem the input of the [inaudible] in the prime of the tests, in the prime of the charges of this contract [inaudible] invaluable.

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

MR. SABA: First, after we are done with the comments it's going to be discussed in the next ACMUI meeting. So our report includes researcher reviews and

calculations. And you can go into details about it.

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

MS. TADESSE: Basically once the solicitation is out it's in the federal website where we could share that information with you and maybe [inaudible] that we would evaluate what your inputs are. We could look at that.

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

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

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

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

MS. TADESSE: I would expect. Yes.

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

MS. TADESSE: We might.

CHAIRMAN THOMADSEN: Dr. Welsh.

MEMBER WELSH: I don't mean to belabor the same point over and over again, but this does strike me as possibly being at odds with what I heard this morning

about effective communication and utilization of medical expertise on the ACMUI and our connections.

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

It's a field study. We'll want to – I'm not talking about the calculations. That's all been done by the subcommittee and we hope that you come up with the same results that will be addressed in the CEMA [inaudible] what that amounts to.

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

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

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

CHAIRMAN THOMADSEN: You're members of the

general public. Right. You have to keep secret things secret from. Everyone in this room is not an NRC employee. This is open session -- well, that can be changed.

But the point is that in closed session, in closed session, right, in closed session we'd all be NRC employees like you and Rebecca and. But you get my point though.

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

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

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

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

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

And I'm looking at Sophie and OGC over there. I think all -- the action that we need to take as the staff coming out of this is make sure that we're within the FACA rules, right. And make sure that we're following those rules and still achieving the results that we want to achieve which is the only engagement.

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

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

And for us if it's making more documents public

earlier, or you know, trying to get them out earlier so that it is a collaborative effort as opposed to a review and dispose and comment. Because that doesn't seem to be the most effective use of people's time or money.

So I think there's an action to take here. I know Rebecca wants to say something. And we're probably not going to solve it. This is a process issue and there's a technical issue that we need to discuss.

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

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

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

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

MS. TADESSE: Yes.

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

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

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

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

MEMBER SULEIMAN: First off, I think for everybody else this process may be far enough along, but we may not have much input. I mean, I think you have

to appreciate they have a procurement process.

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

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

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

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

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

But I think I would hate for this thing to come and we spend another exercise critiquing it. I mean, this patient exposure thing I think goes back to when I got on the committee. I mean, I guess you can drag this out into the 22nd century. I mean, this thing is

just, it's never, never ending.

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

MS. TADESSE: We are in the earliest process right now. So any input that we could get from you guys, it would be helpful. And we're just at the solicitation to get contract. We can change some of the statement. It hasn't been let out yet. So that's what I'm offering.

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

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

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

MS. DUDES: Again – I'm sorry.

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

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

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

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

And if we really care about the people that we're trying to protect we would want the best information now and not in the 22nd century.

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

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

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

MS. DUDES: Yes and we will take that as an action. And we have to, again, I think we're stuck in

a bit of a process but I don't think it's at all insurmountable.

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

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

MR. SABA: Also on the draft report with each stage will be gone through a review.

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

MR. SABA: I'm sorry? That's -- no. Other than this report that we have the other reports that comes from the contractors. Anything -- we are supposed to have a [inaudible]. A * should go to FSME and all the FSME *.

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

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

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

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

For example, in NCRP Report No. 155 and in various papers that in fact the internal contamination dose does appear to be minimal to the point of being negligible. And that the doses to individuals measured in a home environment with dosimeters would find uptake measurements.

And I emphasize a [inaudible] thyroid individual has radioiodine uptakes on the order of 25-40 percent. And those uptakes, the activities can be measured extraordinarily sensitively, the thyroid uptake, probes and [inaudible] methods.

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

contamination.

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

Likewise the estimation of external dose by patient and family members wearing dosimeters, by calculational methods, whether analytic or Monte Carlo, also seem to converge since it's a good point where the total doses are really under the 500 mg limit and often on the order of 100 mg or less.

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

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

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

MR. SABA: No.

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

MR. SABA: No, for child we are not using --

this is for external dose.

MEMBER WEIL: External.

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

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

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

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

MR. SABA: Yes for child. But --

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

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

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

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

the statement of task.

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

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

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

And it's at this point we could possibly put a member of your committee on that review panel to take part and look at the actual designs that come in. Because quite frankly we have no idea what the designs are going to be.

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

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

And that's why in this space we really can't

go into the details about that statement to ask because it could give some contractor an advantage and we can't have that. Otherwise the whole process could be challenged.

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

DR. HOLAHAN: Yes, very much so. Whether it be a contract proposal for this or going to the National Academies you've got to be very explicit in what you're looking for in that statement of task.

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

Dr. Welsh.

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

And there's an advantage regarding approval studies and field studies. A journal can junk out.

And I think that as peer reviewers and journal editors we feel very strongly about that.

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

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

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

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

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

MR. SABA: -- to the calculation.

MEMBER WELSH: Well, I'm talking about field

studies now. So, there's input that could be done that and we're happy to provide that to you.

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

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

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

So yes, it would be wonderful to have our input at all points, at all times in all these projects. But the government is going to issue an RFP and as a conflict of interest issue, we can't do that.

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

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

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

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

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

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

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

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

MR. CRANE: Yes, please.

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

Would you like to make a statement?

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

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

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

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

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

I think that I agree with Dr. Zanzonico that's important to collect field data. I think I agree with Dr. Welsh that this is the best way to assure that the concerns that are felt by members of the patient's community and others are satisfied.

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

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

I have said in the past that I think that as far as patient instructions are concerned, NCRP 155 is

a great place to start. I've praised it in the past and Dr. Zanzonico for his role as co-author.

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

There's an instruction that patients should flush the toilet twice after using it, rinse the shower stall, tub, et cetera. Wipe up spills of urine, saliva and/or mucus with tissues and flush it down the toilet. All of that tells us that bathrooms are a source of contamination that can be harmful to others and that's why I think that you can''t dismiss internal contamination as negligible and you can't do a study of hotel rooms that doesn't look at the bathroom.

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

And that's consistent with the ICRP, consistent with the NCRP that these are on an annual

basis, not per-release.

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

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

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

And if that's true in a hospital, it's certainly true in hotels. I'm interested to see that the -- Dr. Saba's presentation, that one of the scenarios he takes into account is beds in adjoining rooms that are head to head. And if that's the case,

you've got a thyroid to thyroid distance that is a lot closer than the 2.2 meters estimated by Dr. Zanzonico in the 2010 report.

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

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

We have a comment from a member of the general public, if you could identify yourself.

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

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

But we would welcome the opportunity to work with this group on reviewing the instructions that are already out there which, you know, a lot of those of you

in the room have been part of creating those and working with those going forward on that.

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

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

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

I'd just like to clarify some points and whether your citations to 155 are correct.

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

For example, one could reduce public doses further, for example, by somehow confining diagnostic nuclear medicine patients from leaving the hospital. They contain activity; they irradiate individuals around, but at very low doses, but non-zero doses. But that would be completely impractical. The number of patients on a daily basis undergoing diagnostic nuclear

medicine studies would make those sorts of measures impractical.

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

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

The other issue I'd like to emphasize, that you do allude to the 100 millirem limit. And as I said when I was on the NCRP scientific committee that wrote that report, I do not endorse that limit. The committee was bound to adhere to that limit or recommended dose because that was the one promulgated by the NCRP.

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

The -- and just one final item about the flushing twice. That has nothing to do with contamination. Many toilets in non-public buildings, in homes have traps beneath the bowl where the activity

remains until the next flush. Often that's not the case in public buildings and hotels and so forth which have different kinds of plumbing. So I just wanted to make that point.

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

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

CHAIRMAN THOMADSEN: One thing.

MR. CRANE: That in the spirit of ALARA I think that one of the productive areas for thought is are there things we can do short of hospitalization that could reduce dose such as keeping people in a safe room for a few hours until they've had their first urination; for example, something to get past the area in which vomiting is most likely.

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

CHAIRMAN THOMADSEN: Thank you very much for

that final comment. I think thinking outside the box is possibly a good approach in this case.

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

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

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

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

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

molybdenum-99 supply.

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

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

So first and foremost I am the director of the European and African Threat Reduction Office, who also has a functional responsibility for the conversion of civilian research reactors and medical isotope production processes from the use of highly enriched uranium to low enriched uranium to accomplish an international threat reduction objective.

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

The leftmost box under the Convert function defines the HEU minimization aspect of our program. Complementing that are two other offices with the functional responsibility to remove and dispose of

those excess nuclear radiological materials once they have become available for disposition through conversion activities or when they are no longer used.

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

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

And in the United States, we feel it's very important to do what we are asking others to do. And also we have identified that these materials can be stolen and used for illicit purposes in the United States where they're co-located with population centers and/or national interest objectives.

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

First and foremost was our longstanding goal of reaching minimization.

Secondarily, based upon supply shortages primarily that took place in the 2009 time frame of the simultaneous shutdown of several major producers we were tasked with the objective to develop a long-term

reliable supply of moly-99 for patient needs.

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

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

Australia is fully and has always been an LEU-based supply. South Africa through NTP Radioisotopes is transitioning. In fact, we understand they are now approaching 50 percent of their production capacity as LEU-based moly-99.

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

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

To date, IRE is on schedule to meet that

commitment. Mallinckrodt has experienced some technical difficulties, not surprising given the complexity of the process, and they probably won't make their 2015 time frame. Regardless, they are a very strong partner and making tremendous efforts in that path towards conversion to LEU.

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

What's very important and happening in 2016, they''ve clearly and repeatedly stated that they will cease isotope production at their facility in Canada in October of 2016.

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

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

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

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

It's their commercial obligation to attract whatever market share and adjust to whatever market share they can capture. That is their commercial and economic obligation. The same is true for the cooperative agreement partners we're working with.

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

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

future.

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

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

A very important word in that statement is to accelerate the establishment of reliable supplies. And this is done in cooperation with commercial partners both domestically as well as internationally.

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

The Global Threat Reduction Initiative had the primary obligation and responsibility to lead this simply due to our longstanding cooperation with both the foreign and domestic entities that were utilizing the highly enriched uranium or developing processes for the

production of the moly-99.

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

The second bullet is also an extremely important weakness in the current supply chain that by all identifications including by the Organization of Economic Cooperation Development, the OECD, have identified that subsidies by foreign governments has undermined the ability for industry to reinvest in itself to support current and/or ongoing production.

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

Unfortunately, the subsidies continued and in many cases weren't identified that they were even taking place until recently, or was not acknowledged, or the governments were not cognizant that they were taking

place until recently. So all governments have also pledged to remove those subsidies from this commercial activity.

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

In addition, the third bullet highlights events that we've seen take place numerous times, once again over the past several years. But to the commercial industry''s credit, they've learned from past mistakes or just the past situation and they have been able to coordinate and prepare such that patient needs are met while facilities go down.

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

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

approximately a year time frame.

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

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

We are also working towards trying to diversify the technology that the industry works on to ensure that there are no single points of failure in this industry so that we can be sure to achieve our long-term objective of a reliable supply of moly-99 patients.

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

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

In the June 2012 time frame there was a U.S. government Interagency group that is working on

reliable supplies of moly-99. Led by the Office of Science and Technology Policy the White House released six statements to encourage reliable supplies of moly-99 produced without highly enriched uranium.

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

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

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

And as the medical community works and I'm sure you're aware, it's very appropriate and a standard operating procedure that any pharmaceutical product is going to be traced from cradle to grave. It's very difficult to trace the financial aspect of

radiopharmaceuticals and how they're produced, but it is very easy to identify the genesis of the material that is used. So that is a reason that labeling is associated with a non-HEU based moly-99.

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

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

And the status is that the Veterans Affairs had issued a policy statement recently calling for the Veterans Health Administration facilities to begin preferentially procuring non-HEU based moly-99 as they become commercially available.

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

Third is that we will examine potential health insurance payment options that might promote a sustainable non-HEU supply of moly-99. In January 1 of 2013 Centers for Medicare and Medicaid Services issued

a new rule that offers a $10 premium payment to any medical procedure that uses moly-99 based radiopharmaceutical products that are produced without HEU.

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

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

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

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

This is a slide that we used in some recent

meetings with radiopharmacies of trying to educate them of the process that we're working through also.

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

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

The first to follow the lead that we have done with the Veterans Administration to ask for the non-HEU based moly-99 that is available today. That we encourage private payers to adopt the $10 add-on payment. Surprisingly enough, they're not necessarily so enthusiastic to move in that direction. That is their own business decision as we best understand it.

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

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

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

But we are always open to input to CMS. And in fact we congratulate CMS that in very few circumstances can they be proactive, but in this circumstance they actually were proactive that they put the $10 payment on the table based upon their projection of what the cost would be for using that non-HEU based moly-99.

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

So we're working to try to dispel as best we

can with the facts that we're aware of and/or we take from the industry to offset the myths that we perceive are propagating through the industry.

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

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

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

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

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

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

As conversion to LEU is considered an externality on the isotope production facility

governments as I mentioned before about the nuclear security summit objective in 2012 between Belgium, the Dutch, France and the United States, we have as governments pledged to commit money to support those conversion efforts and in fact have provided funding necessary for those conversion efforts as much as commercial industry is willing to accept.

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

The next myth that we're working to try to expel is that hospitals must -- let me say it this way. I'll just read it, actually. I don't mean to insult your intelligence, I was trying not to do that, but it's probably best and most appropriate if I do this.

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

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

And there are numerous ways to overcome this.

In fact, we have examples from radiopharmacies that have made different business models that are being effective, and they are in fact able to also utilize the $10 reimbursement.

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

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

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

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

And I loved that analogy when they stated that, that utilizing this modern technology they were able to

track the materials through the systems and obtain the reimbursements.

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

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

The $10 add-on reimbursement has not had an effect on the uptake of LEU moly-99. There was a previous Society of Nuclear Medicine medical imaging and CMS data that was aligned very well with levels of LEU moly-99. We understand that there's some updated data that does show that the uptake is somewhat smaller than the amount of LEU moly-99 that's available. Regardless, they are definitely in the same range.

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

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

DR. STAPLES: It's roughly 30 percent.

MEMBER ALDERSON: Thirty percent.

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

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

There have been asks to incorporate that. That gets extremely complicated in terms of how the tracking and the financials work.

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

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

Roughly have of that is pure LEU moly-99. The

other half of that is blended as we understand it.

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

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

In fact, the industry uses a unit called the six-day curie. And the six-day curie takes into account the difference in shipping from facilities at different locations. It's how the industry has always functioned.

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

I also understand that from some of the -- for some of the facilities, I'm not going to name any which ones take longer, but that from some of the other

facilities Australia who is geographically the most distant, they can actually get material to U.S. pharmacies faster than some of the other producers can. So, there's again no real validity in terms of the distance being a direct correlation to decrease in supply.

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

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

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

Is it the hospitals receive the $10 add-on payment, not the rest of the moly-99 supply chain. The

best analogy I heard in this case is when you go to buy a car you don't pay for the windshield, you don't pay for the tires, you don't pay for all of the nuts and bolts that are associated with it. You pay a dealership for the car and all of those costs that you pay the dealership propagate down through the supply chain. That's exactly what we are expecting to take place in this industry.

I don't need to go through the facts because it basically gives a very similar analogy. We''re transparent about the $10 being available to pay for the costs of the full cost recovery non-HEU based moly-99 at the beginning of the supply chain and to allow the market dynamics and contract negotiations between commercial entities take place to properly pay for their costs associated with producing the material.

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

Two points here. First and foremost, both through the OECD and our own independent assessment while the transition over the next several years is going to be tight in terms of supply dynamics and emergencies or unplanned outages can always take place we do project that there will be sufficient supplies for

patient needs in that time frame barring any unforeseen outages and/or other dramatic emergencies that take place in that supply chain. But that will cause a shortage more likely than not regardless of how this industry is going to be transitioning.

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

They specifically state that around the 15 percent level is when a subsidy is taking place from government activities. Our rough figure of merit for all of the different commercial projects is roughly that they are $200 million total cost. In that respect we're a minor funding partner and nearer the threshold of the World Trade Organization's 50 percent subsidy threshold.

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

CHAIRMAN THOMADSEN: Thank you very much.

Dr. Alderson?

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

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

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

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

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

DR. STAPLES: I'm happy to as much as possible

in that the entity -- the second entity you're referring to doesn't actually ring a bell.

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

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

I do want to differentiate because there's always a question that comes up regarding Missouri University Research Reactor which is an HEU-fueled research reactor.

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

So at Missouri they have an agreement in place with us and are working strongly towards converting the

fuel of that research reactor to LEU as a completely separate program and process. Just to be very clear in the distinction between those elements.

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

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

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

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

But then there also is other LEU-type

production methodologies. There's Morgridge Shine is one of our cooperative agreement partners as well as B&W. Babcock & Wilcox had a program where they were using a solution, either reactors and/or targets of LEU material to produce the moly-99.

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

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

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

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

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

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

There is also a direct technetium production that is being produced in Canada just as a reference point. And that's where they will take as the PET industry currently utilizes cyclotrons and take targets and they will directly produce tech.

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

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

effective and commercially viable for their interests.

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

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

MEMBER WELSH: This is a question for the Chair. As you and the staff know, I am directly involved in the radioisotope production. And through an entity that has not been named here yet. I know Eric [inaudible] is quite familiar with this.

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

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

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

CHAIRMAN THOMADSEN: Maybe just discretion

would be the appropriate call at the moment.

Any other --

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

DR. STAPLES: Yes, actually that's an excellent question. And what I'll refer to is information from two previous studies that were done, one by the National Academy of Sciences and a more recent one by the OECD reflecting to the cost of conversion activities from HEU to LEU and impact on the industry.

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

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

The cost of the radiopharmaceutical I believe

is roughly $30. And that's the total radiopharmaceutical.

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

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

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

CHAIRMAN THOMADSEN: Thank you. Dr. Suleiman?

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

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

So, depending on the yield because you can yield efficiently or you can yield less efficiently, my

calculations show that the entire cost, the entire cost of the nuclide is on the order of $10, let alone the differential between HEU and LEU.

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

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

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

DR. STAPLES: And what we actually have observed again more just figure of merit is that as different entities have supply availability and depending upon long-term contracts in place or not the cost of generators fluctuates tremendously, sometimes by factors of 4 or 5 at the generator level dependent upon how the supply chain is currently functioning,

where the material is coming from and total magnitude of supply dependent upon facility outages.

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

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

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

In all due respects what we've always heard from the medical industry is they didn't care if it was HEU or LEU. They wanted to know that they have it available to meet patient needs.

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

And this is a very important tool to the medical community. And for the few dollar differential they wanted the supply available. That was really the

basic theme of the response coming from the medical community. And that really did propagate down through.

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

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

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

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

In fact, being able to be in front of this group and the voice and understanding that you have going out through the community also just to help us address this

as a group to ensure this important radioisotope is available for patient needs throughout the future.

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

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

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

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

MEMBER MATTMULLER: I don't either.

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

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

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

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

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

So that's not at the 3,000 6 to 8 curie level is all I think it's appropriate for me to say, but it is well before the 2016 time frame. And it does depend upon a number of factors of their commercial availability.

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

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

We are -- also have a program under evaluation

for additional support through our cooperative agreement partnership. So they actually are a strong program moving forward.

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

Our cooperative agreement with General Electric, which spurred the June 2012 Interagency public statement or White House public statement, our assessment and understanding and agreement with them is that they were actually pausing that program due to commercial status and that it was roughly on a 2-year rolling window once they would resume activities.

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

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

MEMBER MATTMULLER: And while I was familiar with the announcement between Morgridge and GE, but it's somewhat perplexing because it was to -- there wasn't

-- if we're reading the same announcement GE has agreed to buy any amount they might produce.

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

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

MEMBER MATTMULLER: In the UK. The UK generator?

MEMBER SULEIMAN: It's just a --

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

What we've been advocating for is the commercial industry needs to invest in its own future.

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

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

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

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

(Laughter)

DR. STAPLES: To be really honest. But let's say in this case the commercial activities that are associated with us, we're supportive of them. In fact, the activities that we're putting in place for the U.S. Interagency are supportive of all entities that are trying to produce moly-99.

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

We remove all possible obstacles. I think the complement of both the FDA and the NRC from a regulatory

perspective, they obviously do not bypass any of the regulatory process. But they certainly make resources available that these are high-priority projects and try to work them through the system as rapidly as possible to support the process and procedures of their respective regulatory organizations.

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

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

CHAIRMAN THOMADSEN: One minute.

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

DR. STAPLES: Yes.

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

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

So, in a perfect world, yes, they probably have

a policy statement they do that but the reality is not even close.

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

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

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

So, for item 1 this was where we talked about the subcommittee for medical policy statement. And item 2 was where Dr. Thomadsen had added Dr. Alderson to that policy statement subcommittee.

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

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

Item 3 was where the ACMUI recommended to endorse this report which includes the recommendation

to make no changes to the current medical policy statement. That was presented on yesterday. Are there any objections to that? Seeing none I go onto item 4.

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

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

Moving onto item 5. This is just to say that Dr. Thomadsen added Mr. Frank Costello to the medical event subcommittee.

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

The subcommittee is specifically charged with evaluating the cost of the decommissioning funding plan

for the use of germanium-68, its effect on the future clinical use of new gallium-68 radiopharmaceuticals and how appropriate regulatory relief may be gained.

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

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

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

I would provide this to the committee as a whole either tonight or next week.

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

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

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

CHAIRMAN THOMADSEN: Do we have any conflicts?

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

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

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

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

MEMBER WEIL: So do I.

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

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

MEMBER WEIL: I have a conflict.

VICE CHAIRMAN GUIBERTEAU: I have a conflict.

MS. HOLIDAY: Two conflicts. Are there any

other conflicts for October 27 and 28?

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

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

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

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

MS. HOLIDAY: Okay.

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

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

CHAIRMAN THOMADSEN: Dr. Welsh.

MEMBER WELSH: This is [inaudible] on the 29th and 30th?

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

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

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

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

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

MR. FULLER: I just have one point [inaudible] I just want to give you a heads up for something to think about. I've looked historically at the times that we've scheduled these meetings. The idea is to have two per year approximately six months apart.

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

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

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

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

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

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

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

I look forward to trying to find ways within

the FACA process to continue benefit earlier and that we can be contributors rather than review and dispositioners.

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

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

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

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

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

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

MEMBER COSTELLO: So these are sort of ad hoc.

CHAIRMAN THOMADSEN: Yes.

MEMBER COSTELLO: Single issue.

MR. FULLER: Yes.

CHAIRMAN THOMADSEN: Yes. A very narrow

agenda.

MEMBER COSTELLO: But with some advance warning.

CHAIRMAN THOMADSEN: Oh, definitely.

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

CHAIRMAN THOMADSEN: We can't surprise anything.

MS. HOLIDAY: That's right.

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

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