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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SUBCOMMITTEE ON REGULATORY GUIDE 8.39, ''RELEASE OF PATIENTS ADMINISTERED RADIOACTIVE MATERIALS''

PUBLIC TELECONFERENCE MEETING

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WEDNESDAY,

MARCH 11, 2020

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The meeting was convened via teleconference, at 2:00 p.m., Darlene F. Metter, M.D., presiding.

MEMBERS PRESENT:

DARLENE F. METTER, M.D., Chairman

A. ROBERT SCHLEIPMAN, Ph.D., Vice Chairman

GARY BLOOM, Member

VASKEN DILSIZIAN, M.D., Member

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

MELISSA C. MARTIN, Member

MICHAEL O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

CHRIS EINBERG, Chief, NMSS/MSST/MSEB

SAID DAIBES, Ph.D., NMSS/MSST/MSEB

DANIEL DIMARCO, NMSS/MSST/MSEB

LISA DIMMICK, Medical Radiation Safety Team Leader, NMSS/MSST/MSEB

JENNIFER FISHER, NMSS/MSST/MSEB

ANITA GRAY, Ph.D., NMSS/MSST/SMPB

VINCENT HOLAHAN, Ph.D., NMSS/MSST

ESTHER HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSST/MSEB

KELLEE JAMERSON, ACMUI Coordinator, NMSS/MSST/MSEB

PENNY LANZISERA, R-I/DNMS/MLAB

SARAH LOPAS, NMSS/MSST/MSEB

JEFFERY LYNCH, NMSS/MSST/SLPB

MINH-THUY NGUYEN, RES/DSA/RPB

VERED SHAFFER, RES/DSA/RPB

KATIE TAPP, Ph.D., NMSS/MSST/MSEB

JOHN TOMON, RES/DSA/RPB

IRENE WU, NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC PRESENT:

JAIME BARNES, Cook Children's Medical Center

ROLAND BENKE, Renaissance Code Development, LLC

LISA BRUEDIGAN, Texas Department of State Health Services

TINA BUEHNER, Unaffiliated

DAVID CROWLEY, North Carolina Department of Health and Human Services, Radiation Protection Section

ELIZABETH FRANKLIN, Atrium Health

NOELLE GEIER, Froedtert & The Medical College of Wisconsin

JENNIFER GERSMAN, Northwestern Medicine

PHIL GOBLE, Utah Division of Waste Management and Radiation Control

MIGUEL de la GUARDIA, Cook Children's Medical Center

STANLEY HAMPTON, Eli Lilly

CURTIS HICKS, JR., Scripps Health

BILL HINCHCLIFFE, Yale New Haven Health

MARY ELLEN JAFARI, Gundersen Health

TYLER KRUSE, Minnesota Radioactive Materials Unit

RALPH LIETO, St. Joseph Mercy Health System

CAROL MARCUS, Ph.D., M.D., University of

California at Los Angeles

STEVEN MARSH, Baystate Health

RICHARD MARTIN, American Association of Physicists in Medicine

JEFFREY MASON, Department of Veterans Affairs

CANDI MCDOWELL, University of Pennsylvania

MARY MOORE, CMC Veterans Affairs Medical Center

LORA MOYLE, North Carolina State University

MICHAEL PETERS, American College of Radiology

CARMINE PLOTT, Novant Health

DANIEL SAMSON, New York State Department of Health

JEFFRY SIEGEL, Ph.D., Nuclear Physics Enterprises

ERIC SKOTAK, Texas Department of State Health Services

CINDY TOMLINSON, American Society for Radiation Oncology

BRIAN VAMVAKIAS, Texas Department of State Health Services

KAREN WHEELER, Bio-Med Associates

WILLIAM WHITE, Rush University

MATTHEW WILLIAMSON, Memorial Sloan Kettering Cancer Center

MELONIE WISSING, Department of Veterans Affairs

P R O C E E D I N G S

2:09 p.m.

THE OPERATOR: Welcome and thank you for standing by. I would like to turn the conference over to your host, Ms. Kellee Jamerson. Thank you; you may begin.

MR. EINBERG: Okay, this is actually Chris Einberg. Good afternoon. As the Designated Federal Officer for this meeting, I am pleased to welcome you to the public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Chris Einberg; I'm Chief of the Medical Safety and Events Assessment Branch, and I've been named as the federal officer for this advisory committee in accordance with 10 C.F.R. Part 7.11. Present today we have Lisa Dimmick, Medical Radiation Safety Team Leader, and Kellee Jamerson, our ACMUI Coordinator as Designated Federal Officers supporting the ACMUI.

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 may also be transcribed and recorded by others. This

meeting was announced in the January 4th, 2020 edition of the Federal Register, Volume 85, Page 4343.

The purpose of this meeting is to discuss the draft report of the ACMUI Regulatory Guide 8.39 Subcommittee. In its report the Subcommittee provides comments and recommendations on the final draft of the proposed Regulatory Guide 8.39, ''Release of Patients Administered Radioactive Material'', Revision 1, Phase 1.

The function of the ACMUI is to advise the staff on issues and questions that arise on the medical use of by-product material. The Committee provides counsel to the staff but does not determine nor direct the actual decisions of the staff or the Commission.

The NRC solicits the views of the Committee and values their opinion. I request that whenever possible we try to reach a consensus on the various issues that we will discuss today, but I also recognize 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. Darlene Metter, Chairman, diagnostic radiologist.

DR. METTER: Present.

MR. EINBERG: Dr. A. Robert Schleipman, Vice Chairman, healthcare administrator.

DR. SCHLEIPMAN: Present.

MR. EINBERG: Mr. Gary Bloom, patients' rights advocate

MR. BLOOM: Present.

MR. EINBERG: Dr. Vasken Dilsizian, nuclear cardiologist.

DR. DILSIZIAN: Present.

MR. EINBERG: Dr. Ronald Ennis, radiation oncologist. Mr. Richard Green, nuclear pharmacist.

MR. GREEN: Present.

MR. EINBERG: Dr. Hossein Jadvar, nuclear medicine physician, indicated that he cannot attend, so he's not here. Ms. Melissa Martin, nuclear medicine physicist.

MS. MARTIN: Present.

MR. EINBERG: Dr. Michael O'Hara, FDA representative. Dr. O'Hara? Okay. Mr. Zoubir Ouhib, radiation therapy physicist.

MR. OUHIB: Present.

MR. EINBERG: Mr. Michael Sheetz, radiation safety officer.

MR. SHEETZ: Present.

MR. EINBERG: Ms. Megan Shober, Agreement State representative.

MS. SHOBER: Present.

MR. EINBERG: And Dr. Harvey Wolkov, radiation oncologist.

DR. WOLKOV: Present.

MR. EINBERG: Okay. We do have a quorum. We have at least six members present. I would add that all members of the ACMUI are subject to federal ethics laws and regulations and receive annual training on these requirements. If a member believes that he or she may have a conflict of interest as that term is broadly used within 5 C.F.R. Part 2635, with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible before the ACMUI discusses any agenda item.

ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest unless they receive a waiver or prior authorization from an appropriate NRC official.

I now ask NRC staff members who are present to identify themselves. I'll start with individuals in the room.

DR. HOLAHAN: Dr. Vincent Holahan.

DR. HOWE: Dr. Donna-Beth Howe.

MR. DIMARCO: Daniel Dimarco.

MR. TOMON: John Tomon.

DR. GRAY: Dr. Anita Gray.

MR. EINBERG: Okay. That's it for here. Now I'll go to the NRC headquarters employees on the phone. Will you identify yourselves, please?

MS. HOUSEMAN: Esther Houseman, Attorney, OGC.

MR. EINBERG: Thank you. Any other NRC employees?

Okay. Members of the public who notified Ms. Jamerson that they will be participating on the teleconference will be captured in the transcript. Those of you who did not provide prior notification, please contact Ms. Jamerson at kellee.jamerson@nrc.gov, or at 301-415-7408 at the conclusion of this meeting.

We are utilizing a bridge line for today's teleconference, and that phone number is 888-386-8716, and the passcode to access the bridge line is 1049526#. This meeting is also using the WebEx application to view the presentation handouts in real time, and you can access this by going to usnrc.webex,

W-E-B-E-X.com and searching for Event No. 902926517; 902926517.

Individuals who ask a question or make a comment regarding a specific topic the Committee has discussed should dial *1 to signal the operator if you wish to speak. Please clearly state your first and last name for the record. Comments and questions are typically addressed by the Committee near the end of a presentation after the Committee has fully discussed the topic.

We will notify the operator when we are ready for the Public Comment period of the meeting. I would also like to add that the handouts and agenda items for this meeting are available on the NRC's public website.

At this time, I ask for everyone on the call who is not speaking to please place your phone on mute. If you do not have the capability to mute your phone, please press *6 to utilize the conference line mute and unmute functions. I would also ask everyone to exercise extreme care so 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 Dr. Metter.

DR. METTER: Well, thank you, everybody, for attending, and I believe Dr. Ennis has also joined the conference call; is that correct, Dr. Ennis?

DR. ENNIS: Yes, that's right. Thank you.

DR. METTER: Okay. So right now, as Mr. Einberg mentioned, we are going to discuss the release of patients administered radioactive materials Subcommittee Review and Comments. With that, I'll turn it over to the Chair of the Committee, Mr. Michael Sheetz.

MR. SHEETZ: Thank you, Dr. Metter. I would like to provide an overview of the ACMUI Subcommittee comments on the draft proposed Regulatory Guide 8.39, ''Release of Patients Administered Radioactive Material'', Revision 1, Phase 1. The other subcommittee members are Mr. Gary Bloom, Dr. Vasken Dilsizian, Ms. Melissa Martin, Dr. A. Robert Schleipman, Ms. Megan Shober, and our NRC staff resource is Dr. Said Daibes-Figueroa.

The NRC's current Reg. Guide 8.39, Revision 0, was issued in April of 1997, following the rule change in 10 C.F.R. 3575 to allow for the release of patients administered radioactive material on a solely dosed-based criteria.

Since that time, there have been several

challenges to the appropriateness of the release criteria and the associated precautions that are required to be provided to minimize radiation exposure to other individuals from the released patient.

Over the past several years, the NRC staff has conducted an extensive evaluation which included a review of published literature and stakeholder engagements with licensees, patients, and agreement states to determine whether significant regulatory changes to the patient release program are warranted.

A summary of this evaluation can be found in NRC policy issue document SECY-18-0015, titled Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release after Radioisotope Therapy.

One of the recommendations in this document was for the guidance in Reg. Guide 8.39 to be updated, simplified, and made clear and more explicit. The Subcommittee commends the NRC efforts on updating the guidance to licensees on meeting the patient release criteria.

It should be noted that Reg. Guide 8.39 is currently being revised in two phases: Phase 1, revision of Reg. Guide 8.39 updates the patient release guidance, including information for patient

instructions; and updates to Table 3 entitled Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child.

An initial proposed Revision 1 of Phase 1 Reg. Guide 8.39 was issued in March of 2019 and was reviewed by this ACMUI Subcommittee. Of course, the comments and recommendations can be found in our previous Subcommittee report dated June 19th, 2019.

The Subcommittee acknowledges and appreciates the notes to the recommendations from its previous report that have been incorporated into the current NRC final draft Phase 1 revision, issued in December 2019.

In the Phase 2 revision of Reg. Guide 8.39, the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients will be updated. This Subcommittee will review those changes once they have been published. It should be noted that the following Subcommittee comments on recommendations only pertain to the final draft Phase 1 revision.

In the current Subcommittee report provided for this teleconference, there are approximately 35 directed changes pertaining to the

wording, items of emphasis, and formatting of the document. In consideration of everyone's time, I will not be repeating these; however, if anyone has a specific question or concern related to any of the directed changes, we will certainly entertain them.

I would like to provide a summary of the Subcommittee's main comments and recommendations on the draft Reg. Guide. Number one: From the patient precautions and instructions sections it should be emphasized that the major source of radiation dose to other individuals will be from external exposure from the patient; therefore, the most important precautions to take are measures to reduce or avoid the external radiation exposure from the patient, especially in the early time period after administration of the radionuclide therapy.

Although release instructions may also include measures to limit the transfer of radioactive contamination to others, they should not overshadow or detract from the external precautions, and the radiation doses from internal exposures have been demonstrated to be small and negligible.

Number two: The patient instructions should be simple, clear, and concise. Consideration should be given to providing instructions at an

eighth-grade level of understanding and given in the patient's native or primary language. Studies have shown that the primary factor for limiting radiation exposure to others is in influencing the patient's behavior.

As the IAEA has noted, the success of a patient release program is critically dependent on the quality and specificity of the information provided to the patient, the skill with which it is communicated, and whether or not the patient believes the information provided.

Third: Discussions on the radionuclide therapy procedure and release instructions should also include a caregiver or family member, if possible. This may help improve recall and compliance with the instructions.

Four: The instructions should also be provided on how long the precautions should be followed. Per the guideline, licensees may want to consider using several -- three to five -- effective half-lives of the radionuclide therapy.

Consideration should also be given to standardizing this language through all the instructions to keep them simple and easy to follow.

Five: The Regulatory Guide should not

include instructions that are excessive or likely to cause patient anxiety, and not likely to reduce public exposures such as showering three times a day for the first two days; trying to empty your bladder at least every hour for the first eight hours; replacing a toothbrush or using a second rinse cycle when washing linens and personal clothing.

Also, the instruction to drink plenty of fluids should be removed as it may conflict with the patient's medical condition. Excessive fluid intake has been reported to cause hyponatremia or low blood sodium levels, which can cause seizures, coma, and even death.

Sixth: The Tables 1, 2, and A1 should be updated to include the new and potential radionuclides used in medicine, the table provided in the Subcommittee report that lists 13 new radionuclides along with their half-life and gamma constants.

Seven: In Table 3, Activities of Radiopharmaceuticals that Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child, the Subcommittee supports the guidance for a standardized interruption time period of 24 hours for all Tc-99m radionuclides, and the recommended interruption period to limit the

dose to the nursing infant to one millisievert and not the regulatory limit of five millisieverts. This provides simplicity to the instructions and is consistent with the ALARA principle.

Eight: In the Phase 2 Revision to Reg. Guide 8.39, where the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from patients will be updated, the Subcommittee suggests that the following issues be considered: (A) an occupancy factor 0.75 to 1.0 was unrealistic and could not be justified for routine application, even for radionuclides of a physical half-life of less than one day.

Dose calculations should be based on realistic assumptions and not overly-cautious or worst-case scenarios.

(B) The dosimetric models and calculations must consider an option that uses the effective half-life and/or other patient-specific factors for the radionuclide therapy. And (C) a dose-based model should be developed to provide guidance on when precautions or restrictions would be appropriate following the death of a patient administered a therapeutic quantity of radioactive material.

This concludes my presentation and the

Subcommittee report. Thank you.

DR. METTER: Thank you, Mr. Sheetz. Do I have any other comments or questions from the Subcommittee members?

MR. BLOOM: This is Gary Bloom; I have a comment.

DR. METTER: Yes, Mr. Bloom?

MR. BLOOM: Regarding recommendation five; I would like to propose that these items not be removed. I think that it's important to maintain a level of instruction between a physician and a patient, and I would actually assert that removing these items will actually cause more anxiety than removing them will benefit.

DR. METTER: Thank you, Mr. Bloom. Do I have any comments with the Subcommittee regarding Mr. Bloom's comment?

(Simultaneous speaking.)

DR. METTER: Yes, Dr. Dilsizian.

DR. DILSIZIAN: Oh, thanks. I hear both sides, and I guess -- and I do this rather frequently with patients -- the anxiety comes in when the patients are given specific number of, let's say, times I need to empty the bladder or the number of hours.

So, I think that if we make it more general; for example, try to drink a lot of fluids and empty your bladder frequently in order to minimize your exposure of -- and clear radiation in your urinary bladder. Something like that would be sufficient rather than every hour for the first eight hours, et cetera.

I think it's the numbers that make people obsessive-compulsive, but the general theme, as long as they understand why they're doing it, I think would probably be the better way to go.

DR. METTER: Thank you, Dr. Dilsizian. Any other comments from the Subcommittee? Any questions?

MR. OUHIB: This is Zoubir. I was just curious, Mr. Bloom, was there any specific item within that list, A through E, that you feel perhaps should not be removed?

MR. BLOOM: Should not -- I would not remove any of them. I agree with Dr. Dilsizian's explanation about the bladder. I agree with that. As someone who did actually have radiation, having very comprehensive discussion with my physician eliminated all anxiety on my part, and as I continue to speak to patients almost on a daily basis, I think the patients

who have these open discussions are more at peace with going through this experience.

You all have to realize that one of the things that causes anxiety is the word radiation. As a patient, this is a very anxiety-causing word, so anything that we can have a conversation about will remove that anxiety.

MR. OUHIB: Okay. All right, thank you.

DR. METTER: Thank you, Mr. Bloom. Any other comments? Yes, Melissa.

MS. MARTIN: Yes, this is Melissa Martin. I have been a radiation safety officer at three major medical centers over the past, say, 30 years. When we set our protocols if we have these patients, when we have them in-house more than we do now, we certainly did not change our wash cycle for the linens and include a second rinse cycle.

I was wondering if Mr. Bloom had any data that would support the requirement or his documentation as to what level of reduction you would expect to see from any retained radioactivity in the linens after the first wash cycle. I've never seen any of this data, and I've never detected it being a problem with only one wash cycle. So, I'm looking for some supporting data as to why this recommendation

should be kept.

MR. BLOOM: Scientifically, no. I don't have any data. But again, if the stated point was likely to cause patient anxiety, it's the empowerment of feeling like, as a patient, I can do something that is going to protect my loved ones in that wash cycle. Proving them, no; I can't do that. But I just --

MS. MARTIN: Well, I guess --

MR. BLOOM: -- talk to people, and they feel more comfortable with that.

MS. MARTIN: But that's a lot of what we call psychological shielding. It's the same effect of; Oh, maybe we should have three times the shielding on our walls because that might make me feel better. I'm more than willing to support the requirement anytime that is actually a documented and scientifically-proven requirement to do so. But to put this onus onto families with no scientific data behind it I think is not the best recommendation we could make.

MR. BLOOM: I'm sorry; I saw this instruction as a discussion point that a physician could talk to a patient about. If you feel that it's unwieldy, then certainly I could bend on that. I mean, that's not something I'm going to lose sleep

over.

DR. DILSIZIAN: So, this is Vasken again. I think I'm just kind of -- I hear both sides. I think that Mr. Bloom is simply saying that solve these things conceptually, not scientifically on something that's recommended.

For example, the second cycle obviously is unscientifically proven. But to recommend to wash your linen at first including towels but not specifically give the number of cycles, number of days, or frequency is a good thing. I think the theme of all of this is that the patient should be aware that showering doesn't have to be two or three times per day for the first two days, right? Just showering frequently; you don't have to say the number of times or number of days that will clear away any radiation that's in the surface of your skin; emptying your bladder.

So, I think that these can be more general themes, not specific times and hours. But will fulfill both of the needs. There's no science behind this; it's just recommendations and good practice.

MS. MARTIN: Well, I think it's much more important if you want to do that than recommend that you wash the patient's clothing and linen separately.

That, I could actually see a recommendation behind.

DR. DILSIZIAN: Yes.

MR. BLOOM: That's a good point. I'd go for that. I agree.

DR. METTER: Thank you, Melissa. Any other comments?

DR. SCHLEIPMAN: Yes, sorry, this is Robert Schleipman. I agree with Dr. Dilsizian; there is a middle ground here that can happen. I literally counseled several thousand patients receiving these, and I agree with Ms. Martin; a separate wash is more important than a second rinse cycle. And instead of removing completely to drink plenty of fluids, it could be instead to encourage them to drink fluids, but first check with your physician to see if there are any reasons you shouldn't do that. So, there's a way to do this without putting specific numbers or a sort of either-or-none imperative sort of instruction.

MS. MARTIN: This is Melissa. I would agree with that, and that's really my point: make these much more general if you're going to maintain them than all the specific requirements, because that's what patients have a lot of anxiety about; Oh, I only went to the bathroom for the first six hours, or something like that.

You don't want to increase the anxiety of the patient. You would like to make these very reasonable and not something that causes anxiety in the patient.

DR. METTER: So, going back to Mr. Bloom's comment about Number 5, what would you suggest you do with that section now at this point in time?

MR. SHEETZ: This is Mike Sheetz. Again, our comment on removing these was tilted toward the number that was placed in, and we thought that was the excessive part. Again, I have no problem. The first one can be shower or bathe daily.

DR. METTER: Correct. You mean make it more general?

MR. SHEETZ: Correct. Just like Dr. Dilsizian and the others supported; empty your bladder frequently, but leave out the number of times per hour or day, and then wash clothes separately.

I'm still not a proponent of the second wash/rinse cycle. I think that is excessive; it's not necessary. And I guess the Subcommittee didn't want to propagate these because they do very little to reduce exposure to anyone else.

I'd point out it's more harm to -- right now not to do the nanoshielding because it doesn't do

any good, and then causes actually more harm. So, all those things we did in the past, they're not necessarily the best practice or the best thing to do for patient safety, and so just because we did it in the past doesn't mean we should continue to do that. But I have no problem with leaving these easy things in on hygiene and so forth, but without the numbers.

DR. METTER: Would that be acceptable, Mr. Bloom?

MR. BLOOM: Yes, thank you.

DR. METTER: Okay. Well, thank you for the very good discussion, and I'm glad we could come to a common ground. Any other comments from the Subcommittee or the Committee itself?

MR. OUHIB: Yes, this is Zoubir. I think I'd like to go back to one of the points that was made earlier. At the end, perhaps add something like; Call your physician if you have any specific questions on these recommendations or instructions.

DR. METTER: All right.

MR. SHEETZ: This is Mike Sheetz. There is already in the draft regulatory guide in several sections that there should be a contact number available for the patient to use to get back to the institution, someone knowledgeable at the institution,

if they had any questions on the precautions or instructions. So that is currently in the regulatory guide draft.

DR. METTER: Thank you. Are there any other questions or comments with the Subcommittee? Okay, thank you for your work. Now, are there any comments or questions from the ACMUI Committee itself? Okay. So, Mr. Einberg, do we go ahead and vote to accept the -- oh, we have to have the revision made, or can we -- what procedures do we proceed with now?

MR. EINBERG: Yes. So, thank you, Dr. Metter. So, we do need to have exact language there for the Committee to build through. If you all could take a few minutes and go through anything we -- and we can decide on what the best language for each of those is, and then go ahead and vote on these recommendations.

DR. METTER: Okay. I hate to put someone on the spot, but Mike, would you mind maybe revising the showering and the voiding and the drinking plenty of fluids? I believe those were the three items that were addressed.

MR. SHEETZ: Sure. For A, I would recommend shower or bathe daily.

MR. GREEN: I would second that as

revised.

MR. GREEN: Dr. Metter?

DR. METTER: Yes, you know, let's go ahead and look at that, and you'll make your three revisions, and then we'll discuss them, and then we can vote on them.

MR. GREEN: Dr. Metter?

DR. METTER: Yes.

MR. GREEN: This is Richard Green. The first sentence for Item 5 says it should not include instructions that are excessive, likely to cause patient anxiety. Maybe we should not be changing details of A, B, C, D, or E, but reinforcing the first sentence of Item 5.

It says that these are overly-prescriptive and should not contain -- now we should not be crafting a better A, B, and C; we should be reinforcing the statement in 5.

DR. METTER: That's a very good point, Mr. Green. Thank you for that observation. That seems reasonable to me. What do you think, Mr. Sheetz?

MR. SHEETZ: Yes, I'm in favor of that.

DR. METTER: So, Mr. Green, with that, are you saying to leave the statement as is?

MR. GREEN: I would leave A, B, and -- the

substatements the same. I would change Item 5 to read; The Regulatory Guide should not include instructions that are excessively detailed and that are likely to cause -- we should augment that to describe that we don't want specific numbers of showering two to three times a day or after five days, throw away your toothbrush.

I mean, that's the part that causes anxiety; this overly detailed, like, Oh, my gosh, I used my toothbrush for seven days. That's bad.

DR. METTER: Okay.

MR. GREEN: So, we should emphasize the, that are not overly prescriptive with numerical things to hit.

DR. SCHLEIPMAN: This is Robert Schleipman. I have a suggestion then. We could leave these as is as far as examples that are overly prescriptive, and then after each one say, Suggested term would be, you know, shower at least once a day.

B would be overly prescriptive, so we could say, Suggested revision is this. That way you've got some more consensus on the statement to follow, if you feel those are needed.

MR. GREEN: I think that would provide you the bad example and the good example both in the same

context.

DR. METTER: Okay. Can I propose this? Mr. Einberg, could we go ahead and have the Subcommittee -- I'd rather not do this on the fly and on the phone. Let them take some time to think about it and present this section as the revision. And then can we vote as a committee afterwards, after this call? After we have their final wording for this Number 5 recommendation.

MR. EINBERG: Just one moment. Let me confirm about that.

DR. METTER: I'm sorry?

MR. EINBERG: Just one moment. We're going to caucus here for a moment.

DR. METTER: Oh, okay.

MR. SHEETZ: Dr. Metter, this is Mike Sheetz. You look at our full Subcommittee report. On page 7 we did make a directed change regarding these precautions for Section 2.3.3, in which we say, Washing hands frequently and bathe daily. Wash laundry separately from others. Use dedicated or disposable kitchen utensils and not share them with others and so forth.

DR. METTER: Okay.

MR. SHEETZ: So, I think really our

recommendation here in Number 5 was giving examples, whereas the specific wording is contained in one of our directed changes. I'm not sure if we need to change anything.

DR. METTER: Okay. So would you say perhaps with the recommended items being in -- each need to refer to that section of the final report?

MR. SHEETZ: Correct. I'm not looking to eliminate these precautions as far as showering or bathing. We were just concerned with the numbers.

DR. METTER: I think what Mr. Green's comment was to say, though, that these were excessive, and this is an example of what would be recommended. So I guess, and we could refer that section in the final that you have at the beginning of that sentence, you know, as far as the parentheses --

MS. DIMMICK: Dr. Metter, this is Lisa Dimmick, Medical Team Leader. Let me just, for clarification for people that are on the line or may not have the document; so these instructions fall under Section 2.3.3, Patient Instructions. This is intended to provide, and in this section, it provides a list of basic, post-treatment instructions that a patient may need to follow.

It may not be the instructions the patient

has to follow, and again, this is part of the instructions that the facility would be giving to the patient and their caregiver and the fact that these may need to be tailored to the patient. So there are about 15 instructional items in this section, and what I believe the Subcommittee was relaying in its review of this Phase 1 revision final report was that there were a couple of the instructional items that seemed a little bit excessive, and the instructions would be communicated.

So perhaps the ACMUI Subcommittee wants to look at those and say that showering two to three times a day for the first two days may be excessive, and may cause concern for the patient, or a burden. But maybe it's just simply, shower -- something about just showering following treatment and not specify how frequent and how many times, and to sync in with the other ones.

I think you have to -- in order to make an appropriate edit here, you have to read what this section is about and what it's intending to do. So in the final report, please keep that in mind.

DR. METTER: I'm sorry; go ahead, Melissa.

MS. MARTIN: Well, I was just going to say, can you look at -- we did that. If you look at

our suggestions on page 7 of the report, we have the suggested replacements that I think everybody's looking for. We gave specific replacement instructions, and they are listed in Section 2.3.3. There are suggested replacements for these instructions.

DR. SCHLEIPMAN: That's perfect. That's great.

COURT REPORTER: This is the court reporter. Will the last person please identify themselves?

MS. MARTIN: I'm sorry; this was Melissa Martin.

COURT REPORTER: Yes, Ms. Martin; whoever responded to your comments.

DR. SCHLEIPMAN: I'm sorry; I spoke out of turn. This is Robert Schleipman. I think Ms. Martin's absolutely correct. These are all there in general language, so I think we don't have to reinvent that first Section 5 again.

DR. METTER: Okay.

MR. EINBERG: When you all speak, if you would please identify yourselves for the court reporter?

DR. METTER: Yes. This is Darlene Metter.

So I'm looking at it, and it does explain the more practical approach rather than what was listed as excessive. So with that, would it be just adequate to have what is currently written as a document and send it in, or would others suggest to add, do not do the excessive and give those examples, or just leave it as is? Comments?

MS. MARTIN: This is Melissa Martin. I thought, and I'm speaking for Mr. Sheetz, and maybe he should be saying it: Our preference was to replace this, the current version, with our suggested revised version for Section 2.3.3.

DR. METTER: Yes.

MR. OUHIB: This is Zoubir. Melissa, I don't see anything related to fluid consumption like water and things like that; empty the bladder.

MS. MARTIN: You are correct.

MR. OUHIB: So I think if that -- again, this is Zoubir. If that were to be modifying and used in what you have suggested, perhaps that should include those items.

DR. METTER: So that would be an Item 11?

MR. SHEETZ: This is Mike Sheetz. I still feel that there's not an appropriate radiation safety precaution to be in this document, this fluid intake.

I think that is something that needs to be consulted with the physician medically. It is not appropriate in all types of radionuclide therapy, and personally we've had two cases where patients presented to the emergency department with hyponatremia.

So I'd caution that instruction being in there as far as increasing fluid intake. I know it's been recommended and done for decades, but it can cause great harm, and I'm not against increasing fluid intake; it's just something that should be consulted with the patient's physician, and it's not a standard radiation safety precaution.

DR. METTER: Okay.

MR. SHEETZ: I do not feel it's appropriate to be in this guidance document. And I agree with Melissa; I'm trying to move it forward. I think the other accepted items that we generically gave examples of in Number 5, the specific wording is on page 7 of the directed changes.

DR. METTER: Any other comments? So, Mr. Einberg, with that said, are we allowed to vote on this, since they're already accepted?

MR. EINBERG: If that's what the Committee decides, yes. If there are no changes that are required to report then, yes, they can go ahead and

vote.

DR. METTER: Is that all right with you, Mr. Sheetz?

MR. SHEETZ: Yes, it is, but I'm open to other comments or questions.

DR. METTER: Okay. Any other comments or questions before we put this to a vote with the ACMUI Subcommittee and the Committee? Okay. Do I have a motion to approve the Subcommittee report as written?

DR. SCHLEIPMAN: So moved; Robert Schleipman.

MS. MARTIN: Second, Melissa Martin.

DR. METTER: Any discussion? Okay. All in favor?

(Chorus of aye.)

DR. METTER: Any opposed? Any abstentions? Okay. So the Subcommittee report is approved by the ACMUI, and thank you very much for your work.

Any other business right now? Kellee?

MR. EINBERG: This is Chris Einberg once again. Could you open up the lines to members of the public so see if they had any comments?

DR. METTER: Oh, yes. Thank you; I'm sorry, yes. Are there any comments or questions from,

first of all, the NRC staff? And then for any members of the public on the line; Thank you, Mr. Einberg.

MR. EINBERG: There are no questions here in this room.

DR. METTER: Okay, thank you. Any questions or comments from the public?

MS. JAMERSON: Operator, do we have any indications of comments from the public?

THE OPERATOR: Just one moment. Yes, I am showing one comment, but they did not record their name. To ask a question or to make a comment, please press star-1 to record your name. Your name is required. To withdraw your question or comment, press star-2.

Again, to make a comment or question, please press star-1. Thank you; it may take a while for the comment to come through.

DR. METTER: Operator, is that individual who was trying to comment on the line? This is Darlene Metter.

THE OPERATOR: We show no questions at this time.

DR. METTER: Thank you.

THE OPERATOR: You're welcome.

DR. METTER: Okay. So any other business,

Mr. Einberg, to proceed?

MR. EINBERG: Just I want to thank the Committee and the Subcommittee for their work on this effort, it is certainly very timely. We will review the recommendations here and make appropriate changes to the Reg Guide as needed.

While we have everybody on the line, I know everybody is concerned about the travel, the coronavirus issue being spread right now. We still plan on having our spring meeting. I know that some of you have expressed concern about travel. We do plan on, at this time, still planning on having the meeting face-to-face, but for those who want to participate via WebEx, we certainly understand your concerns, and that is an option as well.

Kellee, did you have anything else you want to add?

THE OPERATOR: I have a comment and a question from someone on the phone, Mr. Ralph Lieto.

DR. METTER: Yes.

THE OPERATOR: Mr. Lieto, your line is open.

MR. LIETO: Hello? Can you hear me?

DR. METTER: Yes, we can. This is Darlene Metter. We can hear you. Do you have a comment?

MR. LIETO: Yes. My name is Ralph Lieto; I'm a medical physicist. I just wanted, for the record, to indicate that I would oppose the deletion of the recommendation to have patients, especially iodine therapy patients, drink fluids.

It's well established in science that this will reduce patient dose and as a result, the radionuclide burden over time to a certain point, especially in the first couple of days.

I understand the concern that there might be a certain number of patients that may have a problem with renal function where you might not want to push this very hard. But I think it's something that should still be a recommendation that would have great applicability in terms of a precaution that would reduce radiation exposure in those first few days.

So, I think deleting it altogether from the Regulatory Guidance is not well established. So, I know it's after the fact, since you guys have already voted on this, and you're going to move forward, but I know this is not the final version of the document, and I think that recommendation needs to be reconsidered.

DR. METTER: Okay. Thank you, Mr. Lieto,

for your comments. Operator, are there other individuals on the line from the public who have any comments or suggestions?

THE OPERATOR: No, ma'am. We show no set of questions at this time.

DR. METTER: Okay. Thank you, Mr. Lieto. Mr. Einberg, anything else right now?

MR. EINBERG: Kellee, anything else?

MS. JAMERSON: Nothing from me.

MR. EINBERG: Okay. Nothing else from the NRC here. So, can we adjourn, Ms. Jamerson?

MS. JAMERSON: We can adjourn if you'd like.

MR. EINBERG: Okay. Thank you so much, everybody, and the meeting is adjourned.

DR. METTER: Thank you very much.

(Whereupon, the above-entitled matter was concluded at 2:55 p.m.)