Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Meeting of the Advisory Committee on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Friday, October 9, 2015

Work Order No.: NRC-1942 Pages 1-262

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

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

FALL 2015 MEETING

+ + + + +

FRIDAY,

OCTOBER 9, 2015

+ + + + +

The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Bruce Thomadsen, Ph.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

BRUCE R. THOMADSEN, Ph.D., Chairman

PHILIP O. ALDERSON, M.D., Vice Chairman

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

STEVEN R. MATTMULLER, Nuclear Pharmacist

MICHAEL O'HARA, Ph.D., FDA Representative

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

JOHN J. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Nuclear Medicine Physicist

Non-Voting: DARLENE F. METTER, M.D.

Member-Elect: ZOUBIR OUHIB

NRC STAFF PRESENT:

STEPHEN G. BURNS, Chairman, U.S. Nuclear Regulatory Commission

JOSEPHINE PICCONE, Ph.D., Director, Division of Material Safety, State, Tribal and Rulemaking Programs

CHRISTIAN EINBERG, Acting Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, Designated Federal Officer

SOPHIE HOLIDAY, Alternate Designated Federal Officer, ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

STEVEN BAGGETT, COMM/OCM

TAMMY BLOOMER, COMM/OCMWO

JACKIE COOK, R-IV/DNMS/NMSB-B

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

ANTHONY DELAMOTTE, NMSS/MSTR/MSEB

CASSANDRA FRAZIER, R-III/DNMS/MLB

MICHAEL FULLER, NMSS/MSTR/MSEB

ELIZA HILTON, NMSS/DSFM/IOB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

ANGELA McINTOSH, NMSS/MSTR/MSEB

JOHARI MOORE, COMM/OCM

JAN NGUYEN, R-I/DNMS/MB

KEVIN NULL, R-III/DNMS/MLB

DIANE RENDER, Ph.D., NRR/DORL/LPL1-1

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

JULIAN SESSOMS, NMSS/MSTR/ASPB

JOANN SIMPSON, CFO/DPB/BOB2

ZAHID SULAIMAN, R-III/DNMS/MIB

TORRE TAYLOR, NMSS/MSTR/RPMB

SHEENA WHALEY, NMSS/MSTR/RPMB

MEMBERS OF THE PUBLIC PRESENT:

BETTE BLANKENSHIP, American Association of Physicists in Medicine

ANDREW BUCHAN, Siemens Medical Solutions USA, Inc.

BONNIE CLARKE, Society of Nuclear Medicine and Molecular Imaging

CHARLES COLEMAN, Virginia Department of Health

PETER CRANE, *unaffiliated*

WILLIAM DAVIDSON, University of Pennsylvania

KAREN FLANIGAN, New Jersey Department of Environmental Protection

JAMES HARVEY, NorthStar Medical Technologies

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

KAREN LANGLEY, University of Utah

RICHARD MARTIN, American Association of Physicists in Medicine

CANDI McDOWELL, University of Pennsylvania

RICHARD PEROS, New Jersey of Department of Environmental Protection

MICHAEL PETERS, American College of Radiology

GLORIA ROMANELLI, American College of Radiology

DANIEL SAMSON, New York State Department of Health

MICHAEL SHEETZ, University of Pittsburgh

KAREN SHEEHAN, Fox Chase Cancer Center

ED TRUSKOWSKI, New Jersey Department of Environmental Protection

CINDY TOMLINSON, American Society of Radiation Oncology

CONTENTS

P-R-O-C-E-E-D-I-N-G-S

(8:07 a.m.)

CHAIRMAN THOMADSEN: Welcome back to the second day of the ACMUI meeting. We will start right away with a review of medical event reports for the Fiscal Year 2014, Dr. Ennis.

MEMBER ENNIS: Good morning, everyone. This will be the annual report of medical events. The overview, it's about the same as the year before, so no big changes going on, but we'll go through specifics. Most importantly, thank you to all the subcommittee members because they did a lot of work, including Sue, Steve, Michael, Chris, John, Bruce and Pat. We're going to go through each type of category. 35.200, unsealed byproduct materials for imaging and localization. For the fiscal year that we're reporting on, which ended September 2014, there were six events.

This is compared to two in the previous fiscal year, so we'll have to keep an eye on that to see if that's some kind of trend, but I wouldn't read too much into it right now. Of the six, five events involved the technologists failing to calibrate the dose or issues about selecting the right dose, the right pharmaceutical, and then one was a bit of a

unique one. It involved an indium scan, white blood cell scan, where a patient's blood cells, their white blood cells are extracted, they're tagged, and then the patient's blood cells are then reinfused, and then hopefully home in on the area of inflammation in the body or infection to help detect what's going on. In this situation, the technologist injected the indium into the wrong patient.

Although there's a radiation exposure thing, it makes it a medical event from our perspective. Actually, the bigger problem is the biologic contamination of infusing someone else's white blood cells into another patient. The intended recipient was presumably ill. There's not information about the medical complications, if there were any, within NMED, so we can't say, but in addition to the radiologic events, the biological were even more significant, intensely more significant in that case.

Those were the events related to 200. Any questions or comments on those before we go to the next category? For 300, unsealed byproduct requiring written directives. There were four events, compared to two the year before, so again, we'll watch that over the next couple years. One

event was a technologist selecting the wrong I-131 dose, selecting an expired and, therefore, probably not radioactive or very low activity dose. The other one was a samarium-153 dose that was extravasated, so that a significant proportion, above 40 percent, did not go into the patient, and another event was only one capsule of the two that were supposed to be given for I-131 was given, nothing really about how serious or any kind of medical results.

The first one, the extravasation, I don't know -- it's not clear if there were any reactions due to that. Any questions about that one? The last one in this series is a wrong patient one, I-131. Patient didn't speak English, and whoever registered the patient into the clinic probably gave the patient the wrong ID badge. The physician didn't, presumably, double check the patient's ID and gave the patient the wrong -- the wrong patient the I-131.

They did recognize this before the patient left, and they were able to give him thyroid blocking to prevent some of the effect, at least, on the thyroid. Any questions before we go to the manual brachy? Within manual brachy, there are 30 events in total, but some of them are 1000 events, so we'll talk about them in 1000. The microspheres and

the breast localizations are under 1000. Within 400, there are five events this year. There are four for prostates and one GYN. The prostates are significantly down from the previous fiscal year, and I would presume this is due to a national decline in the use of brachytherapy over the last few years. I suspect that's playing at least some of the role. Whether that's going to be a sustained trend or there'll be reversals is something we can talk about offline. It's more of a medical conversation.

The GYN case was a case of patient who was partially paralyzed and had, I guess, a low-dose-rate implant -- vaginal low-dose-rate implant. Then she moved, so let's go to the next slide, and the implant came out and no one noticed a significant under-dosing of the treatment site and a significant dose given to the thigh, where the radioactive sources were aligned for apparently several hours.

They checked the patient afterwards, but reportedly, she did not get any dermatitis, meaning skin reaction, from the radioactivity, and they instituted corrective action of making sure there's more frequent checks, presumably by the nursing and the radiation oncology staff when they do this

procedure. The prostate ones, there were four. Three were under-dosed, and one was an overdose. One was a calculation error, and three had to do with misplacement of the seeds. All were iodine implants, as opposed to palladium and cesium, but again, I would not really read anything into that, just probably representing the proportion of cases done by either one.

I don't think iodine is more prone to events than any other -- that wouldn't really make any sense. In terms of the more specifics of the prostates, there's a little bit of a trend, if you will, although it's only three, but there's some common theme among three of them. The first one is something called implanting of a scar tissue. The corrective action was training for ultrasound, so presumably, that means that means that someone, they implanted something they saw on ultrasound, they thought was a prostrate, and in retrospect, it was "scar tissue."

I must say, I really don't know what that could exactly be. Scar tissue in that area would not be even unusual. It would be much more than even unusual, so I'm not quite sure. But it is clear that something -- the ultrasound interpretation wasn't

done well. A second case was seeds were placed too far inferior. Again, the corrective action was training on ultrasound. Somehow, they're attributing it -- the Foley balloon was placed in the bladder, and that does help some people localize where the bladder is. They say the balloon was deflated. To be honest, I don't quite understand how that really impacted significantly on the ultrasound imaging issue.

But again, it does seem like there was an uncertainty about what they were seeing on ultrasound and implanted something below the prostate, which is similar to the last one, which we'll get to in a moment. In between one was more of a calculation thing. They used the millicuries instead of air kerma, which we're moving to using air kerma, of course, so obviously they put in a corrective action to double check that before they do it. Again, the third one was mistook the penile bulb for prostate, which is probably what the others really are, more or less, also, in my opinion.

Again, not sure, but that you could make such a confusing thing, you shouldn't, but they are both round structures in the pelvis. If you're not quite sure where you are or not so -- so there's a

little bit of a theme there. Again, it's only three. I don't know that we, as a group, we can talk about -- do anything with that information yet, but maybe. Anything about that?

MEMBER COSTELLO: Just a couple comments on the prostate cases. One is we, in Pennsylvania, had somebody mistake a bulb for the prostate. The other one is I suspect that the reduction in number is coming as people now are adopting an activity-based basis. The NRC's put out the enforcement guidance memorandum, and most States are adopting that now anyway. I think that the change from dose-based to activity-based, I think, is having an almost salutatory effect on the reduction number of reported events.

MEMBER ENNIS: Okay, so for 600, it's over there, the cobalt Gamma Knife, basically the same number, ten this year, compared to nine. Nine were HDRs, and one is Gamma Knife. Of the HDRs, one was a breast, five were GYN, one skin, two bronchus. Nothing really remarkable on that. Four were positioning problems. One was the wrong patient.

One was the wrong dose or wrong source strength. I'm not sure why it's an "or," but that's how it was entered. Oh, I'm sorry, excuse me, one

was dose, one was the wrong source strength and "machine problems." Presumably, that has to do with the source bringing it back. The source goes on a wire out and back, and I guess it didn't work properly, and it led to a medical event. These are the typical kinds of things. Fortunately, this is a small number, so I don't consider that overly remarkable. One Gamma Knife was, again, a wrong patient issue, and one Perfexion, which was the wrong site, the wrong side, so obviously Perfexion can have errors, too. Any comments on that? The last section is the 1000s, so microspheres are in here.

There were 26 events in total this year. That's up from 15. I don't know if that is a reflection of the increased use. I think that may be the case, but I'm not heavily in that space medically to know for sure. Yes. Yeah, that's what I thought -- and radio-specific nuclear radioactive seed localization that we discussed yesterday, there were two events this past year.

Regarding the microspheres, I think these are pretty typical for what happens with this procedure when things don't go smoothly, catheter being blocked, a calculation error, error drawing up the dose, a shunting problem, which we've actually

discussed here. I guess in the future it won't be an event unspecified. Similarly for the TheraSpheres, similar kind of thing, shot once and catheter blocked, material left there quickly. Small numbers, so I think this is kind of what we would expect. In terms of radioactive seed localization, there were two events. One, a seed fell and was found 49 days later, supporting the idea that you need to do all kinds of detections to make sure you got all the seeds at the end of the procedure, in my opinion. In one case, the written directive said they were going to do one seed, but they used two, so again, small numbers across the board.

Now there's a new -- Sue collected some additional data. She's not really here to speak to it, so we'll -- about other things, other types of events, which I think we'll continue to report going forward, that involve medical licensees, but are not quite the same kind of events. They fall into a variety of categories of leaking sealed sources, lost sources, shipping issues, landfill alarms going off, so we'll kind of go over that briefly.

Occupational overexposure, again, not to a patient, but to staff, potential public overexposure once, airborne issue once, equipment

failures, and "suspicious activity" involved cesium, iodine, cobalt. So lost sources ten times. Iodine-125 seeds were lost after a procedure. Other sources were lost twice, found twice, lost and found four times, theft three times, package thrown away, lost during shipment. This is life. Delivered to the wrong address, stored in unsecured area, highway patrol delivery -- accident, I guess, involving the car or truck carrying it, I guess, shipping/packing issues, no license. In terms of landfills, which has been discussed here a bit in the past, again, we don't have comparative numbers.

Going forward, we'll be able to kind of see if there are trends over time. This hasn't really been effective recently, to my understanding. So I-131, as we expect, would be the one that sets off the landfills the most, particularly coming from residences, a little bit of the other sources, potentially, too. There's a disproportionate reporting of cases from California, so I don't know if they're over reporting or everyone else is underreporting, but there's something now on there.

I think the bottom line is these are very few trends, and they're mostly random events that you kind of expect in human interactions with stuff. The

only -- there's some site trends that I think we would have to wait more, see if things are truly increasing or not. Across the ultrasound thing is, I think, something to pay attention to, see if that's an issue that really we need to emphasize extra training if it's becoming a problem. Any comments, any questions?

MEMBER COSTELLO: I have a comment on the landfills. The data tremendously understates how often this happened. I know in Pennsylvania, we probably have 250 to 300 events like this a year, and they're almost all I-131. We can put any of them in NMED, and maybe it's designed for this.

While I've been here there's probably been two or three. It's 85 percent California because they're such a colossal State, and they report them. I'm surprised anybody other than California is reporting them. Pennsylvania, we're the State of radiation detectors. We have them at every transfer station. We have them at every landfill. You can't go any -- you can't shake a stick without hitting a radiation detector. So we have a lot of them, but I don't think -- we don't send them into NMED for what I think are obvious reasons.

MEMBER O'HARA: I correlated the events from the NRC's database to the FDA's database. FDA's database looks for medical device failures - is basically all we look for. There was actually good correlation between what I saw in the database here and the database for the FDA. So I was actually quite pleased when I saw.

MEMBER ENNIS: Thanks. Thank you for sharing that.

CHAIRMAN THOMADSEN: Maybe in the future, if the Committee desires, you might write something about what's seen in the FDA's database.

MEMBER O'HARA: I was running a little late and almost called to tell them. Maybe next year.

CHAIRMAN THOMADSEN: You don't have to say that. You just can say oh, that's a great idea.

(Laughter.)

MEMBER COSTELLO: I just want to ask one other question, Dr. Ennis. When you're evaluating these medical events, do you feel you're getting the information you need on the write-ups of these events to draw any meaningful conclusions?

MEMBER ENNIS: I think from what I'm seeing, and for the people who gathered information,

and that includes myself, sometimes there's enough information to make at least a reasonable understanding of what's going on, and sometimes not. I think the bigger problem, really, was making conclusions. There's so few events, it's very hard to start to make any kind of conclusions about what's going on nationally with so few of them.

CHAIRMAN THOMADSEN: I would give the opinion that in almost no event in NMED is there enough information that you really understand what happened and draw conclusions from -- I guess findings of the reports are very --

MEMBER COSTELLO: That's unfortunate. This is a very important program that we have to evaluate nationally what's going on. I don't know how you fix it, but if you were doing this, and your predecessor did this, it always seems to be there's some sort of sense of frustration that we wish we knew more. We're glad there are not so many events. That's a good thing. But it would be nice if we did have more information.

CHAIRMAN THOMADSEN: Member of the public, please identify yourself.

MR. OUHIB: Yes, Zoubir Ouhib, medical physicist. You actually hit on one of the items that

I wanted to address. That is when I've looked at the data, that's over I don't know, 12 years' data, it was striking that there isn't some sort of a format that every user should follow, basically, and provide adequate information. You look at the -- more important, I can tell you, also, based on what has been reported and what actually took place, you'll find out that there are some differences, also. It's just the way it was reported. I think we need to make some progress in that area to actually draw some meaningful conclusions, but perhaps correct the problem or assist in correcting that problem.

I think that's one area that I feel that perhaps NRC should -- or ACMUI probably should tackle and look into and see how that can be corrected. One, another item -- and I know it's been probably discussed in the past -- and that is one of the case that millicuries versus air kerma trend. I think it's time to move on with one single unit, at some point, so that way, we can eliminate at least these kind of errors. While they are small, they're still errors.

CHAIRMAN THOMADSEN: Thank you. Other comments? Yes, Dr. Metter.

DR. METTER: I just have a technical

comment that on the 35.200, on the indium-labeled white cell, I think it should be 500 microcuries, not 500 millicuries, and the following slide of 35.300, where there's 1.11 megabecquerels, it's 30 microcuries, not millicuries.

MEMBER ENNIS: Thank you. So noted.

CHAIRMAN THOMADSEN: Thank you. Mr. Costello.

MEMBER COSTELLO: There's one other thing about the information in NMED. Most of this information, I think, ultimately comes from the States where things are being reported. I don't know. I can't speak for all 37 of the Agreement States. I'm not sure I can speak for Pennsylvania, but I think if you were to ask the States and provide guidance to the States, if you want more information -- if we want more information -- if you want more information in them, I bet the States would work with the NRC to provide more information in NMED reports if they were so asked and so guided.

CHAIRMAN THOMADSEN: I will point out there is a proposal in the American Association of Physicists Medicine to try to get an interorganizational task group together to write guidances for writing the descriptions of events,

both in -- that could be used across different databases, such as NMED and event reporting systems in the patient safety organizations.

MEMBER COSTELLO: The beginning of this information comes from the licensee through reporting events. Ultimately, they're the source of the information on the events. I'm just saying I think it could be done better.

CHAIRMAN THOMADSEN: I think the beginning of the reports are not from the licensees but from the inspectors, in that I know some years ago, when I was working on one of these, I was working on one case, trying to understand, to put into the report and tell us at the very end. I noticed it came from my institution, and I was the one who was talking with the inspector, that was that case. Because I could not have told from the description that it had anything to do with the event that happened at our place.

MEMBER COSTELLO: We can do this a little better, I think.

CHAIRMAN THOMADSEN: Yes, I think so.

MR. BOLLOCK: Thank you. Yes, if you have recommendations on how to make that better -- because I believe it's SA-300 is our

procedure we use with the Agreement States for the information that we request for event reporting, and as it is, it typically is the event report is the first entrance, and then after that, the follow-on inspections are updated information. The counters that run INL, or NMED from INL, they are very good about reaching out to get that updated information. But it's like anything. The information is as good as we put in here. It does take some effort from the states or NRC to update that. But if you have recommendations -- more pointed information or things we could do to be better and work with the states to be better, we will gladly try to take that.

CHAIRMAN THOMADSEN: Mr. Mattmuller.

MEMBER MATTMULLER: Yes. In preparing the AO report, Dr. Langhorst came across an NRC management directive, NRC assessment program for a medical event or an incident occurring at a medical facility. It talks about the different levels of review and the formation of incident investigational teams or, if needed, augmented investigational team. This is my question for the staff. Do you just investigate those events under NRC purview, or do you investigate all events, even those that occur in an Agreement State?

MR. BOLLOCK: We only investigate the events in our purview. The States have their own investigative procedures or ways to look into incident response. It's funny you bring that up. We actually discussed this -- I discussed this with the outgoing OAS director at the last OAS meeting about working together to share what we do with our augmented investigation team and incident investigation team and provide that to the states. We're hoping to give that training to the States just to show them what we do because we do have -- we have resources in a lot of things that the States -- sometimes there's -- they may not be as robust, but they all have their own that are adequate. That is checked through. So it's not to say the States don't do it. They absolutely do. But we are currently working together to help build that up, as a whole national Materials program.

MEMBER COSTELLO: If I could comment on that. Many States don't have the resources or infrastructure to put together AITs and IITs and so forth. By and large, they do it with the inspection resources that they have. Sometimes, States will ask other States to help them, regionally, in cases, or not.

But I think the States do a good job of investigating events, but you shouldn't think we can -- that we're capable, except for the largest of the States, of providing resources to these major events that the NRC's able to. I think, for the most part, we get the call right, though, with the special resources that we apply.

CHAIRMAN THOMADSEN: Thank you. Oh, Dr. Howe.

DR. HOWE: Since Steve brought up the idea of augmented inspection teams and integrated inspection teams, I think it's important to know that most medical events do not rise to that level. They are looked at, at a normal inspection level. So it is very rare for NRC to have an IIT, and it's equally rare, in medical, to have an AIT. One should not consider those to be routine, and those are the methods that we get information. It's normally inspection.

CHAIRMAN THOMADSEN: Thank you for that clarification.

DR. HOWE: Yes, they are rare.

CHAIRMAN THOMADSEN: Are there any other questions or comments from the committee or from the people in the audience?

(No audible response.)

CHAIRMAN THOMADSEN: Hearing none, thank you very much, Dr. Ennis. I have a note, Sophie, that we should start Item 16 on time, which is 8:45, so we'll be taking a ten-minute break right now.

(Whereupon, the above-entitled meeting went off the record at 8:34 a.m. and went back on the record at 8:45 a.m.)

CHAIRMAN THOMADSEN: We will resume now and have a discussion on our comments -- the ACMUI comments on NUREG-1556, Volume 9. Filling in for Dr. Langhorst is going to be Dr. Zanzonico.

MEMBER ZANZONICO: I'm Pat Zanzonico, and I'm in for Sue Langhorst. I'm Pat Zanzonico, and I'll be pinch hitting today. We all miss Sue and wish she were here, me, especially, at this moment, but we will do our best to persevere.

This is a report on ACMUI subcommittee reviewing and providing comments on NUREG-1556, Volume 9, Revision 3. The subcommittee charge, as I said, was to provide comments on this non-rulemaking update and, in particular, how changes might impact licensees and, further, to make recommendations for ACMUI action and so forth. This is a somewhat difficult to read slide, but the point is that this

task, the updating of the NUREG, was split into two separate or parallel tasks.

The upper line indicates the work and the progress of the NRC working group working on the update, and the bottom line really refers to the work of the ACMUI in reviewing and providing comments on this update. Of course, there's feedback from the ACMUI to the NRC along the way. As indicated, this effort began in 2013, and we're about halfway through, as indicated in the latter part of 2015. What this non-rulemaking update does is revise and reorganize the NUREG to conform more closely and more accurately to Items 5 to 11 listed on NRC Form 313. In the opinion of the ACMUI, the reorganization is an overall improvement, but as is the case always with large and complex documents, it's often challenging to identify the changes that have been made.

The next series of slides are the recommendations of the ACMUI with reference to certain sections of the updated NUREG. The first recommendation is a general one, and that is to extend the comment period for a minimum of 90 days. As noted, this is an extensive reorganization of a large, complex document, so this longer comment period, we feel, is justified.

Section 3.2 of the NUREG deals with the safety culture, which is an increasingly high-profile issue in regulatory circles and so forth. Certainly, we feel it's important for the NRC to introduce safety culture traits in the NUREG, but that it really is inappropriate to include examples of applications of safety culture, at least without further dialogue and feedback and so forth from the ACMUI licensees and other stakeholders, in particular because of some of the special circumstances that we encounter in medical uses of radiation/radioactivity, namely that one is purposely exposing individuals to radiation for some beneficial effect. So it's a very different philosophy, if you will, than one would encounter, for example, in a reactor context, where no one should be exposed, certainly not for any benefit to them individually.

So the safety culture traits, correspondingly, should reflect that. The NRC states that safety culture traits will not develop to be used for inspection purposes. As a result, the subcommittee feels that it's not appropriate to include a radiation safety program audit on safety culture. In other words, it's not an inspectable component, or should not be an inspectable component

of a radiation safety program.

In any case, there is further dialogue and interaction required on this point. Again, our second recommendation is to remove the medical use example in Section 3.2 and the safety culture audit item in Appendix L. As we say, I think further discussion and feedback is required on this point. 8.3, Item 3, the guidance encourages use of a global positioning system coordinates, latitude and longitude. The ACMUI advises against this. Most people, I'm sure, are not so familiar with latitude and longitude, but rather use the more familiar street name and number or building address and so forth in a large medical center. Many large medical centers, and even not-so-large medical centers, are comprised of multiple buildings across a neighborhood or wider geographic area.

I think everyone, including first responders, would be much more familiar with that designation than GPS coordinates. So the recommendation, again, is to use specific addresses, that is a street name and number and building designation, rather than GPS coordinates. 8.7.1, Item 7, deals with a consultant RSO, a consultant or contractor radiation safety officer.

It addresses, among other items, the time commitments and minimum time on site of a consultant or contractor RSO, also the appointment of an on-site, as in in-house representative, as a point of contact in the absence of the consultant RSO. Other components of this section describe the consultant RSO availability to respond to questions, operational issues, so forth and so on. It specifies the maximum time interval for the consultant RSO to arrive when they are off site and need to be on site. The recommendation -- there's no quarrel and disagreement with any of those components of that section. But to amplify that for licensees, our recommendation is that a description of the information that the NRC requires be provided for a consultant RSO actually be included with or accompany the criteria used by the NRC to judge a consultant RSO's acceptability and qualifications.

Item 8.93, Item 9 deals with dose calibrators, and in particular, with terminology. We all recognize that the term dosage and dose is still widely used, not only in the regulatory literature, but in everyday practice, the scientific literature, so forth and so on. But we also recognize that rigorously speaking, that's not correct.

Dose, or more specifically absorbed dose, really refers to energy deposited per unit mass. For the purists among us, that's an offensive concept. The subcommittee nonetheless recognizes that's a fact of life, but we suggest that a footnote be added to Section 8.9.3 to clarify that, in fact, the term dose continues to be used by many medical practitioners and others to refer to the activity of unsealed byproduct material, the activity or administered activity of a radiopharmaceutical, for example. Next, there is material included in the updated NUREG on rubidium-82 generators. The NRC had determined that licensees, because of the special properties of rubidium-82 in the generator, really find it difficult or impossible, in practice, to meet current NRC requirements in NRC-issued EGM-13-003 that provides criteria that the NRC can use for enforcement discretion, and licensees were notified of this in RIS-2013-012.

Section 8.9.3 in the updated NUREG includes these documents as additional guidance for equipment used in measuring dosages or activities from rubidium-82 generators; whereas, the CardioGen-82 Highlights of Prescribing Information does not. Our next recommendation is to remove that

document, that is CardioGen-82 Highlights of Prescribing Information, from the reference list in Section 8.9.3 because it doesn't address these measurement issues.

Continuing, with respect to these generator systems, Section 8.10.20 provides guidance for recording and maintaining the necessary documentation of each dosage. Again, it's important to remind licensees of the enforcement discretion and the special criteria applicable to this generated system. Recommendation 7, again, dealing with the rubidium-82 generator system. It includes all of the aforementioned documents in the reference list -- recommends including all of the aforementioned documents in the reference list to Section 8.10.20 and to add a footnote to Appendix L on the medical audit segment, which directs licensees to this section guidance.

The next item, 8.5.1.5, deals with consortia. Revision 2, Appendix AA was removed in the draft, and references were made to other NUREGs. The subcommittee recommends that the -- well, commends, in general, the NRC on their effort to minimize duplication of guidance and just overall regulatory literature. In particular, by

consolidating guidance into this NUREG, possible discrepancies among free-standing documents and this NUREG are more likely to be avoided, so this is a positive step, we feel.

The next issue deals with one of our favorite issues here on the ACMUI, patient release, and in particular, deals with Appendix U. As you all may remember, the content of Appendix U is essentially a duplicate of Regulatory Guide 8.39, which provides guidance on patient release. As we also know, the update of that Reg Guide is an ongoing, but separate, task of the NRC. But since, at the moment, there's no differences between Reg Guide 8.39 and the content of Appendix U, the recommendation is to just refer to Reg Guide 8.39 and not duplicate its contents in Appendix U to avoid possible discrepancies. So again, this just reiterates what I just said. To minimize duplication and possible discrepancies, remove the content of Appendix U and, instead, simply refer to Reg Guide 8.39.

Having said that, with the removal of Appendix U, the new introduction section to Appendix U could be moved to the body of the NUREG, specifically Section 8.10.18. But again, the subcommittee and the ACMUI wants to emphasize that

the NRC should explicitly state that each patient release is to be treated as a separate event, that is , per event. This reiterates the oft repeated recommendations of the patient release subcommittee of the ACMUI in recent years.

So again, Recommendation 9, the ACMUI recommends to the NRC that it not include guidance on patient release as an Appendix U, but instead, refers to Reg Guide 8.39, and that further, the NRC will not make any statement or implication to the effect that 0.5 rem or 5 millisievert dose limit refers to anything other than a per release or per event limit. Appendix L of the draft NUREG deals with medical audits. It's noted that an NCRP report, Report No. 173, published in 2012, would be a valuable reference on self-assessment of radiation safety programs. The subcommittee recommends including this reference in Appendix L. Again, Recommendation 10 reiterates that recommendation.

I'd like to recognize all of our subcommittee co-members, Frank Costello, Sue Langhorst, who really did the lion's share of the work, I will say, Steve Mattmuller, Chris Palestro, John Suh, and myself. The balance of the slides are just a series of acronyms. That is Sue's

presentation. She did a terrific job.

CHAIRMAN THOMADSEN: Thank you very much, Dr. Zanzonico. Questions or comments from the committee or from the staff on any recommendations? Thank you very much, Dr. Zanzonico. Yes, Ms. Weil?

MEMBER WEIL: I just have a question regarding Recommendation No. 9. The difference between the *per year* and the *per limit* -- *per release*. It's my understanding that the rule talks about *per year*, rather than *per release*?

MEMBER ZANZONICO: Well, my recollection was that the rule, as it appears on paper, still refers to *per release*, and that there may have been subsequent regulatory documents that either implied or referred to an annual limit, but that the current regulation, black-and-white regulation, still refers to a *per release* limit. Maybe the NRC staff can clarify that.

CHAIRMAN THOMADSEN: Dr. Howe.

MEMBER ZANZONICO: That's my understanding.

DR. HOWE: We issued a RIS a number of years ago. The rule itself is ambiguous. It does not say per year. It does not say *per release*. In the RIS, which Dr. Zelac wrote, the NRC went back and

looked at the statements of consideration for the proposed rule and at other documents and, in the RIS, came to the conclusion that the NRC had intended *per year*, but it was ambiguous, and that we would need rulemaking to have it *per event*.

Sue Langhorst has presented at many ACMUI meetings that she comes to a different conclusion. So it is an ambiguous -- it is not clear in the regulations whether -- because we don't have *per year*, and we don't have *per event*, so it is ambiguous.

CHAIRMAN THOMADSEN: Thank you. I'd say it's thank you for that clarification, but it's thank you for the re-ambiguation.

MEMBER ZANZONICO: So this is a follow-up question. If licensees were to currently interpret it -- continue to currently interpret it as a *per release* criteria, they would not be in non-compliance? Is that enough negatives? In other words, that would not be a "violation" or citation if licensees were to -- at the moment were to continue to interpret it as a *per release* criteria?

DR. HOWE: We're on record as saying that it's ambiguous and, therefore, it would be difficult for licensees to absolutely know one way or the other.

CHAIRMAN THOMADSEN: Thank you again.

MEMBER COSTELLO: As someone who inspects this type of thing regularly, I only would ever do *per release*, and I wouldn't know how to begin inspecting on a *per year* basis. I wouldn't know how to ask the question about that. It would be, at least from my point of view, totally non-enforceable as a *per year* thing. I think -- I could not probably speak for all the states. I think we all do it *per event*.

CHAIRMAN THOMADSEN: Thank you. Mr. Fuller.

MR. FULLER: Oh, yes. Thank you, Dr. Thomadsen. If you would be interested, I'm looking at the time, and I see that we have some time on the schedule. Ashley Cockerham is the co-chair of the working group, the Agreement State/NRC working group that's working on this NUREG. Dr. Zanzonico talked a little bit about this is the non-rulemaking portion or aspect of this.

I know that's confusing for a lot of us on staff who are working this. We have a parallel rulemaking activity going on that has its own guidance developed with it, so I asked Ashley -- we have some time. She'd be happy to kind of go through a little more detail about that to help ease some of

this confusion if you would like for us to.

CHAIRMAN THOMADSEN: That would be wonderful. Ms. Cockerham, please.

MS. COCKERHAM: Hello. Okay, so I tried to make this image a little bit bigger, and you can't read it in your handouts at all, so I apologize. Just to sort of describe what we're doing, we have Volume 9, one guidance document. When the Part 35 rulemaking started, we have Commission direction for all rulemakings that guidance accompany the rule, which makes sense. When you put out a new rule, the new guidance goes with it. Donna-Beth is working on that guidance document, along with others on the medical team. You've seen that rulemaking guidance and had opportunities to comment on it. There's been a public comment period. It's just gone in parallel with the rule. Completely separately from that, anything that was sent to the NRC since the last time the guidance was opened, which was 2005, any comments we've received that are not related to the rulemaking have been incorporated into this document.

We have two parallel timelines. The top one is mine. It says -- in green, right now, it's the -- this is hard to read -- the steering committee has looked at it. We had an initial legal review,

which was just a fatal flaw review. Then ACMUI has done their review now. Our next step is that the working group will get back together and look at your recommendations and comments. We will incorporate changes into the guidance, as needed, and then we will issue the entire guidance document for public comment.

That's your recommendation on the 90-day public comment period to have longer for the public to look at this very long, multi-hundred-page document. Then the working group will reconvene again, resolve those comments, and then we'll go through some final internal reviews and approvals, and then it will be issued sometime in 2016. If you look on the last square on the bottom right, the rulemaking is tracking along, as we know. They're going to have final changes that they are making to the guidance. They will give those to me. I will incorporate those, after we've done public comment from my version, and then I'll take Donna-Beth's piece, feed it into mine -- I have it there after tech editing, but whatever that time period is, wherever I can feed them together.

So when management sees the final document, it will include everything that's gone

through the public and ACMUI with rulemaking, and everything that's gone through the public and ACMUI from non-rulemaking. So it will be one document, with one set of changes, in the end. Any questions? Does that help at all?

CHAIRMAN THOMADSEN: Dr. Zanzonico.

MEMBER ZANZONICO: I understand, I think, what's happening. But my question is it seems like it would make more sense to do it sequentially, rather than parallel, because presumably, the rulemaking component is going forward and will be modified and so forth and so on in response to comments in parallel with the guidance. In one sense, it seems like it would make more sense to have the rulemaking component completed, rather than having to go back and forth, as one document changes, and then changes the other document.

MS. COCKERHAM: There's the bigger driver for all of this. There was the GAO sting, what year, 2005, '06 -- '06 or '07, many years ago. As a part of that, lessons learned, we had an action item to update all of our guidance. So we are updating Volumes 1 through 21. This is part of a bigger project to update everything, and it just so happens that it coincided with the rulemaking. So

to meet the timeline for that overall bigger project, we had to get started on these changes.

It would've taken two years. The rulemaking will be done in 2016, and we wouldn't have a final Volume 9 until 2018, so we did it for the sake of time. We looked at different options of do one first, do the other first, and we said, "Okay, let's divide it and conquer two pieces, and then feed it together." So it's complicated, but it saves years.

CHAIRMAN THOMADSEN: Thank you. Mr. Costello.

MEMBER COSTELLO: Do you think when the bottom row part is done and it feeds into the top row, that will require many changes to the guidance at that point?

MS. COCKERHAM: I don't think so.

MEMBER COSTELLO: Okay.

MS. COCKERHAM: Because right now, you guys have redline/strikeout that I can dump in -- Donna-Beth has.

MEMBER COSTELLO: I'm just curious. When you get to that point where the two merge, is that going to be fairly seamless, or is that going to be oh, my God, we have to change every page in the

guidance?

MS. COCKERHAM: No.

DR. HOWE: The reorganization of the guidance document from what it looks like today will make it look that way, but it'll be fitting right into Ashley's. Ashley's essentially revising things around what happens with the rulemaking.

In other words, if it's on training and experience, it's not in Ashley's because we're dealing with a lot of issues in training and experience. So the training and experience things will plug in. I think it's going to be fairly seamless. I think the other thing is we would've come out with two medical reg guides, probably one right after another, and that would be terribly confusing for the medical community, so we're just going to have one.

MS. COCKERHAM: I created a map, essentially, that if the old section was 8.9, and now it's 8.10.9, I have a map for myself to know exactly. So if she gives me a revision to 8.3, I can immediately go find it. I've looked at this document long enough that --

DR. HOWE: We have redline/strikeout on ours, too, so if the text is not changing around it,

our text will just fit right in. For the most part, the text is not changing around ours.

MR. FULLER: Excuse me --

CHAIRMAN THOMADSEN: Mr. Fuller.

MR. FULLER: Yes, the only other thing I would say, just as another way of saying it, is that when we published the guidance for public comment for the rule, anything that had to do with licensing, any changes to the rules that would impact or affect licensing, that guidance was published as simply pages cut out of this NUREG-1556, Volume 9 in redline/strikeout. So folks who are accustomed to using this document for their guidance on how to apply or how to amend a license and so forth, it's exactly what they're used to seeing with the changes. That's what the ACMUI received, also, to review. We think this was well thought out, such that folks who are used to using these documents in their work would see the actual changes in a redline/strikeout form, like Donna-Beth said. What's nice about that is that we were able to take out of 1556, Volume 9, only those pages and those sections that were being affected by the changes in the rule.

So everybody had an opportunity to comment on that -- the ACMUI, the Agreement States,

and then the public. We received those comments. We incorporated all those changes as a result. So when we publish the final rule, which hopefully will be in spring of 2016 -- that's sort of the published schedule -- then our guidance will be ready to go.

That's why for Ashley's project, on the overall revision to 1556, Volume 9, we have communicated internally to make sure everyone understands that's on this larger project that 1556, Volume 9, will be published as soon as possible after the rule is published, it's final, so we only have one document going out at one time, and it has everything in place as a result of Ashley's effort and the rulemaking effort.

CHAIRMAN THOMADSEN: Thank you. Mr. Costello.

MEMBER COSTELLO: So as the things come together again and there's a guidance document which reflects all the changes you're making in the new rule, that final document, will that come to the ACMUI for review?

MS. COCKERHAM: Basically, we're giving you a chance to comment on both of them independently, but the combination of them, I think in the sake of time --

CHAIRMAN THOMADSEN: Thank you. Yes, Dr. Zanzonico.

MEMBER ZANZONICO: I just want to clarify. The current version of the guidance being circulated for comment is redlined.

MS. COCKERHAM: The one I sent to you was not. What Mike was talking about was the rulemaking. For rulemaking, they pulled out pages that were changed, showed what the changes were, and just had miscellaneous pages. That's what their document was. For mine, because it was an entire reorg, totally renumbered, the entire document would have been redlined, so that wouldn't have been helpful to you. So what I provided was the comment list to direct you, "Here's the comment. Here's the section you need to go look in to see what the change was."

MEMBER ZANZONICO: Is something like that going to be available, at some point, to licensees? It just seems like it's going to be real challenging for licensees to look at a revised reg guide or any other regulatory document and have to identify for themselves changes, and more particularly the significant changes, from previous versions that they're used to using.

MR. FULLER: I think that's -- this is

Mike Fuller, by the way. I think that's very, very valuable feedback. We'll have to look at that. But frankly, as Ashley has said, because the entire document has been reorganized, and it's so large, I guess we're kind of used to using those software programs that are available to us to do these sorts of things.

The entire document would be crossed through, and then you'd have another document just like what we have. But we'll take that comment under advisement and see if there aren't ways that we can better communicate the actual changes. We also have to kind of follow our Office of Administration rules on how we publish NUREGs, so I can't make any commitment right now, but we'll certainly take your comment, Dr. Zanzonico, and see if there isn't a way that we can't at least help to clarify where the major changes are in the new guidance.

CHAIRMAN THOMADSEN: Thank you. Any other comments?

(No audible response.)

CHAIRMAN THOMADSEN: Hearing none, thank you very much for that clarification. We're running ahead of schedule. Sophie, do we have the NMSS person here, Ms. Whaley?

MS. HOLIDAY: Yes.

CHAIRMAN THOMADSEN: We do? Maybe we could bring -- would it be okay to bring that topic up now?

MS. HOLIDAY: Sure.

CHAIRMAN THOMADSEN: Okay, we're going to move up Item 18, which is a rulemaking update regarding 10 CFR, Part 35. Thank you for coming in and talking with us.

MS. WHALEY: Good morning. I'm Sheena Whaley. I'm the chief of the rulemaking branch, NMSS. We were asked to provide just a quick status update of where the rule is. We've made significant progress since the last ACMUI meeting in March and just wanted to let you know where we are, although probably some of you are aware. As background, this amendment focused on reporting and notification requirements for medical event definitions for permanent brachytherapy, the T&E requirements, as well as reporting of failed generators, and addressed a request from a petitioner to grandfather certain board-certified individuals.

After the 120-day comment period that closed last November, staff have been analyzing the several hundred comments that we received and

drafting the final rule test. The comments that were received were from a broad spectrum of stakeholders. They were the professional societies, the Organization of Agreement States, Conference on Radiation Control program directors, the individual States, medical professionals, and individual members of the public.

The comments focused on several key areas, such as listing an associate radiation safety officer on a license, medical event definitions for permanent implant brachytherapy, the Agreement State compatibility for medical event definition, training related to qualification for use of alpha and beta emitters, the reporting of the failed generators, and the Act's test term requirements. Staff provided the draft rule text to ACMUI just this week. That was October 6th or 7th -- or October 7th. Then on January 6th, the ACMUI will hold a public teleconference to discuss their review and comments on the draft final rule. This is a change from the date that was previously published of December 18th. There will be a topic on implementation of the final rule during that meeting to cover some of our requirements. This meeting will be noticed in the *Federal Register* and will also be on NRC's public meeting page. If you

have any questions about this meeting or need any further information on it, contact Sophie over here.

The next milestones are we're providing the draft final rule to the Agreement States in November for their preliminary review, and then we intend to send the rule up to the Commission for vote in March. Then after we receive the staff requirements memorandum from the Commission, we'll address any Commission comments and publish the rule. That's where we are.

CHAIRMAN THOMADSEN: Thank you very much. Comments or questions from the committee?

MS. WHALEY: None, okay. It wasn't even five minutes.

DR. PICCONE: Thank you, Sheena.

CHAIRMAN THOMADSEN: Thank you.

MS. HOLIDAY: Dr. Thomadsen?

ACMUI CHAIRMAN THOMADSEN: Yes.

MS. HOLIDAY: If I could just make a comment. Since we do have stakeholders in the room and persons listening in on the webinar and on the bridge line, when we have that public teleconference in January, this is to discuss the Committee's comments on the draft final rule. This is not an opportunity for members of the public to provide

further comments on the draft final rule. If you have comments that you would like to submit, as with all ACMUI meetings, comments are due three days prior to the meeting, and they have to pertain to the Committee's comments on the draft final rule. Thank you.

CHAIRMAN THOMADSEN: Thank you for that clarification. I think that we don't have items that we can move up and fill the next 20 minutes. I don't know that --

DR. PICCONE: The Chairman is not here yet.

MS. HOLIDAY: The Chairman's not here, but if you want, I can at least do the administrative closing part, and we can narrow down the spring meeting date.

CHAIRMAN THOMADSEN: I think that's a great idea. Let's do that. I'll explain, for people listening, we are trying to keep topics that have interest to many people on the schedule because people might be calling in just for that. Items we can move up are just administrative items for the Committee.

MS. HOLIDAY: Okay, sorry, this is the best I could get the Word document to zoom. As all

of you are aware, we have another member rotating off of the Committee in March of next year, so we're limited to just March for a spring meeting. Otherwise, Mr. Mattmuller would not be able to attend his last meeting.

When I sent out the meeting wizard to poll the Committee for their availability, there were actually a few sets of dates that a couple of members had an issue on, but there was one set where nobody had an issue on. Hopefully, that has not changed. In green highlight, I have here March 17th and 18th. That's a Thursday and a Friday. Does that date still work for everyone on this committee, minus Dr. Thomadsen, who's welcome to call in.

MEMBER COSTELLO: I like that you have March 17th in green.

MS. HOLIDAY: Oh, yes?

CHAIRMAN THOMADSEN: That's right.

(Laughter.)

MS. HOLIDAY: Okay, so far I'm not seeing any objections. I'll wait just a few more minutes. So I see no disagreement, so I will have our first choice down for the spring meeting as March 17th and 18th. Of course, we always pick up a backup date. As I just stated, a couple members had conflicts for

all of these dates that are a yellow highlight, but I guess just like with the last meeting, when we were planning for this one, you just pick the lesser of the evils. I guess we'll start with March 1st and 2nd. That is a Tuesday and a Wednesday. It's a little different than our normal Monday/Tuesday or Thursday/Friday, but does anybody have a conflict with March 1 and 2? You do? Okay. Was that a conflict for anyone else? Yes? Okay. What if I had the meeting March 2nd and 3rd, a Wednesday/Thursday? Would that still be a conflict, Dr. Metter?

Does the 2nd and 3rd present a conflict for anyone else? All right. What if the meeting was March 3rd and 4th, a Thursday/Friday? Is that a conflict for anyone? All right. What about the 24th and 25th, also a Thursday/Friday? Is that a conflict? Dr. Ennis. So of those dates that we just said, Ms. Weil has a conflict on March 3rd and 4th, and Dr. Ennis has a conflict on the 24th and 25th. I will defer to our soon-to-be ACMUI Chairman, Dr. Alderson. What would you choose as your alternate meeting date, March 3rd and 4th, or March 24th and 25th?

VICE CHAIRMAN ALDERSON: I would choose

the 24th and 25th.

MS. HOLIDAY: All right, so for the record, we will plan to hold the spring 2016 ACMUI meeting with the first choice as March 17th and 18th, and the alternative backup date as March 24th and 25th. Thank you. Thanks.

VICE CHAIRMAN ALDERSON: Frequently, in the spring, there's a meeting with the Commissioners. Is that planned for this year? Will that be around this time somewhere?

MS. HOLIDAY: Once we have confirmed a date for the ACMUI meeting, I then inform the Office of the Secretary of the date of the meeting, and they will then check with the Commissioners -- because they have to do agenda planning to see if this is a date [that works for them]. Just like this year, if that date -- none of these dates work for them, then we'll bring the Committee in for a separate commission meeting.

CHAIRMAN THOMADSEN: Thank you. Did you want to go through some of the administrative closing items?

MS. HOLIDAY: Sure, I can do that.

CHAIRMAN THOMADSEN: Up to -- from the first day, I guess.

MS. HOLIDAY: From the first day. This is going to be a little unconventional because I can't pull up the file, but I do have hard copies for the table. I apologize for the members in the audience and for those of you on the webcast. I will have this available for distribution once we go for a break. I'll wait until this makes it around the table.

At this time, we will review all the recommendations and actions that occurred yesterday, starting with Item 12 in red font. The ACMUI recommended to make the following change to the patient intervention subcommittee recommendation, Issue No. 2. This is where the Committee voted to remove that phrase "and/or imaging a certainty." This was approved by the Committee. Are there any comments on this? Seeing none, we move to Item 13. This is where the Committee endorsed the patient intervention subcommittee report with the modification that I just mentioned. Are there any comments on this? Seeing none, we will move to Item 14.

This is where Dr. Thomadsen requested that staff provide an update at the spring 2016 ACMUI meeting on staff's response or action to the patient

intervention subcommittee report. Are there any questions on that? Okay, Item 15 was a follow up to that, where Mr. Costello put forth his recommendation, which the ACMUI endorsed, that staff issue a generic communication in the form of either an information notice or a regulatory issue summary to licensees to inform them of the interpretation of patient intervention, as was stated during the time that presentation was given.

This, of course, is something that staff will have to work on and discuss with the Office of General Counsel before we can move forward. Are there any questions on Item 15? Seeing none, we will move to Item 16. Item 16 has to do with when Dr. Thomadsen added a new charge to the training and experience for alpha/beta emitter subcommittee. That charge was to establish a recommendation for the total number of hours for training and experience for authorized users of alpha and beta emitters that is necessary for safety and effectiveness. The subcommittee will give their presentation in the spring meeting, as well. Are there any questions on that? Yes, Dr. Palestro?

MEMBER PALESTRO: I'm not sure about effectiveness. I don't really think it's -- unless

we get it clarified. Because we're not charged with determining the effectiveness of these agents.

CHAIRMAN THOMADSEN: I agree, and I may even have said that when I made the charge, but I understand that we can't really go into that.

MS. HOLIDAY: So we'll modify this, which is necessary for safety?

CHAIRMAN THOMADSEN: Yes.

MS. HOLIDAY: All right, thank you.

CHAIRMAN THOMADSEN: Thank you for pointing that out, Dr. Palestro.

MS. HOLIDAY: Any other comments on Item 16? All right, Item 17, Dr. Ennis recommended that the individual who implants the source for radioactive seed localization be the authorized user only, and not an individual under the supervision of an authorized user. Please note that this motion did not pass. There were eight votes that were not in favor, and of course, we need a majority vote, but this has to be captured on the record. Are there any questions for Item 17? Seeing none, we'll move to Item 18.

Item 18, the ACMUI recommended that the individual who implants the source for radioactive seed localization procedures can do so under the

supervision of an authorized user. Are there any comments on Item 18? Seeing none, Item 19, the ACMUI unanimously endorsed the radioactive seed localization subcommittee report. Are there any questions for Item 19? Thank you. Seeing none, the last item, Item 20, is where the ACMUI endorsed the yttrium-90 microsphere subcommittee report. Are there any comments on Item 20? Seeing none, I thank you.

CHAIRMAN THOMADSEN: Thank you. Yes, Mr. Costello?

MEMBER COSTELLO: Sophie, we had a discussion when we were going over the medical event report. I think there was something of a consensus that we need to get better information in NMED than we're having, and that perhaps, maybe the staff could work with the Agreement States or provide guidance to Agreement States or something could be done so that we, the committee, can make better use of the information that's in NMED. Did we want to make any recommendation to the staff on that, or is just the discussion that we had here sufficient?

CHAIRMAN THOMADSEN: The Committee could make a motion on that. I would recommend waiting on that because the initiative by the AAPM is going to

be inviting the staff from NMED to participate in trying to sculpt what improved descriptions should be. I think that will be underway.

MEMBER COSTELLO: Yes, that's okay with me then.

CHAIRMAN THOMADSEN: Very fine.

MEMBER ZANZONICO: Could I ask a follow-up question? Will the AAPM initiative cover all modalities?

CHAIRMAN THOMADSEN: What does that mean?

MEMBER ZANZONICO: Meaning already --- Part 35.

CHAIRMAN THOMADSEN: I would think that the results of their recommendations would be applicable to any event descriptions. With that, we have the Chairman of the Commission here. I would like to invite him up.

NRC CHAIRMAN BURNS: Thanks, good to see you again. Good to see Frank, who I used to work with a lot in the NRC. This is probably the most important thing you are going to do today at your meeting, that is acknowledge a service of Dr. Thomadsen over these last number of years here on the Advisory Committee on Medical Uses of Isotopes.

I'm here, and I think we all want to acknowledge his service as he departs us in this role, at least. As many of you know, he began service on the Committee in 2007 and was nominated for a second four-year term in 2011. In 2009, he became the Vice Chairman, and then was later appointed as the Chairman in 2013.

Under his chairmanship, the staff has benefited from the Committee's expertise in a number of issues, note a few, the revisions to 10 CFR, Part 35 on medical uses of byproduct material, revisions to abnormal occurrence criteria which are now under discussion, patient release after iodine-131 therapy, and the medical event reporting requirements. He's come before the Commission, itself, on a number of occasions, to brief the Commission on these issues. I can remember him being there when I was General Counsel, and then when I came back, he's a commissioner, and now a Chair. I think that's always appreciated to have that input from the Committee in the public meetings that the Commission holds on the issues related to medical uses of isotopes.

I think the Committee -- my sense is certainly the Committee and the staff have continued to develop a strong collaborative relationship under

Dr. Thomadsen's leadership and presence on the committee. I think this helps us all, and certainly validates the rationale that the commission had for establishing the Committee when it did many years ago. I know his commitment to service goes beyond this Committee and includes membership or service in other groups, including American Association of Businesses, American Brachytherapy Society, American Board of Radiology, and the International Commission on Radiation Units and Measurements, among others.

So I'd like to express to you, Dr. Thomadsen, my gratitude for your service. I know my fellow Commissioners join me in wishing you well. With that, I'm going to ask you to get up because we have a few parting gifts, if you will, to present here. First, I'm going to give you this certificate of appreciation, on behalf of the Commission, in recognition of eight years of service. I always love getting these things because this reminds me of the cubicles. It's the Velcro that you can stick it against the wall. If you have any fuzzy walls, that's what it's for.

CHAIRMAN THOMADSEN: I'll have to put some up.

(Simultaneous speaking.)

NRC CHAIRMAN BURNS: Yes, you're going to have to put some fuzzy wall paper or something like that. But anyway, congratulations.

(Applause.)

NRC CHAIRMAN BURNS: Thank you. So, next, this is the flag. The flag is flown over the capital. I think Congressman Van Hollen, whose district we are in, provided this to us.

CHAIRMAN THOMADSEN: That's great. Thank you.

NRC CHAIRMAN BURNS: So there's that.

(Applause.)

NRC CHAIRMAN BURNS: This is a pin. I think that's what it is. It's a box inside of a box, so it's a mystery there.

(Laughter.)

CHAIRMAN THOMADSEN: Is there one of those levers you have to pull?

NRC CHAIRMAN BURNS: I don't know.

(Laughter.)

NRC CHAIRMAN BURNS: -- congratulations, again, and again, thanks for your service.

ACMUI CHAIRMAN THOMADSEN: Thank you, and thank you.

NRC CHAIRMAN BURNS: You're welcome.

CHAIRMAN THOMADSEN: And thanks to all the Commission for their support of the Committee in all this time.

(Applause.)

NRC CHAIRMAN BURNS: Josie will take care of that stuff for you. Thanks, and I'll let you go on with your meeting. Thanks a lot, everybody.

CHAIRMAN THOMADSEN: I think that actually brings us to a break. We can't follow that. We are on a break until 10:30.

(Whereupon, the above-entitled meeting went off the record at 9:42 a.m. and went back on the record at 10:30 a.m.)

CHAIRMAN THOMADSEN: Dr. Howe, welcome. You're going to be giving us an update on the patient release workshops.

DR. HOWE: I'm going to be talking about -- the NRC currently has two patient release initiatives going on. One is more health physics oriented, where are people going, what kind of doses are they giving to members of the public or their family members if they don't go home.

I'm not going to be talking about that. I'm talking about the second one. The second one, we had a COM paper that came out of Commissioners

Magwood's and Macfarlane's office that asked us to look at the issue of whether the assumptions made in patient release were realistic or not. So we got a staff requirements memorandum in April of 2014, and they asked us to do a number of things.

One of the most important things is they wanted us to reach out to as many stakeholders as possible to get public input on whether the assumptions were correct or not and four different major tasks that I'm dealing with. The stakeholders, as we see them, are the public patients, patient groups, patient advocate groups, individual physicians, professional societies, licensees, both Agreement States and NRC licensees, the ACMUI, and the Agreement States. The best way to reach as many of these stakeholders as possible is to go out with a public request for information. To get a public request for information, you have to go through the Office of Budget and Management Clearance to get permission to ask the public questions and collect information. So we've gone through that process.

We published two Federal Register notices to get comments on the burden. We just got our OMB clearance last week, and the clearance will last until October of 2018. I want to point out that

normally, when a federal agency goes out and asks for information, they're really collecting data. They do a survey. You're given a couple of choices to choose, and they come back and do a statistical analysis, and they collect data to support a certain position. That's not what we're doing.

We're really collecting information. We're going to be going out and we've got four major topics, and we're going to be looking for people to tell us what their best practices are, to tell us topics they think need to be addressed in that issue, to tell us questions they think need to be covered on a particular issue, and provide us with information they already have. We're going to try very hard to make sure we get as much patient input as possible because any time you have to meet a requirement on patient release, whether you can meet it or not is highly dependent on whether the patient can do what you said they need to do or what they absolutely need to do to help reduce the dose to members of the public. I've got my OMB clearance.

I've got my Federal Register notice that will actually be the vehicle that we're asking the public for their input. That is currently in the concurrence process, should be finalized in the near

future. We get the Federal Register notice, nobody reads the Federal Register notice. We know that. So we're going to be actually going out to the professional societies, the patient advocacy groups, and hoping that the information gets passed on through different means at each professional society and at the advocacy group down to individual physicians and patients.

We'll see if they want to respond. No one is required to respond. It's totally voluntary. We're planning on having at least one public meeting. We would like to have more, but we're in a tight budget situation, so I don't know how many we're going to be able to have. The normal time period for people to respond to a Federal Register notice is about 60 days. We're going to ask for 90 days, so that we give people plenty of time to get the information, see what we're asking, and then respond back to us. The biggest thing is we're really asking for information you already have.

If you're a physician and you've got good practices and you've got documentation, then send us your good practices. We're not asking anybody to do anything new. Our focus is going to be on getting information that patients believe will help them

understand their I-131 treatment. There's basically four different objectives here. One is pre-treatment. We've gotten a lot of anecdotal data that patients don't -- it's confusing and inconsistent as to what they need to know when they find out they have a disease that requires I-131.

The first one is kind of pre-treatment. It is that kind of basic information. We understand that the Commission has asked us to get into an area that we don't have expertise, and we probably don't have any regulatory authority over. So what we're hoping for is to go out to the medical community and get information from them. In this particular process, we're going to be looking for developing a website. Our intent would be not to re-invent the square wheel or the round wheel, but to provide links to information that we think is clear and concise, that other people have developed. The second part is you know you have the disease, you're now talking to either a physician or a licensee -- because it doesn't have to be the physician that's talking to the patient.

It could be some other member of the licensee's staff -- and determining when the patient could be released if they had their procedure. We're

looking at that as to being best practices. What's the physician's best practices; what's the licensee's best practices when they're making an informed decision on when to release the patient? That release could be an immediate release.

It could be a delayed release for a short period of time, or it could be a hospitalization. We're not coming in with any concept that one is better than the other. We're just saying how do you arrive at that decision that it's best for you and the patient? Then the third time is now your patient has received the dose, what do you tell them to keep -- what are the instructions that you're providing, your best practices on how for them to keep the doses to other members of the public, including their family, as low as reasonably achievable? There's the pre-treatment -- slightly pre-treatment on when to release, and then the I-131 has been given, so what are the instructions? What should those instructions include, and what should they look like?

Then the Commission also tasked us with if there is an organization of any kind out there that has a brochure or pamphlet that answers many of these things, then we want to know about it and see

if it is acceptable to essentially put out on a nationwide basis to help provide clarity. Those are our major objectives, and that's what my Federal Register is going to be focusing on. This is going to be the website information. It's the I-131 treatment process. We identified what we think are a number of topics that could be addressed -- we don't have shoulds and shalls; it's could be -- in giving this basic information.

So we're just looking for people to tell us different websites that they like and tie it into topics. We have very open-ended topics. We also say, for every group, "If you think there's a topic we don't have, please tell us about it. If you think we've put a topic that you think is absolutely worthless and you don't think it ought to be there, tell us about that, also." Because we're trying to get best practices, and we're trying to get clear and concise information out. We're essentially going to primarily go to the medical community and the patients for the medical information because that's not in our area of expertise.

We may develop some of the radiation safety information, but we also may find that licensees have already developed websites that have

really good basic radiation safety information -- or radiation information for I-131, so we may put that in something, too. We don't want to re-invent any wheels, square or round. I've already talked about the topics, and then we will be providing links to a website. That's our expectation. Here are some of the topics that we thought were just fundamental.

What's radioactivity? What's radioactive iodine? What should I know about the treatment? Basic radiation safety type topics, the appropriate venues for recovery after release -- go home, go somewhere else, precautions to take after receiving the treatment, and risks to others and the expected general behavior after release. That was the first part, the website. The second major objective is the best practices. We think there should be a dialogue between the patient and a member of the licensee staff that leads up to an informed decision on the licensee's part as to when to release the patient. These are the best practices. We're hoping we're going to get best practices from individual physicians, in addition to the professional societies.

We think that these are maybe some of the topics that will be part of that discussion, so we

say possibly would include, not a "shall or a should," because none of this is a new requirement or is expected to be a new requirement. So expect the dialogue. The Commission asked us specifically if there is a voluntary patient/licensee acknowledgment form for documenting the dialogue as part of the physician's best practices. We'll have an item on there.

We think when there's a dialogue of any kind, there's always potential language barriers. We always think that -- so we put that as a topic. Is there a need for a support person to be able to help facilitate retention of the information for the patient? Is the patient suitable for release? What is the transportation? Discussion of normal routine because if a patient has a normal routine and their normal routine would not be a good way to reduce radiation exposure to others, then that normal routine is going to have to shift, or if it can't shift, then the licensee has to find a way around that. We're looking at normal social interactions. Are you an isolated person? Are you a member of a large family?

Do you work and have to work? Do you serve on the salad bar line of Golden Corral?

Whatever it is about social interactions, that's the kind of thing that we think ought to be discussed -- the working environments and tasks and living arrangements. Do you live alone? Do you live with a large family in a small area? And the questions we think would lead to discussions of changing in either living arrangements or in social interactions for a period of time. We also thought maybe there's financial considerations, but that is one of our topics for dialogue.

The ability for the patient to understand and willingness to follow instructions. If you give instructions and the patient is neither willing nor able to follow them, then that's not going to be helpful for the public. Then evaluation of the disruption to the patient into their routine lifestyles and whether those disruptions are reasonable and they can deal with them and they can handle them. Those are some of the topics that we've indicated. In each one of these, we've said if we haven't identified a topic you think is important, tell us about it. If you think one of our topics is totally out in left field, tell us about that.

We're expecting qualitative information. I'm expecting I'm going to have, maybe, as many people

saying A is great as people saying A is horrible. We will deal with that when we get it, but we're not doing a statistical analysis. Because we're asking for information, we're hoping that people will give their own individual experience information. So we're not looking for form letters. Many times, we go out and request comments, we get form letters. We're not looking for form letters. More things about the dialogue.

One of the big things that came up in the data that -- the discussions that the Commissioners had with different members of the public was maybe there's a best time for discussing with patients that they have to make temporary changes to where they're going to be living and how they interact with other people and their family members. What's the best time for this discussion to happen? We hope it's not after the administration. We hope it's before. But it's like, "What would be the best time?" So we're not only seeking the perspective from the physicians, we're also seeking the perspective from the patients. You may have the best document in the world, but your patients may not understand it. They may get confused by it. There are all different levels.

What do the patients really think about

what they're receiving for information? That's one of our most important components of this information gathering. The next one is essentially on guidelines for providing information to patients when they're released. The commission wants us to get best practices, get information from the patients, so that we can go back and see if we need to beef up our guidance in any direction and make it better. The Commission is looking for clear and concise information.

There is an implication that we would have more prescriptive guidance. NRC tends to go to performance-based guidance. I don't know where that's going to fall out when we finally come up with the guidance. We tend to like performance based better because it's more easily adapted to different situations. Then we will be looking at essentially reducing the variability and eliminating uncertainty, and then we may be revising Regulatory Guide 8.39, both with --

(Simultaneous speaking.)

DR. HOWE: -- from our project, which is more qualitative, and the other project that the Office of Research is working on, which is the more quantitative health physics of where do people go and

what kind of doses do they expose members of the public and members of the family to?

We came up with a list of standardized patient guidance objectives. This is, again, a "would" question. Would you have these questions and topics in your guidance? If you do -- the other thing is if you think you've got really good guidance, send it to us. We don't require you to send our guidance for licensing, so this is not information that we already have. If you think you have good procedures, send it to us. If you want to send it anonymously, that's fine.

We don't need to know your name or your location. If you want to give that, that's fine. You, as professional members, can send it anonymously. Patients can send it anonymously. We're just looking to collect the information. These are a number of objectives. If we're going to be performance based, we would provide objectives. We wouldn't tell you how to reach those, and we would expect that you provide the patients with tools that allow them to meet the objectives. If it's prescriptive, it may be very detailed and specific. Then these are some of the questions that we think might be questions that you would have in patient

guidance.

We really want to know when you provide the instructions, and are the instructions provided in a manner that's easy to understand and follow, and what would make the instructions better? Those are the kind of questions we're asking of people. Any guidance documents that you have, as professional members, or things that you've given to patients, we'd get them from patients. What tools? Do you have both oral and written information presented? Is it in the native language for both individuals, and do you have access to interpreting facilities?

We understand there is a federal law now that you have to have, but that doesn't necessarily mean everybody meets things, and it's certainly not something that we inspect against. We would never inspect against that. How are they personalized to fit the individual? How do you explain limiting exposures to others, living arrangements? How long does special care have to be exercised? Do you tell the patients how to reduce exposure to others, inside and outside the home? Transportation's an issue. Managing biological waste, we're getting at the question of the landfills triggering and sending the trash back. Do you provide guidance and information

on that? Do you tell where to go for emergency care if you've got questions?

The final objective, which is the brochure for nationwide distribution, is if you know of a brochure that's in existence now and you think it answers a fair number of -- talks about a lot of these topics and answers the questions, then let us know. We don't want to develop a new brochure. We'd like to be able to see if there is something out there that can be distributed on a nationwide basis.

That's what the Federal Register is going to do. We'll go through a number of different processes. We'll put it on the list server. We'll actually send the information out specifically to the professional societies and to patient advocacy groups that we know about. We're going to try to get the information out as broadly as possible. Do you have any questions?

CHAIRMAN THOMADSEN: Thank you very much, Dr. Howe. Are there questions from the committee? Dr. Alderson.

VICE CHAIRMAN ALDERSON: Yes, I compliment you on this effort. I'd like to just know, for the first question -- I have two, but first question, how often, in the past, has the NRC done

this kind of data gathering within the medical context to the medical community?

DR. HOWE: I don't think we've gone out with this kind of data collection in the past.

VICE CHAIRMAN ALDERSON: Ever before?

DR. HOWE: I don't think so. We've asked specific questions in rulemaking space, but outside of rulemaking space, I think we might've done a survey, but I don't think we've done this kind of thing.

DR. PICCONE: We did, long ago, work with the Society of Nuclear Medicine in the development of a brochure they had on I-131 treatment. This is going way back, like in the '80s.

CHAIRMAN ALDERSON: I think it's a good effort. The NRC is actually communicating to the public. It's going to come back, and then the ACMUI and others are going to be able to comment and guide. I think it's a great process. One of the things that I think is mysterious about -- there is kind of a mysterious side to the NRC. Even though some of us on the Committee have that feeling, certainly the public does, so the idea that you're out there communicating, I think, reduces that problem and is a good thing. Obviously, the outcome, we have to do

something with it once it comes back, but I compliment you on going out like this.

DR. HOWE: Thank you.

CHAIRMAN THOMADSEN: Thank you, Dr. Alderson. Dr. Zanzonico?

MEMBER ZANZONICO: I had concerns about this, which I stated before, and I'll reiterate. I'm very cautious about an NRC or any government-sponsored or managed website. Again, despite the best efforts, there's an element of this with the regulator interposing themselves between the patient and their physician. I know that's not the intent, but that's an inevitable consequence.

I can foresee many instances where, as people do now, they look something up on the Internet and they go to their physicians, "You're telling me Y, but the Internet says X." It's bad enough when it's an unvetted website. Now you have an authoritative website, in principle, the NRC website. I just see, inevitably, conflicts arising between what a physician recommends and what the NRC may recommend or have. I don't know what the solution is because it's a commendable objective, but on general principle, I'm just skeptical of that. I don't think there's a solution. I'm just expressing

my thoughts.

DR. HOWE: I think one of the things we hope will help with that is that the recommendations that we get are recommendations of the people that have used websites that they like, and that the recommendations are going to be coming from the medical community. The medical community will say, "I know kind of what's out there. I like this," and the patients will do the same thing. The vetting is out in the public.

I don't think we're going -- we will definitely put a disclaimer on the top that says this is not NRC's position, and that this is not in place of your discussion with your medical providers. But we're hoping that by getting the recommendations from the medical community and the patients, that vetting that goes on with them deciding what's the best will help, to some extent, in your question. Then there will be lots of disclaimers.

MEMBER ZANZONICO: I think that's certainly a necessary, but perhaps not sufficient condition. I just have worries about a disembodied website with the NRC or any governmental logo and its impact on the patient/physician relationship. But again, this is -- I understand you're making your

good-faith effort to avoid those kinds of complications. Two more specific issues. One is you've mentioned a number of stakeholders that you're reaching out to. I think two very important stakeholders that should be included would be the landfill operators.

I think this issue of waste disposal and very low-level contamination of household waste and the problems it precipitates for patients is a big one. I think the landfill operators need to be as educated as anyone, perhaps more so than anyone, about what positive results by landfill detectors mean and don't mean. I think that's an important group of stakeholders to educate and to reach out to as any of them. Similar vein, I think hotel operators need to understand what having a post-therapy patient in their facility means and does not mean. I think those are two important groups of stakeholders that should be included explicitly in any such effort.

CHAIRMAN THOMADSEN: Thank you very much. Ms. Weil.

MEMBER WEIL: The concerns that Dr. Zanzonico mentions about the website, I think, are certainly going to be real issues, but not

insurmountable ones. One of my concerns about it is that it precludes reaching several very vulnerable populations, those with limited English proficiency, those with low literacy, and those without access to the Internet who really won't have access to this NRC-sponsored portal for information from other entities.

One of the ways you might be able to make it more useful for some of those folks is to specifically solicit information that has been translated into other languages from stakeholders. Because that stuff does exist in many places, and there might be subsets of the portal that could point people toward information in Spanish, or in various Chinese languages and etc. I think you will have to find a way, on the website, to address the fact that there will be discrepant information.

That needs to be very explicit, that this is information that will contradict itself from various sources. Perhaps patients need to be redirected back to their own clinicians, in order to clarify that kind of discrepant instructions.

(Simultaneous speaking.)

MEMBER WEIL: It's a splendid initiative, I think.

CHAIRMAN THOMADSEN: Thanks very much. Dr. Palestro.

MEMBER PALESTRO: Donna-Beth and I have talked about this before, but I do, once again, want to express my concern about something like a brochure on the website. How it's selected and so forth, I think, is a question. If you select more than one brochure or one website that individuals can go to, in all likelihood, there are going to be discrepancies. So the question then is which of the two is better. I don't have an answer for that. I think that tends to create confusion, doubt in the mind of the patients and the licensees and physicians.

Despite all the disclaimers that you can put on the website that the patient or members -- that the procedures are best discussed with your own physician, I think the subliminal message, both to the physician and to the patient, is this is a governmental document, and this is what I really need to look at, so I think there are issues with that.

CHAIRMAN THOMADSEN: Thank you for that comment, Dr. Palestro. Dr. Ennis.

MEMBER ENNIS: Two. One is actually for Committee members. Does the Society of Nuclear

Medicine have already such a recommendation on the website?

DR. HOWE: We believe that there are different professional organizations and patient advocacy groups that have documents out there. One of the things we're also -- I'm kind of hoping to get is that -- those documents that are put together and how are they being implemented? Do you have to -- am I going to get physicians that say, "I kind of go with this, but I modified it a little bit for this practice"?

We're kind of looking for that kind of implementation as we're collecting the information here. We are well aware that there are many websites with information. There are many professional societies with documents, and we're hoping that -- we know we're going to get those documents in, and we're hoping we'll get other folks that implement them and tell us -- show us what they do on the implementation.

MEMBER ENNIS: My second point was to really echo Ms. Weil's comments. To the degree that there are problems with the patient community taking care properly of themselves and their families and their garbage and all the issues, there's no doubt that the higher the illiteracy rate, the lower the

medical knowledge, language barriers, those are the populations that are going to benefit, so targeting whatever you come up with to those populations -- and it's not just about translating into other languages, but that's part of it -- but making it understandable for people of less education.

If it's designed to fit the needs of the committee and their families and the staff and their families, it won't have much of an impact because we don't really need that. We're sophisticated. We talk. We ask questions. We go online already. There's a skill to that and a knowledge base that I don't have, but I would suggest tapping into those kind of resources to try and find ways to reach those populations.

DR. HOWE: That's one reason we're trying to get down to the individual -- we're hoping to get down to the individual physician line, so that their practice may not be the same as the superior medical center, and they have to deal with those issues on a daily basis. They can tell us how they deal with them. So we're hoping to get some of that information. We understand that's a big problem.

CHAIRMAN THOMADSEN: Thank you. Mr. Costello.

MEMBER COSTELLO: A couple of comments. One to reinforce what Dr. Zanzonico had to say about the waste facilities. We get contacted sometimes by patients in Pennsylvania and being told that they're being threatened to have their waste pickup cut off if they continue to put any radioactive material in their trash. I remember hearing from a mother of a woman who we'd been treating for thyroid cancer.

They were being threatened with thousands of dollars of fines if this should happen again. She said she's dealing with a daughter who's got cancer. Now she has to deal with this, too. She complained about the information that was given to her by her provider. I don't have a solution for that. I think some of it is just an educational thing for the people who run the waste sites.

We try and explain to them that there's really no hazard in burying the stuff, but when you hear from a patient who is already dealing with a difficult situation with a family member having cancer, and then being threatened with a cutoff of the trash pickup, it's a difficult thing to deal with. As far as a government website putting out medical advice or guidance like this, just a thought, I can go on the NIH website and get information on the

diagnosis and treatment of Hodgkin's lymphoma or prostate cancer or all sorts of things, which may be consistent with what my physician's telling me or may not be consistent with what my physician's telling me. Sometimes, I'm sure much to my physician's -- I may say, "I found this on this website. What do you think?" She'll growl at me, and then deal with the question.

But I don't think it's unusual for a government website -- and I think of NIH -- to provide information on medical issues. So this is my two comments. One is I don't know if there's a solution for the waste question because I don't want patients keeping the waste in their house. I don't think that's allowable, and I don't think that's a good thing to do. On the other hand, I don't like patients being threatened with large fines and cutoff of their trash pickup if they it there. Good luck with coming up with guidance to address that issue. Thank you.

CHAIRMAN THOMADSEN: Thank you. Dr. Metter.

DR. METTER: I just have to dovetail on that, what Dr. Zanzonico had said. Another stakeholder, perhaps, would also be the transportation industry that use radiation detectors

because they get stopped and all that. For example, I know people that give notices that they did receive radioactive material, but my institution would not allow that because it -- so if there is one, they'll have to call our department directly. So just maybe more of an educational issue because I think with more and more concern about radioactive issues in the public, I think that might be something you might want to consider.

DR. HOWE: We did a RIS a number of years ago because with the security issues we had, alerts triggering when patients went under the New York tunnels to go gamble in Atlantic City. We had professional people driving by the White House and triggering. Some of them are indium ones, which they can trigger from weeks and months later. A lot of the others are more short-lived isotopes.

We don't have a regulation that you have to provide anything to the patient, but we did suggest that you provide something that could have whoever stops them call back to the facility. I recognize you've got to get around the HIPAA rules, so it was a way of facilitating and making it easier for the patient to kind of explain to law enforcement that this was -- they weren't a bomb that's about to go

off, and they weren't a serious risk. We dealt with a RIS on that before, and we'll keep that in mind. Oh, I have to explain what a RIS is. A RIS is a document the NRC puts out. It's not a new policy, but it explains a policy. It's called Regulatory Issues Summary. If you look on the medical toolkit, and the medical toolkit is in the public NRC web pages, and you look under medical, then we've got a toolkit over there.

It provides a list of RIS and information notices and other generic communications that licensees and others can find interesting that are related to medical. We extract all the things that don't pertain to medical, so you're not going to have to wade through 300 RIS's on pumps at power reactors. We selected the things that we think are pertinent to the medical community, so you can find those on our website. I think we have a question.

CHAIRMAN THOMADSEN: Oh, yes, Zoubir.

MR. OUHIB: Zoubir Ouhib, medical physicist. I guess listening to some of the discussion here, perhaps, as you were stating that you're going to be seeking feedback and advice and all that from professional organizations, maybe one way to sort of relieve this concern is to seek

endorsement, after a full review, of the final product to make sure that all these professional and medical associations will agree with what's being implemented in there, perhaps. I think that might be one solution. The other comment that I had is will you be looking back to, say, medical events and say maybe we can implement some -- what actually went wrong, whether that was patient information or whatnot -- into that document to sort of correct -- I guess maybe I should've stated the first question is that what is really the goal of such a document? What is the end point? What's the goal?

DR. HOWE: The end point is to look at our guidance and to try to provide as clear and concise information as we can to the medical licensees, that they can inform their patients, so that the radiation dose exposure to the public is maintained, as well as reasonably achievable, while they're still meeting all of their regulatory requirements. We are not changing the regulatory requirements. We are looking at the qualitative issues that are associated with meeting those requirements.

CHAIRMAN THOMADSEN: Dr. Dilsizian.

MEMBER DILSIZIAN: I concur with all the

discussions, and I think it's well intended. I'm just going to bring the reality of the other side. I think a lot of these documents are available, and as physicians and patients, when we deal with this on a daily basis, there are two sides. There's variability among the physicians. In essence, the information is there. There are those of us who spend 30 minutes with a patient before and after treatment. There are those who may spend five seconds or five minutes. I think it's not the lack of documentation.

It's not lack of the information. It's practice, which I'm not sure if you're going to be able to change that unless education or societies change it. The other part is the patients. I have to say I agree with you, the education of the patient, but even well-educated patients, sometimes they're so overwhelmed with their disease that no matter what you say, they just don't hear you. So there's other aspects of this.

I think that we're going to have a nice guideline, nice forms, but at the end of the day, it's still the medical practice, where there's going to be variability among patients and physicians. I don't think we're going to have complete solution,

but this is a step forward, where the societies, I think, are already doing it, but I just -- I'm afraid that there's more to it than just documentation.

DR. HOWE: This is going to be a really tough thing to do and trying to figure out, in the end, what we can and will do is going to be very difficult. We don't go into it with any apprehensions or any understanding it's going to be a simple process.

CHAIRMAN THOMADSEN: Any other comments?

MEMBER ZANZONICO: Another of the stakeholders are our funeral directors. This is another group that we/I periodically get inquiries about, the patient, short term, or even longer term, post-radionuclide therapy, what can or cannot properly be done? I think that's another group that needs to be in the loop.

CHAIRMAN THOMADSEN: Thank you. We appreciate that. Okay, thank you very much Dr. Howe. This brings us to Mr. Mattmuller, who will be filling in for Dr. Langhorst on the ACMUI comments on the policy statement reporting abnormal occurrences to Congress. Mr. Mattmuller.

MEMBER MATTMULLER: Good morning. I'm Steve Mattmuller, and I will attempt to fill in for

Dr. Langhorst, as she was, yet again, a chair of another subcommittee for ACMUI. I think we might be remiss if we don't have a subcommittee for her to chair before we leave. She'll be disappointed, I'm sure. I wonder if she's listening. I'm presenting the findings of our subcommittee, looking at abnormal occurrence reports.

Our charge was to review the proposed current revisions that the NRC is proposing on the policy statement on reporting AOs to Congress, provide comments, ACMUI recommendations on the AO criteria applied to events involving patients for human research subjects. Why does the NRC have to do this? It's mandated through the Energy Reorganization Act of 1974. The NRC has to submit to Congress an annual report listing, the previous fiscal year, any abnormal occurrences at or associated with a facility.

In generalities, this is an AO per the Energy Act of '74, that an AO is an unscheduled incident or event which the Commission determines is significant from the standpoint of public health or safety. But for the specifics of an AO, the NRC is able to define exactly what the criteria is. Yes, even if there's just one patient or one person

affected in this event, it is appropriate, or it may be appropriate, in terms of public health and safety, to include it in an AO report. Within the Energy Act, they've specified that the report has to include the date and place of the occurrence, the nature of probable consequences, the cons, and any action to prevent reoccurrence. For some of you here who are more experienced ACMUI members, you may remember we've been at this for a bit.

I was going to say mature members, but I'm not sure all of us would fit in that category. In 2013, this same subcommittee presented our proposed criteria. We now affectionately call that our first draft report. Since then, in 2015, the NRC staff has been busy. In March of this year there was a SECY document, where they put out their proposed revisions, what they think are the proper criteria. The Commissioners looked at it and voted on it and moved it along through the process, where it's actually now in the Federal Register.

It came out last August, or August of this year, just two months ago. It's available for comments now until the 16th of next month, in November. We also tabulated the results from past AO reports that went to Congress through the past

eight years. You'll notice that the vast majority of all the occurrences are medically related. In the third column, 35.3047, these are reports due to a dose to an embryo/fetus or a nursing child. All of these occurred during the therapy of women with an unsealed source of iodine-131 for thyroid cancer treatment. Unfortunately, these patients turned out to be pregnant during their therapy.

But fortunately for the vast majority of these embryos, they were, as they say, in the wrong place at the right time. That is, therapy occurred very early in the pregnancy, before the embryonic thyroid starts to produce iodinated thyroid hormones, which this doesn't occur until the third month. Hence, there was no harm to the thyroid. These AOs were deemed to have no negative consequences. The next column is in regards to 35.3045. These are medical events. The vast majority of these reported are from therapies with sealed source material, I-125 seeds for prostate therapy.

Again, most of these were deemed to have no negative consequences. Here's the next three years. Again, the pattern continues. The vast majority, if not all, are medically related and, in fact, for the eight years, 114 total AOs to Congress,

only five were not medically related. This is summarized here on this slide. We've got a slight typo. We had 109 AOs out of 114, so this should be 96 percent of AOs were medically related. That's, on average, two per year for 35.3047 and 14 a year for 35.3045. Part of our charge is to look at what is an appropriate definition of an abnormal occurrence for this report that's submitted to Congress and/or to look at how an AO event can be used to help prevent reoccurrence.

Ideally, there would either be a lesson learned from this event, but if the event has been evaluated as no adverse health are expected, does this event have value in being submitted to Congress? This is where the NRC is at in their proposed criteria, starting, of course, with the existing criteria that was established in 2006. They're trying to restructure and clarify the criteria to be consistent with current NRC regulations and guidance.

Part of this effort is also involved in the current rulemaking for 10 CFR 35, with a new definition or new criteria for 35.3045. That, as you might remember, includes separate medical event reporting criteria for permanent implant brachytherapy, which, of course, would include

therapy of sealed sources, such as I-125 for prostate therapy. The biggest change in this criteria would be based on total source strength administered or activity based, rather than a dose-based delivered criteria. As you know, Dr. Langhorst is always very thorough. She looked into two broader documents that the NRC has published, the NRC strategic plan for Fiscal Year 2014-2018, and also another document, called the NRC Project Aim 2020 documents.

We looked at these and it's clear from these documents -- it's clear that the NRC's focus is on power reactors. The word medical is used very sparingly in these documents, just a few times, and it's mostly just to describe the type of licenses that they regulate. There is no mention of AOs in either of these two documents. There seems, at first, to be maybe a disconnect between what's been in past AO reports and what's in these two documents, as past AO reports, 96 percent of those are medically related.

To fix this, I think we really only want AOs that have medical consequences. We think that should be included in the AO report to Congress. We think we can get there with the proper criteria for the AO report. In trying to get an idea on the

incidence of these AOs compared to total number of procedures, we looked at some very old data. Unfortunately, trying to get procedure numbers is difficult and expensive, so most of the nuclear medicine diagnostic work is from data that's more than ten years old. But if we look down to nuclear medicine thyroid therapy procedures, which is with iodine-131, and this represents 92 percent of the total nuclear medicine therapy procedures, we have just over 16,000, but that's all thyroid therapy procedures.

If we adjust this estimated number at the percent of cancer versus hyperthyroid treatments at my facility, which is about 50/50, that brings it down to 8,000 a year. Then you further have to reduce it to account for a male/female ratio. At our place, it's about a two-third/one-third ratio. This number really should be about 5,300 female patients who are potential AO report candidates, so to speak.

The rate would be the current rate with a historical average of two per year, out of 5,300 a year, is around 0.03 percent. If we move into non-I-131 incidents, this slide fortunately has more up-to-date data. It's 2009 data. This has total radiotherapy, non-radiopharmaceutical patients, so

there are no I-131 patients in these numbers. This is all radiation therapy patients, including those who received therapy by linear accelerator which, of course, is not regulated by the NRC. Of this million procedures, radiotherapy from byproduct material which, again, does not include unsealed byproduct material, we have 36 percent, which is the total, I should say.

Total is around 90,000 patients a year, 36 percent is high dose rate, again, which is about 32,000 patients a year, and again, for Gamma Knife, GK, it's a similar number, 32,000 patients a year. The permanent implants, would be a percent of about 21,000 patients a year. If we take 14 events, on average, data reports per year by 90,000, we get a rate of 0.01 percent, so again, a very low incident rate. This next page that's really hard to read is actually a comparative table that's in our report, which I'm sure you've all read. In the first column are the current 2006 criteria.

The next column is our 2013, our first draft criteria that we put out in the subcommittee. The next column is what, currently, the NRC is proposing, and then finally, the last column is what we're proposing today in our report that we think is

our recommendation for appropriate criteria. As I go through the next slides, it might be easier for you to follow along with that chart. So in the statement and introduction of the criteria, we're in agreement with what the NRC has proposed. We think that's fine. In AO Criteria I, in the title and footnote, again, we're okay with the title. We do have two recommendations for the footnote.

This would be Footnote No. 2, medical patients, and we'd like to add "and human research subjects are excluded from consideration under this criteria. These criteria do" -- and it's a long footnote -- "not apply to events defined in 35.3045 and 35.3047 of 10 CFR." Note 2, Criteria III.A, the title, we're fine with that. I'm sorry; I missed a few comments here. In regards to 35.3047, this, as you might remember, is for reported notification of a dose to an embryo/fetus or a nursing child.

We think it makes much more sense to keep all the medically related AOs in one section of the report, since they all involve the administration of byproduct material. To date, all of the 35.3047 AOs that have occurred have all been because of iodine-131 therapy in pregnant patients. After all, since pregnancy's part of a patient's medical

condition, we believe it ought to be in the medical section, which is Criteria III.C. Now for this -- here we go. III.A, the title, we're fine with that. III.C title, only a slight change here. The current title says radioactive. We recommend this be changed to byproduct material, so it's consistent with 10 CFR regulations. This is the footnote to Criteria III.C, and we agree that Footnote 16 clarifies AO Criteria III.A.2, III.A.3, and III.A.4, also applying to medical licenses.

In Criteria III.C.1 and 2, this is where we sort of part company with the NRC. You might notice in the chart this is pretty much where we deleted practically all of the dose criterion language that the NRC has proposed. The issues we have with the dose criterion are that with modern therapies, they're much more precise, and a slight shift may result in significant doses to nearby healthy tissues or parts of organs with no consequences and may not be recognized.

Another problem with the dose criterion is that you can exclude an event that results in unintended permanent functional damage to an organ or physiological system, but does not exceed the dose criterion. Another potential flaw is that dose to

other tissues or organs is a known risk or side effect, and a physician discusses this type of risk and side effects with the patient as part of the combined medical and personal decision about whether or not to perform the procedure. Another issue we have with the dose criterion is the language, in that it states, in III.C.1.a that it affects a major portion of the bone marrow. By itself like that, it's really too vague, without any evidence of probably consequences.

Other issues we have with the current language, where it states seating, giving expected dose to any other organ or tissue. Again, this really doesn't have the same meaning for high dose rate precision radiotherapy techniques in use today as it did when it was applied to older radiotherapy techniques in the past. The older techniques calculated the dose for a relatively large, uniform target area measured in centimeters. Whereas, current modern techniques work on the periphery in millimeters.

To paraphrase Warren Buffett, who's addressing the economy, but I think it applies to us here, that they studied what was measurable, rather than what was meaningful. That is the dose criterion

to us is measurable, but it's not necessarily meaningful. Instead of relying on problematic dose criterion, this is our recommended criteria, to find meaningful AOs. An event, as defined in 10 CFR 35.3045 or 35.3047, which results in a dose -- excuse me, that should be which results in an unintended, permanent functional damage to an organ or a physiological system, as determined by an independent physician deemed qualified by the NRC or an Agreement State.

The footnote for an independent physician is one who's defined as a physician not on the licensee's staff and who was not involved in the care of the patient or human research subject involved in the event. If we use our proposed criteria for an AO, and then look at past AO events, we're going to talk a little bit how they would now apply it to what we're proposing.

Pretty much all of the AOs for 35.3047, in all of them except for one, the administration of the I-131 occurred very early in the administration -- or excuse me, very early in the pregnancy. Unfortunately, there is one here, the patient was six months' pregnant. She had said she was not pregnant. Unfortunately, the licensee did

not perform a pregnancy test. The I-131 was given, and unfortunately, the child was born without a thyroid. This would continue to be an abnormal occurrence based on our proposed criteria. For this next event, the patient had a negative pregnancy test, and the I-131 was given. They repeated the pregnancy test about 12 days later and it was positive. But then fortunately, again, because the administration occurred so early in the pregnancy, they determined that it should not cause any developmental effects.

We think this one could kind of go either way, but we really think this would still continue to be an AO, based on Criteria III.A.4. The reason for that is the cause was from serum beta HCG test. That doesn't test positive until ten days after conception. So the fix for this licensee was to improve their screening procedure to counsel the potential patients that they need to refrain from sexual intercourse two weeks before the date of treatment.

So Criteria III.A.4, which is a more generic or general criteria, with the implications for similar facilities that could raise a major safety concern. The remaining 35.3047 events, the

general lessons from those -- these all are very, very similar to where pregnancy was not determined until later, but in all of these, the administration occurred very early in the pregnancy. The emphasis is always use the most sensitive pregnancy test and to improve patient counseling. But in all of them, they were evaluated to have no probable negative consequences, so we believe these should not be -- events like this should not continue to be an AO event. The subcommittee, we also read several of the comments by the commissioners and by the staff.

Some had comments that expressed concern that we're really only trying to reduce the number of AOs reported. That's really not our goal. Our goal is for appropriate and meaningful AOs to be reported to Congress. It's also important to remember that all the events in the NMED database undergo review. This all occurs before they even are considered to be an AO. As was mentioned briefly earlier today, there is a program that the NRC has, the NRC assessment program for a medical event or incident involved -- excuse me occurring at a medical facility.

Through this policy or directive, the review can occur at several different levels, first

with staff who performs the initial review, and then that review can escalate to an incident, with an incident investigation team, or even further with an augmented investigational team. But as we heard earlier today, those two steps rarely occur. The first level of review is more than adequate. Another important consideration of this policy is that it already includes when and how to consult with an independent physician. We feel review by an independent physician is critical to determining whether or not an event should be designated as an AO by our proposed criteria.

As we've stated here, what we're curious -- and if we're allowed to give a charge to the NRC, we'd like to ask them to evaluate whether the implementation of our proposed criteria, where an independent physician would review every possible AO, since there's already independent review going on now, how substantial -- what would be the increase, if there is any increase -- in cost to have this occur? Finally, getting towards the end, the Appendix B re-designation and new description, we're in agreement with that.

This is the committee membership. Dr. Langhorst is the chair, and as she would call us, her

minions were myself, Dr. Palestro, Dr. Thomadsen, and Laura Weil. Open the floor to questions for all. Where'd Miss Sophie go? We do have a slight correction to make to the report. Do you want to discuss that now or later?

(Pause.)

MS. HOLIDAY: We can do it now.

MEMBER MATTMULLER: This is in regards to the second AO event that I discussed, where there was some confusion as originally, we thought -- yes. Originally, we thought the patient had a negative test, and then we thought they had a positive test, and then they had the administration.

It turned out that actually, they had the negative test, the administration, and then the positive test came later. So we were able to correct it for the slides, but not quite yet in the language in our report. That would be the first bullet item on Page 11, where we talk about this event. I think we can take care of this just by deleting the phrase, "Involved a miscommunication which resulted in the patient receiving I-131 therapy, in spite of a pregnancy test which confirmed her pregnancy." I think we'll put a period after "embryo/fetus," delete that, we're good.

CHAIRMAN THOMADSEN: Thanks, Mr. Mattmuller. Are there questions from the Committee? Yes, Mr. Costello.

MEMBER COSTELLO: The price on independent medical review and the cost associated with that, most of these events occur in Agreement States. As I mentioned a number of times earlier, the States do not have the same infrastructure as the NRC has. I know states have, in some cases, gotten that run by a consultant. You know, I think last year or early this year, I know we, in Pennsylvania, have no arrangements for an independent medical consultant.

We have the assistance from the NRC in the past with the Agreement States, providing us medical consultants. But things that would be a challenge, if this were to happen very often, for many Agreement States to pay for this. We don't have doctors on staff, or we have doctors with contracts. I would be surprised if you found states coming to the NRC asking for help.

CHAIRMAN THOMADSEN: Thank you, Mr. Costello. Mr. Bollock.

MR. BOLLOCK: I can address the -- some of this. As Frank knows, we've been discussing with

OAS, the OAS, NRC, we've been working with OAS, discussing this back and forth. We do and have, on a case-by-case basis, given support to the States in providing one of our medical consultants.

There are questions about cost and what it takes. There are certain steps that have to be taken by the State. They have to show that they don't have the resources. They can't do it . In working with OAS, there are some things that the other States can do to provide guidance to help states. Different states have different, basically, I guess, resources outside their own -- resources available, whether they have a physician on their staff, or in their regulations, the ability to have the licensee pay for that independent, selected by the State or by the regulator.

So there are many, many options, but we have made it easier now for us to provide that to States if they show that hardship. Basically, the costs are, for what we pay -- essentially, there are medical consultants --

MEMBER COSTELLO: Minimal.

MR. BOLLOCK: Oh, yes, they're minimal. It's essentially what we pay you all for your -- as advisory committee. They're special government

employees. We pay them at a rate of about 15, step 10. But to provide that and get a reimbursement is what is stated now, actually, the State would have to reimburse us at a rate of -- to the, whatever our hourly rate is for services, which is about $275.00 an hour, but something in that range.

So it is actually less expensive for us to provide that. We've already determined it is less expensive for us to provide that service to the States when needed, if they showed a hardship. They have to take -- do their due diligence and go through and show they don't have a medical physician on staff, they don't have the ability to get that reimbursement from the licensee.

It's actually cheaper for us, or more cost-effective for us to provide that assistance than even to go through the administrative burden of getting the reimbursement from the State. That is something that we worked this year to get through. I think we've found our path forward to be able to help that. I think our staff position is we would support, in the cases of AOs, an independent medical consultant to make those determinations.

CHAIRMAN THOMADSEN: That's very good to hear. Thank you for that clarification and that

information. Other comments? Dr. Zanzonico.

MEMBER ZANZONICO: Two comments. The first is it strikes me that a medical event is or should be almost never an AO. My understanding is that AOs reflect an impact on public health. Now in many instances, these are tragic events -- a child born without a thyroid is probably cretinoid, so forth and so on. So it's not to minimize the medical impact of these events, but as Steve pointed out, the incidence of these sorts of things is miniscule, much, much less than a tenth of a percent.

So unless there was an indication of some ongoing problem that, in fact, potentially affected a significant number of people, rather than individual incidents of bad practice, it just strikes me that these events don't impact public health, per se, let's say like a leak of radioactivity from a reactor, which potentially could expose a significant number of people in general population. That's just a comment, a philosophical comment. The other is the conclusion that administration of radioiodine to a pregnant female prior to the onset of thyroid function has no medical consequence.

There's extensive data in the literature, dating back from the seminal studies of Stewart, that

especially in early-term pregnancies, when this is most likely to occur, there's a significant increase in the risk of childhood cancer from fetal radiation exposure, independent of thyroid irradiation or not. That strikes me as -- if we're going to use these sorts of criteria, that's a pretty significant impact. We're talking about an increase of the order of 50 percent incidence of childhood cancer per rad, per centigray, to a fetus. It's even higher in early pregnancy. That conclusion, to me, doesn't jive. There's a lot of controversy. There's more recent data which calls those findings into question, but I think the conventional thinking is that there's a very large increase in incidents of childhood cancer, as I said, per rad of fetal dose.

You will get rads -- you will get mean fetal absorbed doses of the order of several rads per millicuries of I-131 iodine, even in the absence of a functioning fetal thyroid. We're talking about potentially significant increases in that risk. Having said that, pregnant women get radiation procedures and radioactivity all the time, diagnostic procedures very appropriately. That risk is an implicit risk of those procedures, and it's almost always acceptable.

The reason a female is getting a diagnostic procedure or radiation procedure is that they have some compelling medical issue that requires that. There's a delicate line to walk. You don't want to imply that it's inappropriate to do these sorts of procedures in women or pregnant women. It almost always is, although it should be an informed medical decision to do so. On the other hand, just because the fetal thyroid has not begun functioning, I don't think, is a basis for excluding it from an AO if those are the criteria that are going to be used, which I don't necessarily agree with either, but for at least internal consistency, I think that's the case.

CHAIRMAN THOMADSEN: Thank you, Dr. Zanzonico. Ms. Weil.

MEMBER WEIL: I would disagree with Dr. Zanzonico's statement that these events do not have a significance for public health and safety. I think of these events --

CHAIRMAN THOMADSEN: Can you turn your microphone on?

MEMBER WEIL: I think of these events as being harbingers of potential occurrences across a wide range of either population groups or

disease-specific groups. The importance of reporting them is to alert others who treat these populations or these kinds of patients about the potential for these kinds of occurrences occurring in the future. The importance of them being public, and perhaps even being public to the extent that they're brought to the attention of Congress, is important in terms of potentially preventing future occurrences from happening, even if it's only a single occurrence -- a single fetus who may be exposed or any of these examples. I disagree with the necessity for permanent functional damage to be a requirement for something to be an AO because the next occurrence down the road could happen and incur more harm to the next patient. I think the public exposure of events that are of interest to the medical community and the patient community is not harmful. It is, in fact, useful.

CHAIRMAN THOMADSEN: Thank you, Ms. Weil. Mr. Costello.

MEMBER COSTELLO: I have sort of a process question or comment on the AO. Have you already provided these comments to the staff previously?

(Simultaneous speaking.)

MEMBER COSTELLO: What has changed? I believe we've already given these comments to the staff.

CHAIRMAN THOMADSEN: We have presented those comments to the staff. The staff's recommendation was to reassert the dose limit. When I talked with the Commissioners, they found it very interesting. They did not understand our rationale for doing away with the dose limit. I would suggest that in the -- if this document is accepted that there be an introductory paragraph added, we don't have an introductory paragraph in this report, that just explains the rationale behind why we are recommending the change from a dose-based evaluation.

MEMBER COSTELLO: They know our views on this already. I guess we're going to reiterate them or -- okay. I'm fine with that.

CHAIRMAN THOMADSEN: There is the open period for comment, and these are comments on the recommendations.

MEMBER COSTELLO: Okay, thank you.

VICE CHAIRMAN ALDERSON: I'll just ask the question on the other side of this coin, what is the burden created by having the, what is it, 20 some AOs a year that occur? What is the burden from that?

What's going to be a -- I'm not saying there isn't one, but I don't understand it. So what's going to be released or relieved by making these changes?

CHAIRMAN THOMADSEN: We aren't looking for any relief or reduction. That's not our goal. The goal is to have something that's meaningful. Right now, as Mr. Mattmuller explained, the criteria are based on event criteria from the 1970s, where things were broad, the numbers were wide, and changes in positioning would have very slow effects on the dose to neighboring organs. With modern radiotherapy, where doses in the target volume are shaped by many fields, you have non-uniform doses through the target volume, but target doses are defined on the periphery, and you may have very sharp penumbra, very small changes in position, a matter of millimeters, can suddenly be putting the full dose into a neighboring organ, but in a very small volume, which has no medical significance, whatsoever.

So the use of 10 gray is really no longer appropriate. On the other side of it, you can have a case where you're treating near a very sensitive organ and deliver an unintended dose of 6 gray, which would be under the criteria right now, but yet could have very great effects on the patient. That should

be considered an AO, and it's not now. The point is that any dose that you use is going to be inappropriate as a trigger.

It just doesn't apply as a measure anymore. We need to have a measure of what would be consistent with the goal of the abnormal policies, as shown on, I think, the next slide there, that they should report something that is significant from the point of public health and safety. This should be evaluated by the physician, as we said. We had discussed in the committee having a criterion that would try to capture events that weren't significant in themselves, but seemed to be repeated in a given facility, but that did not reach the report, itself. It got eliminated along the way.

VICE CHAIRMAN ALDERSON: So to summarize what I just think I heard you say was that the dose-based criteria, which were generated decades ago, are no longer relevant, and you'd like to see them changed?

CHAIRMAN THOMADSEN: Correct.

VICE CHAIRMAN ALDERSON: That would be important to have that as a preamble because just listening to this, without the preamble, I didn't get that at all.

CHAIRMAN THOMADSEN: Mr. Costello.

MEMBER COSTELLO: I have a question for the NRC. We're making these reports of AOs to the Congress for many decades now. For perhaps all that time, almost all the abnormal occurrences have been related to medical facilities, as opposed to, let's say, power reactors. Do we get any feedback from Congress as to is this what we're looking for, these reports? Do we get many questions from the Congress to elaborate in the report? Are we answering the mail? Are we doing what the Act requires us to do? Are we giving them what they want?

MR. BOLLOCK: Because it is determined by the Commission in the law, we're giving them what they want. As far as feedback, I don't know that we've ever gotten any.

MEMBER COSTELLO: Okay, thank you.

CHAIRMAN THOMADSEN: Thank you for that question. Other comments from the Committee, questions? In that case, I assume that you are moving that the Committee will accept as its own the report from the subcommittee. I would like to add the amendment that we add a paragraph explaining rationale. That is your motion?

MEMBER MATTMULLER: Yes, it is.

CHAIRMAN THOMADSEN: Very fine motion. It does not need a second because --

(Simultaneous speaking.)

CHAIRMAN THOMADSEN: Yes, it does not need a second to come to the floor. We are now in discussions. Dr. Ennis.

MEMBER ENNIS: So this came to mind before, but then Pat's comment, Dr. Zanzonico's comment, about whether there would be cases of iodine painted --

(Simultaneous speaking.)

MEMBER ENNIS: -- really not potential events brings me to wonder who was the medical consultant or the independent reviewer that declared them, and that makes me think is it clear what's the criteria for being an independent reviewer, and does that need to be more clearly addressed in a statement?

CHAIRMAN THOMADSEN: Okay, NRC staff, clarify how you choose medical consultants?

(Simultaneous speaking).

MR. BOLLOCK: Right now, there is no requirement for an independent reviewer in the current AO. I can't say there was or wasn't. I'd have to know the specific case and look back.

DR. PICCONE: Oftentimes, it's the

physician administering the dose making that call.

MR. BOLLOCK: The call would be by the one who's doing the reporting. As far as the criteria for who we select as our medical consultants, basically a physician -- typically a physician in the field that has -- that would meet the needs that we would have to perform that.

Actually, I don't know if you're all aware, we could request any of you to serve in that capacity. Obviously, we'd request it, and you can deny it. Right now, we have three medical consultants. They have also, as are all of you, they're special government employees. In fact, one of them was a former ACMUI member that may not be done at this time. We basically just solicit out and request people for whatever needs there are to fill. That's --

(Simultaneous speaking.)

CHAIRMAN THOMADSEN: Can I just clarify something I thought I heard you say, but maybe not, that the evaluation of effect on the patient is decided upon by the physician involved in the event often?

MR. BOLLOCK: Right, because --

CHAIRMAN THOMADSEN: Not an independent?

MR. BOLLOCK: Not --

DR. PICCONE: There's not a requirement for that.

MR. BOLLOCK: There's no -- right, there's not a requirement. If we, depending on our review -- our inspection review to see if there is more to it, we may request -- I know for NRC States we could request a medical consultant to give us more information based on the medical opinion, on the facts. But right now, it's not a requirement.

CHAIRMAN THOMADSEN: Thank you. Dr. Alderson.

VICE CHAIRMAN ALDERSON: So based on what you said a moment ago, Dr. Thomadsen, about the rationale for doing this, I also looked at the -- there's a whole written document in here, I guess, that Sue created. It goes through in detail what was presented on the slides. In that document -- neither is the rationale presented in that document. At the end of that document, which I expected to be the most complete document, there isn't an action item.

So what do you do with this now? What the document does, like the slide -- very complete, very accurate, hard work. I compliment the group on

it, but I'd like to see also, in addition to the preamble, the statement at the end that would say something like, "Accordingly, we recommend that the criteria for AOs be reconsidered and potentially revised." That would be an action item. I think that would make this a very meaningful report. But as it stands now, I think it's incomplete.

CHAIRMAN THOMADSEN: Thank you very much, very good recommendation. Ms. Weil.

MEMBER WEIL: Steve, can you comment on the other events of interest category?

MEMBER MATTMULLER: The other events, as how they would fare under our new proposed criteria?

MEMBER WEIL: No, I think it's III.A.4. Is that where other events of interest are -- I don't see it here, and I know that you discussed it. These are events that do not rise to the definition of permanent functional damage, etc., but have potential implications for patient safety at other institutions because similar events may arise at other institutions. Do you remember this?

MEMBER MATTMULLER: I think we did mention it as -- it was the incident where negative pregnancy test, they thought -- they did everything right. Negative pregnancy state, they administered

the I-131, and then repeated the pregnancy test ten days later, and unfortunately, she was pregnant. That one we did think would continue to be an AO, but under -- I'll have to look it up -- under the more general -- contrary to what we had just said, that we wanted them all in a medical section, this would be an exception to that, so it would be in the general category.

MEMBER WEIL: Right. I think it's important for the discussion for everyone to realize that there is an opportunity for AOs to exist that don't meet those very stringent criteria and that they, perhaps, shouldn't be eliminated.

CHAIRMAN THOMADSEN: A very good point. We're going to put a pause on this discussion and break for lunch. This is very interesting, and we do need to vote on this. We need to vote on something else that we left undone this morning. Please get back by 1:00, and we will resume.

(Whereupon, the above-entitled meeting went off the record at 12:02 p.m.)

(1:01 p.m.)

20. ABNORMAL OCCURRENCE CRITERIA SUBCOMMITTEE REPORT (CONTINUED)

CHAIRMAN THOMADSEN: I think we're

ready. Ms. Weil?

MEMBER WEIL: So, one thing we've not discussed yet is moving the protection for the fetus and embryo, nursing child, which is -- I can't remember the number --

CHAIRMAN THOMADSEN: That's okay. We know --

MEMBER WEIL: -- it's the one that ends in a 47 --

CHAIRMAN THOMADSEN: Yes, [35.30]47.

MEMBER WEIL: -- into this abnormal occurrence thing. And what that's doing perhaps inadvertently is creating two standards for the protections of this particular class of individuals. There's the medical use, which is then going to be governed by the abnormal occurrence criteria, but the public -- the fetus, embryo, nursing child member of the public has a different standard of protection. And I'm not sure that that's a good thing to be doing. Something that one of the Commissioners raised as an issue.

CHAIRMAN THOMADSEN: There's actually then three categories, because you have the fetus of an undeclared worker, which doesn't fit in anywhere. So we already have two without even looking at this.

What would you recommend?

MEMBER WEIL: I would like to understand the rationale for including the one that ends in 47, into the medical criteria -- medical -- I'm sorry, the abnormal occurrence criteria.

MEMBER MATTMULLER: Well, I think as we discussed the embryo is only getting exposed accidentally because of the failure of the pregnancy test in a woman who is having a medical procedure. And so if not for that, it wouldn't have occurred. So I suppose it's a huge deal, but we just thought it just made more sense since the mother is a patient being treated. It's medical. Those type of events ought to be categorized together. And it's not included in the III.C group together.

MEMBER WEIL: We have different levels of protection then for different kinds of fetus, embryo, nursing child. And I'm not sure that I'm comfortable with those different levels of protection. And it's just creating again a third level. Different- perhaps it's a lower level of protection - because it has to rise to the abnormal occurrence criteria permanent functional damage.

CHAIRMAN THOMADSEN: I'm not sure it's protected in this report, that the embryo/fetus is

protected as much as it can be by requiring a pregnancy test before treatment. And whether it's reported or not, that's not protecting it.

MEMBER COSTELLO: I have a question about that.

CHAIRMAN THOMADSEN: Oh, I'm sorry. Mr. Costello?

MEMBER COSTELLO: Yes, I should know this, right? The abnormal occurrence criteria, does a dose to the embryo/fetus of a declared woman, okay, by a limit of half a rem during the gestation period -- if that were to be exceeded by some value, would that ever rise to being abnormal occurrence?

CHAIRMAN THOMADSEN: Mr. Bollock, do you have a comment on that question?

MR. BOLLOCK: I believe so, because it's -- this is --

MEMBER COSTELLO: It's a violation of this order --

MR. BOLLOCK: Right.

MEMBER COSTELLO: -- but grant you an abnormal occurrence.

MR. BOLLOCK: Yes, I'd have to look through the -- what the other -- just for general -- exposure to the general public what levels are

then reportable by AOs.

MEMBER COSTELLO: Yes.

MR. BOLLOCK: Not as reportable to us. So I don't know what those are.

MEMBER COSTELLO: I'm just sort of trying to compare apples to apples and embryo/fetuses and embryo/fetuses and maybe come to the question you're asking, Ms. Weil, is to report then to the Congress if an AO -- differently.

ACHAIRMAN THOMADSEN: Well, I think one of the differences; and this is probably what you would be seeing here, is by moving it into the medical realm we've said that unless there's actual medical effect on the fetus it would not be an abnormal event. And this was part of what Dr. Zanzonico was saying, too. So the question would be from the numbers that we see it doesn't make very many case differences no matter what we do. Would you feel more comfortable if we kept the embryo or fetus in the general public category where it is now? The nursing child isn't --

MEMBER WEIL: Yes.

CHAIRMAN THOMADSEN: -- usually hasn't been an issue.

MEMBER WEIL: I think it's a situation

for the Committee to consider whether that is fairer. And frankly, having read the Commissioners' response to these suggested changes, I think it's something that the ACMUI needs to be prepared to defend if we move it since there was a very strong statement from one of the Commissioners questioning this particular change. So that's why I raise it.

CHAIRMAN THOMADSEN: Are there other voices for doing so? Anybody would like to speak up in favor of returning the embryo or fetus to where it was in the general public? Yes, Mr. Costello?

MEMBER COSTELLO: I'm not speaking either way because I'm probably very -- I just have this -- I want to discuss it a little bit. Okay?

CHAIRMAN THOMADSEN: Yes.

MEMBER COSTELLO: There are members of the public and then there are members of the public. Okay? The dose limit for members of the public is 100 millirem in a year. Okay? However, the dose limit for an embryo or fetus of a declared pregnant woman is 500 millirem. That's the way it is. Okay?

Now, there are reasons for that. And I don't think they should change. Okay? There's a risk benefit to having the mother working, and I understand that, and I wouldn't suggest changing it,

but I just think it's different. You just can't look at them as members of the public. They're unique members of the public. And the same thing for a woman who's receiving medical treatment that the trigger amount for the reporting is -- I think it's 500 millirem, and that's because there's a cost benefit there, that presumably the embryo or fetus benefits when a mother receives medical treatment. Okay? Same as the embryo/fetus benefits when the mother is employed.

So I'd just point out there are different categories that fall under -- that may look like members of the public, and they're different for reasons.

MEMBER WEIL: I think what you're talking about the exposure for the embryo/fetus of a -- it's the occupational limit --

MEMBER COSTELLO: Yes.

MEMBER WEIL: -- of a member of the public.

MEMBER COSTELLO: Yes. I'll tell you what, though -- because I think if the mother is receiving medical treatment, the embryo/fetus benefits from that, too, just like the embryo or fetus benefits from the mother being employed. So I think

you can't just look at them as members of the public. They're a special classification members of the public.

CHAIRMAN THOMADSEN: Yes. Well, even the public has different limits when they are the family taking care of --

MEMBER COSTELLO: Exactly.

CHAIRMAN THOMADSEN: -- a patient, so there is a precedent for --

MEMBER COSTELLO: And we go back to 500 millirem there.

CHAIRMAN THOMADSEN: We do, yes. Right.

MEMBER COSTELLO: And there's a reason, because a member of that family --

CHAIRMAN THOMADSEN: Yes.

MEMBER COSTELLO: -- presumably gets a benefit from the person getting treatment.

CHAIRMAN THOMADSEN: Okay. Mr. Bollock?

MR. BOLLOCK: Just to clarify, I didn't find in the proposed rule --

MEMBER COSTELLO: Okay.

MR. BOLLOCK: -- what the numbers were, at least in the proposed rule. So for AO -- this is --

MEMBER COSTELLO: Yes.

MR. BOLLOCK: -- proposed AO criteria. For general or adult members of the public to be reportable as an AO they have to receive a total effective dose equivalent of 25 rem. For a -- basically a child, a minor less than 18 years old or embryo/fetus, they have a total effective dose equivalent of 5 rem. So there are differences. I think that's just safe -- I would just -- you had asked, so --

MEMBER COSTELLO: No, thank you, because I had no idea. So, 25 rem for an adult member of the public and 5 rem for people who are under age 18 and --

MR. BOLLOCK: Or embryo/fetus.

MEMBER COSTELLO: Thank you.

MR. BOLLOCK: And again these are AO criteria, not --

MEMBER COSTELLO: Not regulatory criteria.

MR. BOLLOCK: Yes.

CHAIRMAN THOMADSEN: And my guess is it actually makes very little difference in these cases which of those numbers or any other number you use. If the woman is pregnant and receives the iodine, the

fetus probably would exceed any of those numbers.

Yes, Dr. Howe?

DR. HOWE: This is Dr. Howe. Just to clarify the reporting requirements in 3047, we did not have reporting requirements for embryo, fetus or nursing child prior to the Tripler baby incident. And then as a result of that in the 2002 rule they brought in the -- it's not a medical event, but it's reportable if the embryo, fetus or nursing child receives in excess of five rem. That value was not set based on occupational exposure or considerations of benefit to the mother or those types of considerations. It was set because it was the abnormal occurrence reporting requirement for the fetus and the nursing child for the general section of the AO criteria.

CHAIRMAN THOMADSEN: So it sounds circular.

DR. HOWE: So that meant there was a uniform AO criteria for all embryo/fetus/nursing children. And that was said in the general part. And I think what Ms. Weil was saying is that when you move the medical embryo/fetus/nursing child over to the medical section, now you have a different reporting criteria.

CHAIRMAN THOMADSEN: Correct.

DR. HOWE: And if that's what you want to do, you need to articulate well because the Commission's already --

CHAIRMAN THOMADSEN: Yes.

DR. HOWE: -- raised the issue.

CHAIRMAN THOMADSEN: Right. But I think the basis that we have is that; correct me if I'm wrong, the mother was receiving definite benefits, and so does the fetus from having the treatments done, because we all know that the fetus is there, or you wouldn't be doing the treatment. So it's a matter that the situation is different from either being an occupationally exposed person or just a member of the general public whose fetus is being irradiated because of the benefit, the much greater benefit that's derived from that. Does that summarize more or less the discussion?

MEMBER MATTMULLER: Yes, I think it's important to note that in a sense it doesn't matter where they're located because we're proposing the same criteria for adults and the fetus/embryo, so we just think from a practical basis since they're all medically -- from medically-related administrations that it makes sense to put them in one section of the

report. But it's the same criteria for either, so I think we're kind of splitting hairs on where to put it.

CHAIRMAN THOMADSEN: And it would get picked up in the criteria then for medical evaluation if it was felt that there was potential injury to the child. And that could come back to the question that Dr. Zanzonico brought up about statistically increased cancer incidences, if that turns out that that is something that's scientifically backed up.

MEMBER ZANZONICO: Could I just -- I think one thing that's a point to note in that respect, childhood thyroid cancer is a very rare disease, thankfully. So even a 50 percent increase in that incidence, if it's as high as that, and there's more recent data which contradicts the Stewart studies and those sorts of studies, still the gross incidence would remain very, very low, even if the risk pro rata is as high as said.

CHAIRMAN THOMADSEN: Yes.

MEMBER ZANZONICO: So it becomes a judgment call when you're talking about 7 rads or of the order or 10 rads, or whatever, to the fetus whether it's reportable or not. I just raise that as a possibility, but I did want to clarify that.

CHAIRMAN THOMADSEN: Yes. Mr. Bollock and then I think we'll be pulling this discussion.

MR. BOLLOCK: Thank you. I just wanted to bring up a point that this -- to change that in Section 3 would -- it would then make it contradictory to the proposed rule Section 1, 1(a), which is all licensees with the exception of --

CHAIRMAN THOMADSEN: I'm sorry. This is --

MR. BOLLOCK: Okay.

CHAIRMAN THOMADSEN: I'm not hearing you very well. I'm not sure --

MR. BOLLOCK: I just want to point out that -- and it's kind of backing what Ms. Weil is saying about it would make it a separate class. It would. Changing that in Section 3 of the AO criteria -- what we have proposed -- would be contradictory to what is in Section 1 of the AO criteria, which states -- that's where I pulled the any exposure to embryo/fetus of five rem, because the fetus is not the patient.

CHAIRMAN THOMADSEN: Yes.

MR. BOLLOCK: Right? So the medical events are an exception. This is a patient. And that's why we have that separate section.

CHAIRMAN THOMADSEN: Yes.

MR. BOLLOCK: Everyone else falls under Section 1 of that abnormal occurrence.

CHAIRMAN THOMADSEN: Yes.

MR. BOLLOCK: So it would then put -- I'm just pointing out it would be contradictory then and that --

CHAIRMAN THOMADSEN: And in the report the exception is made for medical exposures in those situations in the written report. So, yes, it does make two classes definitely and intentionally in that case.

Well, we aren't making much progress in coming to decisions on this, and I think we need to do that at this moment. We have the motion of the floor which we've been discussing, which is accepting the ACMUI Subcommittee Abnormal Occurrences Report with the provision that there is an introductory paragraph added discussing the rationale for the changes and the criteria that are being recommended and a summary paragraph listing the request that we ask to have these recommendations replacing the abnormal occurrence criteria. And the motion has not been amended, so it includes exactly what has been talked about as far as the embryo and fetus. Without

a motion to make a change, we're voting on the adoption as just specified.

So, drawing a close to the discussion we'll have the vote. All in favor, say aye?

(Chorus of aye.)

CHAIRMAN THOMADSEN: Opposed, say no?

MEMBER WEIL: No.

CHAIRMAN THOMADSEN: Abstentions?

(No audible response.)

CHAIRMAN THOMADSEN: It passes. And realizing that we like to come to a consensus where everybody agrees, I don't think we will on this because it's not clear and I don't think we're making any progress for coming to that consensus.

But do record that Ms. Weil voted against the proposal. Thank you. And thank you, Mr. Mattmuller, for -- take your tent please, as you go up.

We have left over from this morning also the vote on NUREG -- the recommendations of the Subcommittee evaluating NUREG-1556, Volume 9. We did not take a vote on accepting and adopting the recommendations, and I will assume that the Subcommittee presented the report with the goal of having us do so. And so, I'll now open the floor for

discussions on that. Any discussions on the report of NUREG-1556, Volume 9?

(No audible response.)

CHAIRMAN THOMADSEN: Hearing none, we'll have a vote on that. All in favor, say aye?

(Chorus of aye.)

CHAIRMAN THOMADSEN: Opposed, say no?

(No audible response.)

CHAIRMAN THOMADSEN: Abstentions?

(No audible response.)

CHAIRMAN THOMADSEN: Thank you very much. And now I will turn the chair over to you as I'm next. VICE CHAIRMAN ALDERSON: You're up.

CHAIRMAN THOMADSEN: I'm up. That's right.

VICE CHAIRMAN ALDERSON: Please.

CHAIRMAN THOMADSEN: Well, it seems to be a tradition talking about what ones reflections are on leaving the ACMUI. You can't be here for eight years without having some thoughts about that, and it's been a lot more interesting and exciting than I ever thought it would have been. We always are doing something important. And even this discussion that we just had right now you could feel

the importance of what we're doing even though it may not be clear what the answers should be. We do know we have to do things carefully and exactly. That is where the adrenaline rush comes from. You know that it's important. You know that you have to be on top of things all the time and alert and awake, maybe not when you're talking about E2.

(Laughter.)

CHAIRMAN THOMADSEN: We've done a lot of things. I mean, I haven't kept track of all the things that we've done, but my email folder -- or not my email folder, but the folder that I keep all my ACMUI I-documents in -- this is just my email folder, is .66 gigabytes.

(Laughter.)

CHAIRMAN THOMADSEN: Oh, that's not the emails. The emails are -- there's 1,710 that I've saved because I thought they've been significant and I may want to go back to them. And it's amazing, I do go back to them. So we've obviously covered a lot of material while I've been here.

There are things that I think we need to cover in the future, and this is reflections on you, what you might want to consider doing, but I'm not going to be here to participate. And one is the

medical event criteria for everything except permanent implants. And just like the AO criteria where we talked about modern radiotherapy and how different it is than radiotherapy in the 1970s where the whole concept of misadministrations came from, not just AOs, but medical events have to brought up to this current millennium, it's very difficult to evaluate sometimes whether or not you've actually had an event.

And I've been in a situation where we at Wisconsin have called the state and said we've had a medical event and they've said, no, no, you haven't. And surprisingly we came back and said, well, we think we did. And they come back and in the investigation they say, well, we don't think you did. And the whole back and forth is because trying to apply what sounds very clear criteria for a medical event to modern cases doesn't work very well. There's an ambiguity there.

Oh, these I won't even bother going into why that is. We've talked about that. It's just so much more informal nowadays that it doesn't apply to the older criteria.

The other is safety culture, and we know that safety culture is important. And I teach the

patient safety course at Wisconsin, and I've been teaching about safety culture before it was a buzzword that was used throughout the industry and regulatory community. But while it's true that an institution that has the traits, which are actually a very good list that the NRC came up with -- while it's true an institution that has those traits probably has a fairly good safety culture, it is not necessarily true that you have to have those traits to have a safe operation.

And in talking with one of the Commissioners yesterday -- yesterday? Day before. How time flies. We were talking about this and he was saying that that's absolutely true and that you could have an operation like he was familiar with where the person in charge strikes such fear in the employees' hearts that they're going to do the right job and they're going to do it completely because they're so afraid. And they won't bring up an issue, but it will get done.

You also have the problem that trying to force the characteristics unnaturally on an organization does not necessarily make it a safety culture in that you can drive the problems underground. And it can be a lot like trying to grab

tightly onto a water balloon and having the balloon go between your fingers. All this means is that trying to use safety culture in an inspection enforcement-type setting can itself create a chilling culture in the facility that's being inspected.

The air travel industry found that a non-punitive environment works best to find problems and correct the problems, and that having a punitive-type culture, going out and during enforcements punishing organizations and people does not enhance safety, but drives problems underground. It's a very complicated issue, safety culture. It sound simple and it sounds like why can't we just make people be this way? But it doesn't work that way.

Reflections back on the ACMUI is that working with this group, as the Committee has changed over the years and people have fallen off the table and new people have come, has really been one of the greatest collections of people I've ever worked with. They're smart, which is good. They're extremely hard working. Everybody is. They're very nice. They're all very nice to work with and personable. And thank you for the opportunity to work with you. I've really enjoyed it and my work as chair would not have been anywhere near as enjoyable if I didn't have all

of you doing really the hard work.

The NRC staff medical team has just been wonderful to work with. They've been incredibly supportive. They've been helpful, nice, and I --

(Laughter.)

CHAIRMAN THOMADSEN: -- on the slide format I hate having to have all that space on the bottom wasting --

(Laughter.)

CHAIRMAN THOMADSEN: -- space, and I would think something like the Paperwork Reduction Act should eliminate all that wasted space, but --

(Laughter.)

CHAIRMAN THOMADSEN: And it's really been too bad that a lot of the higher level people with whom we work in the NRC staff -- darn it, they keep getting promoted --

(Laughter.)

CHAIRMAN THOMADSEN: -- and getting upstairs and lose them. We've really enjoyed working with them. They've been wonderful individuals, all of them.

Special thanks of course go out to Ashley and to Sophie. Without them this really would not have been fun. They are so supportive and nurturing.

And my wife knows when I'm talking about Sophie nowadays -- I call her my handler.

(Laughter.)

CHAIRMAN THOMADSEN: I just do what she tells me and it keeps me out of most trouble around here.

And here's to Rock's. I think those -- the time that we've spent together as a Committee and with the staff after the Committee meetings has been incredibly invaluable. It builds bridges that are useful for communication in the future. I hope that remains a custom. I hope we don't have to put out a public announcement in enough time to do so.

And people ask me will I miss the ACMUI. Actually, the most common question I keep getting is what am I going to do with all of the time? And I've said, when I got my Ph.D. and I was working full time while I was working on that and people were saying what are you going to do with all that free time, and I was thinking, wow, I am going to have a lot of free time. It never happened.

(Laughter.)

CHAIRMAN THOMADSEN: I don't know where the time went, but it just got filled like a vacuum.

But will I miss the ACMUI? How could I

not? I mean, it's become so much a part of who I am now. But also, I see the wisdom of rotating off forcing us to leave, and we would be very likely to overstay our welcome here if we weren't forced to leave. And it's good for the institution to get new people.

It's been a great honor to serve here. Thank you for the opportunity. Best wishes to all of you, particularly Dr. Alderson as he leads the Committee into the new challenges. And thank you all.

(Applause.)

CHAIRMAN THOMADSEN: Now I have to say thank you again.

(Laughter.)

CHAIRMAN THOMADSEN: Let's see. And we are 15 minutes away -- well, about 13 minutes away from the next item on the agenda. I can go ahead? Okay.

As I said, I always listen to Sophie.

(Laughter.)

CHAIRMAN THOMADSEN: And she's telling me that this item is one we can go ahead and start with. So, I will ask James Harvey.

Hello, James. How are you?

DR. HARVEY: I'm well. How are you?

CHAIRMAN THOMADSEN: I'm fine. Welcome.

DR. HOWE: I need you to wait.

CHAIRMAN THOMADSEN: Oh.

DR. HOWE: My whole working group is going to --

(Simultaneous speaking.)

CHAIRMAN THOMADSEN: I see.

DR. HOWE: We're going to have our working group --

(Simultaneous speaking.)

CHAIRMAN THOMADSEN: In that case, everybody can relax for the next 11 minutes, and just make sure you don't go too far away.

Oh, before we relax, Mr. Costello?

MEMBER COSTELLO: While we're relaxing, okay, you suggested to your successors here now on the ACMUI that we look into reporting criteria for things other than permanent brachytherapy.

ACMUI CHAIRMAN THOMADSEN: Yes.

MEMBER COSTELLO: Well, why delay?

ACMUI CHAIRMAN THOMADSEN: Huh?

MEMBER COSTELLO: Why delay? I mean, you're still the Chairman for another hour or two. Okay? I mean, when do you think that's going to

happen? Right? The way these things happen, I believe, is you appoint a Subcommittee to re-look into it and start making recommendations. I mean, we'll be coming up with things that would represent rulemaking in the end. And, I mean, that could take at least six months or a year sometimes.

(Laughter.)

MEMBER COSTELLO: And so, to get to that point nothing's going to happen until somebody appoints a Subcommittee to start working on it. I mean, it's up to you. You're still Chairman, but if you don't do that, it's going to be March before you're thinking about it again.

CHAIRMAN THOMADSEN: Okay. One moment while we consult.

(Pause.)

CHAIRMAN THOMADSEN: Very fine. I think I'll take that as -- well, it's not a motion because we don't make motions to --

MEMBER COSTELLO: We don't?

ACMUI CHAIRMAN THOMADSEN: -- appoint --

MEMBER COSTELLO: Okay. It's a suggestion.

CHAIRMAN THOMADSEN: Right, I'll take that as a suggestion and I'll appoint a Subcommittee

to propose appropriate criteria for medical event reporting other than permanent implants, and I'll ask is there somebody who would like to be the chair of that Committee?

MEMBER COSTELLO: Not me.

(Laughter.)

CHAIRMAN THOMADSEN: All right. In that case, Dr. Suh, I don't think you've chaired a Committee for a while, have you?

MEMBER SUH: No, I'm happy to do it.

ACMUI CHAIRMAN THOMADSEN: Very fine. And the members of the Committee. We can have up to six, and I would like to have Dr. Ennis on the Committee, I'd like to have Dr. Dilsizian on the Committee, and Dr. Palestro on the Committee, our physicians on there, short of the diagnostic. I don't think you're too involved in the medical events yet for here. And we should have a medical physicist. Let's see. One, two, four. We have the two medical physicists, Dr. Zanzonico. So this is going to have to be done quickly before he falls off the table.

(Laughter.)

MEMBER ZANZONICO: I'm happy to serve.

CHAIRMAN THOMADSEN: Yes, and Mr. Ouhib,

who hopefully will be active on the Committee in time. I think that's six, is that correct?

MS. HOLIDAY: Correct.

MR. BOLLOCK: That is correct.

CHAIRMAN THOMADSEN: Very fine. And the task will be to make the report at the spring meeting on your recommendations. And thank you, Frank, for --

MEMBER COSTELLO: Thank you.

CHAIRMAN THOMADSEN: -- getting this started. Now you can relax for another seven minutes.

(Whereupon, the above-entitled matter went off the record at 1:37 p.m. and resumed at 1:45 p.m.)

CHAIRMAN THOMADSEN: Well, we can I guess un-relax at the moment and welcome Dr. James Harvey, who's the chief science officer for NorthStar Medical Technologies, who will talk to us about NorthStar's RadioGenix, technetium-99m generating system.

Dr. Harvey?

DR. HARVEY: Dr. Thomadsen, thank you. And thank you to the Committee for allowing me to get rearranged so that I could be here today. It worked out and I appreciate it a lot.

What I want to do in the next few minutes is provide to you some background on what we're doing with moly-99 and lead you through why this requires a new generating system. And I hope that in the few slides I've put together and describe how the generating system works you'll have a better feel for what we're doing, and I hope it spurs discussion. When you put together a presentation like this, you never know if you're going to hit everybody's wish list, so hopefully this will just spur the thought process. And if there are questions, I'll be glad to try to answer them.

First of all, what is NorthStar doing? We have two separate paths that we are pursuing to make moly-99 without the use of fission. One is we call the neutron capture. The other is photon capture. More technically in terms of the NNSA jargon the first one is the neutron capture technology track and the second one is the accelerator technology track, non-uranium. I should have added that it's not-LEU.

So, how are we doing that? First of all, we're bringing on line; and we believe we'll be on line within the next six months, the neutron capture at the University of Missouri. We've been working

down there for quite a while and have had a contract in place since 2011. And of course many of you will remember the original way to make moly back in the '60s, '70s, '80s was neutron capture before fission became vogue because it was so easy and, at that time, so inexpensive.

But we also felt it necessary to have a second pathway. If you look at the moly industry; and it has suffered tremendously from lack of reliability, lack of robustness, you couldn't count on the reliability of the supply especially when you look at the aging reactors that are being used and the fact, as we learned in 2009, they could go off line for unknown periods of time at a moment's notice. So we've also had a second technology pathway, photon capture, that we're pursuing, which is to make moly with an accelerator. And I'll describe those momentarily a little better.

Each of these solutions independently of each other will have the capability of producing half of the U.S. supply of material. So we have tremendous redundancy built into our program that allows us to go back and forth between the processes as necessary. And I'll speak to why this works relative to the generating system in a moment.

And as I said, we're going to keep both solutions running. That's our plan. And we may actually turn the U.S. back into a net exporter of moly-99 because we have the ability, the capability to produce that much material, but it does require a new generating system. There's a different type of generating system that's needed to make this work. And NorthStar fortunately already had a platform technology, which I'll describe momentarily to you, and it was just a matter of adapting that platform technology for this process.

Okay. Quick comparison. We are irradiating stable molybdenum targets versus a uranium target. It's a much, much simpler and safer chemistry. No fission products. No alpha emitting isotopes. No uranium. No plutonium to deal with. Minimal waste generation. All of our waste is Class A waste. Very, very easy to handle and dispose in comparison. But the challenges are we have a low yield per gram of target material. Fission moly, upwards of 10 to the 4th curies per gram of molybdenum. I'll show you where we are momentarily. It's quite a bit lower. So that makes this material not compatible with the current distribution system and it requires a new type of generating system.

Primer fission moly, you have to -- a lot of radionuclides you've got to clean up out of it because 94 percent of what's made you don't want, but once you get the moly cleaned up and get it in the right species at the correct pH you can bind it very easily on an aluminum oxide chromatography column. Moly decays to technetium. You want the technetium. So once you've loaded moly onto the aluminum column, you can strip it with normal saline. Chlorine exchanges for the pertechnetate and you produce sodium pertechnetate. And the reason it works is at the bottom down there. The binding affinity on aluminum oxide. Hydroxide is held tighter than molybdate, which is held tighter than chloride and so forth down to technetium.

So, you could run the -- so, the normal saline through the column. The chlorine replaces the tech. It pushes it off, but it doesn't touch the moly. That's why the molybdenum stays on. It stays on mostly. That's why you have a breakthrough standard. Because it can come off. If you have washed the column with enough material, you will see a little bit of it coming off. So, we address that, too, if it were ever a problem.

So, whether it's an HEU or an LEU

generator, they work exactly the same. They're designed the same. They operate the same. They have a product that meets the U.S. Pharmacopeia and FDA guidelines. There are three providers of those here in the U.S.: Mallinckrodt, Lantheus and GE Healthcare. Right now they all source their material from uranium. And only Lantheus has a dedicated run one day a week of purely LEU generators, LEU-based generators. Everyone else has access to LEU, but they don't have a reliable and steady enough supply to make dedicated runs on a weekly basis yet. Only Lantheus does that and they do it only one day a week, on Tuesday. Everyone else is using LEU and HEU blended together. That's been approved by the FDA sometime back, that there's no difference between the two molybdenums, so they blend them together and they make blended generators, but only Lantheus does the dedicated one.

So, let's talk about the non-fission generator now. It's low specific activity. You have a greater volume of moly-99 you're dealing with. It uses a completely different elution system, but fundamentally there is absolutely no difference in the sodium pertechnetate that's produced. It fully meets all USP and EU Pharmacopeia requirements and it

meets the requirements of the nuclear pharmacy. When I say that, they don't have specifications outside of USP, but what they want, what a nuclear pharmacist in a hospital wants is he wants his tech and a minimum amount of normal saline. And that's because they can get a lot of doses out of that if it's very concentrated and that makes their operations very efficient.

So, what's the development history of RadioGenix? It actually has its seeds back at ovarian cancer research in the mid-1990s at the University of Chicago. They had a project that was being supported by an outside funder who was interested in separating bismuth-212 from lead-212. Not the ideal alpha isotope, but it was what was available. Actinium-225/bismuth-213 is better, but there wasn't availability of that at that time. And so they were working on bismuth-212. And the people doing the work were getting a significant dose.

Where does bismuth-212 decay to? Thallium-208, a 2.6 MeV gamma ray. So when you're dealing with millicuries, or even microcuries of bismuth-212 with a 46-minute half-life, but decays very rapidly to thallium-208, you're getting a lot of thallium-208 dose. So the personnel were getting a

lot of dose just doing the separations to prepare it for administration to the patients that were involved, or the other just solo work that they were doing.

So, the inventors of the technology that now have started working on something that they could come up with as a way to automate that separation, make it hands-off so that the personnel doing the separation and preparing the bismuth-212 didn't get a significant dose.

So, this is a picture, an early picture of something that was breadboarded up just to try working. And that happens to be a picture in a hot cell. In 2005 NorthStar licensed the basic technology. The basic technology is a box, the big gray thing that has the pumps and valves and tubes to move the fluids around. Obviously, you know what the little white shielded container is. That's where the moly would be. The white rectangular item in the middle about the size of my hand is the chemistry module. And then it's computer controlled. So, it is this prototype, early prototype that proved that technology worked and it led to the granting of three patents to cover the three types of processes that are going on there.

We then -- with input from nuclear pharmacists and some key researchers around the country in nuclear medicine fields -- we developed a bridge instrument. We took something very similar to what we had licensed and we developed an instrument that we call the Automated Radionuclide Separator, ARSII. The version we had licensed was the ARS. And this was actually deployed in preclinical and mouse trials for actinium/bismuth for treating HIV. It was also deployed in some melanoma work for tungsten-188/rhenium-188 at a couple of different institutes here in the U.S. We were just trying to understand what worked, what didn't work, where could we continue to make improvements in the process.

In 2011 we created the next instrument. We called it TechneGen. And it has a lot of attributes you can see there. A single control system. It can control up to four different sources on one instrument. The chemistry for the technetium is approximately unaffected by the source of the moly. I can put neutron capture moly on it. I can use natural molybdenum targets. I can use enriched molybdenum targets for that. I can put photon transmutation moly on it from enriched moly-100 targets. I can even load fission moly on this system

and it works the same, identically every time. And the reason is it's a chromatographic separation and it doesn't care the source of the moly. So it provides us with a tremendous amount of flexibility.

It's a single administrative computer. It's microprocessor controlled. What does that mean? We built microprocessors into the instrument. The computer only tells the instrument what you want it to do and it logs every step of the instrument. The FDA really liked that, because now you truly had an automated sequence to produce a batch record. Every single step was logged with a UTC time code and it's logged by the operator who did it. So, it's automatically tracked all the way through the system.

But the beauty of it is we can lose the computer and because the instrument has an on-board UPS system, it will run the entire cycle all the way through and complete, which means our desire here to have no radioactivity left in an unknown state was met by being able to -- in the event of a power failure the UPS system to be able to complete the entire elution process and put everything back where it was supposed to be in shielded containers. And with complete automated operation, after you answer the prerequisites, the operator doesn't need to be

there. He can walk off. He can go off and do other things, which is important in a nuclear pharmacy. Efficiency. He doesn't have to stand there. And you can even separate it and do it by either Wi-Fi or a TCP/IP network cable. The computer doesn't even have to be in the generator lab.

Localized shielding for the technetium elution. We have a tungsten shield that the technetium vial sits in, and when you take the top half of that apart, which I'll show you in a moment, the bottom half where the technetium is, is already in a vial shield made of tungsten. And we have a little lid piece that you can put on it, so the pharmacist can now easily and safely handle the technetium even if it's curie quantities of technetium because they're carrying it around in a tungsten vial shield to go take it to their drawing stations where they're doing the work.

Require some disposables. We'll talk about those in a moment. We have an on-board -- in the next version that I'm going to show you, to control bioburden we actually have developed an ozonation system that has never been used in this industry before. We generate ozone in water and we pass ozonated water through the system to sterilize

it. Never been done in this industry before and it's led to several patent applications for us.

The other advantage that I'm going to explain in detail in a moment is as opposed to the current static generators, every time you do an elution you pass the technetium through a virgin Alumina cartridge and a virgin one-time-use sterility filter. So we're doing a final -- irrespective of having sterilized the instrument -- we're doing a final terminal sterilization with a sterility filter. And because we have a fresh Alumina cartridge every time, if there were any breakthrough it always sees a fresh cartridge that has significant orders of magnitude more uptake capability than the moly that would be there.

We also found out along the road that a fresh Alumina cartridge of the type we're using is a depyrogenating agent. So we not only can guarantee a sterile product; we can guarantee an endotoxin-free product. And the source material, especially if it's enriched molybdenum for either 98 in the neutron capture, or 100 from the photon transmutation, it's completely recyclable. We can recover it.

So, this is the box to date, the full cabinet. Now, it looks large, but I'll give you

perspective in the next slide. But remember, in the U.S. we have a capture nuclear pharmacy market. There's about 400 nuclear pharmacies in the U.S. that supply virtually all of the technetium doses in the U.S. on a regular basis. There are some captive hospitals and clinics that have their own pharmacies. But by and large the bulk of the technetium doses every day are done by commercial nuclear pharmacies and are shipped as unit doses to the hospitals and clinics.

So, it's an established technology, fully automated, computerized. This is the fifth generation of a technology that's been in development for 20 years, and it has a number of components to it. You can see the computer control system with the screen. The actual meat of the system, the actual generator or the separation system is the box on top. In the center section is where all the different little doors for the DU containers go that have the moly them it that are hooked up and used on the system for a 14-day period. And then there's two waste doors down there at the bottom. I'm going to show you why we have two of them on board here.

So now, again not completely to scale, but if you look at the system, the RadioGenix system

on the left and you look at a modest-sized nuclear pharmacy in the U.S. that's running six generators a week, if you count the distance of any four of those generators on a -- static generators and you measure that and you measure the width of RadioGenix, they occupy virtually the same floor space. Yes, we go much higher in the z direction, but our x, y floor space that's occupied is virtually the same. Very key design item that was intentional by our engineering team to make it so that we didn't occupy an inordinate amount of floor space compared to the same capabilities in our current system.

This is a front view sliced through so you can see some of the shielding. In the top half you can see there's significant shielding around the various components of the separating system itself. There are three separate sections. The far left is a locked door that has service only. The middle section is a door that the user needs access to every 10 elutions because he has to change one item, the separation cartridge in there that I'm going to show you in a second. The far right door is actually where the fully shielded tungsten collection system is. So he opens the door and he can pull out the fully shielded vial system. The middle section you

can see is all the DU containers where the source material is. The bottom section you can see two bottles for the spent material.

Now, why two? Each individual bottle is large enough to handle somewhere between four and six weeks' worth of elutions by a normal pharmacy. A large pharmacy, it might be closer to four. A small pharmacy it would be closer to six. Because we generate a few milliliters, a few ccs of fluid each time that we do the process that we don't use, by having two we automatically throw the valve. And so one bottle is done. The other bottle is started. The bottle that's done gets four to six weeks of decay in storage right there on the instrument. So when they actually go to change it, it's extremely low on activity at that point.

Here's a top view of just the top part of the instrument where I talked about the left, middle and right sections. And you can see that there's significantly more lead in the left section, less in the middle section and even less in the right section where the tungsten vial shield is. So we built a lot of shielding into the instrument.

So, we have a potassium molybdate/ potassium pertechnetate solution. It's a potassium

hydroxide-based separation system. We do just like the current industry, a 14-day cal. And like the current industry where they use a tungsten or a DU shield, ours is DU. We need to track those. We want them back anyway, because if it's an enriched molybdenum target material, we want to recover it. It's valuable. And we have a recovery process already established for that. You might ask why potassium and not sodium? Turns out molybdate is twice as soluble in a potassium system as a sodium system.

The resin that is the key to the separation system is called an ABEC, and aqueous biphasic extraction chromatographic resin. Has a unique property. It was developed under a Department of Energy grant. I was actually the program manager for it. We did it back in the 1990s at a commercial company. The purpose of it was to take the technetium, the long-lived, the ground-state technetium out of the Hanford tank samples. The Hanford tank samples are highly alkaline, highly radioactive materials. And this resin was developed for one purpose and one purpose only, and the Department of Energy, in their infinite wisdom, has never deployed it yet for that purpose.

So, it has been a solution sitting on the shelf since the mid-1990s looking for a problem to solve. And since I was involved in the development of it for the Department of Energy work, I went to my boss, the CEO of the company, and I said we got something really slick here I know about and we can adapt our platform to moly/tech and tungsten/rhenium because of it. That resin is specific for only two things: technetium as pertechnetate and rhenium as perrhenate. That's it. Nothing else will stick on that resin.

Anyway, it's replaced every 10 elutions even though at the time the Department of Energy was looking at 600-cubic foot resin beds that stayed in there ad infinitum, just were used over and over again. We replace it after every 10 elutions just as a matter of course.

So what are the reagents? Hydrogen peroxide is used to clean the lines and prepare the separation cartridge. Sodium hydroxide to -- actually it's potassium hydroxide to clear the cartridge; that's a typo there, and skip the cartridge, in its correct state to do the chromatography. Sodium acetate neutralizes the cartridge. The normal saline actually removes it.

So, the medical people in here will ask why are you using peroxide and not normal saline -- I mean, SWFI, sterile water for injection, if all you're doing is rinsing with it? Did you know that SWFI will not pass the FDA microbial challenge test if it's left open for more than 72 hours? So, we use three percent peroxide solely because peroxide will pass the microbial challenge test over a 14-day period where SWFI won't. One of those little things that you learn along the way, a pathway as you go through the process of meeting the FDA requirements. You take something and you say, oh, sterile water for injection, that's got to be the best thing you can use, right? No, you can't. It doesn't pass the test.

We have a reagent path that we put on every instrument. Every 10 elutions a reagent pack is put on. It's coded, keyed so it can only go on one way so that it can't be mixed up, which means that hydroxide, acetate and peroxide are always in the same location. So they always get used. Can't be mixed up. And we provide a single-use 10 cc USP normal saline syringe. That is a single-use item. So every time you change the collection, every time

you want to do a technetium collection, you use a brand new, open from the pack right at that moment, saline syringe.

One of the key attributes that we incorporated on here to meet a lot of the FDA requirements and provide the industry something they didn't have is we added the second Alumina cartridge called the guard cartridge. We added the microbial filter. And the system can automatically do a bubble test for the filter. So we can not only do the sterility at the end, terminal sterilization, but we can tell you whether or not the filter integrity was held with the bubble test that's required.

You'll see -- at the very top of the long cartridge with the Alumina in it you'll see a little white circle with a rectangular black dot in it. That's one of the many RFID chips that are on this instrument. We have everything coded so that if you put something on this instrument that is not -- didn't come out our factory from moly-tech, it won't run. The instrument will shut down because it reads those RFIDs, and those are interlocks that are required to be there. And you can see the tungsten vial shield there, too.

So again, what are the reagents? Sorry

for the typo. It's not water. It's peroxide. It's potassium hydroxide, not sodium. Acetate, chloride, sodium chloride and the source material of course is potassium molybdate, potassium pertechnetate in an alkaline solution.

So, what happens? Sophie? We first pass hydroxide through to get the cartridge in the right state, alkaline state and we rinse that out with -- it flows through and then we force the excess through with air. Okay?

Go ahead. Okay. Then we add the source material. The technetium is retained on the cartridge and air clears it.

Now, you see the air doesn't clear all the moly off. That's because it's a chromatographic column and there's interstitial spaces between these. So there is a change that some moly can be trapped there. So then we deal with it.

It's clicking on its own sometimes. Back up to step 3 and start the animation.

So then we rinse the hydroxide through it. And that takes any moly that's trapped in the interstitial spaces off. It doesn't have to be a hydroxide rinse. We could rinse it all with acetate, but -- and that may be a change that we're going to

do is to eliminate one extra chemical on the system, or the volume of the extra chemical. We don't eliminate it completely. But this was a way to get the trapped molybdenum off the system.

Okay. Now, will you start the animation, please? So then we rinse with sodium acetate. Notice what happens here. The hydroxides, the excess hydroxides are released. A little technetium can come off here. We have to be very careful. It's a very fine line. But what it does is it lowers the pH to a point where the normal saline can remove the technetium, but the pH is less than nine, which means that if molybdenum is present, the Alumina guard cartridge will pick it up. If the pH is more than nine, it will start dissolving the aluminum.

So, now let's go ahead and start the animation. We're going to remove the technetium off the column, clear it with air. Technetium is in the vial ready for the pharmacist.

Now, that doesn't end what the instrument does. That just gives the pharmacist his technetium. He can go off and start working. He'll hear an audible in the lab that will -- a sound that says the technetium is ready. He doesn't have to stand there and watch any of this being done, but he just has to

listen for the audible to come back and get his technetium, because then the rest of the system continues to run as I'll show you here in a second, and it repositions fluids.

Thank you, Sophie.

So, one of the questions was what's the dose on this instrument? And so, we have dose measurements and we have modeled what happens. And you can see there's two periods where the molybdenum fluid is moving where if you were right there at 30 centimeters from it -- right in front of it, you would get a dose in the neighborhood of 30 to 35 mR per hour. But again, it's unattended operation. Those are the only two periods where the dose is high. And then you can see during the course of operation the bulk of the time period it's an extremely benign dose. Matter of fact, actual measurements that we have -- we have -- from a 6.4 curie source of moly at 30 centimeters the average dose over the entire period, if you were standing 30 centimeters from it -- and think back to the picture that I showed you a minute ago -- it would be very hard to stand within 30 centimeters of that without leaning over with your face almost right in it.

So, there's some other reasons why the

machine is built the way it is, because it's unattended operation and you -- it's very difficult to just plant yourself for 40 minutes 30 centimeters from it because of that big shelf that's there. So a more realistic number is at one meter, which would be an area that a person could be walking around, the average dose is about an mR per hour. And we actually have not only models that show that, but we have found nanodots at one meter and they have a response that starts at five mR per hour and the nanodots are all coming back non-readable. So, we believe the model is pretty accurate, that it is the integrated dose over the entire run at 1 meter is certainly below 5 mR per hour and it calculates out to about 1 mR per hour with a 6.4 curie source running through the system.

So, comparisons. Non-fission, low specific activity, automated shielded system. The elution time to get to the point that the pharmacist can have the technetium now takes about 40 minutes. But remember, he's not standing there. And what the pharmacists do is they come in at midnight. They start their elution. Right now they come in and they get their work set up and then they go elute the generator. In this concept, using this generator,

the pharmacist would come in and start the elution. And while it's running automatically, then go set up this first round of work. So it's just a matter of rethinking how you do the operation in the pharmacy.

It produces the same high-specific activity technetium-99m, meets USP, EU FDA standards and it labels exactly the same as any other technetium. Matter of fact, we've actually gotten some more than better data. It's a very, very pure material by virtue of the fact of the labor doing it and the fact that it's got terminal sterilization on it. We've got the endotoxin pyrogen collection that could -- if it's there from the extra Alumina cartridge. We know moly's not getting through because we have the extra virgin cartridge on there. So we're seeing a lot of really outstanding results with various kit labelings.

Thank you for somebody putting all those nice acronyms in there for me.

(Laughter.)

DR. HARVEY: I hope that gives you a flavor for how it works and what we've done to build this instrument through its fifth generation. It's not a brand new, hey, wow, let's go build one of these. This is a dedicated process that has gone on

for 20 years and NorthStar's been doing it for 4 years -- I mean, 10 years and we've handled 4 of the 5 generations of the technology. So, we've tried to take into account the various things that we needed. We learned when we submitted our first new drug application, the initial new drug application to the FDA that because of the situations with New England Compounding Pharmacy and the non-sterile steroids that came out, microbiology became more important to the FDA during that period than when we had first met with the FDA in 2010. So as I say, we went back and our engineers developed an on-board ozonation system so we can sterilize the instrument. We met that challenge that way. So again, 5 generations of technology over a 20-year period. And I hope that you have a little better feel for how it works.

CHAIRMAN THOMADSEN: Thank you very much, Dr. Harvey.

Questions and comments from the Committee? Mr. Mattmuller?

MEMBER MATTMULLER: Yes, first of all, thank you for making such an extraordinary effort to get here.

DR. HARVEY: Yes, I had breakfast in London --

MEMBER MATTMULLER: Yes.

DR. HARVEY: -- 15 hours ago.

MEMBER MATTMULLER: Yes.

(Laughter.)

MEMBER MATTMULLER: So we appreciate that. And I hope the Committee appreciates the fact that I've tried to educate them on gallium-68 chemistry and now technetium chemistry. And my ulterior motive is to make chemists out of all of you.

But more realistically, there was also recently a press release where you're talking with Westinghouse now --

DR. HARVEY: Correct.

MEMBER MATTMULLER: -- and so you're using their power reactors as the possible source for moly-99 production. Can all Westinghouse reactors, power reactors -- are they designed to the way to where they could all do this, or is there --

DR. HARVEY: There are two -- and I may not be paraphrasing this correctly. There are two generations of the power -- Westinghouse pressurized water reactor that this is applicable to, and the two more recent versions.

MEMBER MATTMULLER: Okay.

DR. HARVEY: And we've signed an MOU with Westinghouse to explore the possibility of using those power reactors to provide more redundancy and outage reserve capacity. If you're familiar with this industry, there are several buzzwords in it: "full-cost recovery" and "outage reserve capacity" that are outgrowths of all of the shortages through the 2007, '9, '10, '11, '12, '13, whatever time frame. And so, the purpose of the work we're doing with Westinghouse is to look at using those power reactors for that purpose.

The beauty of it is the system that we're using is not within the safety envelope of the reactor and it can be -- the targets can be inserted and pulled at power. They can also -- because it's a benign non-fission, it doesn't change the reactivity of the reactor. The targets can be put in and left in there. They'll cook up to equilibrium. Fine. Which means it makes them great for outage reserve capacity because then you can have targets that are fully at equilibrium activity. And if there's a shortage somewhere like our MURR reactor goes down, we pick up the phone and we pull the targets and, bang, we get them out of the Westinghouse reactor.

That's the idea of the things we're

pursuing with Westinghouse. But there are two versions of -- two generations is maybe not the right way to describe it -- of the current PWR that Westinghouse has deployed. And I believe there's something like 50 of them here in the U.S.

CHAIRMAN THOMADSEN: Yes, Dr. Alderson?

VICE CHAIRMAN ALDERSON: Yes, very interesting presentation. How available is the stable moly source and from what places does it originate?

DR. HARVEY: The natural moly we buy in kilogram quantities in 100 -- we buy it in 200-kilogram drums. And we do some initial purification, then we make the targets to be irradiated. The enriched material right now comes solely from Russia.

VICE CHAIRMAN ALDERSON: Russia?

DR. HARVEY: Yes. And it's gas centrifuge enriched material, but we have kilogram quantities of it already in inventory, more than enough to start the process. And we have contracts, signed contracts for deliveries from the Russians already for more material. So in spite of the various issues with the Russian government, etcetera, we've been able to get what we needed and we still have signed contracts. Money's been placed down and

we expect them to fulfill the order. We don't believe there's going to be a problem. And because we recycle the enriched material, we recover somewhere in the neighborhood of 95 to 97 percent by mass. We need very little makeup material once we build the initial inventory. And as I said, we've already got kilogram quantities of the enriched material in stock.

CHAIRMAN THOMADSEN: So, Dr. Zanzonico?

MEMBER ZANZONICO: so, what would be the source of the photon-produced material?

DR. HARVEY: We're using an electronic accelerator. We accelerate electrons to 42 MeV and we have a beam current of about 3 milliamperes, which means we're putting about a 120 kilowatts on the target. We actually impinge -- we have two accelerators shooting in opposite directions and we impinge both ends of the target so we get the maximum production on the target. And we don't use a converter plate. The electrons convert in the target assembly to bremsstrahlung and the high-energy photons then kick the neutron out of the moly-100 nucleus and allow us to make moly-99.

MEMBER ZANZONICO: So, this is your own accelerator?

DR. HARVEY: No, one of our restrictions we put on that project early on, it had to be a commercially-available accelerator with a high demonstrated duty cycle. And so, there are two companies that can provide those in the world right now. And they're largely used for E-beam sterilization and gemstone work today. One's never been deployed for this until a baby version of one of the -- from one company of what we would need was deployed at the CLS in Saskatoon, Saskatchewan in Canada. And they have a 35 MeV kilowatt machine, which is as I said a baby version of what we're using, going to use. And they've been making moly with it now for a few months, finally. But the technology exists and they're commercially-available electron accelerators.

MEMBER ZANZONICO: And I believe that requires the enriched moly as well?

DR. HARVEY: Yes, it does. The moly-100 nucleus is only nine percent abundant naturally, so it makes no sense to use natural targets on that process. We will use enriched moly-100 targets there.

MEMBER ZANZONICO: And another question. In the purification system is this a pressurized

system?

DR. HARVEY: It is a low-pressure system. Everything is done -- all fluids are moved under vacuum, pulled through so that if there is a leak, we just get air bubbles and things don't move. The only time the system is under any pressure is when saline elutes the technetium off the cartridge, and then it's a few 10s of PSI for that.

MEMBER ZANZONICO: So these are not HPLC columns?

DR. HARVEY: This is --

MEMBER ZANZONICO: Because that would get awfully pricey if that were -- if you were --

(Simultaneous speaking.)

DR. HARVEY: You're correct. We went to school on the HPLC industry, but we built a low-pressure system. But we use Hamilton pumps, Hamilton syringes, much like you see on an HPLC, but we're using in a very benign low-pressure system. And we're using peak tubing rated at 5,000 pounds per square inch on a system that's running at few 10s of psi.

MEMBER ZANZONICO: So changing these columns every 10 runs is not a prohibitive expense?

DR. HARVEY: No, it is not. No, it is

not.

CHAIRMAN THOMADSEN: Dr. Palestro?

MEMBER PALESTRO: Yes, two questions: Number one, it's hard to tell from the pictures; you may have said it, is this system designed exclusively for commercial radiopharmacies, exclusively for in-house hospital-based radiopharmacies, or both?

DR. HARVEY: Obviously, our market is the large commercial pharmacy in the U.S., and we recognize that. What you saw was a very large instrument that fits the commercial nuclear pharmacy. Now, in the FDA process you have to lock the design down and that's what you take on your new drug application for approval. We already know we can make a two-up and a one-up of the same thing. The two-up and the one-up better fits the single pharmacy in a large research hospital or clinic than the big four does. We recognize that. So we know that once we get the approval for the four-up system, we'll deploy the two-up and the one-up, but those become just supplemental submissions. They don't go through the full NDA process anymore.

So again, you lock something down, you lock down what is the most valuable to the industry, which is the big one for the large commercial

pharmacies, and then you have the other sitting so that they just become supplemental submissions.

MEMBER PALESTRO: My second question is what is the cost of producing technetium let's say per curie with this system versus current costs? And I don't mean in terms of dollars and cents, but in terms of percentages, whether it's 50 percent less or 50 percent more?

DR. HARVEY: Okay. We get asked that question all the time, and the answer is we will be more than cost-competitive.

CHAIRMAN THOMADSEN: Mr. Costello?

DR. HARVEY: I mean, think about it a minute. I'm not using fission. I'm not using uranium. I have Class A waste. All of those costs are out of my model. All of them are out of my model. It helps tremendously.

CHAIRMAN THOMADSEN: Mr. Costello?

MEMBER COSTELLO: Thank you, Dr. Harvey. Do you envision your market including community hospitals?

DR. HARVEY: Actually, it could, but most community hospitals are serviced by captive nuclear pharmacies somewhere in this country today.

MEMBER COSTELLO: I have a follow-up on

that. If they were at a community hospital, can you imagine there be a training challenge at those places with authorized users or the staff, which are very different than those at a commercial nuclear pharmacy trying to use this system?

DR. HARVEY: We're committed to the FDA to have robust a training and user certification program, and only those users who are certified to use the instrument and have a password provided by the system administrator are allowed to use it.

MEMBER COSTELLO: Yes, as I said, for pharmacy I think it's great. For a normal small little community hospital with a small nuclear medicine department, I think this may be a challenge.

DR. HARVEY: And I don't disagree with you. Again, there's approximately 400 commercial nuclear pharmacies in the U.S. and they probably provide 80-plus percent of the unit doses every day.

MEMBER COSTELLO: Okay.

CHAIRMAN THOMADSEN: Thank you. Now, Dr. O'Hara?

MEMBER O'HARA: Have you locked down the production device with CDER?

DR. HARVEY: Actually, this is a new drug application, not a PMA, but it touched such new ground

that the FDA had never been at before that we have both sides of the house looking at it. It's being looked at by the drugs folks and the device people.

MEMBER O'HARA: What I was getting at -- it probably isn't a fair question. What I was getting at was how far along in the regulatory NDA are you?

DR. HARVEY: We submitted the DLS in 2012. We submitted the new drug application in January of 2013. We got our complete response letter in November of 2013, and it outlined five pages of questions and concerns. Four pages of it was related to microbiology alone, and then one page had to do with your manuals need some work.

And we've spent multiple meetings with the FDA. We completely revised the microbiology test plan. We resubmitted the test plan to the FDA for review, got their comments from that. And then we went back. The last meeting we had with them was in July where we outlined the test plan, the data we were collecting, how it all fit together and how it answered their questions. And the answer we got during the meeting was impressive.

MEMBER O'HARA: Thank you.

DR. HARVEY: So we felt like we were on

the right track in answering the questions. We will submit the answers to those questions. We believe we're on track for submitting them in December of this year. We hope to have approval by second quarter of next year, because it is just answering questions to an already submitted NDA.

CHAIRMAN THOMADSEN: Mr. Mattmuller?

MEMBER MATTMULLER: Yes, could you comment on, please, the total activity that will be available in a vial depending on the source of how the moly is produced, whether it's produced at MURR, produced with an accelerator, and/or if it's produced at Westinghouse?

DR. HARVEY: First of all, the DOT shipping regulations for a type A container limit me. The maximum I can ship is 20 curies. So in any one single elution, if someone put; and it won't happen, a 20-curie source on the machine, they're going to yield about 17 curies of technetium and 5 ccs of normal saline. That is the absolute maximum from a single elution that could occur. Realistically, Steve, it's probably going to be less than that because we can't make it 20-curie really. Probably the biggest we can ship is an 18 with a next-day tally on it. And then given decay and everything, it will

be less than that. But theoretically the absolute max that could be in a vial is about 17 curies and 5 ccs of normal saline.

MEMBER MATTMULLER: And if I could follow up. And you could produce an 18-curie moly vial with any of your three proposed methods?

DR. HARVEY: Only the two that use enriched material.

MEMBER MATTMULLER: Okay.

DR. HARVEY: In natural molybdenum targets we can't make them hot enough. You literally can't. So the natural targets really fit rest of world better and fit the small hospitals better. But with either of the processes using enriched material we can make the 18-plus-curie generator.

CHAIRMAN THOMADSEN: Dr. Zanzonico?

MEMBER ZANZONICO: A technical question and then a general question. So you referred to a vacuum. Is this a rough pump vac or a house vacuum? It's not something --

DR. HARVEY: Syringe.

MEMBER ZANZONICO: Oh, so, it's nothing.

DR. HARVEY: On-board syringe pump.

MEMBER ZANZONICO: It's nothing.

DR. HARVEY: It's nothing. It's a

syringe pump literally drawing the fluid through.

MEMBER ZANZONICO: So my more general question is now speaking as a scientist, not an entrepreneur, this sounds too good to be true.

(Laughter.)

MEMBER ZANZONICO: What is the down side of this approach?

DR. HARVEY: It's a paradigm shift. It's the first new piece of technology in the industry in 30 years. We are moving the cheese. It's going to take time for pharmacists to adapt to thinking differently about how they get their technetium every day. We've held user group meetings. We've held user evaluations. We've had all the major pharmacies involved to get them ready for this. And, but the challenge is fundamentally it's a paradigm shift in the industry because it's a new way to generate technetium that really hasn't been done by most people working in a pharmacy today. Virtually all those people don't remember the '70s and '80s where you got low-specific activity material and you made your technetium that way. And so, it's a paradigm shift. And that's the biggest challenge.

Second biggest challenge, flawless introduction. We are not going to start making 3,000

6-day curies on week 1 and shipping all over the country. We have made a business decision that probably for the first year with a few selected exceptions if you're not in the mid to upper Midwest you're probably not going to see one of these, because we think a flawless introduction into the market is key here. And that's partially because a flawless introduction overcomes this paradigm shift that the pharmacists are going to face.

And all of the major pharmacy chains have big pharmacies out in the Midwest: Cleveland, Columbus, Chicago, Milwaukee, St. Louis. So all the big pharmacies' chains will get some of these instruments. So they'll be working with it and they'll be used to working with it. It's just that in the beginning we're going to be very careful how far out we distribute material because we want to do a lot of hand holding, we want to make absolutely certain that it's a flawless introduction.

MEMBER ZANZONICO: And one final question. What is your projected cost for the system?

DR. HARVEY: I'm not allowed to talk about that, but we have various models. Depending on how large the contract for purchasing moly is,

there may be some considerations given on the instrument. We may provide a lease-to-own program. We have a lot of options. That's a barrier to entry that we recognized could be there and we have structured the business part of the program to take that barrier to entry away.

CHAIRMAN THOMADSEN: Any other questions?

Oh, yes?

MR. OUHIB: I must say excellent presentation.

CHAIRMAN THOMADSEN: Please identify yourself.

MR. OUHIB: Zoubir Ouhib, medical physicist. Besides the challenge of the paradigm shift, are there any other challenges that still remain that you might be working on?

DR. HARVEY: On the neutron capture, no, because it's an established technology. We've optimized it. On the photon work, we just completed this year a series of tests at Argonne National Laboratory where we were actually producing for the first time curie quantities of moly with targets in a simulated production environment. So, we're still optimizing the photon transmutation route. But as

far as are we inventing, do we still have technology hurdles to come overcome? No.

CHAIRMAN THOMADSEN: Thank you very much for the update.

DR. HARVEY: Okay. Well, I hope it was helpful.

CHAIRMAN THOMADSEN: Hope you get some rest.

DR. HARVEY: I'm going to the airport right now.

(Laughter.)

CHAIRMAN THOMADSEN: And, Mr. Costello, our additional medical meeting.

MEMBER COSTELLO: Good afternoon. I notice that I am the last on the agenda today, which could be good or bad. I'm also the third replacement for Dr. Langhorst.

(Laughter.)

MEMBER COSTELLO: And so, Dr. Langhorst, if you're watching this out there, hello, and I hope that you are feeling better, and I hope that you feel that I did our little group justice. If not, I'm very sorry and I'll make it up to you at Rock's next time when we get together.

Anyway, we discussed this topic last

March when we first brought up the idea of having an additional medical meeting. And we have a lot of names for it, but I'll call it that. And at the time there were a number of -- we had a charge to provide a concrete proposal for meeting. Hold on. I got to -- there we go. This is the original charge: Write a concrete proposal for meeting including cost estimate and how it should be organized.

And to be blunt, I'm not sure that we've even really -- concerning the first part, really achieved the first even now, even in time for the second meeting because the cost estimate is really challenging for us to do as a Subcommittee. I mean, we've talked to the NRC about it, we've talked to RIC about it, but there's a lot of questions that have to be answered before we come close to having anything looking like a realistic cost estimate.

So, we have these questions from the ACMUI, like why are we doing this, and who should come, and what are we trying to accomplish, and what's the problem we're trying to fix. I mean, after all, we already have an ACMUI.

So, we've got another charge: A more refined and complete recommendation considering the ACMUI meeting and a list of questions for the ACMUI

members to consider. And to be blunt, I don't know if we even sent out questions. Did we send out questions to you? I don't think we did. And I saw Sophie's list of things we were supposed to do. I immediately saw that, I thought, uh-oh, I don't think we did that. But maybe in Phase III we will do that. That was the charge.

So the meeting proposal that we're coming up with now for the medical use of byproduct material is a two-day meeting. And I think after a lot of consideration of who we want to have attend this, we basically want to have it be here. And we considered a lot of things. We considered going to OAS meetings, and I spoke to OAS about this. But really, I think our thought was if we want to have senior NRC management participation; and some of you want to have Commissioner participation, those people come to Rockville more often than might come to Kentucky, where I think the next OAS meeting is, and so forth. And we think it's very important that we want to have information exchange reaching the higher levels of the NRC.

We talk to the medical team all the time and we think we've reached them. But the idea is we want to have the senior NRC management, including the

Commissioners, involved. So we think about having it here. And reflecting further, if we wanted to hold down the cost from the beginning, I would think that the NRC auditorium from a cost savings point of view might be the least expensive. I mean, I love the Bethesda North Marriott. I stay there, but I imagine they probably charge a few dollars for their rooms and it might be easier to do it here in the auditorium. But we'll get to that a little more toward the end.

Who's going to be coming? Well, it's people who are in the game, the organizations and regulatory authorities involved in medical use. We would advertise this meeting on the web site similar to the RIC and other interested participants. And perhaps we would have people who represent patient advocates come to a meeting like this as well. So it's not just the industry, but also people representing the patients.

Now, we would encourage an informal open dialogue so this meeting would not just be a matter of talking heads where NRC talks to the medical community and the medical community goes away all the wiser having heard from NRC staff and such. The idea would be an exchange back and forth. It would be

interactive among those who are participating. And the hope is that we all would gain information, including the regulators. I imagine some Agreement States would probably come. I imagine members of the ACMUI would likely come. I hope. And they could share back information.

As someone mentioned earlier, as Sue says often, medical is different. Medical is different. That's a fundamental thing to remember. And that's where we're giving people radiation for beneficial purposes. So you don't, for example -- there's no concept of ALARA when you're talking about giving dose to patients, okay, but that's very prevalent in other areas that we regulate. So we got to recognize and NRC senior staff and Commissioners have to recognize that medical is different than other things that we're involved in. Okay?

We can imagine there will be technical sessions on specific technical issues. There would be the Commission senior staff. The medical community would share their perspectives. We could have panels and round tables on various selected topics. They would get to meet each other and greet each other. So members of various medical organizations could meet Commissioners and talk to

them. I know we in the ACMUI benefit when we get a chance to have one-on-ones with Commissioners. What I think it would be true as well is if other members of the medical community were saying perhaps how we could do things better, or even to say you guys did a good job on the new Part 35, you know, give positive feedback.

We could discuss things like medical event handling. How could these things be done better and be done in a risk-free environment in which you're not talking about mistakes that people made, but in concept mode how -- what are we trying to accomplish with these things and how could we do it in a way that's a benefit to the patient, to the physicians, the medical community and to the regulators?

Sue and I talked about this a lot. And this is her slide. She suggests that we consider August, September, October. I don't know how August works; a lot of people are on vacation in August, but I think that would be a good time. You do want to avoid other meetings. You don't want to have it the same time as the ASTRO meeting, for example. So you have to consider -- I'm sure we could come up with a time for these two days here where you'd get people

to come. But we have to look when other people are having their meetings and avoid those.

Well, need NRC staff to determine cost. And we do. And I'm going to come up with a suggestion at the end of this, which actually goes beyond Sue's slides. It will be my individual contribution. We need to figure out the cost now because, I'm going to be blunt, if the costs are too high, this is not going to happen. Like many government organizations, the NRC right now is looking for an opportunity of ways of reducing costs, right? Aim 2020 is not aiming at how we can spend more money. Aim 2020 is aiming at how can we do things more efficiently at a lower cost? And we are aware of that. So that's why I was suggesting maybe having the auditorium way of doing it.

And I've got this at the end, but we need the NRC staff (A) to come back to us and tell us is this a non-starter or is this something we can really work on? Okay? I don't think we want to have Phase III of our little Subcommittee. We need to have the NRC look this over, look at this proposal and say, yes, we think this is something that's worthwhile doing and we're willing to invest something, at least invest people's time doing a cost estimate, or we

have other fish to fry. We've got 2020 to worry about and maybe in a few more years we'll worry about it. I think it's a good idea and I'm very supportive of it. But we need the NRC to validate that this is a worthwhile thing doing if it can be done at a reasonable cost.

And as Sue says here, the idea of funding five annual meetings, that's not the idea that we expect you to put up the money up front for five meetings. Okay? I think the idea there is we have to commit to having the five meetings so that you don't just judge this project by the first meeting. I don't know how many people came to the first RIC, okay, but I bet you a lot more came to the most recent RIC than came to the first RIC. And if you judge the first Regulation Information Conference by how many people came to the first one, we might say, oh, this isn't a very good idea. Not many people came.

You have to give it time to develop, time for people to understand that, yes, this is worthwhile, and time for attendance to grow. So that means you have to plan for more than one. If you just have one as a trial balloon, I don't know how we're going to do, because no one's done this before. But if people see over a period of time that, yes,

these are worthwhile discussions and, yes, the NRC is listening and the NRC is giving us good information in these round tables, we're sharing information with high-level senior NRC management, then maybe more people will be willing to come and then we could keep doing it.

So, I would encourage the NRC to please not just to think this is a once-and-done, we'll see how we do it, but to commit to doing a number of them and give it time to grow.

Information tracks. What are we going to talk about these things? Well, a lot of these things are things that we talked about at every one of our meetings. I mean, probably if you were to list the topics that the ACMUI talks about, you could come up with most of what we're going to talk about here. Okay?

Medical use of safety culture. Dr. Thomadsen said earlier the application of safety culture to medical use is different. It's different than it is applying it to a light water reactor. Okay? It's just different. And to recognize that. Doesn't mean it's not important. It's very important, but you just can't take a one-size-fits-all and apply as you would to a hospital.

All the justification associated with patient safety. We've discussed this many times here. The patient are benefiting from these treatments. So, and you got to keep that into account if you're doing anything that's going to be limiting their access or discouraging their use. Okay?

Talk about what is our impacts, both the NRC and the Agreement States; I recognize that we're substantial players in this, on medical licensees and patient care? Give us some feedback. I mean, I hope as a member of an Agreement State, and from doing this for most of my life, that we're not having a negative effect on patient care. Okay? I mean, I don't do this for a living, have a negative effect on patient care. But if there's any aspect of it that we are doing that is delaying treatments being able to -- being able to treat patients or discouraging some modalities by making their adoption take too long. Whatever it is that we're doing, if we could do it better, we want to hear those things.

The medical uses of reactive materials are changing. Dr. Thomadsen had said in the beginning that many of our medical event rules are based on cobalt teletherapy. Okay? They go back to

the '70 in Riverside Hospital and things that are like in the distant past. And it's not easy for a regulatory agency to keep up with these things. We have a rulemaking process that was in geologic time. And so we need to be informed by the community of what's going on and how maybe our structure, regulatory structure, which was designed for cobalt teletherapy, maybe doesn't fit, or maybe doesn't fit microspheres, or maybe doesn't fit whatever. So, and a good way to do that is having open discussions. Okay?

Okay. And if we get advice from the community, and not just the ACMUI, on what's the best way to apply regulatory controls to these things, we all benefit. Patients benefit. We the regulator -- I'm a regulator. I'm not a medical practitioner. Okay? And I love to hear from the medical community on how we can do things better.

We could create forums, medical community forums for continuing communications. Probably the NRC perhaps could be the infrastructure that does this, but for people to communicate with each other on issues as they come up and tell us what's coming along and how it could best be regulated.

Medical event trends/lessons learned. I

think the purpose of medical events is to say, well, do we need to do anything different? It's not really about that particular event. It's about what are we learning from the events that could say, well, how could we regulate differently, or what information can we provide to the practitioner so they can do things different to avoid mistakes that other people make?

Are we having -- because there are medical event reporting criteria, are we hearing things that we don't need to hear about? I mean, that's something that came up with the prostate seeds. The conclusion was that maybe the dose-based criteria resulted in us hearing about events that were not terribly important. I think we've addressed that in terms of microspheres. Okay? And we just created the Subcommittee to look into this now.

I would like to hear -- if we have these meetings, have the community in general come and just talk to us about this. Not over-discussing a particular event, whether it's a medical event or not, just talking about the concept of what we're trying to accomplish here and what's the best way to do it.

And is there any way that medical event

reporting impacts patient safety? I certainly hope that medical event reporting, the way we do it today, does not negatively impact patient safety. However, if it is, then we need to do something different, right? But I don't know. I mean, Sue put this question here. I would like to think that it does not negatively affect us -- if anything I hope it benefits patient safety because of the feedback.

But if there's thoughts in the medical community that maybe in some ways the way we do things negatively impacts -- for example, the whole question about prostate brachytherapy, if that whole discussion resulted in fewer prostrate treatments with brachytherapy, well, that may be an unfortunate consequence for therapy that is very good for certain classes of patients. So if the way we're doing our business, the outcome of that is the patients aren't getting the ideal therapy for that, and maybe they're getting external beam when they should be getting prostate seeds. We need to know that because nobody wants to do that, neither we the regulators nor the medical community; and speaking as a patient, not the patients. Okay?

The balance -- well, just take a look at benefits and access to medical procedure. When we

had the presentation on medical events today, the number of medical events compared to the number of procedures is really, really low. I don't know what percentage it is, but I remember it's really tiny. Okay?

Well, considering the benefits and such, what are we learning? Maybe we're at a state where it's as good as it's going to get. I mean, maybe there's an error rate that's -- it's like near absolute zero. I don't know. And what medical event should we consider abnormal occurrences? We talked about that here. I don't know the medical community as a whole in your community hospitals and other places if they even know what an abnormal occurrence is. I don't know.

I'm pretty sure if I were to talk to my licensees and asked them how do you want to have one of the events that occurred here being reported to the Congress of the United States, I don't think they'd be thrilled with that. We talked about how medical events rise up in the organization are looked at negatively. Well, when it's reported to the Congress, it's certainly don't looked at positively.

How are we going to manage this? We imagine the meeting itself will be managed by NMSS,

just like the reactor RIC is managed by NRR, I would think. I would think that we in the ACMUI would support it as much as we can. I think the OAS would probably support it. And certainly the medical stakeholders would provide input as well, because the meeting's not going to work without them. If the only people we have coming to this meeting is NMSS, the ACMUI and the OAS, well, we'd just call it this meeting, right, and I could represent the OAS. Now we need to get the medical community and we need to get them excited about doing this. It won't happen in the first meeting, I can promise you that.

So why have it? And I'll repeat Sue's mantra here. It's different, and we want to reiterate that to the highest levels of NRC management and to the Commissioners themselves. It's a different mindset when we're thinking about this. We just can't think about this even as other materials uses. This is different than industrial radiography. Okay? In some ways HDRs look like industrial radiography. Iridium, the source goes in, the source goes out. But it's fundamentally different in how you should think about it. Okay?

There are a lot of licensees out there. Most of them are in Agreement States. How many are

medical use licensees? I don't know. I think in Pennsylvania it's about half, I think, or something like that. I don't know about other states or the NRC. It's a substantial fraction, particularly when you consider all of the cardiologists and people like that.

Type of medical procedure. I think we've seen this before.

Who should attend? We'd want all of these people to attend. Okay? We want Commissioners to be there, and we want Commissioners to be there not simply to say welcome to the meeting, I hope you have a good discussion, Rockville's a nice place to come and goodbye. Okay? We want them to be active participants in the meeting. We want them to be providing information and to be learning themselves. I realize they may send their technical assistants. We want the Commissioners themselves to be there and learning why medical is different.

NMSS staff. We love the medical team. We really do. And we particularly love Sophie.

(Laughter.)

MEMBER COSTELLO: However, NMSS is bigger than the medical team. Okay? And NMSS has to set priorities for things like rulemaking and

distribution of assets and such. I think it's important that NMSS be there, that senior management be there, for them to realize that the medical team does a lot for them and how important this application of byproduct material is.

Other Agreement States that should be there linked with the NRC. You might have people from research who might want to come. Maybe some of our friends in OGC might want to come. I think a lot of people could benefit in coming. And certainly the medical community. And I think if possible we need people representing patient advocates, patient rights advocates, because we want their point of view as well. Okay? If patients don't have access to medical care for some reason, or a regulatory reason, we want you guys to be screaming about that, okay, and telling us that we don't want to have regulatory hindrances to us getting care that we need.

I think I might mention all these, the informal and so forth, we'll skip over that.

So what problems need fixing? Well, if you recognize these things, these are what we've been talking about. However, this is where we are at this point in time. If we were having this discussion 10 years ago, aside from patient intervention, because

that never goes away, we might have a different list. Okay? And 10 years from now -- patient release, not patient intervention. Ten years from now we might have a different list. Okay? The problems that need being addressing will change over time. I suspect at the various RICs they've changed over time. If you look at the agendas from the RIC from the beginning, it's a very different agenda we have now. But the importance of the discussion will not change over time. If anything, I think it will probably increase.

These are just the topics that we're going now, and I don't think I'm going to go in any more detail.

What is needed? We need people. We need a -- it says NMSS commitment. It's really an agency commitment. It's an agency commitment. Because NMSS by themselves can't commit for the agency. It's an agency commitment from the highest levels of the agency, from Chairman Burns all the way down. We need people to champion this. We need people to champion this out in the medical community, to selling this, how good is it to come here. But I think they'll learn that over time. And we need NRC staff here to be advocates for having such a meeting within the NRC. I know that you are very busy. I

do. We are all very busy. However, if we can get a champion for this to point out how important it will be and how we could do this at a reasonable cost, perhaps using the auditorium, perhaps then we can create an implementation team and so forth.

I don't think -- I'm offering this to the other people here. I don't think we're talking about doing this this year. I don't think we're talking about doing this next year. I think a reasonable target for this might be 2017. That gives us time to develop the concept, to figure out the costing, to get the word out and to build up some enthusiasm for it. Process. We have to develop for each meeting, because it might change from meeting to meeting what we're trying to accomplish. Perhaps in the first meeting we might narrow it a little bit just to get it going. We have to advertise it and get people to come. We would need web site support. We need all of these kind of support that by and large we'd probably have to come to the NRC, I would think. We appreciate that.

Perhaps we'd have a facilitator to run these meetings and people might be trained on how to conduct these meetings. But the NRC has been conducting the RICs for a long time. They know how

to conduct meetings. Okay? Maybe even steal some people from them who've been running meetings like this before. They could help us out. I mean, we're all one NRC, the agency. Right? We've got an NRC badge on today. We're all the NRC today. So even though they're not NMSS, maybe they could collaborate.

My thought here is -- what I'd suggest doing before I suggest your thoughts. I see a little minion there. I love Sue and our minions. And if I could, maybe we could have another assignment for Sophie to put on the -- what we're asking the NRC to do is. I would like to ask the NRC at the next meeting to come back to us with a response and tell us if they think this is something that we should continue to work on. We are all grownups here. Okay? And both Sue and I, as much as we believe in this, if the NRC comes back and says we have a lot on our plate, maybe in a few years, we will lie with that. Okay? But I don't want to hear that, but I want to hear a yes from the NRC, but more important than a yes from the NRC I want to hear an answer from the NRC as to whether this is a project worth pursuing. Thank you.

CHAIRMAN THOMADSEN: And thank you, Mr.

Costello.

Comments from the Committee? Oh, we have a comment from the staff.

MR. FULLER: Well, I don't want to jump out too soon, but I did have -- while you're up there, Frank, I wanted to ask just for some clarification on a couple things. And I think you're probably right in one sense that we've talked about this long enough, that we probably ought to give you some sort of response, although the timing couldn't be much worse. We are in the process now of working in the early stages and starting -- the senior management at the NRC is starting to receive various plans and so forth related to Project Aim 2020, which is, as you said at the very beginning of your presentation, driving in a -- it's aimed at a point below the horizon as far as spending resources and so forth.

So, I guess my question is and something to consider is if this effort might simply could be suspended for maybe a year or something. Of course I can't speak for the Agency. I'm only speaking for Mike right now. But I think to answer your question provides a response there would be more uncertainty associated with that response than might -- in other words, it might not make it all that worthwhile at

this point in time. If you're talking about doing something in 2017, maybe we'd come back a year from now when we have a little more certainty around what it is that we're even dealing with here and then give you a response based upon something that maybe we might just have a little bit more understanding of what our resources are going to be.

And I see Doug's got his hand up over there and he's got some thoughts on it, too. But I just think the timing here is not good at all given what we know about Project Aim 2020.

CHAIRMAN THOMADSEN: Mr. Bollock?

MR. BOLLOCK: And if I can just continue on with what Mike's saying. Yes, the reality of where we are right now is -- we call it Aim 2020. That's the plan to get us down to re-baseline, and essentially re-baseline is get us to a new normal staffing level, resource level, budget level. And right now we are actively looking at things to shed, let alone add. So, if we're going to add something, there has to be basically a safety significant -- this has to be a safety issue to add something else for us to do.

So, I mean, realistically I can't speak for the whole agency, but this -- I've been in enough

of these meetings beamed at Aim 2020 and re-baseline that this -- it's not realistic right now for us something of this magnitude.

And just to give you ballpark numbers of what the current RIC costs. It's somewhere around 2 million a year. I know it wouldn't be that much, however, there are significant costs, there are significant staff resources that we would have to supply to do this. I don't know if any of you are aware; Mike, I'm sure you are with your experience in the Agency, the reactor side is much larger than the material side, let alone the medical use materials side. And so, they have resources to plan the RICs, and it's something that's been in place.

Frankly, my staff doesn't have the resources to be able to do something like that on top of our ACMUI meetings that we currently hold twice a year, the teleconferences, the -- our outreach we already do going to -- we go to as many meetings as we can: ASTRO, AAPM, SNMMI. We go everywhere we can to go out to the medical community realizing it's sometimes easiest for us to send one or two people. And that is very cost-effective. We already do that.

And we'd like to -- Mike and I have been talking about this for a least a year now, about our

outreach plans and having senior staff like Mike go out, or Donna-Beth go out to these societies; she just came back from FICA, and be able to not just give a presentation on what we're doing, but be able to expand that to the ask the regulator, getting the feedback so the medical community, your peers, could ask us -- just get a better understanding and increase those relationships. We realize that is important. But calling everybody in -- we think there are other ways to do that that are much -- well, frankly, much more economical, less resource-intensive for us, less time-intensive for the medical community and having to take another day off to come out.

And also, something that we just had -- Dr. Thomadsen came out and spoke to all of our Commissioners on Wednesday and our senior management, and that was feedback from both sides. I mean, Dr. Thomadsen, I don't want to speak for you, but there was positive on both ends, from our staff, our senior staff, senior management and Commission, and I believe Dr. Thomadsen also thought it was a positive -- that was a positive having that meeting. And those are ways to increase the Commission's awareness of medical and things like that.

So, really, I know you did a good job,

you and Sue did a great job of presenting problems that need to be fixed, but these are things we're working on here in this Committee, and we do outreach, and these are individual problems.

A RIC, I don't know what the problem of a RIC would be solving. It's a communication thing. I believe there are other ways to do that. And again, realistically in our current environment, where the NRC is going over the next few years, I don't see it going anywhere. And to create a new meeting of that magnitude --

MEMBER COSTELLO: Can I comment on that?

CHAIRMAN THOMADSEN: Please.

MEMBER COSTELLO: Okay. If you recall, I think it was when I first started, it might have been in the spring of 2014 when we met with the Commission, and Sue gave, I thought, a very powerful presentation on why medical is different. And she made a point. I think we recognize that certainly on the medical team and even in other parts of NMSS I think there's a recognition that medical is different. But that's not the audience that she's thinking about. Okay? She's really much thinking about the Commission level and senior management level.

I think when Dr. Thomadsen met with some of the Commissioners they said things like, well, oh, we don't understand that. We didn't know that certain points were -- they didn't know. And nobody expected them to know. The Agency is very much -- revolves on the regulation of light water reactors right now. And that's what they do all the time when they're called up to the Hill and such. But we want the highest levels, at the Commission level, the EDO level, some of the office levels, for them to really understand how different medical is and what the impact of that is.

So, I think we all recognize this. In sending Dr. Howe out to an organization that there's a good exchange of information there, but Dr. Howe already knows all that. Okay? Dr. Howe is very knowledgeable. She's not necessarily our intended audience. I mean, she comes to all of our meetings. It's the agency as a whole. We want to recognize that when we're regulating the medical, it's different. And I don't know exactly how to get to that point. Dr. Langhorst talked about that when she met with the Commission. And this is just one suggestion of how to get there. It's not the only possibility.

Members of the ACMUI meeting with the Commission I think is a great thing, and our meeting -- we do it twice a year, we meet with the Commission. And that's a very good thing. But this is just another way.

As far as, Mike, your comment goes; and believe me, I'm not -- I fully understand that, believe me. However, if we were to -- I still want the staff to come back to us at the next meeting and tell us something. Okay? If what you tell us is what you're saying here now, that Aim 2020 -- we don't have the time for that, we will understand that, but you should understand though that if we, let's say, put it off a year, then we're not talking about doing it in 2017, because there wouldn't be time. I mean, right now we would never consider trying to do it in 2016, and a year from now, which will be 2016, you can't think about doing it in 2017. You'd be talking about 2018. Okay?

And I'm not saying that that's something we can't do, but the longer you put off beginning this process, you're talking probably at least two years before we do it. So if next year we say, well, we'll do it the next year, it's going to be 2020 when we're doing it. Aim 2020 will have come and gone.

So, I understand. And I think a little something Sue and myself would understand it if you write -- say it's not the time. And we do get that. We still do think it's a good thing. And by the way, I say Sue and myself. I mean, Sue did 90 percent of the work here, or 99 percent of the work here. Yes.

MR. FULLER: This is Mike. Can I just follow it with one other thing? I'm glad, Frank, that you're the one making this presentation because you're the Agreement State rep. And as I sort of envision and think forward about how we might could possibly maybe somehow pull this off, I recognize that we have about 13 percent of the licensees, and you guys have the other 87 percent. I don't see how we could possibly do this NRC thing and we're talking to the Agreement States and we're working with the Commission and the medical community. I don't see how we could even start to begin to envision something like this unless we started arm-in-arm with a lot of Agreement State resources devoted to it. I think we need to really, really think in those terms. This has got to be a National Materials Program effort. I don't see how it could possibly be an NRC --

MEMBER COSTELLO: Great comment. The Agreement States can provide a lot. They can provide

their experience in regulating. They can provide what's happening at -- there's a lot of thought processes they can provide. What we cannot provide is the infrastructure. Okay? We are funded to basically -- to license and inspect in some space to rulemaking, though they're not really -- what I meant particularly we just stopped NRC rules. But we don't have a deep infrastructure. Okay? I don't think we have yet a place where we could hold a meeting like that. I think we can -- the Agreement States can provide ideas and do it like in working groups. They can provide people. I don't think we can provide infrastructure. We can help provide leadership.

However, the NRC and the Agreement States, we talk a lot. We've got monthly conference calls. I don't think we've got -- we have no difficult time communicating with you. I mean, do you fail to hear from us on every issue? I mean, we speak our minds. I mean, for good or bad the Agreement States say -- what I want is for the senior management to hear from the medical community. You hear from us a lot. You hear from me a lot. I want to hear from the docs a lot and the medical physicists and the practitioners.

CHAIRMAN THOMADSEN: Dr. Alderson?

ACMUI VICE CHAIRMAN ALDERSON: Well, communication is an extremely important issue, and it's an issue that I hope to emphasize when I step into the chair of this Committee. I'm going to side with the Agency on this one. This is not the right time for this initiative for a number of reasons. It doesn't resonate with me at all, really, but communication does. So, I would love to have communication as an agenda item for our next meeting and for several meetings to come and have this be one of the opportunities that we can discuss in a whole group of opportunities perhaps presented by the Agency or by us in terms of how we can improve communication. I think that's a great goal.

I think though that for all the reasons that have been mentioned up to now this is not the right time for this, and I think that because there are so many pieces out on the table the best thing to do is to say let's try to reorganize our thoughts, think about it more, bring it back along with some other ideas at the next meeting and decide where to go with communication.

MEMBER COSTELLO: I think speaking for I think both Sue and myself, I think we'd be fine with that.

CHAIRMAN THOMADSEN: Dr. Dilsizian?

MEMBER DILSIZIAN: Yes, I just want to echo from the physician's perspective since you wanted the medical community. Similar to the NRC, there's a lot of cost-cutting in major universities and hospitals. Our budgets are limited. Some of us go to at least two meetings a year, or more. To add another meeting, for physicians it will be tough. I think that the outreach approach of you guys coming to our meetings with SNMMI or the radiology meetings, several of them, I think would be better.

And the other thing I think that for physicians; and you and I have chatted about this -- I think half a day perhaps we can do this, but not for a couple of days. We can attend a couple of sessions in scientific meetings, but it will be very hard for physicians to do this for a couple of days. Thank you.

MEMBER COSTELLO: Dr. Alderson, when we're talking about communications then, an aspect of it I think we should talk about is how we -- the Committee communicates with the Commission.

VICE CHAIRMAN ALDERSON: Absolutely.

MEMBER COSTELLO: I don't think it's optimal yet. I think of the most recent situation

where we gave our advice on abnormal occurrence. Okay? I would like to think maybe there's a communications issue, that if they really understood what we were trying to accomplish, it might have turned out differently. It might not have, but I think the proposal that we sent to the Commission is a very good one. I was disappointed that they didn't adopt some aspects of it. And maybe if we communicated with them better -- and I think, Dr. Thomadsen, you're reaching out to them this week -- is a step forward in that direction. And we need to do more things like that. And actually, I think the way that you did it is even more effective than our public meetings have been.

CHAIRMAN THOMADSEN: Well, that I think is true.

MEMBER COSTELLO: Okay. Because you can have a heart-to-heart with each of the Commissioners and a very blunt exchange of information in a way that's much easier to do that with the Klieg lights on, all being recorded. Not that we have anything to hide, because we don't. But I think that sort of exchange with each of the Commissioners -- and you may have met with the EDO, I'm not sure. I think this could be very helpful if we could do more of

that.

Dr. Alderson, I look forward to you --

VICE CHAIRMAN ALDERSON: I've already been in touch with the staff --

(Simultaneous speaking.)

MEMBER COSTELLO: Okay. I think that would be really, really good.

VICE CHAIRMAN ALDERSON: Yes, I agree.

CHAIRMAN THOMADSEN: Yes?

MR. BOLLOCK: Just to add, our Commission, they do a lot of drop-ins. As Dr. Thomadsen -- unfortunately Dr. Langhorst was supposed to do the same thing. I believe Ms. Weil, you have done a drop-in with a couple of the Commissioners two years ago. That is -- we encourage that, if that's what you want. But it's up to you. We can't tell you to. We can't tell the Commission that -- we don't tell the Commission what to do and we don't tell you what to do, but we encourage that and we can help facilitate it. I believe Sophie worked with the Commission staff to set up the meetings, and we do encourage that. And that's just to form -- the other parts outside of the medical community, on the reactor side, they receive drop-ins from people all across, every -- basically everywhere we regulate

they have drop-ins with. So, it would not be unusual. It's not anything new for them to do that.

MEMBER COSTELLO: My only suggestion on drop-ins though is perhaps if before you have the drop-ins with the Commissioners -- and you I think in part did it because you're the outgoing Chairman. But when you reach out to the Committee as a whole -- and in essence you're really representing the Committee, and to say, well, here are the issues we want to bring up. And it could be a Committee member will say, oh, here's another issue you might want to bring up, because really when you do this you're representing the whole of the ACMUI and not just yourself. Right? And I encourage you to reach out to the Committee before you do that.

CHAIRMAN THOMADSEN: I won't take that to heart, but I will leave that for --

(Laughter.)

MEMBER COSTELLO: It's not a criticism.

CHAIRMAN THOMADSEN: -- the next person --

MEMBER COSTELLO: It's not --

(Simultaneous speaking.)

CHAIRMAN THOMADSEN: -- may be relevant.

MEMBER COSTELLO: It's not a criticism,

but it's just a thought.

CHAIRMAN THOMADSEN: Whatever that might be.

MEMBER COSTELLO: No, I don't mean as a criticism. I'm very happy that you did it.

CHAIRMAN THOMADSEN: No, no. Understood. So moving forward on this particular topic, the medical RIC, or whatever it may be, we can continue discussing it as appropriate next meeting or the meeting after.

One thing we might do is go to the medical community and see what interest there is there. If there is none, then I don't see a point in pursuing it. But if the medical organizations are interested, then we can see if it's more feasible at that point.

MEMBER COSTELLO: Dr. Alderson's thought of making communications something that we address for several meetings perhaps, right, and finding particular ways of focusing what kind of communications we're talking about, because there's lots of elements of that. And I think we could even start that with the next meeting. I think it's a good idea.

CHAIRMAN THOMADSEN: The next item on the agenda -- thank you very much, Mr. Costello -- is the

open forum. And we basically have been in that for a little while as we've been talking about communications. Now we'll open the floor for other ideas, comments, suggestions, criticisms, whatever anybody would like to bring up now.

(No audible response.)

You were warned a day-and-a-half ago that we would be doing this again.

(No audible response.)

CHAIRMAN THOMADSEN: We've become a Quaker organization.

(Laughter.)

VICE CHAIRMAN ALDERSON: It's the end of a long two-day meeting --

CHAIRMAN THOMADSEN: It is.

VICE CHAIRMAN ALDERSON: -- and I think we've had great discussions and I don't think we ought to just wrench something out of somebody.

CHAIRMAN THOMADSEN: I agree. Which leads us to Ms. Holiday with the administrative closing catching up from this afternoon, or I guess this morning.

MS. HOLIDAY: So, I realize that I am between you and the adjournment of the meeting, and thankfully we did cover yesterday's recommendations

and actions, so this should expedite this particular discussion.

I do want to note that item 21 we had stated that the backup date for the spring meeting was going to be March 24th and 25th; however, I was informed that the 25th is Good Friday, and so we like to avoid holidays that may present religious conflicts for persons that may be attending who are on the Committee or in the public realm. So I suggest that the backup date be March 3rd and 4th. Is that acceptable to the Committee?

(No audible response.)

MS. HOLIDAY: Thank you. So then that brings us to item 22, and this is when we came back from the lunch break and the Committee endorsed the Abnormal Occurrence Criteria Subcommittee report with a caveat that the report be amended to include an introductory paragraph that provides the rationale for the recommendations, as well as a summary paragraph to state that the Committee desires that the recommendations be incorporated into this revision of the NRC's Abnormal Occurrence Criteria Policy Statement. Are there any comments or issues on that? Yes?

MEMBER COSTELLO: A comment.

MS. HOLIDAY: Sure.

MEMBER COSTELLO: Ms. Weil, if imaging uncertainty our process, Committee members can have dissenting opinions that go into the record, right?

MS. HOLIDAY: Yes.

MEMBER COSTELLO: And I very much respected your point of view there, and you made me even hesitate, although I did wind up voting for it. It's up to you, but I think there might be value if you could indicate a dissenting opinion. It's up to you, but you might really consider that. You made some very, very, very good points.

CHAIRMAN THOMADSEN: It would certainly be appropriate given the indecision with which the Committee actually addressed that issue. Our time on that was a little bit short to get in by the November 16th deadline.

MS. HOLIDAY: Okay?

CHAIRMAN THOMADSEN: Yes.

MS. HOLIDAY: Thank you. Item 23, the Committee unanimously endorsed the NUREG-1556, Volume 9 Subcommittee report.

Are there any questions, comments or objections to that item?

(No audible response.)

MS. HOLIDAY: Seeing none, that brings us to the final item where Dr. Thomadsen formed a Subcommittee to propose the appropriate criteria for medical event reporting for events other than permanent implant brachytherapy. Subcommittee members include: Dr. Dilsizian, Dr. Ennis, Mr. Ouhib, Dr. Palestro, Dr. Suh, who will be the chair of that Subcommittee, and Dr. Zanzonico. That Subcommittee will report out during the spring 2016 meeting.

Are there any questions, comments or concerns for item 24?

(No audible response.)

MS. HOLIDAY: Seeing none, I have completed my discussion for the day. Please remember to take your name tags off. I don't want you to travel home with them and I have to reprint them. Thank you.

CHAIRMAN THOMADSEN: And thank you, Ms. Holiday. Thank you for everything.

MS. HOLIDAY: You're welcome.

CHAIRMAN THOMADSEN: And to the Committee, thank you again, and we stand adjourned.

(Whereupon, the above-entitled matter went off the record at 3:34 p.m.)

COMMENTS OF PETER CRANE, NRC COUNSEL FOR SPECIAL PROJECTS (RETIRED)
ON RULEMAKING PETITIONS FROM DR. CAROL S. MARCUS, ET AL.

Re: PRM-20-28, Carol S. Marcus; PRM-20-29, Mark L. Miller; PRM-20-30, Mohan Doss et. al, "Linear No-Threshold Model and Standards for Protection Against Radiation."

ABSTRACT

Dr. Carol S. Marcus has petitioned the NRC for a rule change that would allow embryos, fetuses, children, and pregnant women to receive as much radiation as workers in a nuclear facility. She asks the NRC to scrap the cardinal principle of radiation protection – that radiation doses should be kept "as low as reasonably achievable" – in favor of "hormesis," the theory that radiation is good for you. Though mainstream science, as exemplified by the National Academies of Science, debunks hormesis as unsupported by the evidence, the Marcus petition does have one virtue: its extreme radicalism may help convince the NRC Commissioners of the grievous error that their predecessors made in granting the previous petition for rulemaking filed by Dr. Marcus, relating to nuclear medicine. The resulting rule change, in 1997, has made the United States an outlier in the world radiation protection community, with the weakest standards in the world, laxer even than those of Iran, Indonesia, and other Third World countries. It has put the American public, especially small children, pregnant women, and babies in the womb, at risk from the radiation emitted, excreted, and exhaled by patients given high doses of the radioactive isotope iodine 131 as outpatients. Therefore the Commission should **NOT** dismiss the Marcus petition out of hand, without a proceeding. Instead it should initiate a rulemaking proceeding that publicly examines not only the merits of hormesis, as Dr. Marcus requests, but also whether the NRC's rules on the release of radioactive patients should be made to comply once again with international standards and practices, so that this 18-year aberration can be corrected, and the NRC can resume its rightful place in the mainstream of the world radiation protection community.

I. Hormesis and its Advocates

The three petitions now before the NRC are from Carol S. Marcus, M.D., Ph.D., Mark L. Miller, and Mohan Doss and numerous co-signers. Mr. Miller's petition incorporates large sections of Dr. Marcus's verbatim and is similar to it, although to his credit, he does not ask, as she does, that radiation limits to fetuses, embryos, children, and pregnant women be made the same as for nuclear workers. The petition from Mohan Doss et al. states expressly that it "supports and supplements" the Marcus petition.

The Marcus petition attacks the Linear No-Dose Threshold hypothesis and the "as low as reasonably achievable" (ALARA) principle, which conservatively presume that radiation

exposure is harmful and should be minimized to the extent practicable. The petition asks the NRC to endorse instead the "hormesis" theory, which assumes that radiation is, on the contrary, beneficial. Among other things, Dr. Marcus requests that human fetuses and embryos, pregnant women, and children under 18 be allowed to receive as much radiation in a year as workers in nuclear facilities, up to 100 millisieverts or 10 rem per year.[1] Since many readers may think at this point that this cannot possibly be correct – that no medical doctor, certainly not a professor at a respected university, would ever advocate anything so extreme – they can read her proposals, verbatim and in full, in a footnote.[2]

But those who have followed these issues for years may ask: can this proposal really come from the same Dr. Carol S. Marcus, M.D., Ph.D., who wrote to the Food and Drug Administration on January 5, 2005? That letter said:

> The current RDRC regulations essentially prohibit pediatric research because of the minuscule radiation dose limits permitted (one tenth of that of an adult). This runs counter to the need to obtain pediatric-specific information. **While normal children are more radiosensitive than adults**, a factor of 10 is without scientific basis and is much too conservative. **A working limit of about one third of what a normal adult receives should be sufficient**.... [Emphasis added.]

Clearly, since 2005 **something** has changed by a factor of three. Either children have become three times more resistant to radiation than they were just ten years ago – an evolutionary marvel that the editors of *Science* and *Nature* need to hear about – or a very different developmental process has been at work. Only Dr. Marcus herself can clarify this, and I hope she will.

Mainstream science regards hormesis as pseudoscientific claptrap, to put it bluntly, and would view the idea of letting unborn children and pregnant women receive worker doses of radiation as either a joke in poor taste or, if meant seriously, frighteningly misguided. Yet

---

[1] Because the two systems of measurement now in use lend themselves to confusion, it should be understood that national and international bodies call for members of the public to receive no more than 1 millisievert, or 100 millirems, per year; that the NRC allows all persons, including children and pregnant women, to receive five times this amount; and that Dr. Marcus asks that all be allowed to receive up to 100 millisieverts, or 10,000 millirems, per year.

[2] Dr. Marcus's petition requests, at p. 7, the following:
"1) Worker doses should remain at present levels, with allowance of up to 100 mSv (10 rem) effective dose per year if the doses are chronic.
2) ALARA should be removed entirely from the regulations, as it makes no sense to decrease radiation doses that are not only harmless but may be hormetic.
3) Public doses should be raised to worker doses, as these low doses may be hormetic. Why deprive the public of the benefits of low dose radiation?
4) End differential doses to pregnant women, embryos and fetuses, and children under 18 years of age."

hormesis has its ardent partisans[3], some with advanced degrees, and there are online journals to publish their writings. Foremost among these is *Dose-Response*, overseen by the current leader of the movement, Dr. Edward J. Calabrese.[4] He has already declared the NRC's docketing of the three petitions to be "a vindication of my 30-year career, in many ways."[5]

To explore the back issues of *Dose-Response* is to enter a looking-glass world, a sort of parallel universe in which conventional notions are turned upside down. Take, for example, the articles of a founding father and hero of the hormesis movement, Dr. Thomas J. Luckey, otherwise known as, "Sir Samurai T. D. Luckey, Ph.D."[6] Discussing the effects of Hiroshima in "Atomic Bomb Health Benefits," he has written that "[o]ne burst of low dose irradiation elicits a lifetime of improved health," and suggested that as part of triage, survivors of a nuclear bomb blast should be given *additional* radiation.[7] Or take "Radiation Hormesis: The Good, the Bad, and the Ugly"[8]:

---

[3]Hormesis has won the support of such notable thinkers as Lyndon LaRouche, who has touted it in his publications for some 30 years, and the columnist and author Ann Coulter. For insight into LaRouche's views on hormesis, see *Executive Intelligence Review* (EIR) for March 22, 2013. (In the same issue, one can read his illuminating exposé of Queen Elizabeth II's genocidal plan to eliminate six-sevenths of the world's population.) http://larouchepub.com/eiw/public/2013/eirv40n12-20130322/eirv40n12-20130322.pdf For Ann Coulter's article, "A Glowing Report on Radiation," describing "burgeoning evidence that excess radiation operates as a sort of cancer vaccine," see http://humanevents.com/2011/03/16/a-glowing-report-on-radiation/

[4]See the July 23, 2015, press release, "Hormesis hypothesis may be acknowledged by US regulatory action,"http://www.eurekalert.org/pub_releases/2015-07/uoma-hh072315.php Dr. Calabrese continued: "From being totally marginalized to now an exciting and potentially transforming concept, it makes the possible NRC rule change more special. If something like this can happen on the radiation side with the NRC, there is possibly a whole revolution coming on the chemical side with EPA." It should be explained that in Dr. Calabrese's view, all kinds of stimuli normally thought of as harmful can have a hormetic effect, which may explain the financial support given to the movement over the years by such firms as R. J. Reynolds, Philip Morris, Lorillard, British American Tobacco, ExxonMobil, Rohm & Haas, and NiPERA, an arm of the Nickel Institute. (See: http://dose-response.org/wp-content/uploads/2014/06/www_dose_response_org_conference_2004_overview_htm.pdf)

[5]True believers in hormesis tend to declare victory on the basis of less than overpowering evidence, as we see from the efforts currently being made to persuade the editors of *Science* to retract a paper published **in 1956**, solely because the online journal *Environmental Research* has just published an article by Dr. Calabrese, revealingly titled "On the origins of the linear no-threshold (LNT) dogma by means of untruths, artful dodges and blind faith." So far, the editors of *Science* have refused. See: http://atomicinsights.com/edward-calabrese-challenges-science-magazine-to-right-a-59-year-old-case-of-scientific-misconduct/;http://atomicinsights.com/jerry-cuttler-and-mohan-doss-add-their-voices-to-calabreses-challenge-to-science-rejected-so-far/

[6]"Sir Samurai T. D. Luckey, Ph.D.," *Dose Response*, 2008; 6(1): 97–112.

[7]*Dose Response*, 2008;6(4):369-82.

[8]*Dose Response*, 2006; 4(3): 169–190.

> Premature cancer deaths are caused by insufficient radiation. ... [T]the United States has about 275,000 preventable, premature cancer deaths each year. The cause is attributed to insufficient radiation. ... [W]e live in a state of partial radiation deficiency. [W]e need radiation supplementation for more abundant health (Luckey, 1997b).

Discussing so-called "dirty bombs," Dr. Luckey wrote: "Excepting those who feel the blast, or who receive physical harm from heat or flying debris, low dose irradiation is beneficial (Luckey, 2004)." As for radon in homes, "higher residential radon levels consistently decrease the lung cancer mortality ... lowering radon in homes, as recommended by the EPA, will cause many lung cancer deaths." If cancer patients and their families ever realized the benefits of low dose irradiation, he wrote, they would not only insist on access to it, they would "want to prosecute BEIR and NCRP committee members for their decades of erroneous information causing needless suffering and deaths." He concluded:

> Considerable information indicates that we live in a partial deficiency of ionizing radiation. Nuclear wastes could provide safe radiation spas throughout the world (Luckey, 1995a, 1995b, 2004). Low dose irradiation could be provided in hospitals as a public health measure. If we had 50 times more radiation than we now receive, we would reach a new plateau of health (Luckey, 1999a, 1999b).

Attractive as the idea of the Yucca Mountain Radiation Spa may be, the reader at this point may well be thinking that this is all too goofy for words, and that neither the NRC nor any other agency of the U.S. Government would ever be taken in by it. It has even been suggested to me that to file comments on these petitions is a waste of time, as the Commission would never yield to anything so zany.

The flaw in that reasoning is that the last time Dr. Marcus filed a rulemaking petition, in the 1990's, the Commission not only gave her everything she had asked for but much more, with dire consequences that haunt the NRC to this day, and have caused untold harm to the thyroid cancer community, of which I have been a part for 42 years, and the public at large.[9] That grave error on the part of the Commission was described to me in 1999 by a distinguished professor and nuclear medicine physician at Penn State as "the worst decision from that agency in 40 years," a judgment hard to dispute. It would therefore be unwise to take anything for granted this time around. I hope that many other members of the public will join me in submitting comments; that former NRC Commissioners and staff, realizing that the agency's credibility and reputation are at stake, will add their voices; and also that the Nuclear Energy Institute and other representatives of the nuclear power industry will offer their views, along with representatives of the environmental community,

[9]The argument can be made that it cannot be shown that anyone's exposure to radioactive iodine, as a result of the current Patient Release Rule, has caused a case of cancer or mental retardation. But with health effects of this kind, such proof is usually impossible. There is a world of difference between no demonstrated proof of effects, on the one hand, and demonstrated proof of no effects, on the other.

EPA, FDA, OSHA, and the unions that represent hotel housekeepers.[10]

Dr. Marcus and the other petitioners acknowledge that the consensus of scientists and regulators is entirely against them, but they reject the possibility that this might stem from a good faith disagreement about the underlying science. Rather, they see it solely as the result of corrupt self-interest. Their notion is that these scientists and regulators believe that if they ever confessed what they know to be true – that radiation is beneficial – their jobs would be abolished and their organizations' funding would dry up, so they conspire to perpetuate what the petitions call "the greatest scientific scandal of the 20th century."

While recognizing that for the NRC to embrace hormesis would make it an "outlier," Dr. Marcus uses that word not with embarrassment but with a defiant pride.[11] From the agency's perspective, however, to declare that it was seceding from the international scientific consensus and raising the banner of hormesis would be ruinous for its reputation in the world radiation protection community. The NRC would not merely cease to be taken seriously as a science-based institution, it would become an international laughingstock, like Soviet biological sciences in the era of Lysenko.[12]

---

[10]It may be asked why the nuclear power industry should care one way or another. The answer is that if the NRC were to grant these petitions, banish the ALARA principle from its regulations, and embrace hormesis, the backlash from the scientific mainstream would cast a shadow over every other NRC decision, including its judgments on the safety of nuclear reactors. Why should the hotel workers' unions care? Because about five percent of I-131 outpatients recover in hotels, which means that the housekeepers who clean their rooms, unaware of the presence of contamination and unequipped to deal with it in any case, may be the group most endangered by the current Patient Release Rule, as will be discussed later in these comments.

[11]Dr. Marcus recently wrote: "The NRC plan to make its radiation protection program closer to that of ICRP has no scientific basis. It is instead based upon the idea that uniformity is a good thing. Uniformity makes no sense if it makes everyone uniformly wrong. **It is better to have an outlier that is correct.** At least it sets a good example for the others." [Emphasis added.] (Letter of March 19, 2015.)

[12]For Dr. Marcus, this might be a plus, not a minus, given her frequently stated opinion of the agency. See, e.g., her letter to the Commission of January 24, 1992: "The Commission, with its oversimplifications of medical and pharmacy practice, required willing pawns to do its work. A sort of Darwinian evolution took place in which the scientifically unfit, a few individuals with very poor attitudes, and several cowards inherited the duty. ... In order to support the Commission's desires, and advance their own power agendas, the present staff uses fraud in any convenient form. Data are misrepresented, omitted, ignored, or manufactured for convenience. ... The recent humiliation of NRC by staff of OMB when NRC's fraudulent version of the 'Quality Management Rule' was uncovered is astounding but predictable. Instead of NRC's upper management retracting the material and apologizing, a delegation of NRC staff and management went into frenzied, paroxysmal 'superlying' to cover the original lying, and earned the contempt of all concerned. Some of the statements made in writing by NRC staff to justify the Rule describes actual deaths of patients caused by physicians which in fact did not occur. This would itself constitute a libel suit, but in this case has no point; no damage will be done because no one believes the NRC anyway. Pitiful, isn't it? ... I do not believe that the Medical Use Program is compatible with honesty, integrity, or even simple human decency."

The NRC is not the only agency to receive Dr. Marcus's tongue-lashings. See such postings to the RADSAFE listserv as the following, from December 22, 1998: "NRC's medical regulations are illogical, inconsistent, and completely devoid of any scientific underpinning. It's just arbitrary and capricious self-serving junk. I don't discriminate, though---I trash EPA as well, and then demolish one of FDA's Centers, CDER."

It is easy to poke fun at Dr. Marcus, Dr. Calabrese, Sir Samurai T. D. Luckey, Lyndon Larouche, Ann Coulter and all the rest. But what few Americans realize is that the United States is **already** an outlier in the world radiation protection community. Our country's radiation protection standards in the medical area are not only inadequate in comparison to those in developed nations of Europe and Asia, they are weaker by far than those in the Third World. (NRC Commissioners have been known to discover this only when they travel abroad and compare notes with foreign counterparts.) With regard to the release of radioactive patients after treatment with I-131, the regulatory standards of Iran and Indonesia put ours to shame – all because in the 1990's, under Chairmen Ivan Selin and Shirley Jackson, the Commission acceded to the demands of Dr. Marcus and her allies, for reasons that remain a mystery. The result has been higher radiation doses to the loved ones of I-131 patients and to the unsuspecting public.[13]

Dr. Marcus believes that the NRC's regulations on radiation protection are badly in need of revision. I agree completely – but not in the direction she proposes. Rather, they should be brought back into conformity with the recommendations of expert national and international institutions, so that the grievous harm done in the 1990's can at long last be repaired.

The key event in that process was the 1997 rule change that led to the current Patient Release Rule, 10 CFR 35.75, a regulation so out of step with conventional standards and practices that even its strongest defenders sometimes seem unable to credit that it really says what it does.[14] What the Commissioners undoubtedly did not realize at the time,

---

[13]To give credit where due, Dr. Marcus may have done more to single-handedly change U.S. policy on a major issue of public protection than anyone except Rachel Carson and Ralph Nader. One can admire the energy, tenacity, psychological insight, and force of will behind this remarkable achievement, even while deploring her goals and tactics, and wishing that her talents had been applied to worthier purposes.

It may also be noted that Dr. Marcus's name is to be found among the signers of a 2007 petition opposing the Kyoto protocols on climate change. The petition asserts: "Research data on climate change do not show that human use of hydrocarbons is harmful. To the contrary, there is good evidence that increased atmospheric carbon dioxide is environmentally he1pful." See: www.petitionproject.org/seitz_letter.php

[14]When a subcommittee of the Advisory Committee on the Medical Uses of Isotopes reported to the Commission in October 2010 that 10 CFR 35.75 was fine as is and needed no changes, it told the Commissioners, wrongly, that the rule provided a ceiling of 100 millirems for exposures to children, pregnant women, and the public from released patients. Minutes later, the NRC staff corrected the subcommittee: the actual limit is 500 millirems. The ACMUI subcommittee members had supposedly studied the rule for five months, accepting NRC payment for their labors, and in that time, quite clearly, not one of the members had bothered to read it.

A similar mistake was made by Dr. James Sisson and 15 co-authors in an article in *Thyroid*, the journal of the American Thyroid Association, in April 2011, after a three-year study, but in their case, they were unaware that 10 CFR 35.75 existed, and thought that patient release was governed by Part 20. (A correction and apology appeared in the June 2011 issue.) At an international conference on radiation safety in medicine, held in Bonn in December 2012 under the auspices of the International Atomic Energy Agency, a doctor from Memorial Sloan-Kettering Cancer Center, presiding over a panel discussion, informed the attendees that the NRC rule included a 100 millirem ceiling for exposures to the public. I had to tell him from the floor that this was a commonly held misconception.

because this was never explained to them, was the key role of hormesis partisans in this giveaway. The rule change came about via a petition that was requested by an NRC staff member in the first place; submitted by a hormesis advocate, Dr. Marcus; and then resolved in reliance on the advice of a supposed expert who was in fact a leader of the hormesis movement, the late Dr. Myron Pollycove.[15] It was thus "an 'inside job' from the start," to quote Dr. Marcus's unforgettable description of an earlier NRC rulemaking, one that began with a petition that was nominally filed by her, but actually was solicited by the NRC staff and drafted in part by an NRC staffer.[16]

II. Analyzing the Marcus Hormesis Petition (2015)

Dr. Marcus opens her petition by attacking the Linear No-Dose Threshold Theory (LNT). So far so good, the reader may think: the LNT, like the theory of evolution, is admittedly a theory that remains to be proven. (There are certainly reasonable people who believe that there is some threshold below which radiation probably is not harmful.) She goes beyond that, however, to disparage the expertise of the many bodies that advocate the LNT – she mentions "NCRP, ICRP, IAEA, and NAS-NRC's[17] BEIR Committee" – and the integrity of the "army of regulators at NRC, EPA, FDA, as well as DOE [who] would be unbudgeted if the LNT disappeared."

Dr. Marcus endorses the view of Professor Edward Calabrese, the hormesis guru discussed earlier, that the LNT was based on "amazing misconduct by the nation's leading geneticists in mid-twentieth century." The basis for this assertion is the claim that Dr. Hermann Muller, the 1946 recipient of the Nobel Prize in chemistry, deliberately lied in his Nobel acceptance speech in Stockholm, and that a worldwide cabal of scientists and regulators has

---

None of these people intended to spread misinformation. Rather, they **assumed** that 100 millirems was the NRC standard, presumably because they were so well aware that it **ought** to be the limit that they had not thought it necessary to check. Finally, NCRP Report No. 155, "Management of Radionuclide Therapy Patients"(2006), also says that 100 millirems is the standard for exposure to the public. If this was intended as a description of current standards, it too was erroneous; if it was a recommendation of what the standard **should** be, it constitutes yet another data point telling us that the NRC rules are out of step with expert thinking at home and abroad.

[15]Personally, Dr. Pollycove, who spent years at the NRC as a Medical Fellow, was an endearing gentleman, unfailingly friendly and warm, whether you agreed with his views or not. His passing in 2013, at the age of 92, saddened all who knew him.

[16]The dialogue on the subject of this rulemaking between an appalled Senator John Glenn and a contrite and apologetic Chairman Ivan Selin, in a 1993 oversight hearing, makes for amusing reading. U.S. Senate, S. Hrg. 103-61, Federal regulation of medical radiation uses: hearing before the Committee on Governmental Affairs (May 6, 1993) at 18-19. Glenn's point was that the Commission would never let this happen if nuclear power plants were involved, but seemed indifferent where medical uses were concerned. He had rightly perceived the heart of the matter: the prevalent attitude of "it's only medicine, not reactors, so who really cares?"

[17] "NRC" stands here for the National Research Council, not the Nuclear Regulatory Commission.

perpetuated this scientific deception ever since, cruelly persecuting those who dare to speak the truth.[18] She tells us that "the attitude of today's regulators is reminiscent of the Catholic Church at the time of Galileo. ... [T[he Church threatened to torture Galileo to death unless he rescinded his point of view."

Next, Dr. Marcus reviews the scientific data: the Hiroshima and Nagasaki survivors, nuclear power plant workers, tuberculosis patients given fluoroscopes, radium watch dial painters, hyperthyroidism patients treated with I-131, persons exposed to radiation from the explosion of a nuclear fuel reprocessing plant in Russia in 1957, persons exposed to radiation from accidentally recycled cobalt-60 sources in Taiwan, and Americans exposed to low levels of radon in their homes. Again and again she finds a hormetic effect.

The reader of the petition may at this point wonder how she will deal with Chernobyl, which, as is widely known, has caused over 7000 cases of thyroid cancer to date, almost entirely among persons who were children at the time of the 1986 accident. Her answer is that it did nothing of the kind. She writes, at p. 6 of her petition:

> The affected population in the former Soviet Union was followed for increased cancer incidence. According to UNSCEAR 2000b [citation omitted] and the United Nations Chernobyl Forum in 2006, except for thyroid cancers in the highly contaminated areas, there was no increased incidence of leukemias or solid tumors, and no evidence of increased genetic diseases. The increase in thyroid cancers was found in children under the age of 15 years in 1987, the year after the accident.[19] **However, the radiation doses were too low to have caused this**, and there was no dose-response relationship. In addition, the timing was off – the mean latent period for radiation induced thyroid cancer is about 28 years [citing the UNSCEAR 2000b report.] However, the increase was highly likely due to a mass screening effect [citing S. V. Jargin, "Chernobyl-Related Cancer and Precancerous Lesions: Incidence Increase vs. Late Diagnostics," Dose Response. 2014 Feb 13;12(3):404-14.]. Occult thyroid cancer is actually extremely common....[20] [Emphasis added.]

Just three years ago, however, Dr. Marcus co-authored a practice guideline on I-131 therapy that included the statement: "A causative role for 131I in carcinogenesis, **other than for**

---

[18]Dr. Calabrese's views can be found here: http://www.21stcenturysciencetech.com/Articles_2011/Fall-2011/Interview_Calabrese.pdf

[19]A note of clarification is perhaps necessary here. The cancers were not **found** in 1987, they were found years later in children who had been 15 or under (including in utero) at the time of the accident.

[20]Dr. Marcus overstates Sergei Jargin's position in the cited article. He wrote: "TC [thyroid cancer] was under-reported before the Chernobyl accident and more accurately diagnosed thereafter. This higher incidence of TC was attributed to the accident, **although it was at least partially caused by more complete detection."** [Emphasis added.] Thus Jargin did not dispute that Chernobyl was a cause of childhood thyroid cancer.

thyroid cancer in children at Chernobyl, is difficult to establish."[21] [Emphasis added.] I hope she will explain the apparent contradiction between the two statements.

Mainstream science is well aware that the post-Chernobyl childhood thyroid cancers began showing up long before any screening for cancer took place.[22] The mainstream view of the Chernobyl data is that the appearance of so many thyroid cancers so soon after the accident – the first cluster of cases showed up near Minsk around 1991 – was an indication that I-131 was far more carcinogenic, when inhaled or ingested by the young, than previously suspected. Until then, the latency period had been believed to be much longer.[23] In her petition, Dr. Marcus turns this causal relationship on its head, arguing that since the latency period for radiogenic thyroid cancer is much longer (a mean of 28 years, she says), the cancers found in 2000 and 2006 cannot have been caused by radiation. They were there all along, she tells us, and their discovery can be attributed entirely to better screening.[24]

Is that argument sound? To focus on just one part of the question, latency periods, let us consider "Latency Period of Thyroid Neoplasia After Radiation Exposure," an article

---

[21]SNMMI Practice Guideline for Therapy of Thyroid Disease with 131I 3.0*,Edward B. Silberstein, Carol S. Marcus, et al. (2012), http://snmmi.files.cms-plus.com/docs/I-131_V3.0_JNM_pub_version.pdf (at p. 10).The same document said, citing BEIR VII, "No threshold for radiation-induced carcinogenesis has been firmly established."

[22]In comments filed with the NRC on October 31, 1992, when Dr. Marcus's petition for rulemaking was out for comment, I made the point that, as the *New York Times* had recently reported, a World Health Organization team visiting Belarus "had come up with wholly unexpected findings: deaths from thyroid cancer (normally a disease slow in its onset and progress, with high cure rates) among children exposed to I-131 after Chernobyl." I continued: "This is not the time for the NRC to be approving regulatory changes that will have the effect of exposing American children to more I-131." (Dr. Marcus's response was to jeer at me for citing such "superbly scientific sources as the *New York Times*.") By the time the NRC granted the petition, in 1997, there was an abundance of data confirming the earlier reports, but the NRC final rulemaking notice included no mention whatever of Chernobyl or the resulting childhood thyroid cancer. Chernobyl was more than the elephant in the room; it was a whole herd of elephants.

[23]See, e.g., NIH News for March 17, 2011: "Higher cancer risk continues after Chernobyl; NIH study finds that thyroid cancer risk for those who were children and adolescents when they were exposed to fallout has not yet begun to decline." http://www.nih.gov/news/health/mar2011/nci-17.htm

[24]It would be fascinating to know when this realization came to Dr. Marcus, for in the past, her view of the post-Chernobyl thyroid cancers was quite different. On September 16, 1999, she wrote to the internet bulletin board RADSAFE: "We don't know why young children near Chernobyl developed thyroid cancer, but we have not seen this in other children who received NaI-131 for medical reasons. We do know that babies and young children near Chernobyl received massive doses of SSKI [super-saturated potassium iodide], and it is conceivable that SSKI-induced thyroiditis led to thyroid cancer." This suggestion, incidentally, was utter nonsense. The problem in the former Soviet Union was that there was minimal distribution of potassium iodide, whereas in Poland, 97 percent of children received it promptly. If KI had been the cause of thyroid cancer, rather than the means of preventing it, we would expect to see large numbers of cancers among Polish children. They did not occur.

published in the journal *Annals of Surgery* in 2004.[25] It found, based on a relatively small sample, that the mean latency period for papillary thyroid cancer associated with external radiation was approximately 30 years, whereas the mean latency period for post-Chernobyl cancer, associated with internal radiation, was about six years. There is in fact ample scientific evidence not only that the post-Chernobyl thyroid cancers were caused by internal radiation exposure, but also that there is a linear dose-response relationship.[26]

III. The Merits of Hormesis

Over the years, I have acquired, not always of my own volition, a measure of knowledge about radiation-caused thyroid cancer, its treatment with I-131, and the rules and practices for the protection of family members and the public. But on the scientific merits of the hormesis petitions, I will defer to someone with established credentials in the field, Dr. Ian Fairlie. I am attaching his views and incorporating them by reference. http://www.ianfairlie.org/wp-content/uploads/2015/08/US-NRC-Consultation-4-1.pdf

IV. Relationship Between the Marcus Petition and the Patient Release Rule

If this petition were to be granted, it would have little effect on the average American living near a nuclear plant, because the radiation doses from them are minuscule. The people who would be most immediately and drastically affected would be nuclear medicine patients, their families and loved ones, and the members of the public with whom they come in contact. The effect of the rule change would be to further loosen the already extremely lax NRC rules on release of radioactive patients.

As noted earlier, I agree with Dr. Marcus that a revision of the Commission's radiation protection standards is in order, albeit not in the direction she wants. Eventually, the Commission will have to come to terms with the reality that the current Patient Release Rule is deeply flawed, as is the advice it has received on it from the ACMUI. The filing of the Marcus petition is an appropriate occasion for that reexamination to take place.

---

[25]http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1356259/Ann Surg. 2004 Apr; 239(4): 536–543. Latency Period of Thyroid Neoplasia After Radiation Exposure Shoichi Kikuchi, MD, PhD, Nancy D. Perrier, MD, Philip Ituarte, PhD, MPH, Allan E. Siperstein, MD, Quan-Yang Duh, MD, and Orlo H. Clark, MD

[26]See, e.g., "Risk of thyroid cancer after exposure to 131I in childhood," Cardis E et al., J. Natl Cancer Inst., 2005 May 18:97(10); 724-32: "After the Chernobyl nuclear power plant accident in April 1986, a large increase in the incidence of childhood thyroid cancer was reported in contaminated areas. Most of the radiation exposure to the thyroid was from iodine isotopes, especially 131I. We carried out a population-based case-control study of thyroid cancer in Belarus and the Russian Federation to evaluate the risk of thyroid cancer after exposure to radioactive iodine in childhood and to investigate environmental and host factors that may modify this risk. ... **A strong dose-response relationship was observed between radiation dose to the thyroid received in childhood and thyroid cancer risk. ...Exposure to (131)I in childhood is associated with an increased risk of thyroid cancer**."[Emphasis added.]

Some explanatory history is necessary here. Before 1997, patient release was governed by the 30 millicurie rule, which, as the NRC had explained in codifying it a decade earlier, was a yardstick based on the hazards of I-131.[27] That isotope was chosen because it was "the most commonly used therapeutic radiopharmaceutical" and also "the most radiotoxic byproduct material used for medical use." The NRC stressed the "special contamination hazards of radiopharmaceutical therapy patients," and rejected the idea, proposed by one commenter, of basing release on the probable exposure to others. The calculations themselves were straightforward, it said, but knowing the facts on which to base them – the probable distance from others, length of time of exposure, etc. – was too "tenuous" to be relied on. It concluded that at activity limit of 30 millicuries provided an "adequate margin of safety" for exposure to both external and internal doses.[28]

That the 30 millicurie rule was intended to ensure compliance with the 500 millirem maximum permissible dose to a member of the public was well understood, and not only by the NRC. In 1997, at a time at which the rule seemed to be threatened by efforts on the part of EPA to reduce public exposures to radioactive iodine, it was strongly defended in an article in *Thyroid*, the journal of the American Thyroid Association, by Dr. Pat Zanzonico, then as now a health physicist at Memorial Sloan-Kettering Cancer Center.[29] He showed that the maximum likely dose to the family member of a patient receiving 30 millicuries of I-131 was 500 millirems. His point was that the 30 millicurie standard was adequate to protect the public, and thus that there was no need to make it stricter. To quote the abstract of the paper:

> Based on actual measurements of thyroid activity and of external absorbed dose, the total thyroid and mean extrathyroidal absorbed doses to adult family members from immediately released 131I-treated patients are approximately 0.01 and approximately 0.02 rad/mCi administered, respectively, yielding an effective dose of approximately 0.02 rem/mCi. **A maximum permissible effective dose of 0.5 rem for adults therefore is consistent with a release criterion of retained 131I. Lower-activity release criteria therefore may be unnecessarily restrictive.** [Emphasis added.]

The obvious implication of what Dr. Zanzonico wrote was that any limit looser than 30 millicuries would result in doses to others exceeding the 500 millirem maximum. He also observed, correctly, that the 30 millicurie limit only applied to external doses, from

---

[27]This was an activity cap, meaning that a person leaving a treating facility could have no more than 30 millicuries of activity in his or her system. This translated to an emitted radiation dose of about 6 millirem per hour at a distance of one meter, so that if you were a patient given 150 millicuries of I-131, you would be measured at intervals by someone from the hospital's radiation safety department, and when the emissions fell below 6 millirems, it meant that the activity level had dropped below 30 millicuries, and you could be released.

[28]See 50 FR 30616 (July 26, 1985) and 51 FR 36932 (Oct. 16, 1986.)

[29] Zanzonico, P.B., "Radiation Dose to Patients and Relatives Incident to ^{131}I Therapy," *Thyroid*, Vol. 7, No. 2, 199-204 (1997).

proximity, and commented: "**Of course, the overall hazard is a combination of both the external and internal radiation hazards**." With respect to internal dose, he noted, again quite accurately, that "**saliva and urine [are] the primary sources of such contamination**." [Emphasis added.]

The article also noted that the activity threshold for hospitalization of radioactive patients ranged "from as low as 2 mCi [millicuries] in some parts of Europe **to as high as 30 mCi in the United States**." [Emphasis added.] Thus even before the 1997 deregulation, the NRC's 30 millicurie standard was as loose as any in the world. If we were already outliers then, one can imagine how far wide of the norm we are now.

Dr. Zanzonico evidently did not realize, as he was writing his article, that the NRC was on the verge of ditching the 30 millicurie rule in favor of a dose-based approach, and that outpatient treatment with I-131 in much greater amounts was about to become common. Sloan-Kettering, for example, would soon be giving outpatient treatments of up to 200 millicuries of I-131.[30]

Once the 30 millicurie rule had been abolished, the party line shifted in the blink of an eye. Now it became necessary for the partisans of the nuclear medicine industry to prove that the 30 millicurie rule had been overly restrictive, and lacking a scientific basis, rather than adequately restrictive, and well supported by scientific research, as Dr. Zanzonico had argued in *Thyroid*.

Writing to RADSAFE in 1999, Dr. Marcus claimed that an NRC staff official had confirmed to her that no one at the NRC knew the origin of the 30 millicurie rule.[31] (If he said this, he

---

[30]Bath, C., How can patients who receive radioactive iodine treatment for thyroid cancer reduce the chance of radiation risks to others, ASCO POST 2:4 (March 2011).

[31]Writing to RADSAFE, Dr. Marcus explained that her initial petition to the NRC had asked that the 30-millicurie rule be eliminated for all radioisotopes except I-131, but that she had later amended it to remove that exception: "After the main petition was submitted, I went back and looked at the I-131 case and couldn't figure out where in the world the '30 mCi' had come from. **NCRP no. 37 pooh-poohs the '30 mCi' number,** but did not give its origin. (The NRC originally applied the '30 mCi' to I-131; only in 1987, I think it was, was it applied to ALL radionuclides.) Don Cool admitted that no one at NRC had any idea where it came from or what it was based on; we had a completely arbitrary and capricious standard with no scientific basis at all. It certainly had nothing to do with the 500 mrem limit." [Emphasis added.]

Incidentally, Dr. Marcus's message grossly distorted how the authors of NCRP No. 37 saw the 30 millicurie limit. Anyone who troubles to read that slender volume, and it is well worth the small effort required, will see that the point it made, entirely correctly, was that a "one size fits all" activity limit of 30 millicuries for every radioactive isotope was not the most meaningful basis for release, "since the exposure rates and half-lives of various radionuclides differ greatly." (At p. 17.) For chromium 51, for example, 30 millicuries was unduly restrictive, while for others, such as I-131, it was not restrictive enough, in the authors' view. (At 18.) For I-131, it recommended release without restrictions only for doses of **eight millicuries or less**. Far from advocating the abolition of activity caps, it advocated limiting outpatient treatment with I-131 to 80 millicuries at the absolute maximum, and then only in exceptional situations, with prior notice to local health authorities.

should have known better, for in 1985, the NRC had cited a recommendation of the NCRP as a source.[32]) Soon this became the new orthodoxy for Dr. Marcus and her allies. Articles duly appeared making the claim that the 30 millicurie rule came out of nowhere. We see this, for example, in the articles of Dr. Marcus's allies Drs. Stabin and Siegel,[33]and in a July 2014 article in *Thyroid*, co-authored by Dr. Siegel and Dr. Edward Silberstein,"The AEC/NRC Thirty-Millicurie Rule: Regulatory Origins and Clinical Consequences for Iodine-131 Remnant Ablative Doses." They wrote:

> **Clinical and historical uncertainty exists** surrounding the issue. ... Without any data, these U.S. regulatory agencies caused significant expense, inconvenience, and fear, affecting thyroid cancer patients and their families. ... Studies on this 30 mCi ablative dose indicate that **this activity was never associated with radiation health and safety issues.** [Emphasis added.]

"Clinical and historical uncertainty"? "Never associated with radiation health and safety issues"? One wants to say, "Oh, come **on.**" The proof to the contrary is all there in black and white, in the back issues of *Thyroid*.

Let us now skip ahead to 2010. In the meantime, the following has happened:

- The International Commission on Radiation Protection has issued, in 2004, a report, ICRP 94, detailing the radiation hazard presented by patients treated with I-131;
- I have filed, in 2005, a petition for rulemaking asking for reinstatement of the 30 millicurie rule, for I-131 only[34];
- the NRC has denied the petition, in 2008;
- I have taken the NRC to court, in the Ninth Circuit Court of Appeals;

NCRP 37 was anything but casual about radiation risks to others. Appendix III, at p. 45, is highly instructive. Titled "Radiation Safety Check List for Discharged Patients Containing Radionuclides," it asks for a description of the patient's household, and "in multi-family buildings, possible proximity of neighbors." In addition, the form asks for the names, relationship, and ages of household members, and the names of regular visitors. The radiation safety issues to be discussed are listed, and there are lines for "Film badges issued" and "Identification card, or wristband issued." Sample tags and wristbands, with the trefoil radiation hazard symbol, are included in Appendix II. Appendix IV, at p. 46, provides "Instructions for Family of Released Patient." The authors of NCRP No. 37 would surely be appalled that anyone could ever cite their document as the basis for allowing radioactive patients to go home to their families, ride public transportation, go to hotels, etc., with 400 millicuries or more of I-131 in their systems.

[32]See 50 FR 30616, 30627, col. 2 (July 26, 1985).

[33]Drs. Jeffry Siegel, Carol Marcus, and Michael Stabin,"Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with 131I," Health Phys. 2007 Dec;93(6):667-77, http://www.ncbi.nlm.nih.gov/pubmed/17993847.

[34]I later modified my request to say that I was open to solutions that allowed I-131 outpatient doses in higher amounts than that, under limited circumstances.

- the NRC has secured dismissal of the case, in 2009, not on the merits but on jurisdictional grounds (it agrees with the NRC that my treatments with I-131 were too far in the past for me to be sufficiently affected by the rule to have legal standing;
- also in 2009, the New York City Department of Health has issued a notice warning doctors not to send radioactive patients to hotels[35];
- in 2010, Congressman Ed Markey's staff has issued a lengthy report criticizing the Patient Release Rule; and
- The NRC's Advisory Committee on the Medical Uses of Isotopes has established a subcommittee, headed by Dr. Susan Langhorst, to examine and comment on the Markey report and on the Patient Release Rule.

At a public meeting in October 2010, an NRC staff official, James Luehman, had expressed concern about one class of hotel worker exposed to radiation from I-131 patients: those who work in hotels near major cancer centers, and who may clean numerous contaminated rooms in the course of a year, accumulating a dose each time. But when the ACMUI subcommittee issued its report in December 2010 on the release of radioactive patients, the issue of the worker who cleans multiple rooms was not even addressed.[36] Looking instead at doses to housekeepers from cleaning a single room, the subcommittee found that radiation doses to hotel workers were well within acceptable limits. This conclusion was premised on the assumption that **"dose contribution of possible internal radioactive contamination is considered minor and not included**." [Emphasis added.] (At p. 23.) The ACMUI subcommittee's analysis therefore considered external dose from the urine excreted into bedsheets by radioactive patients, but not internal dose from the urine and saliva that patients leave on bathroom surfaces.[37]

---

[35]It should be explained that in 1997, the possibility that some released I-131 patients might not go directly home, but to hotels instead, had not occurred to the NRC, and the Patient Release Rule was therefore silent as to whether it was permitted. As a result, about four or five percent of patients were going to hotels and motels, where their rooms were cleaned by housekeepers unaware of any radiation hazard and unequipped to deal with it even if they had known. The notice from the New York City Dept. Of Health and Mental Hygiene, Information Notice ORH 2009-01 (June 29, 2009) notice stated: "To avoid sending iodine therapy patients home, do **NOT** advise patients to go to a hotel. A hotel presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious, and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids." [Emphasis in the original.] Similar notices have been issued by state authorities in Minnesota and Washington.

[36]See U.S.N.R.C. Advisory Committee on the Medical Uses of Isotopes (ACMUI), Patient Release Report (Dec. 13, 2010). Sadly, it is a recurrent pattern that if there is no good answer for a troublesome question, the response often is to behave as though it had never been asked.

[37]In response to the criticism that the subcommittee should have considered doses from urine, Dr. Zanzonico replied that it **had** in fact considered urine: the external dose to housekeepers who handle bedsheets in which patients have deposited urine. It takes no advanced degree, however, to realize that the toilet (and in men, its surroundings as well) is a more likely place to look for radioactive urine than the sheets. The failure of

The health physicist whose calculations formed the basis for the subcommittee's report was none other than Dr. Pat Zanzonico, by now a member of the ACMUI. The report's findings directly contradicted what he had written in *Thyroid* in 1997, namely that internal dose mattered, and that the principal sources of it were urine and saliva.[38] Referring to the former 30 millicurie rule, the ACMUI report declared: "The Subcommittee finds no scientific merit in returning to such activity-based release criteria, which have **no identifiable scientific basis."**[39] [Emphasis added.] This too was completely contrary to what Dr. Zanzonico had written in *Thyroid* in 1997. The only person who can explain these apparent inconsistencies is Dr. Zanzonico himself, and I hope he will do so.

My intention is raising these matters is not to cause gratuitous embarrassment to anyone, but for the light they shed on the critical question of whether the NRC was wise or unwise to abolish the activity limit for I-131 patients, and whether the current Patient Release Rule affords the adequate protection to the public that the Atomic Energy Act requires. For the Commission, this is not optional. It is a matter of legal obligation, as much so as the Commission's duties on the reactor side, and at least as important, given that the radiation doses to the public are vastly higher.

Today, the Commission has no idea whether its rules on patient release provide adequate protection or not. The NRC staff wanted to tell the Commissioners that in SECY-12-0011, "Data Collection Regarding Patient Release," in 2012. The draft of that memorandum said, **"It is not known whether members of the public are, in fact, receiving doses that are less than 5 mSv [500 millirems] from the released patients."** [Emphasis added.] Leaving aside the fact that the NCRP and ICRP believe that the standard should be a fifth of that 500 millirem limit, this was highly significant, as it meant that the staff was unsure whether the

---

the subcommittee to consider the doses that might be received in cleaning the bathroom speaks volumes, as does its refusal, year after year, to explain or even discuss its reasons for ignoring them, as we see in the transcript of the ACMUI meeting of April 16, 2012:

MR. CRANE: But as far as the bed sheets, it seems to me that the amount of urine that is going to be deposited in the bed sheet is trifling compared to the amount of urine that is going to be put into a toilet. And if you grant that urine is taken into account, why not count the toilet and why not count the sink? We know about saliva. We know also that a lot of common household products cause radioiodine to volatilize, so people can be inhaling. What is the reason for not taking into consideration toilets?

ACTING CHAIR THOMADSEN: Thank you very much, Mr. Crane, but we are not going to have a debate on this right now. (Transcript at 122.) Dr. Thomadsen might have added,"nor at any other time," for the question remains unanswered to this day.

[38]This is confirmed by data showing that in hospital rooms used by I-131 patients, the highest level of contamination is on the toilet, followed by the pillow (the latter presumably reflecting in part contamination by saliva). Tuncel, N., Karayalcin, B., Koca, G., Budak, E.S., "The environmental dose measurements of high dose iodine-131 treated thyroid cancer patients during hospitalization period" [paper presented at IAEA conference in Bonn, Germany, December, 2012]

[39]Here the subcommittee cited an article by Jeffry Siegel in the Journal of Nuclear Medicine, "Tracking the Origin of the NRC 30-mCi Rule," J. Nucl. Med. 2000;41:10-16N.

regulatory requirements were being met. But the ACMUI subcommittee, like a goalie guarding the net, intervened to keep this information from reaching the Commissioners. Making the specious argument that the Commission's Staff Requirements Memorandum forbade the staff to say this, the ACMUI demanded that the statement be deleted from the paper, and regrettably, the staff gave in.[40] (I will discuss this SECY paper further below.)

In a parallel situation, can anyone imagine the Advisory Committee on Reactor Safeguards trying to block the NRC staff from alerting the Commission to a possible gap in reactor safety? The idea seems beyond belief, but if ever such an attempt were made, it would be shot down in an instant. Why then should it be tolerated on the medical side? The unspoken message seems to be, just as Senator John Glenn had realized nearly 20 years before: it's only medicine and people, not reactors, so it doesn't really matter.[41]

The rulemaking that brought us the Patient Release Rule in 1997 was, in colloquial terms, a scam, or something very close to it. As mentioned earlier, the final rule published by the NRC said not a word about Chernobyl and the upsurge of thyroid cancer in children in the former Soviet Union, even as countries and organizations all over the world, realizing that this meant that I-131 was more dangerous to the very young than previously suspected, were tightening their regulations. This was, however, just one of a great many issues that the Commission never heard about in the package sent to them for approval by the NRC

---

[40]In reality, the Commission had not instructed the staff to tell it that everything was working like a charm; rather, the Commission wanted to know where it needed more information, and of what kind, in order to judge whether the current system was working as it should. Attachments to that staff paper make it possible to see the changes insisted on by the ACMUI subcommittee and the staff's response to them.

[41]The question may be asked: where was the Patients' Rights Advocate when all this was happening? Thereby hangs a tale. In 1990, in an effort to achieve greater balance on the ACMUI, which was heavily weighted to the licensee side, the Commission decided to create the position of Patients' Rights Advocate. The first person named to the post was Judith Brown, a highly competent and conscientious nurse, who sometimes posed pertinent questions that the staff would have preferred not to be asked. Thus in October 1992, when a senior staffer was making the case to ACMUI for granting the Marcus petition and allowing therapy doses of I-131 to be given on an outpatient basis, on the basis of the "emotional benefits" to the patient, she asked, as a point of information, how patients felt **physically** at the time of treatment. This was a question that my own children, then eight and six, could have answered without difficulty, but the staff official had to admit ignorance, which raised the question: how can the NRC staff purport to make judgments on the psychological state of patients when it has not bothered to learn how they are feeling physically?

Clearly, Judith Brown was an inconvenient sort of Patients' Rights Advocate to have around. When her term expired, the person chosen to replace her was someone who, like Dr. Marcus, was a Southern Californian involved in the effort to promote creation of a dump for low-level nuclear waste in the Mojave Desert. She had spent 20 years doing public relations work for the nuclear isotope industry. Her successor came from a lifetime in isotope production at Hanford, and when he left the ACMUI to take a position in the isotope industry, his successor was someone whose name was sent to the Commission for approval in 2006 with no CV attached and no indication of what he did for a living. It was only after his appointment was announced that the Commissioners learned that their new Patients' Rights Advocate was the head of the DOE isotope program. That pattern was broken, thankfully, with the appointment of the current Patients' Rights Advocate, the admirable Laura Weil.

staff. Among other matters that commenters raised during the two comment periods (1992 and 1994), but that the Commissioners seem never to have learned about, were:

- six U.S. states had warned the NRC that iodine 131 was a special case, requiring special protections and standards;
- NCRP Report No. 37, the supposed analytic basis of the rule, had placed an activity cap of 80 millicuries on outpatient treatments;
- the rule change would put the NRC in violation of the IAEA's International Basic Safety Standards, to which the U.S. was a signatory;
- the NRC had rejected the premises of the proposed new rule just 11 years earlier, in 1986, for reasons set forth persuasively in Federal Register notices at the time;
- the importance of internal doses of I-131 from contamination;
- the concerns expressed by commenters about the likely economic pressures it would create;
- the warning from the National Institutes of Health about foreign patients who, disregarding instructions to avoid close contact with others after I-131 treatment, go directly from NIH to the airport to board long transoceanic flights, where they irradiate nearby passengers; and
- the emotional benefits to many patients of knowing that, by being treated as inpatients, they are protecting their families from harm.[42]

From all this, the Commissioners remained largely insulated. (Perhaps they wanted to be; at this point it is hard to know.) The Office of Inspector General made a valiant effort to enlighten the Commissioners as to the magnitude of the changes they were being asked to approve, the issues that were going unaddressed, and the defects in the way the proposal was being packaged and sold. In a brilliant and devastating March 18, 1994, memorandum from the IG to the Executive Director for Operations, Maryann Grodin, then OIG counsel and now General Counsel to the IG, wrote:

---

[42]To make very clear, I am not saying, and have never said, that **every** patient finds inpatient treatment to be emotionally beneficial, compared to outpatient treatment. I would be lying if I said so, for I am personally acquainted with a couple in Seattle who feel very strongly that for them, outpatient treatment is preferable, and that the husband, who is by profession a radiation safety officer, is fully capable of ensuring that everyone's safety is assured. Rather, I am saying that **many** patients find it so. Why? Because, for example, it means (1) not having to worry about exposing their loved ones; (2) if they experience nausea or other ill effects, there will be hospital staff to take care of them; (3) meals will be provided; and (4) they do not have to worry about exposing others while traveling home. Since 1992, the NRC has repeatedly touted the "emotional benefits" of outpatient treatment, even going so far as to claim that it contributes to "better patient outcomes," without so much as once in 23 years acknowledging that there are some patients who take the opposite view. "Emotional benefits" is an argument that cuts both ways. My position is that you cannot, with any intellectual honesty, talk about the emotional benefits of early release to some people without also talking about the emotional benefits to others of being kept in radiological isolation until it is safe to be released to the general population. And by the same token, it would be wrong for me to promote the benefits of hospitalization without acknowledging that there are persons for whom this may not be the ideal option, and for whom exceptions need to be possible, as NCRP No. 37 recognized in 1970.

> Another concern is that the significance of the proposed rule change is not clearly conveyed in the Draft Public Announcement. Enc. 6. While the announcement sets forth the proposed revision, it fails to state that the proposed rule will increase the amount of radiation exposure to some members of the public. Further, the change from an activity-based exposure limit to a dose-based limit is not elaborated on. Instead, the language used in the announcement could mislead a reader to interpret the proposed revision to be merely a regulatory clarification, as opposed to a substantive change.
>
> **As an additional matter we note that the choice of a dose-based vs. activity-based limit was not presented as an issue for comment in the agency's petitions. Enc. 2, p. 16. By not raising the issue in the petitions, an opportunity for full comment on the matter was missed. [at p. 4.]** [Emphasis added.]

Ms. Grodin's memorandum did not use the term "hiding the ball," but the message was clear enough. It was all in vain, however. The staff blew off the OIG analysis, and the IG chose not to press the matter.[43]

V. Do Contamination and Internal Dose Matter?

For a perfect example of why the Commission needs to revisit its regulations in the medical area, let us take the treatment of contamination by I-131 patients and the risk it presents of internal dose to family members and others. On a subject that should be stable scientific fact, we see instead an oscillation, with a return period of approximately 11 years.

For decades, everyone knew that the most dangerous medical isotope was I-131, and that patients were hazardous not only from proximity (external dose), but also from contamination (internal dose), since the isotope is given by mouth, and the patient is thus a "leaky source," as one expert put it:

> It should be realized that the calculation system utilized in NCRP no. 37 assumes that the patient is a "sealed source." It is important to consider situations in which the patient is a "leaky source." In such situations, more conservative considerations need to apply. It is important to consider the patient given NaI-131 in this context.
>
> I-131 appears in urine, feces, sweat, saliva, lacrimal fluid, nasal fluid, and emitted gases. **The radiation absorbed dose to the thyroid in individuals who share households with patients can be much more significant from contaminant I-131 than from the patient as a sealed source. Therefore, the limiting factor in deciding when a patient can go home should be contaminant levels of I-131 that can reasonably be expected to occur.** [Emphasis added.]

[43]The OIG analysis was forwarded to the Commission in SECY-94-054A, a publicly available document which is an attachment to these comments. The cover memo from the EDO to the Commissioners stated that the staff had no intention of making any changes or modifications in the proposed rule, and that the IG did not intend to press the matter.

The expert in question was Dr. Carol S. Marcus, and the quotation is from her amended petition of 1992. Every single word of it was correct and on point, and remains so today.[44]

In highlighting the risk of contamination, Dr. Marcus was not saying anything novel. As early as 1978, Dr. Dade Moeller of Harvard, later to chair the NRC's Advisory Committee on Reactor Safeguards, and a Harvard colleague wrote an article in the *American Journal of Public Health* in which they made the point that I-131 patients were boarding airplanes with amounts of radioactivity in their systems that would make it contrary to NRC rules to ride in the baggage compartment as packages. (This was, moreover, in the days of the 30 millicurie rule.) They wrote:

> The quantity of radioiodine discharged in body wastes treated at a major medical center can substantially exceed that released from a large commercial nuclear power plant. … A person who is treated on an outpatient basis can become an avenue of transport for radionuclides through contamination within the home and through person-to-person contact.[45]

Let us now review the history of the NRC's evolutions on the subject of internal dose.

1985-1986.

In 1985, in proposing a codification of its rules on radioactive patients, the NRC stresses "the special contamination hazards of radiopharmaceutical therapy patients."[46] Its explanation of the 30 millicurie activity standard, 10 CFR 35.75, begins: "A patient whose body contains byproduct material is a source of external radiation and can be a source of

---

[44]In the same year, at the ACMUI meeting of October 22, 1992, we find Dr. Marcus commenting, at p. 505 of the transcript, that it is acceptable for family members of released patients to receive radiation doses of 500 millirems from them, because "they have some benefit to go with the risk." Today, she would probably take issue with anyone who suggested that a radiation dose in that amount carried any risk at all.

[45]"Population exposures from radionuclides in medicine--as low as reasonably achievable?" J Shapiro and D W Moeller Am J Public Health. 1978 March; 68(3): 219–220. Professor Moeller and his co-author, Dr. Jacob Shapiro, a radiation protection officer at Harvard, were responding in part to a study by Jacobson, Plato, and Toeroek, published in the same March 1978 issue of the AJPH, which found significant internal doses in young children of thyroid patients given I-131: 612 millirems in a three-year-old, 1330 millirems in a four-month-old baby. That their comparison to emissions from nuclear plants was on target would be confirmed in 2006, when a draft report by the ICRP included the observation that **a single I-131 patient may give off more radiation than a nuclear power plant emits in an entire year**. But in a June 12, 2006, letter to the ICRP, an NRC staffer asserted that it was "inappropriate" to compare nuclear power plant emissions with "medically authorized discharges," and complained that though the ICRP was asking member nations to revisit their regulations on patients, *i.e.*, with a view to tightening them,"no discussion is provided concerning the benefits, both financially and emotionally, associated with discharging patients." (He did not dispute the accuracy of the statement, however.) The offending sentence was, as the NRC requested, deleted from the final report, ICRP 104, "Scope of Radiological Protection,"issued in 2007. For the NRC comment, see: http://www.icrp.org/consultation_viewitem.asp?guid={6D5B1740-3D6A-4487-A3B4-A324C80531C1}. .

[46]50 FR 30616, 30629 (July 26, 1985.)

radioactive contamination."[47] The proposed rules become final in 1986, with a notice describing I-131 as "the most radiotoxic byproduct material used for medical use," and explaining why the 30 millicurie rule, which was based on the hazards of I-131, provides "an adequate measure of public health and safety."[48]

1997.

We now jump ahead 11 years to 1997, and we have the new Patient Release Rule, based above all on the views of just one expert, Dr. Myron Pollycove, who as noted earlier is a passionate advocate of hormesis. He believes that I-131 is not carcinogenic[49] and that if a nuclear accident occurred, any health effects would be beneficial.[50] Suddenly, internal dose from contamination has gone from being a significant hazard to a non-issue, as we will discover shortly from the NRC's so-called "Regulatory Analysis," NUREG-1492.

Is vomiting by I-131 patients an issue? Anyone who knows the least thing about thyroid cancer and its treatment, including every patient and Dr. Marcus herself, knows that I-131 can produce nausea and vomiting.[51] Not the authors of NUREG-1492, however. They write:

> Vomitus. The occurrence of vomiting is not related to the administration of iodine-131 or any other radiopharmaceutical (personal communication, M. Pollycove, August 1995). (At p. 15.)

And so NUREG-1492 concludes, at p. 16:

> [I]nternal doses from intake of contamination are likely to be much smaller than doses from external radiation and much smaller than the public dose limit. Therefore, **internal exposures will not be considered in this analysis** other than for the breast-feeding infant. [Emphasis added.]

It is not my wish to deprecate the memory of Dr. Pollycove, but it must be said that he was

---

[47] *Id.* at 30627.

[48] 51 FR 36932 (Oct. 16, 1986.)

[49] Memorandum, Myron Pollycove, Visting Medical Fellow, to L. Joseph Callan, EDO, Sep. 3, 1998.

[50] "If a nuclear accident occurred, the radiation exposure would not be harmful and might even be beneficial." M. Pollycove and J. Cuttler, "Nuclear Energy and Health: And the Benefits of Low-Dose Radiation Hormesis," *Dose-Response* 2009; 7(1): 52–89; http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2664640/.)

[51] Dr. Marcus is a co-author of guidelines that say, of I-131 treatments: "Early side effects may include oral mucositis, nausea, occasional vomiting, sialadenitis, loss of taste, or unusual, often metal-like, alterations in taste. ... Vomiting can be prevented by prophylactic administration of oral antiemetics...." SNMMI Practice Guideline for Therapy of Thyroid Disease with 131I 3.0*,Edward B. Silberstein, Carol S. Marcus, et al. (2012) ,http://snmmi.files.cms-plus.com/docs/I-131_V3.0_JNM_pub_version.pdf

almost the last person on whom the NRC should have been depending for expert advice in that rulemaking. The result of that misplaced reliance was a deregulation, still very much in place, that may be the most radical ever by a federal agency charged with protecting health and safety.

2004.

We move on in time to 2004. The ICRP has issued a report, ICRP 94, warning of the danger to children from patients made radioactive by treatment with I-131. It states, among other things, that one kiss from a radioactive parent can transfer enough I-131 to double a child's risk of developing thyroid cancer.[52] Do the staff and/or the ACMUI pass this information on to the Commissioners, and explain that the dismissal of contamination and resultant internal dose in 1997 might have been a mistake? Regrettably, they do not.

2008.

Fast forward to 2008, and the NRC staff is denying a petition for rulemaking, filed by me in 2005, asking the Commission to revisit its regulations on patient release. (The matter is considered too unimportant to require Commission involvement.) One of the commenters has happened to mention ICRP 94, and the NRC staff has therefore felt obliged to address it. In a *Federal Register* notice, the staff explains that it has decided to deny the petition and "**revise the guidance in NUREG-1556, Volume 9, to include the ICRP Publication 94 recommendations** and issue a Regulatory Issue Summary (RIS) to medical licensees to make them aware of the ICRP recommendations."[53] [Emphasis added.] The notice says: "NRC believes that enhancing the guidance is a more efficient way of protecting children and infants than amending the regulations."

The May 16, 2008, press release accompanying the RIS explains that it tells physicians to "consider hospitalizing patients whose living conditions may result in the contamination of infants and young children." (Contamination, in this context, translates to internal dose.) The press release continues:

> These regulations were based on the assumption that internal doses to family members or others from a patient released following iodine therapy would be small compared to external doses received from being near the patient. **However, concern has increased in recent years that contamination of infants and young children with saliva from a patient in the first few days following treatment may result in**

[52] International Commission on Radiological Protection, "Release of Patients after Therapy with Unsealed Radionuclides," ICRP Publication 94, Annals of the ICRP 34(2), Pergamon Press, Oxford (2004). The reference to the doubled risk of thyroid cancer is found at p. 30.

[53] 73 FR 29445, 448 (May 21, 2008.)

significant doses to the child's thyroid. [Emphasis added.]

So the NRC once again accepts that internal doses from contamination are significant, and is revising the NUREG-1556 guidance to include the ICRP 94 recommendations. Surely this means that the aberration of 1997 has been corrected, finally and definitively? So one might think. But at the NRC there can be many slips between the cup and the lip. As of this writing, more than seven years after the NRC's 2008 *Federal Register* notice, the reference to ICRP 94 has yet to be included in NUREG-1556.

2010.

Now it is 2010, and the ACMUI subcommittee is presenting its report on the Patient Release Rule to the Commission. Just the year before, the IAEA, assisted by the ICRP, has issued Safety Report No. 63, "Release of Patients After Radionuclide Therapy." It has reiterated, at p. 7, that treated patients can cause exposure of other persons to radiation in two ways:

> (a) External irradiation of persons close to the patient;
> (b) Internal contamination of persons as a result of excreted or inhaled radionuclides.

IAEA No. 63 has also stressed the importance of appropriate measures to control doses to others, stating: "Without precautions, it is possible to envisage doses up to a number of orders of magnitude higher than the dose limits or dose constraints." (At p. 8.) "This can be controlled and minimized so that dose limits and constraints are not generally breached in practice,"it says, but a "key element in achieving this is the information and instruction provided for the patient and their family." *Id.* Among its conclusions are:

> Thyroid cancer as a result of radiation exposure is a significant risk for unborn children, infants, and younger persons. Particular care should be taken to avoid contamination of pregnant women, infants and children. (At p. 38.) ...
>
> The success of a patient release programme is critically dependent on the quality and specificity of the information provided to the patient, the skill with which it is communicated, and whether or not the patient believes the information provided.
>
> There is a lack of audit data on the behaviour of patients and the consequences of early release programmes. There is some evidence of unanticipated consequences of early release programmes in the USA that requires assessment and evaluation. (At p. 39.)[54]

[54]What the authors might have meant by "unanticipated consequences of early release programmes in the USA" is suggested by SECY-02-0111, in which the NRC staff, evidently at the instigation of Chairman Richard Meserve, proposed amending the NRC's rules to require the agency to be notified if a member of the public received a radiation dose exceeding 5 rems (10 times the permissible dose) from a released patient. The

IAEA No. 63 identifies – just as the NRC had in 1986, when it rejected the idea of a dose-based standard – the "many methodological issues that can compromise external dose calculations." (At p. 8.) It cites studies indicating that external dose from patients far exceeds internal dose from contamination, "with the exception of contact with a patient's urine," and it notes that "removable activity from toilet rims during the first 48 hours post-treatment was much greater for men than for women."[55] (At p. 9.) It says:

> Wellner et al. [citation to 1998 article in *Nuklearmedizin*] calculated that **the effective dose, from air contamination, for relatives of cancer patients treated on an ambulatory basis could be up to 6.5 mSv** and could, thus, exceed the 1 mSv public dose limit. ... The ICRP concludes that, in general, contamination of adults is less important than internal exposure. Notwithstanding this, it is very important to avoid contamination (particularly from saliva) of pregnant women, infants, and young children, owing to the sensitivity of foetal and paediatric thyroids to cancer induction. [Emphasis added.] (At p. 10.)

Note that patients treated with I-131 can, **from exhaled breath alone**, deliver doses to family members of as much as 650 millirems. This is entirely internal dose, and not only does it exceed the internationally accepted dose limit of 100 millirems, it also exceeds the 500 millirems permitted by NRC. Doesn't this seem like something the Commissioners should know about? But the ACMUI report on patient release, while it cites IAEA No. 63, says not a word about internal dose from exhaled breath.[56]

---

proposal was prompted by a July 24, 2001, letter from Joseph Klinger of the Illinois Department of Nuclear Safety, who wrote:

> "The Department would question the basis, including supporting data, for NRC's statements regarding the low frequency of known events associated with patient release. Simply because NRC does not keep records on such events, does not mean that such events are not occurring. Such Events have occurred in Agreement States and means of addressing them have been problematic because hospitals will accept no responsibility for them."

The proposal was voted down, 3-2. Chairman Meserve, in dissent, observed that "members of the public who have received involuntary doses from the release of patients will never be informed of their exposure." He noted that though the NRC had solicited the views of the medical community on the proposal – they were strongly opposed to it – no comparable effort had been made to seek the views of the public: "We have thus ignored the very individuals who have the greatest stake in assuring that there is a reporting and notification process."

[55]This point has special relevance to the hotel workers, possibly pregnant or nursing, who clean the toilets of I-131 patients treated as outpatients and then released to hotels.

[56]There is a great deal of literature, especially in European medical journals, on the subject of the I-131 exhaled by treated patients. See, for example, M. Gründel at al., "^{131}I Exhalation by Patients Undergoing Therapy of Thyroid Diseases," *Rad. Prot. Dosimetry* (2008), Vol. 129, No. 4, pp. 435-438; A. P. Stefanoyannis et al., "Radiation Exposure to Caregivers from Patients Undergoing Common Radionuclide Therapies: A Review," *Rad. Prot. Dosimetry* (2014), pp. 1-10; and K. Schomäcker et al., "Exhalation of ^{131}I after radioiodine therapy: measurements in exhaled air," *Eur. J. Nucl. Med. Mol. Imaging* (2011) 38:2165-2172. See also E. Westcott et al., "Benefits of Automated Surface Decontamination of a Radioiodine Ward," *Health Phys.* 102 (Supplement 1):S4-S7; 2012. The last of these describes the use of robots to clean contaminated surfaces of isolation rooms in Australia, where patients receiving more that 600 MBq [16.2 mCi] of I-131 are hospitalized. The use of robots, it reports, provides "occupational health and safety benefits," since "decontamination with a mop and bucked

Let us put this into practical, real-world terms. A young mother is sent home after I-131 treatment and told to keep at a safe distance from her young child. Fine, she thinks, the playpen will be on the other side of the room, I'll keep an eye on the baby but I will stay 15 feet away. Does anyone tell her that she may be delivering a significant radiation dose to her child simply by being in the same room and breathing? Not, it seems, if the ACMUI subcommittee can prevent it.

The ACMUI report criticizes the NRC staff's 2008 RIS for having repeated the ICRP's warning about the thyroid cancer risk to the children of radioactive patients without also having provided "details regarding the assumptions." (At p. 11.) It "commends the NRC for adopting the current-risk-based [*sic*] criteria," and declares, "Change from the 30-mCi rule to the current 10 CFR 35.75 patient release criteria in no way weakened the NRC rules." (At p. 16.) It says this notwithstanding that the NRC in 1997 frankly acknowledged that "even though released patients are given instructions on how to limit the hazard from contamination, contamination control in a hospital can be more effective than contamination control out of the hospital."[57]

2012.

In late 2011, the staff is preparing a memorandum, "Data Collection Regarding Patient Release,"which will go to the Commissioners in early 2012 as SECY-12-011. The staff wants to include a reference to the fact that I-131 patients can contaminate their children by kissing them – a central point of the 2008 RIS, since reinforced by the 2009 IAEA report. But the ACMUI subcommittee on patient release demands that this be deleted from the paper, claiming that the terms of the of the Commission's Staff Requirements Memo prohibit the staff from mentioning this. Regrettably, the staff gives in and allows itself to be silenced. The paper never mentions the RIS at all. It is as though all trace of it had been wiped from history.

SECY-12-011 says, at page 3-4:

> **The staff determined it may be beneficial to re-examine one of the assumptions in NUREGs-1492 and 1556 guidance which underlies current release practices, specifically that internal dose to members of the public is negligible compared**

---

presents several possible routes of exposure." If the NRC desires copies of these articles, I will be happy to provide them. I myself first raised the issue of exposure to patients' exhalations of I-131 in comments to the docket dated August 25, 1994.

[57] 62 FR 4120, 4123 (January 29, 1997.) The NRC explained that the other side of the coin is that having these patients in the hospital means that there is the potential to contaminate "people who frequent the hospital (e.g. clergy or a hospital orderly)." Thus it is a tradeoff: babies, with no say in the matter, may get more contamination, but clergy members who voluntarily visit a hospital where radioisotopes are used will get less.

> **with external dose.** This re-examination may be warranted because current release practices permit patients to be released with much higher activity than was the case when this assumption was made in promulgating the patient release rule. Accounting for internal dose is particularly important in the case of children and women. [Emphasis added.]

It is to the staff's credit that it is at least trying to alert the Commission to the fact that internal dose matters, especially for children and women. Likewise, it is highly significant that the staff is explaining that patients are being released with far more I-131 in them than had been foreseen in 1997. What is troubling, however, is the suggestion that current release practices treat internal dose as negligible. Wasn't that error acknowledged in 2008, in the RIS and the accompanying press release? It is as though the calendar been turned back to 1997. Radiation biology is not like economic policy, where higher interest rates may be a good idea one year, a bad one the next, and a good one the year after that. This is science, where some kinds of facts are expected to have some staying power, and when new information suggests a change in approach, the reasons for rejecting the earlier position have to be explained.

For all my criticisms of the ACMUI, it sometimes has its uses. For example, the best description of the damage wrought by the 1997 deregulation is to be found in the transcript of an October 23, 2007, ACMUI meeting. There, the longtime chairman, Dr. Leon Malmud, a former head of the Society of Nuclear Medicine, and another member, Dr. Douglas Eggli, discuss how insurance companies have taken advantage of the new rule, and how this in turn has transformed medical practice:

> Dr. Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries, the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies...."
>
> Dr. Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible**. They are given outpatient doses between 100 and 200 millicuries of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient**."[Emphasis added.] [Transcript

at pp. 126-130.]

Given that Dr. Malmud was a strong supporter of the 1997 rule, it would be easy to view this as demonstrating a callous disregard for the consequences of discharging patients whose family situations demand that they be hospitalized. But that may be a misreading of what he is saying. His words are also susceptible to the interpretation that he and other nuclear medicine doctors are merely trying to cope with a situation that they had not asked for, and that was imposed on them by the NRC and the insurance companies. If that is what he meant – and only he can clarify this point – one can feel some sympathy, because in fact, Dr. Malmud had **not** asked for this result. In 1992, he had filed comments on the Marcus petition on behalf of the Society of Nuclear Medicine, of which he was then President, offering a simple solution: incorporate NCRP No. 37 into the NRC's regulations in place of the rule then in force.[58] The NRC could have averted a great deal of harm by taking his advice. Had it done so, we would still have a firm activity cap for patient release, set at 80 millicuries (and that much only in the rare case); inpatient treatment, paid for by insurance, would still be the norm, although exceptions would be possible where conditions warranted; and patients' family members and the public would be far better protected than they are now. Perhaps it is not too late to take that suggestion even today, albeit with some modifications.

VI. Radioactive Patients in Hotels

Since January 2006, I have been urging the NRC that the problem of radioactive patients in hotels, after treatment with I-131 on an outpatient basis, is both a medical and a moral issue. It was wholly unforeseen, and therefore not addressed, at the time that the Patient Release Rule was enacted in 1997. Once the problem came to light, the NRC had a choice between two possible approaches. Either:

> (1) The Commission's intention was that patients would be hospitalized unless they met the criteria to go home, since at home, they would be in a position to protect family members and others from exposure to radiation. Thus a patient who for one reason or another cannot go home (or to a private residence put at his or her disposal) must remain isolated in the hospital.

Or:

> (2) The rule only specified the conditions under which patients must be hospitalized (that is, a likely dose of 500 millirems or more to any other person). If that criterion can be met, it does not matter where the patient goes, whether home, to a hotel, to an airplane, or anywhere else.

[58]The suggestion came in a letter written jointly by Dr. Malmud and the then President of the American College of Nuclear Physicians (ACNP), Robert J. Lull, M.D., dated April 24, 1992.

Put another way, is the issue (1) under what circumstances can patients be allowed to go home, or (2) under what circumstances can they be allowed to leave the hospital, and go where they like?

The NRC opted for the second approach, which I believe is both legally erroneous and contrary to sound policy. The patient who goes home does so, at least theoretically, with instructions that minimize radiation doses to others. (In reality, those instructions are often non-existent or inadequate.) The patient who goes to a hotel, on the other hand, will be putting others at risk without their knowledge. I do not wish to go into detail on these matters, which I addressed in a paper submitted to an IAEA conference on radiation safety in medicine, held in Bonn, Germany, in December 2012. A copy of it is attached and incorporated by reference. Suffice it to say that it was the unwitting exposure of hotel workers, in violation of the most basis principle of radiation protection in the workplace – informed consent – that most shocked and dismayed the delegates to the conference.

A commentary from 2011 in the journal *Clinical Nuclear Medicine* on a study of patients treated with I-131 on an outpatient basis in Brazil offers what is for the most part an excellent summary of where we stand today in the United States:

> The patients in this series were selected because they could read instructions, were willing to follow instructions, and lived in a place where the patient could have a private bedroom and where there is an adequate sewage and water supply system. There were no children or pregnant women present in the household.... The therapeutic doses [100 to 200 millicuries] were administered under the supervision of a nuclear medicine physician, with significant health physics support. The physicians prescribed drugs to prevent stomach acid formation for 3 days from the time of therapy (presumably to cut down on gastric irritation, nausea, and vomiting), as well as antiemetics. The patients left the hospital in personal cars, and were dissuaded against using public transportation. The physician and the radiation safety officer talked to the patients about radiation protection of others and the environment. Not only do they inform the patient of how to behave, but it allays fears that the patients may be harming members of his/her family. This is more or less the way the system should work in the United States, but unfortunately this is not always the case.
>
> Occasionally, patients in the United States are treated and given no personalized radiation protection information, or are given advice only by a technologist, instead of the physician or a radiation protection professional. Some patients are not given antiemetics, and gastric acid suppression is not the standard of practice in the United States. Some patients go home with public transportation, and some are told to go to hotels. Reports of these problems have been taken to the NRC, which is looking into the outpatient treatment issue. After much consideration, I have come to the conclusion that the problems in the United States are partly due to inadequate requirements for physician licensure to perform I-131 NaI therapy, partly due to irrational and expensive NRC requirements for inpatient therapy, and partly due to insurance companies not wishing to reimburse for unnecessarily expensive inpatient therapies. Until these 3 issues are resolved, we will likely continue to have some

> problems in the United States. While the data in this research from Brazil will be very useful for convincing regulators, patients, and their families of the safety of outpatient I-131 NaI therapy when it is performed correctly, we in the United States will still see the perception of radiation safety problems if it is performed incorrectly.

In these two succinct paragraphs, one can find so many of the points that I have tried to make over the past ten years, including:

- patients given inadequate instructions,
- patients on public transportation,
- patients sent to hotels,
- patients vomiting,
- risk to pregnant family members,
- risks to children, and
- patient care dictated by the mercenary interests of insurance companies.

These issues are real, no matter how strenuously the efforts to deny them, whether by the ACMUI subcommittee or anyone else. But if the question is whether these paragraphs were written by me or someone allied with me, the answer is no, they were written by Dr. Carol S. Marcus.[59]

VII. Conclusion

There is a great deal more that could be said about these subjects, citing chapter and verse, but to offer particulars here would only make these comments even longer than they already are. Suffice it to say that if Dr. Marcus or the SNMMI or the ACMUI or anyone else wishes to challenge me on any or all of these points, I will be more than happy to have it out with them, including in an open Commission meeting, if the Commissioners agree.

These comments have been lengthy in part because my institutional memory of the NRC goes back to the agency's first weeks, 40 years ago, and I am therefore in a position to provide today's Commissioners with historical background that they may not learn elsewhere.[60] But as always, my mantra is, "Don't take my word for it, check it out, find out for yourselves." I am confident that the more Commissioners explore, the more they will

---

[59] "Commentary on Willegaignon et al.: Outpatient Radioiodine Therapy for Thyroid Cancer: A Safe Nuclear Medicine Procedure, *Clinical Nuclear Medicine,* Vol. 36(6), June 2011, p. 446.

[60] When I joined the NRC in the spring of 1975, there were various checks and balances built into the system to ensure that the Commissioners got independent technical and policy advice and that institutional memory was preserved. Most important of these was the Office of Policy Evaluation. It was abolished in the early 1980's, a change that unfortunately starved the Commission of information that it badly needed. The present Commissioners, except Chairman Burns, probably know nothing of this.

come to the conclusion that the regulatory problems in the medical area are genuine and demand correction.

In 1975, the NRC was fully in harmony with international radiation protection standards. By 1997, the U.S. was already an outlier, as its 30 millicurie standard was at the edge of the spectrum of what was acceptable. Then the 30 millicurie standard was junked, and we saw patients being sent home to their families, to hotels, public transportation, etc., sometimes with 200 or even 400 millicuries or more of I-131 in their systems. Until Dr. Marcus filed her petition this year, one might have thought that it could not get any worse. But if the Commission embraces hormesis, and makes the rule changes that she asks for, it will be a great deal worse, and this time, it will not merely be the affected thyroid cancer patients and their doctors who are aware of it, the whole scientific world will decide that the NRC has gone off the deep end.

When supposed experts preach that internal doses of I-131 are insignificant, that I-131 is not carcinogenic, that there never was a scientific basis for the 30 millicurie rule, that the health effects of nuclear accidents will be beneficial, and that the post-Chernobyl thyroid cancers were not caused by radiation – this is not expert advice, it is quackery and charlatanism. Whether the hormesis backers are sincere in their beliefs is completely immaterial. Some of them surely are. But what of it? When people are peddling a nostrum, the question for the regulators is not the sincerity of the seller but the safety and effectiveness of the product.

In sum, I strongly urge the Commission **not** to deny Dr. Marcus's request for a rulemaking proceeding. On the contrary, they should grant it, provided that this proceeding is not limited to whether the Commission should embrace hormesis, but instead also considers whether and how the Patient Release Rule should be revised. Organizations, like individuals, sometimes need to find the strength to say, "We made a mistake, we recognize that, but now we are going to do what it takes to set things right." For the NRC, that time should have arrived a decade ago, but regrettably, the opportunity was missed. Today we can only say, better late than never.[61]

---

[61] Although this is not a rulemaking petition, I would be remiss if I did not state, at least in general terms, the kinds of changes I think necessary in the NRC's approach to I-131 therapy. First, inpatient treatment for therapy doses should be the norm, and outpatient treatment the rare exception, as envisioned by NCRP No. 37 some 45 years ago. (M.D. Anderson in Houston, a justly world-famous cancer center, takes this approach, and its guidelines should be a model for others.) Second, doctors should be able to prescribe inpatient treatment in appropriate cases and have it covered by insurance without having to spend their precious time fighting with insurance companies on the telephone, rather than caring for patients and earning a living. Third, limits on radiation doses to family members and the public should be in accordance with international and national recommendations, i.e., 100 millirems (one millisievert) under normal circumstances, with an appropriate activity maximum. Fourth, provision should be made for the unusual exception. (For example, if – God forbid – any grandniece or grandnephew of mine needed I-131 treatment, I would say, "Send her or him to me, to recover at our house. I am old, I have no thyroid, and I am in no danger. I can give informed consent and take my chances with the radiation I receive. I will pick him or her up at the hospital." I would infinitely prefer that to having a

Respectfully submitted,

/s/

Peter Crane
NRC Counsel for Special Projects (retired)
Administrative Judge, Nuclear Claims Tribunal, Republic of the Marshall Islands (1991-92)
Co-facilitator, Thyroid Cancer Survivors' Association support group, Seattle, Washington

child shut away in the loneliness and fear of radiological isolation.) Fifth, whenever exceptions are made, it should be on the basis of a genuine case-specific analysis, and with an activity ceiling, as contemplated by NCRP No. 37. Sixth, under no circumstances should highly radioactive patients ever be sent to hotels, or leave the treating facility by public transportation, crowded against other passengers in a subway or bus, or go directly to an airplane.

RADIATION PROTECTION ISSUES ASSOCIATED WITH OUTPATIENT TREATMENT OF THYROID CANCER USING HIGH DOSES OF IODINE-131: THE U.S. EXPERIENCE

[IAEA Conference on Radiation Safety in Medicine, Bonn, Germany, December, 2012]

P.G. CRANE
Counsel for Special Projects
U.S. Nuclear Regulatory Commission (retired)*
Email address: kinderhook46@yahoo.com

For Session "Protecting patients, carers, comforters, and the public in nuclear medicine"

ABSTRACT

The United States Nuclear Regulatory Commission (NRC) sets no maximum activity level for the release of patients treated with radioactive iodine 131 (I-131). For decades, NRC used an activity-based standard, 1110 MBq, but since 1997, it has allowed medical licensees to use a dose-based standard by which patients can be released without regard to activity level, provided that the probable dose to any other person will not exceed 5 mSv. This limit, applicable even to infants and nursing mothers, far exceeds ICRP, IAEA, and NCRP standards. Outpatient treatment has become the norm in the U.S., even for doses of 7400 MBq and above, as insurance companies refuse to pay for inpatient care. Radioactive patients are frequently released to hotels, where they are a hazard to other guests and above all to housekeepers, who are typically women of childbearing age and may be pregnant or nursing. The dose to unsuspecting hotel workers violates a cardinal principle of radiation protection, informed consent. The NRC has also failed to ensure that practitioners and patients receive appropriate guidance about limiting exposure to others. The 15-year U.S. experience with dose-based standards for I-131 suggests that a major revision of the NRC's rules on radioactive patients is overdue.

1. INTRODUCTION

United States law gives the Nuclear Regulatory Commission (NRC), the agency which oversees nuclear power plants, the incidental duty of regulating the use of radioactive materials in medicine [1]. For decades, the NRC and its predecessor, the Atomic Energy Commission (AEC), required hospitalization for all patients administered 1110 MBq or more of iodine 131 (I-131) [2]. In 1997, however, in response to requests from medical licensees, the NRC changed its rules and began allowing doctors to administer high doses of I-131 on an outpatient basis [3]. The NRC's current rules, unchanged since 1997, present safety issues with respect to therapy doses of I-131 for thyroid cancer, therapy doses for hyperthyroidism, and diagnostic doses for thyroid cancer. This paper focuses exclusively on therapy doses for thyroid cancer.

2. DISCUSSION

2.1 The NRC rule change of 1997

Under the NRC rules in place since 1997, medical licensees treating patients with I-131 can choose between using the 1110 MBq activity standard as a default value and using a dose-based standard, under which patients can be released regardless of activity level if they are found unlikely to expose any other person to 5 mSv in a year [4]. This 5 mSv dose limit applies equally to all persons, irrespective of age, pregnancy status, and relationship to the patient. Only if the external dose to others is likely to exceed 1 mSv do the NRC's rules require licensees to provide patients with guidance on precautions for reducing radiation exposure to others.

In 1985, the NRC stated, accurately, that patients treated with I-131 are "a source of external radiation and can be a source of radioactive contamination" [5]. In 1997, however, the NRC declared that internal dose from contamination was insignificant, except for babies and nursing mothers, and

* Current address: 6545 27th Avenue NW, Seattle, WA 98117, USA

stated: "[I]nternal exposures will not be considered in this analysis other than for the breast-feeding infant" [6]. The NRC conceded that exposure to patients' family members could be better controlled in a hospital setting, but pointed out that sending patients home would mean lower radiation doses to frequent hospital visitors, such as members of the clergy, and hospital orderlies [7].

The NRC's decision that its limits on I-131 should be made less stringent came just as international and national bodies were moving in the opposite direction, toward **more** stringent controls on the isotope. ICRP 60 (1991) had reduced dose limits to the public to 1 mSv per year, and the IAEA's Basic Safety Standards (1996) prescribed hospitalization for any I-131 treatment of more than 1110 MBq [8, 9]. For many nations, moreover, the 1110 MBq activity limit of the BSS was **insufficiently** strict. As of 1998, activity limits in the EU Member States ranged from 95 to 800 MBq, with most between 400 and 600 MBq [10].

2.2 Effects of the NRC rule change

Once the new rule was in place, many physicians found that insurance companies were refusing to pay for inpatient treatment with I-131 on the grounds that it was no longer necessary. For a doctor to insist on hospitalization was, therefore, to risk not being reimbursed. At a meeting of the NRC's Advisory Committee on the Medical Uses of Isotopes in 2007, two doctors (both supporters of the current rule, it should be stressed) candidly acknowledged the dominant role of insurers in the decision whether to hospitalize patients for I-131 therapy[1] [11].

A recent survey of 311 health professionals found that 15% **never** hospitalized patients for I-131 doses below 7363 MBq; 6% **never** hospitalized for doses below 11,063 MBq; and only 22% **invariably** hospitalized for doses between 7363 and 11,063 MBq [12]. In 2002, after receiving reports that released I-131 patients were exposing members of the public to radiation, the NRC Commissioners considered and rejected a proposal to require a report to the NRC if a patient caused a dose to another person of 50 mSv or more [13]. If hard data pointing to the rule's adverse effects is sparse, it is in part because the NRC has chosen not to receive it.

2.3 Radioactive patients in hotels

In changing its rules, the NRC assumed that patients would either meet the criteria for release, in which case they would go directly home, or remain hospitalized. It had not foreseen a third possibility: that some patients, either because the criteria for home release could not be met or because they lived far away, might be sent to hotels. This presents serious risks to hotel

[1] Dr. Douglas Eggli: "We can't get a preceptor to admit most patients to the hospital anymore from the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries [7400 MBq], the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies...."

Dr. Leon Malmud: "It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door. Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible**. They are given outpatient doses between 100 and 200 millicuries [3700 MBq and 7400 MBq] of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ... There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ... Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. ... Within the hospital, this patient is an unwelcome guest currently. **Uninsured, their wonderful insurance stops because it's no longer necessary for them to be an inpatient**. The health care workers are concerned and the hospital will not allow them to stay." [Emphasis added.] [Transcript at pp. 126-130.]

chambermaids, who in the U.S. are typically women of childbearing age. These workers do not "knowingly and willingly" accept their exposure to radiation. Unlike hospital staff and the families of patients sent home, they are unaware of the contamination and cannot take even basic precautions. A chambermaid may receive a substantial internal dose, and if she is pregnant or nursing, her baby's thyroid may also be affected. If the hotel is near a cancer center, moreover, she may clean numerous contaminated rooms in a year. Guests in adjoining rooms may also receive external radiation doses through the walls. Current estimates are that between 4 and 5 percent of patients go to hotels after receiving therapeutic doses of I-131 [14].

In 2009, the New York City Department of Health issued a directive to medical licensees warning in forceful terms against sending radioactive patients to hotels [15]. In 2011, the NRC published a non-binding notice that "strongly discouraged" licensees from doing so [16]. The practice nevertheless continues, and even has defenders. In a March 2011 article in an online medical journal, *ASCO Post,* Dr. R. Michael Tuttle, a distinguished thyroidologist at Memorial Sloan-Kettering Cancer Center in New York, was quoted as saying that Sloan-Kettering gives outpatient doses of up to 7400 MBq of I-131 [17]. "We are absolutely comfortable that it is safe for these patients to be in a hotel," Dr. Tuttle reportedly said, adding, "Many patients don't have a choice, because they are flying in for their treatments." In context, the implication was that if they returned home to countries with stricter standards, airport radiation detectors would identify them. Currently, the chance that a radioactive patient will be identified in a hotel or motel is virtually nil, unless, as happened in Illinois in 2007, the person occupying a room just vacated by an I-131 patient happens to work in a nuclear power plant, and the contamination on his skin sets off the plant's radiation alarms [18].

2.4 The NRC reaffirms the 1997 rule

In 2005, the present writer, a retired NRC lawyer who had in the past received I-131 treatments totaling over 28,000 MBq, filed a petition asking the NRC to revisit its rules on release of radioactive patients [18]. A supplementary filing in 2006 raised the issue of radioactive patients in hotels and the resulting risk to chambermaids [19]. The NRC denied the petition in 2008, in a decision that rejected the idea of adopting a 1mSv limit for infants and children, and made no mention of hotels [20]. (In 2009, a federal court dismissed the resulting appeal on procedural grounds, accepting the NRC's argument that because the petitioner's I-131 treatments had occurred long in the past, he was insufficiently affected by the NRC's rule to be allowed to challenge it in court [21].) At the same time that it denied the petition, the NRC issued a "Regulatory Issue Summary" [22] that drew medical licensees' attention to ICRP 94 [23] and ICRP 103 [24] and their warnings about the hazard to infants and children from I-131 patients. Acknowledging that the 1997 rule had been based on the assumption that internal dose presented insignificant risks, the NRC notice asked doctors to "consider" hospitalizing patients with children at home. It made clear, however, that the request was not binding.

2.5 The current situation

Not only is U.S. practice regarding radioactive patients unconservative by comparison with world practice, it has failed to provide appropriate safety guidance to aid licensees and patients in minimizing radiation doses to others. Although NCRP 155 [25] (a report which reaffirms earlier NCRP recommendations of a 1 mSv dose limit for children, pregnant women, and the public) includes sample precautions for thyroid patients treated with I-131, the NRC has not recommended their use. Instead, current NRC guidance suggests that licensees obtain and use a pamphlet issued in **1987**, when the 1110 MBq activity standard still applied [26]. The NRC's approach to human I-131 patients contrasts with its stringent rules for cats treated with I-131 for feline hyperthyroidism Typically administered doses of 111 to 222 MBq, they must be hospitalized for a minimum of 72 hours [27].

3. CONCLUSION

The IAEA has recently revised the BSS to eliminate the 1110 MBq activity limit on I-131, and endorsed the dose-based approach to protecting the public from treated patients [28]. In its February 23, 2010 "Position statement on release of patients after radionuclide therapy" [29], the IAEA implied that "global harmonization" had been achieved among ICRP 94, SRS 63 [30], EC publication Radiation Protection 97 [10], and the NRC's 1997 guidelines. Any such apparent harmonization is purely illusory, however, so long as the IAEA adheres to the 1 mSv dose standard for exposure to the public, while the NRC's standard is 5 mSv, even for infants and pregnant women. The IAEA and ICRP have yet to address the pressing issue of highly radioactive patients sent to hotels. The exposure of unsuspecting and unprotected hotel chambermaids to I-131 contamination is medically and ethically unacceptable and deserves condemnation. A revision of the NRC's regulations to bring them into conformity with international norms is overdue.

REFERENCES

[1] UNITED STATES CONGRESS, Atomic Energy Act of 1954, 42 United States Code [U.S.C.] 2201 et seq., Energy Reorganization Act of 1974, 42 U.S.C. 5801.
[2] OFFICE OF THE FEDERAL REGISTER, 51 Federal Register [FR] 36932 (Oct. 16, 1986).
[3] U.S. NUCLEAR REGULATORY COMMISSION, Criteria for the Release of Individuals Administered Radioactive Material, 62 FR 4120 (Jan. 29, 1997).
[4] U.S. NUCLEAR REGULATORY COMMISSION, 10 Code of Federal Regulations 35.75.
[5] U.S. NUCLEAR REGULATORY COMMISSION, 50 FR 30616 (July 26, 1985).
[6] U.S. NUCLEAR REGULATORY COMMISSION, NUREG-1492, Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material (Feb. 1997) 16.
[7] U.S. NUCLEAR REGULATORY COMMISSION, 62 FR 4123 (Jan. 29, 1997).
[8] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, ICRP Publication 60: 1990 Recommendations of the ICRP, Annals of the ICRP Volume 21/1-3, Pergamon Press, Oxford (1991).
[9] FOOD AND AGRICULTURAL ORGANIZATION OF THE UNITED NATIONS, INTERNATIONAL ATOMIC ENERGY AGENCY, INTERNATIONAL LABOUR OGANISATION, NUCLEAR ENERGY AGENCY OF THE ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, PAN AMERICAN HEALTH ORGANIZATION, WORLD HEALTH ORGANIZATION, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, IAEA, Vienna (1996).
[10] EUROPEAN COMMISSION, Radiation Protection 97, Radiation Protection Following Iodine-131 Therapy (exposures due to out-patients or discharged in-patients), Office for Official Publications of the European Communities, Luxembourg (1998).
[11] U.S. NUCLEAR REGULATORY COMMISSION, Advisory Committee on the Medical Uses of Isotopes, Meeting Transcript (Oct. 27, 2007) 177, 187-191.
[12] GREENLEE, C. et al., current safety practices relating to I-131 administration for diseases of the thyroid: a survey of physicians and allied practitioners, Thyroid **21** (2011) 151.
[13] U.S. NUCLEAR REGULATORY COMMISSION, Commission Voting Record, SECY-02-0111, Proposed rule to amend 10 CFR Part 35 to require licensees to notify of an individual receiving a dose exceeding 50 millisieverts (5 rem) from a patient released under 10 CFR 35.75 (Aug. 27, 2002).
[14] STERNBERG, S., It kills thyroid cancer, but is radiation safe?, USATODAY (Nov. 19, 2007).
[15] NEW YORK CITY DEPT. OF HEALTH AND MENTAL HYGIENE, Information Notice ORH 2009-01 (June 29, 2009).

[16] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2011-01, NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences (Jan. 25, 2011).
[17] BATH, C., How can patients who receive radioactive iodine treatment for thyroid cancer reduce the chance of radiation risks to others, ASCO POST 2:4 (March 2011).
[18] ALONSO-ZALDIVAR, R., Alarm over radiation from thyroid cancer patients, Associated Press (Oct. 20, 2010).
[19] CRANE, P.G., Petition for Partial Revocation of the Patient Release Criteria Rule (Sep. 2, 2005); see 70 FR 75752 (Dec. 2, 2005); Comment #11 on Petition, NRC Docket No. PRM-35-18 (Jan. 30, 2006).
[20] U.S. NUCLEAR REGULATORY COMMISSION, Peter G. Crane, Denial of Petition for Rulemaking, 73 FR 29445 (May 21, 2008).
[21] U.S. COURT OF APPEALS FOR THE NINTH CIRCUIT, *Peter G. Crane v. U.S. Nuclear Regulatory Commission et al.*, No. 08-72973 (unpublished memorandum, Aug. 19, 2009).
[22] U.S. NUCLEAR REGULATORY COMMISSION, Regulatory Issue Summary 2008-11, Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of Iodine-131 (May 12, 2008).
[23] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, Release of Patients after Therapy with Unsealed Radionuclides, ICRP Publication 94, Annals of the ICRP 34(2), Pergamon Press, Oxford (2004).
[24] INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION, The 2007 Recommendations of the International Commission on Radiological Protection, ICRP Publication No. 103, Ann. ICRP 37 I, Elsevier, Amsterdam and New York (2007).
[25] NATIONAL COUNCIL ON RADIATION PROTECTION & MEASUREMENTS, Management of Radionuclide Therapy Patients, NCRP Report No. 155, NCRP, Bethesda (2006).
[26] U.S. NUCLEAR REGULATORY COMMISSION, Consolidated Guidance About Materials Licenses (NUREG-1556), Vol. 9, Rev. 2, App. U, U-11.
[27] UNITED STATES NUCLEAR REGULATORY COMMISSION, Memorandum to Thomas Essig re Summary of July 9, 2002, Public Meeting with Radiocat, LLC, re Release of Cats Treated with I-131.
[28] INTERNATIONAL ATOMIC ENERGY AGENCY, Radiation Protection and Safety of Radiation Sources, International Basic Safety Standards, Interim Edition, IAEA Safety Standards Series No. GSR Part 3 (Interim), IAEA, Vienna (2011).
[29] INTERNATIONAL ATOMIC ENERGY AGENCY, Position statement on release of patients after radionuclide therapy, IAEA, Vienna (2010-02-23).
[30] INTERNATIONAL ATOMIC ENERGY AGENCY, Release of Patients after Radionuclide Therapy, Safety Reports Series No. 63, IAEA, Vienna (2009).

BIBLIOGRAPHY

AMERICAN THYROID ASSOCIATION et al., Joint Statement on Radioactive Precautions Following Radioactive Iodine Therapy (Oct. 20, 2010)

BARRINGTON, S.F.., et al., Measurement of the internal dose to families of outpatients treated with I-131 for hyperthyroidism, Eur. J. Nucl. Med. Mol. Imaging **35** (2008) 2097-2104.

BARRINGTON, S.F., et al., Radiation exposure of the families of outpatients treated with radioiodine (iodine-131) for hyperthyroidism, Eur. J. Nuc. Med. **26** (1999) 686-692.

BEASLEY, C.W., et al., Release instructions for hyperthyroid patients treated with I-131, Thyroid **21** (2911) 1163-1165.

BRITISH INSTITUTE OF RADIOLOGY, Working Party of the Radiation Protection Committee, Patients leaving hospital after administration of radioactive substances, Br. J. Radiol. **72** (1999) 121-125.

DE KLERK, J.M.H., I-131 Therapy: Inpatient or outpatient? J. Nucl. Med. **41** (2000) 1876-1878.

EUROPEAN COMMISSION, Radiation Protection 100, Guidance for protection of unborn children and infants irradiated due to parental medical exposures, Office for Official Publications of the European Communities, Luxembourg (1998).

GRIGSBY, P.W., et al., Radiation exposure from outpatient radioactive iodine (I-131) therapy for thyroid carcinoma, J. Am. Med. Assn. **283** 17 (2000) 2272-4.

HENNESSEY, J.V., et al., comments regarding practice recommendations of the American Thyroid Association for radiation safety in the treatment of thyroid disease with radioiodine, Thyroid **11** (2912) 336-338.

JACOBSON, A.P., et al., Contamination of the home environment by patients treated with iodine-131: initial results, Am. J. Public Health, **68** 3 (March 1978) 225-230.

KLOOS, R., Survey of radioiodine therapy safety practices highlights the need for user-friendly recommendations, Thyroid **21** (2011) 97-99.

LANGHORST, S., et al., Advisory Committee on the Medical Use of Isotopes (ACMUI), Patient Release Report (2010)

MARKEY, E.J., "Radioactive Roulette: How the Nuclear Regulatory Commission's Cancer Patient Radiation Rules Gamble with Public Health and Safety," report by staff of Rep. Markey, U.S. House of Representatives (2010)

MONSIEURS, M., Real-life radiation to relatives of patients treated with iodine-131: a study in eight centres in Flanders (Belgium), Eur. J. Nucl. Med. Mol. Imaging **25** (1998) 1368-1376.

PANZEGRAU, B., et al., Outpatient therapeutic I-131 for thyroid cancer, J. Nucl. Med. Technol. **33** (2005) 28-30.

REINERS, C., LAßMANN, M., Radioiodine (I-131) treatment of hyperthyroidism: radiation protection and quality assurance, Eur. J. Nuc. Med. **26** (1999) 683-685.

RÉMY, H., et al., Thyroid cancer patients treated with I-131: radiation dose to relatives after discharge from the hospital, Thyroid **22** (2012) 59-63.

SHAPIRO, D., MOELLER, D., population exposures from radionuclides in medicine – as low as reasonably achievable? Am. J. Public Health **68** (1978) 219.

SIEGEL, J.A., et al., licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with I-131, Health Phys. **93** 6 (2007) 667-677.

SISSON, J.C., et al., Radiation safety in the treatment of patients with thyroid diseases by radioiodine I-131: practice recommendations of the American Thyroid Association, Thyroid **21** (2011) 335-346; *see also* Correction, Thyroid **21** (2011) 689.