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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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MONDAY,

JUNE 10, 2019

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The meeting was convened via teleconference at 2:00 p.m., Christopher Palestro, ACMUI Chairman, presiding.

MEMBERS PRESENT:

CHRISTOPHER J. PALESTRO, M.D., Chairman

DARLENE F. METTER, M.D., Vice Chairman

VASKEN DILSIZIAN, M.D., Member

RICHARD L. GREEN, Member

MELISSA C. MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

A. ROBERT SCHLEIPMAN, Ph.D., Member

MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

LAURA M. WEIL, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

ROBERT LEWIS, Deputy Director, NMSS

CHRISTIAN EINBERG, Designated Federal Officer, Chief, Medical Safety and Events Assessment Branch, NMSS/MSST

MARYANN AYOADE, NMSS/MSST/MSEB

STEPHANIE BUSH-GODDARD, RES/DSA/RPB

COLLEEN CASEY, R-III/DNMS/MLB

SAMANTHA CRANE, OCM/DAW

SAID DAIBES, NMSS/MSST/MSEB

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

JULIE EZELL, OGC/GCHA/AGCNRP

CASSANDRA FRAZIER, R-III/DNMS/MLB

ROBERT GALLAGHAR, R-I/DNMS/MLAB

SOPHIE HOLIDAY, NMSS/MSST/MSEB

ESTHER HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, PhD, NMSS/MSST/MSEB

KELLEE JAMERSON, ACMUI Coordinator, NMSS/MSST/MSEB

CYNTHIA JONES, OCM/AXC

HARRIET KARAGIANNIS, RES/DE/RGGIB

SARAH LOPAS, NMSS/MSST/MSEB

MINH-THUY NGUYEN, RES/DSA/RPB

PATRICIA PELKE, R-III/DNMS/MLB

HALFON SCHLOM, RES

VERED SHAFFER, RES/DSA/RPB

DANIEL STROHMEYER, R-III/DNMS/MLB

KATHERINE TAPP, PhD, NMSS/MSST/MSEB

ALEXUS WILLIS, RES/DE/CMB

IRENE WU, NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC PRESENT:

JAIME BARNES, Cook Children's Medical Center

ROLAND BENKE, Renaissance Code Development, LLC

KENDALL BERRY, Fox Chase Cancer Center

JANICE CAMPBELL, Beaumont Health

PETER CRANE, Unaffiliated

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

BRIAN ERASMUS, British Technology Group

SANDY GABRIEL, Unaffiliated

BENNETT GREENSPAN, M.D., Society of Nuclear Medicine and Molecular Imaging (SNMMI)

MIGUEL de la GUARDIA, Cook Children's Medical Center

DAVID HAMBY, Renaissance Code Development, LLC

ALAN JACKSON, Henry Ford Health System

BRANDON JURAN, Minnesota Radioactive Materials

Unit

LINDA KROGER, University of California at Davis

TYLER KRUSE, Minnesota Radioactive Materials Unit

ALEXIS LAVIOLETTE, Boston Children's Hospital, Harvard Medical School

RALPH LIETO, St. Joseph Mercy Health System

TERRY LINDLEY, University of Cincinnati

CINDI LUCKETT-GILBERT, Unaffiliated

CAROL MARCUS, Ph.D., M.D., University of California at Los Angeles (UCLA)

RICHARD MARTIN, AAPM

CANDI MCDOWELL, University of Pennsylvania

CHRIS MITCHELL, Kettering Health

JOSE MORALES, M.D., Unaffiliated

MICHAEL PETERS, American College of Radiology (ACR)

CARMINE PLOTT, Novant Health

ARIA RAZMARIA, UCLA Medical Center

SAMUEL RHOADES, IV, Mercy Health

GLORIA ROMANELLI, ACR

JEFFRY SIEGEL, Ph.D, Nuclear Physics Enterprises

EUGENE SILVESTRINI, Northwell Health

ANDRES SINISTERRA, UConn Health

JOE STEINER, Henry Ford Health System

CINDY TOMLINSON, American Society of Radiation Oncology

JOSEPH WISSING, St. Joseph Mercy Health System

MIYUKI YOSHIDA-HAY, Northwell Health

ANDREW ZIMNOCH, University of Pennsylvania, Environmental Health & Radiation Safety

P R O C E E D I N G S

2:02 p.m.

MR. EINBERG: Good afternoon, everyone. 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 Uses of Isotopes. My name is Chris Einberg. I'm the Chief of the Medical Safety and Events Assessment Branch, and I've been designated as the federal officer for this advisory committee meeting in accordance with 10 CFR 7.11.

Present today, we have Lisa Dimmick, our Medical Radiation Safety Team Leader, and Kellee Jamerson, our ACMUI coordinator, as Designated Federal Officers for the ACMUI.

This is an announced meeting of the Committee that 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 May 9th, 2019 edition of the Federal Register, Volume 84, page 20439.

The purpose of this meeting is to discuss the revised ACMUI bylaws and the draft report of the ACMUI Regulatory Guide 8.39 Subcommittee. In its

report, the Subcommittee provides recommendations with respect to Phase 1 of the revisions to the Reg Guide 8.39, Release of Patients Administered Radioactive Material.

The function of the ACMUI is to advise staff on the 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 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'd like to perform the roll call of the ACMUI members participating today. Dr. Christopher Palestro, Chairman, nuclear medicine physician.

CHAIRMAN PALESTRO: Present.

MR. EINBERG: Dr. Darlene Metter, Vice Chairman, Diagnostic Radiologist.

VICE CHAIRMAN METTER: Here.

MR. EINBERG: Dr. Vasken Dilsizian, Nuclear Cardiologist.

MEMBER DILSIZIAN: Here.

MR. EINBERG: Dr. Ronald Ennis, Radiation Oncologist.

(No audible response.)

MR. EINBERG: Mr. Richard Green, Nuclear Pharmacist.

MEMBER GREEN: Present.

MR. EINBERG: Ms. Melissa Martin, Nuclear Medicine Physicist.

MEMBER MARTIN: Here.

MR. EINBERG: Dr. Michael O'Hara, FDA Representative.

MEMBER O'HARA: Here.

MR. EINBERG: Mr. Zoubir Ouhib, Radiation Therapy Physicist.

MEMBER OUHIB: Here.

MR. EINBERG: Dr. A. Robert Schleipman, Healthcare Administrator.

MEMBER SCHLEIPMAN: Present.

MR. EINBERG: Mr. Michael Sheetz, Radiation Safety Officer.

MEMBER SHEETZ: Present.

MR. EINBERG: Ms. Megan Shober, State Government Representative.

MEMBER SHOBER: Here.

MR. EINBERG: Ms. Laura Weil, Patients' Rights Advocate.

(No audible response.)

MR. EINBERG: Dr. Harvey Wolkov, Radiation Oncologist.

MEMBER WOLKOV: Present.

MR. EINBERG: Okay. We have a quorum with 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 CFR Part 2635 with regards to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and to the DFO as soon as possible before the ACMUI discusses it as an agenda item.

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

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

MR. SCHLOM: Halfon Schlom.

MR. EINBERG: Okay.

MS. DIMMICK: Lisa Dimmick, Medical Radiation Safety Team Leader.

MS. HOUSEMAN: Esther Houseman, Attorney.

DR. DAIBES: Said Daibes, Medical Team.

MS. HOLIDAY: Sophie Holiday, Enforcement.

MS. JAMERSON: Kellee Jamerson, Medical Team.

MS. KARAGIANNIS: Harriet Karagiannis, Office of Research.

MR. EINBERG: Thank you. Are there NRC members on the phone? Sophie is indicating to me that they're on a muted line and can't say who's on the line.

Members of the public who notified Ms. Jamerson that you will be participating in 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, that's K-E-L-L-E-E, dot, Jamerson, J-A-M-E-R-S-O-N, @nrc.gov or at 301-415-7408, at the conclusion of this meeting.

We also have a bridgeline available, and that phone number is 888-282-1673. The pass code to access the bridgeline is 6240665.

The meeting is also using the GoToWebinar application to view presentations in real-time. You can access this by going to www.gotowebinar.com and searching for the meeting ID 386468939. Let me repeat that: 386468939.

Individuals who would like to ask a question or make a comment regarding a specific topic the Committee has discussed should dial *1 to signal the operator that 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 the 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 for this meeting are available on the NRC's public website.

At this time, I ask 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 to ensure that 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 Ms. Lisa Dimmick, who will provide some additional remarks regarding our process for revising Reg Guide 8.39.

MS. DIMMICK: Thank you, Chris. Good afternoon. I'm Lisa Dimmick, the Medical Radiation Safety Team Leader. I would like to provide some additional background on the purpose of today's meeting.

As you know, the purpose of this meeting is to discuss the revised ACMUI bylaws and the draft report of the ACMUI Regulatory Guide 8.39 Subcommittee. In its report, the Subcommittee provides recommendations with respect to Phase 1 of the revisions of Regulatory Guide 8.39, Release of Patients Administered Radioactive Material.

It's important to note and to understand that Regulatory Guide 8.39 is being revised in two phases. Phase 1, updates the patient release guidance, including information for patient instruction and updates to Table 3, Reactivity of the Radiopharmaceuticals that Require Instruction and Records when Administered to Patients who are Breastfeeding an Infant or Child, as well as introduces

a new section titled Death of a Patient Following Radiopharmaceutical Administration or Implant. The Phase 2 update will update the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients.

The Subcommittee's report and recommendation on this preliminary draft proposed Regulatory Guide 8.39, Revision 1, will only pertain to the Phase 1 update. This preliminary draft was provided to the ACMUI for its review and comment for staff consideration. The NRC staff will evaluate the ACMUI's comments following today's meeting. The draft Reg Guide 8.39 will then be published in the Federal Register for public comment.

Thank you. And I will now turn the meeting over to Dr. Palestro.

CHAIRMAN PALESTRO: All right. Thank you, Lisa. This is Dr. Palestro. The first item on the agenda is to discuss the revised 2019 Advisory Committee on Medical Uses of Isotopes Bylaws. At this point, I would ask Ms. Weil to provide this.

MS. HOLIDAY: Dr. Palestro, this is Sophie Holiday.

CHAIRMAN PALESTRO: Yes.

MS. HOLIDAY: I was actually going to do

the presentation on this, as this is incorporation of the comments that the ACMUI Bylaws Subcommittee provided in its spring meeting, which was unanimously endorsed by the Committee.

CHAIRMAN PALESTRO: All right. That's fine.

MS. HOLIDAY: Okay. Everyone should be able to see on their screen a copy of the proposed draft bylaws. And the changes in here are both minor editorial, as well as changes that conform to the recommendations that the ACMUI endorsed during its April 2019 meeting here at headquarters.

So, what you see here on the screen in yellow highlight, the changes are noted in yellow highlight so that everyone can clearly see what the changes are. This is what I would consider a minor edit, which is to simply update the bylaws to reflect the current name of our division and our office. So, it now reads Division of Material Safety, Security, State and Tribal Programs, MSST, Office of Nuclear Material Safety and Safeguards, NMSS.

Here what you see is page three of the bylaws, which is Section 1.3.6. This is directly related to the objective of the previous bylaw subcommittee, which was to review the Chair's

involvement in subcommittees. The new text reads: In matters where the ACMUI Chair's unique experience and knowledge would be especially informative, the chair may serve on relevant subcommittees. The chair will serve at the discretion of the subcommittee members. However, the ACMUI chair will not chair the subcommittees.

Okay. In Section 4, conduct of members, specifically Section 4.1, there has been revised language to reflect the conversation that the ACMUI had related to conflicts of interest. Particularly, the Committee wanted there to be clear distinct language in the bylaws that identifies when ACMUI members must recuse themselves. So, the new text reads as follows: 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 CFR 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 and before the ACMUI discusses it as an 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 the appropriate NRC official.

This language was provided to us from the Office of General Counsel, as was discussed during the April 2019 ACMUI meeting. The ACMUI voted for us to work with the Office of General Counsel to provide us with the appropriate language, and this is what they have provided.

Okay. That concludes the proposed amendments to the bylaws. What I have on the screen here is just to show everybody that, per the bylaw Section 5.1, it states that amendment of these bylaws shall require an affirmative vote of two-thirds of the current ACMUI membership and the concurrence of the director of Nuclear Material Safety and Safeguards.

So at this time, Dr. Palestro, I would like to ask if there's a motion on the table to approve the amended bylaws.

CHAIRMAN PALESTRO: That's fine. Is there a motion.

MEMBER WOLKOV: This is Dr. Harvey Wolkov. So moved.

CHAIRMAN PALESTRO: Second?

VICE CHAIRMAN METTER: This is Darlene Metter. Second.

CHAIRMAN PALESTRO: Any discussion?

MS. HOLIDAY: I'm sorry. Go ahead, Dr. Palestro.

CHAIRMAN PALESTRO: Any discussion? Ms. Holiday, I'm sorry. You were going to say something and I cut you off.

MS. HOLIDAY: That's okay. I was just going to say for the record I have Dr. Wolkov as making the motion and Dr. Metter as seconding.

CHAIRMAN PALESTRO: All right. Any discussion? Any comments or discussion from the public?

MEMBER OUHIB: Dr. Palestro, this is Zoubir.

CHAIRMAN PALESTRO: Yes, Zoubir?

MEMBER OUHIB: Just a comment on item 1.3.6 where it says the Chair may serve on relevant subcommittees. What level would that be? As a voting member, as a consultant, or what?

CHAIRMAN PALESTRO: Given that it's not specified, and Ms. Holiday or Mr. Einberg or Ms. Dimmick, correct me if I'm wrong, would serve on the relevant subcommittee with all of the rights of other members of the subcommittee. That would be my understanding.

MEMBER SCHLEIPMAN: Hello, this is Robert Schleipman. The very first sentence mentions that the Chair may vote.

MS. HOLIDAY: That is also our understanding.

CHAIRMAN PALESTRO: I'm sorry, Ms. Holiday.

MS. HOLIDAY: I was saying, Dr. Palestro, that is also our understanding.

CHAIRMAN PALESTRO: All right. Thank you. Any other questions or discussion? All right. Hearing none, all in favor.

(Chorus of aye.)

CHAIRMAN PALESTRO: Any opposed?

(No audible response.)

CHAIRMAN PALESTRO: Any abstentions?

(No audible response.)

CHAIRMAN PALESTRO: And, again, as I did at the April meeting, I will abstain, but, once again, I want the record to reflect that my abstention does not in any way indicate my agreement or disagreement with the proposed revisions but rather the fact that this, as the current chair, is a potential conflict of interest for me.

MS. HOLIDAY: Thank you so much. Okay.

That concludes topic one. Whenever you are ready to proceed to topic two.

CHAIRMAN PALESTRO: All right. If we can then move on to topic two, which is the draft proposed Regulatory Guideline 8.39, The Release of Patients Administered Radioactive Materials, Revision 1, Phase 1. And, again, just to re-emphasize that Phase 1, which is what we are addressing today, updates patient release guidance, including the information for patient instructions and updates to Table 3, as well as a new section, Death of a Patient Following Radiopharmaceutical Administration or Implants.

At this point, I will turn the session over to Mr. Michael Sheetz, Chair of the Subcommittee.

MEMBER SHEETZ: Thank you, Dr. Palestro. This is Michael Sheetz. I'd like to provide an overview of the ACMUI Subcommittee comments on the draft proposed Reg Guide 8.39, Release of Patients Administered Radioactive Materials, Revision 1, Phase 1.

The other subcommittee members are Dr. Vasken Dilsizian, Ms. Melissa Martin, Dr. Robert Schleipman, Ms. Megan Shober, Ms. Laura Weil, and our NRC staff resource, Dr. Said Daibes - Figueroa.

For background, the NRC's current Reg Guide

8.39 Revision 0 was issued in April of 1997 following the rule change in 10 CFR 35.75 to allow for the release of patients administered radioactive material on a solely dose-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.

The NRC requested public comments on the patient release program in 2017 to receive input on whether additional or alternative criteria are needed and to determine whether regulatory changes to the NRC's patient release program are warranted. The NRC also created a web page to provide patients with standardized information on radioactive iodide treatment procedures so that the patients will understand the reason for the procedures, the process, and how to reduce radiation exposure to others.

As stated previously, it should be noted that Reg Guide 8.39 is being revised in two phases. This first Phase 1 revision 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.

In Phase 2, which will come later, the dosimetric equations, methodologies, and tables used to calculate dose to members of the public from released patients will be updated. The following Subcommittee comments and recommendations only pertain to this Phase 1 revision, as we did not address the dosimetric equations and methodologies.

In the direct report, we published approximately 40 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 direct changes, we will certainly entertain them.

I would like to highlight the Subcommittee's main comments and recommendations on the draft reg guide. First, the Subcommittee supports the addition of a table of contents to the Reg Guide and expanding the section on content of instructions to include subsections on pretreatment discussions, patient precautions, patient instructions, and patient acknowledgment of instructions. While we recognize that some of these subsections are not required in the

regulation, they are reasonable components of a strong patient instruction program and will help to assure patient planning and comprehension.

Second, in Tables 1 and 2, entitled Activities and Dose Rates for Authorizing Patient Release and When Instruction Should be Provided, these tables should be updated to include the new and potential radionuclides to be used in the future.

Third, Table 3 entitled Activities of Radiopharmaceuticals that Require Instructions and Records when Administered to Patients who are Breastfeeding an Infant or Child, also this table should be updated to include the radionuclides activities and recommended duration of interruption of breastfeeding, as contained in the ACMUI Subcommittee report on nursing mother guidelines for medical administration of radioactive materials, final report, dated January 31st, 2019.

Fourth, in the patient precautions and instructions sections, we support the addition of instructions for evaluation of holding trash to allow for radioactive decay as the landfill will likely detect the radiation and send the trash back to the patient, providing information to a family member or caregiver to contact the treating medical facility if the patient

has a medical emergency or passes away, and warning that the patient may trigger the radiation detector alarms at airports and national borders for several weeks or months.

Fifth, in the patient precautions and instructions sections, while most of the precautions address contamination control, it should be emphasized that the major source of radiation dose to other individuals will be from external exposure from the patient, and so this should be the primary focus. Also, after completion of the Phase 2 revisions, these sections should also include the recommended time period for following the precautions. While the list of precautions for patients to follow is fairly standardized, the time period to follow these precautions is highly variable.

And, sixth, the Subcommittee supports the addition of a new section on death of a patient following radiopharmaceutical administration or implants. Most of our directed changes to this section were to format and organize the information by type of postmortem activity, such as autopsy, embalming, funeral, burial, and cremation. Whichever the event, we feel that the RSO is the primary person to be notified to determine the amount of activity remaining in the deceased

patient, determine what precautions should be taken, and to determine if there are any applicable state or municipal restrictions.

While there is adequate guidance on the precautions to take to minimize radiation exposure for postmortem activities of a patient who has died after being administered a therapeutic quantity of radioactive material, there is little or no consistent guidance on what retained activity or time period for when the precautions should be followed. The Subcommittee recommends that a dose-based model 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.

That concludes the Subcommittee report.

CHAIRMAN PALESTRO: Comments from the Subcommittee members? Comments from the ACMUI Committee members?

VICE CHAIRMAN METTER: This is Darlene Metter. I have a couple of comments to make. I thank you for making the recommendations to comply with the nursing mother guidelines final report.

I'd also like to make a comment that there was an item there that talked zirconium-80. I don't

think that was in the nursing mothers guideline. I think that might have been a typo, so it should be zirconium-89. And also I agree with all the other recommendations which are listed in the table of the nursing mother guidelines.

Number two is I just have a question that why did the ACMUI Subcommittee start with the recommendations, why didn't they start with the methodology? Because if that's stage two, there's a change in the methodology, then you'll have to change your appropriate recommendations for the public. And I'm just kind of wondering if maybe you should have done the methodology first to get your exposure limits and then go back and make the recommendations.

That's it. Those are my two comments.

CHAIRMAN PALESTRO: Mr. Sheetz?

MEMBER SHEETZ: It was my understanding that we were to address the revisions from Phase 1 and not comment on the methodologies. That will come in Phase 2.

VICE CHAIRMAN METTER: This is Darlene Metter again. It's just that if we change the methodology, then those recommendations will need to be changed also, I suspect. You know what I mean?

CHAIRMAN PALESTRO: I'm sorry. This is

Dr. Palestro. I think I understand what you're saying, Dr. Metter, and I understand these were the instructions that were given to Mr. Sheetz. I think maybe this is a question that staff is best suited to answer as to why Phase 1 included what it did, as opposed to, say, the methodology first.

MS. DIMMICK: Hi, this is Lisa Dimmick, Medical Radiation Safety Team Leader. So, when staff completed its evaluation for patient release at the end of 2017 and going into 2018, we had identified in the Commission paper that Reg Guide 8.39 would be updated in a phased approach, a Phase 1 approach and then the Phase 2. We were also evaluating or responding to previous Commission direction to update Regulatory Guide 8.39 to encompass all of its instructional information on patient release that was included in generic communications and other guidance documents to consolidate it for one location. So, we had resources available to begin a Phase 1 approach to evaluate or include the guidance information, so that was the path we took.

CHAIRMAN PALESTRO: Thank you. Does that answer your question, Dr. Metter?

VICE CHAIRMAN METTER: I can see what they did, but it just would make it difficult. If there's

a change in the methodology, then the radiation limits may change and then the instructions may need to change and you'll have to go back and redo the recommendations. That would just be what I would think, but I can see that, you know, what you've put forth as Phase 1 and Phase 2.

CHAIRMAN PALESTRO: I understand your point, Dr. Metter, and I think it's a point well taken. At this point, it's moot because it's already begun. It certainly would be something to keep in mind for future revisions.

Other comments from the ACMUI?

VICE CHAIRMAN METTER: I have another comment. This is Darlene --

CHAIRMAN PALESTRO: Yes, Dr. Metter.

VICE CHAIRMAN METTER: Regarding the issues with disposable plates for the individual who has received radioactive material and disposable utensils and the making of radioactive waste and setting off landfills, I don't know how many people do this, but I generally do not encourage my patients to use disposable utensils or plates because of that particular concern. And I just have them use regular plates, a regular plate or a set of dishes that they use for themselves and they wash themselves because

everything just goes down the drain and you don't have to deal with radioactive waste. And they just put that aside for their sole use during the time that they need to be more careful of their exposures to other people. And I don't know if other individuals recommend this for their patients, and maybe we should actually make that, this is what I would prefer, rather than making radioactive waste that then the patients would have to decay and then that would be more work for them. But if they just wash their dishes, there's no need to hold any disposable items for radioactive decay.

CHAIRMAN PALESTRO: Thank you, Dr. Metter. Any comments in response to Dr. Metter's statement?

MEMBER SCHLEIPMAN: Robert Schleipman. That was our same practice to recommend to patients, if they're capable of doing so, to wash their own dishes and not discard items that could potentially set off landfill alarms.

CHAIRMAN PALESTRO: Thank you, Dr. Schleipman. Other comments?

MEMBER MARTIN: This is Melissa Martin.

VICE CHAIRMAN METTER: Go ahead, Melissa.

MEMBER MARTIN: I was just going to say I would certainly support that as an alternative or a recommended alternative and maybe we can phrase it

that way. In lieu of using disposable plates and silverware, an option would be to use a designated set of dishes handled only by the patients.

VICE CHAIRMAN METTER: This is Darlene Metter. I actually would make that the recommendation. The alternative would be the disposable because I think that would make more sense to me.

MEMBER MARTIN: That's fine with me, too. We've used the same recommendation. We've just told them put everything you can, create as little trash as possible by using the alternative method that you've suggested.

CHAIRMAN PALESTRO: This is Dr. Palestro. We follow that procedure, as well. We always recommended to patients that, whenever possible, use an isolated set of utensils and dishes and wash them separately, rather than disposable items, for the exact reasons that that's been mentioned.

Other comments?

MEMBER SHEETZ: This is Mike Sheetz. I agree that the amount of waste that a patient generates should be minimized and disposable should be discouraged, but there will always be potentially some items, you know, diapers, Depends, tissues, and things that will end up potentially in the trash that could

trigger a waste alarm. And I guess my point was that the institution should evaluate that potential, depending on their state, and be able to provide guidance to the patient appropriately.

In Pennsylvania, all of the landfills have radiation monitors, but they also are permitted to dispose of anything radioactive that has a medical radioisotope. And so it never comes back to the patient. So in Pennsylvania, it really doesn't matter if they generate radioactive trash. It's not going to come back to them. Other states it may be different. And so I think the point that I was trying to make that there's an evaluation of that, you know, by the institution depending on the state they're in.

CHAIRMAN PALESTRO: Other comments? Comments from the public?

MS. JAMERSON: Dr. Palestro?

CHAIRMAN PALESTRO: Yes.

MS. JAMERSON: This is Kellee Jamerson. I'd just like to ask Mr. Sheetz if they're going to revise their recommendation.

MEMBER SHEETZ: You want me to recite the recommendations?

MS. JAMERSON: Are you going to revise per the discussion you just had regarding the utensils,

disposable utensils?

MEMBER SHEETZ: I guess we can revise the statement and the instructions -- I don't have it directly in front of me -- to, you know, encourage the use of regular dishware so that it can be washed and not using disposable.

CHAIRMAN PALESTRO: Do we have the exact verbiage as it stands now?

MEMBER SCHLEIPMAN: Robert Schleipman. It's on page 31 under Section 2.3.3, use dedicated or disposable kitchen utensils and do not share them with others. So dedicated would include their own, I suppose, right?

MS. JAMERSON: Correct.

VICE CHAIRMAN METTER: This is Darlene Metter. Maybe since we weren't quite sure about it, maybe we should clarify that word dedicated so that the public can understand.

CHAIRMAN PALESTRO: I'm sorry. Dr. Schleipman, could I ask you to read that again?

MEMBER SCHLEIPMAN: Yes. It's, quote, use dedicated or disposable kitchen utensils and don't share them with others, end quote.

MS. HOLIDAY: Dr. Palestro, this is Sophie.

CHAIRMAN PALESTRO: Yes.

MS. HOLIDAY: If I could add on, the page right before that also says under the fourth sub-bullet, encourage the use of kitchen utensils dedicated to the patient, not shared with other household members, and wash separately from other dishes. Alternatively, encourage patient to use disposable eating utensils. So I think -- I'm sorry. I think Dr. Metter was suggesting that we recommend defining what dedicated means, but I believe the statement that I just read, which is on page 30 of the preliminary draft proposed Reg Guide, kind of clarifies that by saying dedicated to the patient, comma, not shared with other household members.

CHAIRMAN PALESTRO: Dr. Metter?

VICE CHAIRMAN METTER: Yes, that sounds very appropriate.

MEMBER MARTIN: This is Melissa. I would agree with that language also.

MS. HOLIDAY: So then it would sound like there is no recommendation to revise the report because the language is adequately captured in the draft proposed Reg Guide.

MEMBER MARTIN: Correct.

CHAIRMAN PALESTRO: Thank you. Any other

discussion on this point?

MEMBER OUHIB: This is Zoubir. Just minor comments. On page 18, regarding the patient instructions, what happens if you have a language barrier? That's item 2.1.

MS. HOLIDAY: Oh, you mean page 24 of the draft proposed Reg Guide.

MEMBER OUHIB: I guess I'm going from another copy here. Sorry about that.

MS. HOLIDAY: You're referencing Section 2.1 titled Activities and --

MEMBER OUHIB: That is correct.

MS. HOLIDAY: -- Requiring Instruction?

MEMBER OUHIB: That is correct. If you're dealing with a patient that has a language barrier, you know, where's the provision there? What are we recommending?

CHAIRMAN PALESTRO: This is Dr. Palestro. Isn't there a provision in this guidance that suggests, and I can't quote it exactly, but that it's the responsibility of the licensee to determine the individual's ability to follow the instructions?

MEMBER OUHIB: But it doesn't give any detail on that. It says it also provides the licensee with the opportunity to determine if the patient will

be able to follow the release instruction, but then what? What if the patient cannot follow the instruction? There are no other recommendations after that. Or what are the steps? As a matter of fact, that was one of the items that I had also.

MEMBER SHEETZ: This is Mike Sheetz. In Section 2.3.4, patient acknowledgment of instructions, there is a statement there, prior to release of the patient, patient should acknowledge receipt of instructions and the licensee should acknowledge the patient understands the instructions as communicated, so I think it's addressed.

MEMBER OUHIB: I'm not sure if that's sufficient.

CHAIRMAN PALESTRO: What would you recommend, Zoubir?

MEMBER OUHIB: To be honest with you, Dr. Palestro, I haven't thought about it, other than perhaps the licensee should probably take every step possible to ensure that the patient fully understands the instructions, including any language barrier or whatnot, you know, where they use, I don't know, an institution have people that can translate and so on and so forth. I don't know. I don't have the verbiage for that.

CHAIRMAN PALESTRO: My own opinion is that it's already amply covered in the guidance, but other opinions?

VICE CHAIRMAN METTER: This is Darlene Metter. When we consent patients for therapy, for, let's say, I-131 therapy, and they speak a different language than the person consenting them, we have an official hospital translator and it's documented in the report that all questions were answered through the translator.

And the other thing on 2.3.3, it says patient instructions, it says that, you know, the licensee has to comply with 10 CFR 35.75, et cetera, and it says, however, once a patient is released, the licensee has no control of the patient. So, you know, I think you can only do so much. If you ask the patient if they acknowledge, and I believe, I like the idea that the Subcommittee recommended this acknowledgment by the patient and we have a translator and the patient signs it, to me, that's legal documentation that the patient acknowledges that they understand the instructions and the consequences if these are not followed.

CHAIRMAN PALESTRO: I'm sorry. Dr. Schleipman.

MEMBER SCHLEIPMAN: At our institution, we had numerous translated documents in several languages and brought in official interpreters. Not every institution will have those resources, but I think that the general instructions in the regulatory guide really put the onus on the institution and I think it's sufficiently worded, as well.

CHAIRMAN PALESTRO: Zoubir?

MEMBER OUHIB: Yes.

CHAIRMAN PALESTRO: Does that answer your question? Do you wish to make a motion to revise the report?

MEMBER OUHIB: I guess that's probably, to a certain point, convincing maybe. And I would agree with some of the comments that the majority of the institutions have translators and all that, but that's not available at every institution, and that is when there's always a chance of something going wrong.

CHAIRMAN PALESTRO: I think we all agree with you, but, again, the onus is on the licensee to make that determination.

MEMBER OUHIB: Agree.

CHAIRMAN PALESTRO: All right. Thank you. Any other comments, discussion from the ACMUI?

MEMBER OUHIB: I do have one on item 2.4,

death of a patient following radiopharmaceutical administration or implant. Unless I misread it or misunderstood, are we saying somehow that it is okay to cremate under certain conditions?

MEMBER SHEETZ: This is Mike Scheetz. No, that's one of the recommendations. I mean, there are precautions and maybe restrictions that need to be taken, but there needs to be some dose-based model created to recommend what activity levels or at what time period after administration of radioactive material implant per patient do the precautions or restrictions need to apply. So, there may be situations where a patient has been administered radioactive material and the recommendation would be not to cremate that body.

MEMBER OUHIB: Okay. Are those stated clearly in this here? Because I didn't see that for some reason. I was like wait a minute, aren't we saying something that we're not recommending elsewhere?

MEMBER MARTIN: No, I think it's covered -- I'm sorry. This is Melissa. I think it's under other recommendations, number two. It basically says the development of this will be part of the part two revision. It will be a new dose-based model because you can have a patient with a prostate implant that's

20 years old. They could very well cremate that patient without a problem. If the patient had a prostate implant last week, then you don't. It all comes down to the dose-based model.

MEMBER OUHIB: I hear you. Okay.

CHAIRMAN PALESTRO: Does that answer your question, Zoubir?

MEMBER OUHIB: Yes. Thank you.

CHAIRMAN PALESTRO: Thank you. Any other comments or questions?

MEMBER OUHIB: One last item, Dr. Palestro.

CHAIRMAN PALESTRO: Yes, sir.

MEMBER OUHIB: 3.1, records of release, item number two, for immediate release of a patient based on measured dose rate. I see here we put the result of the measurement, the specific survey instrument. Should we add a calibration information of that survey instrument?

MEMBER MARTIN: I think, as long as the institution has got the record of it, that's all you need.

MEMBER OUHIB: Well, that applies to the survey instrument also. They have that information, too. But I think I would depict that one of the two,

I think the calibration information is more important than the specific survey instrument information.

MEMBER GREEN: This is Richard Green. If the operator records the survey instrument that was used to make the survey, then state regulators or NRC regulators or the RSO can go back in and look at the calibration certificate to make sure that that survey instrument used was in calibration and met all the pertinent regulations and requirements. If we don't have that meter used identification, then we can't go any further. So, I think we cover the basis of it.

VICE CHAIRMAN METTER: This is Darlene Metter. This is standard language that, I believe, that's in the Reg Guide already.

MEMBER MARTIN: This is Melissa. I would agree with that, too. You just want the serial number and model. You can look up the calibration, if needed.

CHAIRMAN PALESTRO: Does that answer your concern, Zoubir?

MEMBER OUHIB: Somewhat, yes. Thank you.

CHAIRMAN PALESTRO: Any other comments, questions, discussion?

MEMBER WEIL: This is Laura Weil. I had used the wrong pass code. I apologize. So, I didn't have an open line to get in on the discussion of language

proficiency, and I'd like to make a comment about that, if I might at this point.

CHAIRMAN PALESTRO: Yes, please.

MEMBER WEIL: The provision of instructions regarding post-release precautions for folks who have been administered radiopharmaceuticals is no different from the provision of instructions or information about informed consent or any treatment decision, and you can refer back to the Civil Rights Act of 1964 that language assistance is required for any medical discussions. So I don't think we need to -- I mean, Zoubir, I'm very sensitive and support your concern that there may be situations where language proficiency will be an issue, be it languages other than English or for deaf patients or any number of communication issues, but there's an overriding regulation that requires that language assistance be provided, whether it's a small institution or a large institution, and I'm not sure we need to specify specifically for this particular application that there needs to be interpreters made available or translated documents.

CHAIRMAN PALESTRO: Thank you, Ms. Weil. Zoubir, any comments?

MEMBER OUHIB: None. Thank you.

CHAIRMAN PALESTRO: Any other comments, questions, from the ACMUI? All right. Hearing none, I will now open this session to the public. Is there anyone on the line?

OPERATOR: Thank you. We do have a question from Peter Crane. Your line is open.

MR. CRANE: Yes, please. Thank you. Appreciate it. In a way, it's a pity that you've waited until the very end to ask for public input because, for example, I had what I thought were some constructive questions on the bylaws and there was no opportunity to raise them. I don't know whether I should do so now. Maybe I should to get them out of the way. Is that all right?

CHAIRMAN PALESTRO: That's all right with me. Ms. Holiday?

MR. CRANE: Sophie, is that okay by you?

MS. HOLIDAY: That's fine.

MR. CRANE: Okay. Let me find it quickly. On conflict of interest, Section 4.1, it seems to be a matter of self-reporting sort of in the way that judges of the Supreme Court decide whether to recuse themselves. But suppose it's Member A who thinks Member B shouldn't be taking part in this because of a conflict of interest and Member B doesn't see it that

way? Because my institutional memory is very long, and I can remember when there was a huge flap about nearly 30 years ago because the Office of General Counsel said that a particular person should be recused from acting on a petition which that individual had filed. And the result was that the general counsel was reported to the Office of Government Ethics with a letter saying who's above the general counsel, God, unquote. So I think that ought to be clarified because, you know, some people are just not sensitive to their own conflicts.

Secondly, there is, on page six, item 5.4, where it says the ACMUI should consult with the Office of the General Counsel regarding conflicts that arise from the interpretation of the bylaws. After consultation, the ACMUI shall resolve interpretation issues by a majority vote of the current membership of the ACMUI.

Now, what that leaves a little bit open is, suppose the general counsel says you can't do it, does that provision mean that the ACMUI can, by majority vote, disregard it? That's ambiguous, I think. I'm not hearing any response to this. Is this simply a one-way street? Hello?

CHAIRMAN PALESTRO: Yes, Mr. Crane. This

is Dr. Palestro. In response to your first comment, on conflict of interest, that comes directly from legal. That's the standard verbiage that's used, and that's why it was incorporated.

MR. CRANE: Okay. But, you know, that may be so, but maybe OGC should be asked what do you do with a situation? That's a situation that has occurred in which the member does not see a conflict that other people do see. I'm not criticizing. I'm just suggesting that this is an item that you might want to think about and consult with the lawyers about.

MS. HOUSEMAN: Hi. This is Esther Houseman, attorney in the Office of the General Counsel. I do want to note for everyone on the meeting that the Office of General Counsel does advise the medical team, as well as the ACMUI itself on its obligations as special government employees to abide by the ethics laws that are cited here. The Office of the General Counsel is also available to answer any legal questions concerning those ethics requirements and also any questions the staff have on the ACMUI bylaws. So the ACMUI and the staff do have legal counsel on these matters.

MR. CRANE: Well, I understand that, and, actually, I worked in OGC for 23 years, so I'm fairly

familiar with its responsibilities. My point is can OGC, is OGC the deciding word on what's legal or -- I'm mixing the two issues -- or can the ACMUI override and act in contradiction to OGC advice? Is it unclear to anybody but me?

MS. HOUSEMAN: I think what you're asking right now is a legal question on which OGC would provide legal advice, and I'm not going to provide a legal analysis in the middle of a meeting of this sort. So, I'm not sure what additional information you want.

MR. CRANE: Fair enough. All I'm saying is I think this language leaves it a bit open as to whether ACMUI can override OGC, and I think that these sorts of ambiguities ought to be resolved beyond any dispute before and not after they go into effect. That's all I'm saying. Avoiding problems by foreseeing them.

MS. HOLIDAY: Thank you for your comment, Mr. Crane. We'll take that under consideration when the ACMUI, they are planning to look at the bylaws later on in the near future, and so this feeds on what they take into consideration on a future date.

MR. CRANE: Thank you. If that's Sophie, thanks, because I think I recognize your voice, right?

MS. HOLIDAY: Yes, this is Sophie. Thank

you.

MR. CRANE: Okay. Third point on the bylaws, it says that the NRC will -- this is 3.1, NRC will solicit nominations by notice in the Federal Register and by such other means as are approved by the Commission. Evaluation of a candidate shall be by such procedures as are approved by the director of NMSS. It's a little vague as to what that is. It seems to be unlimited discretion to the director of NMSS. Is there any conceivable public interest in keeping confidential the names of people who nominate themselves or are nominated for ACMUI positions? Can anybody think of a reason?

CHAIRMAN PALESTRO: I'm sorry, Mr. Crane. This is Dr. Palestro. I don't quite understand. Could you restate your concern?

MR. CRANE: Okay. My question is it says procedures to be determined by the director of NMSS. That gives him, seems to give him unlimited discretion to do whatever he wants. And it seems to me that, in an agency that dedicates itself to openness, there ought to be a certain degree of openness as to what those procedures are.

For example, some years ago, when the position of patients' rights advocate was filled, I

wrote to the NRC and the person chosen was the director of isotope production at DOE. I wrote to the NRC and asked who were the other candidates. I was not a candidate, incidentally. And I got back a letter saying we can't tell you and we wouldn't tell you even if you filed a FOIA, Freedom of Information Act request for the benefit of anybody who doesn't know that. And I thought, well, I'll test that out, and I did file a FOIA and I got back, no, this is privileged information. And it seems to me there ought to be an open process. We ought to know who's nominated, by whom, self-nominated, by organizations, by individuals, et cetera, and we ought to know the process by which these decisions are made.

MS. HOLIDAY: Hello, Mr. Crane, this is Sophie.

MR. CRANE: Yes.

MS. HOLIDAY: First, I would like to start off by saying that the scope of this meeting was to discuss the proposed amendment to the bylaws, not necessarily to open up other sections of the bylaws as this is related to the discussion at the ACMUI Subcommittee related to the bylaws presented during the April 2019 meeting. However, I will respond to you regarding the process by which the Director of NMSS

selects individuals. Paired with any HR hiring guidance, we do not disclose that type of information in terms of who has applied and who has supported them -- so on and so forth. Similar to how we do not release that type of information for general NRC staff applications, we would not do the same for our special government employees, i.e., the ACMUI members.

MR. CRANE: I see. Well, you know, I can -- I can -- I hear what you're saying, certainly, but I have -- and I didn't appreciate that -- that the -- the meeting was intended to be limited to very minor changes in the bylaws. It seems to me that when people nominate themselves for a public position, that there is something to be said for greater openness. That it's different from, you know, applying for a job as a -- as a lawyer or a health physicist and having to be listed in the Federal Register as among the rejected candidates. I do think there is a difference. But this isn't the time to debate that.

Okay, well that -- that concludes my -- what I have to say about the bylaws. But I do have things to say about the patient release issue. If I may continue. May I continue?

CHAIRMAN PALESTRO: Please do, sir.

MR. CRANE: Thank you, Dr. Palestro.

Okay, I am -- there is a consistent problem with the NRC -- to me, with the NRC rule in that it tends to minimize the risk of internal exposure. And that has been true for many years. And just to give the briefest of background, in 1986, the NRC staff turned down a suggestion that release be based on dose to the likely person and it said that in fact this was too uncertain -- that the calculations were easy, but knowing just who was going to be where for how long was complicated. And it said that patients presented a risk both from external and from internal dose. Which I think was entirely correct.

And in 1997, when the NRC changed the rules to adopt a dose-based rule, it did so on the basis of advice from a gentleman now deceased -- a nuclear medicine doctor -- who believed that I-131 was no carcinogenic and that the effect of a nuclear accident -- the radiation effect of a nuclear accident would not be harmful on the public's health but rather might be beneficial. And with that kind of attitude, it is understandable that some oddities came into this rule. And one of them was that internal dose was to be ignored, except for the nursing mother. And that everything was to be based on external dose -- calculation of probable external dose.

And, you know, I think there is no -- my own view is that nothing is going to solve this problem without the NRC someday biting the bullet and undertaking a rule change. Now, in the Subcommittee's report, under Other Recommendations, on the last page it says, quote, in the patient's precautions and instructions section, it should be emphasized that the major source of radiation dose to other individuals will be from external exposure from the patient, Reference 1. The Reference 1 referred to is ICRP 94. Now, what ICR -- this is -- now here is the way the American Thyroid Association characterized the ICRP 94 in its comments to the NRC last year. The ICRP has estimated the risks for all cancers in children at 0.1 to 0.2 percent from an effective I-131 dose of one millisievert, which is the equivalent of 100 millirem. Risks the children include those from external radiation exposure as well as potential ingestion of contamination from excreted or secreted I-131 from treated patients. The ATA currently recommends that, quote, having a treated parent staying in the home is often problematic due to children's needs to be near the treated parent. Special arrangements should be made for children to stay with relatives or friends. Alternatively, the treated parent may stay with

relatives or friends where children or pregnant women are absent.

If you go to ICRP 94 it says, the modes of exposure to other people are external exposure, internal exposure due to contamination and environmental pathways. Doses to adults from patients is mainly due to external exposure. Contamination of infants and children with saliva from a patient could result in significant doses for the child's thyroid. It is important to avoid contamination of children or pregnant women. And, I mean it -- why do we -- why does the NRC pay for potassium iodide to be stockpiled around nuclear plants? Why does the government stockpile it against acts of terrorism, if not because there is a risk to the public -- and to children above all -- from internal contamination with I-131? And if we are taught -- if this ICRP estimation quoted by the ATA is correct, that means that the 500 millirems that the NRC allows -- which is five times what the ICRP and NCRP permit -- could mean a dose -- an increase of 1 percent in cancer in the exposed child -- five -- half percent to 1 percent. And I just don't see what the benefit is from this rule that makes that possible. And I don't think that we should have a regulatory guide -- and this is what troubles me about

the ACMUI comment that seems to minimize the significance of internal dose. There's nothing in there about kissing.

The -- on page 11 of the ACMUI comments the following appears. Page 13, Section 2.3.1, add hotel to the list of examples of post-treatment lodging the patient may use. Why is this troubling? Because the word may have two distinct meanings. It could mean either it is possible that a patient will go to a hotel, or patients are permitted to go to a hotel. Now, it wasn't that long ago that the NRC put out a regulatory information summary -- 2011 -- saying that it is strongly discouraged that patients go to hotels. So, unless the NRC has changed its mind and no longer thinks that it's strongly discouraged, this ambiguous comment should not be accepted. On the contrary, the Reg Guide ought to reiterate the warning in the RIS.

I would like, also, to respond to the -- well, okay, under 10 CFR 35.75, if the licensee cannot find that a patient's exposure to others will be under 500 millirems, it cannot release the patient. No ifs, ands or buts. The draft regulatory guide makes this point under Section 2.32, Patient Precautions, but because the entire guide is declared to be non-binding, as in compliance with RGs is not required, the reader

may not realize that this is a requirement of the regulation and not a waivable piece of guidance.

MR. EINBERG: Dr. Palestro?

CHAIRMAN PALESTRO: Yes?

MR. EINBERG: Dr. Daibes here would like to make a comment in response to Mr. Crane's comments regarding internal doses.

(Simultaneous speaking.)

MR. CRANE: By all means.

CHAIRMAN PALESTRO: That's fine, thank you.

DR. DAIBES: Thank you. Mr. Crane, for the next stage of the update, Phase 2, one component that will be considered is internal contamination and the duration of the contamination. So -- but that's something that we are pursuing and the NRC is very aware of.

MR. CRANE: I am very happy to hear that. But then, why, I would ask, is there this comment about stressing that the -- the risk is from external contamination in -- in this stage?

(No audible response.)

MR. CRANE: I mean ---

(Simultaneous speaking.)

DR. DAIBES: The highest -- but the highest

risks would be from external. However, we are aware that there is a risk from internal and that's why we're ---

MR. CRANE: I am sorry, I am sorry -- it's ---

(Simultaneous speaking.)

MR. CRANE: -- Peter Crane again. C-R-A-N-E. I mean, why, I would ask, does the -- does this phase of the report -- this is -- this line, for example, under Other Recommendations, it should be emphasized that the major source of radiation dose to other individuals will be from external exposure to the patient. But I can give you lots of chapter and verse on the fact of, yes, the greatest dose to adults is going to be from external radiation. But the greatest danger is going to be to children from internal radiation. And we saw it at Chernobyl -- you've got 7,000 kids with childhood thyroid cancer. Childhood in the sense that the exposure came in the first four years of life. And it was generally either from inhalation, or from the milk pathway. And I just don't think we should, at any point, be emphasizing one to the exclusion of the other.

You look at ICRP 94 and they're very clear that the -- external, the danger to children -- the

heavy danger to children is from internal. They don't say that it's greater, but they say that it's great. Is that -- am I misstating ICRP 94? Does anybody think I am?

(Pause.)

MR. EINBERG: So, Dr. Palestro, Chris Einberg here again. I think, in the interest of providing other commenters an opportunity to comment as well, we should focus our comments on phase 1 comments. This update to Reg Guide 8.39 focuses on Phase 1. Phase 2, when it gets to, you know, dosimetric cal -- calculations and the methodologies -- but I think for the interest of time, we certainly will be providing the public the opportunity to make comments on Reg Guide 8.39 when we publish this later on this summer. And it will go out in the Federal Register for public comment. But at this stage, I think we would like to hear about the phase 1 comments that members of the public have.

(Simultaneous speaking.)

CHAIRMAN PALESTRO: Thank you, Mr. Einberg.

MR. CRANE: Thank you, Chris. I appreciate that. And I don't want to monopolize the phone. So, let me sign off and go back to listening

mode. And thank you Dr. Palestro and members of the Committee for hearing me out.

MR. EINBERG: Thank you, Mr. Crane.

CHAIRMAN PALESTRO: Thank you, Mr. Crane. Other comments from the public?

OPERATOR: Thank you. Our next comment is from Carol Marcus. Your line is open.

DR. MARCUS: Thank you very much. I would like to make comments on Table 3. The specifics of column 3, which is examples of recommended duration of interruption of breastfeeding. At the bottom of Table 3, the NRC notes that the recommendations in column 3 are from the Advisory Committee on Medical Use of Isotopes Nursing Mother Guidelines for the Medical Administration of Radioactive Material. And there were some meetings about that previously. However, of the 18 non-technetium radiopharmaceuticals, nine of them are not what was recommended by the ACMUI Subcommittee.

I looked in ICRP 106 to see if the NRC was using that instead, but they are not. And I don't know where some of these numbers come from. For example, for I-131 Hippuran, you know, Pat Zanzonico's calculations -- which are the basis of the Subcommittee report -- recommended -- for 100 millirem dose to the

infant -- recommended 4 hours of interruption of breastfeeding. ICRP 106 recommended 12 hours of interruption. But NRC recommends complete cessation of breastfeeding for this infant or child. And I don't know where in the world that comes from. Again, for thallium-201 chloride, Zanzonico's calculation is for the 100 millirem dose is interruption for 4.3 days. ICRP 106 has an interruption of 2 days. NRC lists an interruption of 14 days. And I don't know where that comes from. If fluorine-18 labeled -- it doesn't say labeled what -- but let's call it FDG, the ICRP 106 recommends no interruption. Zanzonico recommends 4 hours of interruption for 100 millirem, and no interruption for 500 millirem, which is the regulatory limit. But the NRC document lists 12 hours for 100 millirem. I don't know where that comes from.

And then there are six more that are not in compliance with the calculations in the Subcommittee report. So, my first problem with this table is that it says it comes from the Subcommittee report, but it doesn't. Other comments --

CHAIRMAN PALESTRO: Dr. Marcus?

DR. MARCUS: Yes?

CHAIRMAN PALESTRO: Dr. Marcus, I am sorry to interrupt you. This is Dr. Palestro. Regarding

your comment on Table -- your comments on Table 3, the way this evolved is that the working group and the subcommittee were not exactly in temporal synch on Table 3. And that recommendations of the subcommittee will in fact be incorporated in Table 3 when it goes out for public comment. Mr. Einberg, correct me if I am wrong on that?

MR. EINBERG: No, that is correct. Thank you for that clarification.

CHAIRMAN PALESTRO: Thank you. All right, go ahead, Dr. Marcus.

DR. MARCUS: Yes, okay, thank you, Chris. So -- so I should ignore column 3 because it is going to be changed? Is that it?

CHAIRMAN PALESTRO: That is correct. There are changes that are going to be made and the time to review it is when Phase 1 is out for public comment.

DR. MARCUS: Okay. While you are doing things like that, there is no such isotope as gallium-55. So please fix that. Maybe they mean gallium-68. But it just listed gallium-55 labeled, and then not even what it is attached to. And -- and this --

CHAIRMAN PALESTRO: So noted.

DR. MARCUS: Okay, as I recall in the last ACMUI meeting when Pat Zanzonico was still on the Committee it was agreed, I think unanimously, by the ACMUI that we should have recommendations for the 500 millirem limit, because that's what the regulatory limit is. And then there was some argument about conservatism with 100 millirem. And then it was decided we should have both. But in this document, there is no mention of any of the 500 millirem calculations and recommendations. However, you know, the subcommittee report contains all of the 500 millirem recommendations. And I think that the 500 millirem recommendations belong in this guidance because that's the regulatory limit. There are a lot of conservatism in the calculation of radiation dose to the nursing child. And putting another 500 percent on it like this is not called for. So, I think we should put in the 500 millirem recommendation of the ACMUI Subcommittee into this document. As far as --

MS. HOLIDAY: Dr. Marcus? Dr. Marcus, this is Sophie.

DR. MARCUS: Hello.

MS. HOLIDAY: Hello. So, if I could just add on to what Dr. Palestro and Mr. Einberg already stated, you know, it was highlighted at the bottom of

page 2 -- going over to page 3 -- of the Subcommittee's report that the table should be updated to reflect the recommendations in the ACMUI January 31st, 2019 Subcommittee report. And if you look at the draft proposed Reg Guide that is attached to this document, Reference 6 is where it is referencing the subcommittee report that was used. And it states there that from the 2018 subcommittee report -- so by virtue of that -- I am raising that point to just simply say that the tables will be updated as appropriate when it goes out for public comment later on this summer. So, realize that it does not reflect the cessation periods or the 500 millirem -- or any of that information that is contained in the January 2019 Subcommittee report. But that's because that's not what was used when this document was routed to the ACMUI for its review.

DR. MARCUS: But Sophie, are you going to include 500 millirem values?

MS. HOLIDAY: I am not a part of that working group, so I can't speak on that. I am simply stating the fact that the ACMUI's report from January of this year will be referenced when the reg guide goes out for public comment. So I -- again, I can't speak whether or not the 500 millirem will be used or not. But any information that the subcommittee provided

-- which was endorsed unanimously by the Committee -- will be used by the working group as it considers the ACMUI's comments during this meeting, as well as any other comments that they may have received internally before it goes out for public comment.

DR. MARCUS: Okay. Well, I encourage the ACMUI to recommend to the NRC that the 500 millirem values be included in this document. I really don't want to start a big discussion on what Peter Crane is saying. We could go on forever. We have already gone on for about 25 years. But when you talk about saliva being a source of internal contamination to babies and young children, you know, I think if adults are French kissing babies and young children, there is a lot bigger problem around than radiation. I think this is really overly exaggerated.

But, the authorized users take into consideration if there are babies and young children around -- and I don't see that there is any problem with any of it. You know, Peter doesn't have any data showing some incredible increase in thyroid cancer in children whose family members were treated for thyroid cancer. You know -- unless it's a genetic basis. And then it isn't from I-131, it's just from a genetic mutation. So I don't think that this saliva issue is

a really meaningful one.

As far as cremating bodies, you can have a service for someone who has died, and you can hold the corpse in the morgue for a month, or weeks, or whatever you need. And you can incinerate it subsequently. There's certainly very safe ways of doing these things. And I don't think that this has led to any bad problems, either. You can have some contamination, but that doesn't mean it's a public health and safety hazard. It doesn't mean that the radiation dose is dangerous. Just a few atoms around doesn't really make it dangerous at all -- which is why the NRC never made it illegal to put mildly radio-contaminated patient waste in a garbage dump. It's the people who regulate garbage dumps that tried to keep it out. And finally they're getting used to the idea that these tiny levels are harmless and not of any concern, and they're letting it go. It's taken them about 30, 40 years, but they're finally getting there.

Okay, I think that's the end of my comments. Thank you, Dr. Palestro.

CHAIRMAN PALESTRO: Thank you, Dr. Marcus. Any other comments from the public?

OPERATOR: We do have one more comment.

Ralph Lieto, your line is open.

MR. LIETO: Yes, can you hear me?

CHAIRMAN PALESTRO: Yes.

MR. LIETO: I have two questions. One is, could staff or --

CHAIRMAN PALESTRO: I am sorry, could you please -- hello? Please state your name?

MR. LIETO: This is Ralph Lieto. I am a medical physicist. And I have two questions. One relates to the reg guide and its relationship to Appendix U of NUREG-1556, Volume 9. Is it going to replace the Appendix U in its entirety? Or is there going to be some kind of a coordination between the two that's going to have to be done in the future?

MS. DIMMICK: This is Lisa Dimmick, Medical Radiation Safety Team Leader. So Reg Guide 8.39 will replace Appendix U so that there is only information -- will be in one location. So that we don't have a situation where we have the guidance in two different locations that could potentially be not in synch with the other.

MR. LIETO: Very good, excellent, thank you. My last question has to do with when this reg guide goes out for public comment. Will that be after Phase 2? Or is it going to go out after Phase 1, get

comments, and then go back out again after Phase 2?

MS. DIMMICK: So this is Lisa Dimmick again. So the plan is to publish Phase 1 for public comment this summer. And the plan is to issue Phase 1 -- the Phase 1 revision by next April. And while this is happening, in the background we will begin the Phase 2 update with a contractor. And then, once the Phase 2 update is ready for public comment, we will post -- we will publish Reg Guide Phase 2 Update for public comments as well.

MR. LIETO: Just for clarification, then, the Phase 2 will go out after you've received all the comments from Phase 1, correct?

MS. DIMMICK: And actually probably after we've published a Phase 1 revision. Correct.

MR. LIETO: All right, thank you.

CHAIRMAN PALESTRO: Any other comments or questions from the public?

OPERATOR: At this time we have no questions from the public.

CHAIRMAN PALESTRO: Any other comments or questions from ACMUI?

(No audible response.)

CHAIRMAN PALESTRO: Any comments, questions, additional information from Ms. Holiday,

Ms. Jamerson, Ms. Dimmick or Mr. Einberg?

MR. EINBERG: Nothing here. This is Chris Einberg.

CHAIRMAN PALESTRO: At this point, then, I believe we can adjourn the meeting.

MS. HOLIDAY: No, Dr. Palestro.

(Laughter.)

CHAIRMAN PALESTRO: Yes?

MS. HOLIDAY: Is there a motion to approve the Subcommittee's report and its recommendations herein?

CHAIRMAN PALESTRO: I'm sorry.

MEMBER WOLKOV: So moved. This is Harvey Wolkov.

CHAIRMAN PALESTRO: Do I hear a second?

MEMBER MARTIN: This is Melissa Martin, I will second.

CHAIRMAN PALESTRO: All right, any further discussion?

(No audible response.)

CHAIRMAN PALESTRO: All in favor?

(Chorus of aye.)

CHAIRMAN PALESTRO: Any opposed?

(No audible response.)

CHAIRMAN PALESTRO: Any abstentions?

(No audible response.)

CHAIRMAN PALESTRO: All right, motion is passed unanimously. Now, Ms. Holiday, can we adjourn the meeting?

MS. HOLIDAY: Almost.

(Laughter.)

MS. HOLIDAY: A very quick summary, since we couldn't hear Ms. Weil earlier, I just need to get on the record whether or not she endorsed the ACMUI Bylaw amendments?

(Pause.)

MS. HOLIDAY: Ms. Weil?

MEMBER WEIL: Yes, I did.

MS. HOLIDAY: Thank you. Okay, then for the record we have that the ACMUI passed a motion where Dr. Wolkov made the motion, Dr. Metter seconded to approve the amended bylaws. This was passed with one abstention by Dr. Palestro. The second motion was to approve the ACMUI draft subcommittee report for the Draft Proposed Reg Guide 8.39 Revision 1, Phase 1. The motion was made by Dr. Harvey Wolkov, seconded by Ms. Melissa Martin. This was unanimously endorsed by the committee. Are there any questions, comments, concerns? Or did I misstate the facts?

(No audible response.)

MS. HOLIDAY: Hearing none, I will capture that and hold to the recommendations from the committee for this meeting.

CHAIRMAN PALESTRO: All right, thank you. Any other discussion? Any other matters of business that need to be addressed?

MS. JAMERSON: I have one other thing. This is Kellee Jamerson, Dr. Palestro.

CHAIRMAN PALESTRO: Yes.

MS. JAMERSON: I would like to announce that the fall meeting of the ACMUI will be September 10th and 11th, 2019.

CHAIRMAN PALESTRO: Thank you. And as I had remembered emailing you about this, just to confirm that it is in fact the second choice, but for reasons of scheduling, that is now the definitive meeting date. Am I correct?

MS. JAMERSON: That is correct.

CHAIRMAN PALESTRO: All right. Any other business?

MR. EINBERG: Yes, and this is Chris Einberg. And I just wanted to thank the subcommittee and the full committee on behalf of the NRC for their hard work on this topic. I know you have put a lot of effort into this and that it's a topic that has a

lot of interest -- public interest -- and I would like to thank the public commenters, also, for their interest and their comments. And you will have additional opportunities to provide input on this topic. So, thank you everybody.

CHAIRMAN PALESTRO: Any other business? Any other comments?

(Pause.)

MR. EINBERG: Nothing here at the NRC.

CHAIRMAN PALESTRO: All right. Anything from the ACMUI?

(No audible response.)

CHAIRMAN PALESTRO: All right, then -- meeting is adjourned. Thank you.

(Whereupon, the above-entitled matter went off the record at 3:32 p.m.)

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May 30, 2019

Christopher J. Palestro, M.D.
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Re: Comments pertaining to draft of NRC Regulatory Guide 8.39

Dear Dr. Palestro:

I have grave concerns about this draft Regulatory Guide (RG) 8.39. I ask that you forward my comments to your committee, at least the subcommittee studying this, and I ask to speak at the June 10, 2019 meeting.

This document fails to repair the mistakes in its predecessor regulatory guide, NUREG-1556 Appendix U. Despite several telephone calls and e-mails and a few letters requesting correction of erroneous material in Appendix U and its predecessor versions, no corrections have ever been made. Finally, in frustration, I, Jeffry Siegel, and Michael Stabin published a paper in Health Physics delineating the errors (this paper did not address the errors in the breastfeeding portion of this RG). The reference is Siegel JS, Marcus CS, and Stabin MG: Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with I-131. Health Phys 93(6):667-677, 2007, and a copy is included with this e-mail. I urge you to read it carefully. Copies were sent to the NRC after publication, but still no corrections were made.

The Health Physics paper addresses the four most flagrant apparently purposeful misrepresentations in the RG. They are (1) assumption of the patient as a point source, with no reduction of exposure to others based upon patient self-absorption, (2) a non-void period for the first 8 hours after I-131 NaI administration, (3) a presumption of an occupancy factor of 0.75 for the non-void period, and (4) a presumption of internal contamination of 10^{-5}. Assumption (1) introduces an overestimate of about 100%, because there are high quality data measuring patient self-absorption. Assumption (2) is ludicrous, as patients are well hydrated before I-131 NaI administration and strongly encouraged to consume copious amounts of fluids. This assumption erroneously raises the calculated exposure to others, as the renal half-time for clearance of the non-thyroidal fraction is about 8 hours. The patients urinate very shortly after I-131 NaI administration and frequently thereafter. Assumption (3) is a completely unsubstantiated

misrepresentation of the occupancy factor and introduces an exposure overestimate of 300%. There is no reason to change the occupancy factor from 0.25 to 0.75. Assumption (4) ignores all the literature and introduces an exposure overestimate of 1000%. All the literature finds that 10^{-6} is an appropriate factor. The present draft RG repairs none of these misrepresentations and also fails to cite literature references which are important and may be found in the Health Physics paper. The NRC appears to be hugely and purposefully overestimating absorbed dose to others in order to dissuade licensees from using the 500 mrem patient discharge rule. There were NRC staff members who fought this rule change for nearly seven years until it was accepted. They still haven't given up.

The draft RG cautions against releasing patients when there are pregnant women or young children at home. This is inappropriate. The radiation limit of 500 millirem is so low that young children and pregnant women may safely receive it. In fact, NRC's limit to the fetus of a declared pregnant woman is 500 mrem, which NRC considers to be safe. The rule does not state this, and neither should this draft RG.

The draft RG amazingly does not reference the Radiation Absorbed Dose Assessment Resource (RADAR) web site, with its excellent tutorial on how to perform these dose calculations and an online exposure calculator for individual patients. The site is free and this past year received 66,000 hits. Unlike this draft RG, RADAR is scientifically solid and uses reliable data for its calculations. Competent nuclear medicine professionals are voting with their mice. They want RADAR, not NRC junk.

The information about breastfeeding patients was always misleading. The original calculations were "take out" calculations using the highest values for breast milk uptake, milk intake, and infant thyroid uptake. No infant ever received these doses, but the idea was that if the administered activity of the radiopharmaceutical in question was less than that which was in the table, it was impossible for the infant to get 100 mrem and no dose calculation needed to be carried out by the licensee. The explanation of the original calculation was in a footnote to the table but was taken out many years ago by Donna-Beth Howe to "save space". What this means is that these are not actual dose calculations but are overestimates by at least 1000%. New calculations were recently performed by Pat Zanzonico, who was formerly on the ACMUI, and were given to the NRC. Dr. Zanzonico's calculations were for infant doses of 100 mrem and 500 mrem. What happened to them? They were supposed to be in this draft RG. In addition, the old RG had calculations for suggested interruption of breast feeding, and often had multiple suggested times for single radiopharmaceuticals based upon administered activity. The lower times for lower administered activities were removed from this draft RG. In addition, this RG only addresses doses of 100 mrem, not the regulatory limit of 500 mrem. They are therefore overestimated by 500 %. So, these values in the RG are *at least* 1500 % overestimates.

The writer of this document opines that she/he is only being "conservative". That is not true. She/he is committing purposeful lying fraud.

In Table 3, NRC lists "Ga-67 and Zr-80 labeled" and doesn't finish the drug. It also lists "C-11, N-13, O-15, Rb-82 labeled" and doesn't finish the drugs. It lists "F-18 labeled" and does not list the drugs. It lists "Lu-177 diagnostic" but Lu-177 labeled compounds are all therapeutic. It lists "Ra-223 and all alpha emitters" and recommends complete cessation of breastfeeding for that infant but there are no calculations and that doesn't make sense. Do the calculation and justify the RBE. Infants are exposed to alpha emitters at least from birth when they are exposed to Rn-222. It doesn't seem to hurt them. Anyway, Ra-223 dichloride is only approved for the treatment of castration-resistant prostate cancer with no known metastases other than bone. It is ridiculously expensive and insurance companies will only reimburse for the FDA approved indication. It is therefore not used off-label, and men don't breast-feed. NRC lists "Ga-55 labeled" but doesn't finish the drug and there is no such radionuclide as Ga-55. Under "Notes" the NRC is behind the times. It certainly does regulate accelerator-produced radioactive material and changed the definition of "byproduct material" to include it. This same erroneous message is in "Notes" in Table 2.

There are many examples of added paperwork requirements that are not in the actual rule and that were not in previous versions of this mess. This is completely inappropriate.

All in all, I find this draft RG, and its predecessors, to be without scientific value and to be grossly dishonest and suggest that the ACMUI recommends that they be trashed. We do not need any NRC "guidance". The NRC only needs to suggest that licensees use RADAR instead.

Thank you for your attention and consideration.

Sincerely,

Carol S. Marcus, Ph.D., M.D.

Prof. of Molecular and Medical Pharmacology (Nuclear Medicine) and of Radiation Oncology. Prof. of Radiological Sciences, ret.
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Paper

LICENSEE OVER-RELIANCE ON CONSERVATISMS IN NRC GUIDANCE REGARDING THE RELEASE OF PATIENTS TREATED WITH ^{131}I

Jeffry A. Siegel,* Carol S. Marcus,† and Michael G. Stabin‡

Abstract—**Medical licensees are required to comply with U.S. Nuclear Regulatory Commission (NRC) regulations pertaining to the release of patients administered radioactive material. However, use of the associated NRC guidance expressed in NUREG-1556, Volume 9, is completely optional and has been shown to be overly conservative. Rigid adherence to the guidance recommendations has placed an undue burden on nuclear medicine therapy patients and their families, as well as licensees responsible for ensuring compliance with NRC requirements. More realistic guidance has been published by other responsible professional societies and will be presented in this work. These more realistic calculations allow for higher releasable activity levels than the widely adopted NUREG levels, particularly for thyroid cancer patients. The guidance-suggested releasable activity limit is similar to our calculational result for hyperthyroid patients, 2.1 GBq (57 mCi) compared to 2.3 GBq (62 mCi), but is significantly lower for thyroid cancer patients, 6.6 GBq (179 mCi) vs. 16.9 GBq (457 mCi) using the regulatory definition of the total effective dose equivalent (TEDE). Higher limits are both possible and reasonable, if the permissible extra-regulatory definition of the TEDE is used in which the effective dose equivalent (EDE), rather than the deep-dose equivalent (DDE), is determined. We maintain that professionals evaluating compliance with the NRC requirements for patient release, pursuant to 10 CFR 35.75, should use the procedures presented here and not rely automatically on the NUREG.**

Health Phys. 93(6):667–677; 2007

Key words: nuclear medicine; dosimetry; safety standards; medical radiation

INTRODUCTION

U.S. NUCLEAR Regulatory Commission (NRC) regulations for the release of patients administered radioactive material, pursuant to 10 CFR 35.75, authorize patient release according to a dose-based limit, i.e., the dose to other individuals exposed to the patient (U.S. NRC 1997). The dose-based limit, which replaced the activity- or dose-rate-based release limit, <1,110 MBq (30 mCi) or <0.05 mSv h^{-1} (5 mrem h^{-1}) at 1 m in 1997, better expresses the NRC's primary concern for the public's health and safety and makes good scientific sense. A licensee may release patients, regardless of administered activity, if it can be demonstrated that the total effective dose equivalent (TEDE) to another individual from exposure to a released patient is not likely to exceed 5 mSv (0.5 rem).

Individuals exposed to released radionuclide therapy patients can potentially receive radiation doses by two distinct sources: external exposure and internal intake. The TEDE concept makes it possible to combine these dose components in assessing the overall risk to the health of an individual. The TEDE, pursuant to 10 CFR 20.1003, is equal to the sum of the deep-dose equivalent (DDE), due to external exposure, and the committed effective dose equivalent (CEDE), due to internal intake. Thus, TEDE = DDE + CEDE.

U.S. NRC regulations, pursuant to 10 CFR 20.1101, require that applicants and licensees develop, document, and implement operating policies and procedures as part of an overall radiation protection program that will ensure compliance and the security and safe use of licensed materials. These radiation protection policies and procedures for their implementation are neither detailed in the regulations nor required to be submitted as part of the license application (Siegel 2004). Some practitioners have developed their own radiation protection programs, but most have relied on model procedures published by the NRC in guidance documents. There is no question that licensees must comply with NRC regulations, but doing so by adopting regulatory guidance is not necessary. The NRC will accept alternative approaches, but a large number of licensees know that use and adoption of NRC-proposed guidance will clearly provide an acceptable approach to the NRC and many licensees are not able to devote the time or resources

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necessary to establish their own alternative implementing procedures and policies. Although guidance documents do not contain regulatory requirements, if licensees commit to following these procedures they will become conditions of their licenses.

We do not take issue here with the NRC regulations related to patient release. We do, however, note that the associated NRC guidance for licensee compliance with 10 CFR 35.75 as promulgated in NUREG-1556, Vol. 9, Rev.1, Appendix U, *Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials*, has been shown to be overly conservative and places a high burden on nuclear medicine therapy patients and their families, as well as on licensees who adopt the guidance. A series of published studies and guidelines issued by other responsible professional societies has provided guidance in compliance with the applicable NRC requirements at a clearly lower burden to all parties involved. Substitution of these approaches for those in the NUREG will provide a clear benefit to patients and their families, and will make the job of licensees easier as well. We will confine our arguments to the release of patients who have received oral $Na^{131}I$ for the treatment of thyroid cancer or hyperthyroidism, but note that the rationale of the arguments applies also to other radionuclide therapy agents.

The purpose of this work is to critically evaluate the compliance-implementing procedures as proposed in the NUREG and to suggest alternative compliance methods. We examine the guidance methods to assess the external dose component, the internal dose component, and thus the TEDE, and by so doing, demonstrate that the guidance procedures are overly conservative and introduce an unnecessary regulatory burden not codified in NRC requirements. We propose alternative procedures to enable licensee compliance with 10 CFR 35.75, and we recommend that all licensees use these procedures instead of automatic reliance on the NRC guidance documents.

PATIENT RELEASE BASED ON NRC GUIDANCE

The external dose component (DDE)

NUREG-1556, Vol. 9, Rev.1, Appendix U (U.S. NRC 2005) provides model procedures for calculating the external dose to others from exposure to released patients. According to the NUREG, compliance with the NRC regulatory dose limit requirement can be demonstrated by licensees by either: (1) using provided default tables for activity or dose rate at 1 m for a variety of radionuclides; or (2) performing a patient-specific dose calculation.

Use of the "default" values. The "default" patient release values are based on integration of external dose to a maximally exposed individual to total decay after release of patients receiving radioactive material. Two very conservative assumptions are involved in modeling this dose in NUREG-1556, Vol. 9: 1) that the activity in the patient can be represented as an unshielded point source; and 2) that removal of activity from the patient is only due to physical decay of the radionuclide involved. This approach fails to consider the distributed nature of most radiopharmaceutical agents and does not account for the often significant biological elimination that diminishes activity levels in the patient (and thus dose rates outside the patient) over time. This method is highly over-conservative for ^{131}I sodium iodide. Therapy patients receiving ^{131}I do not retain 100% of the radioactivity for the physical half-life of the radionuclide (8 d); rather, a significant portion of the administered activity is not taken up by the thyroid gland and is rapidly excreted. For ^{131}I, the 5 mSv dose limit is predicted in the NUREG to be achieved with an administered activity of 1,221 MBq (33 mCi), or a dose rate of 0.07 mSv h^{-1} (7 mrem h^{-1}) at 1 m, for both thyroid cancer and hyperthyroid patients, representing a value of 4.10×10^{-3} mSv MBq^{-1} (15.2 mrem mCi^{-1}) (this dose per unit administered activity is an order of magnitude higher than if a patient-specific dose calculation is performed; compare to values given below based on eqn 1). In essence, use of NRC "default values" for $Na^{131}I$ represents a return to the historical "30-mCi rule" and is quite regressive, especially since there is no credible origin or scientific basis for this rule (Siegel 2000). Further, empirical data recently obtained by measurement of the dose received by family members of thyroid cancer patients receiving ^{131}I (Grigsby et al. 2000) support and confirm that the use of a 1,221 MBq activity limit for all patients is overly conservative.

Clearly, use of only simple knowledge of administered activity, without consideration of such things as radionuclide clearance from the body and the patient's lifestyle, require issuance of patient instructions to maintain doses to others that are as low as is reasonably achievable (ALARA) that would have to be in place for an extremely long time. Rational analysis suggests that the use of overly simplistic "point-source-radioactive-decay-only" models will significantly overestimate doses to others from $Na^{131}I$ (and many other radiopharmaceuticals), and this has been confirmed by actual measurements (Grigsby et al. 2000). Thus, there is no question that patient-specific dose calculations that would permit the release of patients from radioactive isolation with more than 1,221 MBq must be performed for ^{131}I therapy patients to provide a more complete and appropriate

estimation of dose (and patient release instructions) to individuals likely to be exposed to the patient.

Use of the patient-specific dose calculation. The "patient-specific" dose equation provided in the NUREG that can be used to estimate the likely external exposure to total decay, i.e., DDE at infinite time or $DDE(\infty)$ in mSv (mrem), to an individual from a released radionuclide therapy patient receiving oral $Na^{131}I$ for thyroid cancer and hyperthyroidism is:

$$DDE(\infty) = [34.6\Gamma Q_0]/(100\ \text{cm})^2\{E_1T_p(0.8)[1 - e^{-0.693(T_{NV})/T_p}] + e^{-0.693(T_{NV})/T_p}E_2F_1T_{1\text{eff}} + e^{-0.693(T_{NV})/T_p}E_2F_2T_{2\text{eff}}\}, \quad (1)$$

where:

- 34.6 = conversion factor of 24 h d^{-1} times total integration of decay (1.44);
- Γ = exposure rate constant for an unshielded point source, for ^{131}I = 0.595 mSv cm^2 MBq^{-1} h^{-1} (2,200 mR cm^2 mCi^{-1} h^{-1});
- Q_0 = administered activity in MBq (mCi);
- E_1 = occupancy factor for first 8-h non-void period = 0.75;
- T_p = physical half-life in days = 8.04 for ^{131}I;
- 0.8 = an assumed factor indicating that 80% of the administered activity is removed from the body only by the physical half-life of ^{131}I during the non-void period;
- T_{NV} = non-void period in days = 0.33 (8 h);
- E_2 = occupancy factor from 8 h to total decay = 0.25;
- F_1 = extrathyroidal uptake fraction = 0.20 in hyperthyroid patients = 0.95 in thyroid cancer patients;
- $T_{1\text{eff}}$ = effective half-life of extrathyroidal component = 0.32 d in hyperthyroid patients = 0.32 d in thyroid cancer patients;
- F_2 = thyroidal uptake fraction = 0.80 in hyperthyroid patients = 0.05 in thyroid cancer patients; and
- $T_{2\text{eff}}$ = effective half-life of thyroidal component = 5.2 d in hyperthyroid patients = 7.3 d in thyroid cancer patients.

Eqn (1) represents the dose to an individual likely to receive the highest dose from exposure to released ^{131}I patients as it is taken to be the dose to total decay. The equation contains 3 components: (1) a non-void period for the first 8 h after administration; (2) an extrathyroidal component from 8 h to total decay; and (3) a thyroidal component from 8 h to total decay. Eqn (1) can be solved for the external dose component per unit administered activity, Q_0.

In the case of thyroid cancer patients:

- $DDE(\infty)/Q_0$ (mSv MBq^{-1}) = 2.06×10^{-3} {0.135 + 0.0739 + 0.0887} = 6.12×10^{-4} mSv MBq^{-1}; and
- $DDE(\infty)/Q_0$ (mrem mCi^{-1}) = 7.61 {0.135 + 0.0739 + 0.0887} = 2.27 mrem mCi^{-1},

where the percentages of the total dose due to the non-void, extrathyroidal, and thyroidal components are 45%, 25%, and 30%, respectively.

In the case of hyperthyroid patients:

- $DDE(\infty)/Q_0$ (mSv MBq^{-1}) = 2.06×10^{-3} {0.135 + 0.0739 + 0.0887} = 2.39×10^{-3} mSv MBq^{-1}; and
- $DDE(\infty)/Q_0$ (mrem mCi^{-1}) = 7.61 {0.135 + 0.0156 + 1.01} = 8.84 mrem mCi^{-1},

where the percentages of the total dose due to the non-void, extrathyroidal, and thyroidal components are 12%, 1%, and 87%, respectively.

These 2 equations can be solved for the maximum allowable administered activities for authorizing patient release based on the 5 mSv regulatory dose limit. Eqn (1) can also be solved for the maximum allowable dose rates at 1 m, given by $\Gamma Q_0/(100\ \text{cm})^2$. These values are shown in Table 1.

These activity limits, as well as those in later sections, can be applied to all patient releases. According to the NUREG, the parameter values in eqn (1) are "acceptable" values (e.g., the occupancy factors and the representative uptake fractions and effective half-lives) to be used in class-specific dose calculations for patients with thyroid cancer and hyperthyroidism. Thus, individual dose calculations need not be performed on a case-by-case basis for these patients, unless a specific patient's situation warrants the use of parameter values different from those used in eqn (1). For example, the licensee may select more realistic uptake fraction and effective half-life values from the scientific literature or choose to measure the biokinetics in individual patients, measure the dose rate and/or use an occupancy factor <0.25, if appropriate. In these cases, as stated in the NUREG, a patient-specific calculation would be required

Table 1. Maximum activities and dose rates at 1 m for authorizing patient release for thyroid cancer and hyperthyroid patients (based on eqn 1).

	Activity in GBq (mCi)	Dose rate in mSv h^{-1} (mrem h^{-1})
Thyroid cancer	8.2 (221)	0.49 (49)
Hyperthyroidism	2.1 (57)	0.12 (12)

in place of the use of the class-specific values given in Table 1.

This class-specific approach is highly conservative and unnecessarily restrictive. Several assumptions were made by the NRC in assigning values to the parameters used in eqn (1). The two biggest contributors to the conservatism are: 1) use of the exposure rate constant, which is an unshielded point source value; and 2) use of an 8-h non-void period and associated 0.75 occupancy factor. Since a patient is not adequately represented as an unshielded point source (particularly with respect to their extrathyroidal activity distribution), an exposure rate constant accounting for radionuclide distribution and patient attenuation must be used since without such considerations unrealistic and unnecessarily conservative results will be obtained, perhaps as high as a factor of 2 (Sparks et al. 1998; Siegel et al. 2002a).

During the first 8 h after administration, 80% of the ^{131}I administered is assumed to be removed from the body at a rate determined only by its physical half-life to account for the time of the ^{131}I to be absorbed from the stomach to the blood and the holdup of iodine in the urine while in the bladder. The remaining 20% of the administered activity must be associated with some unknown physiological mechanism as it is unaccounted for during this initial 8-h non-void period. It is important to note that there are no scientific data to support the notion of a "non-void" period of any significant length. Patients are hydrated before the administration of $Na^{131}I$ and are strongly urged to drink plenty of fluids for several days afterwards. Patients often void before even leaving the Nuclear Medicine service, and frequently thereafter. $Na^{131}I$ is absorbed within 10–15 min after an oral administration (Loevinger et al. 1988) and upon reaching the blood is immediately filtered out by the kidneys; with large fluid intakes, the patient may typically void hourly.

A recent international controlled study of iodine biokinetics in radioiodine therapy of thyroid cancer (Hänscheid et al. 2006) indicated that the whole body retention of radioiodine was generally described by a biexponential activity-time curve, with no significant activity excretion time delay, based on whole-body probe and gamma camera scanning measurements. The total body residence times obtained (mean value of 24.1 h in hypothyroid patients) were in good agreement with the value of 23.2 h, a value that would be calculated based on the NRC guidance representative values for a 2-component total body retention curve involving extrathyroidal and thyroidal components. In addition, this latter total body residence time of 23.2 h with an associated activity excretion of 48% at 8 h, corresponding to generally hypothyroid patients, is in excellent agreement with that reported in MIRD Dose Estimate Report No. 5 (Berman et al. 1975) for the case of a maximum thyroid uptake of 5% in euthyroid patients. It should be noted that mean whole-body residence times have been observed to be longer for hypothyroid (24.1 h) than euthyroid (17.3 h) patients (Hänscheid et al. 2006). Thus, established models and recent data indicate that approximately 50% of the administered activity is excreted from the body during the NRC's presumed non-void period in the case of a thyroid cancer patient.

The inclusion of the non-void component in eqn (1) has a profound effect on the estimated dose an individual is likely to receive, particularly from released thyroid cancer patients. As demonstrated above, 45% of the total dose is attributable to the non-void component for these patients (Siegel 1999); thus, its inclusion represents an additional factor of 2 conservatism as the 8.2 GBq activity limit in Table 1 is likely to result in a dose of only 2.75 mSv, equal to 3.35×10^{-4} mSv MBq^{-1} (1.24 mrem mCi^{-1}). In support of this claim, a regulatory analysis on the revised 10 CFR 35.75 completed in 1996 (Schneider and McGuire 1996) made no mention of an initial non-void period and estimated, for example, that based on use of only a two-component model consisting of thyroidal and extrathyroidal biokinetics, the maximum likely dose to total decay to individuals exposed to a thyroid cancer patient would be 2.48 mSv from a 7.4 GBq activity administration, equal to 3.35×10^{-4} mSv MBq^{-1} (1.24 mrem mCi^{-1}). For hyperthyroid patients, inclusion of the non-void component has minimal effect (as demonstrated above, the percent of the total calculated dose attributable to this initial non-void period is 12%) and is really not necessary as it is mathematically redundant; approximately 14% of the administered activity is excreted from the body at 8 h based on the NUREG representative uptake fractions and effective half-lives.

Direct measurements are the best way to obtain the dose any individual is likely to receive based on the reality of daily life. Dosimeter measurements obtained in 65 household members of 30 patients who received outpatient ^{131}I therapy for thyroid carcinoma indicated that the measured radiation dose was on average a factor of 10 lower than the radiation dose predicted based on eqn (1) (Grigsby et al. 2000). These empirical data are further evidence demonstrating the overly conservative nature of the dose calculation as implemented through use of eqn (1).

The internal dose component (CEDE)

NRC guidance in NUREG-1556, Vol. 9, Rev.1, Appendix U uses the following equation for the likely internal dose component (i.e., CEDE) for individuals who may come in contact with a released patient who received oral $Na^{131}I$:

- CEDE (Sv) = Q_0 (MBq) × 10^{-5} × 1.43 × 10^{-2} Sv MBq^{-1}; and
- CEDE (rem) = Q_0 (mCi) × 10^{-5} × 53 rem mCi^{-1}, (2)

where 10^{-5} is the NRC assumed fractional intake and 1.43 × 10^{-2} Sv MBq^{-1} (53 rem mCi^{-1}) is the dose conversion factor to convert an intake of ^{131}I in MBq (mCi) to a CEDE in Sv (rem). It is obvious from this equation that the predicted internal dose component per unit activity will always be a constant value of 1.43 × 10^{-4} mSv MBq^{-1} (0.53 mrem mCi^{-1}). Thus, unlike the guidance for the external dose component, which permits variability and thus patient-specificity, only a fixed or case-specific internal dose component is considered for both thyroid cancer and hyperthyroid patients.

A common "rule of thumb" is to assume that no more than 1 millionth of the activity being handled will become an intake to an individual working with the material. This heuristic was developed for cases of worker intakes during normal workplace operations, worker intakes from accidental exposures, and public intakes from accidental airborne releases from a facility (Brodsky 1980), but it does not specifically apply for cases of intake by an individual exposed to a patient. Admittedly, there are limited data for thyroid uptakes in family members exposed to Na^{131}I patients. Two studies performed in the 1970's (Buchan and Brindle 1970; Jacobson et al. 1978) on the intakes of individuals exposed to patients administered ^{131}I indicated that intakes were generally on the order of 1 millionth of the activity administered to the patient and that internal doses were far below external doses. Based on these two studies, NUREG-1492 (Schneider and McGuire 1996), the regulatory analysis for 10 CFR 35.75, concluded that internal doses are likely to be much smaller than external doses and much smaller than the public dose limit, and therefore did not consider internal exposures in their analyses. In addition, the National Council on Radiation Protection and Measurements (NCRP) addressed the risk of intake of radionuclides from patients' secretions and excreta in NCRP Commentary No. 11, *Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients* and concluded that "a contamination incident that could lead to a significant intake of radioactive material is very unlikely."

As given in eqn (2), NRC guidance recommends use of 10^{-5} for the assumed fractional intake. According to NRC, this value was chosen in order to account for the most highly exposed individual and to add a degree of conservatism to the calculation. However, no such "highly exposed" individual has ever been found, and no documentation substantiates that this "factor of 10" conservative approach is advisable, necessary, or accurate.

The total effective dose equivalent (TEDE)

Summing the values of $DDE(\infty)$ per unit administered activity, based on the patient-specific dose calculation given by eqn (1) and the CEDE per unit administered activity values based on eqn (2), the TEDE per unit administered activity is given as follows.

In the case of thyroid cancer patients:

- TEDE/Q_0 (mSv MBq^{-1}) = 6.12 × 10^{-4} mSv MBq^{-1} + 1.43 × 10^{-4} mSv MBq^{-1}; and
- TEDE/Q_0 (mrem mCi^{-1}) = 2.27 mrem mCi^{-1} + 0.53 mrem mCi^{-1}.

In the case of hyperthyroid patients:

- TEDE/Q_0 (mSv MBq^{-1}) = 2.39 × 10^{-3} mSv MBq^{-1} + 1.43 × 10^{-4} mSv MBq^{-1}; and
- TEDE/Q_0 (mrem mCi^{-1}) = 8.84 mrem mCi^{-1} + 0.53 mrem mCi^{-1}.

Using this approach, the internal dose component will always be 23% (1.43/6.12) and 6% (1.43/23.9) of the external dose component for thyroid cancer and hyperthyroid patients, respectively, irrespective of the administered activity.

NRC guidance states that when the internal dose component is less than 10% of the external component, it does not need to be considered (U.S. NRC 2005). Thus, internal contamination will never have to be considered for hyperthyroid patients whereas the summation of internal and external dose components will always be required for thyroid cancer patients if a patient-specific dose calculation is performed. In the case of the NUREG default-value approach, the TEDE is assumed to be equal to the external dose "because the dose from intake by other individuals is expected to be small." The values in Table 1 are therefore valid for the release of hyperthyroid patients, e.g., the maximum releasable activity is 2.1 GBq. However, the Table 1 values cannot be used for thyroid cancer patients, e.g., the maximum releasable activity of 8.2 GBq is not applicable. The dose calculation approach will always result in a maximum releasable activity for thyroid cancer patients of 6.6 GBq (179 mCi) (the constraint that the CEDE is always 23% of the $DDE(\infty)$, which forces a DDE of approximately 4.05 mSv and an associated CEDE of 0.95 mSv to be in compliance with the 5 mSv TEDE limit). Although not applicable, if the same logic is followed, but this time with the constraint that the CEDE always be 6% of the

$DDE(\infty)$, the maximum releasable activity for hyperthyroid patients would be 2.0 GBq (53 mCi).

The advice requiring inclusion/exclusion of the internal dose component in the NUREG for the TEDE calculation has no basis in regulatory requirements; in fact, it adds an "extra-regulatory" burden on licensees. It is also incorrect as it may violate NRC regulations. For example, Example 4 in the NUREG uses the "default" value external dose of 5 mSv for a 1,221 MBq ^{131}I administration and determines a CEDE of 0.17 mSv. Since the internal dose is only 3% of the external dose, it is stated that the CEDE determinations are never necessary in the TEDE calculation if the default-value approach is taken; however, the TEDE will exceed the regulatory limit of 5 mSv (5 mSv + 0.17 mSv = 5.17 mSv) and the licensee would be in violation of NRC regulations.

The maximum activity release values given in this section are based on the assumption that the "patient-specific" dose calculation approach (use of eqns 1 and 2) used for determination of the TEDE is accurate. As described above, the NUREG approach is, at the very least, unjustifiably conservative, potentially by a factor as high as 4 in the case of thyroid cancer patients. The conservatism is due mainly to the assumption of an essentially non-existent non-void period, the use of an exposure rate constant representing an unshielded point source for the extrathyroidal activity biodistribution, and the use of an intake value of 10^{-5}. The more appropriate maximum fractional intake value of 10^{-6} should be used since this level is seldom, if ever, exceeded by the reported data. This "seldom exceeded" criterion was used in the NUREG in Footnote 1 of Table U.6 for selection of the thyroid uptake fraction in the hyperthyroidism case. The impact of these assumptions in the case of hyperthyroid patient release is much less significant since we have shown that the majority of the calculated total dose to others (i.e., 87%) is due to the thyroidal component.

When data are not available, use of conservative calculations may be reasonable, as they can identify or rule out a potential problem and may be used to add a margin of safety to procedures that do not have well-defined outcomes. However, when data are available, as they are in the case of patients treated with Na^{131}I for thyroid cancer and hyperthyroidism, the overuse of conservatism does not serve the goal of radiation protection practice, which is to provide optimization of radiation doses (economic, social, and other factors considered) within a system of dose limitation. Massive conservatism violates the principle of optimization and places an undue burden on those enforcing dose limits and on those subject to the limitations; in this case, radionuclide therapy patients and their families. Importantly, the regulations, pursuant to 10 CFR 35.75(a), do not require any calculational conservatism, let alone that promulgated in the NUREG; licensees must only demonstrate that the TEDE to any other individual from exposure to a released patient is not likely to exceed 5 mSv. Maintaining this calculated dose to others ALARA is the purpose of the required instructions, pursuant to 10 CFR 35.75(b). In point of fact, a patient receiving 1,221 MBq of ^{131}I for hyperthyroidism can potentially expose individuals to a larger radiation dose than a patient receiving 7.4 GBq of ^{131}I for thyroid cancer if appropriate instructions are not provided, due to the much longer retention of a significant fraction of ^{131}I in the body in the former case.

Therefore, we recommend that licensees perform more realistic calculations (e.g., use of an appropriate shielding factor for the exposure rate constant, no non-void period, use of a fractional intake value of 10^{-6}) and not simply automatically adhere to the approaches provided in the NUREG in order to permit realistic release limits and patient instructions that still are clearly in compliance with NRC regulations.

PATIENT RELEASE BASED ON SNM/ACNP GUIDANCE

One alternative approach to that given in NRC guidance that can be used for patient release has been proposed in a Society of Nuclear Medicine and American College of Nuclear Physicians (SNM/ACNP) guidebook (Siegel 2004). Using eqn (1), but substituting an exposure rate constant equal to 0.459 mSv cm^2 MBq^{-1} h^{-1} (1,700 mR cm^2 mCi^{-1} h^{-1}) (Carey et al. 1995), a non-void period of 1 h, and an occupancy factor of 0.25 during this period, the maximum allowable activities and dose rates for authorizing patient release are given in Table 2.

In our opinion, licensees can quite justifiably use the values in Table 2 as their basis for patient release. The maximum activity and dose rate values are higher in Table 2 than in Table 1 due to the use of less conservative and more realistic parameter values. It should be noted that this method assumes that the TEDE is equal to the external dose. This is because the internal dose was

Table 2. Maximum activities and dose rates at 1 m for authorizing patient release for thyroid cancer and hyperthyroid patients (based on SNM/ACNP guidebook).

	Activity in GBq (mCi)	Dose rate in mSv h^{-1} (mrem h^{-1})
Thyroid cancer	18.2 (493)	0.84 (84)
Hyperthyroidism	3.0 (80)	0.14 (14)

considered to be negligible due to the use of an intake factor of 10^{-6}. This is certainly a preferred approach to that given in the NUREG as it results in more realistic activity and dose rate release limits.

PATIENT RELEASE BASED ON METHODOLOGY DESCRIBED IN THIS WORK

We recommend that the patient-specific dose calculation be performed as follows:

$$\text{TEDE} = DDE(\infty) + \text{CEDE},$$

where:

$$DDE(\infty) = [34.6\ \Gamma Q_0]/(100\ \text{cm})^2 \times 0.25\{F_1 T_{1\text{eff}} \times 0.6 + F_2 T_{2\text{eff}}\} \quad (1a)$$

and

$$\text{CEDE} = Q_0\ (\text{MBq}) \times 10^{-6} \times 1.43 \times 10^{-2}\ \text{Sv MBq}^{-1}. \quad (2a)$$

Eqn (1a) includes only 2 components representing the thyroidal and nonthyroidal biokinetic components (the non-void period has been eliminated), the factor 0.6 represents a more accurate correction to the exposure rate constant given in eqn (1) (Siegel et al. 2002a) for the extrathyroidal component (the exposure rate constant is appropriately applicable only to activity confined to the thyroid gland), and F and T_{eff} are the same as those used in eqn (1) for thyroid cancer and hyperthyroid patients. Note that eqn (2a) recommends use of an intake factor equal to 10^{-6}.

Upon rearrangement and summation of eqns (1a) and (2a), the TEDE per unit administered activity is as follows.

In the case of thyroid cancer patients:

- $\text{TEDE}/Q_0\ (\text{mSv MBq}^{-1}) = 2.82 \times 10^{-4}\ \text{mSv MBq}^{-1} + 1.43 \times 10^{-5}\ \text{mSv MBq}^{-1}$; and
- $\text{TEDE}/Q_0\ (\text{mrem mCi}^{-1}) = 1.04\ \text{mrem mCi}^{-1} + 0.053\ \text{mrem mCi}^{-1}$.

In the case of hyperthyroid patients:

- $\text{TEDE}/Q_0\ (\text{mSv MBq}^{-1}) = 2.16 \times 10^{-3}\ \text{mSv MBq}^{-1} + 1.43 \times 10^{-5}\ \text{mSv MBq}^{-1}$; and
- $\text{TEDE}/Q_0\ (\text{mrem mCi}^{-1}) = 7.99\ \text{mrem mCi}^{-1} + 0.053\ \text{mrem mCi}^{-1}$.

In both cases the internal dose component does not have to be taken into account, as it will always be less than 10% of the external dose component. The maximum activities for authorizing patient release are 17.7 GBq (481 mCi) and 2.3 GBq (63 mCi) for thyroid cancer and hyperthyroid patients, respectively, based on the DDE. A better approach would be to neglect the "10% of the external dose" NUREG guidance as discussed above and include the internal dose component in the calculation. The maximum activities for authorizing patient release are then 16.9 GBq (457 mCi) and 2.3 GBq (62 mCi) for thyroid cancer and hyperthyroid patients, respectively, based on the TEDE.

These activity limits are still conservative as they are based on the use of the DDE for the TEDE, which does not account for attenuation and scatter within the exposed individual (pursuant to 10 CFR 20.1003, the DDE is the dose equivalent at a tissue depth of 1 cm), and therefore only approximates the likely surface entrance dose to the exposed individual (Sparks et al. 1998). In situations where doses are calculated rather than measured, we recommend that licensees use the EDE in place of the DDE in the TEDE determination, and according to an NRC Regulatory Issue Summary (U.S. NRC 2003) no prior NRC approval is required. The EDE has been reported to be a factor of 0.6, on average, less than the DDE for ^{131}I (Sparks et al. 1998). Using this permissible extra-regulatory definition of the TEDE (i.e., TEDE = EDE + CEDE), the maximum activities for authorizing patient release are 27.2 GBq (739 mCi) and 3.8 GBq (103 mCi) for thyroid cancer and hyperthyroid patients, respectively. The administered dosages for these patients will virtually always be less than these activity limits, indicating that all patients are immediately releasable based on patient-specific calculations according to NRC regulations.

NRC regulations pursuant to 10 CFR 35.75(b) also require that released individuals be provided with instructions on actions recommended to maintain doses to others ALARA. Pursuant to 10 CFR Part 20.1003, ALARA means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical. NRC has stated that "dose" in this context means the TEDE. Internal and external doses are not minimized separately, and ALARA efforts should be directed at minimizing their sum, the TEDE. Since the internal dose is such a small fraction of the external dose, the TEDE can be most effectively minimized by efforts to minimize the external dose component through adequate patient instructions. A three step approach is necessary (Siegel et al. 2002a):

1. An evaluation of individual's living and working conditions must be performed to ascertain whether or not the patient can be safely released;
2. An appropriate patient-specific dose calculation should be performed to ensure that no individual will likely be exposed to a dose in excess of 5 mSv; and
3. Written, not just oral, instructions that are simple and clear must be provided so that the patient can limit the radiation dose to others to as low as reasonably

achievable. The Authorized User (AU) physician must be satisfied that patient compliance with these instructions is highly likely.

Each of these three steps is equally important. Just because patients are releasable based on the patient-specific dose calculation does not mean that these patients should necessarily be released. For example, it is important to know if infants, young children, or pregnant women reside in the released patient's home (or are likely to come in contact with the patient) in order to conclude that the patient should be released and/or in order to provide meaningful instructions to minimize exposure to these individuals, which in the professional opinion of the AU physician will be comprehended by the patient and likely complied with. Any licensee releasing patients without giving due consideration to the three steps above should be considered to be not in compliance with 10 CFR 35.75 [licensees must also maintain a record of the basis for authorizing patient release pursuant to 10 CFR 35.75(c)]. Clearly, regulations will not prevent all unintended exposures. The underlying premise of NRC regulations is that AU physicians will understand radiation safety principles and practices and will make appropriate decisions. Licensees have certain responsibilities and need to implement policies and procedures to ensure adequate and effective radiation safety practices.

The NUREG is of limited value in providing appropriate and adequate patient instructions. As a good example, the suggested durations of the instructions provided for the occupancy factor selection in Section B.1.2 do not differentiate between thyroid cancer and hyperthyroid patients. As demonstrated by our analyses of eqn (1), 30% of the total dose is attributable to the time period from 8 h post-administration to total decay in the case of thyroid cancer patients, while 87% of the total dose is delivered over this same time period for hyperthyroid patients. It seems appropriate, therefore, that the times necessary for the relevant instructions to remain in effect should differ for these two groups of patients. Finally, it is important to note that radioactive articles in the household trash of patients are sometimes appearing at solid waste landfills that have installed radiation monitors to prevent the entry of any detectable radioactivity. Even though the radioactivity levels potentially contained in any household waste of patients released in accordance with 10 CFR 35.75 pose an insignificant hazard to the public health and safety or to the environment, professionals can take steps to avoid issues with landfill owners and operators and even individual states (Siegel and Sparks 2002). It is probably wise to instruct patients to avoid or minimize use of items that cannot be disposed of via plumbing (toilet, sink, dishwasher, washing machine), such as plastic utensils and paper plates (Siegel 2004).

SUMMARY OF MAXIMUM RELEASABLE ACTIVITIES

Table 3 summarizes the maximum releasable activities for both hyperthyroid and thyroid cancer patients presented in this work.

All values in Table 3 were determined based on an occupancy factor of 0.25 for the extrathyroidal and thyroidal components. If a licensee determines that a lower occupancy factor (e.g., 0.125) is justified for a particular patient, then even higher activities would be calculated.

THE LICENSEE'S ROLE IN PATIENT RELEASE

More realistic calculations allow for even higher releasable activity levels, particularly for thyroid cancer patients. The guidance approach involving patient-specific dose calculations results in a releasable activity limit similar to our calculational approach for hyperthyroid patients (2.1 GBq vs. 2.3 GBq), but the activity limit

Table 3. Summary of maximum releasable activities.

Method (TEDE definition)	Activity in GBq (mCi)	
	Hyperthyroidism	Thyroid cancer
1. NUREG		
a. Default value (TEDE = DDE)	1.2 (33)	1.2 (33)
b. Calculation (TEDE = DDE)	2.1 (57)	8.2 (221) (NA)[a]
c. Calculation (TEDE = DDE + CEDE)	2.0 (53) (NA)	6.6 (179)
2. SNM/ACNP		
Calculation (TEDE = DDE)	3.0 (80)	18.2 (493)
3. This work		
a. Calculation (TEDE = DDE)	2.3 (63)	17.7 (481)
b. Calculation (TEDE = DDE + CEDE)	2.3 (62)	16.9 (457)
c. Calculation (TEDE = EDE + CEDE)	3.8 (103)	27.2 (739)

[a] NA = not applicable.

for thyroid cancer patients is significantly lower (6.6 GBq vs. 16.9 GBq) using the regulatory definition of the TEDE. The similarity in the hyperthyroid case is due to the fact that the majority of the estimated dose to others is due to the thyroidal component and the overly conservative assumptions made in guidance have minimal effect. If a licensee chooses to replace the DDE with the EDE, then the release limits are even higher (27.2 GBq and 3.8 GBq for thyroid cancer and hyperthyroid patients, respectively) and now significantly different even for hyperthyroid patients. Thus, it is reasonable to ask the question, "Why have licensees broadly adopted the NUREG guidance for patient release?"

Given that regulatory requirements for patient release have historically been unrealistically conservative and that the current NUREG guidance procedures are still overly conservative, particularly with regard to thyroid cancer patients, it is difficult to justify providing such information to nuclear medicine physicians to determine patient release limits. Perhaps many licensees have adopted these procedures because most of their clinical treatments involving $Na^{131}I$ can be managed under the guidance release limits of either: 1) 1,221 MBq based on the default-value approach; or 2) 2.1 GBq and 6.6 GBq using the patient-specific calculational dose approach for hyperthyroid and thyroid cancer patient treatments, respectively. Rarely, they might argue, is there a need for hyperthyroid treatments involving >1,221 MBq or thyroid cancer treatments with >6.6 GBq and, therefore, the higher activity release limits in our recommended approaches may not be required. The important point is that, quite distinct from medical judgments by physicians in deciding what activity prescription is best suited for their patients, the activity release limits we have determined here from a radiation safety perspective pose little or no adverse impact on the public health and safety. Many institutions are providing thyroid cancer treatments based on a dosimetric approach, rather than an empiric fixed activity, generally involving an activity prescription >7.4 GBq, and these institutions need not be subjected to an unnecessary "tie-down" license condition preventing them from releasing their patients with activities greater than 6.6 GBq.

If more realistic activity limits, as presented and discussed in this work, were given to physicians by their Radiation Safety Officers (RSOs), higher activity administrations might be more routine. For example, treating autonomous hyperfunctioning nodules with empiric fixed dosages of ^{131}I that have been determined solely on the basis of the quantity of activity that would not require hospitalization (currently believed by many to be 1,221 MBq) is a common practice. However, for large nodular thyroid glands, administered dosages, if calculated based on volume and fractional uptake of iodine, could exceed this activity limit (Iagaru and McDougall 2007). It is important to note that RSOs are not required to blindly accept and adopt optional NRC guidance, but they are required to release radioactive patients in a manner that complies with 10 CFR 35.75 and, therefore, must be proficient in determining the likely dose to others from exposure to such released patients. We have shown that less conservative activity levels can achieve these goals. RSOs generally are not able to devote the time or resources necessary to perform complex modeling calculations to verify the adequacy of NUREG recommendations. Thus, it is common practice for licensees to simply adopt NRC guidance documents without critical assessment of their strengths and weaknesses. Uniform adoption of a single standard across the profession also facilitates the work of NRC inspectors. We have demonstrated, however, that a more scientifically sound but still easily implementable approach, i.e., one not requiring patient-specific biokinetic studies and dose calculations, can achieve the same goals as use of the NUREG, and lessen the burden on licensees, patients, and others.

CONCLUSION

Licensees must comply with NRC regulations but are under no obligation to adopt NRC guidance. Presently, there appears to be a considerable degree of confusion as to what is required by the regulations and what is optional, i.e., guidance. Rigid adherence to the guidance recommendations has placed an undue burden on nuclear medicine therapy patients and their families, as well as licensees responsible for ensuring compliance with NRC requirements. We have shown that guidance-suggested releasable activity limits are similar to those we have calculated for hyperthyroid patients, 2.1 GBq (57 mCi) vs. 2.3 GBq (62 mCi), but are much lower for thyroid cancer patients, 6.6 GBq (179 mCi) vs. 16.9 GBq (457 mCi) using the regulatory definition of the TEDE. Higher limits are both possible and reasonable, if the permissible extra-regulatory definition of the TEDE is used in which the EDE, rather than the DDE, is determined. We maintain that professionals evaluating compliance with 10 CFR 35.75 should use the approaches presented here to comply with NRC requirements. These approaches are easily implementable by licensees, as they do not require patient-specific biokinetic studies and dose calculations.

A repeat of the quiescence with which NRC's "30-mCi rule" was accepted by those in the radiation safety community is not justified. As chronicled by Siegel (2000), this activity limit, lacking scientific justification or evidence demonstrating it would actually

present a hazard to the public health and safety, was responsible for inappropriately low treatment activities, unnecessary patient hospitalizations and increased health care costs for over 50 y.

Use of the 1,221 MBq activity (or 0.07 mSv h^{-1} at 1 m dose rate) patient release limit based on the NRC guidance "default" approach should never be employed by any licensee permitted to release patients pursuant to 10 CFR 35.75. These values indicate lower limits for which NRC does not believe it necessary to perform patient specific calculations to demonstrate that others potentially exposed to a released patient will not likely receive a radiation dose that exceeds 5 mSv. However, the assumptions made by the NRC in arriving at these guidance values are inaccurate and unjustifiably conservative. Even if a licensee were to follow the patient-specific dose calculational approach provided for in NRC's NUREG guidance document, thyroid cancer and hyperthyroid patients receiving greater than 6.6 GBq and 2.1 GBq, respectively, would always have to be hospitalized. There is also no scientific basis or justification for these so-called "forced activity level" confinements. The NUREG patient release methodology also introduces a regulatory burden not as yet codified in NRC requirements. Indeed, patients, particularly thyroid cancer patients, can be released in accordance with NRC regulations with much higher activities, as demonstrated in this work, without adversely impacting on the public health and safety.

Patients and their families share the largest burden when overly restrictive release criteria are enforced. Alternative guidance for patient release by stakeholder professional organizations is available for use (Siegel 2004). Licensees may adopt and implement the approach presented here, or they could develop their own appropriate approach given that a wealth of scientific literature now exists (Siegel et al. 2002b; Mathieu et al. 1999; Barrington et al. 1999; Zanzonico et al. 2000; Venencia et al. 2002; Siegel et al. 2002a). Possible consequences of overly rigid adherence to the NUREG procedures include the under-treatment of patients, issuance of overly restrictive release instructions, and unnecessary confinement of patients to hospital beds. The significant and unjustified additional cost to patients and their loved ones, the requirement for hospitals to prepare and decontaminate unneeded rooms so that staff can receive unnecessary radiation exposures, and the adoption of substandard patient release policies associated with licensee adherence to NRC patient-release guidance should be critically re-evaluated given the guidance presented in this work. These procedures are in compliance with NRC requirements and their use can lessen the burden on licensees.

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June 1, 2019

From: Michael G. Stabin, PhD, CHP
Chair, RAdiation Dose Assessment
Resource (RADAR) Committee of the
Society of Nuclear Medicine and Molecular Imaging
3809 W 48th Ave
Kennewick, WA 99337

To: Christopher J. Palestro, M.D.
Zucker School of Medicine at Hofstra/Northwell
131 Grotke Road
Spring Valley, NY 10977

Re: Comments on new draft of NRC Regulatory Guide 8.39

Dear Dr. Palestro:

I am writing to express my concerns regarding the new draft NRC Regulatory Guide 8.39. I am profoundly disappointed that the scientific basis of this proposed RG contains the same scientific errors as related predecessor documents, errors that have been extensively and repeatedly refuted in the published scientific literature over many years. Your charter states that the committee:

> "...provides advice, as requested by the Director, Division of Material Safety, State, Tribal, and Rulemaking Programs (MSTR), Office of Nuclear Material Safety and Safeguards (NMSS), on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy."

This advice SHOULD be based on the best scientific data currently available, or the advice is not of value. Members of the RADAR Committee have been perhaps the most active in deliberating this issue publicly, but we are certainly not the only ones. The broad consensus of the scientific community is that the science presented in previous versions of this RG, and now amazingly presented again, are in error. I will mention the specific errors that SHOULD be corrected, and provide the extensive literature basis for doing so.

The principal equation proposed for patient release, based on the completely antiquated (1970) NCRP Report No. 37, is:

$$D(t) = \frac{34.6\,\Gamma\,Q_0 T_p\left(1 - e^{\frac{-0.693t}{T_p}}\right)}{r^2} \qquad \text{(Equation 1)}$$

Where D(t) = Accumulated exposure at time t, in roentgens,
34.6 = Conversion factor of 24 hrs/day times the total integration of decay (1.44),
Γ = Specific gamma ray constant for a point source, R/mCi-hr at 1 cm,
Q_0 = Initial activity of the point source in millicuries, at the time of the release,
T_p = Physical half-life in days
r = Distance from the point source to the point of interest in centimeters,
t = Exposure time in days.

The fallacies in this equation are:

1) The assumption that the patient is a point source, with no absorption of emitted radiation by the patient's body,
2) The use of a non-void period for the first 8 hours after I-131 NaI administration,
3) The presumption of an occupancy factor of 0.75 for the non-void period, and
4) The presumption of internal contamination of 10^{-5}.

- In 2002, Siegel et al. made actual measurements of patients whose bodies contained I-131 Tositumomab and found that "measured dose rates were 60% (range, 37%–90%; P <0.0001) of the theoretic dose rates from a point source in air…"
- In 2011, Willegaignon et al. monitored 90 subjects with thermoluminescent detectors after release after treatment of thyroid cancer with I-131 and found significantly lower cumulative doses than predicted by the RG equation.
- In 2007, RADAR members Siegel, Marcus, and Stabin rationally critiqued all of the RG assumptions in the Health Physics Journal article "Licensee Over-Reliance on Conservatisms in NRC Guidance Regarding the Release of Patients Treated with ^{131}I. Health Phys. 93(6):667– 677; 2007." It pointed out flaws in all four of the above assumptions, and showed that the correct equation to use is:

$$D(\infty) = \frac{34.6 \times 0.25 \times A \times T_{1/2} \times \Gamma \left(1 - e^{\frac{-0.693 \times \infty}{T_{1/2}}} \right)}{(100\ cm)^2}$$

$$D(\infty) = 8.66 \times 10^{-4} A \times T_{1/2} \times \Gamma$$

...WITH use of the self-absorption factor of 0.6 for activity in the extrathyroidal component of I-131 retention. The treatment of a patient as an unshielded point source (for any radionuclide) is a completely unrealistic assumption, and hampers licensees' ability to release patients who will be absolutely of no hazard to anyone. All of this, with worked examples, and a FREE patient release calculator for many radionuclides, is well documented on the RADAR web site at http://www.doseinfo-radar.com/ExposureCalculator.html. This calculational tool is used heavily, on a daily basis, by people around the USA and the world.

It completely baffles me, as well as other members of the RADAR Committee and the scientific community, how the NRC and the ACMUI can go on for all of these years ignoring all of this relevant and well-established scientific literature that could be used to update and refine the old RG. Instead, the same clearly refuted scientific basis is repeated, and used to shackle licensees, patients and their families with unrealistic patient release criteria, as well as irrational instructions about family members needing to leave home and live elsewhere for days to weeks, for patients not to touch or be close to others, and for people to live in fear of mildly contaminated objects in their homes. The ACMUI should *take the lead* in dispelling these unscientific propositions, not be complicit in their prolonged improper imposition on the scientific community. If asked, the RADAR Committee would be very pleased to rewrite this document, using an appropriate scientific basis, and to provide appropriate numerical data and rational instructions to radionuclide therapy patients.

Michael G. Stabin, PhD, CHP
Chair, RAdiation Dose Assessment
Resource (RADAR) Committee of the
Society of Nuclear Medicine and Molecular Imaging

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June 10, 2019

Chairman Kristine L. Svinicki
Commissioner Jeff Baran
Commissioner Annie Caputo
Commissioner David A. Wright
Ms. Margaret Doane, Executive Director for Operations
Ms. Marian Zobler, General Counsel
Ms. Sophie Holiday, ACMUI

Dear Chairman Svinicki, Commissioners, Ms. Doane, Ms. Zobler, and Ms. Holiday:

This afternoon, June 10, 2019, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) will hold a teleconference on the subject of patient release: the draft regulatory guide prepared by the NRC staff, and the comments on it by an ACMUI subcommittee. Unfortunately, the emailed notification of the meeting went into my spam folder, and I only found it yesterday.

For the past 27 years, I have closely followed the issue of the release of patients made radioactive by treatment with the isotope iodine 131 (I-131). My interest in the subject originated with my having been treated with that isotope, numerous times, for thyroid cancer. I was at the time a lawyer with the NRC.

I will just briefly review the background. The NRC's 1997 deregulation of I-131 treatments was once described to me by a Penn State nuclear medicine doctor as "the worst decision made by that agency in 35 years." That was 20 years ago. Everything I have seen since confirms the soundness of his comment.

Technical advice for that rulemaking came from an elderly nuclear medicine doctor who was a prominent advocate of "hormesis," the theory, considered crackpot by mainstream science, that radiation, even in what most experts would consider substantial doses, is good for you. This particular doctor, whose name I do not mention because he is deceased, was on record as believing that iodine 131 was not carcinogenic, and that if a serious nuclear accident occurred, the resulting radiation exposure could not be harmful to health and might be beneficial. He also believed, crucially, that the danger posed by released I-131 patients was exclusively from external dose. He dismissed internal dose – from ingestion, inhalation, and skin contact with I-131 – as insignificant.

Only a decade earlier, in a 1986 rulemaking, the NRC had correctly declared that I-131 presented hazards both from external and internal dose. Now, in 1997, it decided that internal

dose did not matter, as it enacted what may be the most drastic deregulation ever by a federal agency created to protect public health and safety. Whereas previously, release had been based on the activity level in the patient, in order to protect loved ones and others from both external and internal dose, the new rule was based on the likely external radiation dose to others.

The effect has been to make the United States, formerly a leader in the world radiation protection community, into an extreme outlier. The United States now has radiation protections far inferior to those of Bangladesh, South Africa, the Philippines, Indonesia, and many other nations. In those countries, no one leaves the hospital with more than 15 millicuries of I-131 in his or her system. In Europe, the limit is even lower than that. In the U.S., by contrast, people are being sent home to their families every day with up to 200 millicuries of I-131 in their systems, and sometimes even more.

These patients also have to **get** home. That often means traveling by public transportation. According to an NRC staff analysis published last year (SECY-18-0015, Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy, Jan. 29, 2018), "all exposure scenarios indicate that transportation scenarios pose a radiation concern for members of the public." (Attachment 1, at p. 6.) It found that a patient with just 100 millicuries of I-131 in his or her system can deliver a radiation dose of 100 millirems (the most that a member of the public should receive from a licensed activity in a year, according to the National Council on Radiation Protection and the International Commission) to a nearby person in as little as 42 minutes. And yet the NRC staff concluded, with one courageous staff member listed as non-concurring in the paper, that no rule change is needed.

Sadly, no one who reviews the history of this issue objectively can avoid the conclusion that regulatory authorities in other countries put a higher priority on protecting children from cancer and other radiation-caused illnesses than do those in the United States. To the extent that the NRC tells itself that America's children are just as well protected by the current rule as children in other countries, it is kidding itself. The thyroid cancer patient community certainly knows better, and if ever the NRC Commissioners would schedule a public meeting on the subject of patient release, they could hear from some patients and doctors directly.

The NRC staff deserves credit for some modest steps it has taken over the years to try to rectify, to some extent, the harm done in 1997. Thus for example, when the staff's attention was drawn to the fact that the International Commission on Radiation Protection (ICRP) had issued a report on the risk posed to others by radioactive patients,[1] including the special risk to

[1] ICRP Publication 94: Release of patients after therapy with unsealed radionuclides. International Commission on Radiological Protection (2005). The abstract, which explains that the ICRP is recommending a tightening of controls on exposures to young children and infants, begins as follows: "After some therapeutic nuclear medicine procedures with unsealed radionuclides, precautions may be needed to limit doses to other

children from contamination, such as that transmitted by a parent's kiss, the NRC put out a Regulatory Information Summary (RIS) encouraging doctors to "consider" hospitalizing patients with young children at home. This was non-binding, and though it changed nothing as a practical matter, it at least acknowledged the problem, and was frank in stating that the 1997 rule had paid insufficient attention to the risk, especially to children, from internal contamination.

A few years later, another RIS addressed the problem of radioactive patients going to hotels, saying that this practice was "strongly discouraged."Again, this was non-binding, and with little or no practical effect, but at least it recognized the impropriety of discharging patients to hotels, where a pregnant or nursing mother may unwittingly absorb I-131 while cleaning the room and bathroom.

This does not mean that the NRC staff could not and should not have gone further than it has. The fact that the rule was premised on a fundamental scientific error should have led the NRC to advocate a rulemaking long ago to correct this error. After more than 20 years in which guidance to licensees has failed to solve the problems with the current rule, the staff continues to put its faith in more and better guidance, rather than a rule change, when only a rule change, imposing mandatory and enforceable requirements, can achieve any meaningful reform. If non-binding admonitions were the answer, they would have worked by now.

The draft report of the Advisory Committee on the Uses of Medical Isotopes subcommittee is problematic in several respects. The ACMUI has for years been a vigorous proponent of the view that no change is needed in the current rule. Consistent with that approach, it has consistently downplayed the risks of internal exposure, the special risks to children, and the undesirability of sending radioactive patients to hotels. (All of these, it will be noted, are areas in which the NRC staff has taken positive, if limited, steps.) The essence of the problem can be seen on the last page of the ACMUI subcommittee's report, under "Other Recommendations." The first one reads as follows: "In 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 (Ref. 1)." The "Ref. 1" referred to is ICRP 94,

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people, but this is rarely the case after diagnostic procedures. Iodine-131 results in the largest dose to medical staff, the public, caregivers, and relatives. Other radionuclides used in therapy are usually simple beta emitters (e.g. phosphorus-32, strontium-89, and yttrium-90) that pose much less risk. Dose limits apply to exposure of the public and medical staff from patients. Previously, the ICRP has recommended that a source-related dose constraint for optimisation of a few mSv/episode applies to relatives, visitors, and caregivers at home, rather than a dose limit. The present report recommends that young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public (i.e. be subject to the public dose limit). **The modes of exposure to other people are: external exposure; internal exposure due to contamination; and environmental pathways. Dose to adults from patients is mainly due to external exposure. Contamination of infants and children with saliva from a patient could result in significant doses to the child's thyroid. It is important to avoid contamination of children and pregnant women."** [Emphasis added.]

quoted above.

Now let us compare that with the way that the American Thyroid Association characterized the views of the ICRP, in comments to the NRC last year:

> The International Commission on Radiological Protection (ICRP) has estimated the risk for all cancers in children is 0.1-0.2% from an effective I-131 dose of 1 mSv [1 millisievert, or 100 millirems]. **Risks to children include those from external radiation exposures as well as potential ingestion of contamination from excreted or secreted I-131 from treated patients.** The ATA currently recommends that "having a treated parent staying in the home with children is often problematic due to children's needs and desires to be near the treated parent. **Special arrangements should be made for children to stay with relatives or friends; alternatively, the treated parent may stay with relatives or friends where children and pregnant women are absent." In circumstances where this is not possible, inpatient isolation is an appropriate alternative.** Development of lower acuity isolation facilities would help reduce the cost of inpatient isolation. [Emphasis added.]

Why cannot the ACMUI state plainly what everyone knows to be the case: that children are far more radiosensitive to I-131 than adults, and that to children, internal exposure is a major hazard? Why does the NRC pay for stockpiles of the drug potassium iodide (KI) around nuclear power plants, if not because internal exposure to I-131 can cause cancer and other harm, especially in small children?

It is worth noting that whereas the ICRP and its domestic counterpart, the NCRP, recommend a maximum radiation dose of 100 millirems to members of the public, the NRC allows five times as much, 500 millirems, to everyone, including babies, infants, pregnant women, and babies in the womb. If the ICRP and the American Thyroid Association are correct, that means that a dose of 500 millirems to a child from I-131 creates a cancer risk of half a percent to one percent.

What benefit does the present rule confer that would compensate for a one percent cancer increase in children? Sadly, I know from experience that this is the kind of question that never gets answered, simply because there is no palatable answer. It is easier to pass over it in silence.

Kissing. It is noteworthy that neither the draft Regulatory Guide nor the ACMUI comments say anything about the risks presented when a radioactive patient kisses a child, although that was a major point made in ICRP 94. Nor does either one make the point that if a

radioactive patient is being transported after treatment, there should be no children in the car.

Hotels. On page 11 of the ACMUI comments, the following appears: "Pg 13, Section 2.3.1, i: Add 'hotel' to the list of examples of post treatment lodging the patient may use." This is troubling, in part because the word "may" has two distinct meanings. In this context, it could mean either: "It is possible that a patient will go to a hotel," or "Patients are permitted to go to hotels." Unless the NRC has changed its mind, and no longer thinks that it is "strongly discouraged" for patients to go to hotels, this ambiguous comment should not be accepted. On the contrary, the Regulatory Guide should reiterate the admonition made in the RIS.

Additional Points.

One of the issues most stressed by commenters was the need for licensees to communicate guidance to patients in a timely and comprehensible way. To do so properly would require a rule change. The NRC staff rejected this, regrettably. The discussion in the draft Regulatory Guide, includes the following, at Section 2.3.4: "Prior to release of the patient, the patient should acknowledge receipt of instructions and the licensee should acknowledge the patient understands the instructions as communicated. These acknowledgments **could** be obtained by using a form signed by both parties."[Emphasis added.] I stress the word "could" just to make the point that the guidance here is so feeble. The NRC will not even go so far as to say, in guidance that it stresses is non-binding, that this is something that licensees **should** do, unless there are issues, such as illiteracy, that stand in the way.

Under 10 CFR 35.75, if a licensee cannot find that a patient's exposure of others will be under 500 millirems, it cannot release the patient – no ifs, ands, or buts. The draft Regulatory Guide makes this point, under Section 2.3.2., "Patient Precautions," but because the entire Guide is declared to be non-binding (e.g., "compliance with RGs is not required," at page 2), the reader may not realize that this is a requirement of the regulations, and thus has the force of law. Clarification may be helpful.

I appreciate the opportunity to submit these comments.

Respectfully,

Peter Crane
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