Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Sodium Iodine I-131 Patient Release Information Collection Public Meeting

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Monday, December 14, 2015

Work Order No.: NRC-2096 Pages 1-43

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

+ + + + +

PUBLIC MEETING

SODIUM IODINE I-131 PATIENT RELEASE

INFORMATION COLLECTION

+ + + + +

MONDAY

DECEMBER 14, 2015

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Public Meeting convened at the Nuclear Regulatory Commission, Two White Flint North, Room T2B1, 11545 Rockville Pike, at 2:19 p.m., Gene Carpenter, Facilitator, presiding.

STAFF PRESENT:

DOUGLAS BOLLOCK, Chief, Materials Safety and Events Assessment Branch

MICHAEL FULLER, Leader, Medical Radiation Safety Team

DONNA-BETH HOWE, Ph.D., Senior Health Physicist, Medical Radiation Safety Team

GENE CARPENTER, NMSS, Facilitator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB*

ASHLEY COCKERHAM, NMSS/MSTR/MSEB*

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

SOPHIE HOLIDAY, NMSS/MSTR/MSEB*

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

ALSO PRESENT:

PETER CRANE, *unaffiliated**

LINDA CROKER, *unknown**

TERESA FISHER, National Institutes of Health

BILL IRWIN, MD Anderson Cancer Center*

WILLIAM LORENZINE, *unknown**

ERIC MUNGER, National Institutes of Health

CAROL MARCUS, David Geffen School of Medicine*

LAURA WEIL, Advisory Committee on the Medical uses of Isotopes*

MIKE WELLING, Virginia Department of Health*

PAT ZANZONICO, Memorial Sloan-Kettering Cancer* Center

*Present via telephone

C-O-N-T-E-N-T-S

P R O C E E D I N G S

2:19 p.m.

MR. CARPENTER: Thank you very much, Operator.

Good afternoon. This is Gene Carpenter. I am an agency facilitator with the U.S. Nuclear Regulatory Commission.

My apologies for the delay in starting the meeting today.

Also with me is Dr. Donna-Beth Howe, who will be giving a presentation.

This is a meeting for sodium iodine I-131 Patient Release Information Collection. What we are looking for here is to give you, the listeners, an overview of the various materials that have been put out in The Federal Register and, also, to answer questions on how to provide information back for the information collection portion of it and, also, any other questions that you might have.

This is an informational meeting. It is not intended to actually be collecting comments on the material that has been presented at this stage. That information on how to provide those comments will be given out during the rest of this meeting.

We have several members of the public here

in the room. What we will do is Dr. Howe will give a presentation. We will pause at several points during the meeting to give the public an opportunity to ask questions. Again, this is about the information on The *Federal Register* notice or it is about how to supply the information. And if you are providing comments back, we will ask that you utilize the appropriate process for doing that.

For those folks that are here in the room, if there is -- and this is the administrative portion of the meeting -- if there is any reason that a fire alarm or something else goes off, we will pause the meeting, ask you to follow us out of the room, and we will continue from there at that point.

Okay. At this time I would like to turn the meeting over to Dr. Donna-Beth Howe.

DR. HOWE: Thank you.

The first thing is, what sodium iodine-131 treatments are we going to be covering in our information collection. This is all about the information collection that we published in The *Federal Register* back on November 14th.

So, we are expecting to receive information back on treatments of either hyperthyroid or thyroid carcinoma patients. It covers any sodium iodine

treatment that requires in our terms a written directive, so it is large enough that we want to keep track of it. So, that is going to be both for hyperthyroid and thyroid carcinoma.

Can you switch it to the next slide?

MR. CARPENTER: My apologies, we are still having some technical difficulties here. Please hold.

(Pause.)

DR. HOWE: We will just have to proceed without the slides. If you have got The *Federal Register* notice, you have the information, the basic information that we are going to be talking about, and I am just going to be hitting some of the highlights.

The next question is, who do we want to receive information from? We are really trying to get a very large number and very wide variety of stakeholders.

Something happened to my slides. I had them this morning. Okay.

And so, who are we looking to get information from? We are looking to get information from patients. We are looking for our patient advocacy groups. We are looking for individual physicians. We are looking for medical facilities that use I-131. We are looking for the professional organizations, the

agreement states, our ACMUI members, and any other interested individuals.

Most of the questions that we have are about making information clear and consistent for patients. So, we really do want to hear the patient perspective from this.

What are we going to be asking for? We are going to be asking for existing information. So, if you are a licensee, we are asking you for your procedures and processes that you already have. If you are a patient, we are asking you for your experience.

So, we are asking for existing information. We are not asking anybody to generate any new data, new information, go off and do any research projects. We are really looking to see what is practical and what works for you.

The information can be provided in the form of websites and links to websites, in the form of procedures and processes that you maybe use and that you recommend for others. And, as I said earlier, it is going to be your personal experiences, either in your practice or as a patient.

What are we collecting? What information are we collecting? Well, if you look in The *Federal Register* notice, you will see there are four main

topics. Just in summary, the first one deals with information that is responsive to patient concerns about the medical treatment involving the use of I-131.

The second point is the information the physicians use to make decisions on when it is safe to release I-131 patients. This is kind of the dialog that we are expecting, that everybody expects between the physicians or the licensee and the patient to determine, yes, the patient can be released immediately; no, they have to be held for a small period of time, or they have to be held longer.

Then, once the patient is getting ready to be released, it is the radiation safety information that is to be used by patients once they are released to keep doses to others as low as possible.

Finally, we are looking to see if there is a brochure that is available for nationwide distribution that has to do with patient release for I-131 patients.

The next question is, how do you submit information to NRC? As my facilitator has indicated to you, we are not collecting information at this point. We are just trying to answer your questions and clarify what we wrote in The *Federal Register*.

Information can be submitted to us

electronically. In the *Federal Register* you will see that the electronic information should come to us through http://www.regulations.gov, and then, you have to search on a specific docket number. That docket number is very specific to this particular information collection. The docket number is NRC-2015-0020.

You can also mail the NRC, and there is a mail address. You would send it to Cindy Bladey, Mail Stop One White Flint North-12H08, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555- -- well, I don't think you need the extra numbers. So, you can send information to us either electronically or by mail.

If you have questions, you can send your questions on the electronic submission to Carol Gallagher. The telephone number for her is 301-415-3463. That number is also in the *Federal Register*. Or you can email her, and her email address is carol.gallagher@nrc.gov, and that information is also in The Federal Register.

Any technical clarifications or questions you should send to me. My telephone number is 301-415-7848. Or my email address is Donna-Beth, D-O-N-N-A hyphen B-E-T-H, period, H-O-W-E @nrc.gov.

So, those are the basic elements of how to

submit information, what we are looking for in general terms, and the fact that we aren't looking for any new information.

Now I will move on to the first of our four components or parts of our information collection, and that is the website. The first one I told you about was where we were looking for information that the patients would want to have to know about their treatment and what is ahead for them.

So, for the website information, we are looking for the public and patients to identify websites that provide potential patients with information on the radioactive iodine treatment procedures, so the patients will understand the medical condition, the reason for the I-131 procedure, the processes, and how to reduce radiation exposure to others.

Now in the *Federal Register* we provided a list, and the list is suggested topics. It is not intended to be a complete list, nor is it intended to be the best list. So, if you are looking through the *Federal Register*, you will see that every time we provide a list we ask people, "Is this list correct? Is there something you would like to see taken off the list? Is there something you would like to see added to the list?"

It is clear to us, when you are going to add something to the list, that you think it would be beneficial. It would be helpful for us to know, if you want something taken off of the list, that you tell us why you think it is not important to be there. It was our first approximation to give you some suggested topics.

When you are submitting information to us, what do we want to see? Well, we want to see you identify a website. But sometimes just identifying a website is just too big. In other words, if I sent you to the NRC website, there's lots of information on it and you might not know exactly how to get to what you are looking for.

So, we would like to have you indicate the topic that you think the website is going to address and, also, provide a link to that specific information on the topic, so that we can go back and look at the information and we can make it clear for people that are looking at it later.

That completes my initial discussion on the web.

MR. CARPENTER: Thank you, Dr. Howe.

We are going to go ahead and take some questions at this time, if we have any.

Before we do so, I would like to focus everyone on the *Federal Register* notice that Dr. Howe referenced on this. That is *Federal Register* Volume 80, No. 220, dated Monday, November 16th, 2015. It starts on page 70843. If you take a look at the right-hand column of three, you will see at the bottom of that addresses. It includes Ms. Gallagher's and, also, Cindy Bladey from the Office of Administration, and, also, Dr. Howe on the following page, 70844. So that, if you did not get a chance to write down the information that was provided just a moment ago, that information is available again on page 70843 following in the F*ederal Register*.

At this time, I would like to open the floor to questions. We will start here in the room. Once we have had a chance to go around the room, then we will go to the operator.

Questions in the room?

(No response.)

No questions in the room.

Operator, any questions online?

OPERATOR: Participants on the phone, if you would like to ask a question at this time, please press *1 and record your name.

One moment, Speakers, for incoming

questions.

MR. CARPENTER: Thank you.

OPERATOR: Our first question comes from Peter Crane.

Your line is open.

MR. CRANE: Thank you very much. I don't think I had a question. I thought I was just supposed to indicate that I wanted to participate in the meeting. So, I have no question at this time. Thank you very much.

MR. CARPENTER: Thank you.

By the way, if anybody on the telephone line or here in the room wishes to ask a question anonymously, you do not have to give your name when you indicate with the *1.

Next question?

(No response.)

No questions online?

OPERATOR: I'm sorry, no questions in the queue.

MR. CARPENTER: Okay. And in that case, we will go to the next section on the presentation.

Dr. Howe?

DR. HOWE: Okay. So, the first part of it in a time sequence was, essentially, once the patient

finds out that they are going to have a treatment and the information that they want to know.

The second part of our information collection is the patient now knows they are going to have this procedure and they are working with a licensee, and the licensee, whether it is the individual physician or someone at the licensee's site, is talking to the patient and getting basic information that they will be using to decide when to release the patient.

We have used a header. That is the second header that you will see in the *Federal Register* notice. That is patient licensee acknowledgment form and best practices in making informed decisions on releasing patients.

So, we are looking at the best practices that are used by individual physicians and licensees that focus on enhancing the ability to make informed radiation safety decisions on when to release patients from their radiation safety control.

In this case, you may be following a national guideline, but you may have to modify it to meet the situation for your particular practice. And so, we are interested in how you modify things to meet your practice and what you think really works well for you as to getting information from the patients and

releasing them in a timely manner.

So, we are asking you to describe the policy or provide the procedure that provides confidence that the patients are released at the appropriate time. If applicable and you have a form that is signed by both the patient and the licensee that acknowledges that these topics were covered and understood, then we would like to see that form, if you have one. We are not asking anybody to generate a form. We're just saying, if you've got one, please share it with us.

We have given a number of topics that we think might be topics that are discussed. Once again, we are saying this is our suggested topics. If you've got topics you think are much more important, please tell us that. If you think our topics are not important at all, then let us know and let us know why you don't think they are important.

We also asked a few timing questions. In this case, when is the best time to have this discussion between the licensee and the patient? We are looking from the patient's perspective and we also want to find out from the licensee's perspective.

We have also asked that patients and other interested individuals give their perspective on the topics that they think are important for this discussion

and, again, the timeline. So, that is the general kind of information that we are asking for.

At this point, I can open it up to questions.

MR. CARPENTER: Very good. Thank you, Dr. Howe.

Again, the topics that we are discussing now are the ones on page 70845 of the F*ederal Register*. It is under the first column, B.

Since we went to the room the first time, we will go to the phones this time. Operator, anyone on the phones?

OPERATOR: Thank you, Speakers. We have three questions in queue. The next question is from Linda Croker.

You may begin.

MS. CROKER: I'm sorry, mine was a little bit maybe more related to the first section, but I didn't queue fast enough, I guess.

MR. CARPENTER: That's perfectly fine. Go ahead.

MS. CROKER: So, relative to your desire for suggestions for a website, the concern would be that there is such a fluid environment. If it gets put into, say, a rewrite on 1556 or elsewhere, how is that going

to be maintained? Because, you know, websites are updated very quickly, much more quickly than things usually are updated by, say, the NRC.

DR. HOWE: Our intent is not to put the website locations in a guidance document. Our intent is to develop an NRC website that has links to the information, so that that could be much more fluid and up-to-date and could be monitored.

MR. CARPENTER: Next question?

OPERATOR: Our next question comes from Dr. Carol Marcus.

You may begin.

DR. MARCUS: Good afternoon. Thank you. Much of the information that is given to patients is verbal and is not one-size-fits-all information, but information that suits the patient's perspective, the patient's education, the patient's ability to research anything or even read.

And the NRC concept that all of this should be written down somewhere I think really missed what is essential, which is a personal approach to each patient, depending on their ability to use media, ability to understand. This really cannot be in a one-size-fits-all document.

DR. HOWE: Thank you, Dr. Marcus.

I think we understand that medical practice is not a one-size-fits-all. We are assuming that, even if there is not specific information that is repeated to every patient, but that it is more tailored to the patient, that there are certain, more or less, performance guidelines that key the licensee and the patient to certain discussion items.

And so, when we ask for best practices and procedures, we understand that they may not be written procedures, but the best practices might be general guidelines of what kind of things need to be discussed. And then, we understand that independent decisions are made based on that dialogue back and forth.

So, we do not think there is going to be a one-size-fits-all. That is one reason many of our regulations are performance-based. Even though it sounds like we are looking for prescriptive information, we understand that we tend to give guidance in performance-based. And so, if your response would be in performance-based, then that would be fine.

Did I answer your question?

DR. MARCUS: Yes.

DR. HOWE: Thank you.

OPERATOR: Thank you, Speakers.

Our next question comes from William

Lorenzine.

Your line is now open.

MR. LORENZINE: Yes, I wanted to just clarify specifically what types of therapies or procedures are you looking to have addressed in this request. Is it all IRB-related use of I-131 as well as clinical practice?

DR. HOWE: We're looking for clinical practice with sodium iodine I-131. We're looking for treatments for hyperthyroidism and for thyroid carcinoma, treatments that require high enough amounts of iodine that a written directive has to be developed.

And that may be jargon to members of the general public, but that means that the amount of activity is specifically written for a patient, so that we make sure that a patient that is supposed to get a very small amount doesn't get a very large amount of sodium iodide.

Does that answer your question?

MR. LORENZINE: I just want to make sure it's clear. It does include investigational use of the I-131 covered under a written directive.

DR. HOWE: Covered under a written directive. But it's not just I-131. It's sodium iodine I-131. So, there are some iodine-labeled

materials where the iodine stays pretty well bound to the material, so it doesn't function quite the same way and it's not used for or you might even block the thyroid to have the material go somewhere else. So, it is primarily material that is going to be going to the thyroid or thyroid-like tissue.

MR. LORENZINE: That's very helpful. Thank you.

OPERATOR: There are no other questions in the queue.

MR. CARPENTER: Okay. Thank you, Operator.

In the room?

MR. MUNGER: I have one question. My name is Eric Munger.

DR. HOWE: Can you push and make sure there's a green dot (referring to the microphone)?

MR. MUNGER: It is a green dot.

DR. HOWE: Thanks.

MR. MUNGER: Some of the administrations are performed on an outpatient basis and some patients are isolated for a period of time before release. Would there be any measures for distinguishing the advice that you would be giving to the patients based on those two methods of release?

The reason I ask is because a lot of people who are isolated will do research online and, then, get nervous when they see the restrictions that are recommended for those being given outpatient doses.

DR. HOWE: An interesting point. We didn't distinguish between the -- and this actually gets into the next topic, because this particular topic is making the decision as to whether to release someone immediately, hold them for a few hours, or isolate them at the medical facility.

But, when we get to the next one, it is the guidance that you provide the patient once they are released. And so, if you have held them for a number of days and, then, you release them, that guidance is different than if somebody treats them as an outpatient and sends them home right away. And we haven't specified that you need to clarify which it is. So, that was a good question.

MR. MUNGER: I think it is important because people that are being held will oftentimes ask about whether or not they should check themselves into hotels or avoid their family unnecessarily, because they are reading recommendations that are normally given to outpatients.

DR. HOWE: Okay.

MR. CARPENTER: Any other questions?

(No response.)

One more time, any other questions, Operator, on the line?

OPERATOR: We have a question from Peter Crane.

You may begin.

MR. CRANE: Yes, please. Part of this goes back to the previous. How large a dose are we talking about for a threshold? I know some therapeutic doses can be as much as 10 millicuries as a diagnostic dose. I'm sorry.

DR. HOWE: Activity. We did not put a threshold on the activity. I have gotten a few comments back. One person was concerned that they thought this covered only the thyroid carcinoma patients, and they wanted to make sure that we were also addressing the hyperthyroid patients, as to when it is safe to release them. The threshold for release is a dose to members of the public. So, it is not an activity.

And I have gotten other information already from physicians which are covering both hyperthyroid and thyroid carcinoma patients.

So, to answer your question, there is not an activity cutoff. Well, there is kind of an activity

cutoff. You have to have a written directive. So, it is not the very small diagnostic test. If you have a written directive, those are the patients we are looking for you to give us information on.

MR. CRANE: Where does the written directive kick in for diagnostic doses?

DR. HOWE: For diagnostic, it kicks in at 30 microcuries. And the reason it kicks in at 30 microcuries was a very long time ago people had problems between writing microcuries and millicuries. And so, we wanted to make sure that people that were getting microcuries got microcuries and people getting millicuries got millicuries. And most of the microcurie diagnostic tests are below 30 microcuries. So, that was where the line was set for the written directive.

MR. CRANE: Okay. So, in that case, an awful lot of diagnostic doses for any thyroid carcinoma patient would be in the written directive bailiwick, right?

DR. HOWE: Some of the initial tests might be in the microcurie level, but, then, when you get to whole-body scans, they would be in the written directive area. And, you know, the licensee can look at what they are giving and who they are giving it to and the expected

doses to members of the public, to determine whether they need to provide information, hold them or release them immediately.

MR. CRANE: Okay. If I could just move on to a couple of other points or questions?

One, I take it that it is all right to refer to international guidelines, things used in other countries, as guidance?

DR. HOWE: Peter, what we are pretty much looking for at this point is we are looking for people's individual experience. What is it you are using if you are a medical facility or a physician to determine when to release patients? And we are also looking at the patient's individual experience as to "I was one of these patients and I thought I had excellent information given to me and I want to have other people get the same information." "I thought the information wasn't as good and I would have liked to have heard more about a certain area or a certain topic."

So, we are not looking for international standards. We are actually looking for what people are doing to determine when to release patients and they are presenting that information to the patients.

MR. CRANE: Got it.

And finally, two other things. One, the

point was made by a caller about website fluidity. I got an example of that just this morning as I was looking for a presentation by a couple of MD Anderson people, which I thought was excellent, and it had vanished from the website in the meantime because the particular organization had updated its site. I have it, but it is gone. So, things do come and go, and sometimes it is useful to print things out and send them in whole, just to guarantee that it is still there when you want it.

Finally, if I could respond to Dr. Marcus' point; she is quite right that one-size-fits-all is not a workable model. But I think it is sometimes true that the people who work for fine institutions -- and I would put Dr. Marcus' in that category -- don't recognize that, down at the level where a lot of patients get treatments, standards are not that high.

If I understand correctly what the NRC is getting at, it is that we want to have some kind of baseline that can, then, be supplemented by individual regard for the patient's situation, not that this is to take the place of individualized discussion that she thinks is unnecessary. Am I correct in that?

DR. HOWE: I think, basically, we are looking for the individual physician's experience.

And so, if they've got a diverse population, then they are going to do things a little bit differently than somebody that has a uniform population. If they've got a population that doesn't necessarily read English or speak English, then they are going to do things a little bit differently. And that is what we are kind of looking for.

MR. CRANE: Okay. Thank you very much on that.

DR. HOWE: You're welcome.

MR. CARPENTER: Any other questions on the line?

OPERATOR: We have another question from Linda Croker.

You may begin.

MS. CROKER: I just want to get back to your mentioning of the term "written directive" so many times. I think, in practice, that that is maybe going to be confusing because of the fact that in the summary statement at the beginning of page 70843 it mentions medical treatment with I-131, and then, in the section we are talking about right now, Section (b) under the Licensee and Patient Acknowledgment, it is the treatment with I-131.

And a written directive, as you already

mentioned, goes down to 30 microcuries. So, there is quite a bit of I-131 use in diagnostics that requires a written directive that is not treatment. And so, I believe that this focus is on only the treatment, the use of I-131 treatment of the patient, not the use of I-131, though it might require a written directive, in the diagnostic range. Correct?

DR. HOWE: Well, I think the starting point is that it requires a written directive. The second point is that patients are released if they can meet criteria for doses to members of the public that are covered under the patient release criteria in 35.75.

So, you've got both parts going together. And so, that means a lot of the diagnostic is not going to rise to the point where you are going to expect to give 100 millirem to the person that is going to receive the highest dose. And so, you would not be providing instructions.

So, we are looking at those patients that have to be released with instructions or have to be held before they can be released with instructions or with written, either oral or written instructions. So, both things come together, and that eliminates many of the smaller activity procedures.

Did I answer your question?

MS. CROKER: Yes. Thank you.

OPERATOR: Speakers, I show no other questions at this time.

MR. CARPENTER: Thank you.

Okay. Going on to the next session.

DR. HOWE: Yes.

MR. CARPENTER: I'm sorry. Before you do, I think we have resolved our technical problems. I hope at this time that people who are tuned into the webcast can now see the presentation. If there is anyone who is on the webcast, if they could so indicate *1, I believe it is, that they are seeing slide 13, Best Practices?

(No response.)

I guess nobody is on the webcast.

Okay. We'll continue on.

DR. HOWE: Next slide.

The third component is guidance for released patients. So, in the timeframe, this is the point at which you are going to be releasing your patient, whether it is immediately after the treatment or after you have held them for a few hours or maybe you have held them in a hospital. And the question is, what guidance will you provide to them? And the next question is going to be, at what time is the best time

to provide this guidance?

So, if we look at the next slide, we were asked to provide standardized guidance to reduce the variability of instructions provided to patients and eliminate some of the uncertainty in the type of information provided. That can be one of two forms. It could be prescriptive, which would be very specific information. As Dr. Marcus pointed out, that may not be the most appropriate way of providing guidance because that would assume one-size-fits-all.

So, we have another option, and that is performance-based guidance. If we go to the performance-based guidance, then we are going to be interested in the tools, the methods or means, that the licensee provides the individual patients so that they can follow the guidance objectives and they can protect others.

Next slide.

So, what are we expecting for information? If you've got guidance documents that you believe provide clear instructions for released patients, we are interested in seeing your guidance documents. We are interested in patient input as to what those instructions should look like to them. Were they easy to understand and follow, and what would have made them

better? And when should the instructions have been provided?

We, once again, have kind of a list in The Federal Register that again is a suggested list of topics and questions. We are always asking it in an open-ended manner, that if you think those topics and guidance are good, that's fine. If you think something else should be added to it, tell us and tell us why. If you think something should be removed, then tell us and tell us why.

Because we want to make sure that our guidance, however we develop it, is going to hit the real important points, and we may or may not have included all of them in our list in The Federal Register. So, we are interested in that input.

Now we can go to questions.

MR. CARPENTER: Okay. Very good.

For those who are following along in the *Federal Register*, we are on page 70845, Item (c), center column, bottom of the page.

Start here in the room. Any questions in the room?

(No response.)

No questions in the room?

On the telephone, please.

OPERATOR: Speakers, we had eight indicate activity on the webcast.

Again, if you would like to ask a question, please press *1 and record your name.

MR. CARPENTER: Okay. If we have eight people, go ahead with the first one.

OPERATOR: Okay. Our next question comes from Peter Crane.

You may begin.

MR. CRANE: I'm sorry. I mean, I'm getting confused by these instructions. Earlier it said, if anybody is following on the webcast, please press *1, and I did so just to say, yes, it's all coming through loud and clear. But it doesn't mean I've got a question.

MR. CARPENTER: Okay. Well, thank you very much for letting us know that you are following it. I take it that you can see the material on the webcast?

(No response.)

Dr. Crane?

MR. CRANE: Yes.

MR. CARPENTER: Okay.

MR. CRANE: I can see it.

MR. CARPENTER: Okay. Excellent. Thank you very much.

But you have no other questions at this time?

MR. CRANE: Do I have any questions? No, I don't. Thank you.

MR. CARPENTER: Okay. Thank you very much for keying back in.

The next questioner.

OPERATOR: Our next question comes from Mike Welling.

Your line is open.

MR. WELLING: No questions. Same comment as Dr. Crane.

MR. CARPENTER: Thank you.

OPERATOR: No questions in the queue, Speakers.

MR. CARPENTER: So, no other questions online?

OPERATOR: No questions at the moment.

MR. CARPENTER: Thank you very much.

Going on to the next section.

DR. HOWE: Our next section is probably the shortest section of all. And that is -- next slide -- and that is a brochure for nationwide use.

The Commission wanted to know if there was a brochure that explained the radiation safety and

concerns for I-131 patient release and, if there is one, whether it could be distributed for nationwide use.

So, we are asking people if there is such a brochure, and if there is such a brochure, for them to please provide us either with a copy or a link if it is located on a website.

And that is our fourth. So, identify the brochure that you believe provides clear guidance and provide us with a copy or a link to it.

Open for questions.

MR. CARPENTER: Okay. No questions in the room?

Operator?

OPERATOR: I'm showing no questions over the phone lines.

MR. CARPENTER: Thank you.

DR. HOWE: Okay. In the closing remarks -- next slide -- if you are watching on the webcast and if you've got your phone on register, submissions for this information collection are due to the NRC on February 16th, 2016. You are highly recommended to get them in before February 16th. If you're a little bit late, we have discretion as to whether we take that information or not. So, February 16th is the date for submissions.

This is the first of two public meetings. The next one is a public workshop where we are expecting more conversation and dialog between people that are coming to the workshop or people that are going to be participating at the workshop through the webcast and the telephone lines.

It is also going to be on patient release. The purpose for our public meeting today is the *Federal Register* notice has been out for about 30 days. If you're thinking about it, you might have some questions you wanted to ask us. Well, the next public workshop, which will be January 21st, 2016, it will be all day from nine o'clock to four o'clock. We will have about an hour-and-a-half for each one of our major topics. It will be webcast and there will be a telephone bridge line. And there will be about an hour-and-a-half for each one of our major topics at that point. So, it will be a much longer meeting.

Next slide.

Once again, I have repeated the information on who to ask questions. If you've got problems with your electronic submission, and sometimes people do have problems with the electronic submissions, then Carol Gallagher is the one to contact. And I've got the information on this slide. It is also in the *Federal*

Register notice.

If you want technical clarification or questions, then I'm the one to contact. My information is on this slide and it is also in the *Federal Register* notice.

So, we want to make sure that if you've got any questions that you get them in, so that you will be able to submit information.

And a reiteration again of how do you submit information to the NRC. Electronically, you go onto the regulations.gov website. You search for our docket number which is NRC-2015-0020, and you have an electronic mechanism where they ask you to provide your comments.

Sometimes that can be frustrating. If you aren't comfortable with electronic submissions, then you can always mail information to us, to Cindy Bladey, Office of Administration, here at the Nuclear Regulatory Commission. That information is in The Federal Register, and it is also on this slide.

Are there any other questions?

MR. CARPENTER: Okay. No questions in the room.

Going to the operator, any questions online, please?

OPERATOR: We have a follow-up question from Dr. Carol Marcus, who may begin.

DR. MARCUS: Thank you.

Donna-Beth, at the time that 35.75 was being discussed and being worked on, you received the brochure that the Society of Nuclear Medicine makes available. Do you still have that?

I mean, it is general; it is not patient-specific, but it certainly covers a lot of the things you're talking about and is being used, I think, by many at least Board-certified nuclear medicine physicians as extra written information to augment their verbal information to the patient.

DR. HOWE: We have a brochure that is much older than that, that was done I believe in probably the '87 rule. That was more of a pamphlet to be passed out, and we put that, I think, on our -- we disseminated that.

Then, it may be the Society of Nuclear Medicine and Molecular Imaging provides us with a brochure that they believe is good for everybody, and maybe other groups or individuals that have pamphlets. So, we are looking for information from whoever has a pamphlet that they believe would be good, Carol.

DR. MARCUS: Okay.

MR. CARPENTER: Any other questions

online?

OPERATOR: I'm showing no questions in the queue.

MR. CARPENTER: Okay. Seeing none in the room, barring no other ones on the telephone, I would like to redirect your attention to the information that is up on your screen right now. That is, again, who to contact if you have any additional questions: Carol Gallagher and Donna-Beth Howe for technical clarifications.

As mentioned earlier, the public meeting on January 21st is going to be located --

DR. HOWE: It's going to be located in exactly the same room that we're in now and we are going to have a webcast. And the telephone bridge lines are going to be exactly the same as the bridge lines we have now.

I will be posting that meeting notice in the next day or two on the NRC website, so that it will be available for everyone. And we will publish the agenda, which will look very similar to the agenda that you saw for today, but with longer time periods.

MR. CARPENTER: And again, the location for the January 21st is here at the White Flint Complex in Rockville, Maryland, for those of you who care to

travel. But, as Dr. Howe said, we will have a webcast and a telephone bridge line for those who opt not to.

So, one last time --

DR. HOWE: One more point.

MR. CARPENTER: I'm sorry.

DR. HOWE: In the case of inclement weather, because one can never predict what is going to happen in January in D.C., if we have snow or some other reason that we're not able to come into the office, we will still hold the meeting via the telephone conference line because you need to get your information by the 16th of February and we won't have an opportunity for another meeting between the 21st of January and the 16th.

MR. CARPENTER: And for those of you who are not here on the East Coast where we are having spring-like weather, I envy you and your snow. But, other than that, yes, we always have the challenges of weather at that time of the year.

One last opportunity for questions. Anyone on the telephone?

OPERATOR: We have a question from Sophie. You may begin.

MS. HOLIDAY: Hey, Donna-Beth, I --

DR. HOWE: Sophie, you're breaking up.

MS. HOLIDAY: Oh. Can you hear me better

now?

DR. HOWE: Yes, I can hear you better.

MS. HOLIDAY: Okay. I was going to say I wanted to take the opportunity or to remind you to let people know that we will have meeting transcripts available in the event that they weren't able to attend or they couldn't hear a full portion of the meeting.

DR. HOWE: Okay. Thank you, Sophie. Yes, we will.

MS. HOLIDAY: You're welcome.

MR. CARPENTER: Okay. Any other questions?

OPERATOR: Yes, we do. We have a second question in the queue. It comes from Peter Crane.

You may begin.

MR. CRANE: Yes, please. Just to respond to Dr. Marcus' point, I think she is referring to the brochure that was prepared jointly by the SNM and the NRC and published in 1987. The author of that was the late Dr. David Becker of Cornell Weill Medical Center.

And it was very useful in its time, but that was in the days of the 30-millicurie rule. And when the NRC published its 35.75 rule change in 1997, it said that you could use that, but just adjust.

And the question is, if you adjust the times

according to the number of millicuries and so forth, then the question is, does that really tell licensees very much; if you have got a 200-millicurie dose and you've got instructions that are appropriate to a 30-millicurie dose? How do you make the transition? My own view is that a new and updated brochure of that obsolete one is long overdue.

DR. HOWE: Thank you, Peter. That is obviously another reason why we are asking for information collection today to find out what people are using.

MR. CARPENTER: Last call for questions.

OPERATOR: One moment, Speakers, for additional questions from the phone.

Our next question comes from Bill Irwin. Your line is open.

MR. IRWIN: Hi. This is Bill Irwin from MD Anderson Cancer Center.

This is more of a comment than a question. SNMMI has updated procedure guidelines for various types of procedures, including treatment of thyroid cancer and hyperthyroidism, which is dated 2012. So, they have updated that. It is a little more current, so it may still be a useful document. It is not so outdated.

DR. HOWE: And we assume that the Society of Nuclear Medicine, SNMMI, will send us a link or a copy of that.

MR. IRWIN: Yes, the link, if you just go to their web page and look under the Practice Standards, it is available for public consumption. There is a link right there. You've got to drill down just a couple of levels, but it is there.

DR. HOWE: Thank you for your comment.

MR. IRWIN: Yes.

OPERATOR: Next, Speakers, we have a follow-up statement from Dr. Carol Marcus.

You may begin.

DR. MARCUS: Dr. Irwin said what I was going to say, basically.

DR. HOWE: Thank you.

OPERATOR: And I'm showing no other questions in the queue.

MR. CARPENTER: No other questions?

OPERATOR: No other questions, sir.

MR. CARPENTER: Okay. Very good.

Okay. At that time, I would like to go ahead and wrap up the meeting.

As was said earlier, we will have a transcript of the meeting that will be published here

in the very near future.

Dr. Howe will be, also, providing additional information regarding the public meeting on January 21st. In the meantime, if you do have any questions regarding electronic submission or any technical clarifications, the names on the screen, Carol Gallagher for electronic submission and Dr. Donna-Beth Howe for technical clarifications, are available to you.

And with that --

DR. HOWE: I think we're good.

MR. CARPENTER: Yes, with that, we're good.

And I thank everyone for their participation.

I wish all happy holidays and a very happy 2016. Thank you very much, and the meeting is closed.

(Whereupon, at 3:11 p.m., the meeting was adjourned.)