Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

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

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Thursday, January 21, 2016

Work Order No.: NRC-2137 Pages 1-124

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

+ + + + +

PUBLIC MEETING

SODIUM IODINE I-131

PATIENT RELEASE INFORMATION COLLECTION

+ + + + +

THURSDAY

JANUARY 21, 2016

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, at 9:00 a.m., Donna-Beth Howe, Ph.D., presiding.

STAFF PRESENT:

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

GENE CARPENTER, NMSS, Facilitator

ALSO PRESENT:

GARY BLOOM, Thyroid Cancer Survivors' Association

SUE BUNNING, Society of Nuclear Medicine and Molecular Imaging

MUNIR GHESANI, M.D., Mount Sinai St. Luke's and Mount Sinai West

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

MIKE LICHTY, *unaffiliated*

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

P R O C E E D I N G S

9:07 a.m.

MR. CARPENTER: Good morning.

My name is Gene Carpenter. I am an NRC Meeting Facilitator.

Thank you for standing by with us. For those of you who are not in the Washington, D.C. area, we had a significant snowfall amount, almost an entire inch, last night. So, that made everything a little crazy around here, and we are just trying to get started a little bit today.

This is the Workshop for Sodium Iodine, I-131, Patient Release Information Collection, public workshop. We have an agenda on the NRC website. I do recommend that you take a look at that.

The presentation will be made today by Dr. Donna-Beth Howe, and it will be in several parts. We're going through the introduction phase right now. In just a moment, we will start with the website information. We have at 10:30 the Patient/Licensee Acknowledgment Form and Best Practices in Making Informed Decisions on Releasing Patients Treated with I-131 Based on Radiation Exposure Considerations.

Beth, you couldn't make that a little longer? Never mind.

(Laughter.)

DR. HOWE: I tried.

MR. CARPENTER: And then, at noon we will break for lunch. And at one o'clock we will come back and start with Guidance for Released Patients, and at 2:30, the Brochure for Nationwide Use, and Conclusion.

We have set out these times. So, we will try to stick to those times. If any one session ends a little bit early, in case there is somebody who wants to specifically check on that one session, the 10:30, the one o'clock, the 2:30 one, we will start approximately at that time for those. So, we may put you back on hold for a time period from there.

For the people in the room, if there is an emergency of any kind, we have to evacuate the building, please follow an NRC staff member.

We do have restrooms right outside door. You do not need to be escorted to those, and they are through the door, into the hall, left and right, male/female.

As we continue through this, as I said, we will be going through this, the meeting is being transcribed. That will be available later, once transcription is complete and we have had a chance to

take a look at it.

Dr. Howe will be giving the presentation. What we will be doing is setting up, once she gives her presentation, we will go for the comments or the questions. What I would like to do is, for this first round, for the website information, once she completes that, we will go around the room, see if there's any questions or comments. And then, I will ask the operator, Christine, to open the lines for anyone who would like to participate from the telephone. At that time, she will tell you to do *1 to request to speak.

As we mentioned, there is the option for anonymity. If you don't wish to give your name, you do not have to. If you do wish to give your name, certainly feel free to do so.

At this time, I would like to turn this over to Dr. Howe and go into the presentation.

DR. HOWE: Thank you, Gene.

The first thing I would like to cover is NRC is collecting information on patient release and what sodium iodide treatments. And what treatments are we hoping to collection information on?

Well, it is both the treatments for hyperthyroidism and for thyroid cancer patients. We

have had some responses from the public that thought that it was only for thyroid cancer patients, but we are also looking for the hyperthyroid information, too.

Who do we hope is going to provide the information? Because we are focusing on patient information, patient instructions, and patient and physician decisions, we really want to hear from patients; we want to hear from patient advocacy groups; we want to hear from individual physicians on their experience; we want to hear from licensees; different professional organizations; agreement states; our Advisory Committee on Medical Isotopes, and any other interested individuals that have an interest in I-131 patient release issues.

Now we are not talking about rulemaking changes. We are collecting information that we hope to use to improve our guidance to the medical community and to patients.

What are we asking for? We are asking for existing information. We are asking for those that respond to us to give their experience. In some cases we have asked for information in four different categories. One is on websites, procedures and processes that you, either as a physician or as a

patient, might recommend.

And we want responses based on your personal experience. So, we are not asking anybody to generate new information. We are not asking any groups to go out and develop any new information for us. This is really what are people doing; how are they doing it, so that we better understand how we can make sure information is clear and concise.

Specifically, I have four topics. This information collection is described in a Federal Register notice. If you are part of our medical list server or you have looked at our public meeting site, we have tried in all cases to make sure that the Federal Register notice that really outlines the information we are collecting and the depth that we want is available to you. If it is not, if you don't have it and you would like a copy, then I have got information on later slides that tell you how to get in touch with me and I will send The Federal Register notice out to you.

It is not long. It is only four pages. We are hoping it is in a level of language that everyone can understand. So, we tried not to make it too technical.

Okay. We have four topics. The first

one is information responsive to patient concerns about medical treatment involving the use of I-131.

Where do patients go to get information? What do patients think are really good sites? And most of this information we are expecting will be website locations.

We are looking for information that physicians use to make decisions on when it is safe to release I-131 patients. We are assuming that is a dialog between physicians or other members of the licensee's staff with patients to determine that it would be reasonable to release patients. And that release can be immediate or it can be delayed. We are not making any distinction.

The third topic is the radiation safety information to be used by patients once they are released. So, you will see a theme. One is the information patients want to know before they get the treatment; the other is the information that the patient and the licensee share to make a good decision on when to give the treatment and, also, when to release the patient. The third one is, what information will help the patient make sure that doses to other members of the public are as low as reasonably achievable.

And the fourth topic is a brochure that people think can be distribution on a nationwide basis that will help provide some clarity on these issues.

This is an information collect effort, and you have two different methods to submit information on this information collection. One is electronically, and I have got the information on this particular slide, where you go into www.regulations.gov. You search for the docket number NRC-2015-0020, and provide an electronic copy of what you want to submit to the NRC.

Now our public meeting today, we certainly will be available to answer questions if you are not sure what we are looking for. We are looking for more of a dialog between the different groups, so that we can hear on a real-time basis what people are doing.

But I must emphasize that, in order for us to process the information, we are going to have to have you submit it to us officially, either electronically or in mail form, to Cindy Bladey in the Office of Administration and to the Nuclear Regulatory Commission. And that information is on the slides. They are also on our meeting notice website.

So, if you end up with any questions about electronic submissions, we have a point of contact, and that is Carol Gallagher. You can email her at carol.gallagher@nrc.gov or you can call her at 301-415-3463. If you have any technical questions or clarifications, then you can certainly call me. My phone number is 301-415-7848 and my email is donna-beth.howe@nrc.gov.

All of this information is located in The Federal Register notice. So, if you didn't get a chance to copy it and you need a copy of The Federal Register notice, you will find the information is in there also.

So, our first topic of the day is the website. For the website information collection, we would like for members of the public to identify websites that provide potential patients with information on radioactive iodine treatment procedures, so the patient will understand their medical condition, the reason for the I-131 procedures, the process, how to reduce radiation exposure to others.

If you look at our Federal Register notice, you will see that we have put a number of bullets or subtopics in each topic. We do not

consider those to be all-encompassing. We have always put a statement in there that says, if you think there is something else that should be addressed, let us know. If you think we have something in here that is not really that important, let us know and let us know why not.

So, we are really asking open-ended questions because we are trying to collect information. This is not the normal type of information collection that you see from the NRC where we ask for a survey, we ask for simple yes/no or multiple choices. We are really looking for information that you have and information from your personal experience.

So, what do we want you to submit for the website? We would like for you to identify the website. We would like for you to indicate the topic that it addresses, and we would like to have you provide us with a link to that specific information. We know there are some general websites out there that have a lot of information, but you really have to do a lot of navigating to get down to specific information.

I could use an example of the NRC website. We think it is very clear to us how to navigate it,

but we know, when we talk to the members of the public, we have to provide a lot more information.

So, in this case if there is a specific topic on, say, the medical use of I-131, then reference that topic, give us a specific link to that website that you think provides good information there. We are trying to make it as clear and as simple as possible for people to respond.

So, I think we can now open it up.

MR. CARPENTER: Okay. Thank you very much, Donna-Beth.

DR. HOWE: Yes.

MR. CARPENTER: As mentioned before, we will go around the room and, then, we will go to the telephones. So, anybody in the room have any comments they would like to make?

MR. BLOOM: Good morning.

Do I need to say my name?

MR. CARPENTER: You can, but you don't have to.

MR. BLOOM: I'm Gary Bloom. I'm the Executive Director of ThyCa, Thyroid Cancer Survivors' Association and I am a 20-year papillary thyroid cancer survivor.

As far as identifying a website, ThyCa

has a very extensive website. It is WWW. T, as in Thomas, H-Y-C-A.-O-R-G. We believe that it follows the entire patient journey from diagnosis through treatments, including radioactive iodine, testing and ablation, if an when necessary; also, discussing precautions that should be utilized.

Our materials are all medically reviewed by a very large medical advisory council. And so, wherever there is medical-related information, it has all been medically reviewed. It is not people like me, patients, who are just laypeople giving medical opinions, because we are not suited to do so.

So, we encourage use of our website. And, yes, as really Donna-Beth said, there is a lot of material to go through. So, people will have to spend some time, but it is meant as, it is a resource, so people can come and go as different parts of their journey become more relevant.

And then, also, we have support groups that we identify on our website, both face-to-face and electronic, where people can go to speak to people about their own experiences. Again, that is not medical advice. It is meant to share experience, to try to help people either create clarification in their journey or to help them coalesce ideas for

questions to ask their medical practitioners when the opportunity presents itself.

Thank you.

DR. HOWE: Thank you, Gary.

I think one point I need to make is NRC is thinking about setting up a website where we have, essentially, topics or high-level items and, then, we would reference over to other websites for that particular item. So, it might be think of our website as kind of an index and, then, over to other websites.

So, members of the public should think in those terms and look at our list of topics and see if the topics are adequate or they are too much or they are too little, and specific links to pieces of that information.

The other point is NRC normally does not get into the practice of medicine and we normally stay away from really medical issues, other than our regulatory. But, in this particular case, our Commissioners have asked us to try to make a place where people can find clear and consistent information. So, your sites would be a part.

MS. KUBLER: Excuse me. Hi. I am Caitlin Kubler. I am with the Society of Nuclear Medicine and Molecular Imaging.

We submitted comments on the website reviews during the last collection information period that NRC had open. We actually reviewed about 15 different websites and we provided the linking. We will be happy to submit that information again.

But one of the things that we did, in addition to submitting the topic and the website link, was to rate the website on a scale of 1 to 5, 1 being the least helpful and 5 being the most helpful. And then, we also clarified which audience it would be good for.

I noticed two kinds of themes we are looking at, patient information and, then, we also reviewed guidelines that physicians would give to patients. So, that area was also addressed.

And so, we do believe that the specific brochure that we have developed would still be beneficial to the NRC to consider. We will be happy to submit that again.

As well, we believe that the ATA guidelines are good. They might be a little outdated, but I want to go ahead and mention that.

We do have a member representative, Munir Ghesani, who is, unfortunately, running a little bit late. But he will be here and he will talk about

some of the patient experiences.

We actually formed a work group, and we are hoping to address some of the areas that Donna-Beth had mentioned in the past. I know we have a lot of urban and city information, but how are some of the rural facilities handling things and the information specifically given the patients? You know, you need to consider the specific patient circumstances. Hopefully, when Munir gets here, he can talk a little more about that and some of the experiences that we addressed in our work group.

I don't know if, Sue, you want to mention anything else?

MS. BUNNING: Hi. Sue Bunning.

MR. CARPENTER: Sorry, if you will come up to the microphone, please?

MS. BUNNING: The only other thing is, if you go to the SNMMI website, I think that there is a lot of information on both the physician guidance side as well as the patient side. And in reviewing it, it is a lot of information and it is sometimes very hard to find.

So, we over the last year have upgraded some of the search capabilities for our website. But one of the tasks we have is to go back and see if

there is a better way to package all of the information because I think we want to be sure online we have all of that. So, we are working on that internally, and we are hoping to get some more information out of this meeting and what is coming, to see how we might package a little bit more neatly for when the patients and physicians go to our site.

DR. HOWE: Thank you.

MR. CARPENTER: Okay. No other comments in the room?

(No response.)

In that case, Christine?

OPERATOR: Thank you.

MR. CARPENTER: If you can go ahead and open up the lines, please?

OPERATOR: Yes, sir.

At this time, if you would like to ask a question, please press *, then 1. If you are asking anonymously, you will receive an identification number prior to asking your question. Once again, to ask a question at this time, press *, then 1. And if you would like to withdraw the question, press *, then 2.

One moment, please.

MR. CARPENTER: Thank you.

OPERATOR: The first question comes from No. 1. You may ask your question.

ANONYMOUS: Yes, thank you for the opportunity.

I just would like to point out to NRC staff that the webcast is about 15 to 20 seconds delayed from what is coming over the telephone bridge. In fact, the last speaker cut out several times. So, it was pretty, very difficult to understand exactly what her point was. So, I just kind of want to point this out to staff, so maybe somebody can kind of tweak this, so that the webcast portal and the bridge line are in sync.

Thank you.

DR. HOWE: Okay. We just got information from my technical person. You have to look at the bridge line and, then, use the telephone line for communication because the telephone line is how we assure that we have an orderly meeting.

(Off-the-record comments.)

MR. CARPENTER: Theron, I believe he is saying that the slides themselves are a few seconds behind what he is hearing. So, we will take that. Thank you very much. We appreciate that heads-up. This may be a technical problem that we are going to

have to address, unfortunately, in future ones, but we will try to be mind of that as we go forward.

DR. HOWE: And I think a point that we want to make is that, in order for you to communicate with us, you need to use the phone lines.

Theron was saying that, if you want the verbal to match the slides exactly, you listen to the webcast. But, in order to communicate with us, you need to use the telephone line. Hopefully, that is clear to everybody.

MR. CARPENTER: Thank you very much, sir.

Next question?

OPERATOR: At this time, sir, I'm showing no further questions.

MR. CARPENTER: Okay. We will go around the room one more time.

(No response.)

Nothing Further?

DR. HOWE: Okay.

MR. CARPENTER: Anything else from the telephones, Christine?

OPERATOR: At this time, I'm showing no questions.

MR. CARPENTER: All right. Again, apologies to those who are listening-in from home.

We will try to make sure that we take into account the delay, and we will deal with that.

I'm showing the time as 9:30. So, we have approximately one hour until our next topic. As mentioned earlier, we were trying to maintain that schedule. So that, if people dialed-in to listen to one particular topic, that we would do that. Otherwise, we would go through the entire presentation at this rate very quickly, and anybody who dialed-in later would not get the advantage of that.

So, at this time, I'm going to ask that we take a break and that we will continue at 10:30. All right?

Christine, we will be back to you in approximately 50 minutes.

Thank you.

(Whereupon, the foregoing matter went off the record at 9:32 a.m. and went back on the record at 10:29 a.m.)

MR. CARPENTER: Yes, this is Gene Carpenter with the Nuclear Regulatory Commission again. Thank you for your patience.

As mentioned earlier, we were going to go right in accordance with the agenda. So, we are now

at the 10:30, Patient/Licensee Acknowledgment Form portion.

We have had a couple of more people join us in the room. I don't know how many people are online.

But we will going forward with this, so we don't have such a long break after we get through and break for lunch, in the afternoon we will start again at approximately one o'clock for the Guidance for Released Patients. And then, once that session is done, instead of waiting until 2:30, if we get done early, we will go ahead and roll through to the Brochure for Nationwide Use, and Conclusion. That way, hopefully, if need be or it supports it, we will get done a little earlier today.

But, of course, if anyone on the phone does need to get some more information, please contact either Donna-Beth Howe or any of the other folks that are listed on the session.

As I said, we are going to go into the Patient/Licensee Acknowledgment Form. Dr. Howe will give the presentation. This time, instead of starting in the room, we will start on the telephone. And once we have gotten through the telephone, we will go to the people in the room.

Dr. Howe?

DR. HOWE: Thank you, Gene.

So now, we have moved to the second topic that we are collecting information on. This is the part where the patient and the licensee or the physician are interacting and really talking about the disease and finding out information that helps the licensee decide when to safely release the patient. 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 their release.

And this release could be immediate or this release could be hospitalization or this release could be somewhere between the two. We are not making any value judgments on this. We believe that in this best practices there will be a dialog between physicians and licensees and patients.

So, we are also looking to see if physicians and licensees have acknowledgment forms. We are looking for licensees to describe any policy that provides a procedure that gives him confidence that the patient is released at the appropriate time, providing an acknowledgment form that both the patient and the licensee may sign, that the dialog

has occurred.

We are looking for responses from patients and from physicians on what is the best timing to have this dialog between the patients and the licensee and when is the best time between the dialog and the release. We are looking for patients and other interested individuals' perspective on this timeframe and on the interaction and the information that is transmitted.

So, that essentially tells you what we are looking for. All of this is talked about in more detail in The Federal Register notice. You will see a number of topics that we believe are probably key topics in this discussion. Once again, we want to reiterate that won't believe that they are all the topics, nor necessarily are they the best topics. So, we are looking for feedback from the general public on if there are other topics they think are more relevant or if they think that some of the topics that we have listed are not really appropriate, to give us that feedback and tell us why.

Once again, we are also looking for experience. We know that there are some general guidance documents that maybe the professional societies put out, but maybe a physician has to modify

that for their individual practice. That is the kind of information we are looking for.

Now we have had a few public comments received. The one thing I will say is that we are looking for putting those procedures in perspective. How do you use those procedures? How do you make the decision? At what point do you make the decision? And we are not looking for a long dissertation on this. We are looking at maybe a sentence or two that the puts the policy or the procedure into the right perspective for how the decisions are being made.

So, at this point, I think we can open it up for discussion and questions.

MR. CARPENTER: Thank you very much, Dr. Howe.

All right. As I mentioned before, at this time we are going to go to the telephones and ask the folks that are on the telephone to *1, and the operator will, then, key you in, so that you can give your comments.

I do also recognize from earlier that there is a delay on the webcast. So, there may be some difficulties between syncing-up what is on the screen and, also, the phone lines. We do appreciate that challenge, and thank you for bearing with us on

that.

As before, if you do not wish to give your name, you can remain anonymous.

So, at this time, Operator, we would like to go ahead and open for any questions or comments from the line.

OPERATOR: Thank you.

Once again, if you would like to ask a question or you have a comment, please press *, then 1. And to withdraw, you may press *, then 2.

One moment.

(Pause.)

At this time, sir, there are no questions.

MR. CARPENTER: Thank you very much. We will come back to the lines in a moment.

We will go around the room now. Any comments in the room?

Yes? Please press the microphone. Thank you.

DR. GHESANI: Hi. I'm Munir Ghesani from SNMMI.

As a Society, we have polled a large number of our end-users and trying to get the idea about the best practices and how they manage. I can

give you some insight into what our local practice parameters are as well.

We, overall, work very closely between the physicians, the technologists, and the radiation safety department to plan out each and every patient's treatment accordingly.

In terms of choosing the right approach, in fact, back in the late nineties, we published an article in Health Physics looking at, is there a way you can quantify the exposure and see how you can use that information in providing more customized recommendations to the patients? If you want, I will give you the reference later on about the article.

But one of the things we found was very interesting was that sometimes the contact restrictions and the impact of exposure to the family and friends is very counterintuitive. You may have a hyperthyroid patient with 70-80 percent uptake and treated with 12- or 15-millicurie dose on one hand, and you may have a thyroid cancer patient with a really good surgery done, less than 1 percent uptake in the neck on diagnostic scan and you are giving a 200-millicurie dose.

And when you look at the output of the software in terms of what the restrictions are going

to be, very interestingly, the one with the hyperthyroidism ends up getting more long-term contact restrictions than the one with the thyroid cancer because the residual of remnant of less than 1 percent is the one that is going to hold on very minimal activity as opposed to more than 99 percent of the dose washes out very quickly.

So, we use that kind of data, that kind of information in customizing the recommendations for the patients and we make sure that we verify it with our radiation safety. They look at the data and they agree that that is the way to address the treatment of the patients.

In fact, if at any point we find an outlier in terms of the patient not being able to follow the instructions or some kind of family or social situations that can prevent them from getting treated as an outpatient, we do not hesitate to recommend that those patients should be treated as an inpatient.

DR. HOWE: Thank you.

And I think that brings back the point that, hopefully, I made early on, that we are not just looking for experience from thyroid carcinoma patients and practices, but we are also looking for

experience from hyperthyroid patients and practices.

DR. GHESANI: Correct.

DR. HOWE: So that we can cover the whole gamut.

MR. CARPENTER: Thank you.

Any other comments in the room?

MR. LICHTY: Hi. My name is Mike Lichty. I was a thyroid cancer patient diagnosed late 1997, had the surgery in 1997 and, then, radioactive iodine treatment in January of 1998. So, that is 18 years ago this month.

My experience with the radioactive iodine treatment was fine. I had no real complaints. I was treated at Washington Hospital Center and came in and took the capsule -- it was several capsules -- and was not allowed to be released, I think based on Washington, D.C., radiation exposure regulations, until my radiation levels being emitted, as measured by some kind of little mini-Geiger counter, for lack of a better term for it, until it met a certain level, which turned out to be a little more than 24 hours, maybe 26 to 28 hours. And then, I was supposed to stay about 3 feet away minimum from people for 48 to 72 hours afterwards.

That was the protocol then. I don't know

what it is exactly now. But I had no real problems with it.

Beyond that, though, I do have -- one of my younger brothers was diagnosed, probably about two or three years ago, with his thyroid just wasn't functioning properly. And his endocrinologist, of course, the treatment was to have radioactive iodine, a smaller dose than what I had, to just cease the function of the thyroid and be put on Synthroid or a thyroid replacement from then on.

I recall that my initial reaction was I didn't think that was the right way to go about it. So, I talked to my endocrinologist as well as his, and they said it was. So, when he had the treatment, it was a lower dosage, but he was able to do it as an outpatient-type thing and go home and just maintain safe distance, I think for 48 to 72 hours.

So, I have direct knowledge, and my experience was fine, and indirect knowledge with my brother, and everything went fine through that. That is what I have to contribute to this discussion.

DR. HOWE: Thank you.

Any other comments?

MR. BLOOM: Do you want my name again?

DR. HOWE: If you want to.

MR. BLOOM: Gary Bloom with ThyCa, Thyroid Cancer Survivors Association.

As I had mentioned earlier, I am a thyroid cancer survivor as well as Executive Director of an association for thyroid cancer survivors. We, as a population, have a perspective that what knowledge is shared with the patient is very important, and it gets to a few points that I made notes about.

The first factor is, is the patient hypothyroid? Because people are still being treated in a hypothyroid state versus using Thyrogen as a part of the therapy. If a patient is hypothyroid, oftentimes, their level of comprehension is diminished. That means that it is very important that the message from the medical professional has to account for that, because, otherwise, it is like talking to a bobblehead. There will be a head nodding, but there is not always the digesting of specialty information.

This is an experience, whether it is the ablative dose or just a small testing dose. Being treated with I-131 is a different experience than most people experience. And so, there has to be a message delivered, but there has to be the ability to digest it. So, I think the dosing facility people

need to know the health condition of the patient they are working with, for one.

I would encourage in any circumstance, but especially if a person is hypothyroid, that it would be great to have a second set of ears in the room, meaning a loved one or friend to the patient, so there is the opportunity for better receipt of instructions.

I am not here to question that facilities give good instructions because, first of all, I have very limited perspective. I have been treated at two different facilities, and I can only speak from my own experience. But I do believe most, if not all, professionals are sharing good information, but that doesn't mean it is being heard well or received well or understood well.

And I feel like that is part of the message out of this meeting, what do we do to improve the receipt of information as much as what do we do about the delivery of the information. So, having more than one person hearing the information would be good.

Also, the timing. In my life as an advocate, I'm amazed how many people I have met who have said their sequence of events was, "Here take

this I-131. Now we're going to talk to you about what precautions to take." Bad sequence. I don't think that happens very often, but if it happened once or twice, it is too many times.

So, it is very important that the sequence be proper. It could be revisited after the dosing, but there has to be a conversation in advance of being treated, so that there is a good dialog. What is the home situation? Is there somewhere for the person to go to once they have received the I-131.

I'm sorry, I didn't get your name.

DR. GHESANI: Munir Ghesani.

MR. BLOOM: Dr. Ghesani?

DR. GHESANI: Yes.

MR. BLOOM: As Dr. Ghesani said, people are being treated with I-131. What are we going to do with them? There is a period of timeline we are hot; we are radioactive. And so, the patient needs to have a plan. Again, better to make that plan before being treated than after.

So, to me, the messages are: are there enough ears in the room for the patient to walk out with good information? Does the patient actually have mental acuity, hypothyroid versus Thyrogen? Does the patient actually have mental acuity,

regardless of hypothyroid or Thyrogen?

Again, I can only speak to a cancer scenario. So, I am not discounting the hyperthyroid patient being treated. But when a person is told they have cancer, some people suddenly stop walking on the planet earth in the same way. They are anxious, and their ability to hear instruction, which is specialty instruction because it is about their health, is diminished. So, we always are encouraging that that person have multiple set of ears with them.

But, also, just what is their ability to digest this special information? This is not here is how you walk to the grocery store or how you find a loaf of bread. This is special information that we are only going to hear for most of us once or twice in our lifetime, and it is just out of the norm.

So, the person giving this instruction has to be aware that the person receiving it is a little off-balance potentially and that the information being addressed is unique. We talk about level of understanding in terms of just a general educational perspective. We encourage lowering the message down to a lower level of education, using more routine words, less big technical terms, and accounting for a language factor. We live in a

melting pot.

I am reminded, when I lived in California years ago, at the time you could take your driver's test in 38 languages, which I thought was pretty remarkable. Now most facilities can't handle that, and I am not asking them to, but they need to make sure that the patient can hear the message.

And what happens when the patient is not a native English speaker and the doctor is an English speaker or the technician is an English speaker? We need to have a pathway to making sure that the message is delivered and heard, again, not so much that the message is delivered; how is it heard?

So, those are some of the points that in my experience are very important to consider, and I just wanted to share that.

Thank you.

DR. HOWE: Thank you.

DR. GHESANI: Can I make some followup comments?

DR. HOWE: Yes, please do.

DR. GHESANI: I liked your points very much. In fact, what we have done is that it is not just hyperthyroidism that you can state, well, you can't remember. All of us have information overload.

Even as a patient when I go to my primary care, I am mindful of the fact that I may not remember everything and I am usually writing little notes on anything that I need to take care of.

So, what we do is, in fact, we had handouts for the patients and we encouraged them to bring the family members with them. The other thing which is very important is it is not just simply giving the handout and saying, "Follow it." What we do is, while they are waiting in the waiting room, we give them the handouts. So, it gives them a chance to review it and ask specific questions about the contents that they are about to receive.

This way, when the consult takes place, we can ask them to write specific customized questions that they may have that they need to have additional information about the points that we are writing in the handout. So, that helps them.

The other important thing you mentioned about giving the instructions before, not after, actually, what we have found a number of times is that, especially in New York, when people have their parents living with them, sharing a bathroom, and having a situation where they may have a pregnant woman that cannot go anywhere -- so, in fact, the

opportunity to have all of that resolved is, in fact, well before you even plan the treatment.

Nowadays, since we use Thyrogen, there is another complicating factor, which is that you have to inject the Thyrogen two days before you even administer the iodine. So, it is not about discussion on the day of treatment. You have to actually provide them at least three to five days before you even order and administer Thyrogen because, otherwise, you are going to waste that dose. If, suddenly, there is some important patient situation that precludes you from treating, then it causes, more importantly, the patient inconvenience of having to reschedule the entire treatment at the last minute.

So, from all that standpoint, we go several weeks before. That also gives us the opportunity to give them the instructions on low iodine diet. Because if you suddenly plan your treatment a few days before, you have not prepared the patient appropriately.

In my opinion, I think the ideal time is about two weeks before, where you can discuss all of the matters that may be more complicated in terms of them being able to follow the contact restrictions;

plus, it gives you all the opportunity to give them proper instructions on preparations, low iodine diet, and anything else they may need. So, you are absolutely right.

DR. HOWE: Can you expand a little bit on -- Mr. Bloom raised some questions about the ability to take the information in. Can you expand on how you try to comprehend what is being taken in?

DR. GHESANI: Yes. So, in terms of addressing that, we almost always require that the patients bring somebody with them who is their close caretaker. If that does not happen, sometimes we have actually arranged a phone call while in the room while we are discussing with the patient, as long as, you know, first, we clear it with the patient that that is okay with them.

While that discussion takes place, you don't want to rush that discussion. So, what we do is our treatment plan, we have a technologist who is working for 40 years in the same department. She has been promoted to be the point person for all thyroid patients. Now that includes whether it is a hyperthyroid, whether it is a multinodular goiter patient coming for just a simple scan, or a complicated thyroid cancer patient who needs multiple

visits.

She has a spreadsheet that she maintains. So, every time we have a phone call from a clinician, we know where we will find information if the patient is already being worked-up for potential treatment.

So, we go to her. We work very closely with her. She spaces out the treatments such that it is never rushed where you treat one patient at one o'clock and, then, suddenly, at 1:15, the next patient is waiting.

This is precisely the reason why. Because when you go in the room and you need to have enough time for discussions, you can never underestimate the time it will need for you to have that consult. So, that is another important point.

You have to re-enter it sometimes. You have to make sure in the notes you put a little marker and put a note in there saying this is exactly what you need to follow for the instructions, especially when there are more complicated contact restrictions for pregnant patients or young children.

We have had several instances where a mother of four, and the oldest one is seven years old, and she needs to be treated. There have been instances where we had to treat them as an inpatient.

It is very interesting when we give them the instructions and say, "Oh, you cannot be in contact with your children and you cannot cook." And then, suddenly, the light goes on and says, "This is heaven. I haven't had that kind of situation for years." And they just are looking forward to that break.

(Laughter.)

And we just laugh it off. You know, this is their opportunity to have -- and they will bring their iPads or their magazines and they are just reading and making sure that they are protecting their close family members, especially young children.

So, every situation is very different. You have to take it early on, well before we plan the treatment. Even at the treatment time, there are very unanticipated questions that come up that you have to be prepared to address, too.

DR. HOWE: Thank you.

MR. BLOOM: I am sure many of the questions are things that you have already covered with them, and that is just another reminder of the acuity issues or the imbalance in people's lives at this critical time, when, again, what you think is routine -- and I don't say that blithely -- but dosing with radiation is something that you do

professionally and you understand it. To us as a layperson, the consumer -- I say that in two ways, I guess; we are buying it and we are ingesting it -- to us, as a consumer, this is a really anxious time. I'm taking radiation. We have all seen these scary pictures.

For me, I am saying that doctors need to -- and likely they are, so forgive me -- they need to be sensitive to the anxiety of the person who is ingesting that radiation because it is not routine. It is not something you just go to the supermarket and buy. So, it is a scary circumstance.

My other question I wanted to quickly ask you is -- I love what you do. I mean, that process is just wondering. So, is that you, as a New York physician, or is that you, as leadership of the SNMMI, speaking and saying this is what the Society is trying to get all of its members to do?

DR. GHESANI: That is a good question. The anecdotes that I gave you were my personal anecdotes in my own practice, but on a broad scale I represent the Society. In fact, in preparation for this meeting -- and there was another one in the summer -- where we, in fact, have created a subcommittee of our Society that meets on a regular

basis and mostly phone calls, but in person when we have our annual meetings or semi-annual meetings. We get together, and we, actually, then, each individual goes out and inquires about the practices in their own geographic area.

So, what you see and what we have provided, and in large part what I mentioned about the ideal way of treating and being sensitive to the patient's understanding and the patient's personal situation and anxiety, it all reflects the Society work. Because, in preparation for this, we actually have been working on it for several months to gather that information.

MR. BLOOM: That is fantastic. I love it, and keep it up. Thank you.

MR. CARPENTER: Any other questions/comments in the room?

MR. BLOOM: I will ask one more, if you don't mind. Do you have a written checklist that the professional follows, whether it is your or someone on your staff? The reason I ask that is you are human. As you can tell, I love to talk. So, when I go to see my doctor, as an example, and the doctor gets to step two out of ten and I interrupt and take it off on a tangent, with my wife slapping my knee

saying, "Okay. Shut up, so the doctor can get back to his message," are you able to resume at No. 3 or have I take you off in this meandering path and it is like, okay, now I am on No. 7? And three through six have gotten overlooked? Again, that is more out of being human than questioning your abilities.

DR. GHESANI: Yes. So, the best way -- I don't know if it is by design or by just practice pattern -- the way it works out in our day-to-day is that we have documents. What we do is they are created in duplicate. So, the patients can send for them, the instructions, everything.

The reason for that is that one of the sets gets scanned in and goes into our electronic medical record, and the second set the patient takes with him or her. It turns out that we have one copy each.

So, while we go over the discussion, you know, we are going through step-by-step. We talk about potential literature, you know, reports of carcinogenesis for a larger dose, then the salivary gland, and all the other instructions. So, we go step-by-step.

As I said, it probably is by design, but it has been rooted in our system for so long that

they are used to following it in a way that the patient has a list and we have a list. So, we go through that one at a time, but we don't necessarily check it off. But, at least in the back of our mind, we have the template and a layout of what we need to discuss. So, that helps.

MR. BLOOM: Perfect. Thank you for explaining that.

DR. GHESANI: Sure.

MR. CARPENTER: Yes. I am going to go to the telephones.

Operator?

OPERATOR: We do have questions. The first question comes from the anonymous No. 2.

You may ask your question.

ANONYMOUS: Hi. Can you hear me clearly?

MR. CARPENTER: Thank you. Yes.

ANONYMOUS: Hi. My name is Deborah Graves. I am a trained scientist and, also, a thyroid cancer patient.

I want to actually thank the previous speakers -- they made some really good remarks -- and, also, thank the NRC for doing this project. Because, as a patient in the modern age of social media, I am in communication with a lot of other patients. It

is no surprise we share information.

One of the things we know is that different people get different instructions, and it is very frustrating to know, gee, I got the same dose as another person, but they were told to isolate for three days and I was told to isolate for seven days. Or I was told I can put my trash out at the street right away, and they are told they have to hold it for 90 days. These kinds of discussions happen amongst patients all the time.

I did receive an acknowledgment form from my nuclear medicine department, and we signed off that we had had a discussion and that their evaluation was that I was competent to follow the instructions they gave me to protect my family members and the public.

My thought on timing is the patient needs to know this information beforehand, partly because it takes time to absorb it. And also, if you are isolating at home, which seems to be the norm in the U.S. nowadays, you need time to prepare your home, to make arrangements for pets and children, to make arrangements for sleeping, so that you are not exposing your family.

So, in my particular case, nothing was

done in a big rush. After surgery, my endocrinologist referred me to nuclear medicine, and they immediately mailed me their instruction paperwork for home isolation and followup to radioactive iodine treatment. So, I have probably read that paper 20 times by now.

So, I am definitely an advocate of getting that information to people sooner, so that they have time to absorb it and prepare. I have heard instances of people, through social media, who took their radioactive iodine pill and thought they were doing isolation in the hospital and, then, were immediately sent home. And that is a very awkward situation for the patient's comfort as well as for them to protect their family, since they were not prepared.

I had a meeting with the radiologist in nuclear medicine as well as the physicist in which we went over that information and in which they interviewed me. And I know they were assessing my home situation. You know, did I have children? Did I have a separate bathroom, that kind of thing? My nuclear medicine department was definitely evaluating those things about me in the opportunity to make sure that I was going to be safe to the public.

Something that frustrated me, as a patient, was the guidelines I got were the guidelines that everyone getting treated at this facility got. I know they were written before they even met me. So, there was nothing specific to my thyroid remnant size, my dosage, my kidney function, any of that.

As a scientist, I like to quantitate things, and I wish I could have known, you know, if I measure at 1 meter with a Geiger counter from myself, at what level is it safe for me to be around my husband or my pet or to go ride on the subway? I don't think that information -- certainly, it is not available to me and the general public. Patients would like to know.

You know, this stuff is invisible. I was told it was there; I can't see it. A lot of times you can't feel it. And how do I know it is safe to sort of go back out there, safe to fix dinner for my family?

I will probably, through the internet, send in a recommendation for thyroid cancer patients to be aware of an internet community in Facebook, the LID Life Community. That was started by thyroid cancer patients to help each other figure out how they are going to eat for those few weeks they are

doing low iodine diet in advance of their treatment.

And it is also a forum for people to share how they have prepared their home for isolation and ask questions about their symptoms. Is this normal? Did other people have this?

It has been a really helpful group for me and a lot of other people. I will try to get that information to Donna-Beth through the internet forum for the comments.

Thank you.

DR. HOWE: Thank you.

MR. CARPENTER: Thank you very much. And thank you, also, for thanking us. It is not often that we at the NRC get members of the public saying thank you to us. So, I appreciate that whenever I hear it.

Operator, is there anyone else?

OPERATOR: The next question comes from anonymous No. 3.

You may ask your question.

ANONYMOUS: Yes. My name is Cherry Wunderlich. I am a thyroid cancer survivor since 1999.

I, too, really appreciate this meeting, that it is webcast, phone, as well as for the people

who are able to come. This is really a terrific forum, and thank you very much.

I was treated successfully in 1999. What I would like to emphasize is that this was a very scarey time for me, to suddenly out of the blue hear that I had cancer and, then, that two months later, I was going to have radioactive iodine. So, I just had lots and lots of questions.

I have very patient, wonderful doctors, both the endocrinology and surgery and nuclear med, as well as there was like a support group locally. So, there were people to talk to in person as well as online, which the previous caller alluded to, how helpful the online communities are.

But, having lots and lots of questions, at that time I called my providers. The professionals really used model procedures. I did receive written instructions. I know now they give patients much more extensive information and it is all in writing, and they get mailed in advance.

But, to suddenly have to absorb being a cancer patient and having to go -- I had never heard of a millicurie; I had never heard of radioactive iodine. I do a lot of writing and editing, including medical, and this was just a field I knew absolutely

nothing about. So, it was incredibly confusing.

So, the written instructions and having them at a very, very basic level, I can't emphasize that enough in terms of how helpful that is, and the opportunity to talk back and forth and have a family member present, which I also did.

I was kept in the hospital overnight. For me, that was a huge relief because just the dosing, of having the people around me very heavily protected in their garb and the special container, all of that, again, it was very unfamiliar.

My doctor did come by, so I could ask questions in person, and there were nurses and people around for that. So, that was just very, very reassuring.

I would suggest that you look to the facilities that are giving lots of instruction and taking lots of time with the patients, both in advance and during the time of the dosing, to develop some models that people in less-specialized centers or in areas that don't have as much specialty practitioners as the major urban areas do, so that can be a leadership role to really help, so that every patient receives the kind of information that I received and that I understand patients at the same facility are

still receiving.

Thank you very much. That is all I have to say.

MR. CARPENTER: Thank you for comments. We appreciate those insights.

Before we go to the next caller, I would like to reiterate, for those callers who self-identified themselves, thank you for that. Again, it is not necessary that you do so. If you wish to remain anonymous, that is certainly acceptable.

Operator, next caller?

OPERATOR: At this time, sir, there are no further questions.

MR. CARPENTER: Very good.

Let me go back around the room. Were there any other comments based on this?

Go ahead.

DR. GHESANI: So, after hearing the two comments over the phone, I can give you a little more insight into the points that you raised.

You mentioned getting, one of you mentioned about getting treatment as an inpatient versus outpatient. We heard of some people who were treated in the nineties were treated in a hospital. So, it may be important to know the background

information.

I don't know the exact dates, but I know there was a transition that occurred where we used to measure the radiation and decide, based on the radiation level, whether the patient can or cannot go home. Instead, we have shifted to a different approach where it is about what is the maximum amount of radiation; anybody in close contact, whether that is a family member or a working colleague in a very close working environment? That ends up getting determination of whether the patient will be treated as an inpatient in the hospital or as an outpatient.

So, that may be, you know, if you find differences in the way you and one of your colleagues or family members were treated, that is one thing to keep in mind. There has been that transition point somewhere in the mid- to late nineties.

The second point, about getting different instructions, I am aware, and we, in fact, in our work that we did, we did find differences. So, there is no doubt that there are variations in the way the patients get information from one institution to the other.

In part, though, that has to be taken into account, that ever patient's situation is very

unique and very different. You had to take into account many factors, including the height and weight, the amount of thyroid iodine that you are able to hold onto your thyroid gland, the amount of iodine pool that individuals have.

With the way, for the last several decades, the way we are supplementing the iodine in our diet, the iodine overall is higher now than it was before. So, that is one point.

Secondly, many people take different types of supplements. Sometimes you don't realize what you have in the supplements, and sometimes there are even more iodine-rich supplements that you can take that can actually overload your system with the iodine. All of those factors have to be taken into account when you give the instructions.

We can't get full details, but we do several uptake measurements. Those measurements can allow us to understand what percentage of iodine that we are giving it in a pill that ends up in the target area, which is typically the neck in the thyroid gland.

So, part of the instructions, the variations that you see are we are aware of it, that there is a variability from site to site. But there

is also a fact that you have to take into account that everybody is very unique and very different, and there will be some variations, based on what we know about individuals, that you need to give the instructions to.

MR. CARPENTER: Thank you.

Yes, sir?

MR. LICHTY: Yes, I have a followup to that. I have heard that there are different regulations in different states and the District of Columbia for how much radiation you can before you can be released. Like I think Johns Hopkins, for example, does not require you to stay overnight, but I was treated in D.C. and they did. I have heard that that is based on different regulations or radioactive emissions. I want to know if that is still the case.

DR. HOWE: The situation you are talking about is that the regulations that are followed for the District of Columbia are the regulations that are promulgated by the Nuclear Regulatory Commission. The regulations at Johns Hopkins comes under, are promulgated by the State of Maryland.

Now there is a level of compatibility and agreement. We have what we call Agreement States.

In the Agreement States, NRC has relinquished its authority to regulate radioactive materials in those states. But there are certain levels of regulatory responsibility for the state to maintain something equivalent, not equivalent, but something that will protect the public health and safety the same way the NRC regulations do.

So, we have something called compatibility. Sometimes the compatibility has to be identical. In other cases, the major elements have to be there. In other cases, it is for health and safety. So, you have to have kind of the same objectives.

For release of patients, it is the same basic objectives have to be in place. And so, most states have over time adopted a similar type of release criteria as NRC puts out.

What happens is NRC will change its regulations and, then, the Agreement States have three years to work on whether regulations up to ours and it depends on the level of compatibility. So, that is why you are seeing a little bit of a change, especially in the timeframe from 1997 until 1980, because there was a three-year timeframe which the Agreement States need to kind of come into somewhat

agreement with the NRC. So, that is one reason for the lag and the lack.

And then, also, as the medical community gets more experience, then it tends to maybe accept a new process better. So, a lot of our NRC licensees wanted to stay with the old type of system and more hospitalization, and gradually that has moved.

Hopefully, that clarifies it a little bit.

MR. CARPENTER: Good.

MR. BLOOM: Okay. One more comment. So, you had mentioned the variability of the individuals, which is very important. Obviously, certainly as a layperson, I am deferring to you as a medical professional on that.

But the thought that came to my mind as you were explaining that was more the thoroughness factor, meaning, as an example, every facility that treats people with I-131 should have to ask a very basic questions: how are you going to get home from here? In a car? On a bus? Oh, wait a minute.

So, that kind of thoroughness, and that is an example, and it is a very basic one. It may be too basic to make the point. But that kind of a question should be uniform. I don't feel like there

is any debate about that. Every patient who is in that position in advance should be asked: how are you going to get home after you are given this radioactive material? Because the person sitting in the next seat could be newly-pregnant woman who doesn't show it. So, why would you assume that that lady is pregnant? Are we exposing people unnecessarily? So, that is what I think of when I think of thoroughness.

DR. GHESANI: That is a very important point to make because, if you are following the ALARA principle, which is, as we call it, as low as reasonably achievable, it is a fundamental basic under which we work on every single case.

And your point about a woman who may not show, in fact, the most significant load of any potential radiation effect is in the earlier stage as opposed to the later stage of pregnancy. So, you always have to operate as if like you are going to be in the worst given situation.

From that standpoint, we have very much -- our coordinator that I referred to earlier, she, in fact, well before even the first Thyrogen injection is done, is going through the logistics of how far they live, how they are going to take the

transportation back home, and how they will make sure that, when they get home, that children and any other young adults or family members are already prepared.

Many times it turns out, which is good for the families and the patients, that they are able to work out the details where the patients are usually by themselves, as long as they are healthy enough to take care of themselves. And then, the family members find a way of making a short trip or going to another family for a few days.

All of that discussion, although as it was earlier mentioned over the phone as well, is that there are so many important points that impact individual's lives and their family's lives. So, they have to be addressed well in advance before you even have the patient come in for treatment.

MR. CARPENTER: Okay. Thank you.

Let me go back to the telephones.

Operator, do we have anybody?

OPERATOR: We do. The next question comes from the No. 4.

You may ask your question.

ANONYMOUS: Yes. Hi.

I have been a technologist and radiation safety officer for almost 30 years now. I know that

doing I-131 therapies, we have come across a lot of different scenarios over the years.

But one thing I would like to say gets overlooked frequently is when you are asking a patient about their work situation to make sure that, if they are doing any kind of risky behavior in their work situation, that you address what they would do in case of being injured.

Frequently, we have had -- well, I wouldn't say "frequently" -- but we have had in the past where patients state, "Well, I work in the outdoors. I work as a firefighter," or such things. If they are not working close to other individuals, frequently, they are told, then, they don't have as much restriction or have to wait as long before they can go back to work.

In one case, we had an arbor who was told that he had no restrictions on work because they felt that he was working outside by himself. So, that would be perfectly fine to go back to work. He did the very next morning and was in a tree with a power saw and cut into his arm, cutting his artery.

So, he did have all the information on him when he presented at the ER to be able to state that he had had this therapy and exactly what type of

therapy, and the patient was amazing. So, everything was contained and very well treated. Everything was cleaned up properly and the patient was treated fast and out again.

But, just so that you consider that when you are writing your instructions, that patients work, if they do any risky behaviors, should be considered as well, and what information to give the patient based on that would be appropriate.

MR. CARPENTER: Very good. Thank you.

DR. HOWE: And I hope you are going to submit information to us, either electronically or in writing.

ANONYMOUS: I'm not quite sure how to do that, but I will look into that.

MR. CARPENTER: Yes. That was the earlier part of the conversation. If you would like to submit this electronically, you can go to www.regulations.gov and search for the docket ID NRC-2015-0020. Alternately, you can mail to Cindy, C-I-N-D-Y, Bladey, B-L-A-D-E-Y, in the Office of Administration. Her mail stop is 1 One Flint North, OWFN-12-H, as in hotel, -8, care of the U.S. Nuclear Regulatory Commission here in Washington, D.C. 20555.

And that information is also available in

the material that Dr. Howe has previously put up onto our website.

ANONYMOUS: Okay.

DR. HOWE: And it is available in The Federal Register notice. So, since you know --

ANONYMOUS: Yes, I was on that website just a minute ago.

DR. HOWE: -- about our meeting, then you probably have a copy of that. So, it is in there also.

MR. CARPENTER: Okay.

ANONYMOUS: Okay.

MR. CARPENTER: And the reason that we want that is to make sure that we are able to accurately incorporate all of your comments. You know, we appreciate all the comments that we are receiving today, but I have personally found that people, when they start writing this stuff down, they tend to expand a little bit more than what they do when they are just talking. So, we greatly appreciate that also.

Okay?

ANONYMOUS: All right.

MR. CARPENTER: Thank you.

Operator, any others?

OPERATOR: The next question comes from No. 5.

You may ask your question.

ANONYMOUS: Yes. Hi. My name is Zoubir Ouhib. I'm a medical physicist.

First of all, let me just commend NRC for taking this initiative. I think this is extremely valuable.

I also commend some of the individuals that have actually contributed to this, especially the patients. I think they have provided us with some extremely valuable information, which will lead me to one item.

I think when it comes to designing this pamphlet or these instructions, or whatnot, it would be great to basically separate the pre-, the during, and the post-treatment. It has to be simply, such that all patients will be able to understand it, to the point, and not like you have spoke, that it is too detailed where they get lost in it.

But it is sent out, and there are patients that might not be able to read these instructions. And therefore, there has to be some sort of a video or something that they can connect with and it will be easy.

In other words, when there is confusion, they go back to it and, then, they simply say, "Oh, okay. They told me not to do this and, instead, to do this." I think that will be valuable.

I think in that pamphlet or that video I think it will be valuable to address this fear factor, because one of the patients actually has addressed that very nicely, and then, to say this is not the end of the world.

The reason the staff have to walk out of that room are the following: it is not the end of the world here. Again, to address the how, the where, the when, and what to do, just like the previous caller has stated, what to do in case of an unusual situation. You know, there might be some points already that can be addressed, but the other one could be just, "Hey, you should have gotten this information and there is a contact person 24 hours," whatnot.

This document should also be viewed by all members, and that is the authorized users, the medical physicists, the nurses, and certainly by the patient, and see if that has addressed all their points.

And one last comment. I think it would be also valuable to use some of the past medical

events that have occurred using iodine 131 and see maybe there are a few points that can be added to avoid some of those that have actually occurred. Example: people are not taking the complete dose. A patient hiding the pill under the pillow, and so on and so forth.

And those are all my comments.

DR. HOWE: Thank you.

MR. CARPENTER: Very good. Thank you.

Operator?

OPERATOR: The next question comes from No. 6.

You may ask your question.

ANONYMOUS: Hi. My name is Tim Lyle, and I am a thyroid cancer survivor since 2004.

A couple of things that I wanted to talk about today in regards to things that I haven't heard discussed already going to patient incompliance. Doctors, medical specialists everywhere deal with the patient incompliance on a daily basis. And whether that is from being told to exercise more, and how many of us actually go out and, then, exercise more? Or we are told to lose a few pounds. How many of us actually go out and lose a few pounds? Or to take this medication or that medication, and we don't take

it exactly as we are prescribed to take it.

Doctors deal with that so often in the healthcare community that, when we are looking at, then, giving patients complex instruction on what to do when they are dosed with a radioactive material, that it doesn't always happen. An example of this would be the receptionist at my endocrinologist's office, when I was diagnosed with thyroid cancer, told me a story of how she was in a restaurant. She was eight months pregnant at the time and she was there with her husband. And she recognized someone in that restaurant as being a thyroid cancer patient from her office, and she knew that person had just been dosed with radioactive iodine the day prior.

That person walked up to her and said, "Hi. How you doing? Hey, nice to see you." It made her very, very uncomfortable because, like I said, she was eight months pregnant at the time. So, she was definitely showing. And this person was in a restaurant and doing something they weren't supposed to do, and coming up to her and exposing her and her unborn child to this radiation. So, it happens frequently.

There is an article I read a few years back in the USA Today that I would like to talk about

where a couple of scientists from a nuclear power plant had to travel to apparently another nuclear power plant and do whatever their business was there. What ended up happening was they stayed in a hotel. The next day when they went to the nuclear power plant that they were supposed to visit, they set off the radiation alarms as they walked into the nuclear power plant. Well, that was a problem.

So, it became, how did this happen? Where did they get exposed to radiation? And they tracked it down to the hotel room that those couple of scientists stayed in the night before, that that same hotel room the previous night had been occupied by a thyroid cancer patient who was dosed with radioactive iodine.

Now there was enough contamination in the room, not necessarily irradiating gamma rays, and whatnot, but there was enough contamination in the room yet of radioactive iodine particles that these scientists got enough of that on them, that they were able to, then, set off radiation alarms at that nuclear power plant.

So, we talked about multiple times at the Thyroid Cancer Survivors Association conferences where we have had roundtables with the NRC

officials -- so, some of you look familiar to me from those roundtables that we have had. And I have brought up some of these points before.

But there is the contamination issue that I don't think has been properly addressed. When we allow people to leave the hospital after they are dosed with radioactive iodine and they are told to take certain precautions, we have to deal with the contamination that they might leave behind wherever they go and we have to deal with the fact that some are going to be incompliant.

Now we have already talked about people who are in the hypothyroid state maybe not processing the information that they are given quite efficiently. But we just have to look at the general populace as not being compliant. I mean, how many people stop for stop signs because it is the law to do so or do they just roll through a stop sign?

So, this isn't necessarily a law that they are being given, told to do when they leave the hospital after being dosed with radioactive iodine, but it is something that is important to public safety. When we don't account for those people who aren't going to follow their instructions, then we are left with other people, pregnant women, young

children, all being exposed to radiation unnecessarily.

We know that radioactive iodine can go to the thyroid of a healthy person and damage a healthy person's thyroid. If the healthy person has come in contact with someone who has been dosed with radioactive iodine and that happens, they get contaminated. We know that they can develop thyroid conditions later on in life.

How many times have we had that happen where -- and this is just pure speculation; we can't really put measurements on this -- but I am sure it has happened many, many times where people have probably developed thyroid cancer because they were exposed to radioactive iodine. And that is disconcerting to me.

We know that the rates of thyroid cancer have been increasing exponentially over the last how many years, and we haven't been able to find the cause of it. But we do know that, since we have been allowing people to leave the hospital and not be required to be inpatients through their radioactive iodine treatment, that that number has continued to skyrocket.

So, I would like to petition the Nuclear

Regulatory Commission here, and add my name to that petition, to say that I think we should really require patients to be inpatient in the hospital while they have their radioactive iodine treatments.

When I had my two treatments of 200-millicurie dose and 150-millicurie dose, they required me to stay inpatient. The room was wrapped in Saran Wrap. The bed I laid in was wrapped in Saran Wrap. The toilet, the faucet, everything, the remote control even for the TV, all wrapped in Saran Wrap to prevent contamination of the room.

And I had to stay in there for three days, according to the nuclear medicine techs as they came up twice a day to check me with a Geiger counter. I had to stay there for three days before they would release me home on both occasions. That was so that my radiation level had dropped far enough that they thought that I was safe to go out into the public again. But it took three days for that to happen.

We know the biological half-life for radioactive iodine can be anywhere from two to three days, and the half-life of radioactive iodine itself is eight days. But it took that time for that radiation level to drop far enough.

Well, how many people are going out of

the hospital and they are walking down the hallways of the hospital past people? They are getting on a bus or a train to travel home because they live far away from the center that is treating them. And we are exposing the public again unnecessarily.

So, in my personal experience, after my second dose of radioactive iodine -- I was in the Marine Corps at the time -- I had to travel through one of the bases to get to the hospital where my whole body scan was going to take place. On the way through the gate of the base, I was stopped by the MPs because I set off radiation alarms at the gate. That was 12 days after I was dosed with a 150-millicurie dose of radioactive iodine.

Now I followed the precautions to the "T" as best I could. I took multiple showers a day. I drank plenty of water. I tried to flush out as much of the radioactive iodine as I could. But I still set off radiation alarms 12 days later on that Marine Corps installation.

That concerned me that people are walking around, and more than just background radiation levels, are exposing the rest of us. I think that is something the Nuclear Regulatory Commission really needs to consider.

Is the insurance lobby that strong, that we don't require people to be inpatient in the hospital? Because what is the downside? If require patients to be inpatient again, we are going to protect the public. If we don't require them to be inpatient, we are just saving a little money for the insurance companies.

And that is why I think this is an issue that needs to certainly be addressed. Thank you.

MR. CARPENTER: Thank you.

Okay. The next caller, please.

OPERATOR: At this time, sir, I am showing no further questions.

MR. CARPENTER: Thank you.

The last time around the room.

(No response.)

No comments?

No one else on the telephone?

OPERATOR: No questions at this time, sir.

MR. CARPENTER: Okay. Very good.

Well, I would like to thank everyone for participating this morning. Since we have had several comments and everything, we have gone around the room a couple of times, I would like to go ahead

and break for lunch at this time.

The schedule, the agenda has us breaking for lunch until one o'clock p.m. this afternoon, at which time we will restart with the Guidance for Released Patients. As opposed to the agenda here, if we finish that topic early, we will just go ahead into the last topic of the day, Brochure for Nationwide Use, and the Conclusion. For people who need to get home here locally and deal with weather conditions, et cetera, we will make sure that they are able to get out.

Again, I do appreciate everyone on the telephone for your participation. Please, if you are able, rejoin us at one o'clock.

At this time, we are going to break.

Thank you very much.

(Whereupon, the foregoing matter went off the record for lunch at 11:36 a.m. and went back on the record at 1:01 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:01 p.m.

MR. CARPENTER: This is Gene Carpenter. I am the NRC Facilitator for this workshop today.

Thank you for those of you who have joined us from the morning and welcome to those of you who are just now joining us.

We do have several people here in the room. This morning we went through two topics of significance, Website Information and, also, an involved discussion on Patient/Licensee Acknowledgment Forms and Best Practices on Making Informed Decisions on Releasing Patients Treated with I-131 Based on Radiation Exposure Considerations. No, I cannot say that in one breath.

This afternoon we are going to be talking about the Guidance for Released Patients. And then, we will roll over into the Brochure for Nationwide Use, and Conclusions.

This meeting is being transcribed. For those of you on the telephone, whenever we do go to asking for comments from the public and we ask for anyone to *1 to speak on the conference, you have the option of giving your name or being anonymous. You

can do either. We don't require your name. It is purely up to you.

At this time, I would like to turn this over to Dr. Howe for the presentation on Guidance for Released Patients.

DR. HOWE: Thank you, Gene.

This is Topic No. 3 of four topics that we are gathering information on I-131 patient release. This morning we talked about website information, which is basically the kind of information a patient might want to find just as they are being diagnosed or find out more about the disease, more medically-oriented; some oriented with radiation; I-131, what is it?

We also talked about Topic No. 2, which was, more or less, a discussion that the patient or licensee have prior to the actual treatment, so that different information can be exchanged.

And this is Topic No. 3, which is essentially the guidance that is provided for patients that are going to be released. Now these could be patients that are released immediately after receiving their I-131 or they could be patients that are released after they have been held in a hospital for a day or two, or possibly only delayed for a few

hours before they are being released.

This morning I made it clear that we are not only talking about thyroid carcinoma patients, but we are also talking about hyperthyroid patients because the hyperthyroid patients do retain more of the I-131 for a longer period of time, even though they get a lower dose.

We also talked this morning about there is a delay between the sound coming through, if you are listening on the telephone, versus the slides, if you are watching on the webinar. So, there is a disconnect there of about 20 seconds and, hopefully, you will bear with us on that. That is a technical thing that cannot be resolved.

Okay. Guidance for Released Patients. What are we asking for? We understand the standard guidance to reduce the variability of instructions provided to patients and eliminate some of the uncertainty in the type of information provided.

So, if one is looking at standardizing guidance, one can go in one of two ways. You can be very prescriptive where you say exactly what the guidance is and there really is no departure or deviation or you can approach it as we are approaching our regulations now, and that is more performance-

based.

In performance-based there are certain goals that should be met or things that you want to achieve. In order to be performance guidance for releasing patients, we think that there are probably certain tools that patients will need or methods that they need to follow, so that the guidance objectives can be met and so that patients can protect others.

That is kind of the main thrust of what we are looking at. We are looking for people's own experience. We are getting information from patients, individual physicians, facilities, professional societies, patient advocacy groups, our Advisory Committee on Medical Isotopes, and also other interested individuals.

We are looking for people's personal experience. If you are going to send us your checkoff list or you procedures, please put it into context. Give us a little bit of information about how you use the document. Give us maybe a sentence or two as to how this document fits into your releasing patients and your discussion with the patients. And that is a general overview of the type of information we are going to be asking for in this particular topic.

The other thing I should point out is

that we have a number -- all of this comes from our Federal Register notice where we indicate the information we are looking for and where it can be sent. We have different bullets or topics, and we are not under the assumption that our bullets are the only bullets or they are the best topics. And so, we are asking open-endedly for people to tell us if they think there are other things that ought to be addressed in the Guidance for Released Patients or whether we have addressed things that they don't believe are that important.

And please explain why they should be in there or why they shouldn't be in there. We are also asking for a time element as to when this guidance should be provided to patients.

So, that gives you a general overview. Particular questions can be looked at from The Federal Register notice. If you don't have it, I have information later on where you can obtain it.

At this point -- oh, I have another slide here. Okay. So, we are asking you to provide your guidance documents that you believe provide clear instructions. And for patient input, we want to know when should you be provided these instructions? Were they easy to understand and follow? What would make

them better? When should the instructions be provided? So, those are the general kinds of things we are looking for.

And I believe we can open our discussion now.

MR. CARPENTER: Very good.

Now, as we did this morning, what I will do this afternoon is, for this topic, we will go around the room, ask the participants here in the room if they have any questions or comments. Once we have gone around the room, I will, then, go to the telephones and ask for comments from people that are on the telephone.

Again, for those who are on the telephone, you do not have to give your name. It is entirely up to you whether or not you wish to remain anonymous.

At this time, let's go and open it up for the floor here in the room. Does anyone have comments?

MR. BLOOM: Thank you again for this opportunity.

I apologize, I feel like I am oversimplifying this, but I feel like we have covered a lot of good ground this morning which touches on

this.

As Dr. Ghesani said, I think that instructions should be handed out two to three weeks in advance. That is when the initial instruction/communication should happen about this topic, and the perfect opportunity, at least, again, from a thyroid cancer standpoint, is when discussion will happen about the low iodine diet. So, it is a perfect opportunity to say, "Here's what is in front of you. And now, let's really delve into these instructions about what you need to do before we get to the dosing and, then, what we are going to need to do during it," as the other doctor mentioned in his comments, and then after. I like that sequence of before, during, and after, breaking it up in that fashion -- and that is at a high level -- and then, getting into more of the details.

Again, as we mentioned earlier, any instruction has to be carefully assessed from an understanding level or simplicity level, but, then, there has to be a comprehensiveness or a thoroughness to it. These instructions can't be so simplistic that they miss points that are very important.

You know, where are you going to stay? What kind of home life do you have? Those are

questions that need to be discussed in advance of dosing because you may have to postpone dosing, and you would rather find that out before the facility has purchased the isotope and before the person has gotten sort of mentally anguished over what is in front of them. And now, at the last moment, it is like we don't have a plan; you don't have a plan. We no longer have flexibility to account for the lack of planning that all of us collectively failed at.

So, I really like Dr. Ghesani's thought process of broaching this early enough that there is opportunity to work through hurdles. And that is a normal, to me, that is a normal byproduct of any interaction, that there are always complications, but especially when you are talking about radiation. So, comment again the doctor for his thoroughness this morning.

So, that is all I wanted to share at this time.

DR. HOWE: What is your experience from being a patient advocate as to the spectrum of the time on giving released instructions?

MR. BLOOM: Sorry, I'm laughing. The spectrum goes from that very advanced notice to the patients we meet after the fact who say, "Well, the

first conversation we had about what was in front of me was when it was behind me."

I am not here to question the medical facilities and I don't know which ones these patients were necessarily talking about. There is always room for confusion. And the idealist in me will say that it is hard to believe that a patient was dosed and, then, talked to about precautions and pathways to where they were going to go and how they were going to get there. So, I hope that is not the case, but I don't think people would make something like that up.

It is this idea of the worst scenario would be no conversation until after. That is the definitely the one that has to be addressed most proactively. But I think that all of these situations should be addressed as, again, the doctor was good enough to share with us, let's be as preemptive as possible. Let's give as much opportunity to build a plan, a roadmap, before we even go into any danger points.

Of course, equally, there is always a chance that, once we go down that path of planning for radioactive iodine treatment, that the physician and the patient will ultimately decide that it is not

necessary. So, that also is part of that upfront discussion.

At least in the olden days where we would have a small dose of RAI to determine if there was going to be uptake, it was very much more likely that there would be a chance you would not go down the treatment path. But I think it still is the case that that can happen.

So, actually, for the patients, to make them understand you may not ultimately have a treatment, and up until the last minute, we could go down that decision path as well. I think it is important to make the patient understand all of the circumstances. And then, of course, if you don't have treatment, there is no guidance as far as how to release a person because it is just, "See you later."

In a certain sense, that is the best we could hope for as a patient, but that won't address any health condition if there is a need. So, really, relative to this discussion, I guess that part is too optimistic.

I don't know; I think I sort of went around your question rather than to it.

DR. HOWE: Thank you.

DR. GHESANI: So, these are important

points. There is an opportunity here. Typically, in a thyroid cancer surgery, after surgery the recommendation is to wait for about six to eight weeks before you administer the radioiodine because that is where all the postoperative changes are resolving in the neck and you don't want to administer it at a time when it goes to the target area and, then, remains near the thyroid gland and potential micrometastic lesions is not optimum.

So, recommendation -- and almost everyone agrees on it -- if you find some variations in the pattern, there is not much controversy about the time. Most people will recommend that, surgeon after surgeon will say, "Well, I will refer you to the endocrinologist," but they will tell you that you will wait for about six weeks, after which you receive your radio iodine. That gives us the opportunity to really work ahead of time.

So, instead of telling the patient now six weeks, "Come back in six weeks and we will start working on it," I think that is when the patient should see an endocrinologist, but also potentially see a nuclear medicine physician or a nuclear radiologist and start having a consult that will include the planning, proper planning, understanding

their individual situation that may impact how they will follow the contact restrictions, and start other processes. You know, their supplements start going in, so they are on Synthroid or Cytomel treatment. They start their low iodine treatment.

And all of that will offer the opportunity to avoid some of the unusual instances we heard about where things went wrong after the treatment. The instructions were very short. There was not enough notice. The location or patient didn't have enough knowledge to follow the instructions. So, that is one part.

I think if we come up with a way to make sure that right after surgery the treatment plan starts, not six weeks after, even though eventually the treatment will be given six weeks later, that doesn't mean you just don't do anything for those six weeks and let that opportunity slide by. So, that is one part.

The second part, as I was hearing more about this, I think the important thing here will also be to make sure that our other clinical sub-specialists are also on the same page. So, I have heard anecdotal examples of where the patients may receive one set of instructions from the clinicians

and, then, those instructions, when they come to the nuclear medicine physician, are quite different.

And there is always that difference in the expertise and the experience that goes with treating patient one after another and on a regular basis treating many patients. There is some set of experiences that the nuclear medicine physicians will have and the knowledge and background of the radioactivity and some of the physics of radiation which is going to be much better handled by the radiation physicists and nuclear medicine physicians within their department, as opposed to the clinicians.

No doubt, clinicians, many clinicians are very tuned into it and they are well aware of what is the impact and what kind of background information they need to provide to their patients, but I think it would be nice upon our imaging and treating community to make sure that we partner with our clinicians and provide all the necessary information, not just to the patients, but also to our clinicians as well.

And then, the third point, which was already elaborated, is that the latest guidelines that came out from the American Thyroid Association,

over the period of time we have learned the evolution of the thyroid cancers and we have learned that there are instances in which the patients may not necessarily need iodine treatment. That would be, also, as important a consideration as giving the treatment itself. That would be a very important discussion that should take place between the surgeon, the endocrinologist, and the nuclear medicine physician.

And the first question, really, you know, when we discuss and train the residents, we usually tell them, "Before you even go to the step of" -- as you know as part of the NRC, we have to do the attestation. We have to show there are six treatments, and they have to participate in the plan. But, before we even go to the plan, we ask them the question, "First, decide when you don't need to treat and, then, only focus on how you will be treating it." And that is very well laid out in the most recent guidelines of the American Thyroid Association that came out. We should be mindful of the fact that there are instances where we may not need to give the treatment in the first place.

MR. CARPENTER: Thank you.

Any other comments?

(No response.)

No? Okay. Very good.

Let's go to the telephones. Operator?

OPERATOR: Thank you.

The first question comes from No. 7.

You may ask your question.

ANONYMOUS: Yes. Regarding the educational process, you know, when should that be done with a patient, obviously, that should be done ahead of time for several reasons. The patient has to make special arrangements, and that has to be taken into consideration.

Also, a patient will go with all the information and, then, all of a sudden, while they thought they understood, while talking to the authorized users, or whatnot, all of a sudden, they have some sort of a confusion about something. They are not quite clear about something. And therefore, they might have additional questions that might require some clarifications.

Also, things might have changed in their life, whatever that might be. And all of a sudden, now that could be a hurdle, and they need to sort of get back with the user and say, "Oh, by the way, here's what going on in my life here, and how do I

deal with this with my treatment per se?"

Maybe the patient needs to be educated about some sort of like a deadline. "Well, we know you might have a question. However, here is the thing: we need to wrap up this by this date because we will order the source, and therefore, there is a cost associated with it. Therefore, after that, you really cannot change." Of course, you can always change it, but there are consequences associated with that as far as the financial burden of the institution or patient, or whatnot. And I think this has to be probably addressed with the patient.

And that's all I have for a comment.

MR. CARPENTER: Good. Thank you very much.

The next person.

OPERATOR: At this time, I am showing no further questions.

MR. CARPENTER: Very good. Go around the room one more time?

MR. BLOOM: Dr. Ghesani, you mentioned how the doctors or the medical professionals have to work across their areas of expertise, and I agree that I think that is very important. As we try to

brainstorm about ways to improve this process, one of the complications that I can think of is when the patient is working across medical centers or out in the community, as opposed to within a center where all of the specialists -- forgive me -- have coffee together, you know, work together routinely.

So, the process is easier in that one environment than in the other environment, which I don't know statistically, but I am guessing is more frequent, that people's doctors are not in the same institutions. And I think somehow that thought process has to enter in. And how do you get people on the same page when they are not working together as a routine?

DR. GHESANI: I can answer that. In fact, there is some good news on this front, which is that in many centers -- first of all, there is a trend for what is called multidisciplinary approach. And that is not just unique to thyroid concerns; it is happening in almost every cancer.

So, on a weekly basis, we have on an average about 20 to 30 multidisciplinary conferences that are taking place. Within each department, we come with a plan and say it is humanly impossible for any one person to attend all of them. What we do is

for every department we decide what are your interest areas and what are your capabilities for attending these conferences. On an average, it turns out maybe in my case about three to four a week is what we end up attending.

So, in those conferences any particular case that is anything out of the ordinary in terms of there is no super treatment and you can just treat it, and if that is not the case, if any case requires more input from the other departments, those cases are discussed at multidisciplinary approach.

And national organizations actually encourage, and if you have accreditation from them, they actually come and audit the number. So, there is a cancer registry, for example, and if you are part of it, they will come and ask you how many of your total number of patients you end up bringing up for discussion at the multidisciplinary conferences.

So, that is actually good news. In fact, just in the break time I was looking at my email, and I got an invitation for one next week which was about thyroid cancer. We usually try to arrange it at a time when most people agree that that is convenient for them to come and attend. So, that is the good news.

Now the other good news is that in this changing paradigm we find that there are many, many centers that are able to join in even remotely. So, there are instances where you may have conferences very similar to here where you have a few people in presence physically, but, then, you have input from others joining in remotely as well. So, we do the webcast. We do the multidisciplinary conferences that are attended by other hospitals remotely.

And that actually is also a new paradigm which I strongly support because now it actually maintains the level of care across the system. It is still not at its fully-mature state yet. I think that would be an important part in going forward in terms of management of patients, is that if there is either direct or indirect access to bringing a case discussion and asking the other departments before we actually deliver the treatment, I think there are a lot of benefits to that approach.

MR. BLOOM: I definitely agree with that. Is that also into community caring physicians?

DR. GHESANI: So, as far as I know, what it turns out to be is that if the community caring physician or that community hospital has affiliation, either direct or indirect, with the larger

institution, then that often becomes available. I'm not sure about what would be happening in a remote area in a community center which does not have that direct or indirect access. I think that there might be still an action to call for a consult and ask for an opinion for a case.

MR. BLOOM: Well, it certainly sounds like that is addressing most of the concern. My guess is that is not going to satisfy in all ways.

I think of, as an example, the patient who goes to MD Anderson for their surgery but lives in Nebraska and decides to work with a local endocrinologist and nuclear medicine treatment center. They are probably not going to have a collaboration of that same measure that you are speaking of. Hopefully, the two local physicians will put their heads together, though, to at least get on the same page between them.

DR. GHESANI: Right. I am glad you mentioned that because that also brings up a point you mentioned earlier when we were having a discussion about patients being equally involved and being a partner in their care.

MR. BLOOM: Yes.

DR. GHESANI: And there is a win/win

benefit to that. In that example, if the patient already had the care at MD Anderson and was aware, and potentially may even have had a consult with the nuclear medicine physician about what they feel, whether this patient needs the treatment or not, if the patient or the family members all together coordinate that communication between the two institutions, even if the treatment is delivered remotely, at least whether the patient needs the treatment or not, and if the patient does, what level of treatment is needed, those are all the points that are agreed upon, sometimes brokered by the patient or their family members. There is still an improvement opportunity for delivering that care as opposed to delivering it in isolation. So, there is clearly valuable to deliver.

MR. BLOOM: I agree. Thank you.

DR. GHESANI: Sure.

MR. LICHTY: Yes, I have a question that might be a little bit off-topic. But as far as releasing patients, is there consideration for some of the other side effects of taking the radioactive iodine, such as, well, one of the major ones is that your salivary glands are affected? Most people, it is just suck on Lemon Drops or something like that.

But I think we have heard from some people in our group that people have more severe reactions, and I wonder if that is a consideration in whether you even remain hospitalized or not.

DR. GHESANI: So, I can answer that. In addition to the Lemon Drops, I think hydration is a very, very important part that it plays. Mainly, it increases the output, and the retention of iodine in the salivary glands is shown to be lower in the more hydrated state. It also increases the likelihood of faster excretion of the iodine that does not end up in the target areas.

The third advantage is that the urinary bladder that is going to end up receiving significant amount of dose, the hydration also will encourage the patients to have frequent voids. That will decrease the potential radiation dose to the urinary bladder, too. So, there are multiple levels at which the hydration really plays out its benefits.

In our case, what it turn out is that we get to see the patients on the followup, too, when they come for their post-ablation scans as well as on their subsequent exams. We often make it a point to ask them, you know, if you followed the instructions appropriately; was the side effect a significant

factor?

It turns out that the other good thing that happens is that at multiple levels patients get the reminders about this. So, the technologist will tell them. The radiologist physicist will remind them. The physicians will remind them.

As a result, it becomes very apparent to the patient that they should be following those guidelines. If they do, we find that really that side effect is very minimal. In fact, I often hear more about just the annoying taste, and I'm sure you can tell me, there is a metallic taste patients mention. That becomes often factor than having the problems with the salivary glands.

And the other thing that I hear often from them is that, when they stop their low iodine diet, that is their first time to rejoice when they go to the regular diet. And then, the second time they mention is about a few weeks after the treatment when that metallic annoying taste goes away. And then, they feel so much better in terms of enjoying their meals. So, that is what I hear from the patients more often.

MR. BLOOM: I really like the fact that you said you follow up with "Did you follow the

instructions?" I like the swinging back on that loop.

When I think of the comment made earlier today about having pre-instructions, during instructions, and post-instructions, to actually evaluate after the fact how did we all do, and you and I talked about this concept of it is a collaboration. So, how did we do? Did I get my message across as the instructor to the physician? And did I, as the patient, follow those instructions? I like that because that gives you feedback really to know, if there were any problems, where did they manifest from? And then, also, what do we need to change within your institution, within your process, and then, also, for the greater good? So, I like that, the feedback loop. I think that is a really excellent extra step.

Thank you.

MR. CARPENTER: Very good.

Personally, I started my low salt diet when I left the military.

But let's go back to the telephones. Anybody on the telephone?

OPERATOR: At this time, I am showing no questions.

MR. CARPENTER: All right.

DR. HOWE: Do we have anybody on the telephone that is from a smaller facility or a private practice that may want to make a comment?

OPERATOR: And once again, if you would like to ask a question or you do have a comment, you may press *, then 1.

One moment.

(Pause.)

DR. HOWE: So, just to repeat, do we have anybody on the phone that is from a smaller facility or a private practice that would like to make comments?

MR. CARPENTER: We will give it a moment.

OPERATOR: We do have a question online at this time. The question comes from No. 8.

You may ask your question.

ANONYMOUS: Hi.

OPERATOR: Your line is open.

ANONYMOUS: Hi. I'm starting my RAI treatment the first week of February. And I can honestly tell you that all I have been given is the date to go in.

MR. CARPENTER: I'm sorry, you said all that you have been given is the date to go in?

ANONYMOUS: I have no idea that I'm supposed to do anything to prepare for isolation. I don't know of any restrictions, what I should do with my family, what I should do with anything in my home.

MR. CARPENTER: You are hearing feedback from the session. Go ahead.

ANONYMOUS: Can you hear me?

MR. CARPENTER: Yes. Thank you.

ANONYMOUS: Okay. Basically, what I was given is the date to go in to start my RAI treatment, and I know nothing until I go in that first day. And that is really not enough time for me to prep. I have four children in my home. I have three pets. I have a husband who works 70 hours a week. I have no idea of anything, and I don't understand why. And I am in northern Kentucky and this is UC Radiology Nuclear Medicine Department I am going to in Cincinnati.

And it just seems not feasible to me that I would be sent in, that I am going to be starting treatments, and I have no idea how to prep.

MR. CARPENTER: Okay. Thank you.

Anybody in the room like to make a comment on that?

DR. GHESANI: So, I mean, I just want to

be sensitive to your personal health information. From that standpoint, I will just make a comment. You don't need to answer me.

But my comment would be that in many ways, well before your treatment there are different settings in which you have to visit the nuclear medicine department, including getting your setup for the Thyrogen injections and all of that. So, I am not sure if that applies to you or not or whether you were on withdrawal.

But, as I mentioned, you don't need to give more details, especially if you are not comfortable describing it, because I understand it is your own personal health matter. But I would recommend you go back and you call them and ask for an appointment to see a nuclear medicine physician. And then, also, you should inquire regarding your schedule for the Thyrogen injections because, typically, at least for two days in a row before you actually will receive your treatment, you will be visiting the department for the Thyrogen injections. So, I recommend that you should make a phone call and ask them to even meet with you even before you receive your first Thyrogen injection.

ANONYMOUS: I am scheduled for the

Thyrogen injections. However, my point is my endocrinologist told me there is no isolation necessary, from his understanding. He said that medicine has evolved and we have moved on; it is not the same RAI treatments as in the past.

Yet, when I called the Radiology Department to ask what time I come in for my Thyrogen injection and asked about isolation, they said I wouldn't know that until my dose on Thursday. That gives me no time to prepare. Is that normal?

DR. GHESANI: Actually, you are correct, especially given your family situation you described. I would recommend -- you still have about 11-12 days. I would recommend that you insist on making an appointment and wanting to see the physician in advance of actually receiving the treatment.

MR. CARPENTER: Okay. Thank you, ma'am. We appreciate that.

Anything else that you would like to share?

(No response.)

Okay. Thank you.

Operator, do we have anybody else on the line?

(No response.)

Hello? Christine?

OPERATOR: Thank you. We do.

No. 9, you may ask your question.

MR. CARPENTER: Thank you.

ANONYMOUS: My name is Ralph Lieto. I'm a medical physicist, and I have been involved in nuclear medicine for over 30 years.

I wanted to address Dr. Howe's inquiry about smaller settings in terms of how they handle iodine therapies. I have worked both in a large urban medical center that was a broad-scope licensed as well as in a community setting. I think the experience that your patient advocate was talking about earlier and somewhat the patient before I got on the line is typical of what happens.

Usually, the nuclear medicine department will not know much about the patient's history until they are referred by the endocrinologist. That can be just a matter of a few days or a week, and they aren't going to know anything until they do an uptake.

So, even though Dr. Ghesani makes some very good suggestions as to what should be done as a long-term preparation, and so forth, very often in a community setting you don't have those kinds of handoffs. Most of these settings do not have a

medical physicist on staff. All the interactions are done between the patient and the nuclear medicine technologist.

And so, the long-term or, in fact, two-week preparation that he was kind of suggesting might be ideal, but I think as you get farther out of the urban setting where you don't have the sort of close collaboration between your endocrinologist and your nuclear medicine and radiology staffs, those handoffs and the timeframes between the patient presenting to the nuclear medicine department to begin their assessment and treatment become quite short.

In some settings, because of patient preference and travel and other things, they will do the uptake. And then, in a matter of a day or even sometimes the same day, administer the radioactive iodine based on the uptake that was done earlier in the day, simply to minimize patient inconvenience.

So, it is a little bit different, and I think that is the more common scenario as you get into the strictly urban -- or excuse me -- community settings where you don't have dedicated nuclear medicine physicians that just do nuclear medicine. There may be a radiologist who is also doing radiology combined with his nuclear medicine practice, and you

don't have medical physics on staff.

Thank you.

MR. CARPENTER: Thank you for those comments.

Do we have anyone else on the line?

OPERATOR: We do. The next question comes from No. 10.

You may ask your question.

ANONYMOUS: Yes. We talked so much so far about a one-way street in a way. At least that is my perception. I think the patient that just called in, and she brought up her case, makes a very important reason for us to talk about what are the expectations from the patient.

What I mean about that is that there should be some information available to them in terms of what to expect going into this type of treatment. And when you go to the institution, request the educational material, the radiation precautions, the instruction after discharge, and so on and so forth.

I think the patient should go with that list in hand, and they are entitled to that information if they are going to go through that kind of a treatment. So, I think the patient should have that available and ask those questions prior to going

through the treatment.

And if they don't get the answers, then I think they ought to perhaps look elsewhere where they will feel more comfortable getting their treatment, as it should be.

Thank you.

MR. CARPENTER: Thank you very much. Good comments on informed consumerism there.

Christine, do we have any others on the telephone?

OPERATOR: The next question comes from No. 11.

You may ask your question.

ANONYMOUS: Well, okay. I am also a new thyroid cancer patient, and I also am starting my radioactive treatment on the 3rd of February. I am going to have the Thyrogen shots, one and two, February.

But I also have not been given any information on how to prepare for this isolation. Now I have gone online myself and found some numerous sites that are helping me, but I am just wondering, is there a way that you are going to be able to -- I don't know how to say it -- police it up, go behind? How are you going to regulate whether the patient

ever gets any information? Because it sounds like there are a lot of patients who never get any information, and that doesn't seem right.

That's all I have.

MR. CARPENTER: Thank you.

Doctor?

DR. HOWE: In regulatory space, we probably won't be able to write specific regulations in that regard, but we can provide guidance to our authorized users. And we are hoping that our website that will send people to other sites to collect information may make for more informed patient consumers to know to ask the questions and to go to the licensees and ask for more.

It is very difficult for us to write prescriptive regulations, and it takes years. So, we are hoping to address some of these issues in clear and concise guidance.

MR. CARPENTER: Does that any your question, ma'am?

ANONYMOUS: I guess so. Thank you.

MR. CARPENTER: Thank you.

Christine?

OPERATOR: At this time, I am showing no further questions.

MR. CARPENTER: Okay. We will go around the room one more time.

Yes, sir?

DR. GHESANI: Yes, I think hearing these comments, it looks like it may be something to consider on our medical practice side, to see if there could be a way for this becoming a standard practice, where just about two or three weeks prior to the actual delivery of the treatment, in addition to the patient seeing a surgeon, you know, obviously, the surgeon is doing the surgery in the OR, they are going to set up a patient for a postop appointment to make sure that the scar has healed; there are no complications. That is a given, right? You don't question that kind of a practice because you expect that to be ingrained in the nature of surgical practice.

What we don't have is a practice of seeing the patients regularly two weeks before you actually deliver the treatment. Hearing more and more about these comments, I think it will be upon the medical community to consider having that norm.

As I mentioned earlier, that also allows you to give the right timing for the patients to realize how important it is to start practicing

hydration and low iodine diet, and what the timeline of their appointment is going to be.

And then, you have a consult that goes into the details of individual patients' situations that may impact how you are going to recommend the contact restrictions and how long that will be and how severe that will be.

So, I think that, short of doing a routine two-week prior treatment consult, I don't think we can accomplish the full preparations for the patients in making sure that they don't have a surprise on the day of treatment or, suddenly, they find out that there is no way I can arrange for all my family to go away for a few days on a very short notice.

So, I think that is something upon the medical community to consider, having it a routine two weeks prior to treatment appointment in the nuclear medicine department.

And I heard about the community practices. Well, potentially, a radiologist can fill in that gap, if that is a possibility in a community hospital, maybe even a short consult, but at least it addresses all the concerns and questions the patients may have.

DR. HOWE: It also raises the gap when

we have been talking this morning about the patient being prepared for the release. But I am thinking that you also need time for the facility to prepare in case they can't release the patient.

DR. GHESANI: Yes.

DR. HOWE: So, the timeframe is important from both perspectives.

MR. BLOOM: Thank you for those comments.

I think that one of the things I am hearing is that we, as a patient organization, need to really step up our side of this and try go make sure that we have very visible and even more comprehensive materials, so that we can be there as an information portal to patients.

We don't exist to provide medical advice, but we can create medical empowerment to people who we reach which will allow them to initiate processes when they aren't aware of them routinely.

As we discussed the different aspects of how we all fit into the relationship, it is hard to prepare for what you don't know anything about. So, either, as Dr. Ghesani said, the medical community has to initiate or those of us who have walked the path before have to help try to lay it out. Either way, unfortunately, there is still some wish and

prayer here, that we are wishing and hoping that people will find us one way or another, meaning finding ThyCa or finding the Society for Nuclear Medicine and Magnetic Imaging, to find these materials which will help provide guidance when, in fact, no guidance was offered.

I am specifically thinking of these two ladies who are going to go into this process within days of each other in less than two weeks. I don't know if you have both been on the phone the whole morning, but I am sure you are more empowered now than you were earlier. There is still time to intervene now, which is the good news for you, but I am equally thinking about the people who are not part of this phone call and don't know that they have a problem. So, we need to strengthen our process all the way from all sides.

DR. GHESANI: Thank you.

I think one consideration would be for all the patient support groups, in addition to providing the information about what kind of side effects to expect or what kind of precautions or personal experiences you share with the patients who are going through it now, I think it may be important if you also mention there insist on having a prior

discussion with your nuclear medicine physician well in advance of receiving your iodine.

I think if you put that comment in, more and more patients will read that in advance, will start thinking about it. So, we can decrease the likelihood that those instances will happen in the future.

MR. CARPENTER: Very good. Fine.

One last time on the telephones, any comments?

OPERATOR: We do have a question.

No. 8, your line is open. I'm sorry, No. 8, your line is open.

ANONYMOUS: Hello. I was just wanting to reiterate, as far as treatment, I do belong to an online support group and the low iodine diet community. Without them, I would not even have known that there was possibly a necessity for isolation for treatment.

I called in earlier. I have my treatment in February.

I just want to say I think it would be divine to meet a nuclear medicine doctor prior to our treatment. Because what I am seeing online in support groups is our endocrinologists are also

giving us varied information. It doesn't seem to be regulated completely.

The diet again, everyone is told something different. We are told something different about isolation, apparently, those who are told, even though I wasn't.

And so, I think if somehow that could become a regulation, that we meet prior, at least two to three weeks, as everyone has been saying, with our nuclear medicine doctor, because endocrinologists, there seems to be some variation for the information they are giving patients, too. And it is really kind of murky and the waters are getting really muddy.

MR. CARPENTER: Thank you, ma'am.

Christine, any other comments?

OPERATOR: At this time, I am showing no further comments or questions.

MR. CARPENTER: Okay.

Shall we go on to the next topic?

DR. GHESANI: Sure.

MR. CARPENTER: Okay.

DR. HOWE: Okay. The next topic is a Brochure for Nationwide Use. The Commission thought that it would be important if there were such a brochure that could be sent out nationwide that would

give patients certain minimum information about the treatment and what they need to do to keep radiation doses to others as well as reasonable, would be a thing that might be important.

And so, what we are asking is for people out there that have a lot more experience with this than we do, do you know of a brochure or a pamphlet that you believe would be good for distribution, either by a professional society or the NRC, for nationwide use that would provide additional clarity to patients on I-131 treatments?

And so, if you do know of such a brochure, to identify it to us and provide us with a copy or a link to it, so that we would have a chance to look at it and see if we thought it was good for a nationwide distribution.

We know that there are several brochures out there from different groups. And so, we are interested in getting as wide a poll as possible for maybe other things that are not as well-known.

And I believe at this point we can open it up for a discussion.

MR. CARPENTER: Okay. Since we went around the room first last time, let's go to the telephones.

Christine, any commenters?

OPERATOR: At this time, I'm showing no comments.

MR. CARPENTER: Okay. We will come back to you on the telephone.

In the room?

MS. KUBLER: Hi. This is Caitlin Kubler with the Society of Nuclear Medicine.

We have a brochure that is available for print as well as online. It covers several topic areas that the NRC is seeking information on. Perhaps we can amend that to include some of the other areas.

But, just to start, it includes what is radioiodine therapy? How long does it stay in the body? How can you reduce exposure to others? And then, it talks about the first eight hours, the first two days, the first week. And then, it also talks about specific recommendations for those who are breastfeeding and pregnancy. And then, it also talks about what you should know during the first week of your treatment.

And there also is a caveat on there for every specific case is different and you should meet with your physician to talk about your specific

situation because, although we can provide general guidance, we can't talk to every specific case. As Dr. Ghesani has mentioned before, those are conversations that you should have with your physician.

We will be happy to provide that in our formal comments, and I will be happy to share the link. That is easily accessible on our website and can be searched, and there is no cost for it. It is provided free.

MR. CARPENTER: Sorry, could you give your website for the people who are on the telephone that may want to look at it now?

MS. KUBLER: Sure. It is snmmi.org. And then, you can just search "patient materials," and it will be under the radioiodine section, the fact sheet.

MR. CARPENTER: Okay. Thank you.

Any other comments in the room?

(No response.)

Okay. Back to the telephone. Any commenters on the telephone, Christine?

OPERATOR: Yes, sir, we do.

At this time, No. 9, your line is open.

ANONYMOUS: This is a question for NRC

staff. What is the end purpose that you are looking to achieve here? Are you looking for a singular brochure? And who would be the entity that would be responsible for this? Is this going to be an NRC document or are you looking to have some professional organization sort of develop, or I mean distribute this and be responsible for its update? Or are you looking for multiple brochures?

DR. HOWE: At this particular point, we are collecting information. I think the Commission in its direction to us was thinking in terms of if there was a brochure that could provide good, basic, clear information to patients, that that is something that we may want to support, to help provide clear and concise information.

So, the actual specifics of whether NRC would distribute it or we would put links to it, that particular part has not been decided yet. We are still in the information-collection mode.

And we are hoping people have things that they like and they will tell us about it.

MR. CARPENTER: Does that answer your question, sir?

ANONYMOUS: Yes. Thank you.

MR. CARPENTER: Very good.

Anyone else on the telephone?

OPERATOR: The next question comes from No. 10.

You may ask your question.

ANONYMOUS: A question regarding the Society of Nuclear Medicine website. If a patient has a question or requires a clarification, who would be handling that?

Thank you.

MS. KUBLER: Well, we don't like to get in the practice of intervening with a patient and their instructions. We advise that patients contact their physician directly for specific instructions.

DR. GHESANI: Actually, your question does bring up an interesting point, which is that, as Caitlin mentioned earlier, we are open at SNMMI to update this document as needed. I think it may be a worthwhile practice to have, that those organizations that are directly dealing with treatment, radioiodine treatment of patients, both for hyperthyroid and for thyroid cancer, can work with the patient groups.

And then, it will be actually very rich material that can come out of it because, on one hand, the Society for Nuclear Medicine does provide the data that is from the professional side. But we

always have learned that many things that science mentions are not ultimately what we hear from the patients.

And patients' experiences, maybe there is a potential for adding some additional instructions that may be even more beneficial. So, I think it may be an ongoing dialog. You know, we have our Societies' meetings where we do have sessions for the patient support groups. And maybe we can create a group, a larger group, which covers both professional organizations and patient support groups, and they can all come on the same platform, whether by call or any other means. But we can work together to refine and update this document as needed.

The other question that came up on the phone was, who will be in charge updating it, right? You know, the document, as good as you refine it, may only be relevant now. If things change in the future, it may lose its relevance. So, it needs to be constantly updated as well.

And we do have our committee that looks at these documents, but I think it will make it richer if there is a partnership with the patient support groups as well on it.

MR. BLOOM: Certainly, we would welcome

the opportunity to work in such a collaboration. We have created materials in collaboration with medical specialists across the disciplines, as you have mentioned earlier. We would welcome this opportunity to help enrich your product and also to distribute it. We distribute materials worldwide free of charge, as well as making them available for download from our website.

So, we are very enthused about the opportunity to partner with you. I mean, we would be coming to your members anyway because this is a product that would require medical validation. So, to actually initiate it out in the open, it is perfect.

And to the gentleman who was speaking for the community side, we would want your participation as well because I think that is an important perspective as well.

MR. CARPENTER: Caller on the telephone, did that answer, if you are still there?

ANONYMOUS: Hello?

MR. CARPENTER: Yes?

ANONYMOUS: Yes, I think that answered the question. Thank you.

MR. CARPENTER: Thank you very much for

the comment or the question.

Christine, any others on the telephone?

OPERATOR: At this time, I am showing no further questions.

MR. CARPENTER: Okay. One more time around the room, any other comments?

(No response.)

No more comments in the room?

One more time to the telephone.

OPERATOR: Showing no further comments.

MR. CARPENTER: Okay. Let's go to the next one.

DR. HOWE: So, that takes us to closing of the meeting. The most important thing I can say to you is that the submissions are due to the NRC on February 16th, 2016. We have heard a lot of important information here, a lot of important concepts here. But, in order for us to respond to it adequately, we need you to submit your information to us on patient release in a formal manner.

If you have questions on electronic submissions -- and this information is in The Federal Register notice -- then you can contact Carol Gallagher. Her telephone number is 301-415-3463. Her email is carol.gallagher, G-A-L-L-A-G-H-E-R, @

nrc.gov.

If you have technical clarification or questions, you can contact me. My telephone number is area code 301-415-7848. Again, that is 301-415-7848. And my email address is donna-beth, D-O-N-N-A, hyphen, B-E-T-H, .howe@nrc.gov.

If you need a copy of The Federal Register to see exactly the information that we are hoping to collect, then just contact me and I will send a copy of The Federal Register notice to you.

How do you submit information to the NRC? You can submit it electronically by going to the website http://www.regulations.gov. Search for our docket number, which is NRC-2015-0020.

And if you are not electronically comfortable, you can send things; you can mail information and comments to Cindy Bladey, the Office of Administration at the Nuclear Regulatory Commission, and her mail stop is OWFN, One White Flint, -12-H08, at the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001.

Are there any other questions that you have for NRC or that you would like answered by us or members on the phone?

MR. CARPENTER: And we will go to the

phone first.

OPERATOR: Once again, if you have a question or a comment, please press *, then 1.

One moment.

(Pause.)

At this time, sir, I am showing no questions.

MR. CARPENTER: Thank you very much, Christine.

Anyone around the room?

DR. GHESANI: I just want to congratulate both of you and NRC. This is a wonderful initiative. This is something that brings up the points about how our patients, our medical community, and our regulators can work together to improve the care.

I am sure many of us have heard the individual experiences as well as the general trends and the differences in the practice patterns throughout the country. I think something like this, to have it in a forum like this, is very refreshing to see.

So, thank you and congratulations.

MR. CARPENTER: And thank you for your participation in this.

Anything else?

MR. BLOOM: I will add my thank you as well. I think it is a great opportunity to connect both with the NRC people, who have great interest in our health as far as this matter is concerned -- so, thank you for that -- and, also, to connect with the medical professionals, both as associations and as individuals. It is a great opportunity to meet and to initiate the opportunities for collaboration, which will benefit everyone.

So, thank you all for putting this together.

MR. CARPENTER: And we do appreciate both the medical community and the patient advocacy committees coming in and talking and giving us this feedback, as well as all the people on the telephone.

Let me go one more time to the telephone. Any other comments on the line, Christine?

OPERATOR: At this time, I am showing no further comments.

MR. CARPENTER: Okay. Christine, thank you very much for all the assistance that you have done today. You have been wonderful.

To the people on the telephone, thank you very much for your participation and for all of your questions and comments.

On a very personal note to those patients who called in specifically, I wish you the very best and a very speedy recovery. Hopefully, everything will work out very soon.

At this time, again, I reference you to both the regulations.gov website and to the materials that Dr. Howe has put out on our website previously.

Please provide any questions/comments that you have to us in as timely a manner as possible.

Thank you very much for your participation again.

With that, I would like to go ahead and conclude the meeting.

Donna-Beth, thank you.

Thank you all.

OPERATOR: This concludes today's conference. Thank you for your participation. You may disconnect at this time.

(Whereupon, at 2:10 p.m., the meeting was adjourned.)