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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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WEDNESDAY, DECEMBER 10, 2014

The meeting was convened by teleconference, at 2:00 p.m. Eastern Standard Time, 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

MICHAEL H. O'HARA, Ph.D., FDA Representative

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

JOHN J. SUH, M.D., Radiation Oncologist
LAURA M. WEIL, Patients' Rights Advocate
JAMES S. WELSH, M.D., Radiation Oncologist
PAT B. ZANZONICO, Ph.D., Nuclear Medicine Physicist

NRC STAFF PRESENT:

CATHERINE HANEY, Director, Office of Nuclear Material Safety and Safeguards
PAMELA HENDERSON, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs
CHRISTIAN EINBERG, Special Assistant, Division of Materials Safety, State, Tribal and Rulemaking Programs
MICHAEL FULLER, Designated Federal Officer
SOPHIE HOLIDAY, Alternate Designated Federal Officer, ACMUI Coordinator
MARYANN ABOGUNDE, NMSS/MSTR/MSEB
ANDREW CARRERA, NMSS/MSTR/RPMB
SUSAN CHIDAKEL, OGC/GCLR/RMR
ASHLEY COCKERHAM, NMSS/MSTR/MSEB
JACQUELINE COOK, R-IV/DNMS/NMSB-B
SAID DAIBES, NMSS/MSTR/MSEB
SARA FORSTER, R-III/DNMS/MLB

SANDRA GABRIEL, Ph.D. NMSS/MSTR/MSEB

LATISCHA HANSON, R-IV/DNMS/NMSB-B

VINCE HOLAHAN, Ph.D., NMSS/MSTR

CARDELIA MAUPIN, NMSS/MSTR/RPMB

PATTY PELKE, R-III/DNMS/MLB

ANDREW PESSIN, OGC/GCLR/RMR

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

ALSO PRESENT:

WILLIAM DAVIDSON, University of Pennsylvania

GLORIA ROMANELLI, American College of Radiology

CINDY TOMLINSON, American Society for Radiation Oncology

P R O C E E D I N G S

2:00 p.m.

MR. FULLER: As the designated federal officer for this meeting, I am pleased to welcome you to this Public Meeting of the Advisory Committee on the Medical Uses of Isotopes. My name is Mike Fuller, and I am the Team Leader of the Medical Radiation Safety Team in the Medical Safety and Event Assessment Branch, and I have been designated as the federal officer for the advisory committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated federal officer is Sophie Holiday, the ACMUI coordinator. 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.

This meeting is being transcribed by the NRC, and it may also be transcribed or recorded by others. The meeting was announced in the October 30th 2014 edition of the Federal Register, and that is in Volume 79 at page 64631.

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 views of the Committee and values their opinions.

I request that whenever possible, we try to reach a consensus on the procedural issue that we will discuss today, but I also recognize that there may be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I would like to perform a roll call of the ACMUI members participating today. Dr. Bruce Thomadsen?

CHAIRMAN THOMADSEN: Present.

MR. FULLER: Dr. Milton Guiberteau?

VICE CHAIRMAN GUIBERTEAU: Present.

MR. FULLER: Dr. Philip Alderson?

MEMBER ALDERSON: Present.

MR. FULLER: Mr. Frank Costello?

MEMBER COSTELLO: Present.

MR. FULLER: Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Present.

MR. FULLER: Dr. Sue Langhorst?

MEMBER LANGHORST: Present.

MR. FULLER: Mr. Steve Mattmuller?

MEMBER MATTMULLER: Present.

MR. FULLER: Dr. Michael O'Hara?

MEMBER O'HARA: Present.

MR. MACLEAN: Dr. Christopher Palestro?

MEMBER PALESTRO: Present.

MR. FULLER: Dr. John Suh?

MEMBER SUH: Present.

MR. FULLER: Ms. Laura Weil?

MEMBER WEIL: Present.

MR. FULLER: Dr. James Welsh?

MEMBER WELSH: Present.

MR. FULLER: And Dr. Pat Zanzonico?

MEMBER ZANZONICO: Present.

MR. FULLER: Okay. I would note that a quorum has been met because we have at least seven members. In fact, we have all of the members of the Committee present.

I now ask NRC staff members who are present to identify themselves. I will start with individuals in the room here, and I will go ahead and name them. Again, my name is Mike Fuller.

We have Ms. Cathy Haney, Dr. Vince Holahan, Ms. Gretchen Rivera-Capella, Maryann Abogunde, Andy Carrera, and Sophie Holiday. Oh, and Mr. Chris Einberg is also here.

Okay, I'll now go to NRC Headquarters, employees who are on the phone. If you are an NRC

employee on the phone, please identify yourself.

MS. HENDERSON: Pam Henderson.

MS. MAUPIN: Cardelia Maupin.

MS. GABRIEL: Sandy Gabriel.

MR. PESSIN: Andrew Pessin.

MS. COCKERHAM: Ashley Cockerham.

MR. FULLER: Okay. Now we will go to the regions. Who do we have on the call from Region I?

Okay, Region III?

MS. PELKE: Patty Pelke.

MS. FORSTER: Sara Forster.

MR. FULLER: Okay, Region IV?

MS. COOK: Jackie Cook.

MS. HANSON: Latischa Hanson.

MR. FULLER: Okay. At this point, I will identify members of the public who notified us that they would be participating today. When I call your name, please answer.

Maxwell Amurao from Columbia University?

(No audible response.)

MR. FULLER: William Davidson, University of Pennsylvania?

MR. DAVIDSON: Present.

MR. FULLER: Michael Peters, ACR?

(No audible response.)

MR. FULLER: Gloria Romanelli, ACR?

MS. ROMANELLI: Here.

MR. FULLER: Mario Sanchez, CSHS?

(No audible response.)

MR. FULLER: Gary Williams, Veterans Health Administration?

(No audible response.)

MR. FULLER: And Cindy Tomlinson of American Society for Radiation Oncology.

MS. TOMLINSON: I am here, thank you.

MR. FULLER: I'll also note that Susan Chidakel from our Office of the General Counsel at Headquarters has joined us.

Okay, is there anyone else here on the call that I did not recognize or that we were not aware of until now?

Okay. Hearing none, I have a -- we have a bridge line available, and that phone number is (888) 864-0940. The passcode to access the bridge line is 34188#.

This meeting is also utilizing the GoToMeeting application to view presentation handouts in real time. You can access this by going to www.gotomeeting, all one word, .com, and searching for the meeting ID 939-952-657.

The purpose of this meeting is to discuss the Committee's comments on the NRC's Advanced Notice of Proposed Rulemaking for Title 10 of the Code of Federal Regulations Part 20, Standards for Protection Against Radiation.

Individuals who would like to ask a question or make a comment regarding specific issues the Committee has discussed should request permission to be recognized by the ACMUI chairperson, Dr. Bruce Thomadsen. Dr. Thomadsen at his option may entertain comments or questions from members of the public who are participating with us today.

Comments and questions are usually addressed by the Committee near the end of the meeting, after the Committee has fully discussed the topic. I would also like to add that the handouts and agenda for this meeting are available on the NRC's public website.

At this time, I would like to ask everyone on the call who is not speaking to place their phones on mute. If you do not have the capability to mute your phone, please press *6 to utilize the conference line mute and un-mute functions.

I would also ask everyone to exercise extreme care to ensure that the background noise is kept at a minimum, as any stray background sounds can be very

disruptive on a conference call this large.

At this point, I would like to turn the meeting over to Catherine Haney, Director of the Office of Nuclear Material Safety and Safeguards, for some opening remarks.

MS. HANEY: Thanks, Mike. Good afternoon, everyone. As Mike said, my name is Cathy Haney. I am the new Office Director in the Office of Nuclear Material Safety and Safeguards and the Advisory Committee on Medical Uses of Isotopes does report up through my organization, so I look very much forward to working with the Committee on this topic of Part 20 as well as it moving forward to other projects.

I do have a past history of having worked with the ACMUI. In fact, I was in Mike's position as the designated federal official back several years ago when Dr. Barry Siegel was Chair of the Committee, so I am very familiar with the charter and the roles and the responsibilities of ACMUI and the value that they add to our regulatory processes.

So with that, I will meet you all in person when you're in for the next meeting, but I did want to again take advantage of this opportunity to at least introduce myself. So with that, I'll turn it to you Dr. Thomadsen to go forward with the meeting.

CHAIRMAN THOMADSEN: Thank you, Cathy. Thank you very much.

One additional caution as far as phone handling: If you are going to be leaving the call, please do not put your phone on hold if your institution plays music during that; mute your phone, please.

And thank you all for attending. Right now, I am going to turn the proceedings to Dr. Langhorst, who chaired the report, to walk through the report and get her comments. During that, I am going to ask not to go through all of the detail of the report. We have had that to look at. But to hit the highlights, and we'll cover the recommendations and have discussions as necessary as it comes up with those.

With that, Dr. Langhorst.

MEMBER LANGHORST: Dr. Thomadsen, thank you very much.

And first off, I want to let everyone know that Sophie Holiday will be taking care of the GoToMeeting. We have our draft report up there, and forgive me, I am still in the mindset of only a vocal teleconference, so didn't even think about potential slides, so I apologize for not having that in mine.

As shown there on the report, there's a few people who may have not muted their phone. That would

be very helpful if you could mute your phone, thank you.

Mr. Costello, Dr. Dilsizian, myself, Mr. Mattmuller, and Dr. Zanzonico are the subcommittee folks, and our charge was to provide specific questions and recommendations in regard to the NRC's advance notice of proposed rulemaking for the Part 20. This was given to us in September, and I so appreciate our subcommittee's time to get this report put together.

The NRC presented -- there is someone who still hasn't muted their phone, and it would be very helpful if you could mute your phone. Thank you.

The NRC presented their information on this proposed rulemaking -- this advanced notice of proposed rulemaking, in six different issues, each having an issue paper, and then in the Federal Register, there were a series of specific questions that they had in regard to each.

We assigned various individuals to each of these topics, each of these issue papers, and drafted our specific recommendations and answers to the questions.

So first of all, let me go through what our general recommendations were on each of these issue papers, and then I will ask each of our subcommittee members to go through their portion of the report and

give some highlights and lead discussion of questions that the Committee may have in regard to each of these topics.

So first of all, Issue Paper 1, we recommend that ACMUI supports the update of Part 20 to align with International Commission on Radiological Protection Publication, ICRP 103, Methodology and Terminology.

Issue Paper 2, ACMUI supports the change of the occupational dose limit for the lens of the eye to 50 millisieverts, or 5 rem.

Issue Paper 3, the ACMUI does not support the change of the dose limit for the embryo/fetus of a declared pregnant occupational worker from 5 millisieverts or 500 millirem over the gestation period.

Issue Paper 4, the ACMUI does not support revising or adding regulatory requirements regarding a licensee's ALARA program.

Issue Paper 5, the ACMUI supports the change to use International System of Units, the SI Units, in radiation protection regulation, but it recognizes the need by some licensees to have a transition period to move from the use of conventional units.

And Issue Paper 6, the ACMUI does not support expansion of additional categories of licensees that should be required to submit annual occupational

exposure reports under 10 CFR 20.2206(a).

Please forgive my editing mistake here. We did talk about this additional phrase that I had here and decided not to move forward with. I'll talk about that more but forgot to delete it here.

As far as cumulative effects of regulation goes, I would like to speak of that at the end of our presentation.

So at this point, I would like to have Dr. Zanzonico lead -- give a short summary of the Issue Paper 1 recommendations and answers and discuss from there. So Dr. Zanzonico, I'll turn it over to you.

MEMBER ZANZONICO: Okay, thank you Dr. Langhorst, and hello everyone. This is Pat Zanzonico from New York.

And the issue I dealt with, Issue Paper 1, was the update of 10 CFR Part 20 to align with ICRP Publication 103, Methodology and Terminology. And as Dr. Langhorst stated, our subcommittee and the ACMUI as a whole support this alignment, and I'd just like to highlight some of the sub-issues, so to speak, that comprise this issue.

The first of these is replacing the regulatory quantity total effective dose equivalent with the quantity effective dose, and as many of you

know, of course, the effective dose is now the standard quantity used internationally and in the U.S. to express overall stochastic risk, and really the total effective dose equivalent or TEDE is only accounted nowadays in the NRC regulatory literature, so it's both scientifically and logistically important, we think, to switch to this more general, more universally recognized, and more current metric of overall radiation risk, namely the effective dose. So we certainly support that alignment.

As part of that, the ACMUI also endorses the use of the latest tabulation of tissue weighting factors, or W sub T quantities, and radiation weighting factors, WR quantities that are used to encapsulate effective dose. These latest values have been tabulated in ICRP 103, and along with transitioning from the total effective dose equivalent as the regulatory dose limit quantity, we of course recommend adoption of these newer weighting factor values tabulated in ICRP 103 as well.

Also included in ICRP Publication 103 are updated isotope-specific biokinetic, obviously for different isotopes, and the associated dose conversion factors or DCFs. And the DCFs, of course, are basically the absorbed dose per unit activity internalized,

inhaled, ingested, administered, however internalized, to each organ.

And these models may impact annual limits on intakes or ALIs and derived air concentration limits, or DACs, to some extent, so these may have both a financial and logistical impact on licensees, but again, we think it's important that the NRC regulations be based on the latest, the most scientifically current and credible models, which are those in ICRP Publication 103.

I should, just for a moment, return to the issue of transitioning from the total effective dose equivalent to effective dose. Although these are technically different, we really don't anticipate that there would be a significant impact other than logistical, administrative, so forth, on licensees, as numerically there probably will not be a significant difference in the values of TEDs versus EDs, total effective dose equivalents versus effective doses.

The other issue was whether with the availability now of increasingly realistic mathematical anthropomorphic models, anatomic models, now including one year-old, five year-old, ten year-old children, fifteen year-old males and females, and adult males, whether the age and gender averaged, those

conversion factors as derived from the different models, should be used as the basis for regulatory dose limits. And we certainly endorse that as well.

Obviously, any exposed or potentially exposed population for whom dose limits are being established, at least among the public, will consist of a combination of different-aged individuals and both males and females, so it makes sense of course to reflect that in dose limits, which will be accomplished by adopting age and gender average dose conversion factors based on the latest ICRP models or phantoms rather.

So those summarize our -- the recommendations of the Committee with respect to Issue 1. Dr. Langhorst, I don't know if we are going to take questions or comments at this point or after all of the issues have been reviewed, but I will defer to you on that point.

MEMBER LANGHORST: This is Sue Langhorst. I would open it up for our Committee to ask questions.

MEMBER ZANZONICO: Understood. I am happy to entertain any questions, comments, et cetera.

CHAIRMAN THOMADSEN: This is Bruce Thomadsen. I don't have a question. I think it's a good analysis and good recommendations.

In the report, I would suggest writing out effective dose rather than using the abbreviation ED

only so it doesn't get mistaken by a casual reader for equivalent dose.

MEMBER ZANZONICO: Understood. Perhaps a more general suggestion might be to include a glossary or appendix of abbreviations to our reports, but that aside, certainly we can -- that can be, ED can be written out as effective dose.

MEMBER WELSH: Pat, this is Jim Welsh.

MEMBER ZANZONICO: Yes.

MEMBER WELSH: I agree that the analysis is sound and the conclusions are logical. However, I have a more fundamental question, or not really a question, but maybe a simple comment, that although the TEDE might be an outdated construct and concept, replacing it with the more modern and more popular ED may or may not truly be a step in the correct direction.

It may be more in line with the rest of the world, but the fundamental question remains regarding the validity of the whole concept of effective dose, and many of us still are highly skeptical of that validity and when it comes to low radiation doses, we still are extrapolating based on a linear non-threshold hypothesis to come up with appropriate weighting factors when using the effective dose concept.

And I just would throw that out there as a

reminder that although this is logically consistent, it may not be scientifically real.

MEMBER ZANZONICO: This is Pat Zanzonico again. I will offer my opinion, and obviously that opens a large and continually controversial issue, namely the validity and applicability of the linear non-threshold hypothesis and so forth.

My understanding, however, is that both the total effective dose equivalent, as well as the effective dose, suffer from that deficiency, so to speak, and that the really -- the real difference, and perhaps the only difference between the effective dose and the total effective dose equivalent is not one of conceptual meaning, or the underlying radiological bases, but rather the tissue weighting factors and radiation weighting factors that are used.

And I believe that also in ICRP Publication 103, more specific normal tissues are identified, and fewer are summed into the remainder of body, and those weighting factors, tissue weighting factors, presumably reflect the latest epidemiological, radiation epidemiological data.

Now, again, to the extent that the linear non-threshold model may not be valid down at below dose range, those values may be questionable as well. But

I think the tissue weighting factors used to calculate the total effective dose equivalent suffer from the same deficiency.

So I don't think either one or the other quantity is superior to the other on the basis of its conceptual meaning, but the effective dose, besides being more widely used nowadays, at least reflects the latest radiation epidemiology data, so on that basis I would still recommend its adoption.

MEMBER WELSH: Yes, I -- this is Jim Welsh again. Yes, I would agree with you on your points that you've raised, yet it remains that if LNT is a fallacy, effective dose and TEDE is a fallacy as well, and since that possibility exists, it raises the specter of should there be different weighting factors at different doses?

I suppose for simplicity, if you assume LNT, well one weighting factor for one particular organ, is going to work fine. You don't have to change the W value for each different organ and for each different dose, which would make it a very complicated and cumbersome mathematical problem.

But we're -- from my perspective, simplicity of the math should not be the driving factor, it should be the scientific accuracy and validity of the conclusions. And therefore, since I am questioning the

validity of LNT, I have to question the validity of TEDE or ED.

And I just raise it as a commentary because I know we need to use something and we're not going to get into great depth on whether we can change this potential fallacy today, but I just remind folks of the potential shortcomings of using LNT and the implications.

MEMBER ZANZONICO: Understood. This is Pat Zanzonico again. I mean, your point is very well taken. Needless to say, I would agree that it is probably beyond the scope of what we can accomplish today and well beyond today.

My only suggestion is perhaps we could include simply a comment, add a comment to our report just briefly raising that point. But beyond that, I just think it's beyond the scope of our mandate and what we can hope to accomplish.

MEMBER WELSH: Agreed.

CHAIRMAN THOMADSEN: And this is Bruce Thomadsen. And I think the point is extremely well taken, but since I haven't seen a good table of dose dependence tissue weighting factors, probably the better way to put it is that the use of the effective dose to predict hazard is probably inappropriate at low

doses.

So rather than saying effective dose has to be thrown out at this case because we need to have something, just rather qualify how useful it might be in predicting health hazards at low doses.

And there are -- there is documentation that we could put on that, particularly the statement from the Health Physics Society.

MEMBER ZANZONICO: Yes, yes.

MEMBER LANGHORST: This is Sue Langhorst. Also, I know that the BEIR Committee is starting to get constituted to look at a new BEIR report, so that may be additional information that comes in the future.

MEMBER ZANZONICO: Yeah, and I know Dr. Boyce from the NCRP is among the leaders of a million man follow-up study that will take some years to complete, needless to say. But that should also provide some quantitative insights into low dose effects and low dose weighting factors, but again, that is some years down the line.

MEMBER LANGHORST: This is Sue Langhorst. Are there any other questions for Dr. Zanzonico?

Okay. This is Sue Langhorst again. Hearing none, Dr. Zanzonico, thank you so very much.

MEMBER ZANZONICO: Thank you.

MEMBER LANGHORST: Now we will move on to Issue Paper 2 on Occupational Dose Limit for the Lens of the Eye. And Dr. Dilsizian was the one who led this effort, and Vasken, I'd like to ask you to summarize this and lead the discussion.

MEMBER DILSIZIAN: Thank you Dr. Langhorst and the subcommittee members for their valuable input in preparing this document.

The ACMUI subcommittee does support the change of the occupational dose limit of the lens from current 15 rems to 5 rems, which is in close alignment with the recent ICRP Publication 118 (2012) recommendations. And this is based on the recent human epidemiological studies which suggest that the radiation cataract may actually occur with significantly lower doses of ionizing radiation than was previously estimated, and this is based on studies that included Chernobyl nuclear reactor accident cleanup workers as well as radiologic technologists, interventional radiologists, and cardiologists.

Unlike other potential radiation effects, however, a cataract can be effectively treated by surgery. However, prevention rather than treatment should be the goal.

And so the recommendation would be to focus

on the personnel that are exposed to these byproduct materials and x-ray sources, and those would be the interventional radiologists performing yttrium-90 microsphere therapies as well as perhaps some cardiologists who are still performing intravascular brachytherapy and all of the personnel that are affected by being in the interventional suite.

And the current approach, therefore, would be three approaches of shielding: one, the portable/moveable transparent scatter-shielding on leaded glass screen; second would be an eyewear such as leaded glasses for personal use; and the third would be the overall personal protection suit that is one of these lead equivalent thickness so-called zero gravity type suit that protects the eye, the brain, as well as the rest of the body.

And so for physicians and trainees who are directly at the table involved with an interventional radioembolization procedure, we feel that the use of eye protection should be mandatory. Regarding the ancillary staff that is in the room, that are three feet away from the table, we felt that the eye protection should be recommended.

As to the -- how do we measure the exposure to the lens? The current most widely used method is

measuring or assessing the dose to the lens from the body dosimeter, which is one at the point of highest exposure. However, if there would be circumstances where the radiation field is non-uniform, that is, the eye would be receiving a higher dose than the body, then there would be eye-specific dosimeters that are currently available which could be worn with a head strap above the eyebrows and near the eyes, and perhaps those can provide a better measure directly of the lens dose.

What is the overall estimated dose to the lens? A current busy interventional suite at a major inner city academic institution, it is estimated that the eye exposure would be between 4 to 8 rems. Using both eyeglasses, as well as a shield simultaneously, may reduce the dose by a factor of 25 or more. The entire personal protection suit does a much better job, although it comes at much more expense.

The whole body suit is estimated to cost about $70,000 per suit, and that would be required for two in one room. The typical shield is about $10,000 and the personal leaded glasses would be approximately $400 per person.

And so how would this be enforced? Obviously, it should be implemented through the institutional Radiation Safety Committee and Human Use

Subcommittee, enforced by the Environmental Health Services, and also perhaps annual inspections and Q&A programs such as The Joint Commission and CMS.

That will be the conclusion of my presentation. Any questions?

CHAIRMAN THOMADSEN: This is Bruce Thomadsen. The recommendations that are stated here seem to all be targeted towards interventional radiology. Do you have -- does the subcommittee have recommendations dealing with brachytherapy?

MEMBER DILSIZIAN: I thought that the brachytherapy is a very local exposure, and we really did not feel that that would be exposing the lens significantly [enough] to alter the current radiation safety approaches.

MEMBER LANGHORST: This is Sue Langhorst. Dr. Thomadsen, we did not, from our experience, feel that there were very high doses of any merit as far as reaching a level of 5 millisieverts, 5 rem in a year, or -- excuse me, 5 millisieverts, 5 rem in a year to brachytherapy personnel. Do you disagree with that?

CHAIRMAN THOMADSEN: I do not disagree. It may be a good idea to include some statement to that effect in the report.

MEMBER LANGHORST: Okay, that sounds like a

good idea.

MEMBER DILSIZIAN: Sure, we'll do that.

MEMBER LANGHORST: Are there any other questions or comments? Sorry, this is Sue Langhorst.

Okay, hearing none, thank you so very much.

Okay, so we will move now to Issue Paper 3, which is Dose Limit for the Embryo/Fetus of a Declared Pregnant Occupational Worker. And I was the one assigned this task, so I will go through it.

We evaluated scientific basis of this risk, and this is still a very controversial subject, and in my write-up of this and sharing this information with our subcommittee, I relied heavily on Dr. Robert Brent's work, who is one of the world's experts in exposure to the embryo/fetus, and we do not recommend that this dose limit be lowered from what it is at this point in time.

It is particularly problematic to have a dose limit at a level if we went to the 100 millirem regulatory dose limit, that is equivalent to one of my workers moving from St. Louis to Denver and getting 100 millirem more than they would here in a year.

In regard to the current recommendations, the NRC Issue Paper 3 did a very good job of going through what were the current recommendations. However, I did want to point out one error in their conclusions. In

the NCRP report, and let me get that number, the NRCP Report No. 174, which was, that writing committee was chaired by Dr. Brent, the NCRP did not change their recommendation for the fetal dose limit.

NCRP made recommendation in their 1993 report which is No. 54, and they continue to recommend a dose limit of 50 millirem per month over the pregnancy, and so that's roughly equivalent to 500 millirem in a -- over the gestation period.

Also, we discussed the application of using a public dose limit for this type of individual dose limit. And typically, public dose limits do not have an identified individual. It is more of a design criterion, and was set low at 100 millirem so that licensees did not have to consider other licensee doses to members of the public.

And so in the case of a declared pregnant worker, this is a radiation worker who is occupationally exposed, who has training in radiation safety, and is most likely assigned a personnel dosimeter into their normal radioactive work or radiation work, and so they are a known entity. When we have one here at Washington University, we do issue a fetal dosimeter that they wear at their waist. And so we feel like it is very acceptable to maintain that limit, the current limit of 500

millirem, rather than going to 100 millirem.

And I know in our instance, pretty much, they are very much lower than 100 millirem anyway, but it is problematic when you have a limit, a dose limit, at that low level, and it's even difficult to measure sometimes a monthly level at that low accumulating dose of 10 millirem, roughly, a month.

I did want to ask the Committee -- hopefully you had a chance to read all of our specific answers, but on the last question of the section it talks about are there data on actual dose distributions to the embryo/fetus of a declared public worker, and what are the trends of these data?

I don't know of any specific report in that regard and certainly would be -- would ask if you all have anything that you can point us to, we could include something.

If you can mute your phone, that would be great. If you have anything specific in regard to that, we would certainly be open to a reference to help the NRC in this regard.

So with that, I will ask if there's any questions or comments from the Committee.

MEMBER ALDERSON: This is Dr. Alderson. I'd like to make a comment.

The potential, if the -- I support the Committee's position. If the threshold was to be lowered to 100, the potential for mathematical overexposures is much higher, and we all know that unfortunately in the best of circumstances there are problems with pregnancies and fetuses. So I think that the potential for a mathematically created liability for many organizations is fairly high. So I think that's another reason to keep the level where it is.

MEMBER LANGHORST: Thank you very much -- oh, this is Sue Langhorst. Thank you very much for that comment.

Are there any other comments?

Okay. Thank you very much. Moving on, Issue Paper Number 4 is Individual Protection -- ALARA Planning, and Mr. Costello was assigned this, and so Frank, I will ask you to summarize and lead that discussion.

MR. COSTELLO: Thank you, Dr. Langhorst. Basically, the current Part 20 that we have has a requirement for ALARA for occupational doses and public doses, but it doesn't provide any more restrictive requirements than that.

And I think that -- and it's our position that we want to keep the regulation the way it is. And the

heart of our argument is the phrase "reasonably achievable." It would be very hard, I think, to have more specific requirements, which apply to all types of licensees from those with gas chromatographs to those who operate nuclear power plants, and have it applied that that be reasonably achievable so they'd be the same.

In going through this, just looking at it from the medical licensee's point of view, there are very few cases where employees of medical licensees receive doses anything like the regulatory limits, and in fact, across the industry, not that many people do that. I think that the safety culture of each type of licensee differs so much, it would be hard to have more prescriptive requirements than that.

In some ways, the answers to the questions follow the same theme. The ALARA programs, by their very nature, have to be tailored to the particular licensee, and so making more restrictive requirements than that is not a good idea; it's a bad idea. And in question four, they had "Should licensees be allowed to establish different ACLs?" And I would say that is certainly the case, and they do.

For those who have medical licensees, they know, for the most part, they have a lot of levels -- level one, level two, based on the experience they have

with the doses that they receive.

The -- we do not recommend any new methodology to make the ALARA requirements more prescriptive. Let's see.

The question of what are the potential impacts to licensees and such that require a licensee to account for exposure, the ALARA requirement that the licensee is responsible for making sure that the workers don't go over the limit from all sources, it's a hard thing sometimes to enforce that because people work a lot of places, but I don't think that a regulatory change is necessary to address this, there is a requirement already there.

With that, it's a pretty short summary. Someone on the Committee suggested that I just say "no". But the bottom line is, I think that the current ALARA requirement is adequate and making it more prescriptive is not recommended at all. Thank you.

MEMBER LANGHORST: Hi, this is Sue Langhorst. Are there any questions or comments for Mr. Costello?

MEMBER ZANZONICO: This is Pat Zanzonico. Just a comment, and I think this is to reinforce what Mr. Costello said.

A, to me, a prescriptive ALARA is the equivalent of a regulation. So you either have ALARA,

leaving it to the licensees to take action to keep doses as low as reasonably achievable, or you introduce new regulations. And so I think there's a logical inconsistency that ultimately dictates that non-prescriptive ALARA recommendations are what should be on the books, and that's exactly as Mr. Costello has said.

MR. COSTELLO: I totally agree. I mean, prescriptive ALARA is almost oxymoronic. It is almost a contradiction in terms.

CHAIRMAN THOMADSEN: This is Bruce Thomadsen. Just another readability issue -- in the answer to question seven. Following the answer, there are some references in the CFR, and all of that is put in italics, which is what designates the questions in this document. I'd recommend doing something different with those citations so that they don't look like another question that's following.

MR. COSTELLO: I agree, that was my fault.

CHAIRMAN THOMADSEN: And we're a non-blame culture here.

MEMBER LANGHORST: This is Sue Langhorst. We will make that change Dr. Thomadsen, thank you very much for that comment.

Are there any other comments or questions?

Great. Hearing none, let us move on then to Issue Paper 5. This is Metrication -- Units of Radiation Exposure and Dose. And Mr. Mattmuller led this effort, so if Steve, if you would summarize that and lead that discussion. Thank you so much.

MR. MATTMULLER: Hi. This is Steve Mattmuller. And of all the issues, this one was probably the least controversial and the one which I think, despite me wanting to take credit for brilliant arguments, everyone was pretty much in agreement with before I even got started.

And really, to be brief, to summarize, I think it could best be summarized by the Health Physics Society's position statement of "Nearly all the countries in the world, many with well-established nuclear industries, have effected this transition successfully, without compromising health and safety, and have demonstrated that complete conversion to current international units is certainly practical and doable."

So perhaps we have an opportunity to get some branding with the Nike corporation and we should just adopt their logo of "Just do it." So the Committee's recommendation is to adopt the SI Units, essentially as soon as possible. And that's the end of my summary.

Open for questions.

MEMBER LANGHORST: This is Sue Langhorst. Steve, thank you so much. That -- I agree, especially in the medical arena, we're just so used to -- some of us more than others -- used to using the SI Units that it would be very helpful to have that ability to switch to those when we can. Any other questions or comments from the Committee?

MEMBER ZANZONICO: This is Pat Zanzonico, just a comment. As we know, radiation, radioactivity, doesn't recognize national borders. And certainly if there are incidents or events where there's radiation exposures that may involve more than one country or even a single country but individuals from multiple countries, as I think we saw in the Fukushima event, it really can complicate addressing these issues when different groups are using different systems of units, so I think it's long overdue and really makes sense to comply with sort of the international standard in using the SI system of units. Thank you.

MEMBER LANGHORST: Any other questions or comments from the Committee? This is Sue Langhorst.

Okay. Hearing none, we will move on to Issue Paper 6, Reporting of Occupational Exposure. And that was -- I guess, being chair, I get two of these sections,

so that's my punishment.

So in regard to 10 CFR 20.2206(a), the NRC requires certain types of licensees to provide them with annual occupational exposure information, and the NRC is asking in this section, should that be increased? Should that be expanded to more types of licensees?

And I looked at the NRC's latest Occupational Radiation Exposure Report, which is referenced here, and in regard to reactor licensees, this makes a lot of sense because the NRC is the sole regulator in regard to radiation exposure in those types of licensees, and in the fuel cycle licensees also.

In regard to material licensees, we all know that's a little bit different of a picture. The NRC does recognize that this requirement is not necessarily imposed by Agreement States, although I think there are Agreement States that do provide that information to the NRC.

And so in this discussion, the NRC was asking the questions of whether this should be expanded to get more occupational exposure for various reasons. And if you go to the answer we put together on question three, Sophie if you can move down to that table, I tried to put together a little bit of an understanding of who all is exposed to radiation and not necessarily just

radioactive material, and who was regulatory authority over this.

So this was my attempt of trying to get a rough estimate, and I think it's consistent with how the NRC has listed numbers of licensees in their Occupational Dose Report in 2012.

As you all know, some of the -- a lot of our radiation exposure in the medical community comes from radiation-producing machines rather than radioactive materials covered by the NRC, and so those are regulated by the States and to some extent to OSHA, Occupational Safety and Health Administration, and so basically, we recommend that there not be an expansion of licensees for this because it would not meet a need for a national data gathering of occupational radiation exposures, and that probably -- if such a data gathering was deemed helpful, then the question of who should be doing that and how it's done needs to be expanded much more than NRC's regulatory purview.

In, as I mentioned, in the beginning that I had inadvertently left a phrase in on the general recommendations that we have listed on the first page, I should have deleted "except for considering the addition of a possession category for 100 curies of fluorine-18." So the reason that I wanted to raise that

question with the subcommittee was, you know, is there need to do some dose -- occupational dose data gathering for these types of licensees that is new to the NRC's regulatory authority as of 2009, I believe, was when this -- well, at least that's when it was implemented for the State of Missouri.

And ultimately what we discussed was that this is a relatively small number of occupational workers and again, it has that same issue of Agreement States needing -- or Agreement States licensing a lot of these cyclotron production facilities, and so they wouldn't necessarily come under this regulatory authority that NRC is discussing. So ultimately we decided that it just didn't need to be expanded to that small set of workers.

And I think that concludes my summary. I am glad to take any questions or comments that the Committee may have. Are you all still there?

CHAIRMAN THOMADSEN: Yes, Bruce Thomadsen here, and one -- in support of what you've recommended here, the concept of trying to come up with some average occupational exposure by looking at reports of exposure misses a very large class of radiation workers at facilities such as the universities here, which are not badged because they have an extremely low likelihood of every getting close to a tenth of their maximum

permissible dose.

And if it were added in to the denominator of occupational workers, it would certainly change markedly that average occupational dose. So going to a great expense to try to expand the numerator of that equation hardly seems worth the expense that it might cause the people who would have to start generating reports.

MEMBER LANGHORST: Thank you. Frank, could you mute your phone please? Thank you.

MR. COSTELLO: Sorry, sorry sorry.

MEMBER LANGHORST: Thank you, Dr. Thomadsen. I will add something in there to that effect. I think that's a very good point. I appreciate that.

Are there any other comments or questions? Okay. Let me go back then to the general recommendations and address that.

One recommendation we had on the cumulative effects of regulations -- there were a series of questions in the advanced notice for proposed rulemaking in regard to this, but we really felt like we only had just one response, as far as the question on how implementation should be handled. And those of you who have been around as long as I have remember that there was a significant change in 10 CFR Part 20 implemented

in 1991, and we felt that the NRC had a really good way of making that implementation change in that when that final rule was published, they allowed licensees to change to the new system, and obviously it was either you had -- you worked under the new Part 20 or you continued working under the old Part 20 -- I think it wasn't as soon as 30 days after the publication of the new Part 20, but definitely within a certain time frame, and I think it wasn't quite two years, but close to that.

And we recognize, while we have been reviewing these questions and answers in regard to medical licensees and those -- what I call a medical support licensee that helps in the medical use of isotopes, that there is a challenge to changing equipment such as meters, there's a challenge of changing computer systems, of recordkeeping, and so on.

And so we would recommend that the NRC again implement an implementation plan much like they did last time, but maybe even have at least three years to allow licensees to switch over, in particular to new units and new -- the new dosimetry methodology and terminology.

I'll ask if the Committee has any questions or comments in regard to that.

MEMBER ZANZONICO: This is Pat. I agree, of course, and I think one point worth noting is so many

of our records are computer-based these days and using commercial as well as homemade software, and one should never underestimate the time it takes to re-code and debug and otherwise test computer code, even for very -- seemingly very simple revisions, so I think a three year time frame for implementation is certainly reasonable and warranted.

MEMBER LANGHORST: Thank you. This is Sue Langhorst again. Any other comments or questions?

So Dr. Thomadsen, this concludes our presentation. I will turn it back over to you for further discussion.

CHAIRMAN THOMADSEN: Thank you very much. Are there any comments from the Committee on this report?

MEMBER ALDERSON: Yeah, this is Dr. Alderson. I'd just like to compliment Dr. Langhorst and her team. I think this was a terrific documentation and excellent report.

CHAIRMAN THOMADSEN: Thank you very much, and I certainly second that. Other comments?

In that case, I will open the floor to other than the Committee who would like to comment on the -- or ask questions.

I am not hearing any. In that case, I think we have two motions that we should look to right now.

The first is to accept the report, and the second is to endorse the report. So given that this is a subcommittee report, we don't need a second, and the subcommittee, I assume, is making the motion to approve its own report. And Dr. Langhorst, is that the case?

MEMBER LANGHORST: Yes, this is Sue Langhorst. I would say with some of the minor adjustments that we said we would be making like the edit on the first page and adding a few extra comments that we have discussed here in the meeting.

CHAIRMAN THOMADSEN: Very good. So we will take a vote on accepting the [recommendations in the] report. And we can probably do it by voice. All in favor, say aye.

(Chorus of ayes.)

CHAIRMAN THOMADSEN: Are there any opposed?

(No audible response.)

CHAIRMAN THOMADSEN: Are there any abstentions?

(No audible response.)

CHAIRMAN THOMADSEN: Then I would say that the ACMUI has accepted the report, and we do certainly give a lot of credit to the Committee for doing a great job on that.

The next would be to endorse the report as the

recommendation from the full Committee. And Dr. Langhorst, again, would you be making that motion, of course with the edits that you mentioned?

MEMBER LANGHORST: Yes, this is Sue Langhorst, and yes, I make that motion.

CHAIRMAN THOMADSEN: Very good. Are there any -- is there any discussion on that motion?

Hearing none, all in favor, please say aye.

(Chorus of ayes.)

CHAIRMAN THOMADSEN: Are there any opposed?

(No audible response.)

CHAIRMAN THOMADSEN: Are there any abstentions?

(No audible response.)

CHAIRMAN THOMADSEN: In that case, we have approved the recommendations of this report as our own.

Is there any other business Sophie that we have to take care of before we go? I don't think we can.

MS. HOLIDAY: No, I don't believe that there are any further actions. I did want to take the opportunity, because I don't think -- it was a little bit of an oversight on our part, but you guys may have heard Mike mention Dr. Michael O'Hara during the roll call. Dr. Orhan Suleiman was the [previous] ACMUI FDA representative, and he retired from federal service in

October. So the FDA has appointed Dr. Michael O'Hara as the new ACMUI FDA representative.

MEMBER O'HARA: It's nice to be working with all of you.

CHAIRMAN THOMADSEN: And congratulations and welcome.

MEMBER O'HARA: Thank you.

CHAIRMAN THOMADSEN: With that --

MEMBER LANGHORST: Dr. Thomadsen, this is Sue Langhorst.

CHAIRMAN THOMADSEN: Dr. Langhorst?

MEMBER LANGHORST: Yes, I would just like to thank the subcommittee members. They did an awesome job, and I really appreciate the Committee coming to this meeting having reviewed our draft report. I know it was some pages long and really appreciate all your comments and suggestions.

CHAIRMAN THOMADSEN: And thank you for that comment. With no other comments waiting, I'll stand in silence. We are adjourned. Thank you all for attending.

(Whereupon, the meeting went off the record at 3:15 p.m.)