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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING ON PATIENT RELEASE

PROGRAM REGULATORY ISSUES

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TUESDAY,

MAY 23, 2017

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ROCKVILLE, MARYLAND

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The Meeting convened in Room T-2B3 at the Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, at 1:00 p.m., Donna-Beth Howe presiding.

PRESENT:

DONNA-BETH HOWE

ROBERT LEE GLADNEY

DANIEL MUSSATTI

C O N T E N T S

P R O C E E D I N G S

(1:01 p.m.)

OPERATOR: Welcome, and thank you for standing by. At this time, participants will be in a listen-only mode until the question and answer portion.

If, at that time, you would like to ask a question, press Star 1. With that, I'd like to turn the call over to your host today, to Ms. Donna-Beth Howe. Ma'am, you may begin.

DR. HOWE: Thank you. I'm going to pass it over to my facilitator.

MR. MUSSATTI: Good afternoon. My name is Daniel Mussatti, from the NRC, and I'd like to welcome you and thank you for participating in this meeting to discuss potential regulatory changes to the NRC's Patient Release Regulations under 10 CFR, Part 35.75.

MR. GLADNEY: And my name is Lee Gladney, also from the NRC. We'll be serving as your facilitators for today's meeting. Our role is to help ensure that today's meeting is informative, productive and on time.

Before we get started, I'd like to take a few minutes to go over some logistics. First and

foremost, the NRC is a safety-based organization, so let's begin with some basic safety concerns.

If we have to evacuate for any reason, please exit calmly through the doors you used to come in here and follow the instructions from the security officers at the door. When we get outside, please stay together so we can make sure we all get out safely.

For personal issues, leave the room through this door and go across the elevator lobby. The ladies' room is through the door to the right, and the men's is to the left.

With regards to getting around in the building, all visitors are allowed unescorted access on the main lobby level. This will allow you to reach the cafeterias, the coffee counter, ATM and NRC's general store.

However, we are on the second floor which means you have to have an NRC escort, even to use the restroom or go back to the lobby. So please find an NRC person to accompany you if you need to leave this room during the meeting. We are happy to accommodate you.

MR. MUSSATTI: This meeting is going to be webcast. Although the webcast includes audio, we

strongly urge you to mute the webcast of sound and listen through the operator-controlled telephone bridge line.

This meeting I also on webinar so that you can type questions to the NRC at any time if you want to have your comment heard. For those of us here in the room, we ask that you turn off or mute anything that rings, buzzes, beeps, alarms or talks back to you in any way.

And for the folks on the phone, please put your phone on mute unless you're speaking. Hopefully everyone is this room is signed in and received a copy of the meeting materials and a feedback form.

If you haven't signed in, the sign-in sheets are at the table near the podium. For those of you on the phone who haven't signed in, please be sure to contact Donna-Beth Howe to ensure that we have your contact information.

Donna-Beth is a senior health physicist with the NRC's Medical Radiation Safety team and is in charge of this meeting. Her contact information is on the meeting announcement.

This is a Category 3 meeting to discuss potential regulatory changes to 10CFR 35.75 which

deals with the regulations related to releasing patients who have been medically administered unsealed by-product material or implants.

A Category 3 meeting provides the NRC with an opportunity to work directly with the public to ensure key issues and concerns are understood and considered in an NRC rulemaking.

The majority of today's meeting will be devoted to public participation --

DR. HOWE: This is a Category 1 meeting.

MR. MUSSATTI: Category 1?

DR. HOWE: Yes.

MR. MUSSATTI: Okay.

DR. HOWE: It is not rulemaking.

MR. MUSSATTI: It is not rulemaking?

DR. HOWE: It is pre.

MR MUSSATTI: This is pre-rulemaking. I stand corrected. It's a Category 1 meeting. Everything else I said still holds. It's to provide us with an opportunity to work with the public to ensure key issues are addressed.

And this is a town hall style meeting with feedback. And the feedback the NRC receives today is not considered to be formal public comments. The NRC invites participants to submit formal written

comments regarding these potential regulatory changes, and the date for that is also in the announcement. Go ahead.

MR. GLADNEY: The meeting for today includes a brief introduction by Donna-Beth Howe followed by a series of six questions for which the staff seeks input and insight. We have dedicated four hours for this meeting, so we plan on keeping to a tight schedule with a half-hour for each question with a short five-minute break at 2:30.

And for the six-question sessions, we will open an hour of free discussion on all six of the questions with a 5 o'clock adjournment.

Because of the number of questions that we need to ask, we ask that any NRC staff members in attendance limit their comments during this meeting as much as possible to facilitate discussion by the public.

For members of the public, we ask that any statements made by on topic and limited to no more than three minutes so everyone will have an opportunity to participate. Anyone participating by phone has to make their comments through the teleconference operator.

At this time, I would like to ask the

operator to explain how these phone comments are done. Melissa?

OPERATOR: Yes, sir. At times, if you would like to ask a question on the phone, please remember to press Star 1 to be queue up to ask your questions.

If you want to withdraw your question it's Star 2. So for questions, you press Star 1. To withdraw your question, it's Star 2.

MR. GLADNEY: Okay, thank you, Melissa. For those of you on the phone, we will take your call at your earliest opportunity, so please be patient. And, if at any time, you have a problem hearing us on the phone, please let the operator know right away so we can work to resolve the problem.

Are there any questions about the agenda or the comment process?

MR. MUSSATTI: Okay, this meeting is being recorded. So to ensure we get a good recording and a transcription of our discussions, please use the microphones and speak clearly.

For the record, we only need you to give your first name. That's all the information that's necessary for us to be able to handle this meeting.

For members of the audience, please

refrain from side conversations. We have a podium microphone at the center post here in the room. So when you want to talk, just queue up and we will get to you as soon as we possibly can.

Also, participants are allowed to use recording devices during this meeting. Although it is not required, it would be polite to make other people aware of your recording them. So at this time, I'd like to ask, does anyone in here plan on recording any or part of this meeting?

Okay, I think we're fine.

MR. GLADNEY: Does anyone on the line plan on recording this meeting? Okay.

MR. MUSSATTI: Okay. Finally, we're looking to improve our meeting, and your feedback to us is important. And the end of the meeting, please complete the feedback forms and return them to us. You can find copies on the podium by the center post here in the room.

And for those of you her in the room, you can contact Donna-Beth Howe at 301-415-7848, and she can get you a copy of the feedback form. Or you can go to the R ADAMS website and find the form at Accession Number ML011160173. Or you can go to our website, www.nrc.gov and type NRC Form 659 in the

search window in the upper right-hand of the page and it'll jump you right to it.

The form folds into its own postage-paid mailer for you, so it won't cost you a thing to send it back to us. If we don't have any questions, I'd like to turn the meeting over to Donna.

DR. HOWE: Thank you, Daniel. Thank you, Daniel. This our Patient Release program public meeting. This is the second public meeting, and the second and last public meeting. And our agenda is as indicated earlier. We will have 30 minute -- we have six questions to go over. We have 30 minutes, roughly, for each question.

At the end of -- at 4 o'clock, we will open it up so that people can talk about any of the above questions, and then we'll wrap up. If we don't have a lot of discussion in one of these 30-minute sessions, we may elect to go back and have people provide comments on earlier questions. But we will not go ahead, and we will try to get to each question at the allotted time.

Just to give you an introduction of why we're here today, on April 28th, 2014, we got a Staff Requirements memorandum from our commission. And, you don't need to know what the COM numbers

are -- it's that requirement memorandum.

And the topic of this was the background and proposed direction to the NRC staff to verify assumptions made concerning patient release guidance. This staff requirements memorandum had an objective to get input from a wide spectrum of stakeholders, the public patients' patient groups, physicians, professional societies, licensees, our Advisory Committee on the Medical Uses of Isotopes and Agreement States.

We published a Federal Register Notice in order to get as much public comment as we could, and we're having public meetings. We actually had two parts to this staff requirements memorandum.

The first part was the Federal Register Notice that we published in November of 2016 with a November to February public comment period where we collected information on what patients believed to help them understand the I-131 treatment procedures. We wanted physician and licensee best practices when making informed decisions on releasing I-131 patients.

We wanted instructions that could be provided to patients on how to reduce radiation doses to others. And we were also looking for brochures.

This public comment period is over. We have collected that information, and now we are moving into Part 2.

In Part 2 we published a Federal Register Notice on April 11th of this year. And in this one, we're going to explore with the public, licensees and state partners whether the Agency should change 10 CFR Part 35.75, which is the patient release part of the regulation, for specific reasons.

We published six questions in the Federal Register Notice. And we are getting public comments provided originally during the 60-day period, but we've extended that period for another 15 days. So the period ends on June 27th, 2017. And your comment must be provided either electronically at regulations.gov or in writing to the NRC.

And later on, I'll have -- where you have to submit your comments is included in the Federal Register Notice, and I'll also have a slide that reminds you where to submit that information.

What are we going to do with these public comments? We're going to use the public comments to form the basis for a SECY paper, which is the way the staff responds to the Commission on whether we should pursue changes to 10 CFR 35.75. So that's the basic

overview of why we're here today.

And we're going to go directly into Question A. Question A is: Should NRC require an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility -- for example, a medical facility or a facility under the licensee's control -- until the standard for release is met?

We're not only asking the question. We want people to explain why they believe the way they believe. So if you believe that we should go to an activity-based patient release threshold, then explain why, and provide a potential activity-based criteria.

If you do not believe we should go to an activity-based patient release criteria, then explain why the regulations -- and right now, our regulations are dose-based criteria -- should remain as is.

In either case, we ask you to describe the resulting health and safety benefits or lack of benefits to the individual being released and to individual members of the public.

So keep in mind, as you're giving your comments over the phone or here in person, we would like you to address the question, why you believe the

way you believe and to describe the resulting health and safety benefits or lack of benefits. And this is the format we'll be using for the rest of the meeting.

At this point, I'd like to open it up to telephone comments. So, operator?

OPERATOR: Ma'am, again, as a reminder, to ask a question or make a comment over the phone, please press Star 1. One moment. And, ma'am, at this time I'm showing no questions or comments.

DR. HOWE: How many do we have on the phone at this time?

OPERATOR: Currently we have 45.

DR. HOWE: Forty-five. Do we have any comments? Okay, I'd like to open it up to the people that are on the webinar. It appears that we have --

MR. MUSSATTI: We have 5 people, but no questions.

DR. HOWE: Oh, we have no questions from the webinar either. Then we'll open it up to the room. And we don't have too many members of the public in the room, but do we have comments from members of the public? Push the button.

PETER: Yes, please. Oh, sorry. Yes, please. My name is Peter Crane. I'm an NRC retiree

with 23 years of service here. I'm also a 44-year veteran of thyroid cancer.

When I was treated long ago with radioactive iodine, there was a 30-millicurie activity limit. In those days, 30-millicuries was considered high by the international community. When the International Basic Safety Standards were issued in 1996, they indicated that 30 was the top, but that many countries thought that the lower standard was desirable for public health purposes.

I believe that an activity standard with flexibility is desirable. Now when the NRC put out petitions for public comment in the 90s, Dr. Malmud, Leon Malmud, then the head of the Society for Nuclear Medicine and later the head of the Advisory Committee on the Medical Uses of Isotopes, suggested that what the Commission should do was simply incorporate NCRP 37, from 1970, into the regulations.

NCRP 37 indicated that the default was in-patient treatment but there ought to -- and, in fact, its authors made clear that they thought that 30 millicuries was too high and that something more like 8 millicuries was desirable. There is correspondence with the authors on that subject.

But they thought that there should be

provisions in unusual circumstances for release of patients with a calculation based on the likely dose to others. That's where the dose-based criteria came from. And the rationale for the Commission's rule change in 1997 was to use the approach of NCRP 37.

But NCRP 37 did say that there should be an absolute maximum of 80 millicuries for release. And they wanted public health officials notified and all kinds of radiation warnings. And I think that what we should have is an activity -- now there are problems with the activity standard.

So that's a point that's frequently made that, for one thing, iodine-131 is a much more serious issue than a lot of other isotopes. And all that I'm saying about an activity standard is related to I-131 solely. I don't have a problem with higher standards for -- higher limits for other isotopes.

Let's see. So I think there should be flexibility in extenuating circumstances. Now one of the points that's often made in contradiction to the 30-millicurie limit for I-131 is that if you have an athyrotic patient, which is to say the thyroid has been removed for -- and this is a follow-up treatment for cancer -- there isn't much tissue there to soak up the iodine.

So it tends to get flushed through the system, through the kidneys and the bladder and out and down the toilet pretty fast. Whereas if you have a hyperthyroid patient with Graves' disease, with an intact thyroid, the person's going to soak up that -- there's much more tissue, much more iodine that's going to be retained.

So I think what one needs to use sensitivity in developing it. I'm not predicting -- I'm not offering a hard and fast solution today, but I do think we need a standard that balances public health needs against, you know, the practicalities of medicine, and I think that can be achieved. Thank you.

DR. HOWE: And, Peter, can you give us what you think the resulting health and safety benefits would be?

PETER: There is significant -- I'm sorry not to have touched that -- there is significant such safety and health benefits. There are people being sent home to their families all the time with high levels of radioactive iodine in their systems, in part, because there is great disparity among institutions and the kind of guidance that is given out.

And people are going home to situations, sometimes with no guidance at all. And their families are getting exposed, and I think we have an extremely serious problem with the discharge of patients to hotels. Because we don't know what kind of doses they may be giving. We don't know how many radioactively contaminated hotel rooms a hotel worker may clean in a year.

Jim Luehman, of the NRC staff made that point as long ago as 2010, that it kind of busts the underlying premise that no member of the public is likely to get exposed to a radioactive patient more than once a year.

DR. HOWE: Thank you. Do I have any comments from those on the phone?

MR. MUSSATTI: Sorry, mute.

DR. HOWE: Do I have any comments from those on the phone?

OPERATOR: Yes, ma'am. We do. We do have someone. Linda, your line is open.

LINDA: Yes, I just wanted to make a comment that --

DR. HOWE: Could you please speak up?

LINDA: Sure. Can you hear me now?

DR. HOWE: Yes, I can.

LINDA: Okay. That I think that going to a dose-based would be a step backwards because I think the rationale for doing it based on a dose rate or the 500 millirem is based on risk-informed information as opposed to just an arbitrary number.

The problems that can arise from like going backwards relative to healthcare is that, I believe that we would be going down the path of creating a situation where there are patients that would possibly not be able to be treated if we were to change is back to the old way because of the fact that either insurance would not be covering the hospitalization, which would put a tremendous financial burden on the patients.

Or, depending on what the regulatory limit was for release, that maybe in some situations families would not have the wherewithal to be able to accommodate a person being away from their home for that long a period of time.

And so I think that this is kind of going at it backwards, basically backwards, though I do understand that maybe the earlier document NCRP Document 37 which was published in 1970 with the information available at that time may have advised certain things.

But then NCRP Report 155, which has come out more recently, much more recently, clearly has the information available there for the calculation of doses that is much more up to date. And so I think that that would be the document I would look to as opposed to the NCRP 37 document that is now over 40 years old.

DR. HOWE: Can you identify yourself by first name?

LINDA: Linda.

DR. HOWE: Linda?

LINDA: Yes.

DR. HOWE: Thank you very much. So you would like to stay with the dose-based activity, and you indicate that you think the health and safety benefits would be from the possibility of patients having to be held longer or not being given treatment.

Keep in mind that part of our patient release is that you can be released if you're given instructions that could keep whatever the patient release criteria is done to the level of release.

LINDA: Yes. Right. I understand. But even now, based on NUREG-1556, the instructions are required for anybody who's going to be released based on the calculated methodology as opposed to just the

absolute less than 33 millicuries even though, from 7 to 33, these instructions are also required, maybe not documented as are required for over 33 millicuries or if you used the 500 millirem calculation method.

But, no, I understand that instructions are required. But I think that if we went back to, for example, saying, okay 30 millicuries or more must be hospitalized, I think that would be a backwards, especially in this day and age when hospitals are already at top census.

And, but the problem is that we have -- managed healthcare is becoming more and more of an issue in terms of putting -- CMS putting caps on certain things. And the burdens of the medical system now are already very onerous.

And now, by creating hospitalization, if this were to go back to an earlier time, requiring hospitalization for thousands of patients a year, which, for no reason, for no medical reason other than to keep them isolated, would seem like a step in the wrong direction in terms of overall healthcare in the United States.

DR. HOWE: Thank you, Linda. And do I have any other commenters on the phone?

OPERATOR: Yes, ma'am, you do. The next

person is Deirdre. Your line is open.

DEIRDRE: Hello. Can you hear me?

DR. HOWE: Yes, I can.

DEIRDRE: Okay, I also -- I agree with the previous speaker that we should never go back to a strictly dose activity-based release criteria. That is going the wrong direction.

There is no evidence that the current system has put anybody at risk. And the cost to these families would be exorbitant if we go back to having a dose-based release criteria.

The way it works now, we can do a calculation. We have our choice. We can release based on the activity. We can release based on a dose rate. Or we can release on a personalized calculation that takes into account the patient's home situation.

And to have to go back to a strictly dose-based or activity-based release criteria is a step in the wrong direction and will not increase the safety of the public because there's no evidence that the safety is at risk at this point.

The literature is full of studies of the doses to the family of the patient when the patient is released. And it consistently shows relatively

low doses, the lower level at which there's any evidence for harm.

So I urge the NRC to continue with the current system that give flexibility which will benefit patients in the long run and keep the patients' families and co-workers and others safe.

DR. HOWE: Thank you, Deirdre. Do I have any other comments on the phone?

OPERATOR: Yes, ma'am. We have one more from Mack. Your line is open.

MACK: Yes, I'm a radiation safety officer at a medical institution. Have been in that capacity for over 35 years. I'm a board-certified health physicist as well.

And I'm going to kind of -- I've already submitted written comments so I'm just going to kind of base these comments on that. And realistically -- I agree with the past two commenters. We don't need to change anything.

And, in fact, as somebody pointed out, the NUREG-1556 Volume 9 actually does provide for licensees that want to use a dosage-based system. It's already there. It gives tabular values for activities that really coincide with the calculational methods that are also explained in that

NUREG.

So, you know, in essence, if a licensee wants to use a dosage-based value, it's already there. And, like the others have said, there are numerous -- I have looked at a number of publications trying to find, you know, significant hazards associated with releasing these patients.

And, granted, you know, the providing appropriate instructions which is -- and those types of things we can address later because there are questions about that. But, yes, that's an important aspect of that.

And so, anyway, I agree with others. What we have now works fine. And there's going to be a problem, again, with payment, insurance companies not wanting to pay. Lots of other difficulties. And again, tell me where -- you know, I need documented evidence that these patients are hazards to somebody. There's nothing out there that I found that really promotes that. I mean, granted, the linear no-threshold depends on how much stock you put in LNT, there's an awful lot of dispute about that at this point in time. So, you know, I believe that what we have in place is fine.

DR. HOWE: Thank you for your comment.

Could you give us your first name again?

MACK: Mack, M-A-C-K, like track.

DR. HOWE: M-A-C-K? Okay, thank you. At this point, we have come to the end of the time for Question A and we'll move on to Question B.

If there are those on the line or those in the webinar that would like to talk about Question A, again, I remind you that we're going to have an open hour from 4 o'clock to 5 o'clock. And hopefully you'll be able to join us at that point to continue the discussion.

So moving to Question B: Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.7(a) for releasing individuals?

And the dose limit in 35.75(a) is 500 millirem. And we don't state whether it is per event or per year. For example -- and so, one, for example, should the regulations explicitly state the criteria is a per year limit? If not, is there a different criterion that the NRC should consider?

In either case, describe the resulting health and safety benefits or lack of benefits to the individual being released and to the individual members of the public as a result of the proposed

clarification. Do I have anybody on the webinar with a question?

MR. MUSSATTI: No.

DR. HOWE: No? No questions on the webinar. I'd like to open it up to the phone line first. Do I have any questions or comments -- not questions, but any comments from those on the phone?

OPERATOR: And, once again, as a reminder, to make a comment please press Star 1. One moment, ma'am. I believe we do have some coming in right now. One moment. I believe the first name was Ilham. Your line is open.

ILHAM: It's Ilham.

DR. HOWE: Could you spell your first name?

ILHAM: I-L-H-A-M.

MR. MUSSATTI: I-L-H.

DR. HOWE: Okay, thank you. Go ahead.

ILHAM: Yes, in fact, I believe that this, that the time frame should be is quantified because when we were trying to read the regulation, we didn't know what the dose referred to, for how long. Is it within a year that they shouldn't exceed this dose or within -- all their life? So I think it will be prudent to add this clarification.

DR. HOWE: And what are you suggesting for a clarification?

ILHAM: Just to determine the time frame that this regulation is concerned with so people don't have to ask the question.

DR. HOWE: Okay. But I guess, for Question B, we said that if you think the regulations need to be explicit, could you provide us with what you think that criteria should be.

ILHAM: I believe it should be within a year.

DR. HOWE: Within a year? Okay, thank you very much. And can you describe the resulting health and safety benefits or lack of benefits to members of the public or the person being released?

ILHAM: I am coming from point of view of being clear rather than health benefits. It's to clarify the regulation rather than the health aspect of it.

DR. HOWE: Okay, thank you very much. Do I have another comment from the phone?

OPERATOR: Yes, ma'am. We have Deirdre again. Your line is open.

DEIRDRE: Hi. I think if you're going to clarify the regulation, it needs to be on a per event

basis because the difficulty in doing it on an annual basis with patient who might receive different kinds of scans or implants at different facilities during the course of a year would be a logistical nightmare.

I think it would be very difficult to show compliance with an annual dose to patient family members or the public. I think it needs to be clarified as being on a per event basis.

DR. HOWE: Can you describe the resulting health and safety benefits or lack of benefits?

DEIRDRE: Well, the benefit of making it on per release basis, clarifying that, is that it'll make it clearer to everyone involved. The danger of making it a per year basis is that it will be a lot of extra paperwork.

It'll possibly result in patients' care being delayed because they will have to wait till the next year to get the next treatment when they would benefit from a treatment again this year. I just don't -- I think it will be expensive to comply with a regulation that's on an annual basis.

DR. HOWE: And I'd like to remind you that part of our patient release requirements are that you can provide instructions to keep doses as low --

DEIRDRE: Right.

DR. HOWE: -- as reasonably achievable. So --

DEIRDRE: And we do that.

DR. HOWE: And so I don't think you're necessarily preventing -- you may not be preventing a treatment. You might have to have different instructions. Have you considered that?

DEIRDRE: I have, but I'm looking at the possibility, how do we prove, even with the instructions, what the patient's family got before if we need to treat again? How do we keep track of all of this? Do we have to keep track of all the diagnostic nuclear medicines, scans and what the doses to the family members would be?

Because if it's on an annual basis, wouldn't it include all of the radiation from that patient to their family members or others? And how do we -- how, on earth, are we going to do that? I just want you to consider how, on earth, you're going to make this an annual limit and have compliance.

DR. HOWE: Okay, thank you for your comment. Do I have any other commenters on the phone?

OPERATOR: Yes, ma'am. We have Mack on the line. Your line is open, sir.

MACK: Yes, this is, again, from my written comments. But the idea of it should be 500 millirem per administration for the reasons that the previous -- partially for the reasons the previous commenter mentioned.

But the other very -- I mean, I, again, look at this on a risk basis. And, you know, if somebody gets, let's say, 500 millirem or 200 millirem, take your pick, or 100. But if they get a hundred millirem or let's use 500 millirem in a 365-day period and then, on Day 366 they get another 500 millirem.

If we specify it on a yearly basis, okay, what is the -- you know, there's no really significant difference in the risk or the assumed risk with that level of exposure. So whether it's 500 millirem or let's say a patient gets treated twice in a single-year period split by 6 or 8 months versus split by 12 or 13 months, the risk is really -- there's no difference in that risk.

So, you know, that's one thing. And again, this goes back to this assumption that there is risk at this level. The Health Physics Society, in a position statement, has basically said that we're, you know, demonstrable risks of less than a

hundred millisieverts, which is basically much higher than we're talking about here, are -- there's no documented evidence of risk to begin with.

So we're talking about levels of dose that are way below that. So I guess I'm kind of approaching this more from the risk standpoint than the benefit. If there's no risk, then the benefit obviously outweighs that.

The other thing that comes to mind is I did talk to some of our clinicians, our physicians, and asked them, you know, how often they do multiple administrations of radio-pharmaceuticals within a year. And it's pretty rare. So I think that's the other thing, that it's a rare occurrence to begin with.

So, again, this all is just based upon risks that are really, really very small. So again, I would support, you know, 500 millirem, I think, is fine for members of the public, family members. But per administration should be the appropriate time frame. But it does, there's no doubt, it does need to be clarified because it is somewhat ambiguous as it stands now.

DR. HOWE: Thank you for your comment. Do I have any other commenters on the phone?

OPERATOR: No, ma'am, I'm showing nothing further.

DR. HOWE: Okay. Do I have a comment from the room?

PETER: Yes, please. This Peter Crane again. An earlier comment -- it may have been Deirdre who cited NCRP Report Number 155, management of radionuclide therapy patients as a more recent and preferable source to go by.

This is what they say at Page 145. "The foregoing limits are annual totals and, therefore, do not apply to individual treatments but collectively to all treatments the patients may receive in a given year."

That's the position that both the NCRP and the ICRP have taken. And what's more, NCRP 155, like the, as the ICRP and NCRP also believe, think that 500 millirems is five times too high, that it ought to be a hundred millirems for family members other than a caregiver and members of the public.

So I'm okay with going by NCRP 155. But if we take it as a whole, I think it supports strongly that it's a per -- that it's an annual limit, not per event.

I think there was confusion only because,

at the outset, the general thinking seemed to be that it didn't make a lot of difference how you expressed it because most people weren't going to get more than one treatment in a year.

In reality, I, myself, have had 150 millicuries one spring and 150 millicuries that fall. That may be a rarity, but it does happen. And, again, my concern is solely with I-131. And it seems to me that it's not as though people go shopping around from one facility to another.

If you're being treated with I-131, it's in your chart. Nobody is going to have difficulty knowing how much you have got and what kind of calculations of dose to your family remain. And so I'm in full agreement with NCRP 155 on that.

DR. HOWE: And, Peter, can you address the resulting health and safety benefits or lack of benefits to individuals being released and individual members of the public?

PETER: Sure. I realize that the Health Physics Society has much -- greatly different ideas about what is hazardous and what isn't. But the National Academy of Science, these international organizations and national organizations, take a conservative view.

And this view was dictated not out of some caprice but because there was a directive from President Ronald Reagan in early 1987, January '87, that expressed concern about the effect of radiation on unborn children, in particular, and small children, and directed all federal agencies to reduce from 500 to 100 the amount, the acceptable dose to individuals.

So I think, especially given that our current standards allow children, including the unborn, the nursing infant and so on, to receive 500 which is too much, we ought to be doing things that make sure they aren't getting 500 times two.

DR. HOWE: Thank you, Peter. We still have time. Do I have any other commenters on the telephone?

OPERATOR: I'm showing nothing further at this time.

MR. GLADNEY: Do we have any commenters on the webinar? No?

DR. HOWE: We still have about 15 minutes left in this session. So I think that's sufficient time that I'll open it back up to Question A and see if anybody has additional comments that they want to make on Question A.

So, Operator, do you have anybody that would like to make additional comments on Question A?

OPERATOR: At this time, if you'd like to make a question, please press Star 1.

DR. HOWE: And I have Question A up on the screen now. Be it a reminder, that's the activity-based patient release threshold or whether we should keep it as it is with the dose-based.

OPERATOR: Ma'am, I'm showing no questions over the phone.

DR. HOWE: Okay. By any chance, do we have any more comments on Question B from the phone? Okay, then, since we don't have any more questions from the public or comments from the public on either the telephone or the --

OPERATOR: Ma'am, I do apologize. Somebody just prompted up. One moment. I apologize. They did not record their first name. If you'd just press Star 1, your line is open. Please announce yourself by your first name only.

BRIAN: My name is Brian. Sorry, it muted on me for a second there. I just want to make a comment regarding this discussion, 100 versus 500 millirem.

I think most of us, when we look at

applying these dose limits, even on the per occurrence, we're really calculating the constraint dose to the highest-exposed individual. And usually that is a caregiver or somebody that is spending a significant amount of time around the patient.

What we do know is that even the dose to caregivers, in actuality, is much less than what is calculated, using, for example, Reg Guide 8.39 methodology. And we know that the dose to the public at large is much, much less.

There's a number of reasons for that. We don't have to get into all the technical reasons for that, but that's just the way it is, right. So I think because of the inherent, very overt over-conservatism, even in the dose estimation methodology, likely dose to your average typical member of the public, even sticking with something under the current system, per release, is really going to be much, much lower, okay.

And as Mack and some of my other colleagues have said, you know, these doses really are not at levels where we've seen actual risk. It's all fine and well to look at the risk estimations and the theoretical projections of ICRP and NCRP and these other bodies. And they're really charged with trying

to produce a systemic framework.

And we respect that and we acknowledge that. However, NRC and radiation protection professionals and scientists are charged also with ALARA, what is reasonable, okay. And we do need to make sure that we maintain enough flexibility, so looking at what is, indeed, reasonable when it comes to balancing risk of radiation exposure with other societal costs.

And so I would charge NRC to look very carefully at that and the downstream consequences that might happen for 100 millirem versus 500 millirem exposure limits to certain populations and also hand-in-hand at how we're calculating and determining those.

You know, any medical professional will tell you that medical records and information following a patient from provider to provider is sketchy. I think it's very overly optimistic to think that an annual dose limit, as commenters have said, would be able to be complied with. It's just not realistic for many patients.

There's no way to know. It's not a controlled environment that's monitored. Everything's based on projections and suppositions.

But all the research says that the actual doses are much lower, okay. So it is complicated, yes.

But this idea of trying to break out for certain populations, 100 versus 500, for example, is getting into sketchy territory, particularly when it comes to workability for certain types of patients and restriction times for families. So we do need to pay close attention to that.

DR. HOWE: Okay, thank you. Do I have comments from the room?

PETER: Yes, please. This is Peter Crane again. I'd like to respond. This is both 1 and 2, acceptable to the --

DR. HOWE: A and B?

PETER: A and B, sorry. I think the commenter who made the point about insurance and the effect on insurance was very much on the right track in that insurance is a dominant force in patient release.

Prior to 1997, if you were being treated with more than 30 millicuries, you had to be hospitalized, and it was very clear to your insurance company that they had to pay. After 1997, it was easy for insurance companies to say, well, it's no longer required, therefore, we don't intend to pay,

and if you tried to argue.

But certain findings have to be made. It's not the health of the patient which is often invoked by the insurance companies. It's the health of those around. It was easy to say, no, no, no. We have a blanket rule. We don't pay.

And doctors were a quick solve in this case because they had requirements from the NRC on the one hand saying you're supposed to make calculations. On the other, we had insurance companies saying, calculate all you like -- we're not paying.

I think if we had greater clarity about what was and wasn't absolutely required from the NRC, it would strengthen the hand of providers to say to the insurance company, I'm sorry, we've got no choice. This is a matter of requirement, not of whim, not of choice. You've got to pay.

And I think we would be doing the medical community a great favor because I know that there are -- I can give you many examples of providers who say, for example, well, I think it's better for you to do inpatient, but you're going to have to work it out with the insurer yourself.

And then when the person comes back and

says I talked to my insurance company, they'll pay, the doctor pumps his fist and says, yes. It's a terrible imposition on doctors to make them spend hours on the phone dealing with recalcitrant insurance companies. They should be using their resources to help patients and not getting the runaround from insurance companies. So I think there is a potential here to benefit the medical community as well as the patient community.

DR. HOWE: Thank you, Peter. Do I have any more comments from the phone on Question A or B?

OPERATOR: Ma'am, I'm showing no questions.

MR. GLADNEY: Do we have any questions on the webinar?

MR. MUSSATTI: No, sir

DR. HOWE: Okay then, I think we'll, since we have no more questions, no more comments on Question A or B, and we're just a little bit ahead, then we'll take a quick break and come back at 2 o'clock and move on to Question C. Thank you. And I'll put up Question C so that you have plenty of time to see the question.

(Whereupon, the above-entitled matter went off the record at 1:52 p.m. and resumed at 2:02

p.m.)

DR. HOWE: Now we're going to look at Question C, which is "Should the NRC continue to apply the same dose criteria of five millisieverts, or 0.5 rem, to all members of the general public, including family members, young children/pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?"

If so, explain why. If not, what criteria should NRC use for an individual, group, or groups? Specify the group, for example, family members, young children/pregnant women, caregivers, hotel workers, or others, for each criteria. In either case, describe the resulting health and safety benefits or lack of benefits to the individual being released and to individual members of the public.

I would like to open the Question C now to comments from the phone.

OPERATOR: Yes ma'am. And once again, for comments, please press star 1. We do have one. Richard, your line is open.

RICHARD: This is just a general comment to --

DR. HOWE: Richard, could you speak up, please?

RICHARD: Yes. This is a general comment to everyone else listening in that I believe the NRC ACMUI committee has dealt with and looked at a number of these issues, and they do have a report available on the NRC website that would be beneficial to any additional comments that they would like to submit in regards to these questions. Thank you.

DR. HOWE: Thank you, Richard. Do I have any other comments?

OPERATOR: Yes ma'am, we do. We have Mack. Your line is open.

MACK: Thanks. This takes a while because you've got a lot of people, a lot of different groups in this category.

First, talking about young children/pregnant women, the -- applying the same dose limit for all those listed I think really is appropriate based on the risk. With respect to -- to pregnant women/children, NCRP Commentary 9, Considerations Regarding Unintended Exposure of Embryo, Fetus, or Nursing Child, the following statement says -- from that says if the dose to embryo, fetus, or nursing child from an independent exposure is less than or equal to an effective dose of 50 millisieverts -- that is 5000 millirem -- there

is no harm from the deterministic effects, and the risk of stochastic effects is less than 1 percent.

So the NCRP kind of acknowledges that, you know, these are -- are based -- these are effects based upon much higher doses, and we're talking about, you know, 500 millirem, not 5000, so we're at 10 percent of what the NCRP says, you know, the risk is -- is made less than 1 percent. Likewise, according to the BEIR VII report, the normal incidence of cancer in the adult population is around 46 percent in males and 37 percent in females, so the -- the cancer risk from exposure as a conceptus or a young child is one-tenth of that value, and really it is statistically insignificant, even when you apply the extrapolated risk estimate. So for -- for that difference, I think that kind of -- that speaks to that.

With respect to members of the public, one of the things that -- that I do a lot in teaching is it talks -- in an EPA document published in 2005, it talks about the variations in radiation exposure in the United States, and it actually says the average background radiation dose to a member of the public in the U.S. is about 294 millirem. In that same publication, it says that the average annual dose equivalent to a Colorado resident is 700 millirem,

and this is per year, by the way. So that is a difference of 400 millirem, which is oddly interesting difference between 100 millirem and 500 millirem.

Pregnant women and children in Colorado are also exposed to that higher level, so -- and those numbers accumulate arithmetically over several years, so, you know, unless there's some paper published I am not aware of that shows that children born to women that live in Colorado, et cetera, are much higher incidence of cancers, leukemias, et cetera, you know, I am not convinced that there is, you know, any significance of the difference between 100 and 500 millirem. So anyway, I think that kind of addresses that. We -- we have to -- we have to use a little science in the -- in the decision-making process.

Now, going to the hotel rooms, that is an interesting issue. I have read about that a lot. A paper published in Medical Physics Volume 42 number 4, April 2015, a group looked at different geometries with patients in hotel rooms that would be seated back-to-back on an adjacent wall, or maybe head-to-head on an adjacent wall, you know, one patient -- the patient in one room, somebody else in the other. It is assuming a 200 millicurie dose in a patient.

For an eight hour period, somebody is sitting back-to-back in the adjacent room. Assuming no decay or biological elimination, the calculated dose equivalent would be about 7.4 millirem per hour, and if you take an eight-hour time period, you get 59 millirem.

If you take the head-to-head geometry, the dose rate is lower. It is only about 1.7 millirem per hour for a 200 millicurie patient, so that gives you 14 millirem in eight hours. Now, you know, both of those are well below 100 millirem, so I am hard-pressed to be a lot -- to be worried a lot about adjacent -- occupants of adjacent rooms. That is not going to happen more than once, so that is not an issue.

When we talk about hotel workers, you know, typically, whenever I have stayed in a hotel, I am usually not there when the hotel worker comes in there to clean the sheets or change the towels or do whatever they do, so they are not going to -- the patient is not going to present a significant external exposure to these hotel workers. I don't care if they deal with five of them a month. It is -- they are not going to run into that.

You talk -- now, of course, obviously, oh

yeah, but they are contaminating the sheets and the towels and this type of thing. You know, I -- I practiced -- I have practiced for so long, when we used to hospitalize all these patients, and, you know what, we did -- you know, we did not get skin exposures. We did not get internal contamination. We did thyroid monitoring on our own staff, and we dealt with every patient, by the way, and we didn't see contamination.

Now granted, maybe we were taking extraordinary lengths to protect ourselves, but most, you know, people, if you wash your hands, that is going to take care of, you know, contamination of any significant degree. Now, we have all seen concerns about people -- you know, the -- I have seen videos of hotel workers cleaning the toilet with a washrag and then cleaning out the coffee pot. Well, that is a bigger concern, but not with radioactivity. I am more worried about other reasons for that, so I don't drink the coffee.

But anyway, that deals with the hotel workers I think. It is a stretch to say there is any risk to them at all.

DR. HOWE: So Mack, could you -- could you concisely --

MACK: Yes. I am sorry. It's a long -- you asked for a lot of different groups.

So anyway, summary, dose limits should be based on science, not conjecture, not concern about, you know, risks that are not there, and, you know, so I think 100 millirem, 500 millirem, it can be -- either one is fine. I don't think we have to -- to worry that much about it.

DR. HOWE: Thank you, Mack. Do I have other commenters on the phone?

OPERATOR: No ma'am. I am showing nothing further.

DR. HOWE: Okay. I will move --

MR. GLADNEY: Oh, do we have any comments on the webinar?

PARTICIPANT: No.

MR. GLADNEY: Okay.

DR. HOWE: Now do I have comments in the room?

MR. CRANE: Yes please. This is again Peter Crane, NRC retiree.

In 1997, there was an article in Thyroid that made the point the overall hazard is a combination of quote "the external and internal radiation hazards." With respect to internal dose,

the article said saliva and urine are the primary sources of such contamination. That suggests to me that bathrooms are an issue, that hotel workers may be exposed.

The article, incidentally, is by Dr. Pat Zanzonico of the Advisory Committee on the Medical Uses of Isotopes, and I think it is quite right. We are talking about an awful lot of radiation. The ICRP 104 in draft made the point that a single patient may be giving off more radiation than a nuclear power plant emits in a year, and as we are going through some of these old reports, ICRP 94 in 2004 dealt specifically with the hazards that I-131 patients pose to their families.

The report stated, among other things, that a single kiss from a radioactive patient to a child could double the child's risk of later developing thyroid cancer. And in 2008, the NRC issued a notice that said -- to licensees, indicating that the risk to children from I-131 contamination was greater than the Agency had assumed in 1997, and that the Agency had mistakenly discounted the risk of contamination. And for that reason, it asked the -- asked doctors to consider hospitalizing patients with young children at home.

I don't -- I think we have to consider external dose as well as internal. It is -- it is an unfortunate thing that at the time that the 1997 rule was put in place, the NRC was under the misapprehension that external dose was the -- was the driver, and that internal dose could be neglected. It is -- it is not so. Sorry. I am looking for a quotation.

DR. HOWE: Peter, we don't necessarily --

MR. CRANE: Sorry.

DR. HOWE: -- need quotations.

MR. CRANE: Okay. Okay. At any rate, I think that it is the responsible thing to do to make some discriminations rather than have 5 millisieverts to everyone. I don't think that that necessarily means 100 millisieverts to everyone. I think, for example, a family member who is a caregiver, a family member who wants to waive the restrictions to say, hey, my kid is coming home, I want things to be normal for my kid, I am not going to run away, I think they ought to have that privilege. I think they ought to be able -- if a child is hospitalized, they ought to be able to sleep in the room across the hall and come sit in the doorway.

And -- and I am referring to somebody I know personally within the last month. You know, sit in the doorway and chat with a child of 13 and keep her spirits up and not have to worry about a limit. It ought to be waivable. But I think -- and in those cases, you have got a situation where the radiation conveys a benefit. I mean, it is a benefit to have a child who is cured. It is a benefit to you emotionally to know that you're doing what you can for your child.

If you're a hotel worker and you're cleaning out somebody's radioactive urine, radioactive saliva in the sink, you're not getting any benefit of it, and we do know that there is the -- the excellent notice from the New York City Department of Radiological Health in 2009, the I-131 that the hotel worker absorbs can go through the bloodstream into the developing fetus and into the milk and then get absorbed by the baby's thyroid, and we know that there is a particular period during pregnancy -- I think it is 8 to 23 weeks or something like that -- where the fetus is hypersensitive to radiation. I just think that we have to make appropriate allowances for that and not use a one-size-fits-all here. Thanks.

DR. HOWE: So Peter, what criteria would you -- it sounds like you broke the groups into family and caregivers who you would increase the limit there, and for young children/pregnant women, you would do what with the public limit?

MR. CRANE: I would say what -- what NCRP 155 says, which is 100 to all these groups, other than a family member who is a caregiver. Make it waivable with informed consent on the basis of a family member. And encourage ALARA below 100 millirem if you're dealing with small children/pregnant women.

DR. HOWE: Okay. Thank you, Peter. Do I have any more comments from the phone?

OPERATOR: I am showing no questions over the phone at this time, but again, as a reminder, to ask a question, press star 1.

PARTICIPANT: No questions on the webinar.

DR. HOWE: Okay. I checked on the webinar, and we have no questions on the webinar. So I -- so we have no questions on -- no comments on Question C from the phone, is that correct, Operator?

OPERATOR: That is correct, no questions.

DR. HOWE: How many people do we have on

the phone at this point?

OPERATOR: 51.

DR. HOWE: Okay. I am showing that we have a lot of time. Well, we have about 12 more minutes before we move to our next topic and break, so do I have anybody on the phone that would like to make a comment about Questions A, B, or C?

OPERATOR: Again, as a reminder, please press star 1.

DR. HOWE: Okay. Question -- let me go back. Do I have any -- so Operator, I have no commenters?

OPERATOR: No ma'am.

DR. HOWE: Okay.

MR. GLADNEY: I will just read the questions just to make sure that we have them again.

Question A is "Should the NRC require an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility, in other words, at a medical facility or facility under the licensee's control, until the standard for release is met?"

Question B was "Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) when releasing

individuals?"

And then Question C, "Should the NRC continue to apply the same dose criteria of five millisieverts, or 0.5 rem, to all members of the general public, including family members, young children/pregnant women, caregivers, hotel workers, and other members of the public while considering the release of patients?"

DR. HOWE: So Operator, do I have any comments?

(No audible response.)

DR. HOWE: Do I have any comments from the room?

(No audible response.)

DR. HOWE: Okay. At that point, let's take a little bit longer break, and we are scheduled to be back at 2:35, and so we will reconvene the meeting at 2:35, and we will start on Question D at that point, and I will put Question D up so that you can see it in advance. Or actually, I have a break, and on the break, you need to submit your comments in writing, either by mail or electronically through regulations.gov, and I have included the mail address for Cindy Bladey at the U.S. NRC on this slide so as we are taking our break you have plenty of opportunity

to copy that address down. The address is also in the Federal Register, as is the -- as is the regulations.gov address. So we will be back at 2:35. Thank you.

(Whereupon, the meeting went off the record at 2:20 p.m. and resumed at 2:38 p.m.)

MR. GLADNEY: Okay. This is the NRC. We are resuming our public meeting on patient release. And with that, I hope you enjoyed your break, and with that, we are -- we will start back on Question D, and I will turn it over to Donna-Beth.

DR. HOWE: Okay. Question D is the fourth of six, and it is "Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?" And we ask you that if you believe that we should, explain why and describe what the requirement should include. If you don't believe we should have a specific requirement, then explain why our current requirement -- why the additional requirement is not needed, and in either case, we would like for you to describe the resulting health and safety benefits or lack of benefits to the individual being released and to a young child or to a pregnant woman.

Operator, I would like to open it up to those on the phone. Do --

OPERATOR: Yes ma'am.

DR. HOWE: -- you have any comments?

OPERATOR: Yes ma'am. At this time, once again, as a reminder, for question or comments, please press star 1. We do have Lou on the line. Your line is open.

DR. HOWE: And who is -- what is the first name?

OPERATOR: Lou, your line is open. Please check your mute button.

DR. HOWE: Lou, are you on mute?

LOU: Hi. I had a comment on the previous one, but I guess I missed the window, so I have no current comments. Sorry. Thank you.

DR. HOWE: If you have a comment on Question C, then we are going -- at 4 o'clock, we are going to be open for all questions, so --

LOU: Okay.

DR. HOWE: -- hopefully, you will stay with us and you will give your comment at that --

LOU: All right.

DR. HOWE: -- point.

LOU: Thank you.

DR. HOWE: Also, if we end up with extra time for Question D, we may also go back. Okay. Thank you, Lou. Hopefully we will hear from you again. Any other comments?

OPERATOR: No ma'am, I am showing nothing further.

DR. HOWE: Do I have a comment -- I don't have a comment from the webinar, I don't think.

PARTICIPANT: No comments from the webinar.

DR. HOWE: And do I have a comment from the --

MR. CRANE: Yes please. This is again Peter Crane, NRC retiree.

I think that it is important to include a specific requirement relating to the release of a patient who is likely to expose young children or pregnant women, and I think it should make clear that these exposures are to be avoided at all cost. And the health and safety benefit is that you are preventing potential cancers and mental retardation in the child.

It is -- and I think it is especially important because, again, the -- the NRC's standard is based on external dose limits, whereas the greater

danger to children is going to be from internal dose from contamination. And let me quote from an authority on the subject: "It should be realized that the calculation system utilized in NCRP 37 assumes that the patient is a sealed source. It is important to consider situations in which the patient is a 'leaky source.' In such situations, more conservative considerations need to apply.

"It is important to consider the patient given sodium iodide-131 in this context. I-131 appears in urine, feces, sweat, saliva, lachrymal fluid, nasal fluid, and emitted gases. The radiation-absorbed dose to the thyroid in individuals who share households with patients can be much more significant from contaminant I-131 than from the patient as a sealed source. Therefore, the limiting factor in deciding when a patient can go home should be contaminant levels of I-131 that can reasonably be expected to occur." And that is from a nuclear medicine doctor and professor in California named Dr. Carol S. Marcus.

DR. HOWE: So Peter, what was -- you -- what was your specific requirement that you think we ought to have?

MR. CRANE: Well, I think that it would

be well to spell out that, you know -- that young children and pregnant women need to be particularly protected. I think 100 millirems is the absolute max, but that at least -- at the very least, encouragement could be given to try to keep it below that.

DR. HOWE: Okay. Thank you. Going back to the telephone lines, do I have any comments from the phone?

OPERATOR: No ma'am, but once again, as a reminder, for comments, please press star 1.

We do have one person. One moment.

DR. HOWE: Oh, good.

OPERATOR: And ma'am, your first comment comes from Brian. Your line is open.

BRIAN: Hi. I think we could all agree that special consideration and more appropriate instructions need to happen when pregnant women and young children could be exposed, right? I think we can all very easily agree with that general statement.

That being said, this idea of the internal dose to others from a patient, from an iodine patient, has been studied. There have been numerous studies, in the presence of precautions that have been given, without precautions being given, looking

at thyroid burdens of patients and family members, and really, if the patient does follow the very basic instructions, and even in many cases if they don't, general hygiene has been shown to really limit that dose to really uphold NRC's initial assertion under most cases that the dose from internal sources is less than 10 percent of the dose from external sources, and for most cases, external cases will still dominate.

And that even includes use of NRC's internal dose model, which is very, very conservative, taking the 10^(-5) transfer factor from the original administered activity to the patient and applying that as transferred internal dose, and that is even using pediatric-specific dose conversion factors and looking at those things. So we know -- we know a lot more than we did in the 1970s. We know more than we did in the '80s. We are still going research. We are still studying. But we know that the internal exposure pathway, yes, it can be important, yes, we need to look out for it, yes, we need to consider it, but I don't think any of that is a new requirement.

I mean, NRC did clarify some language in Rev 3 to NUREG-1556 Volume 9 sort of emphasizing it

because maybe not all licensees were really running the numbers and kind of looking at it carefully, and maybe the guidance really was not there to encourage us all to do that, but I think we already have an existing requirement to consider this exposure pathway. This is why we have some standard restriction times and activity restrictions, for example, some of which were touched on in NRC just last week when you released that summary document for -- for instructions, you know, talking about food preparation and some of these other ALARA things.

You know, there is a lot that we do for ALARA, and really, this is nothing new. I think the debate is what is the calculation methodology, and what magic number do you plug into the input, you know? Do you agree that it is 100 or 500 of the endpoint? And then separate from that, what is the real dose, okay? And we know that pretty much whatever calculation method we come up with, it is going to be a conservative method. It is going to be a conservative methodology, and the more realistic doses are likely to be much lower than whatever we come up with.

Now, where we do need to be very concerned about, as I said, is, you know, of potential risk, if

maybe it exists, maybe it doesn't. We know that we can argue for hours about that at these levels, at background levels, essentially, but there are societal benefit issues for access to care. There are issues when we are talking for example about mothers, young mothers with hyperthyroid conditions that are getting treated. If we're looking at calculations of restriction times, we would get problems there, you know, because we may be restricting for three weeks access to -- to a child if you're using the NCRP and some NRC models, depending on what your inputs are. You know, this is very, very burdensome, you know, and is there an attendant benefit? Is it really warranted?

And I think that is the fundamental question, you know? And I don't think we're all going to agree on that, but, you know, we need to balance the ALARA and these other societal considerations, you know? People have thrown about, you know, quality of life and cost and all these other things, but it is incumbent upon us and NRC to really look hard at the balance of that, quantitatively and qualitatively.

DR. HOWE: Thank you, Brian. So can I summarize that you didn't believe we needed a specific

requirement because you believe our current requirements, if followed, are adequate? Or did you believe that there should be some change?

BRIAN: I believe the current requirement exists and is adequate. You know, there may be -- I mean, you just released some pretty good guidance in that information notice I think it was you just put out there. Raising some profile on licensee -- on the licensee end for some of these issues would be good. I mean, even if you wanted to step up some stuff in benchmarking among licensees for when you inspect licensees to figure out how -- how we are actually doing things out in the real world, you know, there may be some benefit to that.

I think the requirement exists already. I mean, it is pretty well codified. You tie us down to it in the -- in the regulatory information notices and in the guidance and in our licenses, that the expectations are there that we are already supposed to be doing this stuff.

DR. HOWE: Okay. Thank you, Brian. Do I have any other commenters on the phone?

OPERATOR: Yes ma'am, we do. We have Mack. Your line is open.

MACK: Thank you. Yes, I agree with what

the previous commenter just said totally. One of the -- the things that I do think might -- should probably be a requirement is -- that has to do with the written instructions. I think the written instructions should -- all written instructions that are provided to patients should address maybe in one statement -- it could probably be done in one statement -- risks to children or pregnant women, not if they are likely to be exposed to children or pregnant women because they don't know that.

If they are -- if they are at home, they have control over that. If they are not at home, persons riding on the bus, they are sitting in a movie theater and a pregnant lady sits down next to them, so it might be wise to require in the written instructions that a sentence be put in there that -- to deal with, you know, that they should stay at arm's length from women that are pregnant or children, you know? And so I think that is a reasonable thing to do, even though I -- I am not convinced there is any real hazard.

We talked about the 100 millirem a minute ago. My advice is, if you're worried about exposure of 100 millirem, don't move to Colorado while you are pregnant because you are going to get more than 100

millirem in a nine-month period than you do if you live in -- in -- well, in Indiana or wherever else. So anyway, but nevertheless, I do think that it is reasonable to require, in the written instructions, something about caution with pregnant women and children.

The other thing I would also recommend with the written instructions, there should -- in my thought process, should be a requirement that documentation be maintained where the patient acknowledges by signature that they have received the instructions, agree to follow the instructions, and have been provided the opportunity to ask questions. Now, that doesn't guarantee any of those things, but it at least makes the patient think about it a little bit rather than, you know, when you hand them this piece of paper or whatever that says, you know, you need to do these things, if they have to sign something, they may be -- some will be a little more likely to read it. So that would be something else I think I would require, is that the written documentation provided to patients -- or written instructions be documented. So those two things I think.

DR. HOWE: Thank you. Do I have any

other commenters on the phone?

OPERATOR: No ma'am. I am showing nothing further.

DR. HOWE: No questions from the webinar. Questions or comments from the room?

MR. CRANE: Yes please. I think that Mack's point about putting stuff in the written instructions and getting some certainty that the patient has bought into it and understands it and signs it, I think that is very, very helpful.

What I would like to do is to make the point that what we are seeing, the kind of people who call in to talk about these, we have a sort of self-selection of people who actually take radiation protection seriously. So it is easy if you are a good facility and you think, this is the way we do business anyway, the instructions are here, we already follow them, what do you -- you know, why do we need anything more?

If everybody else were doing as well as you all, we wouldn't have the problems we do. But my viewpoint reflects that of literally hundreds of thyroid cancer patients whom I have encountered in person at the annual conferences of the Thyroid Cancer Survivors Association, and many, many, many more than

that, online media, and frequently, they get no instructions at all. They get sent out the door, say oh, don't bother about -- don't worry about a thing. And we had a meeting at a -- a patient who was herself a charge nurse who said yes, they get written instructions. What happens is a stack of papers -- this was from some no-name place in New Jersey -- a stack of papers, and somewhere in the midst of the papers are the written instructions. Nobody has told them what's in it. Nobody has focused them on it.

And, you know, it may seem like overkill to people who are already doing this, but we've got a lot of underkill out there, and it's a matter of getting the rest of the country up to speed.

DR. HOWE: So Peter, can I assume that you're saying that our previous commenter was thinking in terms of a document that the patient signed that they saw and read, that maybe you would have a signature of the healthcare provider that they explained them?

MR. CRANE: Well, yes. I mean, if I had my druthers, we would do better than that. We would have the NRC and the medical community agreeing on a common set of guidelines representing best practices. It would be recorded on a DVD in all the languages

that patients are likely to speak, and when patients were preparing to be treated or to make decisions on treatment, some provider would say I am going to sit you down in front of this computer with this DVD, and when you watch this for half an hour, it will answer a lot of your questions, and after that, when you've got more questions, we will talk about it. And that way, we would have some realistic buy-in, and we would also know that the provider was covered because the provider would certify, yes, they saw the video.

DR. HOWE: Okay. Thank you. Do I have any more comments on the phone?

OPERATOR: No ma'am. I am showing no questions.

DR. HOWE: Okay. Then I think we have still got about four minutes. I had somebody that had a comment about Question C earlier. Are you still on the phone? That would have been Lou.

OPERATOR: Lou, if you are still on the phone, please press star 1. We can go ahead and take your comment or question.

(No audible response.)

OPERATOR: And ma'am, he is not prompted up for the question.

DR. HOWE: Okay. Maybe he is -- maybe

he is going to come back later. Okay then. I think we have just a few minutes that we will wait until we get to Question E, because I don't want to go -- I don't want to get in advance and -- and have someone call in and they miss their question, so we will just take a quick pause right now, and we will be back at 3 o'clock. And while we are waiting for three minutes, I will put the electronic information of how to submit your comments up on the screen.

(Whereupon, the meeting went off the record at 2:57 p.m. and resumed at 3:00 p.m.)

DR. HOWE: Okay. It's about three o'clock. So we'll start with Question E, and since I'm not getting a lot of discussion, I'm getting a little bit of background on this one.

The question is should NRC have a specific requirements for licensees to have a patient isolation discussion with patients in sufficient time prior to administration to provide the patient time to make isolation arrangements, or the licensee to make plans to hold a patient if the patient cannot be immediately released.

Currently, we talk about giving instructions but we don't really -- found that a number of patients go into their final I-131 treatment

and they have not been talked to at all about isolation, and at that point it becomes too late for them to make arrangements, and it also if it's clear that the patient has to be hospitalized, it's too late for the hospital to make arrangements at that time to treat the patient that day and they have to come back. So that's part of why we have this question.

It came out of our public comments from the 2016 Public Comment Section from patients. So the question, and we want you to explain why you think there might be specific requirements that are needed and describe what those requirements should include. If you don't think we need specific requirements, explain why the requirement is not needed. In either case, we'd like you to describe the resulting healthy and safety benefits or lack of benefits to the individual being released, the licensee and to the public.

I'd like to open this up to members on the phone. Do I have any comments from members on the phone?

OPERATOR: And once again, for comments over the phone, please press star 1.

(No audible response.)

OPERATOR: Ma'am, currently I'm showing no comments.

DR. HOWE: Okay. Comments from the room?

MR. CRANE: Yes, please. This is Peter Crane, NRC retiree. When this came up in the previous meeting, my thought was we don't really need a requirement. But the more I think about it, the more I realize that given the fact that we're dealing not with the -- necessarily with the upper three quarters of licensees, but we also have to take into account the bottom quartile, I think it probably does make sense to put in some kind of time requirement.

I'm not sure exactly what it should be, to make clear that this discussion has to begin early in the process. There could be a provision -- I mean you don't want to interfere with scheduling.

Let's say you've got somebody who has flown in from a foreign country for treatment at Sloan-Kettering. You don't want to make them wait around for two weeks because you've got a rigid two week requirement for starting the process of discussion.

On the other hand, you don't want a situation in which the last thing the person hears on their way out the door, after taking the radioiodine,

is oh, and by the way, you know, you've got to stay away from -- send your kids away or where do you live in and so on.

There ought to be -- under the NRC's current rules, there ought to be a serious case-by-case evaluation. That doesn't happen in a lot of places. We know it doesn't happen. It doesn't happen in a lot of agreement states. The Agreement States may not even know that this requirement exists. So I think it is probably a good thing to insert a specific requirement, and make it waivable for good cause with an explanation.

Why did you omit the, you know, one week notice? Because you know, the patient had to leave town and didn't have time to wait.

DR. HOWE: Thank you, Peter. Do I have any comments from the phone?

OPERATOR: No ma'am. I'm showing still no questions or comments.

DR. HOWE: How many people do I have on the phone at this time?

OPERATOR: You currently have 47.

DR. HOWE: And no one has a comment?

OPERATOR: I can go ahead and remind them once again. For questions or comments, please press

star 1. We do have Mack. One moment. Mack, your line is open.

MACK: Yeah. I don't -- I honestly don't think this is something that should be codified in regulations. I mean the NRC's responsibility is to ensure that the licensee meets the requirements of 35.75, and the licensee has the responsibility to meet that.

Licensees will learn very quickly if they don't give patients adequate time to make the appropriate arrangements, they're going to find out very soon that that creates some real problems, either for themselves or for the patients that they serve. And you know, so if they don't give them adequate time they have to delay treatment. The patient is inconvenienced in some ways and then that's going to be problematic for both.

If the licensee doesn't follow through with the requirements, then they're in violation of the regulations and they should be taken to task for that. I do think though that it makes very much sense to put that type of information in guidance, you know, in the licensee guidance or maybe, you know, as information notices sent out to licensees or something of that nature, you know. That's

appropriate.

But to codify them into the rules, I don't think so. I think because of you -- okay, if you make it a week and then okay, I missed it by a day. Does that really matter? Well no, not really. So you know, I think it's a little bit too prescriptive. I think it can be handled otherwise.

DR. HOWE: Do I have any other comments on the phone?

OPERATOR: Yes ma'am, we do. We have one from Brian. Your line is open.

BRIAN: Yeah. I think -- I think you guys did a nice job talking about this in the information notice you just released last week. Honestly, the whole idea of the pre-release assessment and the instruction time frame, you know, to be able to make the isolation arrangements. Those are very practical things that are nuts-bolts things, and I think something that most licensees should aspire to.

I mean I think we'd all agree to that, that we should do that. I don't know that it rises to the level of rulemaking as the best solution though. I think I'm with my colleague on that one, you know. Rulemaking can be very prescriptive and

it could tie, it could tie the licensees and the providers into some corners where we don't really want to be, in terms of being able to provide some just in time therapies that we expect will be on an outpatient basis, for example for hyperthyroidism, for certain types of patients who are symptomatic, you know.

We may not have be able to have that time flexibility to evaluate them a week or two weeks out, even however much we may want to. They could be referrals. I mean there's just a complex issue and a lot of moving parts. So I think guidance, but I think something that Mr. Crane said really kind of hit home for us, and that's, you know, with variability of practice among licensees, you know, the top 50 percent or 70 percent of licensees that are on top of their game and maybe there are some licensees that aren't doing everything the way that some of us would conceive or understand that it should be done with this stuff.

I think that ultimately is probably more of an inspection and education issue between the NRC and the Agreement States, for are people really doing these things that we're committed to be doing and are we doing them adequately and, you know, just for some

of the stories, you know, that we hear about patients not getting information, not understanding what's supposed to happen, you know, questions whether maybe some enhanced attention from inspection may not be warranted, more so than an overhaul in the regulations, the fundamental regulations surrounding this issue.

DR. HOWE: Thank you, Brian. Do I have any other comments from the phone?

OPERATOR: No ma'am. I'm showing nothing further.

DR. HOWE: Brian, let me ask you a question. Last time we had public comments, we had a very good description of the period of time that passes between diagnosis of I-131 cancer therapy -- cancer patients and the length of time that goes to surgery and then finally decision on I-131 and finally giving the I-131. How about the hyperthyroid patients? What kind of time frame are we looking at?

BRIAN: I don't have good averages either at fingerprints, at my fingertips on that, but I do know that we at our center do get patients referred in from outside sources, and they show up fairly quickly. You know, we treat patients that are not -- did not originate within our system, and that's

part of the issue.

One thing we struggle with when it comes to looking at advance education, advance evaluation or screening questionnaires and things is logistically how do we make that happen for these patients without really unduly delaying treatment, right? So it's a struggle area, but I don't have good solid data for you on that.

DR. HOWE: So Brian, do you already know when the hyperthyroid patient comes to you that they have been diagnosed as hyperthyroid, or do you make that diagnosis at your facility, and then do the treatment?

BRIAN: They come to us with a diagnosis. I mean some are internal that we know, right, and some are referrals from outside. They've already been diagnosed outside and referred for treatment.

DR. HOWE: Okay, and those referrals, do you then treat them like within a day or two, or does it take time to set it up?

BRIAN: I think they're put on the schedule fairly quickly, but I don't have the hard data on that.

DR. HOWE: Okay. Thank you, Brian. That gives us a good perspective. Do I have any more

comments on the phone?

OPERATOR: No ma'am. I'm showing no further comments.

DR. HOWE: Do we have any comments in the room?

(No audible response.)

DR. HOWE: Having no comments in the room, then I think we will take a prolonged break until 3:30? 3:30, and that will be Question F. While we're taking a break, I'll once again put up the information for where you can submit your comments to the NRC. Let me point out that we're having two public meetings. This one and the one we had in April 25th.

But you need to submit your comments to be considered by NRC to the NRC outside of this public meeting. So they need to be submitted either electronically, and I've got the website address there for regs.gov, or they need to be mailed in to Cindy Bladey at the NRC and I've got the address there. So we'll take a break now until 3:30. Thank you.

(Whereupon, the above-entitled matter went off the record at 3:12 p.m. and resumed at 3:30 p.m.)

MR. GLADNEY: Okay. So we will now start back with Question F, and I will turn it over to Donna-Beth.

DR. HOWE: Okay. On Question F, this is another question that we got from our Phase 1 of this particular effort on patient release, where we asked people, patients and physicians etcetera who were there, their thoughts in the different areas. And this question is should the NRC explicitly include the time frame for providing instructions in the regulations?

For example, the instructions should be given prior to the procedure. If so, explain why and provide a recommended time period for the instructions to be provided. If not, explain why the requirement is not needed. In either case, describe the resulting health and safety benefits or lack of benefits to individuals being released, the licensee and to the public.

What we heard from the public on Phase 1 was that some people were not receiving instructions until they were getting ready to go out the door, and they needed -- they needed more time and the instructions may not have fit them at that point.

So this is slightly different from

Question E. Question E was a discussion on isolation, and this is should there be a specific time frame for providing instructions in the regulations.

Let me open this up to the telephone lines. Do I have any comments from the phone line?

OPERATOR: And once again for comments, please press star 1. One moment.

Ma'am, I'm showing no comments over the phone at this time.

DR. HOWE: Okay. I'll open it up for the room.

MR. CRANE: Peter Crane, NRC retiree. Here again, during the last session a month ago, I thought probably not necessary, but on further thought for the same reasons articulated earlier, I think it's probably a good idea. But I would couple it with my notion that there should be some standardized guidance developed.

It could be terribly basic. It could be a sheet of bullet points that's saying, you know, we are -- you know, we are recommending you for radioiodine treatment. It doesn't even have to be the nuclear medicine doctor. It could be the endocrinologist, it could be the surgeon. At any

rate, it could be -- realizing that we only have control over licensees.

But if there were a page or two pages of basic instructions that patients could be given, that could be summoned up on the website and saying, you know, as you make your plans, you're going to want to think about this. This is background for your conversations with the nuclear medicine doctors. We want you to be prepared for that, here it goes.

I think that could only be helpful and, y know, it shouldn't be a matter where people are looking to jump down the throats of licensees with violations of no serious safety import. It's just a matter of trying to make sure that good practice is followed across the board and not just by the top performers.

DR. HOWE: And Peter, can you provide a recommended time? That could also be a performance-based time. In other words, it could be at a certain point in the process, in addition to it being say specific weeks, days or months.

MR. CRANE: I would have to think about how that's done. I think there ought to be some -- I think there needs to be some degree of flexibility, so that the doctor can say this person has absorbed

all the shocking news he or she can for one day. We'll follow up, you know. You recently -- then a week later comes a letter saying you recently had an appointment at which it was mentioned that you may be a candidate for I-131 treatment.

In that case, there are certain precautions that will have to be followed, and you should be aware of them so that you can make some advanced planning. That sort of thing.

DR. HOWE: Yeah. That's got more of Question E. F is instructions for release.

MR. CRANE: Oh right, right, right. That's true. Oh.

DR. HOWE: The concept that you're not given a packet as you're going out the door. You get the instructions at that point.

MR. CRANE: Right, right.

DR. HOWE: I think it's what the public was trying to tell us a year ago.

MR. CRANE: Yes, and I think it's important to remember that the instructions aren't just for 500 millirems. They're for 100 millirems. You're supposed to give written instructions any time any member of the public may get 100 millirems, which is probably not that hard a threshold to cross.

DR. HOWE: Okay.

MR. CRANE: Short answer yeah, it probably is a good idea. I'd like to see what your -- I just wasn't aware that the best practices thing had gone out. I'd like to consult that before committing myself, but maybe in the written comments I can do that.

DR. HOWE: Okay. I think we published an information notice within the last week, so you can look on our website.

MR. CRANE: Will do, thank you.

DR. HOWE: Do I have any comments from the phone lines?

OPERATOR: Yes ma'am, we do. Brian, your line is open.

DR. HOWE: Are you on mute Brian?

BRIAN: Sorry, I was. It's been a long afternoon. So I think we could all agree that, you know, these conversations need to happen before we administer the dose. I think if you're looking for performance-based that at the very bare minimum this should happen, is that patient should be able to talk to somebody and review whatever those written instructions are before you dose them.

That's kind of the minimum. Ideally, you

do that before they show up at treatment for all the reasons that we talked about under the last question, right.

But once again, you know, practicality of implementation, I think that needs to happen at the licensee level, maybe either during licensing or during performance-based review on inspection, or something that we demonstrate that we are -- we are giving adequate instruction lead time to at least most patients.

I think it will be licensee-specific in terms of the actual logistics for how patients show up, you know, in what advance notice and all these other issues that will have to be worked out. But I mean I certainly don't think any of us in the industry feel it's appropriate to just say oh, by the way here's your instructions after you dose somebody, right?

I think we can all agree that that patient should know what they're getting, what the ins and outs are, you know, what the very basic ALARA instructions are, you know, and all these other things before that, far before that as reasonable and practical.

DR. HOWE: Thank you, Brian. Do I have

any other comments?

OPERATOR: No ma'am. I'm showing nothing further.

DR. HOWE: No more comments from the phone line? How many do we have on the phone now?

OPERATOR: You have 39.

DR. HOWE: Okay. Our next session is at four o'clock, and that was when we were going to open things for comments on all questions, in case somebody wanted to talk about something that they either weren't tuned into or didn't have a chance to express themselves on.

Maybe we'll start that session now, and see if we -- and then if we can make it to four o'clock and we still have no more comments, then we're going to close the meeting early. So for those of you on the line, do you have any comments you would like to provide on any of our six questions?

OPERATOR: And once again, for questions or comments, please press star 1. The first person we have is Mack. Your line is open.

MACK: Well thank you. This is actually a response follow-up on Question F. I just couldn't get in in time. But I kind of mirror what Brian said, that my initial response to this is similar to

the one, to the previous one is well, this is kind of a licensee beware. If you don't do this right, there are going to be repercussions.

But as I think about it a little bit more, it may make sense to require that the instructions be provided prior to administration, because that way if the patient looks at those and says well, wait a minute, I can't have my child stay with a family member for a couple of days or whatever, then they have an opportunity to say well maybe we need to delay treatment a day or two for me to make those arrangements, etcetera.

So as I think about that more, that's probably not necessarily a bad thing. To just say it has to be provided prior to administration, and as Brian mentioned, the sooner, the longer time frame the better.

It dovetails a little bit into a comment I made earlier about requiring the patient to -- some kind of documentation, a signature that they've received the instructions, agreed to follow them, etcetera. If that were to be implemented, then they have to be provided those things and they have to agree to do that.

You don't want a situation where you

administer the dose and then given that to sign and they go oh wait a minute, I can't do this. Then they can't sign it. Now you've got a kind of conundrum that you've got to deal with. So as I look at it, perhaps either -- I don't think it needs to be in the regulations.

It could be the in the licensing aspect of the process, in that something that the NRC asks in the licensing portion, to say describe to us when you're going to provide these and that kind of thing. It can be handled that way too and make it a license condition, or tied to their license application.

DR. HOWE: Thank you, Mack. Do I have any other comments on the phone line?

OPERATOR: Yes ma'am. The next -- yes ma'am. The next person is Ralph. Your line is open.

RALPH: Yes. I have a statement to make and then I -- but I have two preliminary questions if I may ask.

DR. HOWE: Yes, please.

RALPH: My understanding is that the comment deadline has been extended. Is that correct?

DR. HOWE: That is correct. The comment deadline has been extended 15 days to June 27th.

RALPH: All right, thank you.

DR. HOWE: And that should have been published in the Federal Register notice this week.

RALPH: Okay. I have not seen anything yet. Is that the information notice that you were referring to a little earlier?

DR. HOWE: No. Those are two separate documents. One document is a Federal Register notice that extends the public comment period to June 27th. The other is an information notice that we just got signed out either at the end of last week or at the beginning of this week. So that's hot off the press. You should be able to find it soon in ADAMS and on our medical tool kit. We'll make sure that we put it in the tool kit.

RALPH: Okay. Those of us that subscribe to the listserv, would it be sent out via that route, or is that a future intent or not at all?

DR. HOWE: No. We can send -- we can send both of them out on the medical listserv.

RALPH: Thank you. I do have a statement sort of to address all the questions in a general context if I may. I'm medical physicist and radiation safety officer. I'm also the chair of the American College of Radiology Commission on Medical Physics and the Government Relations Committee. I'm

speaking on behalf of the American College of Radiology.

The American College represents approximately 36,000 radiologists with med physicians, rad ops, and medical physicists. We want to thank the NRC for the opportunity to provide feedback on this information gathering activity, and that we will be submitting formal written comments in response to the NRC's request to address the individual questions that have been addressed today in much more detail.

The NRC's existing requirements in 10 C.F.R. 35.75 currently adequately protect public health and safety, and are aligned with the core principles of a risk-based dose criteria for patient release. There is currently no scientific basis to reopen 10 C.F.R. 35.75 or to support the activity limits of the past.

As has been pointed out earlier, unneeded hospitalization of patients introduces additional concerns, such as significantly increased costs, patient anxiety and subjecting them unnecessarily to added non-radiation risks such as hospital-borne infection, without adding a quantitative safety benefit to counterbalance those concerns.

Therefore, we strongly opposed reverting to the prior activity-based release limits. ACR supports understandable and helpful release instructions. This is a practice of medicine issue. It is most appropriately handled within the medical community through educational offerings, practice parameters and procedure guidelines.

The current regulations is not unambiguous in its limit. The five millisievert per release is only realistic and practical considering the current practice of health care. This limit applies to all radiopharmaceutical administrations, both diagnostic and therapeutic. So setting an annual limit where multiple providers are involved only creates a significant resource burden, where no health or safety issues have been demonstrated.

The ACR and other professional associations freely provide resources already that can be assessed by patients directly or by their providers, and can be really to via electronic health records and patient portals. In our case the American College of Radiology and the Radiological Society of North America offers videos and content on the website radiologyinfo.org.

If the NRC's intention is to develop or

promote educational content for patients, we recommend the agency instead refer to freely accessible resources. Again, the ACR does not support a rulemaking to change 10 C.F.R. 35.75 for patient release. We look forward to submitting written comments, and thank you for the opportunity to make these verbal comments.

DR. HOWE: Thank you, Ralph. Do I have any other commenters on the phone?

OPERATOR: Yes ma'am, we do. Next person is Michelle. Your line is open.

MICHELLE: Hi. I just wanted to make a comment, because I know as far as the patient release instructions and everything, actually in NUREG the guidance is if they receive, you know, anything above seven millicuries you should give them some type of instruction.

I would say that I find it hard to believe that I've actually witnessed where people do not inform the patient of, you know, release instructions before they come in, because to me there's a cost to the hospital because I've actually seen patients who said well, I can't do that and they'll leave and then the hospital's stuck with, you know, paying for the I-131 dose that the patient couldn't take.

So I think that just more guidance and things like that would be better because I still like when it's in regulations. When people are inspected, they don't necessarily look like help from the licensee would sort of make it better. They just look at, you know, look at just a written driven or document-driven type of thing. I think guidance and using best practices could help address all of that.

DR. HOWE: Thank you. Do I have any other comments on the phone?

OPERATOR: At this time, but as a reminder to make comments over the phone, please press star 1.

And ma'am I'm showing nothing further at this time.

DR. HOWE: Okay. I'd like to open it up to all of our questions. So if anybody's got a question, not a question but a comment on any of the six questions, or a general comment as Ralph made for our current effort, then I'd like to open it up now for final comments. Do I have any comments in the room?

MR. CRANE: Yes please. This is again Peter Crane, NRC retiree. I'd like to respond for a moment to Ralph of the American College of Radiology.

I understand his position. He raises a point which hasn't been addressed, because it wasn't really an issue back when this was originally discussed, which is hospital-borne infections as a downside of hospitalization.

I just want to acknowledge that that is an issue worth taking into account, though it cuts against my position. With respect to the anxiety of hospitalization, that may be true for some and having gone through five inpatient treatments myself, I know that it's not a treat.

On the other hand if you knew as I know from many, many examples, the kind of anxiety that parents especially feel about the potential risks they are inflicting on their children, on their loved ones, that's very real too. That needs to be factored in. Anxiety doesn't cut only a single way.

I would like to read something from, let's see, excuse me. The Centers for Disease Control, sorry. It's right here. Here we are. Centers for Disease Control, Radiation and Pregnancy, a Fact Sheet for Clinicians. For those who want to find this, I'll give you the website. It's https://emergency.cdc.gov./radiation/prenatalphysician.asp.

It says "The human embryo and fetus are particularly sensitive to ionizing radiation, and the health consequences of exposure could be severe, even at radiation doses too low to immediately affect the mother.

Such consequences can include growth retardation, malformations, impaired brain function and cancer. If a pregnant woman ingests or inhales a radioactive substance that subsequently is absorbed in her bloodstream, the radioactive substance may pass through the placenta to the fetus.

"The few substances needed for fetal growth and development such as iodine can concentrate more in the fetus than in corresponding maternal tissue. For substances that can localize in specific organs and tissues in the fetus such as Iodine-131 or Iodine-123 in the thyroid, consideration of the dose to specific fetal organs may be prudent.

"Once the fetal radiation dose is estimated, the potential health effects can be assessed. The possible effects associated with prenatal radiation exposure include immediate effect such as fetal death or malformations, or increased risk for cancer later in life."

I think to go back to where Ronald Reagan

was 30 years ago, that that needs to be a central concern. The very young, the unborn and their health, and we do know that MCRP 155, which represents basically state of the art thinking on the part of radiation professionals, does believe that the proper standard for children and family members is not 500 millirems, it's 100 millirems, and I think that the NRC's effort to move things in the direction of greater protection of the public and especially of children is very sound, and you know, we talk about the necessity of giving timely instruction.

You don't know and maybe you don't -- can't imagine that there are facilities out there that are operated by folks who send people out the door with no instructions at all. I go to meetings, conference and somebody says yeah, you know. So and so in my group, she got 145 millicuries, got sent home to her two year old and there were no instructions at all.

So you know, again, we come back to the point it's not the top performers we're worried about. It's the bottom quartile and what we can do to bring them up to speed I think is all to the good, and I commend the NRC for its efforts.

DR. HOWE: Thank you, Peter. Do I have

any more comments on the phone?

OPERATOR: And once again for comments or questions, please press star 1. One moment. Ma'am, the first question comes from Deidre. Your line is open.

DR. HOWE: Can you repeat the first name again?

DEIDRE: Hi. My name is Deidre.

DR. HOWE: Okay, thank you Deidre.

DEIDRE: And I'm a certified health physicist and my profession is to ensure radiation safety for our staff, our patients and the public. I want to make sure that the NRC in any rulemaking keeps in mind that the benefits and the risks need to be weighed for all of the factors that affect these treatments.

The way that we do things in my institution is we work with each patient to ensure that they have a plan to keep the doses to their family members below regulatory limits and as low as reasonably achievable. For some patients, that means we keep them inpatient. For others, we can release them.

We need to have some flexibility that comes from having a radiation dose-based release

criteria and reasonable requirements, so that we can work with each patient. One concern I have with setting a time frame ahead of administration is that that won't work for every patient. That works for our cancer patients; that does not work very well for some of our hyperthyroid patients who come in and have a scan, and then we discuss the plan and we treat them the same day if that works for their families.

So good guidance needs to be put out there, but we also need to have some flexibility to do what's right for the patient, balancing all of the risks.

DR. HOWE: Thank you, Deidre. So you're saying that you do have some patients that you give -- that get the diagnostic procedure. So they're diagnosed with hyperthyroidism and treated on the same day?

DEIDRE: Yes, we do.

DR. HOWE: That's interesting to know. Thank you, Deidre. Do I have any other comments, on any other questions?

OPERATOR: Yes ma'am. The next question is from Mack. Your line is open.

MACK: Thank you. A couple of comments. One is increasing the regulatory requirements does

not necessarily assure compliance by bad actors. It's been said and certainly I'm part of a major medical center and a lot of the other commenters are from major medical centers and yeah, we definitely, you know, we expend a lot more effort to try to make sure that we're doing things using best practices, etcetera, etcetera.

So and but as I said, it doesn't necessarily -- making more requirements for everybody doesn't ensure the bad, the people that don't do things correctly are going to get any better at it. What ensures that falls under the enforcement side of the NRC's charge, and that is, you know, when you see problems with bad actors, then you take actions to make them good actors.

So that's one thing I think needs to be kind of thought about when implementing, you know, more and more requirements, more regulations, what's the net benefit going to be. The second thing that, you know, I think kind of bears to be thought about, and it does go back to this whole idea of ALARA and, you know, where does ALARA -- where does reasonableness come into play with respect to risk and radiation risk?

Regardless of, you know, the MCRP, ICRP,

they both acknowledge that the LNT is not a proven phenomenon, it's not a proven hypothesis. But at the same time, they say well, to be conservative, we'll assume that there's some validity to LNT, and so that's what we're going to follow.

So again, it still goes back to reasonableness, and I like to make analogies especially when, you know, sometimes when I'm teaching this type of information to physicians and people of that type.

One comparison I would make would be the speed limits. I think we can all agree that if we nationally reduce the speed limit for any highway to 35 miles an hour, there would be fewer deaths from traffic accidents. I mean no question about it.

But is it reasonable to do this? Well, I think common sense and the general public says no, that is not reasonable. I've got some place I've got to be, so that's not the case. So I think we have to think about -- again, it goes back to my comments and some other comments about using science and establishing reasonable regulations and requirements based on science and not on emotion or, you know, this uber -- I mean to be uber-conservative, you know.

I think the example of, you know, people that live in high elevations. Colorado, they get higher radiation doses than the average, but there is no documented evidence that I'm aware of that there are higher instances of cancers and that type of thing.

So we're talking about radiation doses in that realm. So I think we have to insert that -- this idea of what's reasonable has to be factored into the whole idea. So off my soap box now. Thank you very much.

DR. HOWE: Thank you. Do I have any other comments?

OPERATOR: The next comment or question comes from Brian. Your line is open.

BRIAN: Just a comment, you know. Mr. Crane did a wonderful reading from the CDC radiation risk general statement for pregnancy. But you know, this goes back to dose, dose, dose. What is the dose, what is the risk? And so yes, we have patients that are pregnant and get radiological procedures. It happens, okay.

We understand fetal radiation risk at a certain level. We know when we recommend certain aspects, certain procedure avoidances and things like

that. That's well-documented. There's great guidance from ACR and all this other stuff. But it goes back to the doses we're talking about from your general public, you know, when couples give adequate instructions, the dose levels that they're likely to get even at the boundary conditions that we're calculating for are down in the statistical noise, okay.

This is not in my personal opinion a public health crisis or for little children and pregnant women who happen to be sitting on the bus next to a released patient. The data and the science is just not there to support that statement. I mean it's just not there.

So but you know, also speaking to another related point is the concern, the fear that some patients have, you know, because of the requirements that may be put on them because of the way that radiation risks are communicated and how things are explained and sort of the information/misinformation and presentation out there, you know.

We need to be careful that yes, patients have good release instructions and they know to be respectful and to minimize doses. But at the same time, our charge as professionals is to not induce

phobia, to terrorize these patients, right? Who's going to be hurt, okay?

Well, you follow the instructions, the bottom line is realistically nobody's going to be hurt, right? You're not going to hurt your child, right? As long as you're not kissing them and some of these big red flag things that you worry about.

But these are relatively simple instructions. This can be done safely. This has been done safely under the current regime for over 20 years. I'm not aware of any documented studies or cases that show any actual harm from current practices, you know. As long as the practices are followed, right, and that goes back to our discussion earlier of bad actors or people that aren't doing what they should, which is a separate issue to a certain extent.

But it does come back to dose. It does come back to risk assessment, and we do need to be very careful in effectively communicating realistic radiation risks and precautions, okay, and making sure that people are well-educated.

DR. HOWE: Thank you. Do I have any other comments?

OPERATOR: There are no further comments

at this time.

DR. HOWE: Do I have any comments from the room?

MR. CRANE: Yes please. This is Peter Crane again. A number of comments about what was just said. We do have -- well, back up. 2001, the state of Illinois wrote to the NRC and said we see your statements about your confidence that nothing bad is happening, that everything is working fine under this rule.

We don't know what your basis is, because we're here on the ground dealing with the licensees, and we see bad things happening, and the results of that was that the then-chairman, Dick Meserve, wanted to get a rule through the Commission that would have required notification of the NRC when the 500 millirem limit was exceeded by a factor of ten and he could not get approval.

I don't think that it is phobia to give people fair warning. The alternative is to give them a sense of false confidence if they don't get instructions at all, which happens. Do you think that everybody out there is told don't kiss your child? It's not the case.

There's this hospital in Seattle where I

live, and I happened to be there for one department and Nuclear Medicine was across the hall. I went there and I said do you give inpatient or outpatient? He said we've given one inpatient treatment in the ten years I've been here. How much do you give on an outpatient basis? Up to 250 millicuries. Do you ever send patients to hotel? Sure. Some of our patients come from Alaska. They've got no choice. They can't go home.

I said you know that the NRC strongly discourages that? Yes, that was taken into account. Do you know that the state of Washington discourages that? Yes, that was taken into account. These things are happening, and my concern and you know, I wouldn't dismiss this as emotional. I think this is strictly rational.

My concern is that my experience of hotel workers in this country is that they are predominantly female, they are predominantly of child bearing age, and for all we know they are pregnant or nursing. They could be, and you know if, as Dr. Zanzonico was saying, we've got saliva and urine being in a place where the Iodine-131 is being excreted, I would be very, very troubled at the idea that a pregnant or nursing housekeeper is cleaning up after a patient,

because not all patients are equally tidy, you know.

If you flush twice, there is data actually that says that men leave 75 times as much urine around the toilet as radioactivity, around the toilet as women do. I think that's a serious concern. If you've got a place like Sloan-Kettering, Sloan-Kettering treats more Iodine-131 patients than any other facility in the world. They get patients from all over. They should. They're a great facility.

But they sent patients to hotels with 200 millicuries of Iodine in them, and presumably most people are going to the same eight hotels listed on the website as giving preferential rates to Sloan-Kettering patients. So you could have a hotel worker cleaning multiple contaminated rooms in a year. I just -- and the dose is going to be cumulative, and I just don't think that that is acceptable.

And it was Jim Lehman of the NRC staff who made the point, as I may have mentioned earlier, that the realization that patients were going to hotels was undercutting the rationale of long ago that exposure to a radioactive patient would be a once in a year or once in a lifetime event. I wonder if there's anybody out there commenting, who thinks that it is acceptable to send radioactive patients to

hotels and if so, why?

DR. HOWE: Thank you, Peter. Do I have any comments from the phone line?

OPERATOR: Yes. We have a comment from Deidre. Your line is open.

DEIDRE: Hi. I would like to address a couple of the things that have been brought up. The first is about patients being released without instructions. If that is happening, that is a regulatory violation. Instructions are required if the dose is likely to exceed 100 millirem, and we give instructions to all of our patients.

But if you've got patients who are leaving following therapeutic I-131 without instructions, that's a violation. That doesn't need new rulemaking; it just needs enforcement. The other question is about hotels. I agreed that we should not send our patients to hotels on a regular basis, and I strongly discourage that. In the time I've been working, I've allowed one patient to go to a hotel, and that was because the roads got closed due to a blizzard and the mother was frantic. What are we going to do?

So we worked out a plan to minimize the risk to the rest of the staff at the hotel and any

place else that this young woman was going to go. I think we need to make sure that we are enforcing the regulations that we have now, and that we use science to determine what is the risk and what is the benefit from any additional regulations that are put into place.

Yes, there may be some small risk associated with the radiation dose from one of these patients. But what is the benefit from not having that person hospitalized? What is the benefit to society? So please use the science and reason in any further rulemaking in this area. Thank you.

DR. HOWE: Thank you. Do I have any more comments?

OPERATOR: There are no further comments by phone at this time.

DR. HOWE: Okay. I think at this time I'll turn the program back over to our facilitator.

MR. GLADNEY: Thank you, Donna. Before Donna-Beth gives her final remarks and adjourns the meeting, I want to remind everyone that please don't forget to fill out your meeting feedback forms. Your input helps us to improve future meetings, and as we say at the beginning of this year, you can contact Donna-Beth Howe at (301) 415-7848, and she can get

you a copy of the feedback form.

Or you can go to the NRC web page, website at https://www.nrc.gov and type NRC Form 659 in the search window on the upper right-hand side of the page. The form folds into its own postage page mailer for your convenience. Now Donna-Beth will adjourn the meeting.

DR. HOWE: Thank you, Lee. I'd like to point out that if you have any technical questions about the Federal Register notice you can contact me at my email address which is my name, D-O-N-N-A hyphen B-E-T-H period H-O-W-E at nrc.gov, or you can call me at (301) 415-7848. The preferred method of reaching me is my email address.

And we do need your public comments to be submitted to the NRC formally. To do that, you can go electronically up to www.regulations.gov, search for and you'll have to input the docket ID NRC-2017-0094. So that's the NRC 2017-0094, and you'll have -- you'll be able to type your comments in at that point and they will come to us automatically.

If you don't feel comfortable sending your comments in electronically or you have difficulties with it, then you can mail your comments to Cindy Bladey, Office of Administration, Mail Stop

2 White Flynn North 8. So that's TWFN-8-D36, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

This information is also included in the Federal Register notice, and is available there. That concludes our presentation for today. I'd like to thank everybody that joined us on the line and in the room for participating and giving us valuable feedback. Thank you very much and have a good idea. Good-bye.

(Whereupon, the above-entitled matter went off the record at 4:15 p.m.)