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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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OPEN SESSION

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THURSDAY, JANUARY 22, 2009

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The committee met at 1:00 p.m. via teleconference, Leon S. Malmud, Chairman, presiding.

COMMITTEE MEMBERS:

LEON S. MALMUD, M.D., Chairman

RICHARD J. VETTER, Ph.D., Vice Chairman

DOUGLAS F. EGGLI, M.D., Member

DARRELL R. FISHER, Ph.D., Member

DEBBIE B. GILLEY, Member

RALPH P. LIETO, Member

STEVEN R. MATTMULLER, Member

SUBIR NAG, M.D., Member

ORHAN H. SULEIMAN, Ph.D., Member

BRUCE R. THOMADSEN, Ph.D., Member

WILLIAM A. VAN DECKER, M.D., Member

JAMES S. WELSH, M.D., Member

MICKEY GUIBERTEAU, Diagnostic Radiologist

NRC STAFF PRESENT:

HECTOR BERMUDEZ, Region II

COLLEEN CASEY, Region III

JACKIE COOK, Region IV

CHRIS EINBERG, Designated Federal Official, FSME

SANDY GABRIEL, Region I

DONNA-BETH HOWE, Ph.D., FSME

ROB LEWIS, Director FSME/DMSSA

GRETCHEN RIVERA-CAPELLA, FSME

ASHLEY TULL, FSME

DUANE WHITE, FSME

JACK WHITTEN, Region IV

ALSO PRESENT:

GARY BECKER, ABR

JENNIFER BOSMA, ABR

DEAN BROGA, ABMP

MARY BURKHART, Illinois

DAWN EDGERTON, CBNC

LYNNE FAIROBENT, AAPM

DONALD FREY, AAPM

EMILY GARDNER, ASNC

ANTHONY GERDEMAN, ABR

BRUCE HAFFTY, ABR

SUSAN LANGHORST, WUSTL

MELISSA MARTIN, AAPM/ACR

ALSO PRESENT: (CONT.)

RICHARD MORIN, AAPM

MIKE PETERS, ACR

DOUGLAS PFEIFFER, AAPM

AMANDA POTTER, AAPM

GLORIA ROMANELLI, ACR

KAREN SHEEHAN, Fox Chase

HARRY SKENE, Geisinger

STEPHEN THOMAS, University of Cincinnati

CINDY TOMLINSON, SNM

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P R O C E E D I N G S

1:04 P.M.

MR. EINBERG: Good afternoon. As the Designated Federal Officer for this meeting, I'm pleased to welcome you to this teleconference public meeting of the ACMUI. I am the Chief of the Radioactive Materials Safety Branch and I have been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

The meeting was announced in the December 24, 2008 edition of the Federal Register, Volume 73, page 79197.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the view of the Committee and values their opinion.

I request that whenever possible we try to reach a consensus of the procedural issues that we

will discuss today. I also recognize that there may be a minority or dissenting opinion. If you have such opinion, please allow them to be read into the record.

At this point I would like to perform a roll call of the ACMUI members that may be participating today.

Dr. Leon Malmud, Chairman, Health Care Administration.

Mr. Malmud? We know he is here. He previously responded.

Dr. Richard Vetter, Vice Chairman, Radiation Safety Officer.

DR. VETTER: Here.

DR. MALMUD: I'm sorry, you couldn't hear me. Malmud is here.

MR. EINBERG: Okay, thank you.

Dr. Douglas Eggli, Nuclear Medicine Physician.

DR. EGGLI: Here.

MR. EINBERG: Dr. Darrell Fisher, patient advocate.

DR. FISHER: Here.

MR. EINBERG: Ms. Debbie Gilley, State Government Representative?

(No response.)

Mr. Ralph Lieto, Nuclear Medicine Physicist.

DR. LIETO: Here.

MR. EINBERG: Mr. Steve Mattmuller, Nuclear Pharmacist.

MR. MATTMULLER: Here.

MR. EINBERG: Dr. Subir Nag, Radiation Oncologist?

DR. NAG: Present.

MR. EINBERG: Dr. Orhan Suleiman. Food and Drug Administration Representative.

DR. SULEIMAN: I'm here.

MR. EINBERG: Thank you. Dr. Bruce Thomadsen, Medical Physicist Therapy.

DR. THOMADSEN: Here.

MR. EINBERG: Dr. William VanDecker, Nuclear Cardiologist.

DR. VANDECKER: Present.

MR. EINBERG: Dr. James Welsh, Radiation Oncologist.

DR. WELSH: Here.

MR. EINBERG: We have a quorum as there is at least seven members present.

Dr. Mickey Guiberteau is representing the diagnostic radiologists. Dr. Guiberteau does not have

voting privileges, but he will listen and speak on behalf of the diagnostic radiologists.

I would like to thank Dr. Guiberteau for acting in this capacity.

Is Dr. Guiberteau on the phone?

DR. GUIBERTEAU: Yes, I am.

MR. EINBERG: Thank you. I now ask NRC staff members who are present to identify themselves. We'll start with the individuals in the room here and then we'll turn it to the other NRC staff members on the phone.

As previously mentioned, my name is Chris Einberg.

MS. TULL: This is Ashley Tull.

MR. LEWIS: Robert Lewis.

MR. EINBERG: That's everybody here at headquarters.

Are there NRC members on the phone?

MS. GABRIEL: From Region I, Sandy Gabriel.

MR. BERMUDEZ: I'm Hector Bermudez.

MS. CASEY: Region III, Colleen Casey.

MR. WHITTEN: Region IV, Jack Whitten and Jackie Cook.

MR. EINBERG: Okay, thank you. Two other

NRC staff members who just joined us, Duane White and Gretchen Rivera-Capella.

Dr. Malmud, ACMUI Chairperson will conduct today's meeting. Following a discussion of each agenda item, the Chair at his option, may entertain comments or questions from members of the public who are participating with us today.

Before we do that, we'd like to identify members of the public who are participating on the phone. Ashley Tull will read off a list of names of people who have indicated that they will be participating.

MS. TULL: James Albright, Gary Becker.

MR. BECKER: Here.

MS. TULL: Jennifer Bosma.

MS. BOSMA: Here.

MS. TULL: Dean Broga.

MR. BROGA: Here.

MS. TULL: Mary Burkhart.

MS. BURKHART: Here.

MS. TULL: Will Davidson. Dawn Edgerton.

MS. EDGERTON: Here.

MS. TULL: Lynne Fairobent.

MS. FAIROBENT: Here.

MS. TULL: Donald Frey.

MR. FREY: Here.

MS. TULL: Emily Gardner.

MS. GARDNER: Here.

MS. TULL: Anthony Gerdeman.

MR. GERDEMAN: Here.

MS. TULL: Robert Hattery.

(No response.)

MS. TULL: Susan Langhorst.

MS. LANGHORST: Here.

MS. TULL: Melissa Martin.

MS. MARTIN: Here.

MS. TULL: Richard Martin.

(No response.)

MS. TULL: Richard Morin.

MR. MORIN: Here.

MS. TULL: Jorge Munoz.

(No response.)

MS. TULL: Mike Peters.

MR. PETERS: Here.

MS. TULL: Doug Pfeiffer.

MR. PFEIFFER: Here.

MS. TULL: Amanda Potter.

MS. POTTER: Here.

MS. TULL: Gloria Romanelli.

MS. ROMANELLI: Here.

MS. TULL: Karen Sheehan.

MS. SHEEHAN: Here.

MS. TULL: Harry Skene.

MR. SKENE: Here.

MS. TULL: Stephen Thomas.

MR. THOMAS: Here.

MS. TULL: Cindy Tomlinson.

MS. TOMLINSON: Here.

MS. TULL: Is there anyone's name I did not call?

MS. GILLEY: Ashley, Debbie Gilley.

MS. TULL: Hi, Debbie.

MS. GILLEY: Thanks.

DR. HAFFTY: Bruce Haffty from the ABR. Also, I'm on the call.

MR. EINBERG: Okay, thank you very much. At this point I'd like to turn the meeting over to Dr. Malmud.

DR. MALMUD: Thank you. Are you able to hear me well?

MR. EINBERG: Yes, we are.

DR. MALMUD: There are two items on the agenda for today. The first item is the NRC briefing on recent meeting with the international regulators on

the issue of medical isotope shortages. And then that will be followed by the ACMUI Subcommittee recommendation for authorized user status delay for the ABR candidates.

So if we may, we'll begin with the NRC staff briefing on the recent meeting with the international regulators.

MR. EINBERG: Thank you, Dr. Malmud. This is Chris Einberg and I'll be giving the presentation on the recent meeting with the international regulators and medical isotope shortages.

As you all are aware of the potential shortages or the current shortages of the medical isotopes. An international meeting was held in Paris, France on January 7th through the 9th and the meeting was hosted by the French Nuclear Safety Authority, ASN.

Representatives from other countries participated and the representatives were from Australia, Belgium, Canada, France, The Netherlands, South Africa and United Kingdom.

Additionally, at the meeting there were several associations represented as well. The Association of Imaging Producers and Equipment Suppliers and the European Association of Nuclear

Medicine were also present as well as the Nuclear Energy Agency.

I participated in the meeting with Dr. Charles Miller who is the Office Director for the Federal and States Material Environmental Management Programs here at the NRC.

The purpose of the meeting was to coordinate the supply of radio pharmaceuticals and manage the transition period between the shut down of old reactors and commissioning of new ones.

There will be a subsequent meeting at the end of the month hosted by the Nuclear Energy Agency, NEA, and the findings from the meeting, the ASN meeting from January 7th through the 9th, will be provided to the NEA as a starting point for their workshop on isotope shortages.

Now I'd like to go through some of the highlights that were discussed, relevant to the various countries that were represented there and the status of their isotope production.

First, alphabetically, we'll go to Australia. Australia's OPAL reactor has recently replaced the HIFAR reactor as the only research reactor and is in the process of hot commissioning a new molybdenum-99 production process using low

enriched uranium, LU targets, and fuel.

Next, Belgium. Belgium's representative indicated that Belgium's BR2 research reactor has been in operation since 1962 and is the only producer of molybdenum-99 in their country. It currently produces approximately 9 percent of the world's supply. On August 22, 2008, an international nuclear events scale level 3 radiological release occurred at the Institute of Radio Elements, IRE, processing facility. Production restarted on November 3rd, 2008.

Canada. The Canadian representative discussed that it has increased its production of molybdenum-99 during the recent outages of The Netherlands HFR reactor, high flux reactor. The National Research Universal Reactor, also known as NRU, its license expires in 2011 at which time a safety case for the life extension will need to be made.

France. The French situation is the OSIRIS Research Reactor will be shut down in 2015. The average capacity has been about three percent of world supply, but it has recently increased production during the shut down of the reactor in The Netherlands.

A new research reactor, JHR, is under

construction and is anticipated to be operational in 2014. JHR will have approximately twice the current capacity of the OSIRIS Research Reactor for molybdenum-99 production. However, no decision has been made to use the reactor for production of molybdenum-99.

The Netherlands. The Netherlands high flux reactor is currently shut down due to a small bubble stream coming from the reactor, from the reducers in the reactor outlet line. A sleeve with epoxy sleeves is now foreseen to be installed in May 2009. However, the epoxy has yet to be qualified.

The representatives from The Netherlands expressed that there is the serious possibility that the HFR reactor will be decommissioned. When operating, it currently supplies approximately 30 percent of the world's supply.

South Africa. The Safari Research Reactor currently uses highly enriched uranium, but is in the process of switching to low enriched uranium. It has been in operation for 43 years and supplies approximately 10 percent of the world's supply.

In the United States, Dr. Miller and I reported that the U.S. currently has no research reactors producing molybdenum-99. However, both the

University of Missouri and Babcock & Wilcox are exploring the possibility of producing molybdenum-99. Any production will be at least four to five years away.

In the United Kingdom, the representative indicated that they currently do not have any plans for molybdenum-99 production and currently do not have any production.

The meeting culminated with the participants preparing a draft report, the findings of the meeting on the safety and availability of radio pharmaceutical production facilities. The draft report stressed that there is an urgent need to act to reinforce the complete production chain leading to the essential service to society. And as I indicated, that report will be provided to NEA as a starting point for their workshop at the end of the month.

With that, I'm willing to take any questions.

DR. MALMUD: Are there any questions? I hear no questions in which case we thank you for the report.

MR. EINBERG: Okay, thank you.

MR. MATTMULLER: I'm sorry, Dr. Malmud, this is Steve Mattmuller. I do have a question.

Could you clarify, I'm sorry, what is going on in The Netherlands? I thought I heard you say they're trying to fix the problem, but they may decommission it?

MR. EINBERG: That's correct. They are trying to fix the problem. They would like to install a sleeve to fix the problem and currently it's anticipated that it will be installed in May 2009. However, the epoxy that will be used to make the repair has yet to be qualified and the regulator has indicator that there is discussion going on whether there's a serious possibility that the reactor may not be restarted at all.

MS. GILLEY: Chris, can you provide the subcommittee that's looking at this for the Commission briefing your notes?

MR. EINBERG: I cannot. There are additional notes on this. They're foreign government controlled information.

MS. GILLEY: Okay. Thank you.

DR. WELSH: Jim Welsh here. I have a quick question. I understood the University of Missouri and Babcock Wilcox may or have they made a commitment to producing molybdenum-99 perhaps in the next four years?

MR. EINBERG: They are exploring the possibility of it.

DR. WELSH: Thank you.

DR. FISHER: Darrell Fisher with one quick question. Chris, the topic of Canada's MAPLE-1 and MAPLE-2 reactors come up and could you give a quick summary of the outcome?

MR. EINBERG: The MAPLE-1 and MAPLE-2 reactors were discussed. However, it's not foreseen that either MAPLE-1 or MAPLE-2 will be operational.

MS. FAIROBENT: Dr. Malmud, Lynne Fairobent from AAPM, may I ask a question?

DR. MALMUD: Certainly, Lynne.

MS. FAIROBENT: In getting ready for the NEA meeting at the end of the month, Chris, are you all looking at the National Academy of Sciences report that just came out and is any of the information from the DOE and SAC meeting last week, will that be factored in at all? And is DOE having anyone participate in the NEA meeting?

MR. EINBERG: First, I know DOE was invited to the NEA meeting. There were numerous representatives invited so I believe that they will be participating.

We have received the National Academy's

report on LEU versus HEU and we're reviewing that. Regarding NRC participation, we will be -- we will have a representative there taking notes and however, we'll be in more of the observation mode.

MS. FAIROBENT: Thank you.

DR. MALMUD: Any other questions?

MR. MATTMULLER: This is Steve Mattmuller again.

DR. MALMUD: Yes.

MR. MATTMULLER: As The Netherlands reactor presents about 40 percent of the world's supply of molybdenum-99, the possibility that that may be shut down is devastating news. I guess I'm stunned and through the process of this teleconference I would assume that most of the other Committee members are stunned also. But that is devastating news.

DR. MALMUD: We would agree.

DR. EGGLI: This is Doug Eggli, can I ask a question?

DR. MALMUD: Please do, Doug.

DR. EGGLI: Did any of the other people representing either reactors or governments that are producing molybdenum-99 in view of that news offer any potential solution to the shortfall for medical isotopes?

MR. EINBERG: Other than that there's a need for coordination amongst the operating reactors to coordinate shutdowns and maintenance schedules. The -- everybody at the meeting recognized the importance of this issue and this needs to be communicated back to the respective governments that this is a potential crisis situation and so there is a heightened awareness of this issue.

DR. EGGLI: Thank you.

DR. VANDECKER: This is Bill VanDecker. Is there a time line for the discussion that this is going to generate to looking towards potential solutions beyond just the current upcoming meeting? I mean where do we see this timeline-wise going over the next year or two?

MR. EINBERG: Well, in the first meeting with ASN, I believe just the start of getting the international dialogue started on this important issue, the next meeting, the NEA meeting at the end of the month. I'm sure they will have recommendation as to a process or a path forward. But as far as a timeline, that's been laid out at this time, I'm not aware of anything.

DR. EGGLI: This is Doug Eggli again.

DR. MALMUD: Yes, Doug.

DR. EGGLI: Just to make sure it's clear what the current impact of the reactor shutdown in The Netherlands is, we cannot currently get generators. We get bulk tech and unit doses during the day and we can get no technetium for emergency after hours studies.

DR. GUIBERTEAU: This is Mickey Guiberteau in Texas, and we are having exactly the same problem down here. And when we get bulk tech, we can't get it in the amounts we need even to compound what we need on a daily basis for our patients. The problem, other than just interruption of good patient care is the fact that when we can't deliver these studies on a dependable basis, then alternative examinations, often more expensive ones are performed. And I'm afraid it becomes debilitating for the entire nuclear medicine community in terms of being able to dependably provide these services.

DR. MALMUD: It is a significant issue and I'm not certain how we can assist in addressing it.

Questions from NRC staff?

MR. LEWIS: One way you can assist the NRC, this is Rob Lewis, is if there are any unnecessary regulatory obstacles that you see are impeding technetium availability, please bring those

to our attention. We can do everything within our walls to make sure the regulations aren't part of the problem. I mean they'll always be some part of the problem, but we can look at the unnecessary burden if there is any.

DR. WELSH: This is Jim Welsh here with a comment.

DR. MALMUD: Yes, Jim.

DR. WELSH: My original question about Babcock & Wilcox and the University of Missouri, whether they have made a commitment or are contemplating it was asked because of this particular problem that is even greater than we initially anticipated.

So I would suggest that the United States seriously look into making isotopes available within our own boundaries since we are the largest consumer of this and make sure that as the decisions are being contemplated that regulatory issues are not likely to present any insurmountable or unnecessary obstacles as we move this forward. This seems like a logical solution to the problem.

MR. LEWIS: I think we've talked to Babcock and Wilcox on that point. I don't know that we talked to Missouri yet.

MR. EINBERG: The other point is that Babcock and Wilcox and the University of Missouri were invited to the meeting at the end of the month and I believe that they'll be participating.

DR. MALMUD: Any other comments?

MR. MATTMULLER: Yes, this is Steve Mattmuller again. I would like to say that I believe someone mentioned this is a potential crisis. For those of us who depend on a generator every week, and have been holding our breaths waiting for The Netherlands reactor to come back on line, I would say we're -- and now with this recent news we are in a crisis.

In terms of what the NRC can do, in looking at a preliminary version of the report on substituting LEU for targetry, the report seems to indicate it's technically feasible and there really shouldn't be any barriers to implementing this right away whereas there's a lot of us, myself included, that say there are some significant issues that weren't necessarily addressed accurately in the report.

So for the NRC today, I would say do not embrace this report. Do not put any pressure at all on our current fragile supply of moly-99 with the

additional burden of converting their HEU targets to LEU targets. It would be the final nail in the coffin I'm afraid for our industry, if that were to happen.

Thank you.

DR. SULEIMAN: This is Orhan. I think this is clearly beyond the scope of the Committee right now, but my observation is that some of this has been generated by Homeland Security interest, the whole issue of going away from highly enriched uranium for security reasons and whatever, and the shift over to LEU has caught some of the reactors and caused them, anyway that transition has been going on.

The other thing is economic. I mean the way I understand the cost of the radionuclide component of radio-labeled drugs is it's really the cheaper component. You've got economic factors. You've got government regulatory policy that comes from Homeland Security, from safety, from a variety of other issues. I -- maybe this will play out all right in the end because it's going to cause a crisis in the short term, but I think the only way to do is put pressure, respectively from any possible source.

I mean if it's a crisis, then people need to hear about it and bring it to the attention -- this is no different than a couple of years ago when the

DOE was going to cut back on the funding for the atomic bomb survivors because they thought all the data that was necessary had been -- you know, the community stood up and hollered and they came back and you know, allowed the funding to continue on this very, valuable, long-term study.

So I think there's no organized way or somebody you're going to go to solve this, but I think it's going to take collective yelling and screaming to raise the issue to a level where people will do something.

DR. MALMUD: Are you suggesting a form of collective yelling and screaming to use the term that you used?

DR. SULEIMAN: From my vantage point, I just see that the nuclear medicine community specifically is the victim of a set of events that it really has no direct control over. And so how do you solve that? I mean you can attend meetings, have committees make recommendations. I'm just wondering you need to get recommendations made that are going to be heard by the powers that be that can do something about it. It's not being heard by other people who can't do anything about it.

So if the Committee -- what's the problem?

Why -- it's not that the reactors are shutting down. Why are the reactors shutting down? Are there economic reasons? Are there security reasons? There's an underlying basis as to why they're shutting down. They're just a symptom of a series of other events.

Is the HEU, that issue looks like it's been resolved, favorably or unfavorably. I mean you've seen all these reactors switching over to lower enriched uranium targets. So debating that to me is of questionable value, but I think the key thing is which reactors are willing to try to get on line. This Missouri thing, I'm sure they're going to look and see if it's cost effective, if they can pull it off, they'll do it. They probably are wondering is the regulatory climate going to change in the next year that will make it less feasible for them, I suspect.

I'm not an economic analyst here. But I think there are other factors that are in play. I think all we can do as a professional group say this is -- this is going to wipe out a very necessary medical profession.

DR. MALMUD: Thank you, Orhan. Any other comments?

MR. EINBERG: This is Chris Einberg. Just to address Dr. Suleiman's comment. One of the major factors why these are shutting down are these are aging reactors. They're all over 40 years old and some are over 50 and so that's the primary reason why these research reactors are shutting down.

DR. MALMUD: Clearly, however, if there were a profit in reinvesting in these reactors, it would be done.

DR. FISHER: Dr. Malmud?

DR. MALMUD: Yes.

DR. FISHER: Darrell Fisher. To that very point, I'm following up on what Orhan Suleiman said. One of the problems is that political pressures are driving production by low enriched targets. According to Fung Sale Devalier (phonetic) of the South African research and development company, NECSA, which operates the reactor in South Africa, he said that there's although it's possible to produce moly-99 using low enriched targets, the problem is higher cost. And there is no proven process for moly-99 production from low enriched uranium on an industrial scale without substantial federal subsidies to make it possible, because the costs are much higher. And there are a number of other factors that come out in

the recent National Academy of Sciences report.

DR. MALMUD: So it clearly is an economic issue. Normally, in the marketplace though if something becomes more expensive to produce, the price goes up. Are there artificial controls on the prices?

DR. FISHER: No, but I think the impact is that companies wanting to invest in future production are impacted by the higher costs that they face for making moly-99, that in fact, it's not competitive with production using high enriched targets.

DR. VANDECKER: This is Bill VanDecker. Dr. Malmud, for clarification sake, look at this from a cost basis. I would say that technetium being the most commonly used isotope and God thank the fact that it is relatively cheap right now to produce it in radio pharmaceuticals for all the uses we use it for. If that pricing begins to go up, given the current reimbursement environments, both on the hospital side and the outpatient side, it could well be a useful medical field that prices itself out of existence, so we're both hurt by the fact that we have access fears and threatened access here in addition to the fact that the fix of the access problem can't take the situation to becoming nonviable in the long-term as well.

DR. MALMUD: Yes, I agree with you, Bill. I guess the question for us is in our role at the ACMUI, what action do we think could be taken to assist in dealing with the current crisis?

Is there someone here representing the SNM?

MS. TOMLINSON: Sorry, I was on mute. Yes, I'm here. This is Cindy Tomlinson.

DR. MALMUD: Cindy, what's the Society planning to do?

MS. TOMLINSON: We have been looking into -- we've talked to BWXT and to MIR and to a few other companies as well. Right now, we are still looking over the NAS report. We have issued a press release where we basically say it's okay, but there are other factors that have -- that we think that they have neglected to look at such as the economics and a few other things.

We're trying to get as much information as we can. This is the first I've heard about the meeting earlier this month, but a lot of that information was very useful and I will be taking it back to our task group. I did know about the meeting at the end of the month, and we will have a representative there. I think we're sort of because

there are so many different people looking into this, we're not quite sure where we necessarily fit in.

DR. MALMUD: Cindy -- I'm sorry, who wanted to speak.

DR. VANDECKER: I'm sorry, Dr. Malmud. This is Bill Vandecker. I think this goes to my question on timeline for flushing out alternatives because I think that all the practitioner society certainly would love to engender grass roots support for letter writing campaigns and pushing a solution, but I think that the first goal here is to have a first round of what are the most viable solutions and therefore that will identify where the push should go and where the letter writing campaigns and concerns should go rather than a more diffuse fear of where we are right now. I think the NRC is going to have to help us in sorting out where those discussions are going and where we can be helpful.

DR. MALMUD: I think we all agree with you, Bill. In order to protest something, we really have to offer a potential solution. That doesn't mean we have to offer the money to solve the problem, but at least a path to solving the problem, hoping that either industry or government will find the resources or the profitability in doing it.

Are there any other suggestions regarding this issue?

MR. LEWIS: Dr. Malmud, this is Rob Lewis. Just a word of caution in terms of the NRC's role and the Committee's role that it can go into promotional aspects. That's really a job for, in the Federal Government, for DOE. We just have to stay on the safety side, on the security side of the equation.

DR. MALMUD: Thank you. And I wasn't suggesting that ACMUI take an aggressive role in it, but if we can -- if we have some individuals within the Committee who can offer potential solutions, they should feel free to make the recommendations.

As Dr. VanDecker pointed out, there's no point in protesting something unless you -- unless there is potential solution that we would be assisting and recommending. But it wouldn't be the function of the ACMUI. It might be a function of some of the members of the ACMUI and their other roles, but not the ACMUI. And I think we appreciate that. Thank you for reminding us of it.

DR. SULEIMAN: Dr. Malmud, this is Orhan again.

DR. MALMUD: Yes, Orhan.

DR. SULEIMAN: In my capacity here at FDA,

we have -- we probably have somebody from the Department of Health and Services attending the meeting later on in the month and with the change in Administration and everything else, we've just been scrambling. But we're trying to do what we can from within because I think it's more of a medical care issue, but that's just one voice. So that's just an FYI.

DR. MALMUD: Thank you. If we may, we'll move on to the next item on the agenda, if there's agreement to do so. Thank you. I take the silence as agreement.

The next item on the agenda is the ACMUI Subcommittee recommendation for authorized user status delay for the American Board of Radiology candidates. And we're scheduled to discuss the Subcommittee recommendation for individuals to achieve authorized user status via the Board's certification pathway with particular attention to the period when a gap exists between the completion of training and the experience and the issuing of the Board certificate.

Who wishes to speak first to this issue?

DR. EGGLI: Leon, this is Doug Eggli, the Subcommittee chair.

DR. MALMUD: Yes, Dr. Eggli.

DR. EGGLI: Hopefully, most of the Committee members have seen the draft report distributed by Ashley. The first three quarters of that report sort of lays out the problem and the last one quarter of the report finds the solution. To be succinct, the Board certification pathway is probably the preferred pathway for obtaining authorized user status for trainees who are trained, whose training leads to certification by a Board that the NRC recognizes.

The alternative pathway exists to provide a pathway to achieve authorized user status for those for individuals who are qualified, but do not train under the auspices of a training program that leads to Board certification that NRC recognizes or for a rare individual who trains on the Board certification pathway, but for some reason doesn't quite get there.

With the change in the training paradigm which is coming down the road for particularly the American Board of Radiology, 100 percent of the people completing the initial training period for the American Board of Radiology will have about a 15-month gap before they could achieve authorized user status. And so we were trying to develop a way of essentially maintaining relevance of the Board, relevance of

primacy of the Board certification pathway for achieving authorized user status.

The solution, we thought, should be designed such that it wasn't a tailored solution for American Board of Radiology, but could be applied by -- could be used by any certification board that perceived a problem with a time gap between when their trainees completed training and when they finally achieved Board certification.

But on the other hand, no Board would be required to implement a solution that they did not need, if they were not experiencing a problem with a time gap and in no way would a solution to the time gap require a change in the training paradigm for any of the Board.

It was the intent of the Committee to provide essentially a way to maintain this Board certification pathway and the proposed solution is basically that the certification boards would provide a certification of completion of all the training and experience requirements for AU eligibility by that certification board and that AU eligible certificate would fulfill the requirements of the Board certification pathway. And it was intended again to then -- what this means -- preserve the primacy of the

Board certification pathway.

DR. MALMUD: Therefore, if I understood what you just said and what is proposed in the document that I've looked at, it is that the Boards themselves would adhere to the alternate pathway requirements within the Board training program.

DR. EGGLI: No, that's actually not the case.

DR. MALMUD: Would you please explain it again.

DR. EGGLI: Okay, that basically the Boards would train residents or trainees as they currently do as their programs -- as their programs are certified to do, maintaining the same kind of record keeping requirements and I think the primary difference between the alternate pathway and the Board certification pathway is the burden of the record keeping requirements as to exactly what goes on during the period of training, but that the Boards would train their residents as they do now, examine their residents as they do now, but provide a separate certification that these individuals have met all of the training and experience requirements for Board certification and with respect to NRC requirements would issue a separate AU eligible certificate that

would be issued prior to the final Board certification certificate.

DR. MALMUD: Thank you for clarifying that. Is there discussion of that proposed solution that Dr. Eggli's Subcommittee has brought forth?

DR. VETTER: This is Dick Vetter. A question for Dr. Eggli, how does that differ -- I assume that a candidate would need to complete some paperwork for the Board to evaluate and how does that differ from the paperwork for the alternative pathway?

DR. EGGLI: The record keeping requirement for the alternative pathway is fairly rigorous on the distribution of the training components and I don't believe the Boards are required to maintain documentation at that level of detail. The Boards have told the NRC that their training program complies with all the requirements of 10 CFR 190, 10 CFR 290, 10 CFR 390 as relevant, but they are not required to document exactly how they achieve that training to meet those requirements. So the program directors document to the American Board of Radiology that the residents have met the training requirement. But documentation -- the detailed documentation that's required by the alternate pathway is not required in the Board certification pathway.

DR. MALMUD: Thank you, Dr. Eggli. Has NRC staff agreed with that observation?

MR. EINBERG: Dr. Malmud, we're still evaluating the report and we haven't had a chance to take a position on it yet.

DR. MALMUD: Okay, so this is a recommendation from Dr. Eggli's Subcommittee, but it has not yet been totally evaluated by NRC staff.

MR. EINBERG: That's correct.

DR. THOMADSEN: Dr. Malmud?

DR. MALMUD: Yes, who is speaking, please?

DR. THOMADSEN: Bruce Thomadsen.

DR. MALMUD: Yes, Bruce.

DR. THOMADSEN: Does the ADR have clarification on the documentation requirement compared to the alternate pathway?

DR. MALMUD: May we address that question to someone from the ABR?

MR. BECKER: Is Mickey on? Did we lose Mickey Guiberteau?

DR. MALMUD: Dr. Guiberteau? I think we might have lost him.

DR. GUIBERTEAU: Who's that? I'm sorry, I punched the wrong button. I was punching the mute button to speak and --

DR. MALMUD: Mickey?

DR. GUIBERTEAU: Yes.

DR. MALMUD: There's a question as to whether or not the ABR has had a chance to review the recommendation of Doug Eggli's Subcommittee.

DR. GUIBERTEAU: Yes, we've basically been moving in this direction in terms of supporting this proposal by actively changing some of our policies in terms of when to provide a certificate, our willingness to provide a certificate stating that one, we have received assurance, as we now do from the training programs that the candidates have completed their training and experience; and two, they have finished the exam related to radiation safety as per the NRC curriculum as expanded by the radiological experience, in providing that certificate at the time they actually finish their training, rather than waiting until they finish their additional post-residency experience for another 15 months.

Essentially nothing has changed in terms of the record keeping would change in terms of the record keeping of the Boards. It would simply be an opportunity because the reason this pathway has been -- for residency has changed, in terms of the Board examination is to come in line with many other medical

specialties who require an additional year of experience before they take their final clinical boards. But in actuality, all we're really doing is decoupling the certificate that we now give with AU eligibility, dividing that into two parts.

We would give the AU eligible part when it is -- everything has been complied with like we now do and the clinical part of that, 15 months later.

So essentially, it's just dividing our current certificate into two parts.

DR. MALMUD: Thank you for that explanation.

Doug?

MR. PFEIFFER: Dr. Malmud, this is Doug Pfeiffer with AAPM, may I ask a question?

DR. MALMUD: Please do.

MR. PFEIFFER: Would these AU certificates have some sort of time limitation on them? If an individual should complete the training portion, but then is unable to make it through the certification process then, is there some method for revoking that AU status?

DR. GUIBERTEAU: This is Mickey Guiberteau. We haven't discussed that in terms of how that would come about. We actually are open to

suggestions, but principally are interested in taking this one step at a time. But I do understand your question.

DR. EGGLI: Leon, this is Doug Eggli to respond to that?

DR. MALMUD: Yes, Doug.

DR. EGGLI: Again, come back to the primary difference between the alternate pathway and the Board certification pathway is the burden of record keeping. What the NRC has said is that based on the -- my interpretation of what the NRC is saying to the Boards is that based on their submission they believe that the Boards' mandated training program meets all the requirements for AU status.

It is the intent of the Subcommittee that this decoupled certificate would serve permanently as having met all the training and experience requirements to be an authorized user and in fact, the final Board certification is a clinical statement and not necessarily relevant, so that the AU eligible certification stands on its own as the certification document that fulfills the requirements of the Board certification pathway.

DR. MALMUD: Thank you for that clarification.

DR. LIETO: Dr. Malmud?

DR. MALMUD: Yes, who is speaking?

DR. LIETO: This is Ralph Lieto. I would also like to support Dr. Eggli's statement in that I would not be in favor of having this training and experience if the candidate has met those requirements, just by failure maybe to complete the Board certification requirements, they've already demonstrated that they've met the radiation safety aspects which is basically what this first part would address before they completed that 15 months' clinical requirement.

So if they've met the requirements for that radiation safety aspect, it should not be rescinded just because they didn't pass the Board certification aspects of it that come later on.

DR. MALMUD: Thank you for that supportive statement, Ralph.

Other comments?

DR. GUIBERTEAU: This is Mickey Guiberteau again. I think what Ralph is saying and what the Committee's intent was as Doug has said is that currently the NRC has said that competence in clinical practice is not its concern, that it is with the safety aspects and that's what the original

certificate, the initial certificate the NRC eligible, AU eligible certificate would be. And the clinical certificate would come after.

So in that sense, any expiration of that certificate would be whatever the expiration, would be under the current portion of the rule that deals with obtaining AU status within a specific time period.

DR. MALMUD: Thank you. Other comments?

MS. CASEY: This is Colleen in Region III.

DR. MALMUD: Yes.

MS. CASEY: I've been listening carefully to what you're saying and I'm just offering some observations and thoughts. I'm a Materials Licensing Reviewer here.

Would it be possible for the -- let's say the first level certificate that is granted after the physician's training and experience is completed, could there be a time-limited provisional certificate that would have a built-in expiration of say a certain number of years, dependent upon the completion of the exam. And say if the exam is not completed successfully within a time frame of say three to five years, then that certificate expires.

DR. EGGLI: Leon, this is Doug Eggli to respond.

DR. MALMUD: Please do.

DR. EGGLI: Again, the final half of that certification is purely clinical. What essentially we are asking the Board to do is to divide their certification process, to earlier on issue a final certification on the training and experience related to radiation safety and that is a final certification for that component of their training.

The other component is clinical and not related and so the training and experience certificate expires as all training and experience certificates expire currently, seven years after the date of the awarding of the certificate. I don't think any other pulling back is required because clinical competence is not required to achieve authorized user status. Ability to safely handle radioactive materials is required. And that's what, again, the alternate pathway does not require demonstration of clinical competence.

The Board certification pathway, again, the training and experience requirements are functionally, except for the record keeping identical to the alternate pathway and if you can achieve authorized user status in the alternate pathway without Board certification you should be able to

achieve authorized user status effectively in the Board's certification pathway if the Board certifies the training and experience without completion of the final clinical component of that Board certification.

So again, what we're talking about is splitting the Board certification in two and offering effectively two separate certifications: one certification applying to the NRC authorized user status and the second certification applying to completion of the clinical part of the training.

DR. MALMUD: Thank you. Colleen, does that clarify anything for you?

MS. CASEY: Yes, I suppose it does. I guess what concerns me a little bit is we're deviating from what we do with other Board certifications and so that just naturally gives me a little pause, but I certainly don't want to see us impact patient care, none of us do.

DR. EGGLI: Leon, can I respond again?

DR. MALMUD: Please do.

DR. EGGLI: And I apologize that this didn't get out in time for all of the NRC people to review it in detail, but this is a solution designed to address the immediate problem of the American Board of Radiology.

I see it as portable to any certification board that sees any problem between the time gaps is to split their certification process.

Other Boards may not have a similar time gap problem, but if they do this solution isn't designed for the American Board of Radiology. This solution is designed for any recognized Board where there is a time gap between completion of training and obtaining the final clinical certification status.

So this is not just American Board of Radiology and I don't think it's been splitting the Board recognition process. It's essentially redefining the Board recognition process to allow Boards to split the clinical and the safety certifications.

DR. MALMUD: Thank you, Dr. Eggli. So what you're saying is that the proposal is immediately applicable to the American Board of Radiology, but will be similarly applicable to other Boards?

DR. EGGLI: Yes, sir.

DR. MALMUD: Thank you. I'm going to put you on mute for a second because I can't stop my other phone from ringing. Okay, we're okay now.

I'm back with you. Sorry.

DR. EGGLI: Okay, yes, so that's exactly

correct, Leon. The process is extendable to any Board who might have me to employ it.

DR. MALMUD: Thank you. Other comments or questions?

MS. CASEY: This is Colleen Casey again. So how are we proposing to do this if you meet the recommendation? Is this a rule making thing?

DR. MALMUD: It's a recommendation from the ACMUI.

DR. EGGLI: But to answer, this is Doug Eggli, to answer Colleen's question directly, yes. And the reason that we pushed ahead on this was so that if appropriate, it could make the next rulemaking cycle. But I think again, Headquarters staff could speak to this more effectively than I could, but I believe this could potentially require rulemaking.

DR. HOWE: This is Dr. Howe at Headquarters. I think we have to look at it more carefully. If you're proposing that there are two Board certifications, one is a Board certification of radiation safety and the clinical work that has to go with the radiation safety component because clinical experience is part of the supervised work experience, then -- and you're asking us only to recognize that certification, we would not look at the certification

that tested the clinical -- that focused more on the clinical side of it.

So I don't know whether we have to do rulemaking or we would just have to reevaluate submissions.

DR. MALMUD: Dr. Howe, would you be evaluating that in the near future?

DR. HOWE: It depends on what we receive. I mean we have certain criteria now that are in place in the regulation. If what is submitted can fit the regulations as they are currently written, then we would not need rulemaking, but we would not necessarily recognize the Board certification document as it currently exists if the Board changed that document to fit the radiation safety only part.

DR. LIETO: Dr. Malmud, this is Ralph Lieto.

DR. MALMUD: Yes.

DR. LIETO: I'm not quite sure if I understood what Donna-Beth was saying. Are you saying, it's not two separate Board certificates, I mean two different certifications. It's just that the process is split into two. They would complete that radiation safety piece which is required to document the training and experience requirements for the

authorized user earlier than they would receive the final certificate of Board certification which documents the completion of the clinical aspect.

So it's -- Dr. Eggli, correct me if I'm wrong, it's not anything that has been different in the past other than the record keeping aspect of -- excuse me, the documentation of the record keeping aspect.

DR. EGGLI: Yes, and this is Doug Eggli, I guess again, the question would come back to NRC, if NRC was willing to accept the AU certification as a legitimate document for the Board certification pathway, then I guess no rulemaking would be required. But in the worst case scenario, it could require and conceivably rulemaking if you don't see it that way.

DR. MALMUD: This is Malmud. If I may, Donna-Beth, it seems to me that this is unique way of avoiding the terminology of Board eligibility which doesn't exist in the eyes of the NRC by producing two certificates for each candidate, potentially, from the ABR. And therefore, it might avoid the issue of rulemaking, given our concern about introducing a new term. But that will have to be reviewed by you and the NRC staff and NRC legal to see if that would be acceptable.

DR. HOWE: I also think that the Subcommittee draft report needs to be clearer on what Dr. Eggli was describing. Dr. Eggli was describing two separate documents.

DR. EGGLI: This is Doug Eggli, that's why this document carries the label draft.

DR. HOWE: Yes. That's my point. You would have to really clarify what it was you were looking for and what it is you expected us to evaluate and to recognize.

DR. EGGLI: This is Doug Eggli again, I hope to use this discussion today to produce the final document, to have the input of the Committee and NRC staff and I do appreciate that input and the document can be made more specific, but this -- it was called a draft today so that it was a topic for discussion to be -- then to be tuned up as required to be submitted as a final recommendation.

DR. MALMUD: This is Malmud again. Doug, would you be seeking some input from a member of NRC staff to help you with the draft?

DR. EGGLI: I would be very happy to have a formal review by NRC staff to make it clear what they want to see in a final draft.

DR. MALMUD: Do we have some NRC staff who

might be able to give Dr. Eggli some time to flesh out the document together?

MR. EINBERG: This is Chris Einberg. We're just discussing that here. I'm not sure that we can draft a report together like that. I think the report has to come from the ACMUI as your recommendation.

DR. MALMUD: Okay, so it appears then that the ball is back in Dr. Eggli's court. And he'll flesh it out, send it to you, let you make your comments and then send it back to him.

DR. EGGLI: This is Doug Eggli again. Is there -- Chris, is there any problem with you verbally telling me where your threshold is?

MR. EINBERG: We can certainly do that and we can answer any questions you have. You can work with our staff here.

DR. EGGLI: Who would you identify for conversation about this, a staff member that I should use as a contact point?

MR. EINBERG: Right now, I would say to contact Cindy Flannery and Cindy will -- if need be, she will parse it out to somebody on the team.

DR. EGGLI: Okay, that's very good. thank you.

DR. HOWE: Dr. Eggli, I have a question. We don't have exactly the same requirements for Boards that we have for the alternate pathway in that we don't require a minimum number of hours for the classroom, laboratory, didactic training.

DR. EGGLI: I understand and it's -- but as I see it, what the Boards have certainly agreed to do is to meet the spirit of the regulation in their training to provide all that regulation and again, what I think we're saying is that the document that the Board will produce is a Board certification type document for that part of the training.

DR. HOWE: Dr. Eggli, let me finish. My -- I think we need to address what happens to those individuals that go through your training program and don't receive the certification for the radiation safety.

DR. EGGLI: Yes.

DR. HOWE: They're disenfranchised.

DR. EGGLI: Yes, let me tell you now how I see that and see if any of my Subcommittee members disagree with me. If a candidate in a program that leads to a certification by one of the recognized Boards fails to achieve that authorized user status eligible certificate from the Board, then they would,

if they were going to become an authorized user, those individuals would have to have a higher quality of documentation to take them down the alternate pathway.

DR. GUIBERTEAU: This is Mickey Guiberteau. I agree with Doug.

Currently in the process if someone in terms of our examination process does not pass the AU eligible portions of our examination process, they get a certificate that does not have AU eligible on it. And it would essentially be simply because either one, they did not submit or their program did not submit the appropriate attestations as to completion of the training which would make them ineligible to receive AU eligible portion on their certificate or they did not pass that portion.

If they're eligible and didn't pass, they do have a way to remediate that by taking a special examination, but essentially what Doug is saying is it's true, that basically you have to fulfill all the requirements and pass the appropriate examinations before an AU eligible certificate would be given.

DR. MALMUD: Thank you, Dr. Guiberteau. So if I may try to summarize the recommendation, it would be in the best of all situations a candidate would receive the first certificate, let's call it the

preliminary with having passed the AU requirements as part of the Board. And then we go on to get the Board, the full Board certification after the additional clinical experience.

And the second possibility, the candidate would get part one with the -- as an AU, but would for some reason either not take or fail the clinical part, but would still be an AU.

The third situation, the individual would not achieve AU status as part of this or her Board training program and the certificate which would make them eligible to take part two, certifying clinical competence, would also not carry AU authorization in which that candidate, in order to achieve AU authorization, would have to take the alternative pathway.

Is that a good summary?

DR. GUIBERTEAU: Yes.

DR. MALMUD: Thank you. Are there other comments regarding the report from Dr. Eggli's Subcommittee?

MS. FAIROBENT: Dr. Malmud, Lynne Fairobent.

DR. MALMUD: Yes, Lynne.

MS. FAIROBENT: Do you know when the

Subcommittee report will be made available?

DR. MALMUD: I'm having a little difficulty hearing you. There's another conversation going on in the background. Could you repeat that, please?

MS. FAIROBENT: Sure. I was asking when the Subcommittee report might be available publicly for us to be able to read it?

DR. MALMUD: That's a good question. I don't know the answer to it. Who would know the answer? When can that Subcommittee report which was distributed to the member of the Committee be made public?

DR. EGGLI: Leon, this is Doug Eggli. I think within the next day or so I will try to contact Cindy Flannery and make sure I understand what potential issues NRC might have and then the Subcommittee over the next week or two will draft a final version. Then the question becomes a parliamentary one. Does the full -- since it's a Subcommittee report to the ACMUI, my assumption is the full ACMUI would have to approve the report before it could be distributed publicly.

DR. MALMUD: That is correct.

DR. EGGLI: So I think that the

Subcommittee can have a final report ready within a couple of weeks and then the question is the process of getting the full ACMUI to accept the report.

So one of the questions I guess Leon that I would like to ask, do any of the ACMUI members have a significant problem with the proposal as made?

DR. MALMUD: Dr. Eggli's question is to the ACMUI members who are on this conference call.

I'll ask the question in this fashion. If anyone has an issue with the recommendation would he or she speak up now?

DR. LIETO: I have a question for clarification.

DR. MALMUD: This is Ralph Lieto, yes.

DR. LIETO: Ralph Lieto, yes. Dr. Eggli, the Subcommittee is composed of yourself and if memory serves me right, wasn't it Dr. VanDecker and Dr. Guiberteau. Was there anybody else?

DR. EGGLI: Yes, Dr. Nag.

DR. NAG: Subir Nag.

DR. LIETO: Okay, my point of clarification would be if you're going to try to have this applicable to other Boards outside the ADR, would it be of value to have either the pharmacy and/or RSO representatives involved in sort of the review of the

final recommendations before it came back to see if there would be applicability of those Boards to this process.

DR. EGGLI: Again, Ralph, we tried to generalize this as best we could. I'd be happy to have the input of any -- essentially, I'd be happy to expand the Subcommittee to include anyone else who has an interest in seeing this final draft before it comes back to the whole ACMUI.

So if Subir is representing radiation oncology, if Steve would like to see this for -- or to have more input for the radio pharmacy training. I guess Dick is our RSO representative. If somebody wants to do this for medical physics, I'd be happy to have -- I think we're sort of in the home stretch on this. I don't think it would be a significant burden for additional people at this point. I'd be happy to have -- expand the Subcommittee wherever the ACMUI would like to see that Subcommittee go.

DR. VETTER: This is Dick Vetter. I think Ralph's suggestion is a good one. That might just take us one step closer to completion by the time we reach our meeting in May.

DR. EGGLI: I could then -- I will add Steve for pharmacy. I will add you, Dick, for RSO.

Should I add someone from medical physics? Ralph, do you want to look for medical physics?

DR. LIETO: I would be glad too.

DR. EGGLI: Okay, is there anyone else that you think would be more appropriate?

MR. BROGA: Dr. Eggli?

DR. EGGLI: Yes.

MR. BROGA: Dean Broga with the ABMPI. I'd be happy to look at it and I'd also like to suggest to the floor that the bottom line question I think that's going to be addressed to the NRC starts off in all these sections with the statement "is certified by the Medical Specialty Board." What is the interpretation of that? Does that mean full certification or whether those Medical Specialty Boards can certify that the person has met the minimum requirements? I think that's what the interpretation is going to come down to, what that statement means.

DR. EGGLI: I think you're absolutely correct on that.

Leon, let me ask a question. Can I extend the Subcommittee beyond the ACMUI?

DR. MALMUD: Can you extend the Subcommittee beyond -- well, we can certainly get input from non-ACMUI members.

DR. EGGLI: Am I allowed to share the draft report or does that have to stay internal with ACMUI or maybe that's a question to the people who keep us legal in NCR, in NRC, rather.

DR. MALMUD: I suspect it's a question for the NRC because my feeling is that we should be able to do that, but we need NRC's opinion.

May we ask someone from NRC?

Cindy? Chris Einberg?

MR. EINBERG: Cindy is not here. She's out ill. Could you please repeat the question?

DR. EGGLI: Okay, we are enlarging the Subcommittee to create the final draft for ACMUI to approve. Can that draft be shared with someone outside of ACMUI for input or is it because it's a Subcommittee report not yet approved by ACMUI as a whole, are we unable to share it?

MR. EINBERG: You're not able to share it.

DR. EGGLI: Okay, so we have to share only with ACMUI?

MR. EINBERG: If you want to share it, it has to be public. If you give it to one person, you have to give it to all the public.

DR. EGGLI: I think the answer is, Leon, until we come up with a final report, we can't share

it.

MS. FAIROBENT: Dr. Malmud, it's Lynne Fairobent?

DR. MALMUD: Yes, Lynne?

MS. FAIROBENT: There have been other ACMUI Subcommittees where you have had non-member consultants participate in the drafting. I'm thinking back to the electronic brachytherapy report.

DR. MALMUD: Yes, we have had consultants.

MS. FAIROBENT: Right.

DR. MALMUD: That is correct, and we have had input.

MS. FAIROBENT: Yes.

DR. EGGLI: So Leon, I need your direction on this.

DR. MALMUD: I would feel free to ask the contributions of non-members, but they would not be official members of the Subcommittee.

DR. EGGLI: I understand and I'm okay to share the document if they are working as a consultant to the Committee?

DR. MALMUD: My understanding is that it is okay if they are an official consultant to the Committee.

DR. EGGLI: Okay.

DR. MALMUD: But we still need to get NRC's approval.

DR. EGGLI: Okay.

MR. LEWIS: This is Rob Lewis. I do not believe we're thinking off the top of our heads here, but I do not believe the Committee can take voluntary consulting services. You have to pay. We have to pay for people to be consultants to the Committee.

DR. NAG: This is Dr. Nag. I have had been on Subcommittees where I have had consultants and they were not paid and basically we needed that input on certain things like the gamma knife and so forth and there was no payment and they were non-voting members. We just asked them for their opinion.

MR. LEWIS: Let us look into it, I guess. It's a legal question and we don't have a OGC person here.

DR. EGGLI: Okay, this is Doug Eggli again. If you send me an email and let me know what the resolution to that is?

MR. EINBERG: We certainly can.

MS. GILLEY: Dr. Malmud, this is Debbie Gilley, may I just make a comment?

DR. MALMUD: Yes, Debbie.

MS. GILLEY: If for some reason we do need

to go through the rule promulgation process, could we please include the agreement states in that activity?

DR. MALMUD: Absolutely.

MS. GILLEY: Thank you.

DR. EGGLI: Debbie, this is Doug Eggli, would you like to be added to the expanded Subcommittee?

MS. GILLEY: Pretty soon that Subcommittee is going to be the entire ACMUI Committee.

DR. EGGLI: I understand that, that's another interesting point that I'll stay away from.

Again, I have no problem with that.

MS. GILLEY: I'll be glad to look at what you all are working on and see if I see any issues that might have impact for the agreement states.

DR. EGGLI: I think that's -- I have had conversations with particularly people from the American Board of Nuclear Medicine about the issues of NRC states versus agreement states and I think it would be desirable if we could propose a solution that the agreement states would also find acceptable, because there's going to be a lot of radiology, graduating radiology residents who are going to be working in agreement states rather than NRC states.

DR. MALMUD: Yes, thank you. Are there

any other comments regarding the report prepared by Dr. Eggli and his Subcommittee?

If not, I would suggest that we have completed our agenda which was two items.

Is there any other comment that a member of the Committee or a member of the public and or course, if NRC staff wishes to make with respect to this issue?

If not, is there a motion for adjournment of this Committee?

DR. VETTER: This is Dick Vetter. I move to adjourn.

DR. MALMUD: Dr. Vetter makes a motion to adjourn.

DR. LIETO: Ralph Lieto seconds.

DR. MALMUD: Second. All in favor?

(Chorus of ayes.)

DR. MALMUD: Thank you all for a very productive session. We thank Dr. Eggli, in particular, for his contribution and the members of his Committee and also to the members of the public for their participation with us. Thank you all.

(Whereupon, the above-entitled matter was concluded at 2:21 p.m.)