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UNITED STATES OF AMERICA
 NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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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

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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

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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
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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

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DANIEL SAMSON, New York State Department of
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ED TRUSKOWSKI, New Jersey Department of
Environmental Protection

CINDY TOMLINSON, American Society of Radiation
Oncology

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CONTENTS

| | |
|---|-----|
| MEDICAL EVENTS SUBCOMMITTEE REPORT | 4 |
| ACMUI COMMENTS ON NUREG-1556, VOLUME 9 | 23 |
| 10 CFR PART 35 RULEMAKING UPDATE | 43 |
| ADMINISTRATIVE CLOSING | 47 |
| SPECIAL PRESENTATION TO DR. THOMADSEN | 54 |
| PATIENT RELEASE WORKSHOPS | 58 |
| ABNORMAL OCCURRENCE CRITERIA SUBCOMMITTEE | 87 |
| REPORT | |
| ACMUI COMMENTS ON NUREG-1556, VOLUME 9 | 132 |
| (CONTINUED) | |
| THOUGHTS ON LEAVING THE ACMUI | 134 |
| NORTHSTAR GENERATOR | 144 |
| ADDITIONAL MEDICAL MEETING | 184 |
| OPEN FORUM | 218 |
| ADMINISTRATIVE CLOSING (CONTINUED) | 219 |
| PUBLIC COMMENTS (Peter Crane) | 220 |

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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.

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

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

19 Those were the events related to 200. Any
20 questions or comments on those before we go to the next
21 category? For 300, unsealed byproduct requiring
22 written directives. There were four events, compared
23 to two the year before, so again, we'll watch that over
24 the next couple years. One event was a technologist
25 selecting the wrong I-131 dose, selecting an expired

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

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

18 They did recognize this before the patient
19 left, and they were able to give him thyroid blocking
20 to prevent some of the effect, at least, on the thyroid.
21 Any questions before we go to the manual brachy?
22 Within manual brachy, there are 30 events in total, but
23 some of them are 1000 events, so we'll talk about them
24 in 1000. The microspheres and the breast
25 localizations are under 1000. Within 400, there are

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

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

18 They checked the patient afterwards, but
19 reportedly, she did not get any dermatitis, meaning
20 skin reaction, from the radioactivity, and they
21 instituted corrective action of making sure there's
22 more frequent checks, presumably by the nursing and the
23 radiation oncology staff when they do this procedure.
24 The prostate ones, there were four. Three were
25 underdosed, and one was an overdose. One was a

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1 calculation error, and three had to do with
2 misplacement of the seeds. All were iodine implants,
3 as opposed to palladium and cesium, but again, I would
4 not really read anything into that, just probably
5 representing the proportion of cases done by either
6 one.

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

18 I must say, I really don't know what that
19 could exactly be. Scar tissue in that area would not
20 be even unusual. It would be much more than even
21 unusual, so I'm not quite sure. But it is clear that
22 something -- the ultrasound interpretation wasn't done
23 well. A second case was seeds were placed too far
24 inferior. Again, the corrective action was training
25 on ultrasound. Somehow, they're attributing it -- the

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1 Foley balloon was placed in the bladder, and that does
2 help some people localize where the bladder is. They
3 say the balloon was deflated. To be honest, I don't
4 quite understand how that really impacted
5 significantly on the ultrasound imaging issue.

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

17 Again, not sure, but that you could make
18 such a confusing thing, you shouldn't, but they are both
19 round structures in the pelvis. If you're not quite
20 sure where you are or not so -- so there's a little bit
21 of a theme there. Again, it's only three. I don't
22 know that we, as a group, we can talk about -- do
23 anything with that information yet, but maybe.
24 Anything about that?

25 MEMBER COSTELLO: Just a couple comments

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

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

17 One was the wrong dose or wrong source
18 strength. I'm not sure why it's an "or," but that's
19 how it was entered. Oh, I'm sorry, excuse me, one was
20 dose, one was the wrong source strength and "machine
21 problems." Presumably, that has to do with the source
22 bringing it back. The source goes on a wire out and
23 back, and I guess it didn't work properly, and it led
24 to a medical event. These are the typical kinds of
25 things. Fortunately, this is a small number, so I

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1 don't consider that overly remarkable. One Gamma
2 Knife was, again, a wrong patient issue, and one
3 Perfexion, which was the wrong site, the wrong side,
4 so obviously Perfexion can have errors, too. Any
5 comments on that? The last section is the 1000s, so
6 microspheres are in here.

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

15 Regarding the microspheres, I think these
16 are pretty typical for what happens with this procedure
17 when things don't go smoothly, catheter being blocked,
18 a calculation error, error drawing up the dose, a
19 shunting problem, which we've actually discussed here.
20 I guess in the future it won't be an event unspecified.
21 Similarly for the TheraSpheres, similar kind of thing,
22 shot once and catheter blocked, material left there
23 quickly. Small numbers, so I think this is kind of what
24 we would expect. In terms of radioactive seed
25 localization, there were two events. One, a seed fell

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1 and was found 49 days later, supporting the idea that
2 you need to do all kinds of detections to make sure you
3 got all the seeds at the end of the procedure, in my
4 opinion. In one case, the written directive said they
5 were going to do one seed, but they used two, so again,
6 small numbers across the board.

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

16 Occupational overexposure, again, not to
17 a patient, but to staff, potential public overexposure
18 once, airborne issue once, equipment failures, and
19 "suspicious activity" involved cesium, iodine, cobalt.
20 So lost sources ten times. Iodine-125 seeds were lost
21 after a procedure. Other sources were lost twice,
22 found twice, lost and found four times, theft three
23 times, package thrown away, lost during shipment.
24 This is life. Delivered to the wrong address, stored
25 in unsecured area, highway patrol delivery -- accident,

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1 I guess, involving the car or truck carrying it, I
2 guess, shipping/packing issues, no license. In terms
3 of landfills, which has been discussed here a bit in
4 the past, again, we don't have comparative numbers.

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

15 I think the bottom line is these are very
16 few trends, and they're mostly random events that you
17 kind of expect in human interactions with stuff. The
18 only -- there's some site trends that I think we would
19 have to wait more, see if things are truly increasing
20 or not. Across the ultrasound thing is, I think,
21 something to pay attention to, see if that's an issue
22 that really we need to emphasize extra training if it's
23 becoming a problem. Any comments, any questions?

24 MEMBER COSTELLO: I have a comment on the
25 landfills. The data tremendously understates how

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1 often this happened. I know in Pennsylvania, we
2 probably have 250 to 300 events like this a year, and
3 they're almost all I-131. We can put any of them in
4 NMED, and maybe it's designed for this.

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

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

23 MEMBER ENNIS: Thanks. Thank you for
24 sharing that.

25 CHAIRMAN THOMADSEN: Maybe in the future,

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1 if the Committee desires, you might write something
2 about what's seen in the FDA's database.

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

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

7 (Laughter.)

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

13 MEMBER ENNIS: I think from what I'm
14 seeing, and for the people who gathered information,
15 and that includes myself, sometimes there's enough
16 information to make at least a reasonable understanding
17 of what's going on, and sometimes not. I think the
18 bigger problem, really, was making conclusions.
19 There's so few events, it's very hard to start to make
20 any kind of conclusions about what's going on
21 nationally with so few of them.

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

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1 reports are very --

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

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

13 MR. OUHIB: Yes, Zoubir Ouhib, medical
14 physicist. You actually hit on one of the items that
15 I wanted to address. That is when I've looked at the
16 data, that's over I don't know, 12 years' data, it was
17 striking that there isn't some sort of a format that
18 every user should follow, basically, and provide
19 adequate information. You look at the -- more
20 important, I can tell you, also, based on what has been
21 reported and what actually took place, you'll find out
22 that there are some differences, also. It's just the
23 way it was reported. I think we need to make some
24 progress in that area to actually draw some meaningful
25 conclusions, but perhaps correct the problem or assist

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1 in correcting that problem.

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

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

13 DR. METTER: I just have a technical
14 comment that on the 35.200, on the indium-labeled
15 white cell, I think it should be 500 microcuries, not
16 500 millicuries, and the following slide of 35.300,
17 where there's 1.11 megabecquerels, it's 30
18 microcuries, not millicuries.

19 MEMBER ENNIS: Thank you. So noted.

20 CHAIRMAN THOMADSEN: Thank you. Mr.
21 Costello.

22 MEMBER COSTELLO: There's one other thing
23 about the information in NMED. Most of this
24 information, I think, ultimately comes from the States
25 where things are being reported. I don't know. I

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1 can't speak for all 37 of the Agreement States. I'm
2 not sure I can speak for Pennsylvania, but I think if
3 you were to ask the States and provide guidance to the
4 States, if you want more information -- if we want more
5 information -- if you want more information in them,
6 I bet the States would work with the NRC to provide more
7 information in NMED reports if they were so asked and
8 so guided.

9 CHAIRMAN THOMADSEN: I will point out
10 there is a proposal in the American Association of
11 Physicists Medicine to try to get an
12 interorganizational task group together to write
13 guidances for writing the descriptions of events, both
14 in -- that could be used across different databases,
15 such as NMED and event reporting systems in the patient
16 safety organizations.

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

22 CHAIRMAN THOMADSEN: I think the
23 beginning of the reports are not from the licensees but
24 from the inspectors, in that I know some years ago, when
25 I was working on one of these, I was working on one case,

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1 trying to understand, to put into the report and tell
2 us at the very end. I noticed it came from my
3 institution, and I was the one who was talking with the
4 inspector, that was that case. Because I could not
5 have told from the description that it had anything to
6 do with the event that happened at our place.

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

9 CHAIRMAN THOMADSEN: Yes, I think so.

10 MR. BOLLOCK: Thank you. Yes, if you have
11 recommendations on how to make that better -- because
12 I believe it's SA-300 is our procedure we use with the
13 Agreement States for the information that we request
14 for event reporting, and as it is, it typically is the
15 event report is the first entrance, and then after that,
16 the follow-on inspections are updated information.
17 The counters that run INL, or NMED from INL, they are
18 very good about reaching out to get that updated
19 information. But it's like anything. The
20 information is as good as we put in here. It does take
21 some effort from the states or NRC to update that. But
22 if you have recommendations -- more pointed information
23 or things we could do to be better and work with the
24 states to be better, we will gladly try to take that.

25 CHAIRMAN THOMADSEN: Mr. Mattmuller.

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

12 MR. BOLLOCK: We only investigate the
13 events in our purview. The States have their own
14 investigative procedures or ways to look into incident
15 response. It's funny you bring that up. We actually
16 discussed this -- I discussed this with the outgoing
17 OAS director at the last OAS meeting about working
18 together to share what we do with our augmented
19 investigation team and incident investigation team and
20 provide that to the states. We're hoping to give that
21 training to the States just to show them what we do
22 because we do have -- we have resources in a lot of
23 things that the States -- sometimes there's -- they may
24 not be as robust, but they all have their own that are
25 adequate. That is checked through. So it's not to say

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1 the States don't do it. They absolutely do. But we
2 are currently working together to help build that up,
3 as a whole national Materials program.

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

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

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

19 DR. HOWE: Since Steve brought up the idea
20 of augmented inspection teams and integrated
21 inspection teams, I think it's important to know that
22 most medical events do not rise to that level. They
23 are looked at, at a normal inspection level. So it is
24 very rare for NRC to have an IIT, and it's equally rare,
25 in medical, to have an AIT. One should not consider

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1 those to be routine, and those are the methods that we
2 get information. It's normally inspection.

3 CHAIRMAN THOMADSEN: Thank you for that
4 clarification.

5 DR. HOWE: Yes, they are rare.

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

9 (No audible response.)

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

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

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

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

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1 This is a report on ACMUI subcommittee
2 reviewing and providing comments on NUREG-1556, Volume
3 9, Revision 3. The subcommittee charge, as I said, was
4 to provide comments on this non-rulemaking update and,
5 in particular, how changes might impact licensees and,
6 further, to make recommendations for ACMUI action and
7 so forth. This is a somewhat difficult to read slide,
8 but the point is that this task, the updating of the
9 NUREG, was split into two separate or parallel tasks.

10 The upper line indicates the work and the
11 progress of the NRC working group working on the update,
12 and the bottom line really refers to the work of the
13 ACMUI in reviewing and providing comments on this
14 update. Of course, there's feedback from the ACMUI to
15 the NRC along the way. As indicated, this effort began
16 in 2013, and we're about halfway through, as indicated
17 in the latter part of 2015. What this non-rulemaking
18 update does is revise and reorganize the NUREG to
19 conform more closely and more accurately to Items 5 to
20 11 listed on NRC Form 313. In the opinion of the ACMUI,
21 the reorganization is an overall improvement, but as
22 is the case always with large and complex documents,
23 it's often challenging to identify the changes that
24 have been made.

25 The next series of slides are the

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1 recommendations of the ACMUI with reference to certain
2 sections of the updated NUREG. The first
3 recommendation is a general one, and that is to extend
4 the comment period for a minimum of 90 days. As noted,
5 this is an extensive reorganization of a large, complex
6 document, so this longer comment period, we feel, is
7 justified.

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

25 So the safety culture traits,

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

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

24 I think everyone, including first
25 responders, would be much more familiar with that

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1 designation than GPS coordinates. So the
2 recommendation, again, is to use specific addresses,
3 that is a street name and number and building
4 designation, rather than GPS coordinates. 8.7.1, Item
5 7, deals with a consultant RSO, a consultant or
6 contractor radiation safety officer.

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

24 Item 8.93, Item 9 deals with dose
25 calibrators, and in particular, with terminology. We

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1 all recognize that the term dosage and dose is still
2 widely used, not only in the regulatory literature, but
3 in everyday practice, the scientific literature, so
4 forth and so on. But we also recognize that rigorously
5 speaking, that's not correct.

6 Dose, or more specifically absorbed dose,
7 really refers to energy deposited per unit mass. For
8 the purest among us, that's an offensive concept. The
9 subcommittee nonetheless recognizes that's a fact of
10 life, but we suggest that a footnote be added to Section
11 8.9.3 to clarify that, in fact, the term dose continues
12 to be used by many medical practitioners and others to
13 refer to the activity of unsealed byproduct material,
14 the activity or administered activity of a
15 radiopharmaceutical, for example. Next, there is
16 material included in the updated NUREG on rubidium-82
17 generators. The NRC had determined that licensees,
18 because of the special properties of rubidium-82 in the
19 generator, really find it difficult or impossible, in
20 practice, to meet current NRC requirements in
21 NRC-issued EGM-13-003 that provides criteria that the
22 NRC can use for enforcement discretion, and licensees
23 were notified of this in RIS-2013-012.

24 Section 8.9.3 in the updated NUREG
25 includes these documents as additional guidance for

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1 equipment used in measuring dosages or activities from
2 rubidium-82 generators; whereas, the CardioGen-82
3 Highlights of Prescribing Information does not. Our
4 next recommendation is to remove that document, that
5 is CardioGen-82 Highlights of Prescribing Information,
6 from the reference list in Section 8.9.3 because it
7 doesn't address these measurement issues.

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

22 The next item, 8.5.1.5, deals with
23 consortia. Revision 2, Appendix AA was removed in the
24 draft, and references were made to other NUREGs. The
25 subcommittee recommends that the -- well, commends, in

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1 general, the NRC on their effort to minimize
2 duplication of guidance and just overall regulatory
3 literature. In particular, by consolidating guidance
4 into this NUREG, possible discrepancies among
5 free-standing documents and this NUREG are more likely
6 to be avoided, so this is a positive step, we feel.

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

22 Having said that, with the removal of
23 Appendix U, the new introduction section to Appendix
24 U could be moved to the body of the NUREG, specifically
25 Section 8.10.18. But again, the subcommittee and the

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

6 So again, Recommendation 9, the ACMUI
7 recommends to the NRC that it not include guidance on
8 patient release as an Appendix U, but instead, refers
9 to Reg Guide 8.39, and that further, the NRC will not
10 make any statement or implication to the effect that
11 0.5 rem or 5 millisievert dose limit refers to anything
12 other than a per release or per event limit. Appendix
13 L of the draft NUREG deals with medical audits. It's
14 noted that an NCRP report, Report No. 173, published
15 in 2012, would be a valuable reference on
16 self-assessment of radiation safety programs. The
17 subcommittee recommends including this reference in
18 Appendix L. Again, Recommendation 10 reiterates that
19 recommendation.

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

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1 terrific job.

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

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

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

19 CHAIRMAN THOMADSEN: Dr. Howe.

20 MEMBER ZANZONICO: That's my
21 understanding.

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

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

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

11 CHAIRMAN THOMADSEN: Thank you. I'd say
12 it's thank you for that clarification, but it's thank
13 you for the reambiguation.

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

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

25 CHAIRMAN THOMADSEN: Thank you again.

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

9 CHAIRMAN THOMADSEN: Thank you. Mr.
10 Fuller.

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

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

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

3 MS. COCKERHAM: Hello. Okay, so I tried
4 to make this image a little bit bigger, and you can't
5 read it in your handouts at all, so I apologize. Just
6 to sort of describe what we're doing, we have Volume
7 9, one guidance document. When the Part 35 rulemaking
8 started, we have Commission direction for all
9 rulemakings that guidance accompany the rule, which
10 makes sense. When you put out a new rule, the new
11 guidance goes with it. Donna-Beth is working on that
12 guidance document, along with others on the medical
13 team. You've seen that rulemaking guidance and had
14 opportunities to comment on it. There's been a public
15 comment period. It's just gone in parallel with the
16 rule. Completely separately from that, anything that
17 was sent to the NRC since the last time the guidance
18 was opened, which was 2005, any comments we've received
19 that are not related to the rulemaking have been
20 incorporated into this document.

21 We have two parallel timelines. The top
22 one is mine. It says -- in green, right now, it's
23 the -- this is hard to read -- the steering committee
24 has looked at it. We had an initial legal review, which
25 was just a fatal flaw review. Then ACMUI has done their

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1 review now. Our next step is that the working group
2 will get back together and look at your recommendations
3 and comments. We will incorporate changes into the
4 guidance, as needed, and then we will issue the entire
5 guidance document for public comment.

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

21 So when management sees the final
22 document, it will include everything that's gone
23 through the public and ACMUI with rulemaking, and
24 everything that's gone through the public and ACMUI
25 from non-rulemaking. So it will be one document, with

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1 one set of changes, in the end. Any questions? Does
2 that help at all?

3 CHAIRMAN THOMADSEN: Dr. Zanzonico.

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

14 MS. COCKERHAM: There's the bigger driver
15 for all of this. There was the GAO sting, what year,
16 2005, '06 -- '06 or '07, many years ago. As a part of
17 that, lessons learned, we had an action item to update
18 all of our guidance. So we are updating Volumes 1
19 through 21. This is part of a bigger project to update
20 everything, and it just so happens that it coincided
21 with the rulemaking. So to meet the timeline for that
22 overall bigger project, we had to get started on these
23 changes.

24 It would've taken two years. The
25 rulemaking will be done in 2016, and we wouldn't have

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1 a final Volume 9 until 2018, so we did it for the sake
2 of time. We looked at different options of do one
3 first, do the other first, and we said, "Okay, let's
4 divide it and conquer two pieces, and then feed it
5 together." So it's complicated, but it saves years.

6 CHAIRMAN THOMADSEN: Thank you. Mr.
7 Costello.

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

12 MS. COCKERHAM: I don't think so.

13 MEMBER COSTELLO: Okay.

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

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

21 MS. COCKERHAM: No.

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

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1 around what happens with the rulemaking.

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

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

17 DR. HOWE: We have redline/strikeout on
18 ours, too, so if the text is not changing around it,
19 our text will just fit right in. For the most part,
20 the text is not changing around ours.

21 MR. FULLER: Excuse me --

22 CHAIRMAN THOMADSEN: Mr. Fuller.

23 MR. FULLER: Yes, the only other thing I
24 would say, just as another way of saying it, is that
25 when we published the guidance for public comment for

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1 the rule, anything that had to do with licensing, any
2 changes to the rules that would impact or affect
3 licensing, that guidance was published as simply pages
4 cut out of this NUREG-1556, Volume 9 in
5 redline/strikeout. So folks who are accustomed to
6 using this document for their guidance on how to apply
7 or how to amend a license and so forth, it's exactly
8 what they're used to seeing with the changes. That's
9 what the ACMUI received, also, to review. We think
10 this was well thought out, such that folks who are used
11 to using these documents in their work would see the
12 actual changes in a redline/strikeout form, like
13 Donna-Beth said. What's nice about that is that we
14 were able to take out of 1556, Volume 9, only those pages
15 and those sections that were being affected by the
16 changes in the rule.

17 So everybody had an opportunity to comment
18 on that -- the ACMUI, the Agreement States, and then
19 the public. We received those comments. We
20 incorporated all those changes as a result. So when
21 we publish the final rule, which hopefully will be in
22 spring of 2016 -- that's sort of the published
23 schedule -- then our guidance will be ready to go.

24 That's why for Ashley's project, on the
25 overall revision to 1556, Volume 9, we have

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

8 CHAIRMAN THOMADSEN: Thank you. Mr.
9 Costello.

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

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

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

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

24 MS. COCKERHAM: The one I sent to you was
25 not. What Mike was talking about was the rulemaking.

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1 For rulemaking, they pulled out pages that were
2 changed, showed what the changes were, and just had
3 miscellaneous pages. That's what their document was.
4 For mine, because it was an entire reorg, totally
5 renumbered, the entire document would have been
6 redlined, so that wouldn't have been helpful to you.
7 So what I provided was the comment list to direct you,
8 "Here's the comment. Here's the section you need to
9 go look in to see what the change was."

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

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

25 The entire document would be crossed

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

11 CHAIRMAN THOMADSEN: Thank you. Any
12 other comments?

13 (No audible response.)

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

18 MS. HOLIDAY: Yes.

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

22 MS. HOLIDAY: Sure.

23 CHAIRMAN THOMADSEN: Okay, we're going to
24 move up Item 18, which is a rulemaking update regarding
25 10 CFR, Part 35. Thank you for coming in and talking

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1 with us.

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

14 After the 120-day comment period that
15 closed last November, staff have been analyzing the
16 several hundred comments that we received and drafting
17 the final rule text. The comments that were received
18 were from a broad spectrum of stakeholders. They were
19 the professional societies, the Organization of
20 Agreement States, Conference on Radiation Control
21 program directors, the individual States, medical
22 professionals, and individual members of the public.

23 The comments focused on several key areas,
24 such as listing an associate radiation safety officer
25 on a license, medical event definitions for permanent

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1 implant brachytherapy, the Agreement State
2 compatibility for medical event definition, training
3 related to qualification for use of alpha and beta
4 emitters, the reporting of the failed generators, and
5 the Act's test term requirements. Staff provided the
6 draft rule text to ACMUI just this week. That was
7 October 6th or 7th -- or October 7th. Then on January
8 6th, the ACMUI will hold a public teleconference to
9 discuss their review and comments on the draft final
10 rule. This is a change from the date that was
11 previously published of December 18th. There will be
12 a topic on implementation of the final rule during that
13 meeting to cover some of our requirements. This
14 meeting will be noticed in the *Federal Register* and will
15 also be on NRC's public meeting page. If you have any
16 questions about this meeting or need any further
17 information on it, contact Sophie over here.

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

25 CHAIRMAN THOMADSEN: Thank you very much.

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1 Comments or questions from the committee?

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

4 DR. PICCONE: Thank you, Sheena.

5 CHAIRMAN THOMADSEN: Thank you.

6 MS. HOLIDAY: Dr. Thomadsen?

7 ACMUI CHAIRMAN THOMADSEN: Yes.

8 MS. HOLIDAY: If I could just make a
9 comment. Since we do have stakeholders in the room and
10 persons listening in on the webinar and on the bridge
11 line, when we have that public teleconference in
12 January, this is to discuss the Committee's comments
13 on the draft final rule. This is not an opportunity
14 for members of the public to provide further comments
15 on the draft final rule. If you have comments that you
16 would like to submit, as with all ACMUI meetings,
17 comments are due three days prior to the meeting, and
18 they have to pertain to the Committee's comments on the
19 draft final rule. Thank you.

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

24 DR. PICCONE: The Chairman is not here
25 yet.

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

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

11 MS. HOLIDAY: Okay, sorry, this is the
12 best I could get the Word document to zoom. As all of
13 you are aware, we have another member rotating off of
14 the Committee in March of next year, so we're limited
15 to just March for a spring meeting. Otherwise, Mr.
16 Mattmuller would not be able to attend his last meeting.

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

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

3 MS. HOLIDAY: Oh, yes?

4 CHAIRMAN THOMADSEN: That's right.

5 (Laughter.)

6 MS. HOLIDAY: Okay, so far I'm not seeing
7 any objections. I'll wait just a few more minutes. So
8 I see no disagreement, so I will have our first choice
9 down for the spring meeting as March 17th and 18th. Of
10 course, we always pick up a backup date. As I just
11 stated, a couple members had conflicts for all of these
12 dates that are a yellow highlight, but I guess just like
13 with the last meeting, when we were planning for this
14 one, you just pick the lesser of the evils. I guess
15 we'll start with March 1st and 2nd. That is a Tuesday
16 and a Wednesday. It's a little different than our
17 normal Monday/Tuesday or Thursday/Friday, but does
18 anybody have a conflict with March 1 and 2? You do?
19 Okay. Was that a conflict for anyone else? Yes?
20 Okay. What if I had the meeting March 2nd and 3rd, a
21 Wednesday/Thursday? Would that still be a conflict,
22 Dr. Metter?

23 Does the 2nd and 3rd present a conflict for
24 anyone else? All right. What if the meeting was March
25 3rd and 4th, a Thursday/Friday? Is that a conflict for

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

9 VICE CHAIRMAN ALDERSON: I would choose
10 the 24th and 25th.

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

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

20 MS. HOLIDAY: Once we have confirmed a
21 date for the ACMUI meeting, I then inform the Office
22 of the Secretary of the date of the meeting, and they
23 will then check with the Commissioners -- because they
24 have to do agenda planning to see if this is a date [that
25 works for them]. Just like this year, if that

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1 date -- none of these dates work for them, then we'll
2 bring the Committee in for a separate commission
3 meeting.

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

7 MS. HOLIDAY: Sure, I can do that.

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

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

17 At this time, we will review all the
18 recommendations and actions that occurred yesterday,
19 starting with Item 12 in red font. The ACMUI
20 recommended to make the following change to the patient
21 intervention subcommittee recommendation, Issue No. 2.
22 This is where the Committee voted to remove that phrase
23 "and/or imaging a certainty." This was approved by the
24 Committee. Are there any comments on this? Seeing
25 none, we move to Item 13. This is where the Committee

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1 endorsed the patient intervention subcommittee report
2 with the modification that I just mentioned. Are there
3 any comments on this? Seeing none, we will move to Item
4 14.

5 This is where Dr. Thomadsen requested that
6 staff provide an update at the spring 2016 ACMUI meeting
7 on staff's response or action to the patient
8 intervention subcommittee report. Are there any
9 questions on that? Okay, Item 15 was a follow up to
10 that, where Mr. Costello put forth his recommendation,
11 which the ACMUI endorsed, that staff issue a generic
12 communication in the form of either an information
13 notice or a regulatory issue summary to licensees to
14 inform them of the interpretation of patient
15 intervention, as was stated during the time that
16 presentation was given.

17 This, of course, is something that staff
18 will have to work on and discuss with the Office of
19 General Counsel before we can move forward. Are there
20 any questions on Item 15? Seeing none, we will move
21 to Item 16. Item 16 has to do with when Dr. Thomadsen
22 added a new charge to the training and experience for
23 alpha/beta emitter subcommittee. That charge was to
24 establish a recommendation for the total number of
25 hours for training and experience for authorized users

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1 of alpha and beta emitters that is necessary for safety
2 and effectiveness. The subcommittee will give their
3 presentation in the spring meeting, as well. Are there
4 any questions on that? Yes, Dr. Palestro?

5 MEMBER PALESTRO: I'm not sure about
6 effectiveness. I don't really think it's -- unless we
7 get it clarified. Because we're not charged with
8 determining the effectiveness of these agents.

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

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

14 CHAIRMAN THOMADSEN: Yes.

15 MS. HOLIDAY: All right, thank you.

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

18 MS. HOLIDAY: Any other comments on Item
19 16? All right, Item 17, Dr. Ennis recommended that the
20 individual who implants the source for radioactive seed
21 localization be the authorized user only, and not an
22 individual under the supervision of an authorized user.
23 Please note that this motion did not pass. There were
24 eight votes that were not in favor, and of course, we
25 need a majority vote, but this has to be captured on

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1 the record. Are there any questions for Item 17?
2 Seeing none, we'll move to Item 18.

3 Item 18, the ACMUI recommended that the
4 individual who implants the source for radioactive seed
5 localization procedures can do so under the supervision
6 of an authorized user. Are there any comments on Item
7 18? Seeing none, Item 19, the ACMUI unanimously
8 endorsed the radioactive seed localization
9 subcommittee report. Are there any questions for Item
10 19? Thank you. Seeing none, the last item, Item 20,
11 is where the ACMUI endorsed the yttrium-90 microsphere
12 subcommittee report. Are there any comments on Item
13 20? Seeing none, I thank you.

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

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

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1 we had here sufficient?

2 CHAIRMAN THOMADSEN: The Committee could
3 make a motion on that. I would recommend waiting on
4 that because the initiative by the AAPM is going to be
5 inviting the staff from NMED to participate in trying
6 to sculpt what improved descriptions should be. I
7 think that will be underway.

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

10 CHAIRMAN THOMADSEN: Very fine.

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

14 CHAIRMAN THOMADSEN: What does that mean?

15 MEMBER ZANZONICO: Meaning already ---
16 Part 35.

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

22 NRC CHAIRMAN BURNS: Thanks, good to see
23 you again. Good to see Frank, who I used to work with
24 a lot in the NRC. This is probably the most important
25 thing you are going to do today at your meeting, that

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1 is acknowledge a service of Dr. Thomadsen over these
2 last number of years here on the Advisory Committee on
3 Medical Uses of Isotopes.

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

11 Under his chairmanship, the staff has
12 benefited from the Committee's expertise in a number
13 of issues, note a few, the revisions to 10 CFR, Part
14 35 on medical uses of byproduct material, revisions to
15 abnormal occurrence criteria which are now under
16 discussion, patient release after iodine-131 therapy,
17 and the medical event reporting requirements. He's
18 come before the Commission, itself, on a number of
19 occasions, to brief the Commission on these issues. I
20 can remember him being there when I was General Counsel,
21 and then when I came back, he's a commissioner, and now
22 a Chair. I think that's always appreciated to have
23 that input from the Committee in the public meetings
24 that the Commission holds on the issues related to
25 medical uses of isotopes.

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1 I think the Committee -- my sense is
2 certainly the Committee and the staff have continued
3 to develop a strong collaborative relationship under
4 Dr. Thomadsen's leadership and presence on the
5 committee. I think this helps us all, and certainly
6 validates the rationale that the commission had for
7 establishing the Committee when it did many years ago.
8 I know his commitment to service goes beyond this
9 Committee and includes membership or service in other
10 groups, including American Association of Businesses,
11 American Brachytherapy Society, American Board of
12 Radiology, and the International Commission on
13 Radiation Units and Measurements, among others.

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

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

3 (Simultaneous speaking.)

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

7 (Applause.)

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

12 CHAIRMAN THOMADSEN: That's great.
13 Thank you.

14 NRC CHAIRMAN BURNS: So there's that.
15 (Applause.)

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

19 (Laughter.)

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

22 NRC CHAIRMAN BURNS: I don't know.

23 (Laughter.)

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

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1 ACMUI CHAIRMAN THOMADSEN: Thank you, and
2 thank you.

3 NRC CHAIRMAN BURNS: You're welcome.

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

7 (Applause.)

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

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

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

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

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

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1 I'm not going to be talking about that.
2 I'm talking about the second one. The second one, we
3 had a COM paper that came out of Commissioners Magwood's
4 and Macfarlane's office that asked us to look at the
5 issue of whether the assumptions made in patient
6 release were realistic or not. So we got a staff
7 requirements memorandum in April of 2014, and they
8 asked us to do a number of things.

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

25 We published two Federal Register notices

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1 to get comments on the burden. We just got our OMB
2 clearance last week, and the clearance will last until
3 October of 2018. I want to point out that normally,
4 when a federal agency goes out and asks for information,
5 they're really collecting data. They do a survey.
6 You're given a couple of choices to choose, and they
7 come back and do a statistical analysis, and they
8 collect data to support a certain position. That's not
9 what we're doing.

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

24 I've got my Federal Register notice that
25 will actually be the vehicle that we're asking the

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1 public for their input. That is currently in the
2 concurrence process, should be finalized in the near
3 future. We get the Federal Register notice, nobody
4 reads the Federal Register notice. We know that. So
5 we're going to be actually going out to the professional
6 societies, the patient advocacy groups, and hoping that
7 the information gets passed on through different means
8 at each professional society and at the advocacy group
9 down to individual physicians and patients.

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

22 If you're a physician and you've got good
23 practices and you've got documentation, then send us
24 your good practices. We're not asking anybody to do
25 anything new. Our focus is going to be on getting

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1 information that patients believe will help them
2 understand their I-131 treatment. There's basically
3 four different objectives here. One is pre-treatment.
4 We've gotten a lot of anecdotal data that patients
5 don't -- it's confusing and inconsistent as to what they
6 need to know when they find out they have a disease that
7 requires I-131.

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

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

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

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

21 Then the Commission also tasked us with if
22 there is an organization of any kind out there that has
23 a brochure or pamphlet that answers many of these
24 things, then we want to know about it and see if it is
25 acceptable to essentially put out on a nationwide basis

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1 to help provide clarity. Those are our major
2 objectives, and that's what my Federal Register is
3 going to be focusing on. This is going to be the
4 website information. It's the I-131 treatment
5 process. We identified what we think are a number of
6 topics that could be addressed -- we don't have should's
7 and shall's; it's could be -- in giving this basic
8 information.

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

21 We may develop some of the radiation safety
22 information, but we also may find that licensees have
23 already developed websites that have really good basic
24 radiation safety information -- or radiation
25 information for I-131, so we may put that in something,

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1 too. We don't want to re-invent any wheels, square or
2 round. I've already talked about the topics, and then
3 we will be providing links to a website. That's our
4 expectation. Here are some of the topics that we
5 thought were just fundamental.

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

21 We think that these are maybe some of the
22 topics that will be part of that discussion, so we say
23 possibly would include, not a "shall or a should,"
24 because none of this is a new requirement or is expected
25 to be a new requirement. So expect the dialogue. The

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1 Commission asked us specifically if there is a
2 voluntary patient/licensee acknowledgment form for
3 documenting the dialogue as part of the physician's
4 best practices. We'll have an item on there.

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

19 Do you work and have to work? Do you serve
20 on the salad bar line of Golden Corral? Whatever it
21 is about social interactions, that's the kind of thing
22 that we think ought to be discussed -- the working
23 environments and tasks and living arrangements. Do
24 you live alone? Do you live with a large family in a
25 small area? And the questions we think would lead to

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1 discussions of changing in either living arrangements
2 or in social interactions for a period of time. We also
3 thought maybe there's financial considerations, but
4 that is one of our topics for dialogue.

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

18 We're expecting qualitative information.
19 I'm expecting I'm going to have, maybe, as many people
20 saying A is great as people saying A is horrible. We
21 will deal with that when we get it, but we're not doing
22 a statistical analysis. Because we're asking for
23 information, we're hoping that people will give their
24 own individual experience information. So we're not
25 looking for form letters. Many times, we go out and

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1 request comments, we get form letters. We're not
2 looking for form letters. More things about the
3 dialogue.

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

19 What do the patients really think about
20 what they're receiving for information? That's one of
21 our most important components of this information
22 gathering. The next one is essentially on guidelines
23 for providing information to patients when they're
24 released. The commission wants us to get best
25 practices, get information from the patients, so that

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1 we can go back and see if we need to beef up our guidance
2 in any direction and make it better. The Commission
3 is looking for clear and concise information.

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

14 (Simultaneous speaking.)

15 DR. HOWE: -- from our project, which is
16 more qualitative, and the other project that the Office
17 of Research is working on, which is the more
18 quantitative health physics of where do people go and
19 what kind of doses do they expose members of the public
20 and members of the family to?

21 We came up with a list of standardized
22 patient guidance objectives. This is, again, a
23 "would" question. Would you have these questions and
24 topics in your guidance? If you do -- the other thing
25 is if you think you've got really good guidance, send

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1 it to us. We don't require you to send our guidance
2 for licensing, so this is not information that we
3 already have. If you think you have good procedures,
4 send it to us. If you want to send it anonymously,
5 that's fine.

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

19 We really want to know when you provide the
20 instructions, and are the instructions provided in a
21 manner that's easy to understand and follow, and what
22 would make the instructions better? Those are the kind
23 of questions we're asking of people. Any guidance
24 documents that you have, as professional members, or
25 things that you've given to patients, we'd get them from

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1 patients. What tools? Do you have both oral and
2 written information presented? Is it in the native
3 language for both individuals, and do you have access
4 to interpreting facilities?

5 We understand there is a federal law now
6 that you have to have, but that doesn't necessarily mean
7 everybody meets things, and it's certainly not
8 something that we inspect against. We would never
9 inspect against that. How are they personalized to fit
10 the individual? How do you explain limiting exposures
11 to others, living arrangements? How long does special
12 care have to be exercised? Do you tell the patients
13 how to reduce exposure to others, inside and outside
14 the home? Transportation's an issue. Managing
15 biological waste, we're getting at the question of the
16 landfills triggering and sending the trash back. Do
17 you provide guidance and information on that? Do you
18 tell where to go for emergency care if you've got
19 questions?

20 The final objective, which is the brochure
21 for nationwide distribution, is if you know of a
22 brochure that's in existence now and you think it
23 answers a fair number of -- talks about a lot of these
24 topics and answers the questions, then let us know. We
25 don't want to develop a new brochure. We'd like to be

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1 able to see if there is something out there that can
2 be distributed on a nationwide basis.

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

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

14 VICE CHAIRMAN ALDERSON: Yes, I
15 compliment you on this effort. I'd like to just know,
16 for the first question -- I have two, but first
17 question, how often, in the past, has the NRC done this
18 kind of data gathering within the medical context to
19 the medical community?

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

22 VICE CHAIRMAN ALDERSON: Ever before?

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

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1 but I don't think we've done this kind of thing.

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

6 CHAIRMAN ALDERSON: I think it's a good
7 effort. The NRC is actually communicating to the
8 public. It's going to come back, and then the ACMUI
9 and others are going to be able to comment and guide.
10 I think it's a great process. One of the things that
11 I think is mysterious about -- there is kind of a
12 mysterious side to the NRC. Even though some of us on
13 the Committee have that feeling, certainly the public
14 does, so the idea that you're out there communicating,
15 I think, reduces that problem and is a good thing.
16 Obviously, the outcome, we have to do something with
17 it once it comes back, but I compliment you on going
18 out like this.

19 DR. HOWE: Thank you.

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

22 MEMBER ZANZONICO: I had concerns about
23 this, which I stated before, and I'll reiterate. I'm
24 very cautious about an NRC or any government-sponsored
25 or managed website. Again, despite the best efforts,

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1 there's an element of this with the regulator
2 interposing themselves between the patient and their
3 physician. I know that's not the intent, but that's
4 an inevitable consequence.

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

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

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

10 MEMBER ZANZONICO: I think that's
11 certainly a necessary, but perhaps not sufficient
12 condition. I just have worries about a disembodied
13 website with the NRC or any governmental logo and its
14 impact on the patient/physician relationship. But
15 again, this is -- I understand you're making your
16 good-faith effort to avoid those kinds of
17 complications. Two more specific issues. One is
18 you've mentioned a number of stakeholders that you're
19 reaching out to. I think two very important
20 stakeholders that should be included would be the
21 landfill operators.

22 I think this issue of waste disposal and
23 very low-level contamination of household waste and the
24 problems it precipitates for patients is a big one. I
25 think the landfill operators need to be as educated as

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1 anyone, perhaps more so than anyone, about what
2 positive results by landfill detectors mean and don't
3 mean. I think that's an important group of
4 stakeholders to educate and to reach out to as any of
5 them. Similar vein, I think hotel operators need to
6 understand what having a post-therapy patient in their
7 facility means and does not mean. I think those are
8 two important groups of stakeholders that should be
9 included explicitly in any such effort.

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

12 MEMBER WEIL: The concerns that Dr.
13 Zanzonico mentions about the website, I think, are
14 certainly going to be real issues, but not
15 insurmountable ones. One of my concerns about it is
16 that it precludes reaching several very vulnerable
17 populations, those with limited English proficiency,
18 those with low literacy, and those without access to
19 the Internet who really won't have access to this
20 NRC-sponsored portal for information from other
21 entities.

22 One of the ways you might be able to make
23 it more useful for some of those folks is to
24 specifically solicit information that has been
25 translated into other languages from stakeholders.

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1 Because that stuff does exist in many places, and there
2 might be subsets of the portal that could point people
3 toward information in Spanish, or in various Chinese
4 languages and etc. I think you will have to find a way,
5 on the website, to address the fact that there will be
6 discrepant information.

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

12 (Simultaneous speaking.)

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

15 CHAIRMAN THOMADSEN: Thanks very much.
16 Dr. Palestro.

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

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1 create confusion, doubt in the mind of the patients and
2 the licensees and physicians.

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

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

12 MEMBER ENNIS: Two. One is actually for
13 Committee members. Does the Society of Nuclear
14 Medicine have already such a recommendation on the
15 website?

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

24 We're kind of looking for that kind of
25 implementation as we're collecting the information

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1 here. We are well aware that there are many websites
2 with information. There are many professional
3 societies with documents, and we're hoping that -- we
4 know we're going to get those documents in, and we're
5 hoping we'll get other folks that implement them and
6 tell us -- show us what they do on the implementation.

7 MEMBER ENNIS: My second point was to
8 really echo Ms. Weil's comments. To the degree that
9 there are problems with the patient community taking
10 care properly of themselves and their families and
11 their garbage and all the issues, there's no doubt that
12 the higher the illiteracy rate, the lower the medical
13 knowledge, language barriers, those are the
14 populations that are going to benefit, so targeting
15 whatever you come up with to those populations -- and
16 it's not just about translating into other languages,
17 but that's part of it -- but making it understandable
18 for people of less education.

19 If it's designed to fit the needs of the
20 committee and their families and the staff and their
21 families, it won't have much of an impact because we
22 don't really need that. We're sophisticated. We
23 talk. We ask questions. We go online already.
24 There's a skill to that and a knowledge base that I don't
25 have, but I would suggest tapping into those kind of

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1 resources to try and find ways to reach those
2 populations.

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

11 CHAIRMAN THOMADSEN: Thank you. Mr.
12 Costello.

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

21 They were being threatened with thousands
22 of dollars of fines if this should happen again. She
23 said she's dealing with a daughter who's got cancer.
24 Now she has to deal with this, too. She complained
25 about the information that was given to her by her

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1 provider. I don't have a solution for that. I think
2 some of it is just an educational thing for the people
3 who run the waste sites.

4 We try and explain to them that there's
5 really no hazard in burying the stuff, but when you hear
6 from a patient who is already dealing with a difficult
7 situation with a family member having cancer, and then
8 being threatened with a cutoff of the trash pickup, it's
9 a difficult thing to deal with. As far as a government
10 website putting out medical advice or guidance like
11 this, just a thought, I can go on the NIH website and
12 get information on the diagnosis and treatment of
13 Hodgkin's lymphoma or prostate cancer or all sorts of
14 things, which may be consistent with what my
15 physician's telling me or may not be consistent with
16 what my physician's telling me. Sometimes, I'm sure
17 much to my physician's -- I may say, "I found this on
18 this website. What do you think?" She'll growl at me,
19 and then deal with the question.

20 But I don't think it's unusual for a
21 government website -- and I think of NIH -- to provide
22 information on medical issues. So this is my two
23 comments. One is I don't know if there's a solution
24 for the waste question because I don't want patients
25 keeping the waste in their house. I don't think that's

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1 allowable, and I don't think that's a good thing to do.
2 On the other hand, I don't like patients being
3 threatened with large fines and cutoff of their trash
4 pickup if they it there. Good luck with coming up with
5 guidance to address that issue. Thank you.

6 CHAIRMAN THOMADSEN: Thank you. Dr.
7 Metter.

8 DR. METTER: I just have to dovetail on
9 that, what Dr. Zanzonico had said. Another
10 stakeholder, perhaps, would also be the transportation
11 industry that use radiation detectors because they get
12 stopped and all that. For example, I know people that
13 give notices that they did receive radioactive
14 material, but my institution would not allow that
15 because it -- so if there is one, they'll have to call
16 our department directly. So just maybe more of an
17 educational issue because I think with more and more
18 concern about radioactive issues in the public, I think
19 that might be something you might want to consider.

20 DR. HOWE: We did a RIS a number of years
21 ago because with the security issues we had, alerts
22 triggering when patients went under the New York
23 tunnels to go gamble in Atlantic City. We had
24 professional people driving by the White House and
25 triggering. Some of them are indium ones, which they

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1 can trigger from weeks and months later. A lot of the
2 others are more short-lived isotopes.

3 We don't have a regulation that you have
4 to provide anything to the patient, but we did suggest
5 that you provide something that could have whoever
6 stops them call back to the facility. I recognize
7 you've got to get around the HIPAA rules, so it was a
8 way of facilitating and making it easier for the patient
9 to kind of explain to law enforcement that this
10 was -- they weren't a bomb that's about to go off, and
11 they weren't a serious risk. We dealt with a RIS on
12 that before, and we'll keep that in mind. Oh, I have
13 to explain what a RIS is. A RIS is a document the NRC
14 puts out. It's not a new policy, but it explains a
15 policy. It's called Regulatory Issues Summary. If
16 you look on the medical toolkit, and the medical toolkit
17 is in the public NRC web pages, and you look under
18 medical, then we've got a toolkit over there.

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

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1 the medical community, so you can find those on our
2 website. I think we have a question.

3 CHAIRMAN THOMADSEN: Oh, yes, Zoubir.

4 MR. OUHIB: Zoubir Ouhib, medical
5 physicist. I guess listening to some of the discussion
6 here, perhaps, as you were stating that you're going
7 to be seeking feedback and advice and all that from
8 professional organizations, maybe one way to sort of
9 relieve this concern is to seek endorsement, after a
10 full review, of the final product to make sure that all
11 these professional and medical associations will agree
12 with what's being implemented in there, perhaps. I
13 think that might be one solution. The other comment
14 that I had is will you be looking back to, say, medical
15 events and say maybe we can implement some -- what
16 actually went wrong, whether that was patient
17 information or whatnot -- into that document to sort
18 of correct -- I guess maybe I should've stated the first
19 question is that what is really the goal of such a
20 document? What is the end point? What's the goal?

21 DR. HOWE: The end point is to look at our
22 guidance and to try to provide as clear and concise
23 information as we can to the medical licensees, that
24 they can inform their patients, so that the radiation
25 dose exposure to the public is maintained, as well as

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1 reasonably achievable, while they're still meeting all
2 of their regulatory requirements. We are not changing
3 the regulatory requirements. We are looking at the
4 qualitative issues that are associated with meeting
5 those requirements.

6 CHAIRMAN THOMADSEN: Dr. Dilsizian.

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

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

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1 aspects of this.

2 I think that we're going to have a nice
3 guideline, nice forms, but at the end of the day, it's
4 still the medical practice, where there's going to be
5 variability among patients and physicians. I don't
6 think we're going to have complete solution, but this
7 is a step forward, where the societies, I think, are
8 already doing it, but I just -- I'm afraid that there's
9 more to it than just documentation.

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

15 CHAIRMAN THOMADSEN: Any other comments?

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

23 CHAIRMAN THOMADSEN: Thank you. We
24 appreciate that. Okay, thank you very much Dr. Howe.
25 This brings us to Mr. Mattmuller, who will be filling

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1 in for Dr. Langhorst on the ACMUI comments on the policy
2 statement reporting abnormal occurrences to Congress.
3 Mr. Mattmuller.

4 MEMBER MATTMULLER: Good morning. I'm
5 Steve Mattmuller, and I will attempt to fill in for Dr.
6 Langhorst, as she was, yet again, a chair of another
7 subcommittee for ACMUI. I think we might be remiss if
8 we don't have a subcommittee for her to chair before
9 we leave. She'll be disappointed, I'm sure. I wonder
10 if she's listening. I'm presenting the findings of our
11 subcommittee, looking at abnormal occurrence reports.

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

22 In generalities, this is an AO per the
23 Energy Act of '74, that an AO is an unscheduled incident
24 or event which the Commission determines is significant
25 from the standpoint of public health or safety. But

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1 for the specifics of an AO, the NRC is able to define
2 exactly what the criteria is. Yes, even if there's
3 just one patient or one person affected in this event,
4 it is appropriate, or it may be appropriate, in terms
5 of public health and safety, to include it in an AO
6 report. Within the Energy Act, they've specified that
7 the report has to include the date and place of the
8 occurrence, the nature of probable consequences, the
9 cons, and any action to prevent reoccurrence. For some
10 of you here who are more experienced ACMUI members, you
11 may remember we've been at this for a bit.

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

23 It came out last August, or August of this
24 year, just two months ago. It's available for comments
25 now until the 16th of next month, in November. We also

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1 tabulated the results from past AO reports that went
2 to Congress through the past eight years. You'll
3 notice that the vast majority of all the occurrences
4 are all medically related. In the third column,
5 35.3047, these are reports due to a dose to an
6 embryo/fetus or a nursing child. All of these occurred
7 during the therapy of women with an unsealed source of
8 iodine-131 for thyroid cancer treatment.
9 Unfortunately, these patients turned out to be pregnant
10 during their therapy.

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

23 Again, most of these were deemed to have
24 no negative consequences. Here's the next three
25 years. Again, the pattern continues. The vast

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1 majority, if not all, are medically related and, in
2 fact, for the eight years, 114 total AOs to Congress,
3 only five were not medically related. This is
4 summarized here on this slide. We've got a slight
5 typo. We had 109 AOs out of 114, so this should be 96
6 percent of AOs were medically related. That's, on
7 average, two per year for 35.3047 and 14 a year for
8 35.3045. Part of our charge is to look at what is an
9 appropriate definition of an abnormal occurrence for
10 this report that's submitted to Congress and/or to look
11 at how an AO event can be used to help prevent
12 reoccurrence.

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

22 Part of this effort is also involved in the
23 current rulemaking for 10 CFR 35, with a new definition
24 or new criteria for 35.3045. That, as you might
25 remember, includes separate medical event reporting

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

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

22 To fix this, I think we really only want
23 AOs that have medical consequences. We think that
24 should be included in the AO report to Congress. We
25 think we can get there with the proper criteria for the

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1 AO report. In trying to get an idea on the incidence
2 of these AOs compared to total number of procedures,
3 we looked at some very old data. Unfortunately, trying
4 to get procedure numbers is difficult and expensive,
5 so most of the nuclear medicine diagnostic work is from
6 data that's more than ten years old. But if we look
7 down to nuclear medicine thyroid therapy procedures,
8 which is with iodine-131, and this represents 92
9 percent of the total nuclear medicine therapy
10 procedures, we have just over 16,000, but that's all
11 thyroid therapy procedures.

12 If we adjust this estimated number at the
13 percent of cancer versus hyperthyroid treatments at my
14 facility, which is about 50/50, that brings it down to
15 8,000 a year. Then you further have to reduce it to
16 account for a male/female ratio. At our place, it's
17 about a two-third/one-third ratio. This number really
18 should be about 5,300 female patients who are potential
19 AO report candidates, so to speak.

20 The rate would be the current rate with a
21 historical average of two per year, out of 5,300 a year,
22 is around 0.03 percent. If we move into non-I-131
23 incidents, this slide fortunately has more up-to-date
24 data. It's 2009 data. This has total radiotherapy,
25 non-radiopharmaceutical patients, so there are no

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1 I-131 patients in these numbers. This is all radiation
2 therapy patients, including those who received therapy
3 by linear accelerator which, of course, is not
4 regulated by the NRC. Of this million procedures,
5 radiotherapy from byproduct material which, again,
6 does not include unsealed byproduct material, which is
7 BPM, we have 36 percent, which is the total, I should
8 say.

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

20 The next column is our 2013, our first
21 draft criteria that we put out in the subcommittee.
22 The next column is what, currently, the NRC is
23 proposing, and then finally, the last column is what
24 we're proposing today in our report that we think is
25 our recommendation for appropriate criteria. As I go

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

8 This would be Footnote No. 2, medical
9 patients, and we'd like to add "and human research
10 subjects are excluded from consideration under this
11 criteria. These criteria do" -- and it's a long
12 footnote -- "not apply to events defined in 35.3045 and
13 35.3047 of 10 CFR." Note 2, Criteria III.A, the title,
14 we're fine with that. I'm sorry; I missed a few
15 comments here. In regards to 35.3047, this, as you
16 might remember, is for reported notification of a dose
17 to an embryo/fetus or a nursing child.

18 We think it makes much more sense to keep
19 all the medically related AOs in one section of the
20 report, since they all involve the administration of
21 byproduct material. To date, all of the 35.3047 AOs
22 that have occurred have all been because of iodine-131
23 therapy in pregnant patients. After all, since
24 pregnancy's part of a patient's medical condition, we
25 believe it ought to be in the medical section, which

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

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

20 Another problem with the dose criterion is
21 that you can exclude an event that results in unintended
22 permanent functional damage to an organ or
23 physiological system, but does not exceed the dose
24 criterion. Another potential flaw is that does to
25 other tissues or organs is a known risk or side effect,

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

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

19 To paraphrase Warren Buffett, who's
20 addressing the economy, but I think it applies to us
21 here, that they studied what was measurable, rather
22 than what was meaningful. That is the dose criterion
23 to us is measurable, but it's not necessarily
24 meaningful. Instead of relying on problematic dose
25 criterion, this is our recommended criteria, to find

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1 meaningful AOs. An event, as defined in 10 CFR 35.3045
2 or 35.3047, which results in a dose -- excuse me, that
3 should be which results in an unintended, permanent
4 functional damage to an organ or a physiological
5 system, as determined by an independent physician
6 deemed qualified by the NRC or an Agreement State.

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

15 Pretty much all of the AOs for 35.3047, in
16 all of them except for one, the administration of the
17 I-131 occurred very early in the administration -- or
18 excuse me, very early in the pregnancy.
19 Unfortunately, there is one here, the patient was six
20 months' pregnant. She had said she was not pregnant.
21 Unfortunately, the licensee did not perform a pregnancy
22 test. The I-131 was given, and unfortunately, the
23 child was born without a thyroid. This would continue
24 to be an abnormal occurrence based on our proposed
25 criteria. For this next event, the patient had a

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1 negative pregnancy test, and the I-131 was given. They
2 repeated the pregnancy test about 12 days later and it
3 was positive. But then fortunately, again, because
4 the administration occurred so early in the pregnancy,
5 they determined that it should not cause any
6 developmental effects.

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

16 So Criteria III.A.4, which is a more
17 generic or general criteria, with the implications for
18 similar facilities that could raise a major safety
19 concern. The remaining 35.3047 events, the general
20 lessons from those -- these all are very, very similar
21 to where pregnancy was not determined until later, but
22 in all of these, the administration occurred very early
23 in the pregnancy. The emphasis is always use the most
24 sensitive pregnancy test and to improve patient
25 counseling. But in all of them, they were evaluated

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1 to have no probable negative consequences, so we
2 believe these should not be -- events like this should
3 not continue to be an AO event. The subcommittee, we
4 also read several of the comments by the commissioners
5 and by the staff.

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

17 Through this policy or directive, the
18 review can occur at several different levels, first
19 with staff who performs the initial review, and then
20 that review can escalate to an incident, with an
21 incident investigation team, or even further with an
22 augmented investigational team. But as we heard
23 earlier today, those two steps rarely occur. The first
24 level of review is more than adequate. Another
25 important consideration of this policy is that it

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1 already includes when and how to consult with an
2 independent physician. We feel review by an
3 independent physician is critical to determining
4 whether or not an event should be designated as an AO
5 by our proposed criteria.

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

16 This is the committee membership. Dr.
17 Langhorst is the chair, and as she would call us, her
18 minions were myself, Dr. Palestro, Dr. Thomadsen, and
19 Laura Weil. Open the floor to questions for all.
20 Where'd Miss Sophie go? We do have a slight correction
21 to make to the report. Do you want to discuss that now
22 or later?

23 (Pause.)

24 MS. HOLIDAY: We can do it now.

25 MEMBER MATTMULLER: This is in regards to

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1 the second AO event that I discussed, where there was
2 some confusion as originally, we thought -- yes.
3 Originally, we thought the patient had a negative test,
4 and then we thought they had a positive test, and then
5 they had the administration.

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

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

21 MEMBER COSTELLO: The price on
22 independent medical review and the cost associated with
23 that, most of these events occur in Agreement States.
24 As I mentioned a number of times earlier, the States
25 do not have the same infrastructure as the NRC has. I

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1 know states have, in some cases, gotten that run by a
2 consultant. You know, I think last year or early this
3 year, I know we, in Pennsylvania, have no arrangements
4 for an independent medical consultant.

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

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

15 MR. BOLLOCK: I can address the -- some of
16 this. As Frank knows, we've been discussing with OAS,
17 the OAS, NRC, we've been working with OAS, discussing
18 this back and forth. We do and have, on a case-by-case
19 basis, given support to the States in providing one of
20 our medical consultants.

21 There are questions about cost and what it
22 takes. There are certain steps that have to be taken
23 by the State. They have to show that they don't have
24 the resources. They can't do that. In working with
25 OAS, there are some things that the other States can

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1 do to provide guidance to help states. Different
2 states have different, basically, I guess, resources
3 outside their own -- resources available, whether they
4 have a physician on their staff, or in their
5 regulations, the ability to have the licensee pay for
6 that independent, selected by the State or by the
7 regulator.

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

13 MEMBER COSTELLO: Minimal.

14 MR. BOLLOCK: Oh, yes, they're minimal.
15 It's essentially what we pay you all for your -- as
16 advisory committee. They're special government
17 employees. We pay them at a rate of about 15, step 10.
18 But to provide that and get a reimbursement is what is
19 stated now, actually, the State would have to reimburse
20 us at a rate of -- to the, whatever our hourly rate is
21 for services, which is about \$275.00 an hour, but
22 something in that range.

23 So it is actually less expensive for us to
24 provide that. We've already determined it is less
25 expensive for us to provide that service to the States

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1 when needed, if they showed a hardship. They have to
2 take -- do their due diligence and go through and show
3 they don't have a medical physician on staff, they don't
4 have the ability to get that reimbursement from the
5 licensee.

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

15 CHAIRMAN THOMADSEN: That's very good to
16 hear. Thank you for that clarification and that
17 information. Other comments? Dr. Zanzonico.

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

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1 of these sorts of things is miniscule, much, much less
2 than a tenth of a percent.

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

15 There's extensive data in the literature,
16 dating back from the seminal studies of Stewart, that
17 especially in early-term pregnancies, when this is most
18 likely to occur, there's a significant increase in the
19 risk of childhood cancer from fetal radiation exposure,
20 independent of thyroid irradiation or not. That
21 strikes me as -- if we're going to use these sorts of
22 criteria, that's a pretty significant impact. We're
23 talking about an increase of the order of 50 percent
24 incidence of childhood cancer per rad, per Centigray,
25 to a fetus. It's even higher in early pregnancy. That

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1 conclusion, to me, doesn't jive. There's a lot of
2 controversy. There's more recent data which calls
3 those findings into question, but I think the
4 conventional thinking is that there's a very large
5 increase in incidents of childhood cancer, as I said,
6 per rad of fetal dose.

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

17 The reason a female is getting a diagnostic
18 procedure or radiation procedure is that they have some
19 compelling medical issue that requires that. There's
20 a delicate line to walk. You don't want to imply that
21 it's inappropriate to do these sorts of procedures in
22 women or pregnant women. It almost always is, although
23 it should be an informed medical decision to do so. On
24 the other hand, just because the fetal thyroid has not
25 begun functioning, I don't think, is a basis for

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1 excluding it from an AO if those are the criteria that
2 are going to be used, which I don't necessarily agree
3 with either, but for at least internal consistency, I
4 think that's the case.

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

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

11 CHAIRMAN THOMADSEN: Can you turn your
12 microphone on?

13 MEMBER WEIL: I think of these events as
14 being harbingers of potential occurrences across a wide
15 range of either population groups or disease-specific
16 groups. The importance of reporting them is to alert
17 others who treat these populations or these kinds of
18 patients about the potential for these kinds of
19 occurrences occurring in the future. The importance
20 of them being public, and perhaps even being public to
21 the extent that they're brought to the attention of
22 Congress, is important in terms of potentially
23 preventing future occurrences from happening, even if
24 it's only a single occurrence -- a single fetus who may
25 be exposed or any of these examples. I disagree with

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1 the necessity for permanent functional damage to be a
2 requirement for something to be an AO because the next
3 occurrence down the road could happen and incur more
4 harm to the next patient. I think the public exposure
5 of events that are of interest to the medical community
6 and the patient community is not harmful. It is, in
7 fact, useful.

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

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

13 (Simultaneous speaking.)

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

17 CHAIRMAN THOMADSEN: We have presented
18 those comments to the staff. The staff's
19 recommendation was to reassert the dose limit. When
20 I talked with the Commissioners, they found it very
21 interesting. They did not understand our rationale
22 for doing away with the dose limit. I would suggest
23 that in the -- if this document is accepted that there
24 be an introductory paragraph added, which we don't have
25 an introductory paragraph in this report, that just

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1 explains the rationale behind why we are recommending
2 the change from a dose-based evaluation.

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

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

9 MEMBER COSTELLO: Okay, thank you.

10 VICE CHAIRMAN ALDERSON: I'll just ask the
11 question on the other side of this coin, what is the
12 burden created by having the, what is it, 20 some AOs
13 a year that occur? What is the burden from that?
14 What's going to be a -- I'm not saying there isn't one,
15 but I don't understand it. So what's going to be
16 released or relieved by making these changes?

17 CHAIRMAN THOMADSEN: We aren't looking
18 for any relief or reduction. That's not our goal. The
19 goal is to have something that's meaningful. Right
20 now, as Mr. Mattmuller explained, the criteria are
21 based on event criteria from the 1970s, where things
22 were broad, the numbers were wide, and changes in
23 positioning would have very slow effects on the dose
24 to neighboring organs. With modern radiotherapy,
25 where doses in the target volume are shaped by many

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1 fields, you have non-uniform doses through the target
2 volume, but target doses are defined on the periphery,
3 and you may have very sharp penumbra, very small changes
4 in position, a matter of millimeters, can suddenly be
5 putting the full dose into a neighboring organ, but in
6 a very small volume, which has no medical significance,
7 whatsoever.

8 So the use of 10 gray is really no longer
9 appropriate. On the other side of it, you can have a
10 case where you're treating near a very sensitive organ
11 and deliver an unintended dose of 6 gray, which would
12 be under the criteria right now, but yet could have very
13 great effects on the patient. That should be
14 considered an AO, and it's not now. The point is that
15 any dose that you use is going to be inappropriate as
16 a trigger.

17 It just doesn't apply as a measure anymore.
18 We need to have a measure of what would be consistent
19 with the goal of the abnormal policies, as shown on,
20 I think, the next slide there, that they should report
21 something that is significant from the point of public
22 health and safety. This should be evaluated by the
23 physician, as we said. We had discussed in the
24 committee having a criterion that would try to capture
25 events that weren't significant in themselves, but

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1 seemed to be repeated in a given facility, but that did
2 not reach the report, itself. It got eliminated along
3 the way.

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

8 CHAIRMAN THOMADSEN: Correct.

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

13 CHAIRMAN THOMADSEN: Mr. Costello.

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

25 MR. BOLLOCK: Because it is determined by

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1 the Commission in the law, we're giving them what they
2 want. As far as feedback, I don't know that we've ever
3 gotten any.

4 MEMBER COSTELLO: Okay, thank you.

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

12 MEMBER MATTMULLER: Yes, it is.

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

15 (Simultaneous speaking.)

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

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

22 (Simultaneous speaking.)

23 MEMBER ENNIS: -- really not potential
24 events brings me to wonder who was the medical
25 consultant or the independent reviewer that declared

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1 them, and that makes me think is it clear what's the
2 criteria for being an independent reviewer, and does
3 that need to be more clearly addressed in a statement?

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

6 (Simultaneous speaking).

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

11 DR. PICCONE: Oftentimes, it's the
12 physician administering the dose making that call.

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

19 Actually, I don't know if you're all aware,
20 we could request any of you to serve in that capacity.
21 Obviously, we'd request it, and you can deny it. Right
22 now, we have three medical consultants. They have
23 also, as is all of you, they're special government
24 employees. In fact, one of them was a former ACMUI
25 member that may not be done at this time. We basically

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1 just solicit out and request people for whatever needs
2 there are to fill. That's --

3 (Simultaneous speaking.)

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

8 MR. BOLLOCK: Right, because --

9 CHAIRMAN THOMADSEN: Not an independent?

10 MR. BOLLOCK: Not --

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

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

20 CHAIRMAN THOMADSEN: Thank you. Dr.
21 Alderson.

22 VICE CHAIRMAN ALDERSON: So based on what
23 you said a moment ago, Dr. Thomadsen, about the
24 rationale for doing this, I also looked at
25 the -- there's a whole written document in here, I

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1 guess, that Sue created. It goes through in detail
2 what was presented on the slides. In that
3 document -- neither is the rationale presented in that
4 document. At the end of that document, which I
5 expected to be the most complete document, there isn't
6 an action item.

7 So what do you do with this now? What the
8 document does, like the slide -- very complete, very
9 accurate, hard work. I compliment the group on it, but
10 I'd like to see also, in addition to the preamble, the
11 statement at the end that would say something like,
12 "Accordingly, we recommend that the criteria for AOs
13 be reconsidered and potentially revised." That would
14 be an action item. I think that would make this a very
15 meaningful report. But as it stands now, I think it's
16 incomplete.

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

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

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

23 MEMBER WEIL: No, I think it's III.A.4.
24 Is that where other events of interest is -- I don't
25 see it here, and I know that you discussed it. These

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1 are events that do not rise to the definition of
2 permanent functional damage, etc., but have potential
3 implications for patient safety at other institutions
4 because similar events may arise at other institutions.
5 Do you remember this?

6 MEMBER MATTMULLER: I think we did mention
7 it as -- it was the incident where negative pregnancy
8 test, they thought -- they did everything right.
9 Negative pregnancy state, they administered the I-131,
10 and then repeated the pregnancy test ten days later,
11 and unfortunately, she was pregnant. That one we did
12 think would continue to be an AO, but under -- I'll have
13 to look it up -- under the more general -- contrary to
14 what we had just said, that we wanted them all in a
15 medical section, this would be an exception to that,
16 so it would be in the general category.

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

22 CHAIRMAN THOMADSEN: A very good point.
23 We're going to put a pause on this discussion and break
24 for lunch. This is very interesting, and we do need
25 to vote on this. We need to vote on something else that

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1 we left undone this morning. Please get back by 1:00,
2 and we will resume.

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

5 (1:01 p.m.)

6 20. ABNORMAL OCCURRENCE CRITERIA SUBCOMMITTEE REPORT

7 (CONTINUED)

8 CHAIRMAN THOMADSEN: I think we're ready.
9 Ms. Weil?

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

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

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

18 CHAIRMAN THOMADSEN: Yes, [35.30]47.

19 MEMBER WEIL: -- into this abnormal
20 occurrence thing. And what that's doing perhaps
21 inadvertently is creating two standards for the
22 protections of this particular class of individuals.
23 There's the medical use, which is then going to be
24 governed by the abnormal occurrence criteria, but the
25 public -- the fetus, embryo, nursing child member of

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1 the public has a different standard of protection. And
2 I'm not sure that that's a good thing to be doing.
3 Something that one of the Commissioners raised as an
4 issue.

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

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

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

24 MEMBER WEIL: We have different levels of
25 protection then for different kinds of fetus, embryo,

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1 nursing child. And I'm not sure that I'm comfortable
2 with those different levels of protection. And it's
3 just creating again a third level. Different.
4 Perhaps it's a lower level of protection because it has
5 to rise to the abnormal occurrence criteria permanent
6 functional damage.

7 CHAIRMAN THOMADSEN: I'm not sure it's
8 protected in this report, that the embryo/fetus is
9 protected as much as it can be by requiring a pregnancy
10 test before treatment. And whether it's reported or
11 not, that's not protecting it.

12 MEMBER COSTELLO: I have a question about
13 that.

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

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

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

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

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

3 MR. BOLLOCK: Right.

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

6 MR. BOLLOCK: Yes, I'd have to look
7 through the -- what the other -- just for general
8 -- exposure to the general public what levels are then
9 reportable by AOs.

10 MEMBER COSTELLO: Yes.

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

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

18 ACHAIRMAN THOMADSEN: Well, I think one of
19 the differences; and this is probably what you would
20 be seeing here, is by moving it into the medical realm
21 we've said that unless there's actual medical effect
22 on the fetus it would not be an abnormal event. And
23 this was part of what Dr. Zanzonico was saying, too.
24 So the question would be from the numbers that we see
25 it doesn't make very many case differences no matter

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1 what we do. Would you feel more comfortable if we kept
2 the embryo or fetus in the general public category where
3 it is now? The nursing child isn't --

4 MEMBER WEIL: Yes.

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

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

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

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

22 CHAIRMAN THOMADSEN: Yes.

23 MEMBER COSTELLO: There are members of the
24 public and then there are members of the public. Okay?
25 The dose limit for members of the public is 100 millirem

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1 in a year. Okay? However, the dose limit for an
2 embryo or fetus of a declared pregnant woman is 500
3 millirem. That's the way it is. Okay?

4 Now, there are reasons for that. And I
5 don't think they should change. Okay? There's a risk
6 benefit to having the mother working, and I understand
7 that, and I wouldn't suggest changing it, but I just
8 think it's different. You just can't look at them as
9 members of the public. They're unique members of the
10 public. And the same thing for a woman who's receiving
11 medical treatment that the trigger amount for the
12 reporting is -- I think it's 500 millirem, and that's
13 because there's a cost benefit there, that presumably
14 the embryo or fetus benefits when a mother receives
15 medical treatment. Okay? Same as the embryo/fetus
16 benefits when the mother is employed.

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

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

23 MEMBER COSTELLO: Yes.

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

25 MEMBER COSTELLO: Yes. I'll tell you

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1 what, though -- because I think if the mother is
2 receiving medical treatment, the embryo/fetus benefits
3 from that, too, just like the embryo or fetus benefits
4 from the mother being employed. So I think you can't
5 just look at them as members of the public. They're
6 a special classification members of the public.

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

10 MEMBER COSTELLO: Exactly.

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

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

15 CHAIRMAN THOMADSEN: We do, yes. Right.

16
17 MEMBER COSTELLO: And there's a reason,
18 because a member of that family --

19 CHAIRMAN THOMADSEN: Yes.

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

22 CHAIRMAN THOMADSEN: Okay. Mr. Bollock?

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

25 MEMBER COSTELLO: Okay.

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

3 MEMBER COSTELLO: Yes.

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

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

17 MR. BOLLOCK: Or embryo/fetus.

18 MEMBER COSTELLO: Thank you.

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

21 MEMBER COSTELLO: Not regulatory
22 criteria.

23 MR. BOLLOCK: Yes.

24 CHAIRMAN THOMADSEN: And my guess is it
25 actually makes very little difference in these cases

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1 which of those numbers or any other number you use. If
2 the woman is pregnant and receives the iodine, the fetus
3 probably would exceed any of those numbers.

4 Yes, Dr. Howe?

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

18 CHAIRMAN THOMADSEN: So it sounds
19 circular.

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

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1 criteria.

2 CHAIRMAN THOMADSEN: Correct.

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

6 CHAIRMAN THOMADSEN: Yes.

7 DR. HOWE: -- raised the issue.

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

20 MEMBER MATTMULLER: Yes, I think it's
21 important to note that in a sense it doesn't matter
22 where they're located because we're proposing the same
23 criteria for adults and the fetus/embryo, so we just
24 think from a practical basis since they're all
25 medically -- from medically-related administrations

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1 that it makes sense to put them in one section of the
2 report. But it's the same criteria for either, so I
3 think we're kind of splitting hairs on where to put it.

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

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

20 CHAIRMAN THOMADSEN: Yes.

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

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

3 MR. BOLLOCK: Thank you. I just wanted to
4 bring up a point that this -- to change that in Section
5 3 would -- it would then make it contradictory to the
6 proposed rule Section 1, 1(a), which is all licensees
7 with the exception of --

8 CHAIRMAN THOMADSEN: I'm sorry. This is
9 --

10 MR. BOLLOCK: Okay.

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

13 MR. BOLLOCK: I just want to point out that
14 -- and it's kind of backing what Ms. Weil is saying about
15 it would make it a separate class. It would. Changing
16 that in Section 3 of the AO criteria -- what we have
17 proposed -- would be contradictory to what is in Section
18 1 of the AO criteria, which states -- that's where I
19 pulled the any exposure to embryo/fetus of five rem,
20 because the fetus is not the patient.

21 CHAIRMAN THOMADSEN: Yes.

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

25 CHAIRMAN THOMADSEN: Yes.

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

3 CHAIRMAN THOMADSEN: Yes.

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

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

12 Well, we aren't making much progress in
13 coming to decisions on this, and I think we need to do
14 that at this moment. We have the motion of the floor
15 which we've been discussing, which is accepting the
16 ACMUI Subcommittee Abnormal Occurrences Report with
17 the provision that there is an introductory paragraph
18 added discussing the rationale for the changes and the
19 criteria that are being recommended and a summary
20 paragraph listing the request that we ask to have these
21 recommendations replacing the abnormal occurrence
22 criteria. And the motion has not been amended, so it
23 includes exactly what has been talked about as far as
24 the embryo and fetus. Without a motion to make a
25 change, we're voting on the adoption as just specified.

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

3 (Chorus of aye.)

4 CHAIRMAN THOMADSEN: Opposed, say no?

5 MEMBER WEIL: No.

6 CHAIRMAN THOMADSEN: Abstentions?

7 (No audible response.)

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

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

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

25 (No audible response.)

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

3 (Chorus of aye.)

4 CHAIRMAN THOMADSEN: Opposed, say no?

5 (No audible response.)

6 CHAIRMAN THOMADSEN: Abstentions?

7 (No audible response.)

8 CHAIRMAN THOMADSEN: Thank you very much.
9 And now I will turn the chair over to you as I'm next.

10 VICE CHAIRMAN ALDERSON: You're up.

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

13 VICE CHAIRMAN ALDERSON: Please.

14 CHAIRMAN THOMADSEN: Well, it seems to be
15 a tradition talking about what ones reflections are on
16 leaving the ACMUI. You can't be here for eight years
17 without having some thoughts about that, and it's been
18 a lot more interesting and exciting than I ever thought
19 it would have been. We always are doing something
20 important. And even this discussion that we just had
21 right now you could feel the importance of what we're
22 doing even though it may not be clear what the answers
23 should be. We do know we have to do things carefully
24 and exactly. That is where the adrenaline rush comes
25 from. You know that it's important. You know that you

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1 have to be on top of things all the time and alert and
2 awake, maybe not when you're talking about E2.

3 (Laughter.)

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

10 (Laughter.)

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

17 There are things that I think we need to
18 cover in the future, and this is reflections on you,
19 what you might want to consider doing, but I'm not going
20 to be here to participate. And one is the medical event
21 criteria for everything except permanent implants.
22 And just like the AO criteria where we talked about
23 modern radiotherapy and how different it is than
24 radiotherapy in the 1970s where the whole concept of
25 misadministrations came from, not just AOs, but medical

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1 events have to brought up to this current millennium,
2 it's very difficult to evaluate sometimes whether or
3 not you've actually had an event.

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

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

17 The other is safety culture, and we know
18 that safety culture is important. And I teach the
19 patient safety course at Wisconsin, and I've been
20 teaching about safety culture before it was a buzzword
21 that was used throughout the industry and regulatory
22 community. But while it's true that an institution
23 that has the traits, which are actually a very good list
24 that the NRC came up with -- while it's true an
25 institution that has those traits probably has a fairly

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1 good safety culture, it is not necessarily true that
2 you have to have those traits to have a safe operation.

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

13 You also have the problem that trying to
14 force the characteristics unnaturally on an
15 organization does not necessarily make it a safety
16 culture in that you can drive the problems underground.
17 And it can be a lot like trying to grab tightly onto
18 a water balloon and having the balloon go between your
19 fingers. All this means is that trying to use safety
20 culture in an inspection enforcement-type setting can
21 itself create a chilling culture in the facility that's
22 being inspected.

23 The air travel industry found that a
24 non-punitive environment works best to find problems
25 and correct the problems, and that having a

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1 punitive-type culture, going out and during
2 enforcements punishing organizations and people does
3 not enhance safety, but drives problems underground.
4 It's a very complicated issue, safety culture. It
5 sound simple and it sounds like why can't we just make
6 people be this way? But it doesn't work that way.

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

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

22 (Laughter.)

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

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1 (Laughter.)

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

5 (Laughter.)

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

10 (Laughter.)

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

15 Special thanks of course go out to Ashley
16 and to Sophie. Without them this really would not have
17 been fun. They are so supportive and nurturing. And
18 my wife knows when I'm talking about Sophie nowadays
19 -- I call her my handler.

20 (Laughter.)

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

23 And here's to Rock's. I think those -- the
24 time that we've spent together as a Committee and with
25 the staff after the Committee meetings has been

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1 incredibly invaluable. It builds bridges that are
2 useful for communication in the future. I hope that
3 remains a custom. I hope we don't have to put out a
4 public announcement in enough time to do so.

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

13 (Laughter.)

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

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

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

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1 (Applause.)

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

4 (Laughter.)

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

8 As I said, I always listen to Sophie.

9 (Laughter.)

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

13 Hello, James. How are you?

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

15 CHAIRMAN THOMADSEN: I'm fine. Welcome.

16 DR. HOWE: I need you to wait.

17 CHAIRMAN THOMADSEN: Oh.

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

20 (Simultaneous speaking.)

21 CHAIRMAN THOMADSEN: I see.

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

24 (Simultaneous speaking.)

25 CHAIRMAN THOMADSEN: In that case,

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1 everybody can relax for the next 11 minutes, and just
2 make sure you don't go too far away.

3 Oh, before we relax, Mr. Costello?

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

8 ACMUI CHAIRMAN THOMADSEN: Yes.

9 MEMBER COSTELLO: Well, why delay?

10 ACMUI CHAIRMAN THOMADSEN: Huh?

11 MEMBER COSTELLO: Why delay? I mean,
12 you're still the Chairman for another hour or two.
13 Okay? I mean, when do you think that's going to happen?
14 Right? The way these things happen, I believe, is you
15 appoint a Subcommittee to re-look into it and start
16 making recommendations. I mean, we'll be coming up
17 with things that would represent rulemaking in the end.
18 And, I mean, that could take at least six months or a
19 year sometimes.

20 (Laughter.)

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

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1 about it again.

2 CHAIRMAN THOMADSEN: Okay. One moment
3 while we consult.

4 (Pause.)

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

8 MEMBER COSTELLO: We don't?

9 ACMUI CHAIRMAN THOMADSEN: -- appoint --

10 MEMBER COSTELLO: Okay. It's a
11 suggestion.

12 CHAIRMAN THOMADSEN: Right, I'll take
13 that as a suggestion and I'll appoint a Subcommittee
14 to propose appropriate criteria for medical event
15 reporting other than permanent implants, and I'll ask
16 is there somebody who would like to be the chair of that
17 Committee?

18 MEMBER COSTELLO: Not me.

19 (Laughter.)

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

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

24 ACMUI CHAIRMAN THOMADSEN: Very fine.

25 And the members of the Committee. We can have up to

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1 six, and I would like to have Dr. Ennis on the Committee,
2 I'd like to have Dr. Dilsizian on the Committee, and
3 Dr. Palestro on the Committee, our physicians on there,
4 short of the diagnostic. I don't think you're too
5 involved in the medical events yet for here. And we
6 should have a medical physicist. Let's see. One,
7 two, four. We have the two medical physicists, Dr.
8 Zanzonico. So this is going to have to be done quickly
9 before he falls off the table.

10 (Laughter.)

11 MEMBER ZANZONICO: I'm happy to serve.

12 CHAIRMAN THOMADSEN: Yes, and Mr. Ouhib,
13 who hopefully will be active on the Committee in time.
14 I think that's six, is that correct?

15 MS. HOLIDAY: Correct.

16 MR. BOLLOCK: That is correct.

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

20 MEMBER COSTELLO: Thank you.

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

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

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

6 Dr. Harvey?

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

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

23 First of all, what is NorthStar doing? We
24 have two separate paths that we are pursuing to make
25 moly-99 without the use of fission. One is we call the

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1 neutron capture. The other is photon capture. More
2 technically in terms of the NNSA jargon the first one
3 is the neutron capture technology track and the second
4 one is the accelerator technology track, non-uranium.
5 I should have added that there. It's not-LEU.

6 So, how are we doing that? First of all,
7 we're bringing on line; and we believe we'll be on line
8 within the next six months, the neutron capture at the
9 University of Missouri. We've been working down there
10 for quite a while and have had a contract in place since
11 2011. And of course many of you will remember the
12 original way to make moly back in the '60s, '70s, '80s
13 was neutron capture before fission became vogue because
14 it was so easy and, at that time, so inexpensive.

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

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1 little better.

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

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

20 Okay. Quick comparison. We are
21 irradiating stable molybdenum targets versus a uranium
22 target. It's a much, much simpler and safer chemistry.
23 No fission products. No alpha emitting isotopes. No
24 uranium. No plutonium to deal with. Minimal waste
25 generation. All of our waste is Class A waste. Very,

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1 very easy to handle and dispose in comparison. But the
2 challenges are we have a low yield per gram of target
3 material. Fission moly, upwards of 10 to the 4th
4 curies per gram of molybdenum. I'll show you where we
5 are momentarily. It's quite a bit lower. So that
6 makes this material not compatible with the current
7 distribution system and it requires a new type of
8 generating system.

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

24 So, you could run the -- so, the normal
25 saline through the column. The chlorine replaces the

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1 tech. It pushes it off, but it doesn't touch the moly.
2 That's why the molybdenum stays on. It stays on
3 mostly. That's why you have a breakthrough standard.
4 Because it can come off. If you have washed the column
5 with enough material, you will see a little bit of it
6 coming off. So, we address that, too, if it were ever
7 a problem.

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

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1 So, let's talk about the non-fission
2 generator now. It's low specific activity. You have
3 a greater volume of moly-99 you're dealing with. It
4 uses a completely different elution system, but
5 fundamentally there is absolutely no difference in the
6 sodium pertechnetate that's produced. It fully meets
7 all USP and EU Pharmacopeia requirements and it meets
8 the requirements of the nuclear pharmacy. When I say
9 that, they don't have specifications outside of USP,
10 but what they want, what a nuclear pharmacist in a
11 hospital wants is he wants his tech and a minimum amount
12 of normal saline. And that's because they can get a
13 lot of doses out of that if it's very concentrated and
14 that makes their operations very efficient.

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

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1 Where does bismuth-212 decay to?
2 Thallium-208, a 2.6 MeV gamma ray. So when you're
3 dealing with millicuries, or even microcuries of
4 bismuth-212 with a 46-minute half-life, but decays very
5 rapidly to thallium-208, you're getting a lot of
6 thallium-208 dose. So the personnel were getting a lot
7 of dose just doing the separations to prepare it for
8 administration to the patients that were involved, or
9 the other just solo work that they were doing.

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

16 So, this is a picture, an early picture of
17 something that was breadboarded up just to try working.
18 And that happens to be a picture in a hot cell. In 2005
19 NorthStar licensed the basic technology. The basic
20 technology is a box, the big gray thing that has the
21 pumps and valves and tubes to move the fluids around.
22 Obviously, you know what the little white shielded
23 container is. That's where the moly would be. The
24 white rectangular item in the middle about the size of
25 my hand is the chemistry module. And then it's

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1 computer controlled. So, it is this prototype, early
2 prototype that proved that technology worked and it led
3 to the granting of three patents to cover the three
4 types of processes that are going on there.

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

19 In 2011 we created the next instrument.
20 We called it TechneGen. And it has a lot of attributes
21 you can see there. A single control system. It can
22 control up to four different sources on one instrument.
23 The chemistry for the technetium is approximately
24 unaffected by the source of the moly. I can put neutron
25 capture moly on it. I can use natural molybdenum

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1 targets. I can use enriched molybdenum targets for
2 that. I can put photon transmutation moly on it from
3 enriched moly-100 targets. I can even load fission
4 moly on this system and it works the same, identically
5 every time. And the reason is it's a chromatographic
6 separation and it doesn't care the source of the moly.
7 So it provides us with a tremendous amount of
8 flexibility.

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

19 But the beauty of it is we can lose the
20 computer and because the instrument has an on-board UPS
21 system, it will run the entire cycle all the way through
22 and complete, which means our desire here to have no
23 radioactivity left in an unknown state was met by being
24 able to -- in the event of a power failure the UPS system
25 to be able to complete the entire elution process and

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1 put everything back where it was supposed to be in
2 shielded containers. And with complete automated
3 operation, after you answer the prerequisites, the
4 operator doesn't need to be there. He can walk off.
5 He can go off and do other things, which is important
6 in a nuclear pharmacy. Efficiency. He doesn't have
7 to stand there. And you can even separate it and do
8 it by either Wi-Fi or a TCP/IP network cable. The
9 computer doesn't even have to be in the generator lab.

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

21 Require some disposables. We'll talk
22 about those in a moment. We have an on-board -- in the
23 next version that I'm going to show you, to control
24 bioburden we actually have developed an ozonation
25 system that has never been used in this industry before.

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1 We generate ozone in water and we pass ozonated water
2 through the system to sterilize it. Never been done
3 in this industry before and it's led to several patent
4 applications for us.

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

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

25 So, this is the box to date, the full

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1 cabinet. Now, it looks large, but I'll give you
2 perspective in the next slide. But remember, in the
3 U.S. we have a capture nuclear pharmacy market.
4 There's about 400 nuclear pharmacies in the U.S. that
5 supply virtually all of the technetium doses in the U.S.
6 on a regular basis. There are some captive hospitals
7 and clinics that have their own pharmacies. But by and
8 large the bulk of the technetium doses every day are
9 done by commercial nuclear pharmacies and are shipped
10 as unit doses to the hospitals and clinics.

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

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

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

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

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1 where the source material is. The bottom section you
2 can see two bottles for the spent material.

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

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

22 So, we have a potassium molybdate/
23 potassium pertechnetate solution. It's a potassium
24 hydroxide-based separation system. We do just like
25 the current industry, a 14-day cal. And like the

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1 current industry where they use a tungsten or a DU
2 shield, ours is DU. We need to track those. We want
3 them back anyway, because if it's an enriched
4 molybdenum target material, we want to recover it.
5 It's valuable. And we have a recovery process already
6 established for that. You might ask why potassium and
7 not sodium? Turns out molybdate is twice as soluble
8 in a potassium system as a sodium system.

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

22 So, it has been a solution sitting on the
23 shelf since the mid-1990s looking for a problem to
24 solve. And since I was involved in the development of
25 it for the Department of Energy work, I went to my boss,

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1 the CEO of the company, and I said we got something
2 really slick here I know about and we can adapt our
3 platform to moly/tech and tungsten/rhenium because of
4 it. That resin is specific for only two things:
5 technetium as pertechnetate and rhenium as perrhenate.
6 That's it. Nothing else will stick on that resin.

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

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

21 So, the medical people in here will ask why
22 are you using peroxide and not normal saline -- I mean,
23 SWFI, sterile water for injection, if all you're doing
24 is rinsing with it? Did you know that SWFI will not
25 pass the FDA microbial challenge test if it's left open

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1 for more than 72 hours? So, we use three percent
2 peroxide solely because peroxide will pass the
3 microbial challenge test over a 14-day period where
4 SWFI won't. One of those little things that you learn
5 along the way, a pathway as you go through the process
6 of meeting the FDA requirements. You take something
7 and you say, oh, sterile water for injection, that's
8 got to be the best thing you can use, right? No, you
9 can't. It doesn't pass the test.

10 We have a reagent path that we put on every
11 instrument. Every 10 elutions a reagent pack is put
12 on. It's coded, keyed so it can only go on one way so
13 that it can't be mixed up, which means that hydroxide,
14 acetate and peroxide are always in the same location.
15 So they always get used. Can't be mixed up. And we
16 provide a single-use 10 cc USP normal saline syringe.
17 That is a single-use item. So every time you change
18 the collection, every time you want to do a technetium
19 collection, you use a brand new, open from the pack
20 right at that moment, saline syringe.

21 One of the key attributes that we
22 incorporated on here to meet a lot of the FDA
23 requirements and provide the industry something they
24 didn't have is we added the second Alumina cartridge
25 called the guard cartridge. We added the microbial

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1 filter. And the system can automatically do a bubble
2 test for the filter. So we can not only do the
3 sterility at the end, terminal sterilization, but we
4 can tell you whether or not the filter integrity was
5 held with the bubble test that's required.

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

16 So again, what are the reagents? Sorry
17 for the typo. It's not water. It's peroxide. It's
18 potassium hydroxide, not sodium. Acetate, chloride,
19 sodium chloride and the source material of course is
20 potassium molybdate, potassium pertechnetate in an
21 alkaline solution.

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

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1 air. Okay?

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

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

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

12 So then we rinse the hydroxide through it.
13 And that takes any moly that's trapped in the
14 interstitial spaces off. It doesn't have to be a
15 hydroxide rinse. We could rinse it all with acetate,
16 but -- and that may be a change that we're going to do
17 is to eliminate one extra chemical on the system, or
18 the volume of the extra chemical. We don't eliminate
19 it completely. But this was a way to get the trapped
20 molybdenum off the system.

21 Okay. Now, will you start the animation,
22 please? So then we rinse with sodium acetate. Notice
23 what happens here. The hydroxides, the excess
24 hydroxides are released. A little technetium can come
25 off here. We have to be very careful. It's a very fine

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1 line. But what it does is it lowers the pH to a point
2 where the normal saline can remove the technetium, but
3 the pH is less than nine, which means that if molybdenum
4 is present, the Alumina guard cartridge will pick it
5 up. If the pH is more than nine, it will start
6 dissolving the aluminum.

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

11 Now, that doesn't end what the instrument
12 does. That just gives the pharmacist his technetium.
13 He can go off and start working. He'll hear an audible
14 in the lab that will -- a sound that says the technetium
15 is ready. He doesn't have to stand there and watch any
16 of this being done, but he just has to listen for the
17 audible to come back and get his technetium, because
18 then the rest of the system continues to run as I'll
19 show you here in a second, and it repositions fluids.

20 Thank you, Sophie.

21 So, one of the questions was what's the
22 dose on this instrument? And so, we have dose
23 measurements and we have modeled what happens. And you
24 can see there's two periods where the molybdenum fluid
25 is moving where if you were right there at 30

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1 centimeters from it -- right in front of it, you would
2 get a dose in the neighborhood of 30 to 35 mR per hour.
3 But again, it's unattended operation. Those are the
4 only two periods where the dose is high. And then you
5 can see during the course of operation the bulk of the
6 time period it's an extremely benign dose. Matter of
7 fact, actual measurements that we have -- we have
8 -- from a 6.4 curie source of moly at 30 centimeters
9 the average dose over the entire period, if you were
10 standing 30 centimeters from it -- and think back to
11 the picture that I showed you a minute ago -- it would
12 be very hard to stand within 30 centimeters of that
13 without leaning over with your face almost right in it.

14 So, there's some other reasons why the
15 machine is built the way it is, because it's unattended
16 operation and you -- it's very difficult to just plant
17 yourself for 40 minutes 30 centimeters from it because
18 of that big shelf that's there. So a more realistic
19 number is at one meter, which would be an area that a
20 person could be walking around, the average dose is
21 about an mR per hour. And we actually have not only
22 models that show that, but we have found nanodots at
23 one meter and they have a response that starts at five
24 mR per hour and the nanodots are all coming back less
25 than, non-readable. So, we believe the model is

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1 pretty accurate, that it is the integrated dose over
2 the entire run at 1 meter is certainly below 5 mR per
3 hour and it calculates out to about 1 mR per hour with
4 a 6.4 curie source running through the system.

5 So, comparisons. Non-fission, low
6 specific activity, automated shielded system. The
7 elution time to get to the point that the pharmacist
8 can have the technetium now takes about 40 minutes.
9 But remember, he's not standing there. And what the
10 pharmacists do is they come in at midnight. They start
11 their elution. Right now they come in and they get
12 their work set up and then they go elute the generator.
13 In this concept, using this generator, the pharmacist
14 would come in and start the elution. And while it's
15 running automatically, then go set up this first round
16 of work. So it's just a matter of rethinking how you
17 do the operation in the pharmacy.

18 It produces the same high-specific
19 activity technetium-99m, meets USP, EU FDA standards
20 and it labels exactly the same as any other technetium.
21 Matter of fact, we've actually gotten some more than
22 better data. It's a very, very pure material by virtue
23 of the fact of the labor doing it and the fact that it's
24 got terminal sterilization on it. We've got the
25 endotoxin pyrogen collection that could -- if it's

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1 there from the extra Alumina cartridge. We know moly's
2 not getting through because we have the extra virgin
3 cartridge on there. So we're seeing a lot of really
4 outstanding results with various kit labelings.

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

7 (Laughter.)

8 DR. HARVEY: I hope that gives you a flavor
9 for how it works and what we've done to build this
10 instrument through its fifth generation. It's not a
11 brand new, hey, wow, let's go build one of these. This
12 is a dedicated process that has gone on for 20 years
13 and NorthStar's been doing it for 4 years -- I mean,
14 10 years and we've handled 4 of the 5 generations of
15 the technology. So, we've tried to take into account
16 the various things that we needed. We learned when we
17 submitted our first new drug application, the initial
18 new drug application to the FDA that because of the
19 situations with New England Compounding Pharmacy and
20 the non-sterile steroids that came out, microbiology
21 became more important to the FDA during that period than
22 when we had first met with the FDA in 2010. So as I
23 say, we went back and our engineers developed an
24 on-board ozonation system so we can sterilize the
25 instrument. We met that challenge that way. So

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1 again, 5 generations of technology over a 20-year
2 period. And I hope that you have a little better feel
3 for how it works.

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

6 Questions and comments from the Committee?
7 Mr. Mattmuller?

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

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

13 MEMBER MATTMULLER: Yes.

14 DR. HARVEY: -- 15 hours ago.

15 MEMBER MATTMULLER: Yes.

16 (Laughter.)

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

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

25 DR. HARVEY: Correct.

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

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

11 MEMBER MATTMULLER: Okay.

12 DR. HARVEY: And we've signed an MOU with
13 Westinghouse to explore the possibility of using those
14 power reactors to provide more redundancy and outage
15 reserve capacity. If you're familiar with this
16 industry, there are several buzzwords in it: "full-cost
17 recovery" and "outage reserve capacity" that are
18 outgrowths of all of the shortages through the 2007,
19 '9, '10, '11, '12, '13, whatever time frame. And so,
20 the purpose of the work we're doing with Westinghouse
21 is to look at using those power reactors for that
22 purpose.

23 The beauty of it is the system that we're
24 using is not within the safety envelope of the reactor
25 and it can be -- the targets can be inserted and pulled

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1 at power. They can also -- because it's a benign
2 non-fission, it doesn't change the reactivity of the
3 reactor. The targets can be put in and left in there.
4 They'll cook up to equilibrium. Fine. Which means it
5 makes them great for outage reserve capacity because
6 then you can have targets that are fully at equilibrium
7 activity. And if there's a shortage somewhere like our
8 MURR reactor goes down, we pick up the phone and we pull
9 the targets and, bang, we get them out of the
10 Westinghouse reactor.

11 That's the idea of the things we're
12 pursuing with Westinghouse. But there are two
13 versions of -- two generations is maybe not the right
14 way to describe it -- of the current PWR that
15 Westinghouse has deployed. And I believe there's
16 something like 50 of them herein the U.S.

17 CHAIRMAN THOMADSEN: Yes, Dr. Alderson?

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

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

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1 VICE CHAIRMAN ALDERSON: Russia?

2 DR. HARVEY: Yes. And it's gas
3 centrifuge enriched material, but we have kilogram
4 quantities of it already in inventory, more than enough
5 to start the process. And we have contracts, signed
6 contracts for deliveries from the Russians already for
7 more material. So in spite of the various issues with
8 the Russian government, etcetera, we've been able to
9 get what we needed and we still have signed contracts.
10 Money's been placed down and we expect them to fulfill
11 the order. We don't believe there's going to be a
12 problem. And because we recycle the enriched
13 material, we recover somewhere in the neighborhood of
14 95 to 97 percent by mass. We need very little makeup
15 material once we build the initial inventory. And as
16 I said, we've already got kilogram quantities of the
17 enriched material in stock.

18 CHAIRMAN THOMADSEN: So, Dr. Zanzonico?

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

21 DR. HARVEY: We're using an electronic
22 accelerator. We accelerate electrons to 42 MeV and we
23 have a beam current of about 3 milliamperes, which means
24 we're putting about a 120 kilowatts on the target. We
25 actually impinge -- we have two accelerators shooting

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1 in opposite directions and we impinge both ends of the
2 target so we get the maximum production on the target.
3 And we don't use a converter plate. The electrons
4 convert in the target assembly to bremsstrahlung and
5 the high-energy photons then kick the neutron out of
6 the moly-100 nucleus and allow us to make moly-99.

7 MEMBER ZANZONICO: So, this is your own
8 accelerator?

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

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

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

5 MEMBER ZANZONICO: And another question.
6 In the purification system is this a pressurized
7 system?

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

15 MEMBER ZANZONICO: So these are not HPLC
16 columns?

17 DR. HARVEY: This is --

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

20 (Simultaneous speaking.)

21 DR. HARVEY: You're correct. We went to
22 school on the HPLC industry, but we built a low-pressure
23 system. But we use Hamilton pumps, Hamilton syringes,
24 much like you see on an HPLC, but we're using in a very
25 benign low-pressure system. And we're using peak

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1 tubing rated at 5,000 pounds per square inch on a system
2 that's running at few 10s of psi.

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

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

6 CHAIRMAN THOMADSEN: Dr. Palestro?

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

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

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1 So again, you lock something down, you lock
2 down what is the most valuable to the industry, which
3 is the big one for the large commercial pharmacies, and
4 then you have the other sitting so that they just become
5 supplemental submissions.

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

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

15 CHAIRMAN THOMADSEN: Mr. Costello?

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

21 CHAIRMAN THOMADSEN: Mr. Costello?

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

25 DR. HARVEY: Actually, it could, but most

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1 community hospitals are serviced by captive nuclear
2 pharmacies somewhere in this country today.

3 MEMBER COSTELLO: I have a follow-up on
4 that. If they were at a community hospital, can you
5 imagine there be a training challenge at those places
6 with authorized users or the staff, which are very
7 different than those at a commercial nuclear pharmacy
8 trying to use this system?

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

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

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

22 MEMBER COSTELLO: Okay.

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

25 MEMBER O'HARA: Have you locked down the

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1 production device with CDER?

2 DR. HARVEY: Actually, this is a new drug
3 application, not a PMA, but it touched such new ground
4 that the FDA had never been at before that we have both
5 sides of the house looking at it. It's being looked
6 at by the drugs folks and the device people.

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

10 DR. HARVEY: We submitted the DLS in 2012.
11 We submitted the new drug application in January of
12 2013. We got our complete response letter in November
13 of 2013, and it outlined five pages of questions and
14 concerns. Four pages of it was related to microbiology
15 alone, and then one page had to do with your manuals
16 need some work.

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

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1 MEMBER O'HARA: Thank you.

2 DR. HARVEY: So we felt like we were on the
3 right track in answering the questions. We will submit
4 the answers to those questions. We believe we're on
5 track for submitting them in December of this year. We
6 hope to have approval by second quarter of next year,
7 because it is just answering questions to an already
8 submitted NDA.

9 CHAIRMAN THOMADSEN: Mr. Mattmuller?

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

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

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1 ship is an 18 with a next-day tally on it. And then
2 given decay and everything, it will be less than that.
3 But theoretically the absolute max that could be in a
4 vial is about 17 curies and 5 ccs of normal saline.

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

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

10 MEMBER MATTMULLER: Okay.

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

17 CHAIRMAN THOMADSEN: Dr. Zanzonico?

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

22 DR. HARVEY: Syringe.

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

24 DR. HARVEY: On-board syringe pump.

25 MEMBER ZANZONICO: It's nothing.

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1 DR. HARVEY: It's nothing. It's a
2 syringe pump literally drawing the fluid through.

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

6 (Laughter.)

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

9 DR. HARVEY: It's a paradigm shift. It's
10 the first new piece of technology in the industry in
11 30 years. We are moving the cheese. It's going to
12 take time for pharmacists to adapt to thinking
13 differently about how they get their technetium every
14 day. We've held user group meetings. We've held user
15 evaluations. We've had all the major pharmacies
16 involved to get them ready for this. And, but the
17 challenge is fundamentally it's a paradigm shift in the
18 industry because it's a new way to generate technetium
19 that really hasn't been done by most people working in
20 a pharmacy today. Virtually all those people don't
21 remember the '70s and '80s where you got low-specific
22 activity material and you made your technetium that
23 way. And so, it's a paradigm shift. And that's the
24 biggest challenge.

25 Second biggest challenge, flawless

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1 introduction. We are not going to start making 3,000
2 6-day curies on week 1 and shipping all over the
3 country. We have made a business decision that
4 probably for the first year with a few selected
5 exceptions if you're not in the mid to upper Midwest
6 you're probably not going to see one of these, because
7 we think a flawless introduction into the market is key
8 here. And that's partially because a flawless
9 introduction overcomes this paradigm shift that the
10 pharmacists are going to face.

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

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

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

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

6 CHAIRMAN THOMADSEN: Any other questions?
7 Oh, yes?

8 MR. OUHIB: I must say excellent
9 presentation.

10 CHAIRMAN THOMADSEN: Please identify
11 yourself.

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

16 DR. HARVEY: On the neutron capture, no,
17 because it's an established technology. We've
18 optimized it. On the photon work, we just completed
19 this year a series of tests at Argonne National
20 Laboratory where we were actually producing for the
21 first time curie quantities of moly with targets in a
22 simulated production environment. So, we're still
23 optimizing the photon transmutation route. But as far
24 as are we inventing, do we still have technology hurdles
25 to come overcome? No.

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1 CHAIRMAN THOMADSEN: Thank you very much
2 for the update.

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

5 CHAIRMAN THOMADSEN: Hope you get some
6 rest.

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

9 (Laughter.)

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

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

16 (Laughter.)

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

23 Anyway, we discussed this topic last March
24 when we first brought up the idea of having an
25 additional medical meeting. And we have a lot of names

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1 for it, but I'll call it that. And at the time there
2 were a number of -- we had a charge to provide a concrete
3 proposal for meeting. Hold on. I got to -- there we
4 go. This is the original charge: Write a concrete
5 proposal for meeting including cost estimate and how
6 it should be organized.

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

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

21 So, we've got another charge: A more
22 refined and complete recommendation considering the
23 ACMUI meeting and a list of questions for the ACMUI
24 members to consider. And to be blunt, I don't know if
25 we even sent out questions. Did we send out questions

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1 to you? I don't think we did. And I saw Sophie's list
2 of things we were supposed to do. I immediately saw
3 that, I thought, uh-oh, I don't think we did that. But
4 maybe in Phase III we will do that. That was the
5 charge.

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

21 We talk to the medical team all the time
22 and we think we've reached them. But the idea is we
23 want to have the senior NRC management, including the
24 Commissioners, involved. So we think about having it
25 here. And reflecting further, if we wanted to hold

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1 down the cost from the beginning, I would think that
2 the NRC auditorium from a cost savings point of view
3 might be the least expensive. I mean, I love the
4 Bethesda North Marriott. I stay there, but I imagine
5 they probably charge a few dollars for their rooms and
6 it might be easier to do it here in the auditorium. But
7 we'll get to that a little more toward the end.

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

17 Now, we would encourage an informal open
18 dialogue so this meeting would not just be a matter of
19 talking heads where NRC talks to the medical community
20 and the medical community goes away all the wiser having
21 heard from NRC staff and such. The idea would be an
22 exchange back and forth. It would be interactive among
23 those who are participating. And the hope is that we
24 all would gain information, including the regulators.
25 I imagine some Agreement States would probably come.

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1 I imagine members of the ACMUI would likely come. I
2 hope. And they could share back information.

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

14 We can imagine there will be technical
15 sessions on specific technical issues. There would be
16 the Commission senior staff. The medical community
17 would share their perspectives. We could have panels
18 and round tables on various selected topics. They
19 would get to meet each other and greet each other. So
20 members of various medical organizations could meet
21 Commissioners and talk to them. I know we in the ACMUI
22 benefit when we get a chance to have one-on-ones with
23 Commissioners. What I think it would be true as well
24 is if other members of the medical community were saying
25 perhaps how we could do things better, or even to say

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1 you guys did a good job on the new Part 35, you know,
2 give positive feedback.

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

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

22 Well, need NRC staff to determine cost.
23 And we do. And I'm going to come up with a suggestion
24 at the end of this, which actually goes beyond Sue's
25 slides. It will be my individual contribution. We

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1 need to figure out the cost now because, I'm going to
2 be blunt, if the costs are too high, this is not going
3 to happen. Like many government organizations, the
4 NRC right now is looking for an opportunity of ways of
5 reducing costs, right? Aim 2020 is not aiming at how
6 we can spend more money. Aim 2020 is aiming at how can
7 we do things more efficiently at a lower cost? And we
8 are aware of that. So that's why I was suggesting maybe
9 having the auditorium way of doing it.

10 And I've got this at the end, but we need
11 the NRC staff (A) to come back to us and tell us is this
12 a non-starter or is this something we can really work
13 on? Okay? I don't think we want to have Phase III of
14 our little Subcommittee. We need to have the NRC look
15 this over, look at this proposal and say, yes, we think
16 this is something that's worthwhile doing and we're
17 willing to invest something, at least invest people's
18 time doing a cost estimate, or we have other fish to
19 fry. We've got 2020 to worry about and maybe in a few
20 more years we'll worry about it. I think it's a good
21 idea and I'm very supportive of it. But we need the
22 NRC to validate that this is a worthwhile thing doing
23 if it can be done at a reasonable cost.

24 And as Sue says here, the idea of funding
25 five annual meetings, that's not the idea that we expect

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1 you to put up the money up front for five meetings.
2 Okay? I think the idea there is we have to commit to
3 having the five meetings so that you don't just judge
4 this project by the first meeting. I don't know how
5 many people came to the first RIC, okay, but I bet you
6 a lot more came to the most recent RIC than came to the
7 first RIC. And if you judge the first Regulation
8 Information Conference by how many people came to the
9 first one, we might say, oh, this isn't a very good idea.
10 Not many people came.

11 You have to give it time to develop, time
12 for people to understand that, yes, this is worthwhile,
13 and time for attendance to grow. So that means you have
14 to plan for more than one. If you just have one as a
15 trial balloon, I don't know how we're going to do,
16 because no one's done this before. But if people see
17 over a period of time that, yes, these are worthwhile
18 discussions and, yes, the NRC is listening and the NRC
19 is giving us good information in these round tables,
20 we're sharing information with high-level senior NRC
21 management, then maybe more people will be willing to
22 come and then we could keep doing it.

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

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1 give it time to grow.

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

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

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

22 Talk about what is our impacts, both the
23 NRC and the Agreement States; I recognize that we're
24 substantial players in this, on medical licensees and
25 patient care? Give us some feedback. I mean, I hope

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1 as a member of an Agreement State, and from doing this
2 for most of my life, that we're not having a negative
3 effect on patient care. Okay? I mean, I don't do this
4 for a living, have a negative effect on patient care.
5 But if there's any aspect of it that we are doing that
6 is delaying treatments being able to -- being able to
7 treat patients or discouraging some modalities by
8 making their adoption take too long. Whatever it is
9 that we're doing, if we could do it better, we want to
10 hear those things.

11 The medical uses of reactive materials are
12 changing. Dr. Thomadsen had said in the beginning that
13 many of our medical event rules are based on cobalt
14 teletherapy. Okay? They go back to the '70 in
15 Riverside Hospital and things that are like in the
16 distant past. And it's not easy for a regulatory
17 agency to keep up with these things. We have a
18 rulemaking process that was in geologic time. And so
19 we need to be informed by the community of what's going
20 on and how maybe our structure, regulatory structure,
21 which was designed for cobalt teletherapy, maybe
22 doesn't fit fiorite, or maybe doesn't fit microspheres,
23 or maybe doesn't fit whatever. So, and a good way to
24 do that is having open discussions. Okay?

25 Okay. And if we get advice from the

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

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

13 Medical event trends/lessons learned. I
14 think the purpose of medical events is to say, well,
15 do we need to do anything different? It's not really
16 about that particular event. It's about what are we
17 learning from the events that could say, well, how could
18 we regulate differently, or what information can we
19 provide to the practitioner so they can do things
20 different to avoid mistakes that other people make?

21 Are we having -- because there are medical
22 event reporting criteria, are we hearing things that
23 we don't need to hear about? I mean, that's something
24 that came up with the prostate seeds. The conclusion
25 was that maybe the dose-based criteria resulted in us

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1 hearing about events that were not terribly important.
2 I think we've addressed that in terms of microspheres.
3 Okay? And we just created the Subcommittee to look
4 into this now.

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

11 And is there any way that medical event
12 reporting impacts patient safety? I certainly hope
13 that medical event reporting, the way we do it today,
14 does not negatively impact patient safety. However,
15 if it is, then we need to do something different, right?
16 But I don't know. I mean, Sue put this question here.
17 I would like to think that it does not negatively
18 affects -- if anything I hope it benefits patient safety
19 because of the feedback.

20 But if there's thoughts in the medical
21 community that maybe in some ways the way we do things
22 negatively impacts -- for example, the whole question
23 about prostate brachytherapy, if that whole discussion
24 resulted in fewer prostate treatments with
25 brachytherapy, well, that may be an unfortunate

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1 consequence for therapy that is very good for certain
2 classes of patients. So if the way we're doing our
3 business, the outcome of that is the patients aren't
4 getting the ideal therapy for that, and maybe they're
5 getting external beam when they should be getting
6 prostate seeds. We need to know that because nobody
7 wants to do that, neither we the regulators nor the
8 medical community; and speaking as a patient, not the
9 patients. Okay?

10 The balance -- well, just take a look at
11 benefits and access to medical procedure. When we had
12 the presentation on medical events today, the number
13 of medical events compared to the number of procedures
14 is really, really low. I don't know what percentage
15 it is, but I remember it's really tiny. Okay?

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

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

9 How are we going to manage this? We
10 imagine the meeting itself will be managed by NMSS, just
11 like the reactor RIC is managed by NRR, I would think.
12 I would think that we in the ACMUI would support it as
13 much as we can. I think the OAS would probably support
14 it. And certainly the medical stakeholders would
15 provide input as well, because the meeting's not going
16 to work without them. If the only people we have coming
17 to this meeting is NMSS, the ACMUI and the OAS, well,
18 we'd just call it this meeting, right, and I could
19 represent the OAS. Now we need to get the medical
20 community and we need to get them excited about doing
21 this. It won't happen in the first meeting, I can
22 promise you that.

23 So why have it? And I'll repeat Sue's
24 mantra here. It's different, and we want to reiterate
25 that to the highest levels of NRC management and to the

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1 Commissioners themselves. It's a different mindset
2 when we're thinking about this. We just can't think
3 about this even as other materials uses. This is
4 different than industrial radiography. Okay? In
5 some ways HDRs look like industrial radiography.
6 Iridium, the source goes in, the source goes out. But
7 it's fundamentally different in how you should think
8 about it. Okay?

9 There are a lot of licensees out there.
10 Most of them are in Agreement States. How many are
11 medical use licensees? I don't know. I think in
12 Pennsylvania it's about half, I think, or something
13 like that. I don't know about other states or the NRC.
14 It's a substantial fraction, particularly when you
15 consider all of the cardiologists and people like that.

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

18 Who should attend? We'd want all of these
19 people to attend. Okay? We want Commissioners to be
20 there, and we want Commissioners to be there not simply
21 to say welcome to the meeting, I hope you have a good
22 discussion, Rockville's a nice place to come and
23 goodbye. Okay? We want them to be active
24 participants in the meeting. We want them to be
25 providing information and to be learning themselves.

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1 I realize they may send their technical assistants. We
2 want the Commissioners themselves to be there and
3 learning why medical is different.

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

6 (Laughter.)

7 MEMBER COSTELLO: However, NMSS is bigger
8 than the medical team. Okay? And NMSS has to set
9 priorities for things like rulemaking and distribution
10 of assets and such. I think it's important that NMSS
11 be there, that senior management be there, for them to
12 realize that the medical team does a lot for them and
13 how important this application of byproduct material
14 is.

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

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1 that we don't want to have regulatory hindrances to us
2 getting care that we need.

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

5 So what problems need fixing? Well, if
6 you recognize these things, these are what we've been
7 talking about. However, this is where we are at this
8 point in time. If we were having this discussion 10
9 years ago, aside from patient intervention, because
10 that never goes away, we might have a different list.
11 Okay? And 10 years from now -- patient release, not
12 patient intervention. Ten years from now we might have
13 a different list. Okay? The problems that need being
14 addressing will change over time. I suspect at the
15 various RICs they've changed over time. If you look
16 at the agendas from the RIC from the beginning, it's
17 a very different agenda we have now. But the
18 importance of the discussion will not change over time.
19 If anything, I think it will probably increase.
20 These are just the topics that we're going now, and I
21 don't think I'm going to go in any more detail.

22 What is needed? We need people. We need
23 a -- it says NMSS commitment. It's really an agency
24 commitment. It's an agency commitment. Because NMSS
25 by themselves can't commit for the agency. It's an

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1 agency commitment from the highest levels of the
2 agency, from Chairman Burns all the way down. We need
3 people to champion this. We need people to champion
4 this out in the medical community, to selling this, how
5 good is it to come here. But I think they'll learn that
6 over time. And we need NRC staff here to be advocates
7 for having such a meeting within the NRC. I know that
8 you are very busy. I do. We are all very busy.
9 However, if we can get a champion for this to point out
10 how important it will be and how we could do this at
11 a reasonable cost, perhaps using the auditorium,
12 perhaps then we can create an implementation team and
13 so forth.

14 I don't think -- I'm offering this to the
15 other people here. I don't think we're talking about
16 doing this this year. I don't think we're talking
17 about doing this next year. I think a reasonable
18 target for this might be 2017. That gives us time to
19 develop the concept, to figure out the costing, to get
20 the word out and to build up some enthusiasm for it.

21 Process. We have to develop for each
22 meeting, because it might change from meeting to
23 meeting what we're trying to accomplish. Perhaps in
24 the first meeting we might narrow it a little bit just
25 to get it going. We have to advertise it and get people

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1 to come. We would need web site support. We need all
2 of these kind of support that by and large we'd probably
3 have to come to the NRC, I would think. We appreciate
4 that.

5 Perhaps we'd have a facilitator to run
6 these meetings and people might be trained on how to
7 conduct these meetings. But the NRC has been
8 conducting the RICs for a long time. They know how to
9 conduct meetings. Okay? Maybe even steal some people
10 from them who've been running meetings like this
11 before. They could help us out. I mean, we're all one
12 NRC, the agency. Right? We've got an NRC badge on
13 today. We're all the NRC today. So even though
14 they're not NMSS, maybe they could collaborate.

15 My thought here is -- what I'd suggest
16 doing before I suggest your thoughts. I see a little
17 minion there. I love Sue and our minions. And if I
18 could, maybe we could have another assignment for
19 Sophie to put on the -- what we're asking the NRC to
20 do is. I would like to ask the NRC at the next meeting
21 to come back to us with a response and tell us if they
22 think this is something that we should continue to work
23 on. We are all grownups here. Okay? And both Sue and
24 I, as much as we believe in this, if the NRC comes back
25 and says we have a lot on our plate, maybe in a few years,

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1 we will lie with that. Okay? But I don't want to hear
2 that, but I want to hear a yes from the NRC, but more
3 important than a yes from the NRC I want to hear an
4 answer from the NRC as to whether this is a project worth
5 pursuing. Thank you.

6 CHAIRMAN THOMADSEN: And thank you, Mr.
7 Costello.

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

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

24 So, I guess my question is and something
25 to consider is if this effort might simply could be

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1 suspended for maybe a year or something. Of course I
2 can't speak for the Agency. I'm only speaking for Mike
3 right now. But I think to answer your question
4 provides a response there would be more uncertainty
5 associated with that response than might -- in other
6 words, it might not make it all that worthwhile at this
7 point in time. If you're talking about doing something
8 in 2017, maybe we'd come back a year from now when we
9 have a little more certainty around what it is that
10 we're even dealing with here and then give you a
11 response based upon something that maybe we might just
12 have a little bit more understanding of what our
13 resources are going to be.

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

18 CHAIRMAN THOMADSEN: Mr. Bollock?

19 MR. BOLLOCK: And if I can just continue
20 on with what Mike's saying. Yes, the reality of where
21 we are right now is -- we call it Aim 2020. That's the
22 plan to get us down to re-baseline, and essentially
23 re-baseline is get us to a new normal staffing level,
24 resource level, budget level. And right now we are
25 actively looking at things to shed, let alone add. So,

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1 if we're going to add something, there has to be
2 basically a safety significant -- this has to be a
3 safety issue to add something else for us to do.

4 So, I mean, realistically I can't speak for
5 the whole agency, but this -- I've been in enough of
6 these meetings beamed at Aim 2020 and re-baseline that
7 this -- it's not realistic right now for us something
8 of this magnitude.

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

20 Frankly, my staff doesn't have the
21 resources to be able to do something like that on top
22 of our ACMUI meetings that we currently hold twice a
23 year, the teleconferences, the -- our outreach we
24 already do going to -- we go to as many meetings as we
25 can: ASTRO, AAPM, SNMMI. We go everywhere we can to

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1 go out to the medical community realizing it's
2 sometimes easiest for us to send one or two people. And
3 that is very cost-effective. We already do that.

4 And we'd like to -- Mike and I have been talking
5 about this for a least a year now, about our outreach
6 plans and having senior staff like Mike go out, or
7 Donna-Beth go out to these societies; she just came back
8 from FICA, and be able to not just give a presentation
9 on what we're doing, but be able to expand that to the
10 ask the regulator, getting the feedback so the medical
11 community, your peers, could ask us -- just get a better
12 understanding and increase those relationships. We
13 realize that is important. But calling everybody in
14 -- we think there are other ways to do that that are
15 much -- well, frankly, much more economical, less
16 resource-intensive for us, less time-intensive for the
17 medical community and having to take another day off
18 to come out.

19 And also, something that we just had -- Dr.
20 Thomadsen came out and spoke to all of our Commissioners
21 on Wednesday and our senior management, and that was
22 feedback from both sides. I mean, Dr. Thomadsen, I
23 don't want to speak for you, but there was positive on
24 both ends, from our staff, our senior staff, senior
25 management and Commission, and I believe Dr. Thomadsen

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1 also thought it was a positive -- that was a positive
2 having that meeting. And those are ways to increase
3 the Commission's awareness of medical and things like
4 that.

5 So, really, I know you did a good job, you
6 and Sue did a great job of presenting problems that need
7 to be fixed, but these are things we're working on here
8 in this Committee, and we do outreach, and these are
9 individual problems.

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

17 MEMBER COSTELLO: Can I comment on that?

18 CHAIRMAN THOMADSEN: Please.

19 MEMBER COSTELLO: Okay. If you recall, I
20 think it was when I first started, it might have been
21 in the spring of 2014 when we met with the Commission,
22 and Sue gave, I thought, a very powerful presentation
23 on why medical is different. And she made a point. I
24 think we recognize that certainly on the medical team
25 and even in other parts of NMSS I think there's a

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1 recognition that medical is different. But that's not
2 the audience that she's thinking about. Okay? She's
3 really much thinking about the Commission level and
4 senior management level.

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

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

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1 Commission. And this is just one suggestion of how to
2 get there. It's not the only possibility.

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

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

21 And I'm not saying that that's something
22 we can't do, but the longer you put off beginning this
23 process, you're talking probably at least two years
24 before we do it. So if next year we say, well, we'll
25 do it the next year, it's going to be 2020 when we're

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1 doing it. Aim 2020 will have come and gone. So, I
2 understand. And I think a little something Sue and
3 myself would understand it if you write -- say it's not
4 the time. And we do get that. We still do think it's
5 a good thing. And by the way, I say Sue and myself.
6 I mean, Sue did 90 percent of the work here, or 99
7 percent of the work here. Yes.

8 MR. FULLER: This is Mike. Can I just
9 follow it with one other thing? I'm glad, Frank, that
10 you're the one making this presentation because you're
11 the Agreement State rep. And as I sort of envision and
12 think forward about how we might could possibly maybe
13 somehow pull this off, I recognize that we have about
14 13 percent of the licensees, and you guys have the other
15 87 percent. I don't see how we could possibly do this
16 NRC thing and we're talking to the Agreement States and
17 we're working with the Commission and the medical
18 community. I don't see how we could even start to begin
19 to envision something like this unless we started
20 arm-in-arm with a lot of Agreement State resources
21 devoted to it. I think we need to really, really think
22 in those terms. This has got to be a National Materials
23 Program effort. I don't see how it could possibly be
24 an NRC --

25 MEMBER COSTELLO: Great comment. The

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

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

25 CHAIRMAN THOMADSEN: Dr. Alderson?

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

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

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

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1 CHAIRMAN THOMADSEN: Dr. Dilsizian?

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

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

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

22 VICE CHAIRMAN ALDERSON: Absolutely.

23 MEMBER COSTELLO: I don't think it's
24 optimal yet. I think of the most recent situation
25 where we gave our advice on abnormal occurrence. Okay?

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

13 CHAIRMAN THOMADSEN: Well, that I think is
14 true.

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

24 Dr. Alderson, I look forward to you --

25 VICE CHAIRMAN ALDERSON: I've already

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1 been in touch with the staff --

2 (Simultaneous speaking.)

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

5 VICE CHAIRMAN ALDERSON: Yes, I agree.

6 CHAIRMAN THOMADSEN: Yes?

7 MR. BOLLOCK: Just to add, our Commission,
8 they do a lot of drop-ins. As Dr. Thomadsen
9 -- unfortunately Dr. Langhorst was supposed to do the
10 same thing. I believe Ms. Weil, you have done a drop-in
11 with a couple of the Commissioners two years ago. That
12 is -- we encourage that, if that's what you want. But
13 it's up to you. We can't tell you to. We can't tell
14 the Commission that -- we don't tell the Commission what
15 to do and we don't tell you what to do, but we encourage
16 that and we can help facilitate it. I believe Sophie
17 worked with the Commission staff to set up the meetings,
18 and we do encourage that. And that's just to form
19 -- the other parts outside of the medical community,
20 on the reactor side, they receive drop-ins from people
21 all across, every -- basically everywhere we regulate
22 they have drop-ins with. So, it would not be unusual.
23 It's not anything new for them to do that.

24 MEMBER COSTELLO: My only suggestion on
25 drop-ins though is perhaps if before you have the

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1 drop-ins with the Commissioners -- and you I think in
2 part did it because you're the outgoing Chairman. But
3 when you reach out to the Committee as a whole -- and
4 in essence you're really representing the Committee,
5 and to say, well, here are the issues we want to bring
6 up. And it could be a Committee member will say, oh,
7 here's another issue you might want to bring up, because
8 really when you do this you're representing the whole
9 of the ACMUI and not just yourself. Right? And I
10 encourage you to reach out to the Committee before you
11 do that.

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

14 (Laughter.)

15 MEMBER COSTELLO: It's not a criticism.

16 CHAIRMAN THOMADSEN: -- the next person --

17 MEMBER COSTELLO: It's not --

18 (Simultaneous speaking.)

19 CHAIRMAN THOMADSEN: -- may be relevant.

20 MEMBER COSTELLO: It's not a criticism,
21 but it's just a thought.

22 CHAIRMAN THOMADSEN: Whatever that might
23 be.

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

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

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

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

17 CHAIRMAN THOMADSEN: The next item on the
18 agenda -- thank you very much, Mr. Costello -- is the
19 open forum. And we basically have been in that for a
20 little while as we've been talking about
21 communications. Now we'll open the floor for other
22 ideas, comments, suggestions, criticisms, whatever
23 anybody would like to bring up now.

24 (No audible response.)

25 You were warned a day-and-a-half ago that

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1 we would be doing this again.

2 (No audible response.)

3 CHAIRMAN THOMADSEN: We've become a
4 Quaker organization.

5 (Laughter.)

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

8 CHAIRMAN THOMADSEN: It is.

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

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

16 MS. HOLIDAY: So, I realize that I am
17 between you and the adjournment of the meeting, and
18 thankfully we did cover yesterday's recommendations
19 and actions, so this should expedite this particular
20 discussion.

21 I do want to note that item 21 we had stated
22 that the backup date for the spring meeting was going
23 to be March 24th and 25th; however, I was informed that
24 the 25th is Good Friday, and so we like to avoid holidays
25 that may present religious conflicts for persons that

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1 may be attending who are on the Committee or in the
2 public realm. So I suggest that the backup date be
3 March 3rd and 4th. Is that acceptable to the
4 Committee?

5 (No audible response.)

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

18 MEMBER COSTELLO: A comment.

19 MS. HOLIDAY: Sure.

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

23 MS. HOLIDAY: Yes.

24 MEMBER COSTELLO: And I very much
25 respected your point of view there, and you made me even

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1 hesitate, although I did wind up voting for it. It's
2 up to you, but I think there might be value if you could
3 indicate a dissenting opinion. It's up to you, but you
4 might really consider that. You made some very, very,
5 very good points.

6 CHAIRMAN THOMADSEN: It would certainly
7 be appropriate given the indecision with which the
8 Committee actually addressed that issue. Our time on
9 that was a little bit short to get in by the November
10 16th deadline.

11 MS. HOLIDAY: Okay?

12 CHAIRMAN THOMADSEN: Yes.

13 MS. HOLIDAY: Thank you. Item 23, the
14 Committee unanimously endorsed the NUREG-1556, Volume
15 9 Subcommittee report.

16 Are there any questions, comments or
17 objections to that item?

18 (No audible response.)

19 MS. HOLIDAY: Seeing none, that brings us
20 to the final item where Dr. Thomadsen formed a
21 Subcommittee to propose the appropriate criteria for
22 medical event reporting for events other than permanent
23 implant brachytherapy. Subcommittee members include:
24 Dr. Dilsizian, Dr. Ennis, Mr. Ouhib, Dr. Palestro, Dr.
25 Suh, who will be the chair of that Subcommittee, and

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1 Dr. Zanzonico. That Subcommittee will report out
2 during the spring 2016 meeting.

3 Are there any questions, comments or
4 concerns for item 24?

5 (No audible response.)

6 MS. HOLIDAY: Seeing none, I have completed
7 my discussion for the day. Please remember to take
8 your name tags off. I don't want you to travel home
9 with them and I have to reprint them. Thank you.

10 CHAIRMAN THOMADSEN: And thank you, Ms.
11 Holiday. Thank you for everything.

12 MS. HOLIDAY: You're welcome.

13 CHAIRMAN THOMADSEN: And to the
14 Committee, thank you again, and we stand adjourned.

15 (Whereupon, the above-entitled matter
16 went off the record at 3:34 p.m.)
17

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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

¹Because 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 partisans³, 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:

³Hormesis 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/>

⁴See 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)

⁵True 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]he 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,

⁹The 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

¹⁰It 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.

¹¹Dr. 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.)

¹²For 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,

¹³To 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 helpful." See: www.petitionproject.org/seitz_letter.php

¹⁴When 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’s¹⁷ 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.

¹⁵Personally, 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.

¹⁶The 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**

¹⁸Dr. Calabrese’s views can be found here:
http://www.21stcenturysciencetech.com/Articles_2011/Fall-2011/Interview_Calabrese.pdf

¹⁹A 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.

²⁰Dr. 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

²¹SNMMI 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.”

²²In 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.

²³See, 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>

²⁴It 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](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

²⁶See, 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

²⁷This 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.

²⁸See 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 ¹³¹I 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

³⁰Bath, 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).

³¹Writing 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 only³⁴;
- 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.

³²See 50 FR 30616, 30627, col. 2 (July 26, 1985).

³³Drs. Jeffrey Siegel, Carol Marcus, and Michael Stabin, "Licensee over-reliance on conservatism in NRC guidance regarding the release of patients treated with I-131," *Health Phys.* 2007 Dec;93(6):667-77, <http://www.ncbi.nlm.nih.gov/pubmed/17993847>.

³⁴I 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 hotels³⁵;
- 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

³⁵It 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.

³⁶See 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.

³⁷In 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 in 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.

³⁸This 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]

³⁹Here the subcommittee cited an article by Jeffrey 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

⁴⁰In 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.

⁴¹The 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:

⁴²To 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.]

⁴³The 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

⁴⁴In 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}. .

⁴⁶50 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 carcinogenic⁴⁹ 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.

⁴⁸51 FR 36932 (Oct. 16, 1986.)

⁴⁹Memorandum, 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/>.

⁵¹Dr. 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 I-131 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**

⁵²International 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.

⁵³73 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

⁵⁴What 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.”

⁵⁵This 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.

⁵⁶There 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 et al., “¹³¹I 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 ¹³¹I 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 than 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 bucket

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.

⁵⁷62 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.

⁵⁸The 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 basic 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.

⁶⁰When 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,

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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]

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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

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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 therapy¹ [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 ORGANISATION, 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.