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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

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THURSDAY,

APRIL 8, 2004

The ACMUI met via teleconference at 1:00 p.m., Thomas Essig, Designated Federal Official and Acting Chair, presiding.

COMMITTEE MEMBERS PRESENT:

DAVID DIAMOND, M.D.

DOUGLAS F. EGGLI, M.D.

NEKITA HOBSON

RALPH P. LIETO

RUTH McBURNEY

SUBIR NAG, M.D.

SALLY WAGNER SCHWARZ

ORHAN SULEIMAN, M.D.

RICHARD J. VETTER, Ph.D

JEFFREY F. WILLIAMSON, Ph.D.

ALSO PRESENT:

DR. CAROL MARCUS

DR. JEFFREY SEIGEL

NRC STAFF PRESENT:

THOMAS ESSIG, Designated Federal Official

DONNA-BETH HOWE

ROBERTO TORRES

ANGELA R. WILLIAMSON

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

1:05 p.m.

ACTING CHAIR ESSIG: Well, let me open the meeting then. This is Tom Essig speaking. As the Designated Federal Official for this meeting, I'm pleased to welcome you to this publicly noticed conference call meeting of the ACMUI.

As I mentioned, my name is Thomas Essig. I'm the Branch Chief of the Materials Safety and Inspection Branch and have been designated as the Federal Official 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 rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

The meeting was announced in the March 29, 2004 edition of the *Federal Register*.

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 them very much.

I request that whenever possible, we try to reach a consensus on the issue before us today, but I also value any minority or dissenting views by Committee members on the matter that's in front of us. If you have such views, please allow them to be read into the record.

As part of the preparation for the meeting, I have reviewed the agenda for the members and employment interests and based on the general nature of the discussion that we're having today. I've identified that the lone agenda item we have, which is the St. Joseph Mercy Hospital dose reconstruction is posing a conflict for Committee Ralph Lieto because that hospital's Mr. Lieto's current employer. I ask that he not participate in any of the Committee's decision making activities, other formal actions or recommendations or conclusions related to the dose reconstruction effort for the St. Joseph Mercy Hospital case.

If during the course of our business other members determine that they have a conflict of interest related to this matter, would they please state it for the record and recuse themselves from that particular part of the discussion.

At this point I would like to perform a

roll call recognizing that we've already done this, but this will be the official roll call.

I would note that Dr. Manuel Cerqueira, chair of the ACMUI regrettably had to be absent today and Dr. Leon Malmud, Vice Chair of the ACMUI also had to be absent today.

So next I will just go down the list of Committee members.

Nekita Hobson?

MS. HOBSON: Here.

ACTING CHAIR ESSIG: Ruth McBurney?

MS. McBURNEY: Here.

ACTING CHAIR ESSIG: Dr. Eggli?

DR. EGGLI: Here.

ACTING CHAIR ESSIG: Dr. Diamond?

DR. DIAMOND: Here.

ACTING CHAIR ESSIG: Dr. Nag? Dr. Nag.

DR. NAG: Can you not hear me?

ACTING CHAIR ESSIG: Can you not hear me?

DR. NAG: No, I can.

ACTING CHAIR ESSIG: Okay. I was just calling to see if you were present?

DR. NAG: Yes. Right.

ACTING CHAIR ESSIG: Okay. Sally Schwarz?

MS. SCHWARZ: Here.

ACTING CHAIR ESSIG: Dr. Vetter?

DR. VETTER: Here.

ACTING CHAIR ESSIG: Dr. Williamson?

DR. WILLIAMSON: Here.

ACTING CHAIR ESSIG: Mr. Lieto?

MR. LIETO: Here.

ACTING CHAIR ESSIG: And Dr. Suleiman?

DR. SULEIMAN: Here.

ACTING CHAIR ESSIG: And were there any of the newly appointed Committee members who are participating today? Dr. Robert Schenter? Dr. William Van Decker? Or Mr. Ed Bailey? Okay.

None were able to make the call.

And now I would just go around the room here at NRC headquarters to ask NRC staff to identify themselves.

As I mentioned, my name is Tom Essig. I'm serving as the Designated Federal Official and Acting Chair of the ACMUI today. My name is spelled E-S-S-I-G.

Next?

MS. HOWE: Donna-Beth Howe. And I'm here in the MIS Branch.

MS. WILLIAMSON: This is Angela Williamson here at NRC headquarters in the Medical Inspection

Branch.

MR. TORRES: I'm Roberto Torres. I'm a section chief in the Materials Safety Inspection Branch.

ACTING CHAIR ESSIG: And do we have any other members of the NRC staff on the phone today? Okay. Hearing none, following -- I recognize that we have members of the public also participating today. And following the discussion of the agenda item, we will entertain comments or questions from members of the public who are participating with us today.

And as I mentioned, in the absence of the ACMUI Chair and Vice Chair, as provided by the bylaws, I will serve as Acting Chairperson today.

And so with that I would like to -- Dr. Williamson, if you would summarize for us the report of the Subcommittee for the membership as a whole. I believe they were separately emailed the Subcommittee's report so that we may entertain a motion to accept and move on from there.

DR. WILLIAMSON: Okay. This is Jeff Williamson speaking representing the Dose Reconstruction Subcommittee.

Well, I will refer to the memo dated 4/01 that Dr. Malmud our Chair has prepared. I will just

briefly summarize the main points in it. I will not read it.

Point one in the memo basically states that the report was based on largely on my technical review of the information at hand, including both what the inspection from Region III on site were able to provide, factual material -- and in addition, I also interviewed Mr. Ralph Lieto and had available to me other documents that St. Joseph Hospital had submitted for consideration by Region III.

The resolve was is that I concluded that the individual involved, who was the patient's daughter, received in kind of a best case/worse case scenario between 4 and 9 rem. This was somewhat lower than the 15 rem estimated by the Region III staff.

I assume it's not necessary for me to rehearse the details and chronology of the event, that it's all well known to us. But if anyone wishes to, we can certainly do that. Okay.

Would it be appropriate for me to just march through the memo or do you want to hear more technical description of how I came up with that?

DR. NAG: Yes, I think we can go through the -- just go through the memo so that we have the plan. And then if anybody has any points or questions

they can ask.

DR. WILLIAMSON: Okay. All right.

So even in the lowest case estimate, it's important to note, which was 4 rem, the radiation burden would have exceeded the 100 millirem limit then current for exposure to a member of the general public. And so in this sense, you know, this discrepancy has no bearing on the regulatory issue at hand. Okay.

Point two states that the calculation of 4 to 9 rem that Dr. Williamson submitted to the Subcommittee would mean that the NRC Regional Office overestimated the exposure to the daughter by 3.75 to 1.67 times its calculation. I mentioned that since, you know, this was one of the phrases that was considered controversial.

The reason for the differences, like three in the estimated radiation burden, had to do with the assumptions of the time and distance of exposure of the daughter to the patient. I won't go into the details here, but I'm happy to talk about them.

There was agreement among members of the Committee that the calculations performed by the Regional Office of the NRC which produced the radiation burden of 15 rem were overly conservative

because they assumed extended close contact between the patient and the daughter at an unrealistically close distance and ignored use of local shielding.

More specifically, Monte Carlo simulation, use of Monte Carlo simulation to reconstruct the bedside distance suggested that this distance, which was estimated by me to be about 20 centimeters, seemed a bit unrealistic given the scenario of where the patient and daughter were positioned relative to one another given by the regency staff.

Use of continuous decay would have lowered the dose estimate about ten percent. But most importantly the licensee post-incident interviews and dose reconstruction lead to an alternative scenario regarding the use of body shields and daughter dwell-time distribution and that derived from the Region III interviews.

The Subcommittee strongly feels that these differences should have been outlined in the inspection report and used to, at least in this case, define upper and lower bounds on the exposure.

When NRC requests that a medical consultant assess medical risk, the NRC should provide to the consultant an estimate of total body exposure as well as TEDE since the former is better correlated

with any adverse medical effects associated with the exposure.

We suggest that a discrepancy of any between the licensee and the NRC inspectors should be described in the final presentation with the data and high dose/low dose estimates be reckoned on the basis of that.

So, any questions in this part so far? Hello?

ALL: No.

DR. WILLIAMSON: Okay. I hear some other strange noises in the background. I just wanted to check I was still live here.

Okay. Point number five. Perhaps prompt contemporaneous notification to the NRC Regional Office of the unwillingness of a member of the general public to comply with the directions with the RSO would have had the desirable effect of assisting and better documentation of the event.

Six. A concern of the Subcommittee is how such a similar situation in the future might be handled in a more optimal manner by both the public and licensee. Therefore, the Subcommittee recommends that the ACMUI recommend the following to the NRC:

Firstly, that NRC should develop an

information notice regarding contemporaneous notification of the Regional NRC Office basically of such situation. This IN should summarize all available guidance on exposure limits and licensee options when a family member insists on attending a radioactive patient. And specifically it should address licensee options and responsibilities when a member of the public is basically noncompliant with their directions; and (b) the latitude allowed licensees and enforcement personnels to grant exemption from these regulatory limits on compassionate or medical necessity grounds. That's the first recommendation.

Essentially, write an information notice based on this event and let licensees know where they stand, what sorts of regulatory solutions exist under the current body of regulations.

The second recommendation is that a process should be developed by NRC to grant in real time exemptions from the 500 mR exposure limits to family members or by extension other individuals who desire closer proximity with and/or time with the radioactive patient than would be permitted by the current limits. The exemption should be based on humanitarian or compassionate grounds or possibly on

the grounds of medical necessity.

So that's the second major point, which is based on the presumption that the current system really doesn't allow enforcement personnel to, you know, really have much latitude in granting exemptions from this particular regulatory limit.

Okay. So that concludes my summary.

DR. SULEIMAN: I have -- this letter is going to be the ACMUI's report to the NRC or is that the Subcommittee's report to the ACMUI?

DR. WILLIAMSON: This is the Subcommittee's recommendations to the ACMUI.

DR. SULEIMAN: Okay.

DR. WILLIAMSON: You know, these committees really -- I mean, I don't think other the summary that was given in the last ACMUI conference call, these regulations have really never seen -- or this recommendation or this document has really not be exposed to public discussion.

DR. SULEIMAN: Okay. And this is my first opportunity to discuss it in front of the Committee.

DR. WILLIAMSON: Let me before you continue make just one more comment, that to all the Committee members, and I hope everybody else who is curious about this matter or interested in it, I did

send, you know, a more a technical document that I had prepared summarizing my findings for the Subcommittee along with the slides that I presented at the last physical ACMUI meeting.

ACTING CHAIR ESSIG: Jeff, if I may ask or may make a point of clarification, I believe that although Dr. Malmud's cover memo to Dr. Cerqueira indicated that the product of the Subcommittee was the two page memorandum dated April 1st, I believe since it references the first point of that memorandum references your analysis, that the complete report of the Subcommittee should probably be your slides plus the supplemental analysis that you performed.

DR. WILLIAMSON: I think that would be reasonable.

ACTING CHAIR ESSIG: Because then if we don't do that, then it's leaving a key piece of the information out that if someone were interested and wanted to look at the details behind the four to 9 rem range, for example, you have that in your slides and additional findings.

DR. WILLIAMSON: In fact, I will say that I would appreciate it if somebody went over it very carefully in the event that, you know, I made some error or erroneous assumption. I'm not sure that

anybody on our Subcommittee has gone through every single detail of it, to be honest.

ACTING CHAIR ESSIG: Okay. So I think to answer Dr. Suleiman's question what will happen from this point is if we have a motion to accept the report as a Subcommittee, and consequently then with a recommendation that it be forwarded to the NRC as part of the -- as its deliverable or its product of its efforts. In order to accomplish that last piece, then Dr. Cerqueira will write a transmittal memorandum which basically attaches the April 1st memorandum from Dr. Malmud plus Dr. Williamson's slides and the additional findings. That will all be one package attached to a transmittal memo.

MS. WILLIAMSON: I believe the April 5th-- I think I heard you say April 1st.

ACTING CHAIR ESSIG: No. The April 1st.

MS. WILLIAMSON: I'm sorry.

ACTING CHAIR ESSIG: Yes.

MS. WILLIAMSON: I stand corrected.

ACTING CHAIR ESSIG: Yes.

And so I believe we're in the process of getting any additional comments or discussion from other Committee members, and maybe we should see if there are any further points of discussion.

DR. VETTER: There were some comments on this April 1st memo that have not been incorporated into the memo.

And I'm happy with the Subcommittee report coming to ACMUI the way it reads, but there are some things that I would suggest be changed a bit if it's forwarded to the Commission as the report of the ACMUI.

ACTING CHAIR ESSIG: Yes.

MS. McBURNEY: I agree with that. There were several suggestions on depersonalizing it and some other ideas that were floated that sounded -- as far as what the ACMUI was going to forward on to the Commission. I don't know what the process for that would be, whether the memo would have to go back and be changed or whether we put something on top of it saying, you know, this is -- or a separate memo from the ACMUI to the Commission.

DR. SULEIMAN: I agree with what's just been said. I think the Subcommittee report is fine with me, it represents the work and thinking that they did. But I, too, have some reservations of just forwarding this Subcommittee's report and saying it reflects, you know, the message that we want to transmit to the NRC as the ACMUI.

Some of it is editorial, some of it's grammatical and a few technical things.

For example, the 3.7 to 1.67 when you consider the uncertainty with these estimates -- reads significant figures, this is not. So I mean, these are minor things that I don't think -- I don't know whether we want to spend a lot of time on it now. Maybe we could ask the Chair or we could discuss this in the fall meeting. I'm not sure.

ACTING CHAIR ESSIG: Dr. Suleiman, I think it would be very -- if people have comments, now is the time that we need to discuss them because this is the only time, or at least it was the only scheduled time that we have to make any additions or corrections to the report of the Subcommittee. Because it will -- I think it would be best if there are changes made to that as part of this call, and then Dr. Cerqueira can put a cover memo on there which doesn't condition the report of the Subcommittee in any way. It just merely forwards the report of the Subcommittee.

DR. WILLIAMSON: Okay. Well, why I don't volunteer to be the collector of the changes, unless someone from the staff, perhaps, would like to be involved in this. I'm just trying to nail the process down. I think there are going to be a number of

suggestions. Somebody has to make them.

And then is it possible under the existing framework of Sunshine laws to circulate the final document for final comments to the Committee members, ACMUI members without a publicly noticed --

ACTING CHAIR ESSIG: Well, yes, Jeff, I think it is possible because as long as all the comments that are being made are fairly well summarized today in this call.

DR. WILLIAMSON: Yes.

ACTING CHAIR ESSIG: The folks wouldn't see them necessary in writing, but they would have the substance of the comments.

DR. WILLIAMSON: Well, I would say there's, you know, several good comments that have been made. I would just like to save time, summarize them and basically propose that they be made.

Secondly, I think the first comment is I think the whole memo -- this memo should be depersonalized. My name should be removed and it should say the Subcommittee -- the calculations derived by the Subcommittee estimate the range of radiation exposure to be. And so everyplace where my name occurs, I think it should be removed.

MS. McBURNEY: I agree with that.

DR. WILLIAMSON: I'm okay with my technical input being an addendum to this.

ACTING CHAIR ESSIG: Yes. That sounds very reasonable.

DR. WILLIAMSON: Yes. Okay.

ACTING CHAIR ESSIG: So, Jeff, if you would as a member of the Subcommittee, you had -- I heard you more or less volunteer, and I would second motion that you -- I would accept your volunteering --

DR. WILLIAMSON: All right.

ACTING CHAIR ESSIG: -- to serve as scribe to collect these comments. And then this will have to be -- the memorandum will have to be basically redone and then forwarded to Dr. Cerqueira.

DR. WILLIAMSON: Okay.

ACTING CHAIR ESSIG: And unfortunately, Dr. Malmud is undergoing surgery today and we won't be able to touch base with him. And so it'll have to go ahead on the presumption that he would not object to any of the comments that are being made.

DR. WILLIAMSON: Yes. I think that's what I guess what we're going to have to do. He's out of action, so therefore he's not going to be in a position to vote or discuss this. so we just have to go on with the members that exist.

ACTING CHAIR ESSIG: Yes.

MS. SCHWARZ: I have a question as to when you would like to -- the deadline for receiving comments to change the memo?

ACTING CHAIR ESSIG: Sally, we're going to try to do that today, right now during this call. Because we need to give -- because this is a noticed call, we need to give any members of the public who are participating a sense of what the changes are going to be made to the memo.

DR. WILLIAMSON: Going on, I would like to make the proposal for the second change. And that is, I think that I would like to suggest we delete point two.

MS. McBURNEY: Yes.

DR. WILLIAMSON: I think it's redundant. And, you know, I think that anybody who wants to can calculate the ratio to as many significant figures as they want.

MS. SCHWARZ: That's good.

MS. McBURNEY: I agree. And that takes Dr. Suleiman's, one of his comments, the email into account.

DR. WILLIAMSON: Right.

MS. McBURNEY: Where you don't have how

much the over estimate was.

DR. WILLIAMSON: Okay. So I am going to delete that then, if nobody objects.

DR. SULEIMAN: No objection.

DR. WILLIAMSON: Okay. I'm fine with that, Orhan.

Okay. Then I think that another of Dr. Suleiman's suggestions that is very good is in point six, which will now be the new point five where we make the recommendations for the information notice and the process for granting exemptions from the 500 mR TEDE limit that the -- basically if the scope be broadened to include the concept of more general caregiver rather than just family member.

MR. LIETO: Since this is not the dose reconstruction issue. I made several comments a few weeks ago on the new item five. I really think we ought to strike the bullets altogether and just make it a general statement of future action by the ACMUI and/or NRC. Because I think we are quite prescriptive in these bullets and I think that we ought to -- based on the emails from both Dick Vetter and Orhan about possible suggests for change, I think we ought to leave ourselves a flexible opening on what we want to do regarding suggestions for future action.

DR. SULEIMAN: I tend to agree, Ralph. I think maybe a general statement that says we recommend that the NRC consider formal rulemaking to address this issue of family members, caregivers or whatever. Because I think it needs to be discussed a little bit more, and I don't think we can do it in a telephone conference. And I think we need to do a little bit more research and homework.

MR. LIETO: I agree with the one exception. I don't agree with the fact of putting this into future rulemaking space. I really think putting it in rulemaking space on how to respond to these situations is going to come back to bite licensees in the future.

Just as a suggestion to start the discussion, what I would like maybe just to suggest is that the second sentence of the new item five state something to the effect that therefore the Subcommittee recommends -- or I guess it should say -- well, therefore the Subcommittee recommends that the ACMUI in collaboration with NRC staff develop guidance regarding notification to the Regional NRC Office of Noncompliance by a member of the general public, period. And that's it.

MS. HOBSON: And I'm going to have to

leave you all, but it looks like you have a quorum without me.

So, if you'll forgive me, I'm going to say goodbye. And you guys can continue doing a good job.

DR. WILLIAMSON: Okay. Let me speak in behalf of what we have written here.

There are two points here. So I think the first point is, more or less, a passive one that simply since an event has occurred that could repeat itself in the future, that it would be helpful for licensees to be apprised of, you know, the current status of guidance and regulations, anything that NRC has that would be helpful at the moment in resolving this situation. So at least they know what the score is.

So, for example, they would know that there is no legal basis for transforming a caregiver into a worker, for example. They wouldn't need to worry about that because this would make it clear, and it would have other advice that when such happens, maybe extra vigilance in terms of gathering data that could make the dose reconstruction issue easier to solve in the future, and various other things. So, you know, to me it seems it's a very neutral recommendation. It's simply that the NRC distribute

information to the licensees about the implications of the current regulatory system for future events of this kind and offer what advice might seem reasonable. So I don't know why anyone would object to that.

MR. LIETO: As I've pointed out previously to the Subcommittee and others, the Commissioners asked us at the meeting to provide this type of guidance. I think if it had been out there in NRC regulatory space or in some type of guidance space for just the regions, I wouldn't think that the Commissioners would be asking us --

DR. WILLIAMSON: No, I think you misunderstand our charge. We were given one charge by the Commission, and that was essentially to evaluate this particular dose calculation formalism and speak to the criticisms made by Dr. Marcus' paper and, you know, address basically some technical concerns about the calculation system and the level of conservatism used.

It was the ACMUI action that charged us with two -- you know, with essentially two additional goals. One was to make any general recommendations, not just for this specific dose calculation, but for dose calculations in general. And the third point was to offer recommendations on the difficult issue before

us of what do you do with a family member or caregiver who insists or wishes to take on the burden of additional risk to themselves.

MR. LIETO: Well, I'm not arguing with that. The issue that I'm arguing with is that we're doing both those two and three when the deadline for those issues was not with this report. It was task number one that had the deadline that we're facing today. Okay. And the report meets that requirement.

What I'm suggesting is that the recommendations to meet those tasks two and three, that those not be included in this report.

ACTING CHAIR ESSIG: If I may comment at this point. I think Ralph Lieto's point is well taken, that is the issue that's in front of us today that we need to forward with some degree of expediency is the, as Jeff summarized, it would be basically the point number one, which would have been the review of the NRC's dose reconstruction approach as well as the critique provided by Dr. Marcus and Seigel and to provide us some input on those.

The recommendations two and three are really beyond the -- I mean, they're very -- it's something that we have to make sure is done, but I would -- I guess I'm tending to agree, if I may just

put on my acting chairman hat for a moment, tending to agree with Mr. Lieto that the charge of the Subcommittee to do those items two and three justice, I think we need more -- to discuss them more than just append them to a subcommittee report and get that into us with a rather short deadline for those two items. I think they deserve more of an airing than we're able to give them during this conference call.

MS. McBURNEY: I agree with that, because determining if the information notice route and/or rulemaking is going to be needed, I think that needs more research or more thought out. Because I had some questions on whether the information notice route was the appropriate way to go as well.

So if we just make it more general at this time, such as some of the language that Ralph had suggested for this first step, then we will have met the intent of what the Subcommittee was charged to do for the first step.

DR. SULEIMAN: I think first we need to bring closure on the letter. I think we just need to shorten and cut out some of the things, I think, and get that over with.

I think what was part six probably could be summarized -- and maybe we do defer to you, Jeff,

in terms of we want the ACMUI will recommend that the NRC consider addressing the issue about exposing certain people, members of the family separately. In other words, we don't have time to go into detail and argue all the size of the issues. Because I think other members have something else to contribute on this. So this is something that I think we should mention, but defer for subsequent discussion, you know, that it's not something that maybe we can address simply in this letter.

I have some other opinions that I'm just not going to share right now because I don't think I have -- you have the time nor I to discuss them amply.

DR. WILLIAMSON: Right. Well, I guess -- you know, that's fine if we want to take these items out.

I guess the remaining question is if there really any point in conducting a discussion of these issues via the Subcommittee? Perhaps it should just be put on the agenda for the next full ACMUI meeting.

DR. VETTER: I think that's exactly what needs to be done. The second sentence says "Therefore the Subcommittee recommends that the ACMUI" and then whatever words. So it will be the Subcommittee will have completed its report and the ACMUI will need to

pick this up and begin to work on this at their next meeting.

And these two paragraphs that you have here are an excellent start, and then take into consideration NCRP commentary 11 and other materials that I think will help us develop some pretty decent recommendations to the NRC staff.

MS. SCHWARZ: I agree with Dick Vetter in this regard particularly. The commentary 11 from NCRP. And he had made the suggestion in his email as well that the Committee be provided a copy of the commentary 11 and it would be nice if we could gather that information before the fall meeting so that we would have enough time to actually contemplate how to proceed on an individual basis and come together as a Committee in the fall.

DR. SULEIMAN: I have one question that maybe everybody else knows but for some reason I missed it, was the patient's daughter monitored with a badge?

DR. WILLIAMSON: No.

DR. SULEIMAN: Okay.

DR. WILLIAMSON: No. Okay. So maybe we should try to draw this number five.

So I think that maybe someone should

submit a, perhaps one of our Committee members could submit to me alternative wording for the second sentence of the new paragraph five and then I'll delete all the information from it in the final copy.

DR. NAG: Hello.

DR. WILLIAMSON: Hello. We all here? Okay.

DR. SULEIMAN: I'm willing to submit some wording.

DR. WILLIAMSON: Okay. Good. And then I'll put it in and send it out with the final copy.

ACTING CHAIR ESSIG: Okay. That sounds like a plan.

DR. SULEIMAN: So we can do that electronically?

DR. WILLIAMSON: I think we were told that we could. I think we've got the sense of the ACMUI is on record that we want to make a -- you know, more or less, nonspecific recommendation that the issue of caregivers who wish voluntarily or who voluntarily or involuntarily place the licensee in some jeopardy, you know, should be further considered.

DR. NAG: Yes. I think the suggestion someone made about having a dosemeter -- the question of a dosemeter should be incorporated in that portion.

MS. WILLIAMSON: Identify yourself, please.

DR. NAG: Dr. Nag.

DR. WILLIAMSON: Well, I think, Subir, nothing that specific is going to be incorporated at this time. That will become a topic of future discussion. I think that's the consensus.

DR. SULEIMAN: To the NRC staff, isn't it a requirement that when an individual is likely to receive 10 percent of a dose limit that they're supposed to be monitored?

MR. TORRES: Only if they're an occupational worker.

ACTING CHAIR ESSIG: That's occupational exposure.

DR. SULEIMAN: Okay. So let me tell you the wording I've worked up for that sentence. That the ACMUI recommend, and the wording starts from here, "that the NRC or the ACMUI at some future date consider either formal rulemaking or policy," that addresses Ralph's concerns, you know, "to address family members, caregivers who are neither medical patients nor occupational workers and who would otherwise be considered members of the general public" -- they're general members of the public? That's all

that applies to them, but they --

ANNOUNCEMENT: Your conference is scheduled to end in 15 minutes.

ACTING CHAIR ESSIG: That's good.

DR. SULEIMAN: Okay. Let me work out a--

DR. WILLIAMSON: Why don't you just work on it and send it to me.

DR. SULEIMAN: Okay.

DR. WILLIAMSON: And then we'll -- I think it would be --

ACTING CHAIR ESSIG: The shorter the better.

DR. WILLIAMSON: Yes. Dr. Suleiman alluded to the fact that there may be some -- if we return to now what is the main body of the report, there may be some sort of technical issues that the group might want to discuss or what the basis of, you know, my calculations were and so forth.

DR. NAG: One thing, I thought the Commissioners, they wanted not only the dose reconstruction, but they also wanted some suggestions. So I would say that, you know, some of the suggestions that we have should be incorporated at this point. And say additional recommendations will be discussed. So that at least they'll have some sense that, yes, we

are working on it and not just that we will be working on it.

DR. WILLIAMSON: Well, I think that what we should concentrate the suggestions on are point two of our charge, which was addressing dose calculation, dose reconstruction issues in general and not necessarily in this particular scenario, that what are the lessons learned with respect to dose calculation and how to avoid such controversies in the future. We tried to do that to some extent in our report by suggesting when there are contrasting views of the scenario that, you know, they be at least described in the report and dealt with.

MS. SCHWARZ: And you also, Jeff, made the recommendation that consultants should be provided more relevant data than the TEDE. I mean, you've made specific recommendations.

DR. WILLIAMSON: Yes. That's true. But we haven't really made, you know, a lot I guess.

MS. SCHWARZ: No, no. I agree.

DR. WILLIAMSON: Yes.

DR. MARCUS: Mr. Essig, this is Dr. Marcus.

At some convenient point I would like to make a few comments.

ACTING CHAIR ESSIG: Please do.

DR. MARCUS: Okay. The first comment I would like to make has to do with the TEDE versus the effective dose as defined by ICRP.

The TEDE is an attempt to get to that effective dose. It's somewhat conservative, which generally is okay. But in a situation where the TEDE does not represent the effective dose as it does not in this case, there should be a way to substitute the effective dose as the dose of record.

This is a very unusual situation. The TEDE was mainly put together for workers. And there should be a way to establish an objective dose that has a risk meaning instead of leaving a TEDE in place that is not indicative by a factor of perhaps four or so of an actual dose.

And the second comment I want to make is that I think that someone, perhaps Ralph Lieto, should inform the daughter that her likely dose is much lower than what was estimated. Because she's probably worrying. And I have known people who have worried a lot about radiation dose. And we should not forget her because we could probably save her a lot of grief.

The third point I want to make, and the last point, is that when I originally wrote the 500

millirem patient discharge rule position and it was being discussed by Chairman Carr at a meeting of the agreement states, the whole issue of what do we do if people don't listen to what the radiation safety officer or the authorized user tells them. And it was agreed at the time that this could happen, but that the responsibility of the licensee was to inform the people that they have no legal ability to force anything on them.

I also checked with my radiation control people in California after this incident. One of our regulators is also a lawyer as well as a physicist. And she said that basically if the members --

ANNOUNCEMENT: Your conference is scheduled to end in ten minutes.

DR. MARCUS: I won't take that long.

If a member of the public is about to be exposed to a level of radiation that is truly dangerous, then you can call the police and have them bodily dragged out. But if the only problem is that the dose of radiation is above a regulatory limit but not a clear and present danger to that person, that there's nothing you can do at all. You cannot forcibly get them out of there.

And that's the end of my comments. And I

thank you.

ACTING CHAIR ESSIG: Thank you for your comments.

DR. SEIGEL: And Tom Essig, if you wouldn't mind, Jeff Seigel, I'll make one comment.

ACTING CHAIR ESSIG: Fine.

DR. SEIGEL: Really quickly.

I was under the impression that part of the charge of the Subcommittee was to assess the article that I and Carol wrote. Currently that charge is not included at all in the ACMUI Subcommittee evaluation.

DR. WILLIAMSON: That was not my impression at all. We certainly reviewed your article and considered it. But, you know, I didn't understand we were charged to make a review of your article specifically.

DR. SEIGEL: I was under a misunderstanding. I thought you were.

ACTING CHAIR ESSIG: If I may, I can read the charge to the Subcommittee, which says "The Subcommittee is specifically requested to evaluate the approach to dose reconstruction taken by the NRC Region as well as the critique of the inspection report prepared by Drs. Marcus and Seigel. In

preparing its report the Subcommittee should indicate for each aspect of the dose reconstruction and the Marcus/Seigel critique whether it agrees or not with the evaluations and representations presented and why."

DR. SEIGEL: Okay. So I'm correct. So then I think the Subcommittee should stop bickering about minor points and address their task, which was to address our paper.

DR. WILLIAMSON: Well, members, would do you suggest we do about this?

MS. McBURNEY: Who is else is on the Subcommittee?

MS. SCHWARZ: Sally Schwarz.

DR. WILLIAMSON: Yes. So I guess as an acting chair of the Subcommittee, is that what I am, Tom?

ACTING CHAIR ESSIG: Yes. Because I'm acting chair of the full Committee.

DR. WILLIAMSON: I would like to ask for a volunteer from our Subcommittee to basically go through, you know, carefully the Marcus/Seigel report and contrast with my technical report and determine whether we would agree with the points therein or not.

I think in many respects we do. I thin in

other respects, probably, not -- I'm not sure of particular importance, we may not.

DR. VETTER: As you know, I reviewed Marcus/Seigel paper and shared my comments with Jeff. But I'm not a member of the Subcommittee, and that was for his information only. But if I may, I would like to just make a comment that I think in general, just speaking in general terms, that the report of the Subcommittee agrees fairly substantially with the Marcus/Seigel paper. It doesn't agree in detail, of course, because they looked at many different scenarios and suggested that the dose would be lower by a factor of whatever it was because of some very specific things that they were looking at for each scenario. But in general they concluded that the -- to get back to Dr. Marcus' comments a little bit earlier about looking at effective dose as opposed to TEDE, in general they suggested that the dose had been over estimated and the Subcommittee made the same conclusion.

DR. WILLIAMSON: Yes. Yes. I don't think at this point we would be prepared as a Subcommittee to suggest a rulemaking initiative to modify Part 20 to rearrange all those dose quantities. I think it's certainly something worth talking about. I would

support personally. But I don't think we had discussions of that nature and I don't feel personally--

DR. SEIGEL: I'm sorry, Jeff. But nor did our paper advocate the change in regulatory definition of TEDE. It just said that there were regulatory criteria which had to be meet, but also criteria that should be met in addition if risk assessment were to be involved.

DR. WILLIAMSON: And that's indeed what we said.

DR. SEIGEL: Correct. So we're not trying to change the definition of the TEDE vis-à-vis the--

DR. WILLIAMSON: I think the major difference is, is that we looked at alternatives basically --

ANNOUNCEMENT: Your conference is scheduled to end in five minutes.

DR. WILLIAMSON: -- time distributions. That's where we -- we had somewhat more documentation to examine that I suspect you had. So we went down a different pathway. But many of the points you made are -- we do agree with. And I think that perhaps someone from our group can maybe make a list and go through to indicate, you know, the points on the

paper, the Marcus/Seigel paper and what the Subcommittee's response was.

So I'm wondering if someone would volunteer to do that?

ACTING CHAIR ESSIG: If I may suggest, I believe the person that's best equipped to do that because there's familiarity with the Marcus/Seigel paper, is Dr. Rich Vetter. And although, Rich, as you acknowledged, you weren't an official member of the Subcommittee but you are a member of the main Committee, would you agree to taking on that task and maybe doing that summarization and then forwarding it to Jeff so that he can put it in the Subcommittee's report?

DR. VETTER: Well, I could do that except I'm leaving town shortly and won't be back until next Friday.

ACTING CHAIR ESSIG: Oh. Okay. Well then maybe --

DR. VETTER: That would be problematic in terms of trying to meet a short --

ACTING CHAIR ESSIG: I understand.

DR. WILLIAMSON: Do we have that short of a deadline or --

MS. SCHWARZ: I was going to say, isn't

two weeks acceptable or --

ACTING CHAIR ESSIG: No. Unfortunately, we've had one deadline that we've already had to extend. And if I need to extend it again, I will -- I guess I will have to, but --

MS. SCHWARZ: But it seems that since Richard Vetter has actually performed calculations--

ACTING CHAIR ESSIG: Yes.

MS. SCHWARZ: -- he's in the best position. And if he's not available, that certainly would be worth the wait.

ACTING CHAIR ESSIG: I can't argue that.

DR. WILLIAMSON: Well, it's your call, Tom. I think you know alternative people who might do it, you know, perhaps Dr. Suleiman might agree to do it or Sally herself.

MS. SCHWARZ: Right.

DR. VETTER: Right. I can share what I've done with whomever.

ACTING CHAIR ESSIG: Would Dr. Suleiman be willing to receive Dr. Vetter's insights and then craft some additional language for the Subcommittee report that you would forward to Dr. Williamson.

DR. SULEIMAN: I've got to consider that. Specifically what would you be asking for?

ACTING CHAIR ESSIG: You, I believe, had separately receive a copy of Drs. Marcus and Seigel's critique of our Region III inspection report. And there were several points made, perhaps six or seven observations that they had made with recommendations and conclusions. And what we need to do is compare that report with the current Subcommittee report and where it doesn't address the Marcus/Seigel report, provide some language as to whether or not the Subcommittee or the full Committee should agree with the observation or not. But I think that would be based on input from Dr. Vetter as well as your own insights.

DR. SULEIMAN: What sort of deadline would you be asking for?

ACTING CHAIR ESSIG: Well, I'm probably asking for an impossible deadline. I mean, we -- currently -- I'll just tell you what currently --

ANNOUNCEMENT: Your conference is scheduled to end in one minute.

DR. SULEIMAN: Because I'll be out of the office for the next couple of days, too.

ACTING CHAIR ESSIG: Okay. Well, then I don't know that it's doable. I expect what we're probably just going to have to do is extend the due

date. We're probably going to have to schedule another conference call and to go over this.

I think there are enough loose ends, we haven't even brought it to a vote yet in front of the Committee. And so what I would propose that we would schedule a conference call at the nearest possible time. We'll have to notice another one in the *Federal Register*, and we have to have a --

ANNOUNCEMENT: Your conference time has now expired. Thank you.

ACTING CHAIR ESSIG: So until I'm cut off, I'll keep talking.

We'll schedule another conference call and we'll communicate with you further by email.

(Whereupon, at 1:59 p.m. the conference call was concluded.)