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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 2016 MEETING

+ + + + +

FRIDAY, OCTOBER 7, 2016

+ + + + +

The meeting was convened in Room T-02B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

PAT B. ZANZONICO, Ph.D., Vice Chairman

FRANCIS M. COSTELLO\*, Agreement State  
 Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

SUSAN M. LANGHORST, Ph.D., Radiation Safety  
 Officer

DARLENE F. METTER, M.D., Diagnostic Radiologist

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

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

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

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING: RICHARD GREEN

NON-VOTING: ZOUBIR OUHIB\*

\*via telephone

NRC STAFF PRESENT:

DANIEL COLLINS, Director, Division of Material  
Safety, State, Tribal and Rulemaking Programs

PAMELA HENDERSON, Deputy Director, Division of  
Material Safety, State, Tribal and Rulemaking  
Programs (MSTR)

DOUGLAS BOLLOCK, ACMUI Designated Federal  
Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated  
Federal Officer and ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

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

CLIFF DOUTT, NRR/DLR/RASB

MICHAEL FULLER, NMSS/MSTR/MSEB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

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ANGELA MCINTOSH, NMSS/MSTR/MSEB

TANYA PALMATEER OXENBERG, Ph.D., RES/DSA/RPB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

REANN SHANE, COMM/OCMJB

MICHELLE SMETHERS, NMSS/MSTR/MSEB

KATHERINE TAPP, Ph.D., NMSS/MSTR/MSEB

TORRE TAYLOR, NMSS/MSTR/RPMB

JENNY WEIL, OCA

MEMBERS OF THE PUBLIC PRESENT:

BETTE BLANKENSHIP, American Association of  
Physicists in Medicine (AAPM)

KATHLEEN BRILL, Spectrum Pharmaceuticals

SUE BUNNING, Society of Nuclear Medicine and  
Molecular Imaging (SNMMI)

BRIAN CAREY, Spectrum Pharmaceuticals

ASHLEY COCKERHAM, Sirtex

JENNIFER CULTRERA, Florida Cancer Specialists

ROBERT DANSEREAU, New York State Department of  
Health

WILLIAM DAVIDSON, University of Pennsylvania

ALBERTO DEJESUS, Spectrum Pharmaceuticals

MORTON DIAMOND, NSU Physician Assistant Program

JENNIFER ELEE, Conference of Radiation Control  
Program Directors (CRCPD)

BRIAN ERASMUS, BTG

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FRANK FACCHINI, BTG

LYNNE FAIROBENT, American Association of  
Physicists in Medicine (AAPM)

STEVEN FEIN, Miami Cancer Institute, Member of  
American Society of Hematology

SANDRA GABRIEL, International Atomic Energy  
Agency

WENDY GALBRAITH, University of Oklahoma College  
of Pharmacy

MUNIR GHESANI, NYU Medical Center

IRA GOLDMAN, Lantheus Medical Imaging

MICHAEL GUASTELLA, Council on Radionuclides and  
Radiopharmaceuticals, Inc (CORAR)

BONNIE HAMILTON, BTG

JAMES HARVEY, NorthStar Medical Radioisotopes,  
LLC

GEORGIA HEARN, American Society of Nuclear  
Cardiology (ASNC)

NICKI HILLIARD, University of Arkansas for  
Medical Sciences

CLARE JENNINGS, Bayer Healthcare

JASON KELLY, Texas Department of State Health  
Services

KSENIJA KAPETANOVIC, American Society for  
Radiation Oncology (ASTRO)

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CAITLIN KUBLER, Society of Nuclear Medicine and  
Molecular Imaging (SNMMI)

JOSEPH MACE, Florida Cancer Specialists

RICHARD MARTIN, American Association of  
Physicists in Medicine (AAPM)

CLARINE NARDI RIDDLE, Spectrum Pharmaceuticals

SHAHIN NASSIR KHANI, Walter Reed National  
Military Medical Center

ABRAHAM OLER, Spectrum Pharmaceuticals

MARK PAULSON, Wisconsin Department of Health  
Services

ERIC PERRY, Kentucky Department for Public  
Health

MICHAEL PETERS, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

DEVON REED, United States Army

GLORIA ROMANELLI, American College of Radiology  
ACR)

RIAD SALEM, BTG

KARL SCHWARTZ, Patients Against Lymphoma

MICHAEL SHEETZ, University of Pittsburgh

RAJESH SHROTRIYA, Spectrum Pharmaceuticals

DAVID SMITH, Medstar Georgetown University  
Hospital

BRUCE THOMADSEN, Center for the Assessment of

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Radiological Sciences (CARS)

CINDY TOMLINSON, American Society for Radiation  
Oncology

KARL VON AHN, Texas Department of State Health  
Services

KARA WEATHERMAN, Purdue University

KRISTINA WITTSTROM, University of New Mexico

ANDREW ZACH, House Committee on Energy and  
Commerce

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

Yttrium-90 Microspheres Brachytherapy	
Licensing Guidance.....	4
NRC's Abnormal Occurrence Criteria Policy Statement	
Update.....	48
Training and Experience for All Modalities.....	69
Spectrum Pharmaceuticals Proposal for Training and	
Experience Requirements.....	104
Worldwide Supply of Molybdenum-99.....	141
NorthStar Generator Licensing Guidance	
Donna-Beth Howe.....	180
Vasken Dilsizian.....	200
Germanium-68/Gallium-68 Medical Use Generator	
Licensing Guidance.....	217
Germanium-68/Gallium-68 Medical Use Generator	
Decommissioning Funding Plan Update.....	220
Enhancing Communications with the Medical	
Community.....	225
Administrative Closing.....	232
Adjourn.....	245

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

8:03 a.m.

1  
2  
3 CHAIRMAN ALDERSON: Thank you. All  
4 right, we're ready to open the Friday, October 7th  
5 session of the ACMUI, and the first item on the agenda  
6 today is Discussion of Yttrium-90 Microspheres  
7 Brachytherapy Licensing Guidance. It will be  
8 presented by Katie Tapp and Darlene Metter.

9 DR. TAPP: Thank you, Dr. Alderson. Good  
10 morning.

11 This morning, I'm going to start with a  
12 discussion on a draft revision to the Yttrium-90  
13 Microspheres Brachytherapy Licensing Guidance,  
14 Revision 10. This is a revision that we sent over --  
15 this is a draft revision that we sent over to the ACMUI  
16 for their consideration and recommendations. I want to  
17 stress that this document sent over to the Working Group  
18 -- or to the ACMUI, is a draft, and its sole purpose is  
19 for the NRC to solicit comments from the ACMUI and their  
20 recommendations.

21 This is not a final document at this time.  
22 It is not used for licensing at this time at the NRC.  
23 Therefore, the NRC has not issued this document as a  
24 publically available document, but I'd like to discuss  
25 some of the elements of this document today to kick off

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1 what the ACMUI is going to be discussing here.

2 First, I would like to start off with the  
3 Agreement State and NRC Working Group members. I am the  
4 co-chair of this Working Group, and Bob Dansereau from  
5 New York State is my Agreement State co-chair. Penny  
6 Lanzisera is from Region I of the NRC. Victor Diaz is  
7 from New Mexico, and Sara Forster is from Region III.

8 The Working Group task that we considered  
9 during this draft revision to the document was the  
10 training and experience pathway, specifically related  
11 to the manufacturer-provided training pathway, known as  
12 Pathway 2. We looked at the waste disposal section, and  
13 then potentially adding information regarding autopsy  
14 and cremation. I am going to go over each of these  
15 topics one at a time.

16 First, I wanted to start with the training  
17 experience. The current and proposed revision to the  
18 licensing guidance has two components to training.  
19 First, it has a radiation safety training and  
20 experience. This is including the classroom training,  
21 the didactic training, basic training during residency,  
22 and other experience outside of specific Y-90 hands-on  
23 training.

24 Then there is an additional component on  
25 specific clinical experience to yttrium-90 microsphere

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1 therapy, including the operation of the delivery  
2 system, safety procedures, and the clinical use. In  
3 this component, there are -- the applicant should have  
4 three supervised in vivo cases. These three supervised  
5 in vivo cases can be done in two different ways.

6 The first is if the applicant could have  
7 these cases done before they apply to be added on the  
8 license, and the supervision coming from an authorized  
9 user already on a license. This pathway is known as  
10 Pathway 1. The second pathway is the applicant  
11 completes all their training, and then they be asked to  
12 be added to a license. They are added to a license, and  
13 then they receive the three in vivo cases from a  
14 manufacturer representative. This is the current  
15 training experience guidance in the document.

16 Pathway 2 was introduced when there was  
17 limited numbers of authorized users that could provide  
18 supervision. This manufacturer supervision is a  
19 unique pathway specific to yttrium-90 microspheres and  
20 is not found in other 10 CFR 35 modalities.

21 The Working Group wanted to, in the draft  
22 revision, to ask the ACMUI to consider the potential to  
23 remove Pathway 2 following two years of issuance of  
24 Revision 10. The reasoning that the Working Group was  
25 considering this was after 10 years of licensing

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1 authorized users for these microspheres, there's more  
2 AUs available today, and we believe they would have  
3 enough to provide the supervision.

4 With this, we wanted to make sure there was  
5 adequate time for the industry to adapt. We know this  
6 would be a substantial change, so we are recommending  
7 a two-year grace period where the Pathway 2 would still  
8 be in the guidance and available, specifically spelled  
9 out in the guidance document.

10 During the grace period and another  
11 recommendation from the group was to recommend a  
12 six-month limit for those applicants who got added to  
13 a license using Pathway 2, a six-month limit for them  
14 to complete their three supervised in vivo cases after  
15 being added. This would avoid substantial time  
16 difference between their training, their in vitro  
17 training before they would have their first hands-on  
18 case in a clinic. We understand that there may be cases  
19 where patient load wouldn't allow for this, so we want  
20 to highlight in the document that there should be -- that  
21 this should really be reviewed by the license reviewers,  
22 and the six-month limit is a recommendation, but should  
23 specifically be reviewed on a case-by-case basis.

24 The second topic that the Working Group was  
25 considering was long-lived contaminants in the waste

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1 and disposal section. In 2007, the NRC was notified  
2 that there's long-lived impurities in the microspheres.  
3 We issued an information notice at that time that gave  
4 information regarding these impurities. The Working  
5 Group considered updates that were provided and new  
6 information and added that into the licensing guidance  
7 for ACMUI recommendation.

8 Finally, we looked at the addition of  
9 autopsy and cremation, if we wanted to add additional  
10 information. The current draft, we were looking at  
11 adding just a reference to NUREG-1556, Volume 9 and NCRP  
12 Report Number 155 because we believe there was no  
13 substantial safety issue beyond -- specific to the  
14 yttrium-90 beyond what would be found in permanent  
15 implants, so we're referencing reports that have this  
16 or are also in the draft process, that are adding  
17 information on the autopsy and cremation. We didn't  
18 believe there were specific safety issues that would be  
19 unique to yttrium-90 that it should be spelled out  
20 separately.

21 I now would like to turn it over to Dr.  
22 Metter to hear the recommendations and the ACMUI  
23 subcommittee's thoughts.

24 MEMBER METTER: Well, good morning, and  
25 this morning, I will be presenting the ACMUI

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1 Subcommittee Report on three draft guidance issues in  
2 the Draft Y-90 Microsphere Brachytherapy Licensing  
3 Guidance, Revision 10.

4 But before I start, I would like to thank  
5 the work of my subcommittee members Mr. Frank Costello,  
6 Dr. Susan Langhorst, and Dr. Christopher Palestro.

7 So we know that the liver is a common site  
8 of primary and secondary malignancies that are  
9 traditionally managed by surgery or various routes of  
10 chemotherapy. In the last several years, the  
11 introduction of intra-arterial brachytherapy implants,  
12 specifically radioembolization of yttrium-90  
13 impregnated resin or glass microspheres, have been used  
14 to treat these primary and secondary malignancies and  
15 really has emerged as a very important therapy in the  
16 management of these patients.

17 Y-90 microspheres are regulated under 10  
18 CFR 35.1000, Other Medical Uses of Byproduct Material  
19 or Material from Byproducts. The NRC licensing  
20 guidance on Y-90 microspheres brachytherapy sources and  
21 devices draft revision is near complete. As you heard,  
22 the ACMUI was tasked to comment on three draft guidance  
23 issues that Katie Tapp nicely reviewed, and these are:  
24 one, to consider the elimination of Pathway 2, the  
25 manufacturer AU training; second, update the waste and

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1 disposal section; and third, review the Y-90 radiation  
2 safety issues in autopsy and cremation.

3 So let's look at issue one, the authorized  
4 user training and experience. The draft guidance  
5 delineates first an update of the AU qualifications for  
6 Y-90 microtherapy; second, the didactic clinical and  
7 the clinical work experience, specifically, the three  
8 hands-on in vivo cases which can be accomplished in one  
9 of two pathways. The first pathway is supervision by  
10 an authorized user, and the second pathway is  
11 supervision by a manufacturer representative or  
12 proctor.

13 So again, to review, Pathway 1, the AU  
14 training pathway, where one or more physician AUs for  
15 a specific Y-90 microsphere therapy supervises an  
16 individual for the training and clinical experience of  
17 three hands-on in vivo cases for which the specific Y-90  
18 microtherapy is being sought. After completion of the  
19 third case, the training is complete. The individual  
20 can then be listed on their license and perform this  
21 therapy on patients for this specific therapy on their  
22 own.

23 The manufacturer training, Pathway 2: a  
24 Y-90 microsphere manufacturer supervises three in vitro  
25 simulated Y-90 therapies for the specific AU therapy

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1 being sought. They also provide certain uniform  
2 didactic content, and it is very standardized, very  
3 thorough review of the therapy.

4 The individual then goes back to their home  
5 institution and is placed on the radioactive license for  
6 that specific therapy, and then the individual also  
7 commits that the first three in vivo-specific Y-90  
8 therapy cases for which the approval is being sought  
9 must be supervised by the manufacturer, proctor, or  
10 representative and completed within six months after  
11 the date of license amendment. The individual then can  
12 perform the therapy on their own.

13 So as you heard with Katie the history of  
14 Pathway 2, in 2004, the NRC licensed AU for Y-90  
15 brachytherapy, but there were few AUs available to  
16 provide the clinical supervision. So in 2008, Pathway  
17 2 was created.

18 So as you all know, the current issue is  
19 elimination of Pathway 2, and there are pros and cons  
20 for this. So let's review the rationale for  
21 eliminating the pathway. So after over 10 years, or  
22 over a decade of authorizing authorized users via  
23 Pathway 1 and Pathway 2, there are sufficient AUs to meet  
24 the clinical demand and provide the required clinical  
25 experience to train future authorized users.

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1           Licensees that list AU on their license do  
2 not differentiate AUs who have completed the three  
3 clinical cases through Pathway 1 or Pathway 2 from those  
4 AUs in Pathway 2 who have not. Tracking AUs in Pathway  
5 2 who have or have not completed the clinical experience  
6 is difficult and at times impossible, and if you look  
7 at the NRC state regulatory authority of the licensees,  
8 you see there is far less NRC licensees than there are  
9 agreements.

10           Manufacturer AU proctors are not  
11 physicians. There are some physicians, but they may or  
12 may not be physicians, and Pathway 1 AU training will  
13 be more clinically based on the AU physician proctor's  
14 direct clinical experience. And when these three cases  
15 are complete, the physician seeking the AU status is  
16 then listed on the radioactive license and then can  
17 perform these cases on their own.

18           The NRC is proposing a multi-year delayed  
19 removal of Pathway 2 with a subsequent deadline date.  
20 Individuals may enter Pathway 2 up until this deadline,  
21 which, as you heard, is a two-year grace period.

22           The rationale for not eliminating Pathway  
23 2: how do we know we have sufficient AUs? Are there  
24 enough AUs to provide the training, clinical  
25 experience, and to provide the resources to train future

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1 AUs? What about access? Are there enough AUs,  
2 particularly in the rural communities without AUs?  
3 Could this have a negative effect on patient safety and  
4 access to care?

5 Pathway 2 provides a uniform standard of  
6 training, and with the Pathway 2 elimination, there may  
7 be no uniform training standard and potential gaps in  
8 training for future authorized users. Patients may not  
9 receive timely care, and there may be a potential lack  
10 of cooperation between networks and institutions to  
11 train authorized users. And in fact, authorized users  
12 may say, look, I am too busy; I can't supervise you for  
13 the clinical cases.

14 So the subcommittee reviewed the pros and  
15 cons of rationales for eliminating Pathway 2 and came  
16 up with the following comments: if there is a sufficient  
17 need for Y-90 microsphere therapy, sites performing a  
18 large number of therapies might offer many fellowships,  
19 and this includes didactic and the clinical training  
20 experience, and they may also even partner up with the  
21 manufacturer current uniform training standard.

22 If a current AU for Y-90 microspheres joins  
23 a new site, their prior training and experience will  
24 apply to that site, and they won't need further  
25 training. The subcommittee also encourages current

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1 AUs for Y-90 microsphere therapy to drive the proctoring  
2 experience in their community.

3 Issue two, waste and disposal: the  
4 production of Y-90 varies, being it generator- or  
5 reactor-produced, and with that, it results in the  
6 mixture of impurities with varying half-lives. The  
7 current guidelines are as follows: for disposal of  
8 byproduct material with the half-lives less than 120  
9 days, that is short-lived, and you are allowed to decay  
10 these in storage. The concern, however, is for the  
11 long-lived half-life agents, such as greater than 120  
12 days, and these cannot be decayed in storage, and these  
13 would be byproduct materials such as europium-152,  
14 -154, cobalt-60, and strontium-90.

15 Licensees need to be aware of these  
16 long-lived impurities, which can increase with  
17 partially used or unused vials. Long-lived impurities  
18 do present disposal issues, and the subcommittee  
19 supports -- although impurities may not be listed on an  
20 NRC license, licensees are responsible to ensure the  
21 microspheres are handled and disposed of in accordance  
22 with 10 CFR Part 20 and 35 requirements.

23 So the waste and disposal options are two:  
24 if your impurities are short-lived, you are allowed to  
25 decay this in storage. If they are long-lived, they

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1 need to be returned, used or unused vials, to the  
2 manufacturer if the manufacturer is authorized to  
3 receive them. If the manufacturer is not authorized to  
4 receive them, you need to transfer it to a recipient  
5 authorized to receive the Y-90 microsphere vials.

6 So in the end, if you have measurable  
7 long-lived impurities, you need to return the vial or  
8 transfer it to an authorized recipient. However, the  
9 good news is that most licensees are not detecting these  
10 impurities, and measurable long-lived impurities is an  
11 uncommon problem. Therefore, the majority of material  
12 can be decayed in storage. The subcommittee supports  
13 the NRC draft and this additional guidance on waste  
14 disposal.

15 Issue three, autopsy and cremation: we know  
16 that Y-90 microspheres is a unique device. It's the  
17 implantation of millions of permanent brachytherapy  
18 implants, and these are not biodegradable. Yttrium-90  
19 has a half-life of 64 hours. It's a pure beta emitter.  
20 It has a maximum energy of 2.27 MeV, maximum tissue reach  
21 of 11 millimeters, and it is very small in size,  
22 depending on whether it is glass or resin.

23 So the current guidelines are really  
24 related to the autopsy personnel. Radiation exposure  
25 can be increased with the handling of radioactive

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1 autopsy material that is impregnated with Y-90  
2 microspheres. On the death of a Y-90 therapy patient,  
3 the RSO and the patient's authorized users need to be  
4 notified upon the death, and if an autopsy is requested,  
5 the RSO must approve the autopsy. During the autopsy,  
6 ALARA principles need to be adhered to and assessed and  
7 directed by the RSO.

8 So, the subcommittee agrees with the  
9 current guidelines with the additional comment.  
10 Deceased Y-90 microsphere patients do not generally  
11 present a radiation hazard to those individuals  
12 handling the deceased body. However, if the autopsy is  
13 performed within two to four weeks after the Y-90  
14 therapy, this may call for additional precautions to  
15 manage the autopsy radiation workers' exposure.  
16 Additionally, if cremation occurs within two to four  
17 weeks after the Y-90 therapy, we may also require  
18 additional precautions, and potentially beyond that,  
19 due to long-lived contaminants.

20 So in summary, the ACMUI Subcommittee  
21 recommendations are the following: considering the  
22 elimination of Pathway 2 of the manufacturer authorized  
23 user training, we recently received several stakeholder  
24 comments, and the committee could come to no consensus.  
25 So, we would like to present this to the full ACMUI Board

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1 for discussion and a vote.

2 Second, update the waste and disposal  
3 section. We think it is adequate, and the subcommittee  
4 supports the current guidance.

5 And three, review the Y-90 radiation safety  
6 issues in autopsy and cremation. We currently support,  
7 however, as a comment, to edit on autopsy or cremation  
8 timing, with addition of potential precautions. Thank  
9 you.

10 CHAIRMAN ALDERSON: All right. Thank  
11 you, Dr. Kapp, Dr. Metter. We will open this particular  
12 session up to the ACMUI for questions and comments.  
13 Director Ennis?

14 MEMBER ENNIS: I heard some -- oh. I heard  
15 some theoretical arguments regarding the possible  
16 change to remove company representatives as the  
17 trainers for new authorized user applicants, and I heard  
18 some arguments from you presented about why maybe we  
19 should not do that, but I did not hear any substance  
20 behind those theoretical arguments. In other words,  
21 are those theoretical arguments actually a problem in  
22 the country right now: rural access, not having  
23 authorized users available, those were arguments that  
24 were raised, and my question is, well, what is the  
25 reality? What is people's experience nationally? Do

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1 we have any information that would support those  
2 theoretical arguments, or are they only just  
3 theoretical answers?

4 MEMBER METTER: Well, I spoke to Frank  
5 Costello, who, as you know, is on our committee, and he  
6 said that as a regulator, he sees a lot of the Pathway  
7 2 still being utilized.

8 MEMBER COSTELLO: Yes, this is Frank, can  
9 I comment on that?

10 CHAIRMAN ALDERSON: Yes, Frank, please go  
11 ahead.

12 MEMBER COSTELLO: Yes, I would turn that  
13 question around. I don't know that there is any data  
14 to indicate that there are a sufficient number of  
15 authorized users because, I'll tell you, in  
16 southeastern Pennsylvania, which is not really a rural  
17 area, I see mostly Pathway 2 being used, and I think it  
18 is partly because I don't know that authorized users  
19 really want to be the ones doing this.

20 In addition to that, we may recall from our  
21 discussions on medical events yesterday that many of  
22 these medical events occur because of problems with the  
23 administration set, and the manufacturers'  
24 representatives often are more familiar with the  
25 problems of a current administration set because

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1 they've seen so many of these issues.

2 So the two reasons I am thinking I would  
3 like to retain it is I don't see a pressing need to  
4 eliminate it. I don't know that there are enough  
5 authorized users everywhere that are willing to do this,  
6 and finally, I see that most of these, currently,  
7 institutions are choosing manufacturers'  
8 representatives when they could be choosing authorized  
9 users, so right now, I am not -- I don't find the evidence  
10 compelling to eliminate that option.

11 CHAIRMAN ALDERSON: Dr. Ennis, did that  
12 satisfy your question?

13 MEMBER ENNIS: Yes.

14 CHAIRMAN ALDERSON: Yes, Dr. --

15 MEMBER LANGHORST: This --

16 CHAIRMAN ALDERSON: -- Langhorst?

17 MEMBER LANGHORST: -- is Sue Langhorst.

18 Can we go to Dr. Metter's tenth slide, I think? These  
19 -- mine are not numbered, and I think it is number ten.  
20 Yes. And I wanted to discuss the point on -- the second  
21 point, and ask Dr. Tapp this: licensees do not put what  
22 category their AUs are in. It's the NRC and Agreement  
23 States who are issuing those licenses that put in that  
24 designation.

25 And so I understand that one of the

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1 difficulties that there are is that the Pathway 2  
2 authorized users are put on the license before they have  
3 their three cases, and that has to be, especially if it's  
4 a new license for them, or a new type of use under that  
5 license, but you all are frustrated by not knowing when  
6 they have their three cases and would like to put a time  
7 frame on that to have them get done. And in fact, I  
8 think we have heard anecdotally that there are some AUs  
9 that just never did do their -- or maybe not all their  
10 three cases.

11 So I wanted to ask Dr. Tapp as far as the  
12 Working Group goes if you discussed, were there other  
13 ways to fix that problem, such as putting on the license  
14 that they are required to do these three cases within  
15 six months of the date of -- or put the date on, because  
16 maybe the license changes in the meantime?

17 DR. TAPP: This has been discussed in the  
18 past. The way the NRC licenses, to put something on a  
19 license and call it like a limited scope or a temporary  
20 authorized user, we don't have that ability to do it.  
21 Now, I do know some Agreement States do have that  
22 ability, but in the past, we have looked at that, and  
23 we were told we could not put provisional status, I  
24 believe was the term that was looked at, on our licenses.  
25 So --

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1 MEMBER LANGHORST: So it is an issue?

2 DR. TAPP: -- it is evaluated during  
3 inspection space at the NRC.

4 MEMBER LANGHORST: Yes. Did you explore  
5 what it would take to do that? I mean, that sounds like  
6 another problem to fix, short of getting rid of the whole  
7 pathway.

8 DR. TAPP: Yes. Our reasoning for looking  
9 at getting rid of the pathway, just evaluating, was to  
10 see if we could bring it back closer in line with the  
11 other modalities. It was not on -- specifically on the  
12 difficulty in tracking it, but bringing it back into  
13 like 10 CFR 35 modalities, if it was a possibility, and  
14 that is why we went up to ACMUI with those  
15 recommendations. If that's the recommendations, we  
16 could look at that further.

17 MEMBER LANGHORST: Well, I am in agreement  
18 with Frank that I don't think elimination of Pathway 2  
19 is -- it's worth discussing, but I don't agree that it  
20 is worth getting rid of at this point in time. I will  
21 have a couple other questions when we go to the other  
22 parts, but I think we need to talk through this topic.

23 CHAIRMAN ALDERSON: Ms. Weil?

24 MEMBER WEIL: Is there any way to know,  
25 since there are so many -- thank you. Is it possible

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1 to determine, because there's so many medical events  
2 involving microspheres, which pathway the authorized  
3 users were approved under?

4 DR. TAPP: Yes, the Working Group actually  
5 asked that question, and unfortunately, when we track  
6 medical events, we do not track which pathway they fall  
7 under, as well as some of these are under broad scope  
8 licenses, and they have the ability to approve their  
9 authorized users in different pathways as well, so we  
10 do not have that ability at this time.

11 We have -- one thing I would mention was the  
12 Agreement State representatives have issued a survey to  
13 the Agreement States asking them if they have any  
14 information in their state level to see if we have that,  
15 so we are gathering a survey with our Agreement State  
16 representatives to look into that.

17 CHAIRMAN ALDERSON: So what is -- this is  
18 Dr. Alderson -- what is implicit in this, and I have not  
19 heard anyone say it yet, so I just want to state this  
20 and then have you confirm it. No one has really  
21 commented on the equality of the educational experience  
22 during the training by the manufacturer representative.  
23 It's in vitro simulation and then followed by the  
24 manufacturer being present; that's how the slides  
25 describe it. Do we know that the outcomes of that

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1 educational experience in practice are generally the  
2 same as the person trained with live patients by an AU?

3 So do we know that it is an equivalent  
4 experience? Do we know that the outcomes are the same?  
5 Do we have any idea whether it's a good experience at  
6 all, or what the outcomes are? Yes, Sue?

7 MEMBER LANGHORST: This is Sue Langhorst.  
8 I would say at my license, more than likely, we have our  
9 own AUs training new AUs.

10 CHAIRMAN ALDERSON: Right.

11 MEMBER LANGHORST: But if the manufacturer  
12 comes in and trains, that is okay with us too. I mean  
13 --

14 CHAIRMAN ALDERSON: Yes.

15 MEMBER LANGHORST: -- we have not seen the  
16 difference. I can only talk from --

17 CHAIRMAN ALDERSON: So just --

18 MEMBER LANGHORST: -- institution --

19 CHAIRMAN ALDERSON: -- kind of  
20 subjectively in your local experience, you haven't  
21 noticed a --

22 MEMBER LANGHORST: Yes.

23 CHAIRMAN ALDERSON: -- difference in those  
24 trainees, so --

25 MEMBER LANGHORST: And it's a good

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1 training for -- I think as some of the letters that we've  
2 received, for the whole team because it is really a team  
3 administration.

4 CHAIRMAN ALDERSON: All right. Yes, we  
5 have two more comments. Dr. Ennis?

6 MEMBER ENNIS: Since we don't have  
7 information, this is more I guess speculative, but  
8 nevertheless, just extrapolating if you will from the  
9 types of brachytherapy procedures that I do, which is  
10 not these, but to the degree that they may be similar,  
11 and interacting with manufacturer representatives and  
12 physicians to do this, I cannot -- I feel fairly strongly  
13 that the depth of the training, at least for the  
14 authorized user himself, maybe not the team, is very  
15 different if a physician who is actually doing the  
16 procedure is training you.

17 The depth of the understanding of what you  
18 are trying to do and the subtleties and the problems that  
19 can develop in the procedure itself and the proper  
20 handling of the radioactive materials, I think the depth  
21 that you're going to get from a physician who is actually  
22 doing it is much, much deeper, richer, and valuable than  
23 from a drug company or, you know, a representative.

24 I share -- and I hear what Sue was saying  
25 about maybe the team as a whole and maybe the tubing

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1 issues and things like that, but on the medical and  
2 proper handling of the isotope by the authorized user,  
3 I don't think there is a comparison. I guess this is  
4 all opinion, but I don't think there is a comparison in  
5 the information and the depth of the training.

6 Adding that to the notion that it is  
7 possible that they get trained only in vitro and then  
8 go out and never -- and we don't know if they are getting  
9 that three or not, it makes me very uncomfortable with  
10 Pathway 2.

11 CHAIRMAN ALDERSON: Mr. Green, you had the  
12 next statement. Then we'll let Dr. Metter --

13 MR. GREEN: Follow-up on Dr. Ennis's  
14 comments: with the in vitro training from a sales  
15 consultant representing their manufacturer's product,  
16 is that going to be specific only to that product and  
17 not generally applicable to the other manufacturers'  
18 products, so we have an individual who is doing three  
19 simulated cases of Brand A, and really won't understand  
20 the nuances and the clinical issues that might come up  
21 if they happen to acquire the product from Brand B?

22 And with Ms. Weil's comment about can we  
23 attribute this medical event to an authorized user who  
24 was a Pathway 1 trainee or a Pathway 2 trainee, is that  
25 applying to the preceptor or the student? I don't know.

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1 DR. TAPP: Can I --

2 CHAIRMAN ALDERSON: I think --

3 DR. TAPP: -- answer --

4 CHAIRMAN ALDERSON: -- Dr. Metter had the  
5 next comment, but Dr. Tapp would like to respond? Yes.

6 DR. TAPP: Yes, there is -- when added to  
7 a license or added for one type of specific  
8 manufacturer, so if they were to switch the manufacturer  
9 and use the other, they would have to do, retrain  
10 specific to the type.

11 MR. GREEN: And once they're on the  
12 license, do you think if they do trade vendors, they are  
13 doing three new case studies?

14 DR. TAPP: We have no indications or  
15 violations that they have never received their  
16 training.

17 CHAIRMAN ALDERSON: Dr. Metter is next,  
18 and then we have a comment from the audience.

19 MEMBER METTER: Well, I agree with Dr.  
20 Ennis's comment regarding the subtleties of a direct AU  
21 with their supervision and their clinical experience.  
22 The manufacturer training program, however, is very  
23 standardized and encompasses the -- since 2008, all  
24 their experience, and they actually do, like what Sue  
25 said, regarding the team approach, the nuclear

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1 medicine, the radiopharmacist, the whole team approach,  
2 and then they give -- the in vitro simulated cases also,  
3 I believe, apply to, like what happens if the hub came  
4 undone, or the different scenarios so that you know how  
5 to approach the problem issues.

6 But again, I still think that the direct  
7 clinical training with the authorized user is very  
8 important, and that is why my first thing is that as far  
9 as if you provide mini fellowships, that you may  
10 hopefully incorporate the manufacturer's didactic  
11 training and then provide the direct training with the  
12 authorized user.

13 CHAIRMAN ALDERSON: Next comments from the  
14 audience here, and then we'll go to Dr. Palestro.

15 DR. FACCHINI: Good morning, and I  
16 appreciate the ability. My name is Frank Facchini, and  
17 I'm in interventional radiologist, but I am actually  
18 also the Head of Medical Affairs for BTG, which is one  
19 of the manufacturers of Y-90. I am a product of the --  
20 I am an authorized user, a product of the second pathway  
21 about ten years ago.

22 I will make a point that the medical events  
23 are extremely low: when we at BTG looked at this, over  
24 the last five years, on the order of 0.14 percent, and  
25 so it's an incredibly low rate of medical events.

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1           The second point I will make is we have done  
2           that survey. We have reached out to products of the  
3           training courses, the physicians that have gone through  
4           it, and it is overwhelmingly positive, overwhelmingly  
5           positive. In fact, the amount of people that responded  
6           is above the average you would expect in any other  
7           survey, so people giving us feedback that they want to  
8           keep it, they appreciate it, and that the quality of  
9           education is excellent.

10           I will take some exception to the point of  
11           they're not sales representatives that are doing this.  
12           These are actually medically educated people that are  
13           under me, personally, as a physician, as an  
14           interventional radiologist, and as an AU, so they fall  
15           directly in line. They are not sales-compensated  
16           whatsoever.

17           And the depth of education, sir, is  
18           incredibly deep because, remember, they have the  
19           ability to harvest the pharmacovigilance that we do and  
20           the device vigilance feedback that we do and get  
21           incorporated. A regular AU that sits out there that  
22           might have done three, and by the way, an AU is qualified  
23           as three cases, that depth of experience, then, if they  
24           have done four cases, they can proctor someone that has  
25           done none. That does not represent depth of experience

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1 in any way, shape, or form.

2 So with great respect, I appreciate  
3 everybody's comments, but I wanted to give you the  
4 perspective from a user and from someone that has the  
5 responsibility of overseeing these educational  
6 programs.

7 CHAIRMAN ALDERSON: Very good, thank you,  
8 good comment. Dr. Palestro is next.

9 MEMBER PALESTRO: Yes, I think I come at it  
10 from a slightly different perspective. Putting the  
11 quality of the training aside and so forth, the rules  
12 governing the relationship between medicine and  
13 industry today I think are so incredibly strict and  
14 well-defined that there is a clear separation between  
15 the two, that I find it somewhat incongruous that the  
16 training for microsphere administration is given by a  
17 vendor or vendors, that -- and clearly, that is not to  
18 impugn the quality of the training.

19 But to a disinterested observer, you have  
20 to wonder why it is being done, and clearly, it could  
21 be construed as being self-serving. And I understand  
22 that at the beginning, there are no alternatives, and  
23 I suspect looking ahead to new generators for  
24 technetium, clearly, it's going to have to be  
25 industry-sponsored training because they are the only

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1 individuals or only group who is familiar with it, but  
2 at some point down the road, that training should move  
3 on to other groups, other organizations, and I would  
4 think this agent or these agents have been available now  
5 for about a decade, that there should be an alternative  
6 to company- or industry-sponsored training, so that is  
7 my concern.

8 CHAIRMAN ALDERSON: Good, thank you.  
9 Excellent comment. The spectrum of the training is a  
10 key issue, and the previous speaker gave some good  
11 examples of the depth and the quality of the training  
12 provided on the manufacturer side, but the presentation  
13 itself and the rules and -- the rules that we saw don't  
14 make that distinction. It could go all the way the  
15 other way.

16 We have another comment from the audience.

17 DR. SALEM: Thank you, sir. My name is  
18 Riad Salem. I am also an interventional radiologist,  
19 and actually, I was here, what, 12 years ago when these  
20 pathways were devised.

21 So when you're referencing vendor training  
22 on this on the BTG side, I am a trainer. So I have  
23 trained about 1,000 people now who have come through the  
24 course over a decade, and there is no doubt that there  
25 are sort of multiple pathways that are beneficial, but

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1 I too would take exception that at least high-level MSLs  
2 or highly trained sort of vendors aren't able to assist  
3 with the administration.

4 What we do in our course, which is a  
5 whole-day course, eight, ten hours or so, people come  
6 to Chicago, is go through the entire clinical scenario,  
7 the patient selection criteria.

8 We learned from our early experiences, and  
9 I think that has translated into a very low sort of mod  
10 reporting and sort of adverse event rate, and for those  
11 of you that have radiologists, nuke med, rad oncs that  
12 have come to Chicago, if you see, the evaluations  
13 themselves are pretty high. And so I think there are  
14 multiple things that we have learned over a decade, and  
15 the fact that you can teach physicians sort of the  
16 patient selection and all of these things, the medical  
17 aspect, I would argue that the MSL or the vendor  
18 representative that has now done 500 cases, 1,000 cases,  
19 he is much better-versed to manipulate and help with  
20 administration, the kit, et cetera, than a physician who  
21 has done, theoretically, three based on AU to AU.

22 So I just think there are multiple pathways  
23 that we need to consider, and this has certainly been  
24 something that we developed ten years ago with this  
25 committee. It has worked extremely well, and the

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1 evaluations are good, and it is really sort of, in my  
2 opinion, parallel to sort of stent graphing; you really  
3 need a lot of expertise onsite to help you do these  
4 things safely.

5 CHAIRMAN ALDERSON: Thank you. Yes?

6 MR. OUHIB: Hello, this is Zoubir.

7 CHAIRMAN ALDERSON: Yes, Zoubir, please,  
8 go ahead.

9 MR. OUHIB: Yes. I just thought I'll  
10 throw out a question: should the manufacturer  
11 representative be defined, so that way we understand all  
12 these comments that have been submitted?

13 CHAIRMAN ALDERSON: Yes, should it be  
14 further defined? I think that is a good point. I'll  
15 expand on that in a moment. Dr. Ennis has a comment.

16 MEMBER ENNIS: I was thinking something  
17 similar. Perhaps to satisfy my, for example, anxieties  
18 about level 2, if we were to continue it, we'd need to  
19 be much more prescriptive about what that means, along  
20 the lines of what we have been talking about in training  
21 experience in general, that we need to have more  
22 defined, not just company representative coming, but --  
23 and, you know, what we have heard from some of the  
24 companies sounds quite good, but maybe we can't just  
25 leave it up to the company, but it needs -- if Pathway

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1 2 continues, it needs to be defined, and I'm not going  
2 into details of what that might be, but something very  
3 robust, and then maybe we could be comfortable with it.

4 But without that definition, although a  
5 company may be doing a wonderful job, this really allows  
6 someone with modest education coming in and watching you  
7 do a couple cases, and the NRC and I and ACMUI have no  
8 idea that that is not happening, so those are my  
9 thoughts.

10 CHAIRMAN ALDERSON: Another comment from  
11 the audience.

12 MS. COCKERHAM: This is Ashley Cockerham  
13 with Sirtex Medical. Just for the committee's  
14 clarification, we have approximately 30 proctors.  
15 They are all physicians. They have about 159 years'  
16 combined experience, and they do up to about 400 cases  
17 per year, so all of our in vivo cases are supervised by  
18 physician proctors. Yes, Sue?

19 CHAIRMAN ALDERSON: Sue Langhorst.

20 MEMBER LANGHORST: At our institution,  
21 radiation oncologists serve as the authorized users,  
22 and our interventional radiologists are what we term  
23 approved physicians. I know several of our physician  
24 -- our interventional radiologists have served as those  
25 representatives for some of the manufacturers to go and

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1 do training elsewhere and to proctor elsewhere, so those  
2 interventional radiologists at our site are not AUs, but  
3 they could be. It is just that is not the model that  
4 we use at our institution.

5 So I am very comfortable with the training  
6 and the physician-level oversight of those training  
7 proctoring sessions.

8 MS. COCKERHAM: This is Ashley again, one  
9 more quick comment. All of our physician proctors are  
10 interventional radiologists.

11 CHAIRMAN ALDERSON: Well, yes, Dr.  
12 Zanzonico?

13 DR. ZANZONICO: You know, all these points  
14 are very well-taken. I think one thing we need to  
15 recognize is these procedures are very labor-intensive,  
16 labor- and time-intensive, and I think while in  
17 principle, peer-to-peer training, in this case,  
18 physician-to-physician, AU-to-AU training, is always  
19 preferred, I am just not sure how receptive busy IR, busy  
20 interventional radiologists and other attending  
21 physicians will be in terms of providing the amount of  
22 training.

23 So just because there is a growing number  
24 of qualified individuals who could provide this  
25 training in principle, physicians who could provide

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1 this training, I don't necessarily think that  
2 translates into the number of physicians who would be  
3 willing and able to do it on the basis of time and  
4 logistics, and so eliminating Pathway 2 at this point  
5 may compromise at some point in the near future the pool  
6 of individuals qualified to perform these procedures  
7 just because of the inability of those users to dedicate  
8 the time and effort to do so.

9 CHAIRMAN ALDERSON: All right. Well so it  
10 was the lack of definition in the current presentation  
11 and regulations, I presume, that led to my question,  
12 which resulted in the recent exchange, and I am very  
13 pleased at the attestations of quality that we've heard  
14 from several manufacturers. I think when you combine  
15 that with the low level of complications in the field  
16 over time, I think we can say that it is probable that  
17 things are working out reasonably well.

18 But I think the comments that have been made  
19 by Dr. Palestro and Dr. Ennis about better defining this  
20 type of training in the future, particularly such  
21 training of the type, this may become more common in the  
22 future for certain reasons, that better definitions, at  
23 least in guidance, if not in regulation, I think would  
24 be very helpful to letting all people know that high  
25 quality education was being provided. Thank you.

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1                   Next question: any other comments on this  
2 presentation? Yes, Dr. Langhorst?

3                   MEMBER LANGHORST: And, have others -- if  
4 we're going to move away from the pathway to discussion.

5                   CHAIRMAN ALDERSON: Yes.

6                   MEMBER LANGHORST: Okay. I think it's on  
7 Dr. Metter's slide 22 with regard to autopsy and  
8 cremation and what you labeled as current guidelines.

9                   This is recommendations from the NCRP  
10 report. It's not any recommendations from NRC  
11 guidance. And, in fact, I have no authority over  
12 patients who pass away after they leave our hospital and  
13 are released under 35.75.

14                   So, these are not what are in the guidance  
15 document. I mean, you reference that, but it's not  
16 something that the NRC is saying you have to do.

17                   I'll yield to Dr. Tapp.

18                   DR. TAPP: You're correct. It's not a  
19 requirement specific to autopsy or cremations. The  
20 requirements are, as you stated, in 10 CFR 35.75  
21 regarding patient release and keeping it to a 100  
22 millirem or the 500 millirem as the maximum.

23                   So that requirement does encompass autopsy  
24 and cremation of some -- if you knew there's a situation  
25 where someone could be exposed to 500 millirem, you

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1 could then fall under 35.75 and need a license.

2 But, we are not recommending at this time  
3 new rules for autopsy and cremation. It's just a  
4 reference for information for RSOs to use.

5 MEMBER LANGHORST: I just wanted to  
6 clarify that point. And, as far as the waste disposal  
7 section goes, this really isn't anything new to how  
8 people are doing waste disposal of microspheres. The  
9 NRC, I think very rightly, is trying to be consistent  
10 in their RAD waste disposal guidance, and especially on  
11 their 35.1000 licensing guidances. So, it's nothing  
12 new. It just states what us RSOs have had to do all  
13 along. So, we were -- I was happy with how that was  
14 stated.

15 CHAIRMAN ALDERSON: Yes, Dr. Dilsizian.

16 MEMBER DILSIZIAN: So, regarding the waste  
17 and disposal issues, I am -- I was curious to know why  
18 you listed a number of long decaying isotopes. You also  
19 said that most licensees are not detecting these  
20 impurities. Do we know what the cause of variability  
21 is? I mean why is there like very little, and then at  
22 times there are long-term impurities.

23 DR. TAPP: The very small amount of  
24 activity that falls -- that is in the -- that comes from  
25 the manufacturing process, it is so small that it would

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1 require very sophisticated detection instruments to see  
2 it. So, manufactures or licensees are not seeing it.

3 The times where they possibly could detect  
4 it is if they had a vial that wasn't used at all. So,  
5 there's more long-lived impurities in it. It is  
6 possible in those situations that they could detect it  
7 because you have a -- more amount. But, a used vial is  
8 --

9 MEMBER DILSIZIAN: So, is it possible that  
10 they are not detecting; is that what you're saying? I  
11 mean, it's difficult to detect, in essence, it exists  
12 and that we not --

13 DR. TAPP: Yes.

14 MEMBER DILSIZIAN: -- actually keep it for  
15 a long time?

16 DR. TAPP: Yes, it's below the detection  
17 limits.

18 MEMBER DILSIZIAN: Okay.

19 MEMBER LANGHORST: It's in very small  
20 amounts. It's very small amounts, if at all.

21 MEMBER DILSIZIAN: So, what is then -- why  
22 are we even discussing it, I guess?

23 MEMBER LANGHORST: Because they have been  
24 observed, and it's just an alert that if you still have  
25 activity that you're measuring, that you can't decay and

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1 storage it.

2 More than likely, we would ship it with our  
3 radioactive waste shipments.

4 MEMBER DILSIZIAN: Okay.

5 CHAIRMAN ALDERSON: Mr. Green?

6 MR. GREEN: For Dr. Dilsizian, there may be  
7 two things. One is the partially unused vial may be  
8 more detectable because normally it's infused in the  
9 patient and you don't have much leftovers.

10 It also may be in a certain production cycle  
11 of that batch, whether they had a longer bombardment  
12 time in the reactor where you could actually make  
13 europium. We see the same thing with samarium-153  
14 lexidronam, or Quadramet, where we get europium-154.

15 On slide 19, which is the waste issue, too,  
16 waste and disposal. I just have a -- I don't know the  
17 answer, but since both manufacturers are outside the  
18 U.S., if we were to ship unused vials back to the  
19 manufacturer, would the licensee have to be licensed for  
20 export of rem materials to use that pathway for  
21 disposal?

22 DR. TAPP: If they were to ship it to their  
23 outside locations. I believe that, and Sue could  
24 answer this, a lot of times, it goes through an  
25 authorized recipient, but it is an option that we wanted

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1 to remain in the licensing guidance in case, if  
2 manufacturers would like to do that in the future.

3 MEMBER LANGHORST: I may be wrong, but  
4 isn't there a level that you have to reach as far as  
5 activity goes? And, I don't think this would be  
6 anywhere near, but it's -- I guess it's waste. If you'd  
7 count it as waste. But, if it's unused material,  
8 presentation is everything.

9 CHAIRMAN ALDERSON: We have another  
10 comment from Ms. Cockerham.

11 MS. COCKERHAM: This is Ashley Cockerham  
12 with Sirtex Medical.

13 Our manufacturing facility is here in the  
14 U.S.

15 CHAIRMAN ALDERSON: Dr. Langhorst?

16 MEMBER LANGHORST: I have one final  
17 comment, I think.

18 And, I know that the NRC has explained this,  
19 but it is very frustrating not to have these draft  
20 licensing guidance made publically available so that  
21 all can look at them well ahead of time and know what  
22 they say, rather than inferring it from just our review  
23 of their -- of the draft.

24 That's very frustrating. If NRC can  
25 figure out a way to be able to let the public see these

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1 draft licensing guidance, I think it would be very  
2 helpful. Thank you.

3 CHAIRMAN ALDERSON: Thank you. And, Dr.  
4 Zanzonico?

5 VICE CHAIR ZANZONICO: I agree. The  
6 long-lived contamination is a non-issue. Having said  
7 that, in terms of cremation, there have been estimates  
8 that range from completely insignificant to fairly  
9 significant radiation doses to members of the general  
10 public from the fluence from crematoria. And, they're  
11 fairly well established models, plume models and so  
12 forth and so on for making those dose estimates.

13 So, has the NRC done those calculations to  
14 verify with conservative assumptions of the amount of  
15 radio contaminates, long-lived contaminates if a  
16 patient were to undergo or the deceased would undergo  
17 cremation, that, in fact, the dose to the general public  
18 would be well below regulatory limits?

19 DR. TAPP: I believe you presented on this  
20 a few -- a year ago.

21 VICE CHAIR ZANZONICO: Right, that was  
22 more -- yes.

23 DR. TAPP: And, there was a paper in that  
24 presentation. I did look at that paper. I have more  
25 data on the impurity levels. And, I used their plume

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1 models, which was very conservative, in that.

2 And, we did do some evaluations and some  
3 numbers. I don't have that available with me today, but  
4 I -- the NRC has looked at that.

5 VICE CHAIR ZANZONICO: And, so, everyone's  
6 comfortable that the dose limits are below like 100  
7 millirem --

8 DR. TAPP: Yes.

9 VICE CHAIR ZANZONICO: -- a year. Okay,  
10 that's fine. Thank you.

11 CHAIRMAN ALDERSON: Do we have further  
12 comments on this area? I think to summarize it, and  
13 I'll say this a little more directly than I did a few  
14 moments ago, it seems that there's virtually a consensus  
15 around the table that Training Pathway 2 should be  
16 maintained at this time. And that better definitions  
17 through guidance of what comprises manufacturer-based  
18 training would be useful in the future. Other comments  
19 on this issue? Dr. Tapp?

20 DR. TAPP: Can I ask, you said at this time.  
21 I didn't know if the ACMUI would want to continue to look  
22 into this, if there'd be some time where it could be  
23 brought back in, or is your recommendation that it  
24 remains as is? I was just trying to follow up and make  
25 sure I understand the recommendation.

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1 CHAIRMAN ALDERSON: Dr. Ennis?

2 MEMBER ENNIS: My opinion would be I would  
3 not want to maintain Pathway 2 unless it is better  
4 defined. So, I would like to see that process happen  
5 and then be able to support maintaining Pathway 2.

6 CHAIRMAN ALDERSON: Dr. Palestro?

7 MEMBER PALESTRO: I also would, under the  
8 current structure being company- or vendor-sponsored  
9 would be opposed to a continuation of Pathway 2.

10 CHAIRMAN ALDERSON: All right. Well, it  
11 seems then that perhaps we should actually take a vote  
12 on this issue just so we can show the NRC what's really  
13 here. I had assumed that we had sort of a consensus  
14 given that we would better define training and that the  
15 training that seems to be provided now is high quality,  
16 but that -- but your issues are reasonable issues.

17 So, given what we know today, among the  
18 members here, how many believe that we should maintain  
19 Pathway 2?

20 MEMBER COSTELLO: This is Frank, I do.

21 CHAIRMAN ALDERSON: Okay.

22 MEMBER COSTELLO: But only -- I do with  
23 proviso that we better define who a manufacturer's  
24 representative can be.

25 CHAIRMAN ALDERSON: Okay, with the proviso

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1 that it's better defined, all right. So, but, without  
2 that proviso, there's still -- we have five people, I  
3 believe, who have suggested one, two, three, four and  
4 Frank.

5 MEMBER COSTELLO: Oh, include me in that  
6 group, too.

7 CHAIRMAN ALDERSON: Right, right, right.  
8 So, we have five. This is just generally for your  
9 advice, it's not a binding -- we're not doing a binding  
10 referendum here, it's just for your advice.

11 I think we have five people who support that  
12 idea and, if the manufacturing standards are -- the  
13 training by manufacturers are made more precise and more  
14 rigorous, then how many would support the idea that  
15 Pathway 2 would be maintained?

16 MEMBER COSTELLO: That would be me, too.

17 CHAIRMAN ALDERSON: Then a couple of the  
18 people who opposed would now agree, although one would  
19 not. So, just as general advice, I think, at the  
20 moment, that goes back to my, at this time, you know,  
21 I think Pathway 2 stands, but we do need to take these  
22 models that we've heard about today of really high  
23 quality training and do whatever we can to promulgate  
24 that throughout the industry and, in the future, to be  
25 more prescriptive about what that training should

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1 entail. Yes?

2 MEMBER LANGHORST: I would be prepared to  
3 make a motion so that this can be a little more formal  
4 for --

5 CHAIRMAN ALDERSON: All right.

6 MEMBER LANGHORST: So, I would move that  
7 Pathway 2 remain and that we recommend that the working  
8 group evaluate what additional definition can be put or  
9 requirements be put on the proctoring of those cases --

10 CHAIRMAN ALDERSON: By the manufacturers.

11 MEMBER LANGHORST: -- of the three  
12 manufacturers.

13 CHAIRMAN ALDERSON: Yes.

14 Okay, so that's a motion. Is there a  
15 second on that motion?

16 MEMBER ENNIS: I second that.

17 MR. COSTELLO: I second.

18 CHAIRMAN ALDERSON: All right, it's  
19 seconded, and we've had a fair amount of discussion  
20 already. Is there further discussion? People --

21 Yes, Ms. Weil?

22 MS. WEIL: Just a quick question. Would  
23 we want to specify that the training, the industry  
24 training be performed by physicians?

25 MEMBER LANGHORST: This is Sue Langhorst.

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1 I would say that is something to be evaluated by the  
2 working group and to be brought back.

3 CHAIRMAN ALDERSON: I agree, yes, that's  
4 part of the work to be done. Further questions or  
5 comments before we take a vote on this issue? All  
6 right, all those in favor of Dr. Langhorst's motion,  
7 please say aye or raise your hand.

8 (Chorus of aye.)

9 CHAIRMAN ALDERSON: Opposed? One.  
10 Abstaining?

11 So, it carries. So, the group is in favor  
12 of this approach.

13 MS. HOLIDAY: I'm sorry, I just need to  
14 clarify how many abstained and how many dissented?

15 Is Dr. Metter abstained.

16 DR. METTER: Abstain.

17 MS. HOLIDAY: And Dr. Palestro dissented?

18 CHAIRMAN ALDERSON: Yes, that's correct,  
19 very good. All right, thank you. Well, excellent  
20 report and I think this led to good knowledge and --

21 MEMBER LANGHORST: Dr. Alderson?

22 CHAIRMAN ALDERSON: Yes?

23 MEMBER LANGHORST: I'd like to move that we  
24 support the recommendations of the subcommittee on the  
25 waste disposal and the autopsy and cremation

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1 recommendations.

2 CHAIRMAN ALDERSON: Okay. Is there a  
3 second to that?

4 MEMBER DILSIZIAN: Second.

5 CHAIRMAN ALDERSON: Any further  
6 discussion? All in favor?

7 (Chorus of aye.)

8 CHAIRMAN ALDERSON: Are any opposed? Any  
9 abstaining? That's unanimous. Thank you very much.

10 All right, our next report is on Abnormal  
11 Occurrence Criteria and Policies Update and it's to be  
12 given by Ms. Oxenberg of the NRC.

13 DR. OXENBERG: Good morning. I'm filling  
14 the position intermittently as the Abnormal Occurrence  
15 Coordinator. I started on a rotation in May, and so,  
16 we've -- after office turnover, and I'm in the Radiation  
17 Protection Branch permanently, but I'm not a medical  
18 health physicist. So, we're going to be hiring -- we've  
19 hired a medical health physicist that'll be starting  
20 later in the month.

21 So, I'm here to give an update, as you may  
22 know, an abnormal occurrence is on the schedule of  
23 incident or event which the Commission determines is  
24 significant from the standpoint of health and safety to  
25 the -- health or safety, it's not necessarily both,

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1 required by the Energy Reorganization Act of 1974.

2 The first policy was in place in 1977.  
3 And, we've periodically updated the policy; the last was  
4 in 2006. The current proposed change, which you were  
5 briefed on in 2015, was proposed to the Commission, and  
6 it was actually a work in progress since about 2011.

7 The Commission proposed the changes with  
8 minor edits. But, they directed the staff to go back  
9 to the public and specifically ask on comments on  
10 whether exposures to embryo and fetuses or a nursing  
11 child as an AO should be as it is now under criterion  
12 1.A.2 or under criterion III.C as a medical event as a  
13 result of treatment to a pregnant patient.

14 It was published in the Federal Register in  
15 the summer of 2015, and the comments were received from  
16 the Advisory Committee, Organization of Agreement  
17 States, the State of Washington and the Commonwealth of  
18 Virginia.

19 And, basically, with criterion 1, the  
20 original footnote had just said that medical patients  
21 were excluded from consideration of criterion 1. The  
22 Commission had added that specifically those, the  
23 criteria that did not apply as defined in Part 35.3045,  
24 which of course are medical events under criterion  
25 III.C. But, in response to comments from the public,

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1 we added medical patients and human research subjects.

2 As far as criteria 1.A and III.C, the staff  
3 did not agree -- are not making a recommendation for a  
4 change. We're recommending that it remain and  
5 applicable to all licensees under 1.A.2 as it is. And,  
6 the basis for this is that the staff felt that the  
7 embryo/fetus dose of 50 millisieverts or 5 rem is 50  
8 times what the public dose is allowed, and it's intended  
9 for all licensees.

10 And, we really didn't want to have two  
11 thresholds: one for an, unintended for anything else but  
12 medical; and then one for, as a result of treating a  
13 pregnant patient.

14 Under III.A, events at facilities other  
15 than nuclear power plants and all transportation  
16 events, the Commission just deleted "of licensed  
17 facilities or regulated materials." They thought it  
18 was redundant.

19 Under criterion III.B, fuel cycle  
20 facilities, the Commission added -- they replaced the  
21 second bullet with the first. And, basically, they're  
22 saying any high consequence events for facilities  
23 licensed under Part 70 are those that seriously could  
24 harm a worker or a member of the public in accordance  
25 with 70.61.

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1           And, basically, 70.61 are performance  
2 requirements, and here, it should be stressed that these  
3 are physical engineering controls that you have to  
4 prevent an exposure. And, for an abnormal occurrence  
5 here, doesn't necessarily have to result in an exposure.  
6 But, if those engineering controls fail, then that,  
7 under Part 61, could then be an abnormal occurrence.

8           Under III.C, the only change that the  
9 Commission recommended was in the first criterion 1,  
10 they added which results in a dose, and they spelled out  
11 the word gray.

12           Under criterion III.C.2, they added a  
13 medical event as defined in Part 35.3045. They did not  
14 add Paragraph (iii) that pertained to the independent  
15 physician; they crossed that out.

16           And, so, currently, we've received  
17 comments; we've staffed the changes with the offices and  
18 the regions. We've received those comments. We're  
19 now incorporating them and prepared to go up to the EDO  
20 and to the Commission with the recommendations. If  
21 those recommendations, if they approve it, then it will  
22 be incorporated in the next fiscal year's 2016 Abnormal  
23 Occurrence Report to Congress.

24           And that concludes.

25           MEMBER LANGHORST: Dr. Alderson, thank

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1 you.

2 CHAIRMAN ALDERSON: Dr. Langhorst?

3 MEMBER LANGHORST: For those of you new on  
4 the committee, and maybe those of you who are just a year  
5 or two on the committee, probably abnormal occurrences,  
6 you've never heard of them before, never aware that they  
7 went up to Congress, and this is all brand new. It was  
8 brand new to me, too.

9 It is very disappointing that the  
10 recognition of medical use being different is applied  
11 -- is not applied to the criteria for an embryo/fetus  
12 of a pregnant, especially I-131 therapy patient, who is  
13 in this initial throws of pregnancy that no one could  
14 recognize. That is an abnormal occurrence.

15 And, whenever a 35.3047 occurrence  
16 happens, or excuse me, event happens and a licensee  
17 reports that, that is automatically an abnormal  
18 occurrence; that just puts it right in that category.  
19 There have been since 2007, like, maybe one to three a  
20 year that show up in abnormal occurrences.

21 So, our recommendation of what that should  
22 be was not in what was published for the proposed change  
23 to AO criteria. But, the question was asked as the  
24 Commission directed.

25 I should say, let me get to this here,

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1 Commissioner Ostendorff said there may be unintended  
2 consequences of using the medical use criteria.  
3 However, I do not think that it's reasonable for the NRC  
4 to offer less protection to the embryo/fetus or nursing  
5 child of a patient than that afforded the embryo/fetus  
6 of a declared pregnant worker.

7 That had nothing to do with this AO  
8 criteria. And, so, there is confusion over what an AO  
9 criteria is and what it's supposed to do.

10 I looked at the comments from the ones that  
11 I could find from the proposed AO change. And there  
12 were two I could see, and I know there was one -- one  
13 was from the State of Washington; one was State of  
14 Virginia; one was from the OAS, and I could not find that  
15 document, so I don't know what their comments were; and  
16 then our comments. That was the public response.

17 And, it wasn't clear to me that the two  
18 states didn't agree with us, it was kind of unclear  
19 because I think the question was unclear being asked.

20 So, I did want to tell the committee what  
21 Dr. Svinicki said. And, I'd like to, if you would,  
22 allow me to read this here.

23 She said in her vote on the proposed change  
24 of AO criteria, "I regretfully observe that the staff's  
25 proposed revision of criterion III.C.3, that's the

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1 embryo/fetus, does not appear to have garnered the  
2 support of the" -- or excuse me, that was the, sorry,  
3 that was the additional paragraph to the criteria -- did  
4 not support -- or garner "the support of a Commission  
5 majority.

6 "I agree wholeheartedly with the NRC staff  
7 and the Advisory Committee on the Medical Uses of  
8 Isotopes that reporting medical events each year to the  
9 Congress have not resulted and are not forecast to  
10 result in any significant adverse effect or permanent  
11 medical harm that is inappropriate.

12 "As I have reviewed these reports year to  
13 year during my service on this Commission, noting that  
14 most of the descriptions of the abnormal occurrence  
15 events reported to this Agency conclude with a statement  
16 to the effect that no adverse health effects from the  
17 misadministration of radiation are expected, I can only  
18 imagine the anguish created for patients and family  
19 knowing that their medical treatments are labeled  
20 abnormal by a federal government agency and, yet, their  
21 medical care provider has concluded that no harm will  
22 follow.

23 "This is made all the more confusing when  
24 the policy statement clearly states that the criteria  
25 use a high reporting threshold so that only those events

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1 considered significant from the standpoint of public  
2 health and safety are reported.

3 "Clearly, the circumstance should be  
4 corrected. The staff's proposed revision to this  
5 criterion would have moved in that direction. I hope  
6 the staff and the Advisory Committee will continue to  
7 bring thought and attention to this issue in spite of  
8 the Commission's actions here."

9 So, we're not going to change it at this  
10 point in time, but I just encourage the ACMUI to fight  
11 the good fight the next time it's up for revision.

12 Thank you.

13 CHAIRMAN ALDERSON: So, this issue of a  
14 high reporting threshold does, in fact, seem to be one  
15 of the key things that we should discuss at this time.

16 I'll just make an opening comment that will  
17 follow what Dr. Langhorst just commented. And, it has  
18 to do with criterion III.C, which is slides 8 and 9,  
19 which, again, confused me a bit. So, slide 8, it talks  
20 about a medical event, and then it talks about 100 rads  
21 to the bone marrow; it talks about 250 rads to the  
22 gonads; a 1,000 rads to -- high doses that clearly  
23 represent a high threshold. And, if something like  
24 that happens, however it happened, perhaps Congress  
25 should know about that.

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1           But, then on the very next slide it says  
2           that a medical event using the same terminology again  
3           and then just goes through the same definition that  
4           we've used for clinical events in the field, the wrong  
5           -- a route of administration for an otherwise -- that  
6           is not a high threshold. That happens frequently in  
7           regular practice. That, to me, criteria, this part on  
8           slide 9 should not be part of an AO; this should not be  
9           reported to Congress. And, so, I, too, have a problem  
10          with how this is all rolled out.

11                   MEMBER LANGHORST: I think the paragraph  
12          that was dropped --

13                   CHAIRMAN ALDERSON: Yes.

14                   MEMBER LANGHORST: -- took that into  
15          account. And, there had to be certain criteria that  
16          were met.

17                   DR. OXENBERG: And the staff proposed it.

18                   MEMBER LANGHORST: Right.

19                   DR. OXENBERG: The Commission did not  
20          accept it. And, they dropped -- and that was the  
21          paragraph that specifically stated results in one or  
22          more of the following as determined by an independent  
23          physician deemed qualified by the NRC and/or Agreement  
24          State, unintended or unexpected permanent functional  
25          damage to an organ or physiological system, a

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1 significant unexpected adverse health effect, or death.  
2 That's what you wanted; they didn't accept it.

3 CHAIRMAN ALDERSON: They didn't accept.  
4 Yes, we have Dr. Howe who hasn't spoken on this. Let  
5 her speak on this.

6 DR. HOWE: This is just for clarification.  
7 If you look at the slide, you'll see that C.1 ends with  
8 an "and". And, then, you go to C.2. So, C.2 does not  
9 stand alone. It has to meet the very high dose criteria  
10 that you see in C.1.

11 CHAIRMAN ALDERSON: No, I didn't follow  
12 that. So --

13 DR. OXENBERG: It's C.1, okay, the one  
14 slide, in addition to, "and", and the next slide,  
15 paragraph two.

16 CHAIRMAN ALDERSON: I see.

17 DR. OXENBERG: It's both. You have to  
18 have both conditions to have an abnormal occurrence.

19 CHAIRMAN ALDERSON: I see. So, if a  
20 radiopharmaceutical were given the wrong route of  
21 administration and resulted in a 100 rad exposure to --

22 DR. OXENBERG: Yes, sir.

23 CHAIRMAN ALDERSON: -- the bone marrow,  
24 that would be an abnormal occurrence? Is that what is  
25 being said?

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1 DR. OXENBERG: Yes, sir.

2 CHAIRMAN ALDERSON: I see.

3 MEMBER LANGHORST: But -- this is Sue  
4 Langhorst again.

5 CHAIRMAN ALDERSON: Yes.

6 MEMBER LANGHORST: But, if you meet the  
7 criteria of 35.3047 of an event dealing with an  
8 embryo/fetus or a nursing child, that automatically  
9 becomes an AO event because it is included in the group  
10 of if a power plant releases radioactive material and  
11 all these pregnant women are exposed.

12 CHAIRMAN ALDERSON: Okay.

13 MEMBER LANGHORST: Now, I will remind the  
14 committee that with -- since 2007 through 2015, we've  
15 had, like I said, one to three of these embryo/fetus  
16 doses that have been I-131 pregnant patients.

17 There has been 7 to 19 medical events that  
18 reached the current criteria. And, only in 2012 and  
19 2011 have there been any other AO events. So, they're  
20 all medical. And, so, that's what Congress sees are all  
21 these medical problems out there. And, so, that's what  
22 we were trying to help fix.

23 CHAIRMAN ALDERSON: Dr. Howe would like to  
24 comment again.

25 DR. HOWE: This is just for a historical

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1 perspective. With the 2000 Part 35 Rule, this is the  
2 first time that the embryo/fetus from a medical event  
3 was added to the regulations.

4 And, when they were trying to decide on what  
5 level of reporting there should be, they set the  
6 reporting level at the AO criteria so that medical  
7 events which are set at a much lower dose level, you  
8 wouldn't trigger. You'd only trigger at the abnormal  
9 occurrence level. And, that's why you see those two  
10 numbers matching up.

11 CHAIRMAN ALDERSON: So, Dr. Tapp's going  
12 to comment in a moment. So, I've got to still clarify  
13 this. I think maybe everyone else is very clear about  
14 this; I am not.

15 So, if we have the sort of thing that  
16 happens frequently in the clinic where a patient who is  
17 pregnant is there and doesn't know they're pregnant, and  
18 they get a bone scan and then the next week, they turn  
19 up and say, well, I was pregnant then. Now, we have just  
20 exposed the fetus during a normal situation, but with  
21 the regular dose given in the regular way and so on.  
22 Does that become an abnormal occurrence?

23 DR. HOWE: It's not a medical event, but,  
24 if the dose to the fetus exceeds the levels put in 30.47,  
25 which is not a medical event, then it meets the criteria

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1 of an abnormal occurrence and would be reported.

2 CHAIRMAN ALDERSON: Only if those levels  
3 of exposure are very high?

4 DR. HOWE: Yes.

5 CHAIRMAN ALDERSON: Thank you.

6 MEMBER LANGHORST: Which is 5 rem to the  
7 embryo/fetus.

8 CHAIRMAN ALDERSON: 5 rem?

9 MR. BOLLOCK: Right, so, in that case, they  
10 would have to -- the licensee would have determine the  
11 5 -- that the fetus got 5 rem from the bone scanner or  
12 whatever it was.

13 CHAIRMAN ALDERSON: Yes, right. All  
14 right. And, Katie Tapp had the next comment, then we'll  
15 go to Ron Ennis.

16 DR. TAPP: I was going to go back to the  
17 medical events themselves. You said there were 7 to --

18 MEMBER LANGHORST: 19.

19 DR. TAPP: -- 19 for a year. There is a  
20 change, though, in this III.C criteria that will reduce  
21 it slightly, where it is in the -- on the screen right  
22 now, it's C.1(b) that, in the past, it was exceeds 5 --  
23 exceeds 10 Gray to another organ or tissue not listed  
24 in A.

25 But, now it is, exceeds 10 Gray above what

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1 you had defined in a written directive.

2 So, this would deal with, if it's something  
3 happened, and they exceed the dose very closely to the  
4 written directive, but it was with the wrong patient,  
5 if they switched the vials but they're similar, that  
6 used to be reported. That will no longer report. It  
7 has to exceed the prescription by 10 Gray or the written  
8 directive by 10 Gray.

9 CHAIRMAN ALDERSON: Okay.

10 DR. TAPP: It will drop some.

11 CHAIRMAN ALDERSON: And, now, Dr. Ennis?

12 MEMBER ENNIS: So, for people on this side  
13 of the table who haven't had that much experience with  
14 this, just so I'm understanding, so, it's like a bit of  
15 a question for Sue to make sure I'm summarizing this  
16 correctly. The definition of AO is supposed to be  
17 something of big health and safety that, to the level  
18 that Congress ought to be notified?

19 MEMBER LANGHORST: I will say public  
20 health and safety. I think it's very important to put  
21 public --

22 MEMBER ENNIS: Thank you.

23 MEMBER LANGHORST: -- because that doesn't  
24 mean individual.

25 MEMBER ENNIS: Yes, very good. Right.

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1                   MEMBER LANGHORST: But, they assume it's  
2 individual, that should be --

3                   MEMBER ENNIS: And, the vast majority of  
4 these actually turned out to be medical, and the medical  
5 community at least as represented by ACMUI has weighed  
6 in, and that the criteria that are being used right now  
7 do not match that definition of a serious public health  
8 and safety issue in the vast majority of cases.

9                   Despite all that, what I'm hearing is that  
10 the regulation has decided to remain the same.

11                   DR. OXENBERG: But, the key is what's  
12 significant as determined by the Commission. That's  
13 the definition.

14                   MEMBER ENNIS: So, back to the Commission  
15 --

16                   DR. OXENBERG: So, the Commission says  
17 this is what we determined.

18                   MEMBER ENNIS: Right. So, the  
19 Commissioners decided to ignore the advice of the  
20 medical community on medical issues where basically all  
21 the authorized -- to keep things consistent when, the  
22 fact is, that the vast majority of the AOs are medical,  
23 but we still have the medical to be consistent with the  
24 minority of other situations. I don't understand that  
25 logic.

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1 CHAIRMAN ALDERSON: We have a comment from  
2 the audience.

3 MS. MCINTOSH: Yes, I'm actually an NRC  
4 employee. My name is Angela McIntosh. I just wanted  
5 to make a clarification that, with the AO criteria in  
6 general, there does not have to be a safety consequence  
7 in order for it to be considered a reduction to the  
8 degree of the public health and safety.

9 We did try to introduce the concept of a  
10 safety consequence in the medical arena only because we  
11 agreed with the committee that there were an awful lot  
12 of medical events that were easily making the AO  
13 criteria and, perhaps, misrepresenting the medical  
14 community in that regard.

15 And, so, as Dr. Oxenberg pointed out, we  
16 forwarded ACMUI's recommendation to the Commission to  
17 have these very high safety consequence criteria to  
18 include death and the Commission didn't agree.

19 So, the criteria largely have stayed in the  
20 medical area of AO criteria as they are except for, as  
21 Dr. Tapp mentioned, now, for the C.1(b), it has to exceed  
22 by 10 Gray rather than just meet 10 Gray.

23 So, we did -- we were able to get that piece  
24 through, but it's remained largely as it has because the  
25 Commission just didn't agree that, even in the medical

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1 area, that a safety consequence has to be adjusted.

2 MEMBER ENNIS: And, do we have an  
3 articulation from the Commission of their rationale?

4 MR. BOLLOCK: I could say a little, because  
5 that was actually Angela, Katie and myself that briefed  
6 the Commission on this two years ago or so. I can't  
7 speak for the Commission; I can't say verbatim what  
8 their reasoning was, but, essentially, in that  
9 briefing, the Commission -- the majority of the  
10 Commission, they just felt that the more reporting --  
11 the general understanding is that the more reporting,  
12 the better.

13 They just wanted to know what is going on  
14 in the medical field and they felt, because the  
15 reporting had been coming in, it should kind of maintain  
16 what we've had in the past. So, just, that was the  
17 general understanding that we got following our  
18 briefing of the Commission. We tried -- we argued the  
19 same points that you did. You know, we agree with you  
20 that, without serious medical consequence, we didn't  
21 believe it was necessary to report to Congress.

22 But, you know, the Commission, that's their  
23 prerogative. They felt that they wanted to maintain  
24 the similar reporting to what we've had.

25 CHAIRMAN ALDERSON: And, would it then,

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1 and I ask this as a question, is it then -- would it be  
2 reasonable for the next time that this group, the ACMUI,  
3 meets with the Commission to once again bring up this  
4 AO issue? Because, right now, it seems like that many  
5 people in the ACMUI remain frustrated by the way this  
6 is being done.

7 MR. BOLLOCK: And, that would be your  
8 prerogative.

9 CHAIRMAN ALDERSON: That would be our  
10 prerogative?

11 MR. BOLLOCK: Yes.

12 CHAIRMAN ALDERSON: Good, thank you.

13 Yes, Dr. Langhorst?

14 MEMBER LANGHORST: This is Sue Langhorst.

15 I don't think it'd do any good. Well, and,  
16 let me explain why, and nothing against -- the  
17 Commission wouldn't want to hear it and whatever, but  
18 I think this is pretty much a done deal. This what it's  
19 going to be. They're not going to re-review it for a  
20 time, and there'll be whole new set of Commissioners by  
21 the time it does make any difference.

22 And so I would just as the ACMUI to keep it  
23 in mind and fight the good fight next time and try to  
24 inch it down the road again.

25 CHAIRMAN ALDERSON: Right.

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1           So, I think that it's not unreasonable for  
2 us to consider putting it on our proposed agenda for our  
3 next meeting. And I, in fact, in the time that I've been  
4 on the ACMUI, that the Commissioners have changed  
5 dramatically, in fact.

6           So, this is a much different group now, and  
7 they might feel about it a different way. But, we will  
8 have to -- the ACMUI will have to be extremely careful  
9 about how it words what it has to say and so that it makes  
10 a specific, precise point without getting global.

11           Because, if it gets at all diffuse, I  
12 understand why the Commission will say, no change. All  
13 right, there are -- would anyone have more comments on  
14 this?

15           Dr. Zanzonico?

16           VICE CHAIR ZANZONICO: I have a question.  
17 What happens to these reports when they go to Congress?  
18 Is it -- I mean, I haven't even heard Senator Markey have  
19 a press conference about it.

20           MR. COLLINS: Yes, so, I would say that --  
21 and this is Dan Collins -- we rarely get any  
22 congressional questions about the abnormal occurrence  
23 reports that we send. Every once in a while, we may get  
24 a question from a particular member of Congress who  
25 wants some additional detail about what the

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1 circumstances of a specific case were. And, we provide  
2 that back and usually that kind of answers the mail, if  
3 you will.

4 If I might make another point, though, Dr.  
5 Ennis had a thought about the small numbers of actual  
6 events in totality when you compare it to all of the  
7 medical uses or actually any uses of radioactive  
8 materials that occur in any given year.

9 In our annual report, we do try to provide  
10 context to highlight the fact that this is a very, very  
11 small percentage of the actual total numbers.

12 So, if you go and look, you'll find language  
13 that says, you know, something along the lines of there  
14 are more than a million uses of radioactive material in  
15 any given year and that the five or six or seven events  
16 represent a very small percentage of it.

17 So, and, sometimes, we actually put the  
18 decimal points in there, but we do provide -- try to  
19 provide that context.

20 MR. OUHIB: Hello, this is Zoubir.

21 CHAIRMAN ALDERSON: Yes, Zoubir?

22 MR. OUHIB: Yes, I'm just thinking here,  
23 because I recall reviewing some of these cases over  
24 periods of 12 years.

25 I recall running into a case where a

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1 patient, well-educated in the medical field, was asked  
2 for a pregnancy test. And, that patient literally  
3 refused the test.

4 Well, what happened, after the injection,  
5 it turned out a couple weeks later, that that patient  
6 was actually pregnant.

7 The point that I'm making here is that, the  
8 institution might very well find themselves with such  
9 implications that they might decide that, if a patient  
10 is not willing to have a pregnancy test prior to the  
11 injection, they might simply say that we cannot do it  
12 and you'll have to find another institution. Perhaps  
13 that's what they need to do here.

14 I guess it's -- we need to think about the  
15 patient and the implications a little bit more about  
16 this.

17 CHAIRMAN ALDERSON: Yes, I wonder whether  
18 that's an issue of regulation or clinical practice?

19 MEMBER LANGHORST: It has nothing to do  
20 with the AO criteria.

21 CHAIRMAN ALDERSON: I agree.

22 MEMBER LANGHORST: It's --

23 CHAIRMAN ALDERSON: I agree.

24 MEMBER LANGHORST: Yes.

25 CHAIRMAN ALDERSON: I mean, it's a true

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1 statement but it's unrelated.

2 All right, are there any other comments  
3 about AO criteria?

4 Hearing none, thank you, Dr. Oxenberg.

5 And, now, we'll move on to another  
6 uncontroversial subject with Dr. Palestro, training and  
7 experience for all modalities.

8 MEMBER PALESTRO: All right, I'm going to  
9 present the report of the standing subcommittee on  
10 training and experience requirements.

11 And, I would like to acknowledge and thank  
12 the members of the subcommittee Dr. Sue Langhorst,  
13 Darlene Metter, John Suh and Ms. Laura Weil for their  
14 invaluable contributions and patience with me.

15 This is a newly formed standing  
16 subcommittee and our charge is to periodically review  
17 the training and experience requirements that are  
18 currently in effect, making recommendations for changes  
19 as warranted.

20 It would probably behoove us to review once  
21 again some background to the formation of the  
22 subcommittee.

23 Beginning about two years ago in 2014,  
24 stakeholders expressed concerns that the 10 CFR 35.396  
25 training and experience requirements currently in

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1 effect, which is 700 hours in total, adversely affects  
2 patient care by limiting use of parenterally  
3 administered Alpha and Beta emitting  
4 radiopharmaceuticals to physicians who complete the  
5 requisite 10 CFR 35.390 training and experience  
6 requirements, the end result being a shortage of  
7 authorized users.

8 At that time, the subcommittee of the  
9 ACMUI, which was charged with looking into the situation  
10 provided a report in March of 2016 and could not find  
11 evidence to support these concerns.

12 Therefore, the subcommittee recommended  
13 against changing the training and experience  
14 requirements that are currently in effect.

15 However, as a corollary to that or as an  
16 outcome of our work, the subcommittee also noted that  
17 over the nearly 15 years since these requirements went  
18 into effect, new radiopharmaceuticals, both diagnostic  
19 and therapeutic, have been developed.

20 Furthermore, the educational paradigm has  
21 evolved from experience-based to competency-based.

22 Consequently, the subcommittee  
23 recommended, and the ACMUI approved, your creation of  
24 a standing subcommittee to periodically review and,  
25 when warranted, recommend changes to the training and

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1 experience requirements.

2 So, what's the focus of the standing  
3 subcommittee? Part 35 of the Code of Federal  
4 Regulations pertains to the medical use of byproduct  
5 material.

6 And, the specific parts of Part 35 that will  
7 be the initial focus of the subcommittee includes  
8 Subpart D, unsealed byproduct material, a written  
9 directive not required, 35.190, training for update  
10 dilution and excretion studies, 35.290, training for  
11 imaging and localization studies and Subpart E, the  
12 unsealed byproduct material for which a written  
13 directive is required.

14 35.390, training for use of unsealed  
15 byproduct material for which a written is required,  
16 35.392, training for the oral administration of sodium  
17 iodide I-131 requiring a written directive in  
18 quantities less than or equal to 1.22 gigabecquerels or  
19 33 millicuries.

20 35.394, training for the oral  
21 administration of sodium iodide I-131 requiring a  
22 written directive in quantities greater than 1.22  
23 gigabecquerels or 33 millicuries.

24 35.396, training for parenteral  
25 administration of unsealed byproduct material

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1 requiring a written directive.

2 So, the subcommittee is charged with the  
3 responsibility to, quote, unquote, periodically review  
4 the training and experience requirements.

5 However, what constitutes a reasonable  
6 periodic review, a reasonable length of time? Well,  
7 it's been 15 years since the regulations were revised  
8 and it seems to the subcommittee that 15 years is too  
9 long an interval.

10 At the other extreme, one year probably is  
11 neither a practical nor a useful interval -- interval,  
12 excuse me.

13 The subcommittee believes that the  
14 training and experience requirements should be reviewed  
15 at least once every five years and more frequently if  
16 warranted.

17 The subcommittee also is not certain, and  
18 it's really unclear to us how training and experience  
19 changes in once section of Part 35 will affect training  
20 and experience requirements in other sections.

21 Could there be an implication of changing  
22 say, 35.390 on 35.290? And, the answer is we don't know  
23 for sure.

24 The subcommittee is also uncertain, given  
25 the time needed to make changes to Part 35 and the status

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1 of the most recent changes to Part 35, how quickly any  
2 proposed changes to Part 35 training and experience  
3 requirements can be considered and instituted.

4 An important issue that the subcommittee  
5 will need to address is competency. In other words,  
6 what constitutes satisfactory completion of training  
7 and experience requirements?

8 Is merely completing a predetermined  
9 number of hours of training and experience equal to  
10 competency or can it be equated with competency?

11 At the present time, this really is not an  
12 issue because the vast majority of physicians seeking  
13 authorized user status satisfy the training and  
14 experience requirements by obtaining certification  
15 through a medical specialty board whose certification  
16 process is recognized by the NRC or by an Agreement  
17 State.

18 The situation becomes different, however,  
19 for individuals or for physicians seeking authorized  
20 user status through an alternate pathway.

21 For example, it's been suggested that 80  
22 hours of training and experience is sufficient for  
23 hematologists to administer one or perhaps two  
24 different parenterally administered therapeutic  
25 radiopharmaceuticals to patients with malignant

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1 diseases.

2 Number of hours assigned, how will a  
3 consistency and quality of the training and experience  
4 be assured and how competency be determined?

5 Would a medical specialty board or boards  
6 assume the responsibility for establishing a curriculum  
7 and administering a, quote, unquote, certification  
8 examination? If so, what criteria would the NRC use to  
9 recognize this board?

10 How many different categories of  
11 therapeutic radiopharmaceuticals can the NRC and  
12 Agreement States manage for medical licenses?

13 So, what's the plan for our subcommittee,  
14 for the standing subcommittee?

15 First and foremost, we recognize that any  
16 recommendation for or against changes in training and  
17 experience should be made to ensure that the  
18 requirements and provisions in Part 35 which, quote,  
19 provide for the radiation safety of workers, general  
20 public, patients and human research subjects are  
21 satisfied, end quote, while simultaneously ensuring  
22 that patient access to these procedures is not  
23 unnecessarily compromised.

24 So, the subcommittee intends to begin a  
25 thorough a review of the training and experience

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1 requirements and the CFR Subparts D and E and to make  
2 recommendations for or against changes in these  
3 training and experience requirements for presentation  
4 at the spring 2017 meeting.

5 However, I want to make it abundantly clear  
6 that we don't anticipate being able to make  
7 recommendations for all of these Subparts at the spring  
8 meeting. We're going to take it one step at a time, so  
9 I don't want any misunderstanding there.

10 In addition, the subcommittee welcomes,  
11 and we've already received letters and comments,  
12 stakeholder and NRC input throughout the process. We  
13 clearly cannot accomplish our task operating in a  
14 vacuum.

15 We also, along that vein, ask the full ACMUI  
16 for suggestions on how to improve our considerations and  
17 our plans.

18 And, finally, we request that the medical  
19 team appoint an NRC contact or resource to assist us in  
20 our work.

21 Thank you.

22 CHAIRMAN ALDERSON: Thank you, Dr.  
23 Palestro.

24 All right, this report is now open for  
25 discussion by the ACMUI. Do we have comments?

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1 Comments or questions? Apparently, this very thorough  
2 report has not resulted in any initial comments or  
3 questions.

4 I'll turn to the audience and ask if there  
5 are any comments there?

6 Oh, yes, Mr. Green?

7 MR. GREEN: Yes, just for Dr. Palestro,  
8 it's quite a large task that you had in front of you to  
9 look at this whole spectrum of all of the Subpart D and  
10 Subpart E uses.

11 It seems like, from what I've seen on the  
12 agenda, that it's probably 35.396 is the most interest.  
13 Is that one that you'll take up first?

14 MEMBER PALESTRO: Yes, it's certainly been  
15 the lightning rod for the controversy that has gone on.  
16 I'm not sure if that's going to be the one we take up  
17 first, because I think we need to figure out how to  
18 approach the matter. And, I'm not sure we've solved  
19 that yet.

20 And, then, taking up any one of these  
21 particular categories, we also need to think about the  
22 ramifications on another category.

23 For example, on 35.390, if we suddenly  
24 decide to come up with say, a reduced number, X of hours,  
25 well, what about 35.290? Does that then become

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1 applicable to that? Is that appropriate to consider  
2 that? I'm just not sure.

3 CHAIRMAN ALDERSON: Good.

4 Yes, we have a comment from the audience.  
5 Ms. Fairobent?

6 MS. FAIROBENT: Thank you, Dr. Alderson.  
7 Lynne Fairobent with the American Association of  
8 Physicists in Medicine.

9 Dr. Palestro, I applaud you all for  
10 attempting to tackle this initiative. However, I think  
11 I might make a different suggestion and step back and  
12 take a look and start with a clean sheet of paper and  
13 look at T&E from a high level perspective.

14 And, if we started with a clean sheet of  
15 paper today, how would we write T&E requirements for all  
16 of the medical sections rather than looking at  
17 individual subparts?

18 We have had a number of issues that have  
19 surfaced since, I believe we started the drafting of the  
20 revision to Part 35 in 1998.

21 There has been a lot that we've learned over  
22 the history of the various discussions and debates and  
23 changes that have occurred. We are still awaiting  
24 final changes to the T&E sections that are included in  
25 the major revision right now at the Commission.

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1           And, I think maybe it's time that we all  
2 stood back and just say, with a blank sheet of paper,  
3 if we started from square one today, what would we draft  
4 T&E without any preconceived notions of what's  
5 currently there? I think it might be a very different  
6 outcome than what we would have in the current  
7 regulation.

8           And, AAPM would be happy to have any  
9 discussions that are applicable or able to happen with  
10 the ACMUI subcommittee.

11           CHAIRMAN ALDERSON: Thank you.

12           We have another comment from the audience.

13           DR. DIAMOND: Thank you, Dr. Alderson. My  
14 name is Dr. Morton A. Diamond from Fort Lauderdale,  
15 Florida.

16           I was planning to speak later, but Dr.  
17 Palestro's comments have prompted me to address you at  
18 this time in very brief fashion.

19           I speak from a perspective afforded to very  
20 few, a physician forced to leave medical practice  
21 because of multiple serious medical issues including  
22 some Stage IV Non-Hodgkin's Lymphoma all attributed to  
23 my military service in Vietnam.

24           A patient in a clinical trial, who, I am  
25 told, I am the sixth person ever to receive Zevalin

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1 therapy as first line therapy for incurable lymphoma.  
2 So, please understand my hoarseness and breathlessness  
3 are part of my medical issues.

4 I respect the goal of this committee, safe  
5 administration of radioisotopes in order to protect the  
6 patient, the caregiver and the public citizen.

7 With 80 hours of required instruction,  
8 endocrinologists are safely administering radioactive  
9 iodine. But for a medical oncologist to administer  
10 Zevalin, as you know, 700 hours are required.

11 It is clear that a radioisotope can be given  
12 safely without onerous educational requirements.

13 I live in South Florida. Though I did not  
14 feel a single raindrop or a wisp of wind, I was battered  
15 leaving home by four cancelled flights and shuffling  
16 between two airports as a result of Hurricane Matthew.

17 My sole purpose in appearing today was to  
18 try to defend and save Zevalin. But, as I listen to the  
19 discussion, I realize that the issue is not Zevalin.

20 I am reminded of the infamous killer in  
21 Ancient Greece, Procrustes. Every victim had to fit  
22 perfectly into his bed. If the victim were too tall,  
23 the limbs were cut off. If the victim were too short,  
24 the body was stretched with ropes to fit into bed, not  
25 one-size-fits-all, all sizes fit one.

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1           It seems that this honorable committee is  
2 trying to have a single Procrustean answer for all  
3 radioisotopes, alpha and beta emitters.

4           Indubitably, more and more radioisotopes  
5 will be developed for diagnosis and treatment. This  
6 must be addressed promptly. Patients are demanding new  
7 and better treatment. Payers are demanding  
8 cost-effective therapy.

9           As a result, I believe that legislatures  
10 and the media will be increasingly mindful of your  
11 decisions and your rules. Heavy-handed Procrustean  
12 regulations will no longer be accepted.

13           I urge you, I urge you to develop a system  
14 of required competencies for administration of  
15 radioisotopes.

16           I believe that this can be accomplished  
17 with dispatched. And, at the same time, the patient,  
18 caregiver and public citizen would be protected.

19           Patients cannot wait for another four or  
20 five years for new regulations to be promulgated.

21           I leave you with this thought, medications  
22 and humans have much in common. We are born, we live  
23 and we die. For a medicine to die because another  
24 affects a higher rate of cure or eases pain more safely  
25 or prolongs useful life is the essence of pharmaceutical

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1 progress.

2 But, for a medicine to die slowly and  
3 tortuously in the full flower of its efficacy because  
4 of overbearing regulatory restriction is a tragedy no  
5 less, a tragedy no less than the tragedy of human death  
6 in the full flower of life.

7 Thank you very much, Dr. Alderson.

8 CHAIRMAN ALDERSON: Thank you, sir.

9 All right, here's another comment from the  
10 audience.

11 MS. TOMLINSON: Cindy Tomlinson from  
12 ASTRO.

13 I'm just going to read this because, if I  
14 don't, it'll be terrible.

15 Chairman Alderson, members of the ACMUI,  
16 NRC staff, thank you for allowing me to provide this  
17 statement on training and experience requirements for  
18 the administration of radiopharmaceuticals on behalf of  
19 ASTRO.

20 ASTRO is the largest radiation oncology  
21 society in the world with more than 10,000 members who  
22 specialize in treating patients with radiation therapy.

23 As the leading organization on radiation  
24 oncology, biology and physics, the society is dedicated  
25 to improving patient care through education, clinical

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1 practice, advancement of science and advocacy.

2 ASTRO's highest priority has always been  
3 ensuring patients receive the safest, most effective  
4 treatments.

5 Radiopharmaceuticals, including Zevalin,  
6 are highly effective in treating cancer, but also  
7 potentially hazardous drugs with possible harmful  
8 effects to both the patient and the public if not used  
9 correctly and under the supervision of a highly trained  
10 physician.

11 ASTRO strongly opposes any reduction in the  
12 T&E requirements found in 10 CFR 35.390, training for  
13 the use of unsealed byproduct material for which a  
14 written directive is required.

15 Under this section, the NRC requires an  
16 authorized user to be certified by a medical specialty  
17 board recognized by either the NRC or an Agreement State  
18 or has completed 700 hours of T&E in, quote, basic  
19 radionuclide handling techniques applicable to the  
20 medical use of unsealed byproduct material requiring a  
21 written directive.

22 ASTRO believes that these requirements are  
23 appropriate, protect the safety of patients, the  
24 public, and practitioners and should not be changed.

25 The rigorous T&E requirements contribute

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1 to the excellent safety record of radiopharmaceuticals.  
2 We believe that it is important that the person  
3 administering the radiopharmaceutical is appropriately  
4 trained in the safe handling, exposure risks and the  
5 management of side effects of radiation.

6 In addition to ensuring patient safety,  
7 ASTRO is unaware of data that suggests a shortage of AUs.  
8 ASTRO asked NRC staff for the number of AUs licensed  
9 under 35.390 to assess whether there is a shortage of  
10 AUs, but learned that the NRC only tracks AUs license  
11 under 35.300.

12 Without being able to identify which AUs  
13 are licensed under 35.390 and 35.300, it is not possible  
14 to confirm whether there is an actual AU shortage or a  
15 perceived one.

16 Additionally, ASTRO has not heard what  
17 would be an ideal number of AUs. ASTRO estimates that  
18 there are approximately 2,200 radiation oncology  
19 facilities in the United States which means, aside from  
20 the many nuclear medicine trained AUs nationwide, there  
21 are likely enough AUs just among the radiation  
22 oncologists.

23 Indeed, ASTRO is not aware of a perceived  
24 shortage of radiation oncologists anywhere in the  
25 country. ASTRO's members are ready to care for

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1 patients needing any radiopharmaceutical.

2 Results from the ASTRO 2016 membership  
3 survey show that those medical directors responding,  
4 over half reported current use or plans to use  
5 radiopharmaceuticals in the next 18 months.

6 When asked to indicate the reason or  
7 reasons radiopharmaceuticals are not being  
8 administered, 74 percent said that another department  
9 is responsible, 33 said that there were not enough  
10 patients to make it a viable part of their practice and  
11 25 percent indicated that radiopharmaceuticals were not  
12 a critical component of their practice. Only 9 percent  
13 said that they were not comfortable administering  
14 radiopharmaceuticals.

15 In conclusion, for the reasons stated  
16 above, ASTRO opposes a reduction in the training and  
17 experience requirements for 10 CFR 35.390 and supports  
18 the ACMUI's standing subcommittee on training and  
19 experience requirements plan to thoroughly review the  
20 current requirements and looks forward to providing  
21 input to the subcommittee as it begins its  
22 deliberations.

23 Thank you.

24 CHAIRMAN ALDERSON: Thank you.

25 And, we have another comment from the

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1 audience.

2 MS. BUNNING: Hi, Sue Bunning with the  
3 Society of Nuclear Medicine and Molecular Imaging.  
4 Thank you for allowing me to be here today.

5 Dr. Ghesani was to deliver a brief  
6 statement but he got called away on an urgent matter.

7 So, I don't have his written remarks, but  
8 we've talked about this before. We fully support the  
9 creation of this subcommittee and we look forward to the  
10 work that you're going to do.

11 The SNMMI Board of Directors met a couple  
12 weeks ago and this was on the agenda. And, they believe  
13 that they could be useful, helpful. We want to be a  
14 resource. We are forming an internal work group for  
15 this and any way that this group deems appropriate will  
16 be willing to be helpful and support your work.

17 Thank you.

18 CHAIRMAN ALDERSON: There seem to be no  
19 other comments from the audience at this time.

20 Are there some comments from the ACMUI?

21 Dr. Zanzonico?

22 VICE CHAIR ZANZONICO: I just have a  
23 question for the NRC staff. So, a change in the  
24 training and education requirements, the number of  
25 hours, for example, that would be rulemaking, correct?

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1 MR. BOLLOCK: Yes, correct.

2 VICE CHAIR ZANZONICO: And, so, the usual  
3 time frame for that?

4 MR. BOLLOCK: Right. Once, yes, once we  
5 have a basis for change and would work through the  
6 rulemaking process.

7 VICE CHAIR ZANZONICO: One other question,  
8 if I may?

9 CHAIRMAN ALDERSON: Please.

10 VICE CHAIR ZANZONICO: Could anyone sort  
11 of tell us the history or into where the 700 hours  
12 originated from?

13 MR. BOLLOCK: Yes, we can -- we actually,  
14 our staff actually worked on that. I don't know, if  
15 Maryann, you want to speak on it or you want me to?

16 DR. ABOGUNDE: And, when you say 700 hours,  
17 are you referring to the 390 or just the hours in  
18 general? Because there is 80 hours for diagnostic --  
19 or 200 hours for diagnostic and then 700 hours which  
20 includes the classroom and lab and the --

21 VICE CHAIR ZANZONICO: Yes, that is  
22 correct, the classroom.

23 DR. ABOGUNDE: The second one?

24 VICE CHAIR ZANZONICO: Yes.

25 DR. ABOGUNDE: So, what NRC --

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1 CHAIRMAN ALDERSON: Please identify  
2 yourself.

3 DR. ABOGUNDE: I apologize, Maryann  
4 Abogunde from NRC.

5 So, when the medical regulations were  
6 initially included in 10 CFR, the T&E training  
7 requirements were specifically just with hours. And,  
8 they were -- well, before they were specifically with  
9 hours, but more of this in guidance documents.

10 In the regulations, however, they were more  
11 generic and performance-based and so, it referenced  
12 words like -- yes, so they basically said for you to  
13 complete your -- for you to have training and  
14 experience, you should have significant experience in  
15 different therapeutic uses or diagnostic uses.

16 And, so, moving forward, after that, we had  
17 specifics in terms of hours in our guidance documents.

18 And, so, at about 1987, that's when we  
19 formalized our guidance documents that started to  
20 include board certificates. And, the board  
21 certificates were based on those hours that we had in  
22 our guidance documents, but they weren't formalized at  
23 the time in our regulations.

24 And, so, moving forward, by about 2000,  
25 that was when we formally included in our regulations

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1 the actual number of hours that we wanted for our  
2 training and experience for the different modalities.

3 And, so, for the therapeutic uses, we  
4 started out with the 700 hours from there. But, we  
5 don't have any evidence that showed how the number of  
6 hours came about from the beginning.

7 VICE CHAIR ZANZONICO: Just to follow up,  
8 I gather that they were originally based on some board  
9 requirement. So, was that figure from a board  
10 requirement specifically?

11 DR. ABOGUNDE: Can you repeat that  
12 question?

13 VICE CHAIR ZANZONICO: Yes. I gathered  
14 from one of the things you said that that 700 hour  
15 requirement was based on a board requirement.

16 DR. ABOGUNDE: No.

17 VICE CHAIR ZANZONICO: So, you know, did I  
18 have a sense --

19 DR. ABOGUNDE: Initially --

20 VICE CHAIR ZANZONICO: Initially?

21 DR. ABOGUNDE: Yes, so the board  
22 certificates came in, you know, for approval for us to,  
23 you know, approve their different programs and they came  
24 in based on the hours that we had specified.

25 VICE CHAIR ZANZONICO: Oh, so you guys

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1 specified to the board what would satisfy your  
2 requirements --

3 DR. ABOGUNDE: Yes.

4 VICE CHAIR ZANZONICO: -- for recognition,  
5 so to speak?

6 DR. ABOGUNDE: Yes.

7 VICE CHAIR ZANZONICO: Okay. But, I'm  
8 still not understanding, that number seems critical in  
9 all of this because we're parsing numbers. So, I'm  
10 trying to understand what the origin, the rationale for  
11 that number of hours originated from.

12 MS. HOUSEMAN: Hi, my name is Esther  
13 Houseman with the NRC Office of the General Counsel.

14 In the proposed rule around 2000 that  
15 Maryann was referencing, the number of hours for  
16 therapeutic uses was much lower. And, you can see in  
17 the Statement of Considerations for the final rule that  
18 the NRC received several adverse comments on that much  
19 lower number.

20 There were some public commenters who  
21 stated that that number was too low and that number was  
22 changed to 700 in response to those adverse comments.

23 I apologize, I don't have the reference on  
24 me right now, the actual Federal Register cite for that,  
25 but that was discussed in the Federal Register notice

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1 for the final rule.

2 VICE CHAIR ZANZONICO: And, so, what I'm  
3 inferring is that that number of hours did not actually  
4 originate in the sense with the NRC, it was in response  
5 to comments to an NRC proposed lower number of hours?

6 MS. HOUSEMAN: Yes.

7 VICE CHAIR ZANZONICO: And, what was that  
8 lower number of hours at that time?

9 MS. HOUSEMAN: I believe it was 80, but I  
10 would have to double check the proposed rule.

11 VICE CHAIR ZANZONICO: I guess what I'm  
12 trying to understand is, I mean, any number is arbitrary  
13 to a certain extent, but there should be, hopefully, a  
14 compelling logic in coming up with some number of hours.  
15 I'm just trying to understand what that logic was.

16 CHAIRMAN ALDERSON: Dr. Palestro, the  
17 chair of the committee?

18 MEMBER PALESTRO: Yes, we have had -- the  
19 subcommittee has had the same difficulty in trying to  
20 understand exactly how all of these numbers developed  
21 and it's not really clear. And, there's probably a  
22 certain amount of arbitrariness to it.

23 What we're trying to do and, admittedly,  
24 it's not easy, is we're trying to put hours aside for  
25 the moment and define competency. What does it take for

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1 an individual to be competent as an authorized user,  
2 didactic training and so forth and so on, experience,  
3 without categorizing or without classifying hours.

4 Ultimately, we'll have to come up with some  
5 sort of hours. But, hopefully, we'll be able to do a  
6 job of basing it in some sort of fact or some sort of  
7 reference that we can point to.

8 For example, and this is just off the top  
9 of my head, if we're talking about didactic lectures in  
10 radiation safety, we know the elements that we want to  
11 be covered.

12 How many hours does it take? Well, I  
13 really don't know off the top of my head but, perhaps  
14 there is a medical physics course given at a university  
15 that covers these same topics and you look at it and you  
16 say it's 8 hours or 16 hours.

17 In that sense, I think it makes the hours  
18 a bit more logical, rational approach to it. So, as I  
19 say, at the moment, we're putting hours aside. The  
20 first step is to define competency and then try to  
21 determine how you achieve it.

22 VICE CHAIR ZANZONICO: Can I just follow  
23 up?

24 CHAIRMAN ALDERSON: Okay, follow up then I  
25 have --

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1 VICE CHAIR ZANZONICO: So --

2 CHAIRMAN ALDERSON: -- Dr. Langhorst was  
3 next after.

4 VICE CHAIR ZANZONICO: I agree completely,  
5 there should be competency-based and less ad hoc and so  
6 forth.

7 But, when I think about 700 hours, that's  
8 a full year of matriculation at college. I mean, that's  
9 -- it's more -- it's actually more than that if you count  
10 up numbers of hours for typical courses for full-time  
11 matriculated students.

12 It just strikes me as a lot of hours for any  
13 sort of thing. But, I agree, competency is the key.

14 DR. ALDERSON: Dr. Langhorst and then Dr.  
15 Ennis?

16 MEMBER LANGHORST: And, so it's not credit  
17 hours, it's hours, it's not credit hours? Heaven  
18 forbid we have to pay for that.

19 But, I think we are kind of, as Ms.  
20 Fairobent had suggested, trying to start from scratch.  
21 Because what -- I don't think we're going to find the  
22 rationale because it wasn't there, put down, it wasn't  
23 documented.

24 But, the number of hours will be helpful  
25 once we set the competency and I don't think we want to,

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1       okay, so rad safety has to be this many hours and this  
2       has --- we're not looking at that fine detail.

3               But, the number of hours helps be a  
4       measurable guide or measurable level of training and  
5       experience that NRC can use in their regulation and that  
6       we all can recognize.

7               And, this, then, also, not only impacts the  
8       alternate pathway, but it impacts what the boards are  
9       judged against, too. Because they are judged against  
10      whether they meet that criteria in providing their  
11      training and experience.

12              Doesn't mean that the boards don't go well  
13      beyond it, but I just wanted to support Dr. Palestro in  
14      that. We're looking at competency, but we may come back  
15      to hours because it's a ready measure that we all can  
16      agree upon.

17              CHAIRMAN ALDERSON: Dr. Ennis?

18              MEMBER ENNIS: So, thinking about 700  
19      hours, just since that's kind of out there, for a 40-hour  
20      work week, we're talking about less than 20 weeks, four  
21      months.

22              I think about the depth, the amount of time  
23      it took me to get the depth so that I feel confident and  
24      comfortable administering Xofigo and all the possible  
25      scenarios that could come up, and not just for the

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1 routine. I mean, I guess, this is a big part of it for  
2 me.

3 If everything goes well and it's a routine  
4 thing, much less training is necessary. But, what  
5 we're trying to do is protect the public and protect  
6 patients for essentially all possible variabilities and  
7 that requires a lot more depth of understanding than  
8 might be presented.

9 And, my thinking that four or five months  
10 seems very short, frankly, for the amount of depth  
11 necessary to really know how to handle all  
12 radiopharmaceuticals properly in essentially all  
13 scenarios when you're out in practice on your own,  
14 whoever you might be.

15 CHAIRMAN ALDERSON: Yes, Dr. Dilsizian?

16 MEMBER DILSIZIAN: I just wanted to bring  
17 up the fact that we keep talking about competency versus  
18 hours. But, take any medical subspecialty training,  
19 competency comes after specific number of years of  
20 training.

21 For example, to become a competent  
22 internist, you have to spend three years of training.  
23 So, I think that we're making this assumption that  
24 competency can be defined with a short training.

25 For example, if you're going to become a

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1 good surgeon, you really need to do four years of surgery  
2 and then be competent.

3 In essence, you can't say, well, in six  
4 months, I learned to do all of the surgery. Let me take  
5 my competency test and pass it. There's no such thing,  
6 surgeons still have to do a certain number of years.  
7 Internists still have to do a certain number of years.

8 Just because you're competent in six  
9 months, it doesn't mean that, you know, you can take the  
10 test earlier.

11 So, I just wanted to -- so competency goes  
12 hand in hand, but there's a predefined training period  
13 for every subspecialty.

14 CHAIRMAN ALDERSON: So, seeing no other --

15 VICE CHAIR ZANZONICO: Yes, one --

16 CHAIRMAN ALDERSON: Certainly, Dr.  
17 Zanzonico?

18 VICE CHAIR ZANZONICO: The reason why I ask  
19 is, it's easy to be dismissive and critical at the number  
20 of hours because it appears so ad hoc. So, I'm just  
21 trying to understand, was there originally a logic and  
22 a thought process that rationally supported that that  
23 we're just not understanding?

24 But, I, you know, I fully appreciate that  
25 there is a sort of an in-residence requirement for

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1 experience in any field to become fully competent.

2 CHAIRMAN ALDERSON: So, Dr. Bollock?

3 MR. BOLLOCK: Yes, just to go into a little  
4 bit more detail and the 2002 rule, there was -- because  
5 I talked with staff that had worked on it back at the  
6 time, so in the late '90s, '97, '98 when this was coming  
7 out.

8 You know, prior to 2002, it was 80 hours for  
9 unsealed sources. But, a lot of the mindset, at least  
10 of the staff, was this was for P32 and iodine.

11 Note that there were other  
12 radiopharmaceuticals coming down and, you know, the  
13 therapeutic radioactive drugs coming down and the  
14 importance of those, that was one of the main reasons  
15 for getting into opening up the training and experience.

16 At the same time, the diagnostic training  
17 and experience alternative to board certifications was  
18 1200 hours.

19 So, that was actually -- the initial  
20 thought was go to 1200 hours for therapeutic. And, this  
21 is in, again, this is like NRC going out talking to the  
22 communities and working out.

23 So, and in that process, they recognized in  
24 opening alternate experience for both diagnostic and  
25 therapeutic, they recognized there was a lot of the

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1 redundancies in the training, 500 hours of experience  
2 given for the diagnostic uses.

3 So, that is basically how the numbers got  
4 down from 1200 to 700. And, then, comparing diagnostic  
5 and therapeutic, I mean, these are, you know, it's --  
6 I mean, you know better than I do, diagnostic, these are  
7 much, much lower doses of radiation than the  
8 therapeutic. There's different reasons, different  
9 things in the diagnostics with elations and certain  
10 things you do with -- in the diagnostic practice.

11 But, those were the thoughts. So, there  
12 was a lot of thought in there. And, I think they did  
13 go back to, yes, there is some time frame of, you know,  
14 that experience. The majority of the 700 hours is the  
15 500 hours of work experience, practical experience  
16 under an authorized user, that is the majority of the  
17 700. The 200 hours is the classroom, just, you know,  
18 basic radiation safety use, safety that.

19 So, there, yes, it wasn't necessarily  
20 arbitrary. There was thought in that. It did go, you  
21 know, back and forth. But, there was a time that it was  
22 considered -- they were considering 1200 just because,  
23 again, diagnostic which was much, much lower, while  
24 you're injecting much, much lower levels of radiation  
25 to a patient for therapeutic. So, you know, maybe

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1 therapeutic should be 1200.

2 So, there -- all these things were  
3 discussed back then. And, it was worked out to come up  
4 with the 700 as an alternative to the board  
5 certifications which is much, much more in depth and,  
6 you know, yes, years, residencies.

7 You know, this is the alternative to going  
8 for doctors that want to prescribe this going to another  
9 residency and taking three-plus years. You know, this  
10 was a -- it's the alternate pathway.

11 And, yes, one of the questions I may have  
12 for the -- for Dr. Palestro's subcommittee and the  
13 ACMUI, as we try to -- as the NRC tries to understand  
14 that going forward, if we're going to make, you know,  
15 to make changes, we want to stay in line with what the  
16 medical community does in educating. You know, we  
17 don't want to be -- we don't want to stay on the path  
18 of hours if the medical community has other means from  
19 their boards and everything to go for competencies.

20 And, so, we want to stay, you know, we don't  
21 want to go too far off that. We want to stay in line  
22 with, you know, general medical practice and what the  
23 boards do. So, that is something that we, as the NRC,  
24 you know, we rely on you for that input and the medical  
25 community as a whole for that input.

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1 CHAIRMAN ALDERSON: Good. So, I'd like to  
2 compliment the subcommittee on getting this process  
3 started. And, I do want to emphasize that this process  
4 is getting started, it isn't over. It isn't probably  
5 going to be over extremely soon if the work that is done  
6 is thorough. And, I believe that Dr. Palestro and his  
7 subcommittee plan on doing thorough work.

8 I would also point out that all of the  
9 things that the boards do, those -- the ability that  
10 people eventually demonstrate is the result of an  
11 educational process and then a learning outcome that is  
12 documented by an assessment.

13 And, so, ultimately, I think whatever we  
14 come up with is going to have to contain those elements.  
15 There's going to have to be a learning process and  
16 there's going to have to be an assessment.

17 And, in line with maintenance of  
18 certification, which, itself, is sometimes come into  
19 harder times these days because it wasn't administered  
20 by the boards in exactly perhaps the ideal way.

21 But, a maintenance of competence or  
22 certification is also going to be, I think, important.  
23 It's not just an initial amount of training and some sort  
24 of assessment, but the fact that people who want to  
25 continue without the board certification or a

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1 maintenance of certifications through that board that  
2 they are still capable, will have to find another way  
3 to be reassessed, to demonstrate, again, on a periodic  
4 basis that they know the safety and security principles.

5 So, it's a large and complex process and I,  
6 again, compliment the committee on starting with the  
7 concept that, as you just mentioned also, Dr. Bollock,  
8 that not all types of use of radionuclides are as  
9 complicated as other types so that one size of education  
10 or type may not fit all of these processes.

11 On the same -- at the same time, we don't  
12 want to inhibit patient access to radionuclide  
13 therapies in an unreasonable way.

14 So, I also urge the committee to not sort  
15 of just start with the easy things and go slowly in time,  
16 but to grasp the issues that the public is asking us to  
17 grasp and try to get into what we can do to assess whether  
18 those are currently handled in the correct way through  
19 the current regulations or whether a new approach needs  
20 to be approached.

21 DR. DIAMOND: May I have 15 seconds?

22 CHAIRMAN ALDERSON: Yes, Doctor, you may  
23 speak again. Please identify yourself again, Doctor.

24 DR. DIAMOND: Morton Diamond.

25 I appreciate, as a patient, that this

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1 committee is addressing competencies. But, I wish to  
2 make one comment.

3 One can gain competency without having to  
4 know every potential complication. I recently saw a  
5 wonderful movie, Sully, and when Captain Sully ran into  
6 this problem in New York City in Manhattan, he didn't  
7 know and he asked his co-pilot to look up in the book  
8 how to deal with the problem. Unfortunately, the  
9 answer wasn't in the book.

10 So, please, I ask you, respectfully, to  
11 reject the notion that competency means the individual  
12 must understand and address every single possible  
13 complication. It's not reasonable.

14 Thank you, Dr. Alderson, thank you, ladies  
15 and gentlemen.

16 CHAIRMAN ALDERSON: Fine, thank you.

17 And, thank you, Dr. Palestro, and the work  
18 of this committee. And, we look forward to hearing your  
19 reports on a regular basis.

20 All right, at this particular time, are  
21 there any comments on this subject from the people that  
22 are on the phone? Would we like to have -- are there  
23 any people who are not in the room here who would like  
24 to comment on this subject?

25 OPERATOR: If anyone on the audio lines

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1 does have a question, please press star followed by the  
2 number one at this time. You will be prompted to record  
3 your name and then announced into conference.

4 Sir, we've had no one queue up at this time.  
5 Thank you.

6 CHAIRMAN ALDERSON: No one wants to speak?  
7 Very good. Hearing that no one wants to speak on the  
8 line, I believe that this session has come to a close.

9 The schedule now shows a 15 minute break.  
10 So, we will reconvene at, that may actually be about 20  
11 minutes from now, we will reconvene at 10:30.

12 Thank you very much. Session's closed.

13 (Whereupon, the above-entitled matter went  
14 off the record at 10:10 a.m. and resumed at 10:32 a.m.)

15 CHAIRMAN ALDERSON: We're ready to  
16 reconvene. And the next section will be given by people  
17 at Spectrum Pharmaceuticals who will discuss their  
18 proposal for training and experience requirements.

19 DR. SHROTRIYA: Chairman Anderson, thank  
20 you very much for inviting us this morning. I am Rejesh  
21 Shrotriya, a physician and have been involved with novel  
22 treatments for cancer for the last 30 years. And for  
23 the last 14 years I have been Chairman and CEO of  
24 Spectrum Pharmaceuticals.

25 Today's meeting is not about Spectrum and

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1 it's not about Zevalin as misquoted here. It's about  
2 the access to drugs that help treat cancer, all alpha-  
3 and beta-emitters. These are experts in radiation and  
4 it's surprising that nobody is talking about the  
5 differences between the different emitters, what risks  
6 do they propose?

7 Cancer is a killer. The moment we have the  
8 diagnosis of cancer, people are looking for help and the  
9 drugs that we give to treat cancer patients are killer  
10 drugs. Side effects of drugs cause hair loss, nausea,  
11 vomiting. So we, the oncologists, the hematologists  
12 are used to treating with very deadly drugs. Sometimes  
13 they say the drugs are worse than the disease itself.

14 So what I'll be talking about is beta --  
15 other drugs, Zevalin is supplied in this kit. It's a  
16 good emitter. Radiopharmacies make a patient-ready  
17 dose that is supplied in a container like this, all the  
18 physicians have to do is take it out. This is contained  
19 here in this syringe. No gowns, no lab, nothing and  
20 then they put in this device and it's a ten minute push  
21 to the patient. That's it. After that, the patient  
22 goes home. And this is put back in the kit and sent back  
23 to radiopharmacy. There is no manufacturing or making  
24 of the radioisotope at the site. Seven hundred hours

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1 of training. I looked into it after you asked the  
2 question.

3 NRC says that the increase from 80 hours of  
4 training under the existing 35.93 to 700 hours of  
5 training under the final rule is required because the  
6 new rule would authorize physicians to elute generators  
7 and prepare radioactive drugs on site, as well as to  
8 administer a wide variety of nucleotides.

9 Zevalin isn't about any of this, and  
10 therefore -- and I have also been told, best of my  
11 knowledge, not a single in 15 years, not a single  
12 physician has gone through 700 hours of training. So  
13 if you say that rulemaking will be delayed for the next  
14 five years and we still have 700 hours, I'm sorry, I have  
15 to pull Zevalin out of the market. Bexxar has already  
16 been pulled out of the market. We can't support it.  
17 Period. People don't use it because they say hey,  
18 managing a cancer patient with lymphoma means these  
19 patients need continuity of care. The continuity of  
20 care is missing when you refer this patient to an  
21 authorized user. Authorized users don't want to manage  
22 a cancer patient because when you give any of these  
23 drugs, there's a fall in white blood count.

24 A hematologist knows how to manage the

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1 white blood count drop. A nuclear medicine doc doesn't  
2 have to manage that. So even if there are 2,200 or  
3 whatever the number I heard, this is wrong. This is a  
4 misnomer. They don't give Zevalin. They don't treat  
5 neutropenia of these patients. So I think there's a  
6 real problem you're dealing with.

7 Today, I request you, make no mistake. The  
8 future of cancer patients is at stake. Future  
9 innovation is at stake.

10 Dr. Palestro, rightly said, that we should  
11 be looking at safety of the patients, patient access,  
12 and innovation. Two things are missing. Safety -- we  
13 can't just focus on safety when we're dealing with  
14 cancer. You have to also be looking at are we denying  
15 the access to these patients? And are we hampering  
16 innovation?

17 Zevalin has a safety record of 15 years of  
18 safety and efficacy. Eighty-three percent of  
19 patients, it's a single-dose treatment. How many  
20 people here in this room knew that Zevalin is given once.  
21 The time for second dose is eight years. For that one  
22 injection, you want someone to go to 700 hours of  
23 training? What are we talking about?

24 As I said, we are ready to pull this drug.

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1 This drug is now approved in 46 countries around the  
2 world. It's only the United States where we are  
3 required 700 hours of training.

4 I've got stakeholders. I've got all these  
5 doctors, Dr. Steven Fein, Dr. Cultrera is online and Dr.  
6 Julius. They're all stakeholders. They're not  
7 employees of Spectrum. They are physicians who take  
8 care of these patients. And they've had it.

9 And they are here to appeal to your good  
10 judgment and say please, how can we keep this drug  
11 available to cancer patients?

12 Zevalin is a combination of monoclonal  
13 antibody called CD-20 and the radioisotope is Y-90  
14 yttrium which is one of the safest radioisotopes I'm  
15 being told. I'm not a nuclear physician.

16 We would like to request today an expedited  
17 rulemaking. We don't have five years. Patients who are  
18 suffering from lymphoma, if anybody in this room who had  
19 cancer, they would know what I'm talking about.  
20 There's an urgency. There's death knocking at their  
21 door. These people want treatment today.

22 By pushing this, what has been a useless  
23 rule for the last 15 years, you want to continue for  
24 another 5 years before making a decision? I'm sorry,

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1 this is travesty. While educators and innovators are  
2 trying to discover new treatments for cancer, how do we  
3 treat these patients? In burdensome regulations. We  
4 want seven hundred hours to wait another five years. To  
5 me, that is disgusting, as disgusting as I could hear.

6 I'm here, a physician just like many of you  
7 are in this room. And I'm just saddened to hear that  
8 this approach that is at least being proposed by the  
9 stakeholders here.

10 Please open your hearts and minds and let's  
11 call a spade a spade, in answering Dr. Zanzonico's  
12 comments to the prior panel. What you are hearing here  
13 is a shameful turf war that is hurting patient care.  
14 Seven hundred hours? That's like two years of  
15 fellowship. You think a practicing oncologist wants to  
16 go for a two-year fellowship to give Zevalin one dose,  
17 give a push? Doctors don't even give this push. It's  
18 given by a nurse.

19 And nobody here can justify why it changed  
20 from 80 to tantamount to forcing hematologists and  
21 oncologists to become nuclear medicine doctors or  
22 radiation oncologists, but they are not. And they're  
23 not going to bicker.

24 Ladies and gentlemen, it is beyond time to

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1 end this turf war. Mr. Green asked a good question  
2 about the steps in the subcommittee process. The first  
3 step of the subcommittee's work should not wait for next  
4 five years and I urge you, please. Think of the poor  
5 patients. Don't think of Spectrum or Zevalin. We may  
6 not be there tomorrow, but these patients will be here  
7 forever. That does not balance safety record. It  
8 balances access of these patients. There is other  
9 responsibility, everybody's responsibility to make  
10 sure that the patients have access. And of course we  
11 want to protect the safety of these. These are  
12 board-certified hematologists and oncologists who do  
13 this every single day.

14 The request for ACMUI to vote and act now  
15 in advising NRC to deal with alpha- and beta-emitters  
16 now. In fact, Commissioner Christine Svinicki wrote  
17 very nicely in her report. I just happened to read it  
18 and she's talking about we don't want to kill  
19 innovation. We want to make sure that patients have  
20 access and we should revisit all these rules that have  
21 been in existence. I'm telling you, I was told, I've  
22 investigated how many people have gone through 700 hours  
23 of training. They could not find one person who has  
24 gone through 700 hours of training. And you want to

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1 continue with this rule?

2 We are focusing and asking -- for you to  
3 focus here not on all modalities as Dr. Palestro  
4 addressed, but on therapeutic patient-ready dose of  
5 alpha- and beta-emitter radiopharmaceuticals, I  
6 repeat. Patient-ready dose just the way I  
7 demonstrated, please focus on that. What is needed so  
8 that a hematologist, oncologist in his office can give  
9 this drug and continue with the care of this patient.

10 We started this conversation five years  
11 ago. I have been to NRC. In five years, I have met all  
12 of the Commissioners of NRC and they all are very  
13 empathetic. They say you know, we are dealing with  
14 nuclear submarines, nuclear plants, we're worried about  
15 terrorist attacks on these. What in the hell are we  
16 doing here with a beta emitter in a cancer patient  
17 setting? I also need to point out that this section is  
18 misnamed the Spectrum Pharmaceuticals Proposal for  
19 training and experience requirement. That's not so.

20 Spectrum is sharing the time here today  
21 with ACMUI to hear from a broad group of experts  
22 including AU educators and interested parties about  
23 making a more reasonable and rational competency based  
24 on training pathways made possible for alpha- and

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1 beta-emitters.

2 The rest of the speakers are AU educators  
3 and CORAR, Council of Radionucleotides and  
4 Radiopharmaceuticals. They have instructional material  
5 which they have submitted with the committee.

6 In a moment, I will turn it over to these  
7 AU educators and ask them to introduce themselves.  
8 Professor Kristina who comes from the University of New  
9 Mexico; Professor Nicki Hilliard from the University of  
10 Arkansas; and Professor Kara Weatherman from Purdue  
11 University, are all on the call and at this time I will  
12 turn over the call to Professor Kristina Wittstrom and  
13 her colleagues. And I will come back with my concluding  
14 remarks after all the presentations.

15 Dr. Kristina.

16 DR. FEIN: I'm not sure is she on the phone,  
17 Dr. Wittstrom.

18 DR. SHROTRIYA: Dr. Wittstrom? Is she on  
19 the telephone?

20 DR. FEIN: We might have lost her.

21 DR. FEIN: Can we move on to Dr. Cultrera's  
22 remarks?

23 CHAIRMAN ALDERSON: Is the line muted?

24 MS. HOLIDAY: It is not muted.

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1 DR. FEIN: Can we move on to Dr. Cultrera's  
2 remarks for the moment?

3 DR. SHROTRIYA: In that case for the  
4 benefit of time, let's move on to Dr. Cultrera's  
5 comments, please?

6 DR. FEIN: Is Dr. Cultrera on the phone?  
7 Is the phone okay? Is anyone on the line?

8 I have a copy of Dr. Cultrera's planned  
9 remarks and I'm just going to start. If she joins us,  
10 then she can continue.

11 Dr. Cultrera and I are hematologists.

12 MS. SMETHERS: We can hear you now.

13 OPERATOR: The parties you have been  
14 asking have been on line and they do have open line.

15 DR. FEIN: Well, this is Dr. Cultrera and  
16 Dr. Joseph Mace. They were both planning to come today.

17 DR. CULTRERA: This is Dr. Cultrera, can  
18 you hear me?

19 DR. SHROTRIYA: Yes, we can hear you, Dr.  
20 Cultrera. Please continue.

21 DR. CULTRERA: Is Kathleen still on the  
22 line, because she should be able to hear -- you should  
23 be able to hear her as well.

24 DR. WITTSTROM: This is Kristina

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1 Wittstrom. Am I being heard?

2 DR. FEIN: Okay, let's go on with Kristina,  
3 please.

4 DR. SHROTRIYA: Kristina Wittstrom, will  
5 you please -- you start first, please.

6 DR. WITTSTROM: Okay, and everyone I'm  
7 trusting can hear me. I am here representing a group  
8 of us who provide authorized user training to  
9 physicians, pharmacists and nuclear medicine  
10 technologists. My background is approaching 40 years  
11 of experience in nuclear medicine, primarily in the  
12 education arena, as well as being a practitioner.

13 What we have to offer the group is a sample  
14 or an example, if you will, of a competency-based  
15 curriculum derived from the expectation of the  
16 Commission, the Nuclear Regulatory Commission, as well  
17 as some best guesses, if you will, on expectations of  
18 critical competency that an individual user would need  
19 to have strong working skills and abilities to safely  
20 handle these alpha and beta, patient specific  
21 radiopharmaceuticals.

22 And as you can see, they parallel and it's  
23 kind of structured very similar to what we're all  
24 familiar with in the hourly or the time-driven

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1 curriculum. But instead of specifying hours, the  
2 difference is that there's some kind of an assessment  
3 process by which the individual user demonstrates a  
4 level of competency.

5 In the more knowledge-oriented aspects  
6 such as understanding basic physics or the theory behind  
7 operation of measurement and detection equipment, those  
8 would be by written examination. The other probably  
9 more important from a safety standpoint, operation and  
10 ability to perform specific tests.

11 MR. BOLLOCK: Professor Wittstrom, are you  
12 still with us? We can't hear you right now.

13 DR. FEIN: Summarize Dr. Wittstrom's -- is  
14 Dr. Cultrera still with us?

15 DR. WITTSTROM: And saying that I would be  
16 willing to entertain any questions. So anyone can give  
17 me -- or an example of a proposed curriculum.

18 MS. HOLIDAY: Dr. Wittstrom, I'm sorry.  
19 This is Sophie Holiday, and it appears that our phone  
20 line cut out maybe within the last few minutes of your  
21 discussion.

22 DR. WITTSTROM: Are there any questions?

23 DR. SHROTRIYA: Yes, so maybe I can just  
24 kind of summarize what her point was. Her point was

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1 that the training and competency training can be divided  
2 into five or six different headings where people would  
3 be given training, once again, are physics,  
4 instrumentation, radiation, biology and there will be  
5 a written exam and then there will be a competency  
6 requirement.

7 I think basically she's giving a syllabus  
8 which again we can share with the subcommittee and with  
9 others. She has provided this in writing.

10 So basically what she has done is a target  
11 program that can be run anywhere within 20 hours to 80  
12 hours.

13 As you heard from Professor Mort Diamond,  
14 he's a professor of cardiology at the University of  
15 Miami and he himself suffered with lymphoma and received  
16 one dose of Zevalin and he's been cancer free for the  
17 last seven years. And he came here on his own volition.  
18 He departed the storm and came here to talk about that  
19 how ridiculous it is to require 700 hours of training.  
20 We will support a training that's more reasonable that  
21 hematologists and oncologists would like to become  
22 authorized users. So that is the main purpose of her  
23 presentation.

24 So we finally ask Dr. Jennifer Cultrera if

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1 you are available now?

2 DR. CULTRERA: Yes, I'm on the line.

3 DR. SHROTRIYA: Please go ahead.

4 DR. CULTRERA: Good morning, ladies and  
5 gentlemen of the NRC and ACMUI Committee. As Dr. Rajesh  
6 has told you, my name is Dr. Jennifer Cultrera. I'm a  
7 Board-certified hematologist and medical oncologist  
8 with Florida Cancer Specialists. We are the  
9 largest-based community practice in the country at this  
10 time.

11 I had hoped to be there in person, but I  
12 appreciate you letting me call in. Our area is  
13 currently being hit by Hurricane Matthew, so any prayers  
14 and support you can send our way, thank you.

15 I appreciate your time and presence here  
16 today to further discuss the need for competency-based  
17 training and education for alpha- and beta-emitters. I  
18 was initially introduced to radiopharmaceuticals in my  
19 training at MD Anderson Cancer Center in Houston where  
20 I participated in the registration trials for the  
21 lymphoma-directed agents both Zevalin and Bexxar. I  
22 then became comfortable working with my radiation  
23 oncologist and managing lymphoma patients who were  
24 treated with Zevalin and Bexxar as a lymphoma specialist

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1 at Moffitt Cancer Center.

2           Upon moving my practice to Florida Cancer  
3 Specialists in The Villages, Florida which is a rural  
4 community about one hour north of Orlando, I found  
5 myself unable to utilize these agents because of a lack  
6 of authorized users, despite the prevalence of those who  
7 were potentially qualified to administer it as we  
8 discussed this morning.

9           I do have nuclear medicine physicians and  
10 radiation oncologists that I work with every day to help  
11 treat my patients and give concurrent  
12 radioimmunotherapy, radiation therapy with  
13 chemotherapy, as well as several diagnostic nuclear  
14 medicine tests. But if they are not an authorized user  
15 or if they are not incentivized to become authorized  
16 users, we cannot partner to help these patients.

17           Upon inquiring to others in my practice of  
18 over 200 medical oncologists and hematologists, I found  
19 that this was the norm, rather than a rarity in the  
20 majority of the communities throughout Florida that did  
21 not have either large cancer centers or academic  
22 centers.

23           I have come before this committee several  
24 times and spoken with several NRC Commissioners before

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1 to express this unmet need that my patients are  
2 experiencing. And it is disappointing to see that the  
3 changes to the current training and education  
4 requirements are not going to be in the proposed rule  
5 draft. But I do appreciate the hard work that everyone  
6 is doing to help make future changes.

7 As a medical oncologist, I work with highly  
8 toxic chemotherapeutic agents on a daily basis. We are  
9 trained for the safe handling and management of these  
10 agents, as well as for the serious, adverse events in  
11 our patients. Nobody can ever be trained for every  
12 single possibility that can occur, but I feel  
13 comfortable with the agents that I'm utilizing that I  
14 can react in a timely fashion to help keep my patients  
15 safe.

16 Unlike radiopharmaceuticals, chemotherapy  
17 is often prepared and administered in our own infusion  
18 centers. Alpha- and beta-emitters are provided to the  
19 authorized user as a patient-ready dose as you have  
20 seen, prepared at radiopharmacies. The administration  
21 is simple requiring little manipulation and preventing  
22 little safety risk.

23 Lymphoma is a disease of the elderly and  
24 most of my patients are very frail, debilitated, and

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1 have been treated with highly-toxic treatments prior to  
2 them receiving some of these drugs. They are unable to  
3 travel 80 to 100 miles which is the current issue to the  
4 nearest authorized user.

5 In cancer care, where there is rarely a  
6 simple treatment, radiopharmaceuticals are a safe,  
7 efficacious, and minimally toxic treatment that is  
8 saving patient lives. I have co-managed over 25  
9 patients who have received Zevalin and I am pleased to  
10 continue to follow the majority of them living their  
11 lives cancer free with an excellent quality of life.

12 How can deprive these patients that have  
13 such a devastating disease of any modality of treatment?  
14 Cancer is ever changing, ever mutating. Every day, we  
15 discover resistance to the established agents. I urge  
16 you to please not take away a piece of our ever-limited  
17 arsenal against cancer.

18 It is very imperative that a targeted  
19 competency based training and education framework be  
20 developed to allow medical oncologists such as myself  
21 and my colleagues to demonstrate competency and  
22 administer these therapeutic patient-ready doses to our  
23 patients.

24 Also, I am the primary physician for my

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1 cancer patients. They look to me to manage their  
2 disease, to manage their treatments and their  
3 toxicities. Patients having to travel miles to see an  
4 authorized user face disruptions in both their  
5 continuity of care and further burden their needs.

6 Medical oncologists are well versed in all  
7 the toxicities of these agents, even though we aren't  
8 administering them because they are intravenous,  
9 systemic, and their main toxicity is systemic, bone  
10 marrow suppression. Administration is just one simple  
11 step in the complex management of a cancer patient. We,  
12 as medical oncologists and hematologists, are prepared  
13 and willing to use these agents if we have the  
14 designation to provide them. And we are asking only for  
15 limited authorization to administer patient-ready  
16 doses of alpha- and beta-emitters.

17 We do not see the need to train for hours  
18 to learn certain material that will not benefit the  
19 precaution and practice that is specific to the safe  
20 administration of this patient-ready dose. And due to  
21 the constraints of caring for patients in a community  
22 practice, competency versus time-based training and  
23 education is the only way a medical oncologist and  
24 hematologist will ever be able to deliver these vital

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1       therapeutics.

2                   Dr. Joseph Mace, who couldn't be here with  
3       us today is one of my colleagues at FCS and he resides  
4       in the Tampa Bay Area. He currently takes time away  
5       from his primary practice and his patients to travel  
6       across the state to administer radiopharmaceuticals.  
7       He was trained over ten years ago prior to the new  
8       requirements under a shortened course and he has had no  
9       safety events and successfully administered alpha- and  
10      beta-emitters for over these ten years throughout the  
11      state.

12                   In conclusion, I just want to express that  
13      I and my fellow medical oncologists and hematologists  
14      are asking for a limited authorized user license that  
15      is currently not available to us and there's no feasible  
16      pathway to obtain. And as you deliberate, I look to you  
17      to assess for competency, not time-based training  
18      requirements that will still give us the skills and the  
19      knowledge to safely administer these patient-ready  
20      doses that have been prepared by a licensed  
21      radiopharmacy and to continue to allow us to provide  
22      cutting-edge care and the best care that our patients  
23      deserve and expect. Thank you very much and if there  
24      are any questions, I'd like to field them.

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1 DR. FEIN: I'm the final  
2 hematologist/oncologist here with you. We all work --  
3 coming from Florida, but I managed to escape the storm.  
4 I'm Dr. Steven Fein.

5 I'm on faculty at the University of Miami  
6 School of Medicine. I trained at Johns Hopkins and I'm  
7 in the Miami Cancer Institute. We're affiliated with  
8 Sloan-Kettering and I'm the Chief of the Hematologic  
9 Malignancies Section of the Miami Cancer Institute and  
10 I've been a lymphoma expert for 15 years. I've been  
11 using radioimmunotherapy or I should say offering and  
12 prescribing radioimmunotherapy although I myself don't  
13 administer it, because I'm not trained.

14 Now I'm also here to represent the ASH,  
15 American Society of Hematology and I was invited and  
16 offered myself to come from the storm on behalf of  
17 American Society of Hematology. I'm a member of the  
18 Foundation and Development Committee of the American  
19 Society of Hematology. You probably know that ASH  
20 advocates and educates hematologists and oncologists  
21 about standards of care for treating hemalogic  
22 malignancy. And ASH, in conjunction with the NCCN  
23 are strong advocates of radioimmunotherapy for  
24 follicular lymphoma.

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1 I'm here to discuss the ASH position and  
2 also the reality of being a lymphoma doctor and lymphoma  
3 expert in our era.

4 First, I'm just going to review a couple of  
5 comments made by the President of ASH last December in  
6 a letter to this committee or to the NRC. The President  
7 of ASH, Dr. Charles Abrams wrote in the letter  
8 supporting the position that we're here to request. He  
9 said, "Since the implementation of the 700-hour  
10 requirement, it has become more difficult for patients  
11 in certain parts of the country to locate authorized  
12 users who are licensed to administer alpha- and  
13 beta-emitters outside of the academic medical center  
14 setting. With this current rulemaking, the NRC has the  
15 opportunity to improve access to these potentially  
16 life-saving, anti-cancer treatments by addressing the  
17 shortage of authorized users able to administer them."  
18 And he also commented, "This could significantly  
19 improve patient access to life-saving treatments in the  
20 community hematology/oncology setting."

21 Now I know we're short on time, but I want  
22 to make a few comments as a hematologist/oncologist who  
23 specializes in lymphoma. Probably everybody is aware  
24 that Non-Hodgkin's Lymphoma is one of the most common

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1 types of cancer and it affects young people and old  
2 people and all kinds of individuals, all equal  
3 opportunity cancer. Fourteen thousand new patients a  
4 year, 100,000 people estimated to be living with  
5 lymphoma. Most eventually need anti-tumor therapy,  
6 radioimmunotherapy and right now Zevalin is the only one  
7 of these available. For the longest time all  
8 chemotherapy as you heard an average of eight years and  
9 sometimes even longer. There's no other treatment that  
10 we know for follicular lymphoma comparable in terms of  
11 duration of benefit and for quality of life.

12 Now hematologists and oncologists rarely  
13 prescribe and rarely refer for radioimmunotherapy. I  
14 want to make the plea to you --- speak to you that the  
15 reason for this is that there's a penumbra of  
16 inaccessibility of this agent and this class of  
17 innovative, and as I said very effective, safe and  
18 effective medications. And the penumbra of  
19 inaccessibility is something that I confront with my  
20 patient. So I'm there with a patient and I'm deciding  
21 with the patient whether or not it's time to refer you  
22 to a new face to give this treatment that I know is so  
23 beneficial and so safe and effective. And yes, it's on  
24 my radar. I'm a lymphoma expert, but it's not that easy

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1 for the other thousands of medical oncologists to have  
2 this on their radar.

3 There's a penumbra of inaccessibility  
4 related partly just to the fact that it's a referral to  
5 another provider. A cancer patient is my patient. I  
6 don't actually want another provider to be discussing  
7 life and death with this cancer patient who they've  
8 never met. I want to actually be the one to provide  
9 these treatments that as you hear are safe and effective  
10 and easy for us to be trained to administer.

11 So point number two, requires referral  
12 right now to another provider because I'm not trained  
13 and authorized to infuse this medication.

14 Each of us, point number three, each of us  
15 has -- a medical oncologist has anecdotes about  
16 incredible successes with this agent. There's no doubt  
17 that it's beneficial, but we're not using it because of  
18 this penumbra of inaccessibility.

19 The first point on this slide, the newer  
20 anti-tumor treatments we've been waiting for to  
21 supplant or improve upon, radioimmunotherapy, they're  
22 coming, slowly but surely, but they're just not as good.  
23 The only other one approved in the past probably 15 years  
24 I think for follicular lymphoma is idelalisib and this

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1 one is -- we're using this, it's targeted therapy.  
2 We're all excited and optimistic about it. But we're  
3 talking about one or two years of benefit, not 8 or 12  
4 years and we're talking about a treatment that has  
5 toxicities that are challenging. And in fact, most  
6 recently over the past few months this agent has been  
7 found to increase mortality for follicular lymphoma  
8 patients if it's given too early. So we're really not  
9 enthusiastic about different treatments.

10 At one time, radioimmunotherapy was looked  
11 at as too expensive, but in the modern era over the past  
12 10 or 15 years, radioimmunotherapy is now extremely cost  
13 effective compared to almost everything we have to offer  
14 our patients. It's something we would like to be able  
15 to use.

16 In addition, radioimmunotherapy is a type  
17 of innovative treatment that we would like to see used  
18 for other radiopharmaceuticals in general for other  
19 cancers and right now, the fact that the door is possibly  
20 closing on radioimmunotherapy makes me fear that we  
21 won't have that kind of innovation.

22 So in closing, I'm just going to say I  
23 support the development of a limited authorization for  
24 hematologists and oncologists who seek to administer

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1 therapeutic patient-ready doses of alpha- and  
2 beta-emitters that we feel are not that challenging to  
3 be trained upon. And I say that by enabling us  
4 hematologists and oncologists to get trained, more  
5 patients will have access to Zevalin and potentially  
6 other important radiopharmaceuticals that will be  
7 coming along. That's it for me. Closing comments?

8 DR. SHROTRIYA: Any questions you have to  
9 Dr. Fein?

10 CHAIRMAN ALDERSON: I would say thank you  
11 to Dr. Cultrera and to Dr. Fein for their presentations  
12 and yes, let's open up their presentations to questions.  
13 Do the members of the ACMUI have a question they'd like  
14 to ask?

15 VICE CHAIR ZANZONICO: Thank you very  
16 much. We empathize with you with your travel  
17 difficulties and making it here to present to us. We're  
18 all with you.

19 DR. FEIN: My heart's in this. Actually,  
20 it was so important for me to get out. Thank you.

21 VICE CHAIR ZANZONICO: I just have a  
22 question. It's not to be argumentative, but I'm trying  
23 to understand. I'm from Sloan-Kettering. We see a lot  
24 of lymphoma patients. We have many authorized users

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1 and obviously many hematologists and oncologists who  
2 are treating these patients. Yet, in the last number  
3 of years, I would say in the last five years, probably  
4 fewer than 30 patients at Sloan-Kettering have been  
5 treated with Zevalin. And we have a very robust  
6 radionuclide therapy program and radioimmunotherapy  
7 program, in particular.

8 So I'm trying to understand as a  
9 non-specialist in this area trying to reconcile why in  
10 a center which has an ample number of authorized users,  
11 a large number of patients, the choice is to use  
12 therapies other than Zevalin.

13 DR. FEIN: I'd like to answer that question  
14 from the perspective of a lymphoma expert and now a  
15 Sloan-Kettering affiliate. My first thought is that  
16 Sloan-Kettering is a tertiary care center, probably  
17 getting referrals later and maybe in some of the ones  
18 that are getting have already received possibly. I  
19 would think that Sloan-Kettering has trials of newer  
20 agents and they're trying to use that more, although I  
21 don't know the spectrum of trials that they have, and  
22 that maybe this is maybe standard treatments like  
23 radioimmunotherapy aren't actually the main thrust of  
24 the medical oncology group.

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1           But I still argue, my main argument and  
2 still stands with that idea of the Sloan-Kettering issue  
3 is that the penumbra of inaccessibility may even pervade  
4 Sloan-Kettering. It may be there where the medical  
5 oncologist doesn't really want to hand off their patient  
6 to a different face to discuss life and death, to discuss  
7 the toxicities that the medical oncologist is going to  
8 be dealing with anyway. And even though they may all  
9 be friends on the same committee and the same meetings  
10 and where they have this colleague that's ready to give  
11 the drug, it may be challenging even for a tertiary care  
12 doctor to want to hand off their patient.

13           DR. CULTRERA: So if I could also comment,  
14 this is Dr. Cultrera.

15           CHAIRMAN ALDERSON: Yes, Dr. Cultrera,  
16 please.

17           DR. CULTRERA: Thank you. So I did  
18 actually have this conversation with some of my  
19 colleagues back at Moffitt and I have discussed it why  
20 was it so easy for us to be able to work in conjunction  
21 when I was down there. And ironically, Moffitt did  
22 experience a loss of a couple of their authorized users  
23 after I had left, and they were beginning to have issues  
24 and their usage of Zevalin did decrease as the

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1 authorized user was not present. And one of  
2 the things that they started turning to also was stating  
3 that they had several clinical trials that they were  
4 utilizing with newer targeted agents that weren't  
5 available to the public. So yes, I think clinical  
6 trials is a main concern, as well as the fact that some  
7 of the younger physicians, they're not -- the younger  
8 medical oncologists are not even learning about this.

9 I had fellows that I go and do talks to at  
10 the University of South Florida and they come back and  
11 they tell me we've never heard of radiopharmaceuticals.  
12 And I try to explain to them these drugs have been around  
13 since 2005. You need to be able to know that they're  
14 there.

15 One of the things that I know ASH has made  
16 a statement of is that if we are not -- if medical  
17 oncologists are not able to administer the drugs,  
18 they're not going to include it in a training program,  
19 so one of the options that I do want the committee to  
20 understand is that by withholding our capability of  
21 being able to administer the drug, you're actually  
22 taking it away from our future physicians because out  
23 of sight is out of mind. Thank you.

24 CHAIRMAN ALDERSON: Dr. Langhorst.

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1                   MEMBER LANGHORST: Thank you. I just  
2 wanted to echo Dr. Zanzonico's experience at Washington  
3 University and Siteman Cancer Center. It's our  
4 physicians' jobs to partner up to fight cancer and to  
5 treat patients in the best way they can. And our  
6 radiation oncologists are authorized users for these  
7 types of radiopharmaceutical administrations and they  
8 have partnered with interventional radiology to do  
9 hundreds of microsphere cases in a year. In the past,  
10 they partnered with cardiologists in doing beta-cath  
11 treatments that wasn't cancer, but again it was to treat  
12 patients.

13                   And in the past several years, even though  
14 we work with our oncologists all the time, we've done  
15 one or two Zevalins a year. And so if it was so great  
16 I would think they would be prescribing it. I just  
17 don't understand that disconnect and I find it very hard  
18 to believe that our oncologists would not work with our  
19 radiation oncologists in order to give their patients  
20 the best care. So I'm confused by that.

21                   CHAIRMAN ALDERSON: Dr. Fein.

22                   DR. FEIN: Just my answer to that is I'm  
23 agreeing with Dr. Cultrera that it's actually not even  
24 on the radar of new oncologists being trained, and it

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1 could be that some of the training programs don't have  
2 access and there's not even a way to hear or see this.  
3 So some of the reasons that there may not be referrals  
4 to Wash U or Sloan-Kettering might be that some of the  
5 newer oncologists may not even have this on their radar  
6 because it's already falling away. It's certainly not  
7 because of lack of efficacy and safety of the agent. In  
8 fact, I again argue it's probably the single most  
9 efficacious and safe anti-lymphoma treatment, but it  
10 has to do with this penumbra of inaccessibility and  
11 unawareness.

12 CHAIRMAN ALDERSON: Ms. Weil will be next.

13 MEMBER WEIL: Thank you. So you describe  
14 a penumbra of inaccessibility and I'm a little confused  
15 about your choice of that word because it sounds to me  
16 like this more a penumbra of ignorance, that there's  
17 been a failure perhaps on the part of companies like  
18 Spectrum to market and make the appropriate  
19 practitioners aware of this particular agent and its  
20 availability. And I'm not quite sure why.

21 DR. FEIN: It could very well be both. You  
22 know a lot of times patients who are savvy and hear about  
23 it through patient support groups or online will  
24 approach us and say why haven't you prescribed this?

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1 Some of us might say well, it's not something I normally  
2 prescribe. So it's not necessarily that we've never  
3 heard of it. It's just not on our radar. Maybe some  
4 of us haven't really heard of it or used it and these  
5 are patients that don't come so often because individual  
6 hematologists and oncologists have maybe a handful of  
7 these patients, so it's not all the time on our radar.  
8 So I'd say it's both lack of awareness and education.

9 CHAIRMAN ALDERSON: Dr. Dilsizian.

10 MEMBER DILSIZIAN: Thank you very much.  
11 Again, I would like to echo the comments made regarding  
12 major medical centers. As you know, being at Hopkins,  
13 I'm at the University of Maryland. I'm an internist,  
14 cardiologist, head of the Nuclear Medicine Division.  
15 And what I was bothered with your comment I have to be  
16 honest is that you don't trust your patients to be  
17 managed by someone like me.

18 We have a lot of oncologists that send  
19 patients for iodine-131 treatment, radium-223  
20 treatment. To suggest that we are not a team of  
21 physicians with expertise, that we trust each other and  
22 refer patients to each other, I find that disingenuous,  
23 I must say.

24 CHAIRMAN ALDERSON: Dr. Ennis was next.

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1                   MEMBER ENNIS: So I had two comments. My  
2 first actually was similar to that and then maybe -- the  
3 notion that the hematologist doesn't want other  
4 physicians to discuss -- let me finish, life and death  
5 issues is -- it's not the reality, because I'm sure you  
6 are referring to radiation oncologists and surgeons all  
7 the time to manage other diseases, so in what way is a  
8 lymphoma patient not able to converse with other  
9 specialists? Or how would that ruin the patient's  
10 management is something I don't understand and I find  
11 disappointing. So that would be comment number one.

12                   Comment number two would be I don't have  
13 actual numbers in front of me, but from what I hear,  
14 other radiopharmaceuticals like Xofigo, for example, is  
15 doing great. I understand they're setting up a new  
16 manufacturing plant. So what is the difference? Why  
17 is that company doing well with its agent when again a  
18 medical oncologist is presumed to be referring the vast  
19 majority of those patients to nuclear medicine or  
20 radiation oncologists for that. Why is that working  
21 out well? Why are those doctors able to work together?  
22 Why is that company making money? And Spectrum and this  
23 great drug is struggling?

24                   CHAIRMAN ALDERSON: Dr. Cultrera.

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1 DR. CULTRERA: This is Dr. Cultrera. So  
2 I'd like to comment to the latter point first. One of  
3 the issues is also the number of patients. Xofigo is  
4 indicated in the treatment of relapse refractory  
5 prostate cancer with bone disease which is a much larger  
6 population of patients than Non-Hodgkins' Lymphoma.

7 I will tell you just based on the numbers  
8 that I don't have in front of me, but I can see if I can  
9 provide from my large practice is that the numbers of  
10 Xofigo administrations in our communities without the  
11 AUs is also decreased in comparison when you see them  
12 as related to when there's an academic center locally  
13 or the AU is present locally. I have seen that need for  
14 both my prostate cancer patients and my lymphoma  
15 patients.

16 I'm a lymphoma specialist, even though I  
17 treat everything right now so that's what I'm focusing  
18 on here in this discussion.

19 For the first comment, in no way did I ever  
20 once mention and I don't think any of my colleagues did  
21 either that we don't partner and use a  
22 multi-disciplinary approach. Even though I'm  
23 practicing in the community, Florida Cancer is a hybrid  
24 practice and we have a very strong research focus. We

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1 have a very strong multi-disciplinary approach. We  
2 have tumor boards that occurs across the state as well  
3 as with our local academic centers.

4 And like I said, I know my radiation  
5 oncologists. I partner with my nuclear med. doctors  
6 and honestly, I sat down with the ones in my area in Lake  
7 County, Florida and they have all told me that they don't  
8 want to become authorized users because they don't feel  
9 the need. The nuclear medicine doctors, in particular,  
10 have told me they want to continue as a diagnostician  
11 and they don't want to have to deal with some of the side  
12 effect profiles or liabilities that some of these  
13 systemic medications can occur. I can't speak for  
14 them, but I will tell you what they have sat down and  
15 discussed with me. Thank you.

16 DR. FEIN: If I may, also -- I really didn't  
17 mean to imply that we don't partner and I appreciate that  
18 comment. I apologize for making that disingenuous  
19 comment.

20 The partnership that I'm talking about that  
21 isn't necessary is a single ten-minute infusion of a  
22 medicine that we think will potentially give somebody  
23 eight years of progression-free survival without  
24 needing an on-going relationship with a radiation

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1 oncology provider. It could be a one-time infusion.  
2 And so I would think that they wouldn't really need a  
3 strong partnership or even a strong relationship with  
4 that doctor. If anything, I view it sometimes and I  
5 think the other radiation oncologists view it as not  
6 really a great investment of their time to sit down and  
7 explain all this and then see that patient once for the  
8 infusion and then refer back for the potential side  
9 effects to the medical oncologist. Really, it's not so  
10 much a partnership in that case. On the other hand,  
11 prostate cancer and everything else, certainly  
12 partnership we're taking about palliation closer to  
13 terminal disease.

14 CHAIRMAN ALDERSON: Dr. Palestro would  
15 like to comment.

16 MEMBER PALESTRO: Yes, I have to tell you  
17 at this point I'm a little bit confused about what  
18 exactly you said and I'm going to go back to the  
19 discussion on Sloan-Kettering. The way I understood it  
20 you said that there were one or two possible reasons why  
21 Zevalin is so infrequently used. One is the fact that  
22 there are large numbers of clinical trials and patients  
23 are being moved into those trials. And the other is  
24 perhaps a reluctance -- I'm not trying to put words in

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1 your mouth, I'm just trying to understand, a reluctance  
2 on the part of the hematologist/oncologist to turn the  
3 patient over for the Zevalin treatment, whether it's a  
4 nuclear medicine specialist or a radiation oncologist.  
5 Is that correct?

6 DR. FEIN: In terms of my ideas for why  
7 Sloan-Kettering doesn't have so many referrals for RIT,  
8 I would say that their patient group is different  
9 including patients that have already possibly even  
10 received radioimmunotherapy or those that are sent for  
11 potential clinical trials, more innovative ideas and  
12 maybe patients that have other reasons not to use RIT  
13 as a tertiary part in their care centers. So I just  
14 don't know all the reasons why they don't have so many  
15 patients.

16 I would say the reason is certainly not  
17 because of lack of efficacy and safety of the  
18 medication. And just to finish, in terms -- I still say  
19 the idea is it's not really so much on our radar that  
20 it's that the idea of referring to another provider for  
21 the one infusion it's just not something on the radar  
22 of the community of hem/oc doctors. Even if it's  
23 something that we think works and works well, the  
24 patient wants to stay with us. We want to keep the

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1 patient. We want to keep giving them treatments. And  
2 so you see doctors continuing to give every two or three  
3 month treatments, rather than sending them to another  
4 doctor for a once in eight year treatment. And it's  
5 just not on the radar, maybe not even in their training  
6 to hear about it.

7 MEMBER PALESTRO: All right, and if I may,  
8 a couple of points. I'm the Chief of Nuclear Medicine,  
9 Molecular Imaging what is now known as Northwell Health  
10 which used to be North Shore Long Island Jewish Health  
11 System. And we have a very large patient population,  
12 large number of lymphoma patients. We're certainly not  
13 Sloan-Kettering. And I think the likelihood of our  
14 patients being shepherded into a variety of clinical  
15 trials as an explanation for why we do two to three  
16 Zevalins a year probably doesn't hold up. I don't think  
17 that explains the reason.

18 If on the other hand, an important, perhaps  
19 not the only reason, but an important reason is a  
20 reluctance on the part of hematology/oncology to send  
21 that patient to the treatment for whatever reason, I'm  
22 not sure that that's a justification for shortening  
23 training because that doesn't say to me that there's a  
24 lack of availability. It says to me that there's a

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1 resistance to sending the patient to another physician.  
2 And I'm only basing that on what I've understood you to  
3 say.

4 DR. FEIN: I'd say that as not just a lack  
5 of availability, it's also more than anything a lack of  
6 it being on our radar. So if we had this list of five  
7 possible options, we'd have the ones that we're capable  
8 of using ourselves and we feel closer to and then the  
9 one that's sort of distant from us is the one where we  
10 have to send them away.

11 MEMBER PALESTRO: Now if I could respond to  
12 that, I don't believe that education of your specialties  
13 is the responsibility of the NRC or the ACMUI. If the  
14 treatment, any treatment, any technique -- forget  
15 treatment -- procedure, is as efficacious as it is  
16 claimed, I would find it hard to believe and I speak as  
17 a past chair of a review committee for the ACGME Nuclear  
18 Medicine that it wouldn't be included in the training.

19 I'm sure, for example, hematologists and  
20 oncologists for the most part don't perform PET/CTs or  
21 CTs or MR. And yet, I'm sure you're all extremely well  
22 acquainted with the capabilities of these technologies  
23 and modalities. So again, I just don't quite  
24 understand why you would not be equally familiar with

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1 something as efficacious as Zevalin, even if you're not  
2 administering it.

3 CHAIRMAN ALDERSON: So I will take the  
4 chair's prerogative to do a follow up on that question.  
5 And I'd like to indicate that despite the fact that  
6 Zevalin may be a case in point, the ACMUI's current  
7 reconsideration of training and experience  
8 requirements is not about Zevalin. It is a much more  
9 generic consideration of whether the current  
10 regulations are appropriate to current training and  
11 experience and on-going safety in the utilization of a  
12 wide variety of materials. In that sense, the comment  
13 was said earlier that the ACMUI was withholding access  
14 to Zevalin. And the ACMUI is not withholding access to  
15 Zevalin.

16 The ACMUI has agreed to reconsider this  
17 whole issue of training and experience, the rules of  
18 which were made long before anyone who sits before you  
19 today on this panel was involved in that decision. So  
20 we plan to continue that activity and look at a broad  
21 variety of things that relate to that activity, but I  
22 did just want to make the point that this is not about  
23 Zevalin. It is only one of the effects of what's going  
24 on.

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1 Mr. Green has a comment.

2 MR. GREEN: I appreciate those comments.  
3 I heard repeatedly the phrase used patient ready dose  
4 of alpha and beta. And this is not about Zevalin. And  
5 we do want to have the effective review of the T and E  
6 requirements for all modalities and all practitioners  
7 who potentially handle radiopharmaceuticals. But  
8 specifically, I'll use brand names because they're  
9 easier to pronounce and the stenographer can actually  
10 type them. Zevalin, Quadramet, Metastron, and Xofigo  
11 are the four available FDA approved  
12 radiopharmaceuticals. We've lost Bexxar. So those  
13 are the four that come out typically from a  
14 radiopharmacy on a unit dose basis that we perhaps  
15 should consider whether or not we can find a way to  
16 provide a training and education mechanism for limited  
17 scope use of unit dose of alphas and betas. Those are  
18 the four that I wanted to picture that we're not just  
19 focusing on Zevalin. It's those four.

20 DR. FEIN: If I may augment that we're also  
21 expecting new ones to come along and the idea of opening  
22 -- or figuring out how to do this in a way that's  
23 accessible to hematologists and oncologists and might  
24 encourage development of new agents that are even

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1 better.

2 CHAIRMAN ALDERSON: Yes, fine. Yes,  
3 thank you. Who else would like to make a comment on this  
4 particular subject? Yes, Mr. Collins.

5 MR. COLLINS: Thank you, Dr. Alderson. So  
6 I guess one thing, just a thought for consideration.  
7 Dr. Ennis talked earlier today about the importance of  
8 a physician having the knowledge to deal with the off  
9 normal or abnormal situations rather than just the  
10 textbook when everything goes well. So wherever this  
11 ends up landing in terms of the number of hours or the  
12 training requirements, I would think we need to really  
13 focus on that.

14 And I would express, Dr. Fein, what you  
15 described as kind of an exclusive relationship that you  
16 would maintain with the patient would concern me if  
17 whatever training program doesn't provide adequate  
18 knowledge for those off norm moments. So something to  
19 be considered.

20 CHAIRMAN ALDERSON: Are there other  
21 comments on this particular discussion?

22 DR. HILLIARD: I'd like to --

23 CHAIRMAN ALDERSON: Yes, hello. Is there  
24 someone online?

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1 DR. HILLIARD: Hi, this is Nicki Hilliard  
2 at the University of Arkansas. I'm a professor  
3 teaching nuclear pharmacy and nuclear medicine.

4 One of my comments is that it's 700 hours  
5 of training, but historically, physicians have done 200  
6 hours of didactic work and 500 hours of experiential  
7 work. And that's what most people do. But I can say  
8 in this case, I'm trying to -- how would you have these  
9 physicians do 500 hours of experiential work for a  
10 patient-ready dose? They don't need to learn how to  
11 interpret images. They don't need to learn all the  
12 things that you need to learn about nuclear medicine.

13 So I think that if you look at the training  
14 experience, look at it not on who's referring to whom,  
15 but on what does it take to administer these safely.  
16 And I think that it would behoove us to look at a  
17 competency-based education model. That's all my  
18 comments.

19 CHAIRMAN ALDERSON: Thank you.

20 DR. WEATHERMAN: I'd like to make a comment  
21 as well.

22 CHAIRMAN ALDERSON: Yes, and who is  
23 speaking now?

24 DR. WEATHERMAN: Kara Weatherman from

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1 Purdue.

2 CHAIRMAN ALDERSON: Yes, please.

3 DR. WEATHERMAN: So I agree entirely with  
4 Nicki's statement, but I also think we need to keep in  
5 mind that the technology that we're seeing from the  
6 education perspective is changing dramatically which  
7 allows us to do a lot more interactive and engaging type  
8 of assessments and evaluating the training of some of  
9 our folks when they actually go through training  
10 programs.

11 And so I think a lot of times we kind of  
12 started this discussion with paper, pencil, and taking  
13 a test and things like that and I think as we embrace  
14 the changes in technology that we see in education, I  
15 think we're seeing much better educational models and  
16 training methodologies that can be done in a lot shorter  
17 period of time. And that's only going to improve with  
18 time.

19 CHAIRMAN ALDERSON: Yes. Thank you for  
20 that comment. We certainly are aware of those  
21 educational changes and we'll take those into  
22 consideration.

23 Are there other comments from people on the  
24 line?

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1 MEMBER COSTELLO: Yes, this is Frank. Can  
2 you hear me?

3 CHAIRMAN ALDERSON: This is Frank. We  
4 hear you Frank. Speak up.

5 MEMBER COSTELLO: Okay, I think in some  
6 ways it's irrelevant at this point whether -- why  
7 medical oncologists do or do not refer patients to  
8 nuclear medicine or radiation oncologists. I think the  
9 question really is what is the appropriate amount of  
10 training necessary to administer alpha- and  
11 beta-emitters. And I think that's what our  
12 subcommittee is going to be looking into.

13 But I think the problem that comes from that  
14 is that the current Part 35 changes are too far down the  
15 line and they're not going to be held up for this.  
16 Whatever the subcommittee comes up with and whatever the  
17 full committee winds up approving, even if it were to  
18 say 80 hours is enough, people should recognize it's  
19 going to be years and years before that can come into  
20 effect. That's just the way the rulemaking process  
21 works.

22 So ultimately, I think, our subcommittee is  
23 going to look at it, what's the perfect number of hours?  
24 And do you use competency-based training? But we

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1 should recognize that this is not going to be a fast  
2 process and I don't know anything that could improve  
3 that. Thank you.

4 CHAIRMAN ALDERSON: Thank you, Frank.  
5 Frank is a member of this committee, but he could not  
6 be here today, so he is speaking by phone from his home.

7 Are there any other calls from outside?

8 OPERATOR: Yes, sir. We have just one at  
9 this time. Karl Schwartz, your line is open.

10 CHAIRMAN ALDERSON: Very good.

11 MR. SCHWARTZ: Yes, thank you. My name is  
12 Karl Schwartz. I'm President and Founder of Patients  
13 Against Lymphoma. I've also served as a research  
14 advocate on the Alliance, the Cooperative Groups, and  
15 the NCI Steering Committee. I want to thank the  
16 committee for hearing the concerns of patients. I  
17 think many of the prior speakers have done that  
18 eloquently on behalf of the patients.

19 I'll limit my comments to what hasn't been  
20 discussed or what still appears to be an open question  
21 among the committee members. I want to point out that  
22 a study I've cited in my written statement shows that  
23 80 percent of patients are diagnosed and treated in the  
24 community setting. So I think the point made earlier

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1 that elderly patients and patients in the community with  
2 lower incomes may not be able to even be referred to a  
3 nuclear medicine center.

4 So as a member of the Alliance, I worked  
5 with Dr. Bruce Cheson, who was the chair at the time and  
6 he didn't say this then, but he has said that I could  
7 make this quote, "That oncologists must send their  
8 patients elsewhere to receive radioimmunotherapy is the  
9 major reason for the low usage of this effective  
10 treatment."

11 So I think we should not expect that  
12 research concepts will develop when there is this lack  
13 of access to a drug. Why put your resources into the  
14 study of a treatment that is not widely available to the  
15 patient?

16 So I also want to make a comment that --  
17 about the Cancer Moonshot. The purpose of that is to  
18 foster treatment innovation, but it's also to ensure  
19 that innovations are accessible to the patients. Here,  
20 we have a new kind of drug that's half drug, half  
21 radiopharmaceutical, if you will. And I think it's a  
22 precedent-setting situation. It's a new type of  
23 therapy. It really is easy to administer and I know  
24 that first hand.

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1           My final point is it's not a me-too drug.  
2           It is perhaps the least burdensome treatment available  
3           to patients. It takes very little time to give it as  
4           described by the speakers. And it can lead to very  
5           durable remissions lasting many years. My spouse is in  
6           remission now for 12 years.

7           Finally, about conflict of interest. I  
8           think it's important to recognize that it exists, but  
9           it's not an inferred way. It is often unconsciously --  
10          it leads to unconscious decisions. We have many  
11          choices for lymphoma, but this drug is a unique choice.  
12          It has unique aspects that make it better suited for  
13          elderly patients who cannot tolerate chemotherapy.  
14          It's the only drug that can be given with so little  
15          burden to the patient that can achieve that goal. So  
16          I think it's important that we recognize that the  
17          patients are the primary stakeholders in the healthcare  
18          system, and we need to adapt and adjust our policy when  
19          new drugs come on the market for this drug and for future  
20          drugs. Thank you very much.

21                   CHAIRMAN ALDERSON: You're welcome. Are  
22                   there any other final comments on the phone?

23                   OPERATOR: There are none, sir. Thank  
24                   you.

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1 CHAIRMAN ALDERSON: There are none, so  
2 we're finished with those comments. And we'll turn our  
3 final comments here around the table.

4 Dr. Fein, do you have such comment?

5 DR. FEIN: Just, I'd just like to reiterate  
6 that it isn't just Zevalin. I'm here to talk about  
7 lymphoma and ASH's perspective which is focused on  
8 Zevalin for now. The bigger issue is this sort of  
9 practice for training and future access for  
10 hematologists/oncologists will enable, if we can find  
11 a path to get trained, it would enable and encourage  
12 companies to develop more radioimmunotherapy that will  
13 be part of the innovative treatments for the future.  
14 This is not just about what we have now. It's really  
15 focused on the future.

16 CHAIRMAN ALDERSON: Thank you. Thank  
17 you. Are there other comments?

18 DR. SHROTRIYA: I'd just like to make some  
19 final comments.

20 CHAIRMAN ALDERSON: One from the audience.

21 MR. SHEETZ: Mike Sheetz, University of  
22 Pittsburgh. I can understand your position to reduce  
23 the training and experience requirements for Y-90  
24 Zevalin, similar to what was done on I-131 sodium

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1 iodide. But I caution the committee on reducing the  
2 training and experience requirements for patient-ready  
3 doses as the FDA will likely approve lutetium-177,  
4 dotatate later this year, lutathera which is a 200  
5 millicurie administration, slow infusion, concomitant  
6 with an amino acid cocktail that could have adverse  
7 reactions so the patient would have to be admitted and  
8 so there are other products that may come down later.  
9 Patient-ready doses require much more knowledge and  
10 effort on radiation safety and issues of  
11 administration.

12 CHAIRMAN ALDERSON: Thank you, Dr. Sheetz.  
13 I don't want to get off into a discussion of that comment  
14 because that comment is generically relevant to these  
15 discussions, but not otherwise.

16 Are there other comments? Yes, from the  
17 audience.

18 MR. GOLDMAN: Good morning. I'm Ira  
19 Goldman from Lantheus Medical Imaging. We're the  
20 manufacturer of Quadramet. Just speaking on behalf of  
21 CORAR which Spectrum is a member. CORAR which is the  
22 Council Radionuclides and Radiopharmaceuticals.  
23 We're an industry group. We have corresponded with the  
24 committee.

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1           We are supportive of a new look at these  
2 requirements. We do think that there needs to be a  
3 reduction in the requirements because as several people  
4 have noted, not only are there a number of  
5 radiopharmaceuticals on the market today which we  
6 believe are under utilized. There's a complex of  
7 reasons for that, but we do think these training  
8 requirements are excessive, but as noted, we do see new  
9 radiopharmaceuticals coming out in the market very soon  
10 which, you know, have a lot a promise for treating cancer  
11 and it would be a shame if some of these new drugs  
12 suffered some of the difficulties and under use that  
13 we've seen from some drugs that have been on the market  
14 for some time. Thank you.

15           CHAIRMAN ALDERSON: All right, any final  
16 comments? We're about to close the session. Yes.  
17 Dr. Shrotriya.

18           DR. SHROTRIYA: Chairman Alderson, thank  
19 you very much for giving me this opportunity to make some  
20 final comments. I'll make four points.

21           First of all, we didn't invent this drug.  
22 Biogen Idec did. And after 700 hours of training killed  
23 their interest in this drug. And four years later, they  
24 walked away from it. Bayer Germany was the developer

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1 of this drug in Europe and they walked away from it.  
2 Spectrum came onto the scene about ten years ago. And  
3 we made this patient-ready dose. It was not a  
4 patient-ready dose at that time. In fact, when FDA  
5 approved this drug, it was only for a lapse of refractory  
6 indication for lymphoma. We dictated their trials and  
7 got approval from the FDA in 2007 as a first-line  
8 palliative treatment for lymphoma. And were really  
9 aggressive. We have 50 people transferred to educate  
10 physicians and to get this done. We were absolutely  
11 frustrated by 700 hours of training. Physicians  
12 dropped their hands. And keep in mind, the other  
13 treatment that the people use for this was given every  
14 three weeks for two years to these elderly patients and  
15 it cost them hundreds of thousands of dollars and  
16 inconvenience.

17 So FDA has been really kind to us that we  
18 have received now another indication for this drug and  
19 we have gotten rid of the requirement that first we have  
20 to give a dose and get a bioscan. So patients that to  
21 really be in a hospital setting.

22 The second point I want to make is that  
23 innovation, if these drugs walk away like Bexxar has  
24 gone away and Zevalin will go away. I can assure you,

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1 I'm not investing and continuing to market this drug,  
2 but it's not about Zevalin.

3 I'm here to talk about the  
4 radioimmunotherapy. As a practicing physician, I want  
5 these drugs not to go away, as you heard from Dr. Mort  
6 Diamond. We want these drugs to be encouraged that they  
7 should be used. If physicians and oncologists, 80  
8 percent of these patients are treated in community  
9 centers, not in major centers where they have access to  
10 authorized users. And their people want to be able to  
11 give this drug to their patients like they give other  
12 treatments. Right now, they cannot do it.

13 Third point is our safety and access,  
14 patients' access. And please, I urge this committee to  
15 make recommendations for a revised training, that I  
16 believe is somewhere between 20 to 80 hours, but  
17 certainly not 800 hours. And I would like to urge you,  
18 request you that we don't wait for the next five years.  
19 Please do this as soon as you can. Thank you very much  
20 for this time.

21 CHAIRMAN ALDERSON: So I am going to take  
22 the chairman's prerogative to call this session to  
23 close. We're almost ten minutes over time. I think it's  
24 been a wonderful discussion from people on all sides,

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1 both in the room and on the phone, and clearly it's going  
2 to be an issue of great interest to the committee, the  
3 subcommittee, as the ACMUI moves forward. So with  
4 that, this session will conclude and we will reconvene  
5 at 1 p.m. Thank you very much.

6 (Whereupon, the above-entitled matter went  
7 off the record at 11:35 a.m. and resumed at 1:00 p.m.)

8 CHAIRMAN ALDERSON: All right. We're  
9 going to reconvene the meeting of the Advisory Committee  
10 on the Medical Uses Isotopes for the Friday afternoon  
11 session.

12 Before we begin this session and for the  
13 record Esther Houseman would like to enter a numerical  
14 correction from the discussion of the last session.

15 MS. HOUSEMAN: Yes, thank you. I wanted  
16 to correct a number that I provided in response to Dr.  
17 Zanzonico's question of how many hours of training and  
18 experience the NRC proposed in its -- it was the 1998  
19 proposed rule. And that's the training and experience  
20 requirement for therapeutic use of unsealed byproduct  
21 material.

22 I said that I thought it was 80 hours. It  
23 was actually 120 hours. That's 80 hours of didactic  
24 training and plus 40 hours of practical experience.

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1 And then as we all know in the final rule that changed  
2 to 700 hours. So I just wanted to be sure to correct  
3 that number for the record. Thank you.

4 CHAIRMAN ALDERSON: Thank you very much.

5 All right. We'll proceed now with the new  
6 session, which is the worldwide supply of  
7 molybdenum-99. And Mr. Richard Green will provide and  
8 update for us.

9 MR. GREEN: Good afternoon. Thank you,  
10 Dr. Alderson. It's kind of a horrific experience to try  
11 to summarize the worldwide supply, and I don't speak on  
12 behalf of any of the suppliers. In my position as a  
13 nuclear pharmacist I'm a consumer of molybdenum and  
14 technetium, so I'm going to give you my perspective as  
15 a purchaser and user of technetium. I'm pleased that  
16 we do have some representatives in the room today who  
17 are actually manufacturers in that supply chain and hope  
18 they'll be able to speak.

19 So we'll look at the supply chain, and it  
20 is a global supply chain. One thing we can say today,  
21 none of the moly is made in America. And that will be  
22 changing I think in the near term. We'll look at how  
23 we might have a ripple in the supply chain with the later  
24 this month closure of the Canadian Chalk River reactor,

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1 the NRU reactor, the National Research reactor that's  
2 been the major supplier of worldwide molybdenum for the  
3 last 50-plus years.

4 Can't get away from this topic without  
5 throwing in some comments about how changes from highly  
6 enriched uranium to non-highly enriched uranium will  
7 also impact supply, and that's got to do with the Global  
8 Threat Reduction Initiative. And then we'll get into  
9 some bright aspects of potential new supplies that have  
10 not been on the map before that are actually  
11 domestically located in the U.S.

12 First of all, for those who may not know,  
13 we're talking about molybdenum, but I don't use  
14 molybdenum in patients. It's the decay product of  
15 moly-99, which is tech-99m, the six-hour half-life  
16 gamma emitter that we use in diagnostic imaging and  
17 nuclear medicine. And so from the worldwide standpoint  
18 the U.S. consumes approximately 44 percent of the  
19 worldwide supply of this isotope, but probably since the  
20 mid-'80s we've not manufactured any of this on our  
21 shores. It's all been sourced from outside the United  
22 States. So we consume at least half of the world supply  
23 of moly-99.

24 What do we do with moly-99? It is used to

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1 prepare technetium-99m radiopharmaceuticals where we  
2 could attach a compound to the isotope that's going to  
3 take this radiopharmaceutical to a different organ  
4 system: hearts, lung, liver, gall bladder, whatever the  
5 physician would like to see. And today there are 14  
6 tech-labeled radiopharmaceuticals where as you can see  
7 from the graph the vast majority of which are used in  
8 myocardial perfusion imaging, at over half of the entire  
9 volume. Coming in second would be the bone scan looking  
10 for metastatic spread of cancer.

11 But, so technetium is today the workhorse  
12 in nuclear medicine and it will continue to be so in the  
13 future. There's new compounds that are gallium  
14 labeled, gallium-68 that was a topic for discussion  
15 again later this afternoon, which is new and upcoming,  
16 but tech is always going to be our workhorse as long as  
17 we have access to it.

18 So real briefly, today's supply of  
19 molybdenum-99 originates in a nuclear reactor. There  
20 are lots of reactors around the world that can produce  
21 fission and split atoms and make heat and make steam and  
22 make turbines, go around to make power, but there are  
23 very few that are dedicated or available for  
24 radiopharmaceutical production. And today that is

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1 seven reactors in the entire world. Well, seven that  
2 produce moly commercial scale that are used in  
3 generators that are available in the United States.  
4 There are smaller reactors in Argentina, Russia, South  
5 Korea that can produce small-scale quantities that  
6 might serve local markets, but for U.S. use there are  
7 seven today.

8 And so it's when uranium-235 fissions are  
9 split by being hit by an incident neutron, we're going  
10 to break that atom into pieces. Six percent of fission  
11 byproducts are molybdenum-99, so they're going to sort  
12 through the pieces and pull out moly-99 and send it off.  
13 That sorting occurs at a processor. So you have the  
14 reactor that's going to take the target of clad  
15 uranium-235, put it in neutron flux, have it smashed  
16 into pieces, if you will, and then the processor is going  
17 to chemically dissolve that in a hot cell and purify bits  
18 and pieces.

19 We're specifically talking about moly-99,  
20 but also from this fission process we'd be getting  
21 iodine-131, xenon-133 and many other nuclides that are  
22 useful in nuclear medicine. So there are five  
23 processors that are going to sort through the bits and  
24 pieces.

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1           Here in the United States we have three  
2 commercial manufacturers that have FDA approval to  
3 provide molybdenum-99 generators. There are three  
4 depicted on the slide here. The first one, the upper  
5 left-hand corner is GE's product that is actually made  
6 in Amersham, United Kingdom and flown across the  
7 Atlantic in finished form. The Lantheus Medical  
8 Imaging is the white with the blue label. That comes  
9 out of Boston, Massachusetts, or -- what's the suburb?  
10 Anyway, Boston.

11           Billerica. Thank you. North Billerica.  
12 And Mallinckrodt Medical in St. Louis is the one  
13 depicted in the lowest picture. So there are three  
14 commercial manufacturers that can provide the industry,  
15 whether that be hospitals or radiopharmacies, moly  
16 generators today.

17           We need to have a little discussion about  
18 where the world is going. We talked about uranium-235,  
19 enriched uranium. We have to dig uranium ore in the  
20 earth to find the ore to make yellow cake to enrich.  
21 There's a threshold. Twenty percent or below is  
22 considered low enriched uranium. Above 20 percent is  
23 called high enriched uranium. And as you get higher  
24 enrichment -- with low enriched uranium you can fuel the

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1 nuclear reactor, you can make pellets and put them in  
2 a reactor and have fission.

3 Well, when you get high enriched uranium,  
4 you have the potential to make a nuclear bomb, make a  
5 weapon out of it, to weaponize it. And so there have  
6 been efforts in the recent past to limit the use of  
7 highly enriched uranium to manufacture radionuclides  
8 and molybdenum-99. And there's a slide on that later.

9 So there are concerns going forward that  
10 will affect this whole dynamics of supply is what are  
11 you using to make the moly? Is your reactor fuel highly  
12 enriched? Is your target highly enriched? And when  
13 are you changing to low enriched, because that is the  
14 directive we received from Congress to link the threat  
15 of potential terrorism acts by limiting access to high  
16 enriched. So it is the reactor fuel and the targets  
17 that are both involved.

18 I've attempted to take this -- I apologize.  
19 There are some very small font on this, but it shows the  
20 complexity of the moly-99 supply chain. The top bar in  
21 blue is all in the reactor. And so it's around nine days  
22 total time to take targets of clad uranium and put them  
23 down into the target chambers, the slots, and bombard  
24 them with neutrons for four to eight days to split

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1 uranium into pieces and then take out that very highly  
2 radioactive target and take it into a hot cell and  
3 chemically purify that, separate it out and come out  
4 with the pieces that you want. The rest gets relegated  
5 to radioactive waste. So it's got nine days on that  
6 first horizontal bar.

7 Middle bar in the yellow or orange is a  
8 transportation cycle to get that to the manufacturer,  
9 to Lantheus Medical Imaging or Mallinckrodt or GE where  
10 they have to put it into a form that's been approved by  
11 the FDA as a commercial drug product that comports with  
12 their license application package insert.

13 And then logistics, to get that to the point  
14 of use. So as you'll see in a minute as I pull up a  
15 worldwide map, we may be going from Central Europe to  
16 North America to San Antonio. So there's a lot of  
17 logistics that is behind the scenes that if pharmacists  
18 do their job, it's transparent to the physician, it's  
19 transparent to the patient. The stuff is just there.  
20 But there's a lot involved in this process.

21 The very last line, the line in greenish  
22 tint is local. In your community, at your hospital, at  
23 Sloan Kettering or in your communities where the  
24 generator arrives Federal Express, where a pharmacist

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1 or technician can get access to that and extract  
2 short-lived technetium from that molybdenum generator  
3 and then finally prepare kits and get doses out to the  
4 patient.

5 In the U.S. today over 90 percent of all  
6 radiopharmaceuticals, not just technetium-labeled, but  
7 all pharmaceuticals originate from a centralized  
8 nuclear pharmacy. So that's why we have the unit dose  
9 led pig depicted in the car, because we're going to make  
10 that at one site and then transport those to the 15 or  
11 20 hospitals in town and out-patient clinics that are  
12 there as well. So it's part of the logistics process.

13 If we go back to the beginning, to the  
14 reactors, let's look at a list of reactors and  
15 physically where they are and; although this is a little  
16 bit shocking, how old they are. The NRU is in Chalk  
17 River, Canada. It was commissioned in 1957 and it is  
18 closing 24 days from today. Okay? Halloween. That's  
19 a kind of scary day. But October 31st is when they will  
20 stop the commercial manufacture of  
21 radiopharmaceuticals. They're still going to be up and  
22 running for other industrial purposes. It's a great  
23 source of neutrons, but they're not going to be  
24 manufacturing molybdenum.

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1           So with that impending closure is that  
2 going to destabilize the market? Will there be no  
3 supply? If anyone lived through the 2009-2010 moly  
4 crisis, you're thinking, oh, my God, here we go again.  
5 Well, I can tell you the world is different. Back then  
6 we didn't have the collaboration between the  
7 Association of Imaging Producers and Equipment  
8 Suppliers or AIPES. We didn't have the Organization of  
9 Economic Cooperation and Development, or OECD, that  
10 coordinate between reactors so that they're not  
11 inadvertently all down at the same time for maintenance.

12           They coordinate their maintenance and say,  
13 okay, you go down this month. I'll stay up and I'll go  
14 down the next month. Because these guys, if you look  
15 at that list, there are many generators here that I can  
16 say are older than I am. And if my knees are rickety,  
17 I'm sure theirs are, too. The only one at the bottom,  
18 the Australian reactor in Lucas Heights, the ANSTO OPAL  
19 reactor, is new, 2007.

20           In addition to this list you can see the  
21 fuel type. Many of the reactors are still using highly  
22 enriched uranium or HEU. That's no longer going to be  
23 available I believe this year or next. So they're going  
24 to have to convert over to using LEU as a fuel type. And

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1 then the targets will have to convert over from HEU to  
2 LEU.

3 Now, is that a big deal? Well, it affects  
4 the commercial scale of manufacturing. I don't know  
5 what -- I stop at the enrichment they're using for their  
6 targets, but if we just simplify it, LEU is 20 percent  
7 is less. HEU could be as high as 100. So if you go from  
8 H to L, you may have to have five times as many targets  
9 to get the same amount of moly. You're also going to  
10 generate up to five times as much waste to get the same  
11 amount of moly. So that will affect the ability to  
12 produce and the cost to produce. So more on that later.

13 But as you can see they're old and none of  
14 them are in the United States.

15 Here's another way to depict the current  
16 supply chain maintenance. The HFR, which is closely  
17 associated with Mallinckrodt, is in the Netherlands.  
18 They're a large-scale producer. After the 2009-2010  
19 moly crisis Mallinckrodt was able to pull up additional  
20 resources. I know that the Maria reactor in Poland was  
21 an additional new entrant to the commercial  
22 marketplace. Same with the LVR-15 in the Czech  
23 Republic.

24 And very recent is the OPAL reactor in

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1 Australia. They've been producing for quite a while  
2 for domestic use in Australia, but they now can produce  
3 for the U.S. I know that Lantheus is sourcing some  
4 material from Australia and is able to provide not just  
5 moly, but on certain production cycles LEU generators  
6 that are entirely manufactured without any HEU product  
7 within them.

8 So those three commercial manufacturers of  
9 generators: Mallinckrodt, GE and Lantheus are  
10 connected, interconnected with multiple reactors and  
11 multiple processors. They don't put all their eggs in  
12 one basket. We've seen that have bad outcomes. So  
13 they've diversified their supply chain, which we in the  
14 industry are very appreciative of.

15 So the other thing is that the OPAL reactor  
16 has invested in the Australian Nuclear Medicine Project  
17 and they will be tripling their capacity. I made the  
18 business trip of a lifetime a year ago and flew to  
19 Australia to see that reactor. It's an amazing thing  
20 and they will play a more important role in domestic  
21 supply of moly in the U.S.

22 Another way to look at it, geographically  
23 superimposed on a map. You can see that the only  
24 reactor in North America is that Canadian reactor, which

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1 was opened in 1954 and she will be closing Halloween of  
2 this year. Okay. Now that's -- depending on how you  
3 look at your numbers, that may have been 40 percent of  
4 the supply. So will we manage without them? It's my  
5 opinion that we will. Because of the coordination  
6 between the reactor producers, the processing plants  
7 that target the targets and the generator manufacturers  
8 I think we'll have very good supply going forward.

9 As I mentioned earlier the American Medical  
10 Isotopes Production Act of 2009 for the first time that  
11 I can recall put forth U.S. money to support the  
12 production of isotopes used in nuclear medicine. And  
13 I think that's great. At the same time they said let's  
14 reduce the risk of potential terrorists acts using  
15 highly enriched uranium. So let's keep that to  
16 ourselves and not send it out there to places where it  
17 may become vulnerable.

18 So seven years after enactment; so I guess  
19 that's 2016, right, we're not going to provide HEU to  
20 a reactor that might be giving us moly. They need to  
21 convert over to LEU. So that will change their  
22 efficiencies and their number of targets and their  
23 waste. But I think that's a good thing going forward  
24 for stability of supply and for safety and the world.

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1 So as we talk about supply, this is a part of it,  
2 conversion to LEU from HEU. So the Global Threat  
3 Reduction Initiative was enacted to eliminate HEU as a  
4 source of medical isotopes. So GTRI is a worthwhile act  
5 and it's going to also play a role in supply.

6 Currently HEU is only sourced from the  
7 United States and from Russia. You can't buy it at a  
8 convenience store. There are very limited supplies and  
9 sellers that sell that. So you can see on the slide here  
10 that of the number of reactors; at that time it was 10,  
11 that only 3 have converted to LEU targetry. And that's  
12 a very small percentage.

13 Now there are lots of folks who can theorize  
14 in why this has been a slow conversion to non-HEU, and  
15 I think it's all based on economics. We have a large  
16 supplier to our north in Canada that's using highly  
17 enriched targets and highly enriched fuel, and they're  
18 economical. But once they're out of the mix I think  
19 we'll see a much more rapid adoption to the LEU targetry  
20 and LEU fuel. But that does have to happen. That will  
21 be the case going forward.

22 So we've talked about supply of moly from  
23 reactors. There is a bright spot on the horizon. Oh,  
24 I got my slides mixed up.

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1           So there may be disruptions. There's  
2 going to be unplanned shutdowns with old reactors.  
3 Hopefully they can schedule coordination of  
4 maintenance. There are permanent shutdowns coming in  
5 Canada. We've already had one French reactor, the  
6 OSIRIS, go down two years ago and is completely offline  
7 today. And the other large producer in the  
8 Netherlands, HFR, is targeted for replacement. So it  
9 has a finite life cycle as well.

10           Another thing that's on the horizon is  
11 what's called full-cost recovery. Where we've always  
12 thought that neutrons were cheap and they were  
13 available, we could just kind of use that reactor to make  
14 isotopes in addition to whatever else it's doing, that  
15 has undervalued the production of isotopes and made them  
16 perhaps artificially cheap. So now with full-cost  
17 recovery the OECD has said we've got to stand on our own  
18 two feet and we can't have government subsidizing that  
19 reactor. So we're going to see much more transparent  
20 perhaps of costing of the production of isotopes. We  
21 have to pull our own freight.

22           But the light that I see is that there are  
23 some U.S. producers coming on the market. I think are  
24 blessed to have a presentation shortly from NorthStar

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1 Medical Isotopes. Oddly both of these folks are up in  
2 Wisconsin, but they are going back to an old technology.  
3 They were the very first nuclear moly generators that  
4 were made in the U.S. were made with irradiated moly-98.

5 And so it produces moly-99, but it's low  
6 specific activity. It takes a large column or other  
7 ways to concentrate the product. And NorthStar is  
8 submitting before the FDA, as you can see depicted here,  
9 a multi-unit computer-controlled generator. Today's  
10 generators are a giant chunk of lead or depleted  
11 uranium, no user service to the parts inside. You don't  
12 plug it in. It's very simple. You use a vacuum and you  
13 suck saline through and you withdraw the technetium from  
14 the mother isotope. It's very simple.

15 They're looking an innovative technology  
16 to separate and concentrate the technetium from this low  
17 specific activity moly. So their short-term use  
18 intention is to produce moly from moly-98. I believe  
19 this will be the MURR, the Missouri University Research  
20 Reactor in Columbia, Missouri. And then longer term  
21 use a nuclear accelerator to take moly-100 with a P2N  
22 reaction to moly-99.

23 The second firm that I should mention is  
24 Shine Medical Technologies. They are looking at an

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1 innovative way to use -- to obtain neutrons, not from  
2 a reactor, but from an accelerator, where they  
3 accelerate protons to hit a target to generate neutrons  
4 to cause fission in a source of liquid uranium salts.  
5 They can colloquially open the tap, take some of it out,  
6 chemically purify the moly and put the leftovers back  
7 in. And so that will be again another domestic source  
8 of moly-99 that won't be using a traditional reactor.

9 Now just recently, it may have been the last  
10 week, there was the National Academy of Sciences  
11 publication that in my mind was Chicken Little. Is the  
12 world going to fall? Is the sky falling? Are we going  
13 to have a repeat of 2009-2010? It's my opinion that we  
14 won't see that. I think there's been great  
15 collaboration between the reactor managers and the  
16 producers.

17 The OECD has projected this out. And you  
18 can see the green line is the demand, current demand with  
19 a slight increase over time. We see nuclear medicine  
20 getting slightly higher volumes as we recuperate and  
21 come back from that moly crisis in '09 and '10.

22 The blue line is the drop in processing  
23 capacity. Again with the departure of this Canadian  
24 reactor we're also losing one of our processors who used

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1 to dissolve targets and separate out the moly.

2 The yellow and red lines represent  
3 production capacity with outage reserve capacity. And  
4 this is where they planned. A reactor may have -- and  
5 I'm making up numbers in my head. A reactor may have  
6 50 target slots where you could put something in there  
7 and bombard with neutrons. And because of the supply  
8 and demand the manufacturer of the generators rents out  
9 16 slots and they put targets in those 16 slots, and that  
10 gives them enough moly to meet their demand.

11 Well, what they've done now is they don't rent out  
12 16 slots. They may rent out 20 or 24 slots. They may  
13 not slip targets in all of the, but they've got reserved  
14 space, outage reserve capacity. So if a reactor goes  
15 down or has a maintenance issue, they can insert their  
16 targets into their reserved spots to produce moly.

17 So now; and knock on wood, we have the  
18 ability to -- even with one less reactor and one less  
19 processing plant I think we'll have a fairly stable  
20 supply of moly going into the future. Again, in  
21 addition to this we have the opportunity to have some  
22 domestic supply and some innovative sources that we have  
23 not had in the past.

24 So in my mind; and this is my opinion, I

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1 don't think the sky is falling. I think we'll be able  
2 to serve our patients and look forward to some  
3 innovative ways to get the moly that we need. Thank  
4 you.

5 CHAIRMAN ALDERSON: Questions from the  
6 ACMUI? Dr. Zanzonico?

7 VICE-CHAIR ZANZONICO: It was my  
8 understanding at one time that I guess it was Medicare  
9 or one of the payers was paying incrementally higher  
10 reimbursement for using technetium from a low enriched  
11 uranium. Is that still in effect?

12 MR. GREEN: That's still the case. CMS  
13 does offer, if you ask for it, a \$10 supplemental  
14 reimbursement for unit doses or patient doses of  
15 technetium-99m radiopharmaceuticals that were  
16 prepared; and I'm going to correct you slightly, with  
17 technetium obtained from non-HEU sources. Now we have  
18 to call it non-HEU. It's so much simpler to say LEU,  
19 but as I just showed you on that last slide we have a  
20 couple processors here who'll be making uranium  
21 -- making moly that doesn't start from uranium. So it  
22 really is correct to say non-HEU.

23 So, yes, they're trying to realize that  
24 with the full-cost recovery, with using much less

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1 efficient low enriched uranium as targetry and a fuel  
2 the cost is going to go up. And so they said if you are  
3 going to get unit doses of tech-99m pharmaceuticals from  
4 sources that are 95 percent or greater non-HEU and you  
5 submit the request, we'll give you \$10 per patient. I  
6 don't know exactly how long that will be, but there does  
7 need to be a little bit of a readjustment with  
8 reimbursement because the world is not going to be as  
9 cheap as it is today.

10 VICE-CHAIR ZANZONICO: Another question.  
11 So as we transition, at least in part, from  
12 international to domestic suppliers, I can't imagine  
13 shipping radioactive materials in general  
14 internationally is cheap. Could we anticipate a  
15 reduction in overall cost of technetium as it becomes  
16 more domestically produced and shipping costs  
17 presumably go down?

18 MR. GREEN: I'll let the manufacturers  
19 speak to actual -- I would think that transportation is  
20 probably one of the smallest cost variables. I mean,  
21 it's one flight out of Belgium, I mean from the IRE  
22 reactor, from the Netherlands reactor. We had a  
23 problem where there was terrorism in Belgium. We had  
24 problems when there was a volcano on Iceland. That

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1 shouldn't be a problem if we have a domestic source.

2 I think any domestic production puts more  
3 moly in the pie. So whether it's a U.S. producer or some  
4 produced in South Korea or Russia or Argentina, that's  
5 just more in the worldwide supply. So I think  
6 transportation of the bulk moly -- it's one cask on one  
7 flight, so I really don't think that will play much role.

8 CHAIRMAN ALDERSON: You describe, Mr.  
9 Green, that short term the reactor at the University of  
10 Missouri is going to come on line to fulfill an amount  
11 of the need. How much of that need and how long? I  
12 mean, you say "short term." What does that really mean?

13 MR. GREEN: Well, I think they're standing  
14 up a processing plant so that they can chemically  
15 separate out isotopes from their targetry. So that's  
16 nice that we'll have a domestic processor. I know that  
17 -- and again, I won't speak for their; they're coming  
18 up shortly, but I think NorthStar has a short term  
19 -- with the unenriched moly-98 they can only make I think  
20 a generator that may be a six-curie generator.

21 Well, once they get the other processor using  
22 enriched moly-98, they can make a higher activity yield.  
23 Because right now as a nuclear pharmacist I can get my  
24 hands on and 18 or 19-curie generator. So having to

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1 have multiple six curies would be quite inconvenient and  
2 quite cumbersome. So their first out-of-the-gate is  
3 make some and then later make improvements and make it  
4 more available. So we'll have more.

5 Again, I don't know what market share  
6 they're targeting to acquire, but any moly produced in  
7 America I think is positive.

8 CHAIRMAN ALDERSON: Thank you.

9 Dr. Langhorst?

10 MEMBER LANGHORST: Just to clarify,  
11 University of Missouri Research Reactor is working with  
12 these companies, and NorthStar is one of them, to  
13 irradiate this, but MURR is not setting up their own  
14 processing plant. So they're working through some of  
15 these other companies that are trying to establish  
16 domestic --

17 MR. GREEN: Good. Okay.

18 MEMBER LANGHORST: -- production.

19 MR. GREEN: Good. Thank you.

20 CHAIRMAN ALDERSON: Other questions?

21 (No audible response.)

22 CHAIRMAN ALDERSON: From the audience,  
23 anything?

24 (No audible response.)

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1 CHAIRMAN ALDERSON: Yes?

2 OPERATOR: If anyone on the audio lines  
3 would like to press star, one to queue up for questions  
4 or comments.

5 CHAIRMAN ALDERSON: We'll take one  
6 question here in the audience.

7 OPERATOR: Thank you.

8 CHAIRMAN ALDERSON: Yes.

9 MR. GOLDMAN: Ira Goldman, Lantheus  
10 Medical Imaging. I'm also the co-chair of the CORAR  
11 Isotope Supply Committee and the vice-chair of the AIPES  
12 Reactor and Isotope Working Group.

13 I'd like to thank Rich. I think you made  
14 a very good concise presentation about the current state  
15 of supply and the perspective. A couple things I would  
16 just add.

17 People are worried about the end of isotope  
18 production in the NRU, which is less than a month from  
19 now. As he noted the NRU will continue to operate even  
20 though they won't be producing moly-99 and the Canadian  
21 government has announced that they will have an  
22 arrangement in place that if there is some severe  
23 disruption of isotope supply up until the time of the  
24 end of March of 2018 when the reactor will close

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1 permanently, then they will be prepared to reenter the  
2 market to provide an emergency backup supply  
3 arrangement. So that's an important insurance policy.

4 At the same time, he mentioned, Rich  
5 mentioned, the Australian Nuclear Medicine Project,  
6 which is going to -- which is building a new processing  
7 facility. And they're currently hoping to be online by  
8 the middle of next year. But at the same time Australia  
9 has recently increased its capacity from its existing  
10 processing facility, whereas they were making about  
11 1,000 curies a week and now they're up close to 2,000  
12 curies per week.

13 So with the NRU and Nordien not supplying  
14 after the beginning of November of this year there has  
15 been already a step up in capacity from Australia. Plus  
16 Belgium has been authorized to produce at a higher  
17 level. Mallinckrodt has announced that they're going  
18 to be producing moly at a higher level. So it looks like  
19 there is new capacity already coming into the system  
20 even before some of these new projects, including the  
21 U.S. projects, actually would produce moly-99.

22 So the only thing is, is that there will be  
23 fewer processors and fewer reactors even if there is  
24 equivalent capacity that does create some

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1       vulnerabilities and less overall spare capacity in the  
2       system.

3               So we do expect industry -- both AIPES and  
4       CORAR are confident that the industry because of the  
5       measures that have been taken over the past five years  
6       to further diversify supply, bring new reactors online,  
7       bring new capacity online, that there will be the  
8       ability to reliably supply sufficient moly to make  
9       technetium generators.

10              The one thing I would note is that without  
11       a local processing capacity here in North America, which  
12       provided us the ability sometimes to get last-minute  
13       moly when there was a disruption, even just a logistics  
14       disruption -- because the moly that does come from  
15       overseas comes on commercial aircraft. And so there  
16       are sometimes problems with that. So we've had the  
17       luxury of being able to kind of call up Nordien at the  
18       last minute. And since, at least for Lantheus, it's  
19       only an hour flight away, they've been able to kind of  
20       ruffle out some short-term problems. That's not going  
21       to be available.

22              So we may see just a little bit more kind  
23       of fluctuation where you may have a problem on a day  
24       basis because of a transport problem or the like, which

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1 is inevitable in this far-flung supply chain.  
2 But the message is we do feel that the situation is  
3 manageable. New capacity will further be coming online  
4 in the next year and beyond that. And we're pretty  
5 confident that barring some unforeseen disaster there  
6 will be a sufficient reliable supply over the next few  
7 years.

8 CHAIRMAN ALDERSON: Thank you. Are there  
9 other comments or questions? Yes?

10 MR. FULLER: I just had a question, and I  
11 think, Mr. Green, you should probably be able to help  
12 me out here, but others in the room might also as well.

13 Years ago, many years ago; I'm old enough  
14 to remember when, basically moly and technetium-99m was  
15 the absolute workhorse when it came to nuclear imaging  
16 studies and so forth. But now we have other pet  
17 pharmaceuticals and so forth. Could you give us an idea  
18 of the mix now? If you talk about total imaging  
19 studies, how many are moly-based and how many are -- or  
20 what percentage -- just kind of like a big picture,  
21 please?

22 MR. GREEN: Eighty-five percent are still  
23 technetium-based. Xenon, thallium, gallium-67,  
24 gallium-68, all the fluorinated compounds, Y-90

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1 compounds. But still 85 percent is technetium.  
2 They're still our workhorse and are going to be in the  
3 future.

4 CHAIRMAN ALDERSON: Thank you, Mr. Fuller.

5 Any other questions?

6 (No audible response.)

7 CHAIRMAN ALDERSON: Seeing none, thank you  
8 very much, Mr. Green, for a fine report.

9 And that will carry us onto the next  
10 presentation. Dr. Howe and Dr. Dilsizian are going to  
11 talk to us about the NorthStar Generation Licensing  
12 Guidance.

13 DR. HOWE: Thank you, Dr. Alderson.

14 Let's see. Oh, let me back up a little bit.  
15 The subject of my discussion is going to be the NorthStar  
16 and our licensing guidance. The first thing you're  
17 going to notice on the cover slide is it's not just  
18 medical use licensees. It is also for commercial  
19 nuclear pharmacies. This is one of the first guidance  
20 documents that has covered more than just 35.1000.

21 On my next slide I'm going to -- I'm showing  
22 you an image of the NorthStar generator. The first  
23 thing you notice is it's not your grandparents' moly  
24 generator. There's a little square over to the

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1 left-hand side that says, source vessel. That source  
2 vessel is roughly the size of a current big technetium  
3 moly generator. And Richard Green gave us a nice  
4 description of the current fission moly generators  
5 where you put liquid in the top, you elute the technetium  
6 off of the column. Then you have your technetium for  
7 your radiopharmaceuticals.

8 In this case you have a source vessel. The  
9 source vessel is a vial inside of a heavily-shielded  
10 transport container. And if you look at the diagram,  
11 you'll see four different doors that are labeled as  
12 transfer doors. And those are the locations that you  
13 put each one of these source vessels in. You have to  
14 connect it out to the rest of the device. And that's  
15 where the moly is going to come from.

16 Now the source vessel goes into the  
17 transfer door, gets connected by tubing. It goes up  
18 into the service bay door. The service bay door is  
19 where the heart of the NorthStar generator is located.  
20 It's where the syringe pump is located. It's where the  
21 multi-barrel distribution point is. Because you're  
22 going to do a lot of -- you're going to do some chemical  
23 separation preparation here. And at the top right  
24 above the service bay door there's a white thing, and

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1 that white thing happens to be the chemicals that you're  
2 going to be processing through this device.

3 So what happens is you take the moly and you  
4 pull it out of the source vessel. You ship it up through  
5 the service bay door. You distribute it to where it  
6 needs to be at that particular point of the process.  
7 All of this is computer-run. And you see the computer  
8 screen over to the side. There are about six protocols.  
9 Each protocol is a step in the moly production or a step  
10 in changing out a source vessel or a step in changing  
11 out a waste area, and it's multi steps.

12 So now the moly goes from the service bay  
13 door into a column behind the PSC door. The PSC door  
14 -- unlike the technetium moly generator that holds the  
15 moly and lets the technetium come off, this particular  
16 device holds the technetium and lets the moly flow  
17 through.

18 So where does it flow? It flows down to the  
19 box between the four transfer doors, and that's the  
20 -- well, the four source doors -- and that's the transfer  
21 door. And it goes into a location there. And then  
22 later on, once the process is finished for that  
23 particular amount of moly, it is transferred back to the  
24 source vessel that it came from. Okay?

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1                   And so then you process further behind the  
2 PSC door and eventually you wash it with chemicals  
3 coming from the top of the device and it will come off  
4 in the product door. And that's where your technetium  
5 is produced.

6                   Now, this particular device is regulated by  
7 both the NRC from a radiation safety perspective and  
8 also the FDA, because this particular device is the  
9 final step in the manufacturing of technetium. And  
10 because it's regulated by FDA, there are some  
11 considerations that FDA has that we're not concerned  
12 with, but they definitely affect radiation safety.

13                   You're seeing a device with a lot of doors.  
14 All of those doors are locked. A pharmacy will have to  
15 go in to almost every one of those doors at some part  
16 of the process to take out a component, to set up another  
17 component, to change out a chromatography column, to  
18 change the product door column, and everything has to  
19 be done in a sterile manner. So there's also an ozone  
20 sterilization process associated with this device, so  
21 that adds additional steps.

22                   And each time you open one of those doors  
23 the source shield is highly shielded, the doors are  
24 shielded, the container -- the cabinet that you have the

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1 door connected to is shielded. You now are opening up  
2 a shielded area if you have a potential for high  
3 radiation levels depending on where the moly is in the  
4 process, because the moly is being moved throughout this  
5 device at various times in its processing. And so you  
6 end up with additional radiation safety concerns that  
7 you don't have with a regular generator.

8 The other thing I want to point out is the  
9 heart and soul of this device is the service bay door.  
10 It is locked. It has components that are specifically  
11 designed for NorthStar to be used with this moly that  
12 are not accessible or available or need to be accessible  
13 or available to the end user. So that door is  
14 incredibly important and there's only one person at the  
15 facility that has a key to that door. And that door  
16 doesn't open without the direct -- I don't want to say  
17 supervision, but the direct correspondence with  
18 NorthStar. So as you're seeing from this description  
19 this is not your grandparents' generator.

20 So we were tasked -- we had a committee made  
21 up of NRC and Agreement State individuals to look at this  
22 generator and see whether it could be regulated under  
23 our current regulations or it would need to come under  
24 -- for the medical use, 35.1000. Our

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1 committee is -- as co-chair we have Marc Paulson from  
2 the State of Wisconsin and myself from the NRC. We have  
3 three other Agreement State representatives, Elaine  
4 Crescenzi from Pennsylvania; Karl Von Ahn, who started  
5 out from and then transferred to Texas; and Jason Kelly,  
6 who is in Texas; and three more NRC employees, Lymari  
7 Sepulveda, who is a member of the Sealed Source and  
8 Device Registry Group, because we felt we needed to look  
9 at this device in the same level of detail that you would  
10 for a device in the Sealed Source and Device Registry;  
11 and Cassandra Frazier in Region III and Maryann  
12 Abogunde, who is here in headquarters.

13 So we looked at this device and we said it's  
14 a closed system. It contains, moves and shields all  
15 moly-99. And this moly-99 comes in as a mixture,  
16 because it's always decaying, of moly-99 and  
17 technetium. And it can either come from moly-98 or it  
18 can either come from moly-100. It is computer-driven,  
19 so that makes sure things are going in the right  
20 sequence, the right valves are opening, the right valves  
21 are closing, but there is a lot of human intervention  
22 in here to change out from one procedure -- from one  
23 protocol to the next.

24 The materials used in this generator and

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1 the components are engineered to maintain the device's  
2 integrity as a closed system, withstand high radiation  
3 fields for extended periods, and to maintain adequate  
4 shielding when all the doors and the excess shielding  
5 is in place. It's designed and constructed with  
6 components that differ significantly from conventional  
7 moly generators, fission moly generators.

8 It needs additional information and  
9 commitments in order to be used safely. And it needs  
10 additional training and experience for individuals and  
11 it needs additional components to address specific  
12 training and safety -- commitments to address specific  
13 training and safety provisions. And for those reasons  
14 we put it in 35.1000.

15 You will see at this slide it says not only  
16 35.1000, but 30.33. 30.33 is the general licensing  
17 regulation that we have for regulating all byproduct  
18 material. And we felt that in order to put this  
19 generator in a commercial nuclear pharmacy that the  
20 current commitments that a commercial nuclear pharmacy  
21 has made are not adequate and the current training and  
22 experience requirements for the commercial nuclear  
23 pharmacy are not adequate to safely use this device.  
24 And so we are addressing those issues in our guidance

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1 also.

2 So our guidance is pre-decisional at this  
3 point. The ACMUI has reviewed the guidance. The  
4 Agreement States are reviewing it. Our regions are  
5 reviewing it. They're providing comments back to us.  
6 Dr. Dilsizian will give you a summary of the ACMUI review  
7 of the document.

8 So in our licensing guidance we're going to  
9 have some of the things that you see in all licensing  
10 guidance. We're going to talk about radionuclides,  
11 possession limits and purpose. We're going to have  
12 posting requirements. We're going to have training and  
13 experience for authorized individuals.

14 And why do we have authorized individuals?  
15 Because this could go into a medical facility and the  
16 authorized individual could be a physician AU. It  
17 could go into a big medical facility and the authorized  
18 individual that's running the device would actually be  
19 a nuclear pharmacist. And it goes into a commercial  
20 nuclear pharmacy, then the authorizing individual would  
21 be the authorized nuclear pharmacist.

22 We believe that the authorizing  
23 individuals need additional training and experience in  
24 using the RadioGenix and we believe that they need

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1 practical experience in running protocols and that they  
2 need an attestation that they have successfully  
3 completed that training.

4 We have a radiation safety officer and we  
5 believe this device is sufficiently different from  
6 anything else that the medical facility or commercial  
7 nuclear pharmacy has that he needs. He or she also  
8 needs specific training in the NorthStar RadioGenix  
9 system.

10 We have included training and experience  
11 for supervised individuals. We believe most people  
12 that are operating the unit on a day-to-day basis will  
13 be supervised individuals, supervised by the authorized  
14 individuals. But because this device has a number of  
15 protocols that have highly specific steps and radiation  
16 safety concerns associated with them, that these  
17 supervised individuals need to have highly specific  
18 training with the NorthStar generator and they need to  
19 be approved for each protocol that they will be using  
20 before they can use it and that they also will be tested  
21 to make sure that they can do things safely.

22 We've got a new individual that you've  
23 never heard of before. It's a RadioGenix system  
24 administrator. This person is responsible for putting

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1 the people that can run the protocols into the computer  
2 system that allows them to run the protocols. They are  
3 also the person that has control of that one key that  
4 we were talking about earlier for an area that should  
5 not have any one at a licensee's facility going into it  
6 without direct NorthStar oversight.

7 And there's also -- we recognize that the  
8 system -- one system administrator isn't going to be  
9 present all the time, so we designated a system  
10 administrator designee, and that responsibility is the  
11 person that has responsibility for the key if the system  
12 administrator is not there.

13 So in licensing commitments we realize that  
14 this particular device may go on the market before our  
15 current new Part 35 takes effect, so we have  
16 incorporated the new moly-99 concentration limits into  
17 our guidance. We have put in for training in licensing  
18 procedures. And we've also given licensees freedom  
19 that if there are changes to the training resulting from  
20 -- changes to the system that affect safety, we're going  
21 to set up a procedure where they can go ahead and  
22 incorporate those changes and not have to get a license  
23 condition because they'll already be granted an  
24 authorization for it.

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1           And then emergency procedures, we're also  
2 going to do the same thing with that, that if there are  
3 changes in the device that affect safety, if they've got  
4 a procedure that we've accepted, they can go ahead and  
5 make those changes without having to come in for us and  
6 special safety radiation.

7           We have notes to licensees. Many of these  
8 are general things that you've seen before. We are  
9 -- you cannot alter the RadioGenix without needing an  
10 amendment. You cannot use any other moly in the system  
11 without an amendment. You cannot use another generator  
12 with the NorthStar moly without needing an amendment.  
13 Can't change the physical conditions.

14           We are going to allow flexibility just as  
15 we do in Part 35 about notification. If you've got a  
16 trained authorized user that's already listed for this  
17 device, they can go to another licensee without having  
18 to provide their training already. And they can start  
19 working within -- as long as the agency is notified  
20 within 30 days. And if we've got things that change  
21 because we change our guidance, we have a provision that  
22 allows the licensee to adopt those provisions without  
23 having to come in for an amendment. So those are  
24 typical types of boilerplate procedures that we see for

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1 other 1000 devices.

2 And I've only used two abbreviations, moly  
3 and technetium.

4 CHAIRMAN ALDERSON: Thank you, Dr. Howe.

5 Questions for Dr. Howe?

6 DR. HOWE: Yes, Dr. Zanzonico?

7 VICE-CHAIR ZANZONICO: I have a couple  
8 questions. This may be over-thinking this, but on your  
9 photograph of the system --

10 DR. HOWE: Yes.

11 VICE-CHAIR ZANZONICO: -- the radiation  
12 trefoil symbol is only on two of them. That's not to  
13 imply that those are the only cabinets that contain  
14 radioactive material?

15 DR. HOWE: No, when they are using  
16 radioactive material in this device, we are going to  
17 require the trefoil on all places that have the material  
18 because the material will constantly be moving from one  
19 location to another location.

20 VICE-CHAIR ZANZONICO: And you also said  
21 that in these transfer doors the source -- so the source  
22 vessels are identical in terms of content? It's just for  
23 redundancy? So you don't have to change them that  
24 often?

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1 DR. HOWE: It's part of what Mr. Green was  
2 talking about. In order to have enough technetium to  
3 us on say a commercial pharmacy they may have four of  
4 these source vessels. Right now it's going to be about  
5 six curies so that they can make moly from each one of  
6 these source vessels, take -- make technetium from each  
7 one of these source vessels so they have enough  
8 technetium for a day's workload.

9 VICE-CHAIR ZANZONICO: But I presume you  
10 could operate it if there was some catastrophic  
11 shortage. And then someone who has the generator could  
12 only get one or two source vessels. You could still  
13 operate it under those circumstances? In other words,  
14 you don't have to have --

15 DR. HOWE: You do not have to have four.  
16 You can have one, two, three, any number. They've built  
17 it with four for the maximum.

18 VICE-CHAIR ZANZONICO: Yes. And --

19 CHAIRMAN ALDERSON: Mr. Green?

20 VICE-CHAIR ZANZONICO: Can I ask just one  
21 last question?

22 And I presume you still have to -- since  
23 there is radioactive modeling you still need to do some  
24 sort of moly breakthrough test with --

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1 (Simultaneous speaking.)

2 DR. HOWE: Yes, I mentioned that because  
3 this generator may go on the market before the new Part  
4 35 takes effect, that we have incorporated into the  
5 guidance the new moly breakthrough procedures.

6 CHAIRMAN ALDERSON: Mr. Green?

7 MR. GREEN: On slide 7 your second bullet,  
8 the note to licensees, you say there will most likely  
9 be a prohibition of using other moly or tech solutions  
10 or other generator systems. And I certainly do not want  
11 to advocate the combining or mixing, but I don't want  
12 that to be confused. If a pharmacy or hospital has a  
13 RadioGenix system, they will likely have a Mallinckrodt  
14 or a Lantheus or a GE grandfather-style,  
15 grandparent-style unit as well in the same room where  
16 you could elute the new one or the old style. You just  
17 can't put solutions in from the unit. But I don't want  
18 it to be --

19 DR. HOWE: No, my --

20 MR. GREEN; -- misinterpreted as --

21 DR. HOWE: If --

22 MR. GREEN: -- mixing.

23 DR. HOWE: I'm giving a really quick  
24 overview of the guidance. This is intended to address

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1       only the fact that you cannot take another moly and run  
2       it through this generator.    You cannot take the  
3       NorthStar moly and run it through some other generator  
4       other than RadioGenix.    I am not saying that a pharmacy  
5       can not have both a Lantheus, Mallinckrodt, NorthStar  
6       moly supply and use those for all of those materials.

7                The other point to make is that this  
8       technetium is -- has to meet the same standards of all  
9       technetium, so there is really virtually no difference.

10               CHAIRMAN ALDERSON:   Dr. Langhorst.

11               MEMBER LANGHORST:   More than likely this  
12       will be a central nuclear pharmacy, I would guess, and  
13       so more than likely the authorized individual will be  
14       an authorized nuclear pharmacist.   But you talk about  
15       authorized users.   Does that only mean an authorized  
16       user who's a physician, or can that authorized user be  
17       a non-physician authorized user and be responsible for  
18       this working also with -- perhaps with a pharmacist?

19               DR. HOWE:   Currently our regulations are  
20       set up -- so for a medical use licensee an authorized  
21       individual would be the nuclear pharmacist or the  
22       physician.   We would have to think about --

23               MEMBER LANGHORST:   Yes, you might want to  
24       clarify that.    I can't imagine it being a

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1 non-physician, but it could happen. And so I --

2 DR. HOWE: We --

3 (Simultaneous speaking.)

4 MEMBER LANGHORST: -- think you might want  
5 to clarify that.

6 DR. HOWE: We're having trouble imagining  
7 it being a non-physician and a non-commercial nuclear  
8 pharmacy.

9 MEMBER LANGHORST: Right.

10 DR. HOWE: And that's what you're talking  
11 about, having somebody that is either of those.

12 CHAIRMAN ALDERSON: Dr. Palestro?

13 MEMBER PALESTRO: Regarding the source  
14 vessel --

15 DR. HOWE: Yes.

16 MEMBER PALESTRO: -- which contains the  
17 molybdenum, with the conventional generator,  
18 molybdenum/technetium generators they expire after a  
19 certain date and they're shipped back to the  
20 manufacturer, to the processor. What happens here? I  
21 assume the molybdenum is in the source vessel. Where  
22 does that go?

23 DR. HOWE: The molybdenum will be sent back  
24 to the source vessel each time it's used. And so if it

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1 has gotten to a level that you really can't more  
2 technetium out for practicality, then that source  
3 vessel will be shipped back to NorthStar. And  
4 NorthStar will reprocess the source vessel and take the  
5 used moly out and then clean out the source vessel and  
6 the current -- as we understand, will send it off to MURR  
7 to have new moly put into it and then MURR will ship it  
8 to the end user.

9 MEMBER PALESTRO: One other question, if I  
10 may, a quick question.

11 CHAIRMAN ALDERSON: Yes.

12 MEMBER PALESTRO: It's hard looking at the  
13 image or the photograph to get a sense of the dimensions  
14 or the size of the generator.

15 DR. HOWE: Well, that's why I included the  
16 source vessel. The source vessel is essentially the  
17 same size as a traditional moly/tech generator. So the  
18 manufacturer has said in many public meetings that this  
19 occupies a surface area that's about the same as four  
20 large generators. It's a big thing. You stand and  
21 look eye to eye with the computer screen.

22 MEMBER PALESTRO: Thank you.

23 CHAIRMAN ALDERSON: Mr. Green?

24 MR. GREEN: Dr. Palestro, I believe it's a

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1 four-foot left to right. Again, since it has the  
2 capacity for four source vessels, if you elect or need  
3 that much activity, it is -- it's about four feet left  
4 to right.

5 Dr. Langhorst, there are very -- there are  
6 much fewer nuclear pharmacists in hospital practice  
7 settings than there were and the market is predominantly  
8 centralized nuclear pharmacy. There are more places  
9 where generators are used under the direction of the  
10 authorized user physician, but the technical hands-on  
11 users are nuclear medicine technologists. So you want  
12 to make sure that the regulations do not prohibit the  
13 nuclear medicine technologists from eluting this as  
14 they would a Lantheus or Mallinckrodt generator today.

15 DR. HOWE: Our current licensing scheme is  
16 to have -- in the case where you do not have a nuclear  
17 pharmacist and you are in a medical facility, the  
18 physician will be the responsible person. We are  
19 making sure they get adequate training. And then we are  
20 also recognizing that the supervised individual, which  
21 in your case that you're talking about would be the  
22 nuclear med tech, also has adequate training and  
23 authorization for each one of the protocols. So we  
24 think we have covered the spectrum.

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1 CHAIRMAN ALDERSON: Dr. Langhorst?

2 MEMBER LANGHORST: I wanted to ask about  
3 the training and experience documentation. And I agree  
4 this needs a lot of training and that needs to be  
5 documented that you have experience with it. And I  
6 appreciate the radiation safety aspect of things, too.

7 But am I understanding that all of the  
8 authorized individuals will have to have a preceptor  
9 signatures in order to show they've done this --

10 DR. HOWE: Yes.

11 MEMBER LANGHORST: -- documentation?

12 DR. HOWE: Absolutely.

13 MEMBER LANGHORST: And then you say for the  
14 system administrator they're not going to be there 24/7.  
15 Well, the RSO's not going to be there 24/7 either. Will  
16 all of the radiation technologists have to be? I mean,  
17 will health physicist or rad techs have to go through  
18 that preceptor training, too? Is that --

19 DR. HOWE: The -- what we have envisioned  
20 is that the radiation safety officers will get training  
21 from NorthStar on the radiation safety and emergency  
22 procedure aspects of this device, not on running the  
23 safety. Anybody that is going to run the device, if  
24 you're an authorized individual, will need a preceptor

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1 statement saying that they have done this. But also the  
2 supervised individual has to show they've -- they're  
3 proctored and they need to show they can successfully  
4 go through this before they're added to the system.

5 So they're -- but all the authorized  
6 individuals have to meet training and experience  
7 requirements to be on the license. The supervised  
8 individuals, that's the licensee's responsibility, but  
9 we explain what we think that responsibility is. And  
10 then the system administrator, that's the licensee's  
11 responsibility, and we explain what we think that  
12 responsibility is.

13 MEMBER LANGHORST: And so the radiation  
14 safety officer you're just saying needs to be trained,  
15 but there's no experience I'd have to show, or --

16 DR. HOWE: No, you have to go --

17 MEMBER LANGHORST: -- I'm confused on why  
18 I need a preceptor statement. I mean, I agree I need  
19 training and experience. But we will have the vendor  
20 signing off as our preceptor, is that correct?

21 DR. HOWE: Initially because no one else  
22 knows this system but the vendor.

23 CHAIRMAN ALDERSON: As we go onto the  
24 detail we really should hear from Dr. Dilsizian --

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1 DR. HOWE: I think so.

2 CHAIRMAN ALDERSON: -- who's going to talk  
3 a lot more about this generator. So let's let him speak  
4 and then we'll see where the questions are.

5 MEMBER DILSIZIAN: Thank you, Dr.  
6 Alderson, Dr. Howe, for that outstanding introduction  
7 to this topic already.

8 Dr. Alderson asked us as the Subcommittee  
9 members, which include Mr. Costello, Dr. Palestro, Dr.  
10 Zanzonico, and of course Dr. Howe was a key member of  
11 the NRC staff facilitating the conversation, to provide  
12 comments to the licensing guidance that was just  
13 described on this RadioGenix NorthStar agenda.

14 And so the Subcommittee's charge were  
15 rather twofold. One is to particularly focus on the  
16 training and experience, all individuals interacting  
17 with the generator, and safety precautions to minimize  
18 the potential of radiation exposure for individuals  
19 running the protocols and others in the room.

20 So as a background, which was already  
21 stated, just briefly, as you know the conventional  
22 column-based generator utilizes exclusively fission-  
23 produced molybdenum. Since foreign reactors,  
24 according to Mr. Green, are aging and increasingly

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1 unreliable there a welcome need for domestic supply of  
2 molybdenum-99. And the RadioGenix generator uses a  
3 linear-accelerator or neutrons from --- that's an  
4 accelerator, and thus should be addressing this unmet  
5 need for non-HEU molybdenum-99.

6 One thing the Subcommittee noticed as Dr.  
7 Howe was very elegantly going through all of these boxes  
8 this was very complicated for most of us. And we  
9 thought that despite putting labels and elegantly going  
10 through it, even third time around it was very difficult  
11 for me. So we thought that perhaps the best way to go  
12 through this is to have a video quick of the generator  
13 that actually shows the movements of how things are done  
14 from each box to the next box. And that would be  
15 probably the first recommendation for those who are  
16 going to be trained with the system to familiar with it.

17 Regarding training requirements, again  
18 there are a number of individuals involved with this  
19 equipment. Those who actually operate it, those are  
20 called the training individuals. And all of the  
21 individuals would have to go through these individual  
22 protocols, which I'd rather call them, as you can see  
23 later, individual tasks. And then there's going to be  
24 the system administrator or designee, a radiation

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1 safety officer, and of course an authorized user or an  
2 authorized nuclear pharmacist.

3 And so what is the -- again, the company  
4 calls protocols, but these are in essence steps,  
5 individual tasks, if you will, within -- there's only  
6 one protocol producing tech-99 and one software. These  
7 are simply steps to get that accomplished. And you can  
8 see it's initializing the system, adding or changing  
9 reagent kit, separating tech-99m, removing the source  
10 vessel, sterilizing and exchanged use reagent  
11 container.

12 The administrator, system administrator  
13 needs to make sure that the training individuals have  
14 actually gone through each of these individual tasks and  
15 signs off on it. And one individual obviously can't do  
16 all six, but you can imagine that several individuals  
17 can be doing several of these tasks at different times.

18 So the training and experience. So how  
19 shall we go about this? Well, it's a new system. And  
20 if you think about all of these individuals that needs  
21 to be trained, it will be difficult to have this all  
22 started. So since there's going to be large number of  
23 individuals to be trained and it's impractical, we felt  
24 that it is appropriate for NorthStar to start training

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1 the AUs and ANPs first.

2 And we also noted that as was discuss here  
3 given the complexity of the system this is not going to  
4 be in units, hospitals. It's probably going to be  
5 mostly in large pharmacies. And again, we estimate  
6 that it's probably going to be less than 10 percent of  
7 all clinical imaging programs that may even go here. So  
8 with that in mind, we felt that if the AUs or ANPs are  
9 trained first and then they go about and training each  
10 of these individuals that's probably much more  
11 practical than everybody going to NorthStar to be  
12 trained first.

13 And so what about the course itself?  
14 Should NRC be involved in deciding whether the course  
15 is appropriate or not? This was discussed. And given  
16 the unique design of the system and the operation of the  
17 NorthStar system, the Subcommittee agreed that  
18 NorthStar should probably be the sole responsibility  
19 for the content and the training course and  
20 certification because they really know the system best  
21 than the NRC Subcommittee members.

22 What about the system administrator or  
23 system administrator designee. It seems to be a unique  
24 position. As Dr. Howe very nicely described, this is

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1 a unique role to make sure that the operators are well  
2 trained and also has that key, specific key to so-call  
3 the brain of the system that only under unique  
4 situations that would be needed to open that box. But  
5 then we noted that perhaps given the unique role of the  
6 system administrator maybe this individual should be  
7 named on the license.

8 And we also noticed that it's was -- maybe  
9 there should be more than one designee, and that wasn't  
10 clarified. And perhaps it should be clarified whether  
11 it could be only one designee, several designees, and  
12 that's not very clear on the current guidance.

13 What about the changes? What if within six  
14 months or a year there's a new software or new changes  
15 that occur in the boxes? How will that be implemented?  
16 We feel that the changes should be the responsibility  
17 of the manufacturer, but there should be a specific time  
18 that should be specified from the change to how long will  
19 take to implement that change and how will this go about  
20 to introduce these changes to the AUs, RSOs and all those  
21 trainees? Again, this has not been defined well and we  
22 feel that there should be a time frame defined and  
23 perhaps -- again should the system be non-operational  
24 until all these occur or should it be continuing until

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1 everybody's trained? These have not been well defined  
2 and we felt that this was important to define in the  
3 document.

4           Again, the term "protocol, "software,"  
5 when I read it first I was very confused. I thought that  
6 there were a number of software, different protocols.  
7 To me it's individual tasks, but I understand that the  
8 way the company has written it each of those tasks is  
9 defined as protocols. To me a protocol has a multitude  
10 of tasks. But anyway, I thought that that should be  
11 clarified and the Subcommittee recommendation agreed on  
12 that.

13           Regarding safety precautions, which is our  
14 second main task, we felt that the licensing guidance  
15 was largely silent on the emergency response other than  
16 defer it to the procedures of the manufacturer. While  
17 the Subcommittee appreciates that NRC endeavors to be  
18 non-prescriptive, given the potential severity of the  
19 spill however with such large quantities of  
20 radioactivity in liquid form, perhaps the  
21 manufacturer's procedures should be reviewed and  
22 incorporated into the license guidance itself.

23           Regarding the surveys and survey meter and  
24 monitors, the guidance currently states that it is

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1 necessary for the licensee to routinely perform  
2 additional surveys to identify, "higher than expected  
3 radiation fields and system failures." Again, the  
4 Subcommittee recommendation was that the term "higher  
5 than expected" was rather vague. It should be defined  
6 in terms of maximum specific exposure or exposure-rate  
7 limit which a survey meter should be capable of  
8 measuring.

9 In conclusion, we felt that the Draft  
10 Licensing Guidance overall was reasonable and not  
11 particularly onerous for prospective users. And given  
12 the new and novel features of the NorthStar generator  
13 systems, licensing under 10 CFR 35.1000 is reasonable.  
14 Thank you very much.

15 CHAIRMAN ALDERSON: Thank you, Dr.  
16 Dilsizian.

17 So to those who would like to continue the  
18 discussions we've been having about the generator or ask  
19 questions, the floor is open. Anyone from the ACMUI  
20 that would like to ask? Dr. Langhorst?

21 MEMBER LANGHORST: I would just suggest  
22 for the Subcommittee the first ones needing to be  
23 trained are AUs, ANP and RSO, because you need the RSO  
24 to be able to get it licensed.

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1 MEMBER DILSIZIAN: That's a good point.

2 MEMBER LANGHORST: So you might want to add  
3 that.

4 MEMBER DILSIZIAN: Sure. That's a great  
5 point.

6 CHAIRMAN ALDERSON: Yes, Mr. Green?

7 MR. GREEN: Normally the preceptor is an  
8 authorized user. If the preceptor is the corporate  
9 representative, are they an authorized user or  
10 authorized nuclear pharmacist?

11 DR. HOWE: In 35.1000 guidance many times  
12 when you have a brand new device coming in there is no  
13 one other than the manufacturer that knows how to  
14 operate the device. And so we tend to let the  
15 manufacturer be the preceptor, specifically under this  
16 guidance, for a period of time. And then once there are  
17 more authorized users or authorized individuals, then  
18 they can assume the responsibility. But we do allow the  
19 manufacturer. And they may not be an authorized  
20 nuclear pharmacist, but they now their device.

21 MR. GREEN: Similar to our discussion  
22 earlier today about medical science liaisons training  
23 individual authorized users on the Y-90 spheres  
24 products where they attest that those are primarily

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1 physicians conducting that, individually all just  
2 conducting that training, it might be something to  
3 consider that the training staff that proctor or precept  
4 will be nuclear pharmacists.

5 MEMBER DILSIZIAN: Well, yes, I mean,  
6 unlike the Y-90 case it's really physician-patient  
7 relationship and a procedure that has complications and  
8 has implications about using it more frequently, in  
9 particular patients where industry's involvement may  
10 influence that. I think in this case we're talking  
11 about equipment that's complicated and we're talking  
12 about producing a product that's going to be used. And  
13 there's no real direct influence of that, if you will,  
14 by industry of utilizing technetium-99m, where in the  
15 Y-90 case I could understand the potential impact of  
16 influencing.

17 DR. HOWE: And let me add that we have built  
18 into our guidance that the training is provided either  
19 by NorthStar or someone that NorthStar certifies to  
20 provide the training. So when they feel comfortable  
21 that someone really understands what they're doing and  
22 how to train and certifies them to do the training, that  
23 person can start providing training. So that is the  
24 role I would see for your nuclear pharmacists down the

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1 road.

2 MR. GREEN: One question on the safety  
3 precautions, the higher than expected exposure rates.  
4 That may differ whether you've got one source vessel  
5 with six curies, for example, or four source vessels.  
6 So I'm not sure that the manufacturer can give you a  
7 number. If you exceed so many MR per hour, it may be  
8 difficult to do.

9 DR. HOWE: And our intent with higher than  
10 normal was because everything is behind closed doors and  
11 you are required to open these doors at different times  
12 to perform different functions, that the survey be made,  
13 and if it looks like it's higher than you would normally  
14 expect, then that's a good indicator that maybe you  
15 don't want to open that door and you want to step back.

16 MEMBER DILSIZIAN: So for that particular  
17 case for example what is more than expected? Some range  
18 right, I mean, and we will be --

19 DR. HOWE: Yes.

20 CHAIRMAN ALDERSON: Other questions? Dr.  
21 Langhorst?

22 MEMBER LANGHORST: I'll just weigh in on  
23 answering that. When you have a new source -- whatever  
24 you -- container, it'll have a high dose rate to it. If

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1 you have a lower one but it's still in use, yes, it may  
2 be -- I don't think you need to define that number. I  
3 think that's part of what you learn in the training and  
4 so on and part of your experience. I would be nervous  
5 of having the NRC set a number, because it's very hard  
6 to do.

7 DR. HOWE: And the difficulty with this one  
8 at setting a specific number is that you have this  
9 material moving --

10 MEMBER LANGHORST: Right.

11 DR. HOWE: -- between the different  
12 cabinets. And so at any given time that number can  
13 change based on the time in the protocol or maybe what's  
14 happening behind the closed door that may or may not be  
15 good.

16 I would like to also mention that we do have  
17 Jim Harvey on the phone, and so he is the NorthStar  
18 person that's responsible for this device.

19 CHAIRMAN ALDERSON: All right. So, Mr.  
20 Harvey's on the phone.

21 Can you hear us, sir?

22 DR. HARVEY: Yes, I can hear you and I'd be  
23 happy to provide a couple of clarifications and  
24 supporting statements to what Dr. Howe has already said,

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1 if you would like to hear them.

2 CHAIRMAN ALDERSON: Why don't you do that,  
3 sir? Yes, we'd be pleased to hear from you.

4 DR. HARVEY: First of all, there was a  
5 question on the professional photograph of the  
6 instrument that we had provided. That was just a  
7 professional photograph. The commercial units will go  
8 out with the radioactive materials label on all doors.

9 Secondly, all the training that Dr. Howe  
10 has described to you is the same that we are committed  
11 to to the FDA. There were many questions about training  
12 that came up as part of the review of our new drug  
13 application and NorthStar had already made the same  
14 commitments to the agency as part of the NDA review.

15 The next item, the source size, the source  
16 vessel size of six curie was used. That is six curies  
17 at noon, next day of production. So if it arrives at  
18 a pharmacy a little bit before noon, it'll be a little  
19 bit higher than six curies. If it arrives a little  
20 after noon, it'll be lower than six curies just because  
21 of the decay.

22 Another question came up about moly  
23 breakthrough. The FDA still requires that  
24 technetium-99m produced by the RadioGenix to meet the

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1 definition of the U.S. Pharmacopeia for sodium  
2 pertechnetate technetium-99m. And of course the  
3 instrument does do that and we've shown that in the new  
4 drug application. But that requirement meeting the  
5 U.S. Pharmacopeia includes a moly breakthrough test.

6 The life of a source vessel is the same as  
7 the current systems that are out there today, which is  
8 14 days. Dr. Green was correct. It is 48 inches wide  
9 and it holds four of the source vessels, which is the  
10 equivalent of four -- face-wide four individual units  
11 in the pharmacy today.

12 As far as changes are concerned, we already  
13 have an understanding and an agreement with the FDA.  
14 There is a process through the FDA that we have to go  
15 through to notify the agency if we're making any  
16 changes. And we understand that we will follow the same  
17 process with the -- under our guidance from the working  
18 group. So that is not unexpected either.

19 And just as an additional piece of  
20 information, yes, NorthStar will be doing the training.  
21 Our people are well-versed in the instrument. And in  
22 addition to that we have four nuclear pharmacists on our  
23 staff.

24 I'll be happy to answer any other

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1 questions. Those are just some additions and  
2 clarifications that I thought might be useful.

3 CHAIRMAN ALDERSON: Good. Are there  
4 questions from members of the ACMUI? Dr. Zanzonico?

5 VICE-CHAIR ZANZONICO: I have a question.  
6 In the USP the -- for conventional moly generators there  
7 is a requirement of course for alumina breakthrough.  
8 That doesn't apply to this instrument, but in terms of  
9 sort of -- in a bookkeeping sense has that requirement  
10 been appropriately eliminated for this system, or to  
11 comply with the USP requirements that need to be  
12 retained for some reason?

13 DR. HARVEY: Actually the alumina  
14 breakthrough does still apply because the way this  
15 system works the guard column, which is one of the last  
16 things that the product sees before it goes into the  
17 product vial is an alumina cartridge. It's changed  
18 with every elution so that it helps protect further  
19 against any unwanted moly breakthrough, but the alumina  
20 test does still apply. We do not have any exemptions  
21 so to speak under the U.S. Pharmacopeia other than the  
22 fact that because it is a non-fission process we don't  
23 make fission strontium and we don't make alpha emitters.  
24 So those tests are -- we've proven that that material

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1 is not there. And so those tests are typically not  
2 performed or required. But the basic tests, moly  
3 breakthrough, alumina, that's still required.

4 VICE-CHAIR ZANZONICO: Okay. Thank you.

5 DR. HOWE: And let me clarify. NRC does  
6 not require an alumina test. We only require the  
7 moly-technetium breakthrough.

8 MEMBER DILSIZIAN: Right, that's a USP  
9 required test.

10 DR. HOWE: Yes. And so by meeting the USP,  
11 they're going to meet the NRC requirement.

12 CHAIRMAN ALDERSON: Do we have other  
13 questions from the ACMUI?

14 (No audible response.)

15 CHAIRMAN ALDERSON: Do we have questions  
16 from anyone here in the audience?

17 (No audible response.)

18 CHAIRMAN ALDERSON: Do we have questions  
19 from anyone who is on the phones, either for our current  
20 speak or for anyone who has spoken on this subject?

21 Operator, do we have any requests?

22 OPERATOR: Currently there are no  
23 requests, sir. I'll remind them it's star followed by  
24 the number one. If you wish to queue up, you will be

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1 prompted to record your name.

2 CHAIRMAN ALDERSON: We'll wait just a  
3 little bit and let you see if anyone comes on. Please  
4 tell us momentarily.

5 OPERATOR: All right, sir. Thank you. I  
6 will do that.

7 (Pause.)

8 CHAIRMAN ALDERSON: Has anyone come on?

9 OPERATOR: No. Thank you.

10 CHAIRMAN ALDERSON: Very good.

11 DR. HOWE: And thank you, Dr. Harvey.

12 CHAIRMAN ALDERSON: Yes.

13 DR. HARVEY: Thank you.

14 CHAIRMAN ALDERSON: So seeing no more  
15 questions; and thank you all and thank you for the  
16 outside speaker. And that will conclude this  
17 particular --

18 MS. HOLIDAY: Dr. Alderson?

19 CHAIRMAN ALDERSON: Yes?

20 MS. HOLIDAY: May I request if the  
21 Committee will endorse the Subcommittee's report which  
22 contains all of those recommendations?

23 CHAIRMAN ALDERSON: I was afraid of that.

24 (Laughter.)

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1                   CHAIRMAN ALDERSON: Well, so that's the  
2 question. The question is does the Committee wish to  
3 endorse this report that had like six different  
4 recommendations on multiple different pages? And I  
5 really have to say that if the answer is no, if the  
6 Committee is not ready to do an on-block endorsement,  
7 then we have one or two minutes left and we cannot really  
8 go through paragraph by paragraph in six different pages  
9 to decide what we want to endorse or not to endorse. So  
10 we could perhaps move to do this at another time, or  
11 there might be someone who says this is very straight  
12 forward and we'd like to move that we endorse the report  
13 on block.

14                   Yes, Dr. Langhorst?

15                   MEMBER LANGHORST: I would like to move to  
16 endorse the Subcommittee's report. I think we need to  
17 move it forward. I think the Subcommittee has looked  
18 at this very carefully. I think it's worth moving it  
19 forward.

20                   CHAIRMAN ALDERSON: Very good. So that's  
21 the motion. Is there a second?

22                   (No audible response.)

23                   CHAIRMAN ALDERSON: Is there a second?

24                   MEMBER O'HARA: Second.

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1 CHAIRMAN ALDERSON: There's a second.  
2 Good. All right.

3 Now we're open for discussion. Would  
4 anyone like to discuss this motion on the ACMUI?

5 (No audible response.)

6 CHAIRMAN ALDERSON: Hearing none, is there  
7 a motion to approve? Well, all in favor, I should say.

8 (Laughter.)

9 (Chorus of aye.)

10 CHAIRMAN ALDERSON: Any opposed?

11 (No audible response.)

12 CHAIRMAN ALDERSON: No. Any abstaining?

13 (No audible response.)

14 CHAIRMAN ALDERSON: It's unanimous. The  
15 report is endorsed.

16 MS. HOLIDAY: Thank you.

17 CHAIRMAN ALDERSON: You're welcome. I  
18 think that that brings this session to a close. So we  
19 now are on break and we will reconvene at 3:00. 3:00  
20 p.m. Thank you.

21 (Whereupon, the above-entitled matter went  
22 off the record at 2:25 p.m. and resumed at 3:00 p.m.)

23 CHAIRMAN ALDERSON: We'll reconvene the  
24 session. We are now going to hear from Katie Tapp about

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1 the Germanium/Gallium-68 Medical Use Generator  
2 Licensing Guidance.

3 DR. TAPP: Thank you, Dr. Alderson.  
4 First, I would like to say that the Eckert and Ziegler  
5 GalliaPharm Germanium-68/Gallium-68 Generator  
6 Licensing Guidance has been published.

7 Final it is now available for use by our NRC  
8 regional offices for licensing. It was issued on  
9 September 28th and has now been posted to our medical  
10 toolkit website I believe on Thursday.

11 I would like to thank many groups for  
12 helping in the development and the review of this  
13 guidance. First, I would like to thank the Agreement  
14 States and NRC Working Group.

15 The Co-Chair is actually in the Region III  
16 office, it was Vered Shaffer. The Co-Chair for the  
17 Agreement States was Andy Halloran from Washington. We  
18 had another member from Agreement State North Carolina,  
19 which is Caleb Smith, our Region I representative, Jan  
20 Nguyen, and then myself, and then when I was unavailable  
21 Said has filled in my place to make sure this got issued  
22 in a timely manner.

23 Next, I would like to thank the ACMUI  
24 Subcommittee for their expedited review. I know you

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1 guys reviewed it quicker than the 60 days generally  
2 allotted and we really thank you for that, it helped us  
3 get it published in a timely fashion.

4 As well I would like thank a past ACMUI  
5 member, Steve Mattmuller, for his support as NRC  
6 consultant in the development of this and also when he  
7 was here at the ACMUI.

8 The ACMUI provided comments and endorsed a  
9 draft version of this licensing guidance on August 25th  
10 of this year. Based on the ACMUI comments the final  
11 licensing guidance tried to make it very clear that this  
12 guidance is for the use of the generator and not for the  
13 use of Gallium-68 radiopharmaceuticals.

14 We put a note at the top of the guidance  
15 before you would even get into the body of this report  
16 specifying that it's for the use of the generator itself  
17 and not for the radiopharmaceuticals. The  
18 radiopharmaceuticals are licensed under 35.200.

19 Additionally, like we heard from Dr. Howe  
20 earlier, this licensing guidance applies to both  
21 commercial and nuclear pharmacies and medical  
22 facilities if they are using this generator for medical  
23 use.

24 This guidance provides recommendations for

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1 breakthrough limits set to the manufacturer's stated  
2 limits for this generator in its drug master file.

3 Additionally, this guidance talks about  
4 the frequency of elution because the breakthrough could  
5 build up and that's set to manufacture-stated operating  
6 procedures.

7 As well as this guidance recommends the  
8 reporting of breakthrough similar to what is for the  
9 moly and technetium-99 generators in the proposed final  
10 rule of the 10 CFR 35.

11 And then, finally, this licensing guidance  
12 has a note to remind licensees that the Germanium-68 has  
13 a half-life of greater than 120 days so there is some  
14 waste disposal issues that they need to think about and  
15 go back to refer to Part 20 on that.

16 This licensing guidance as shown in the  
17 title is specific to the Eckert and Ziegler GalliaPharm  
18 Generator because the working group only evaluated the  
19 safety considerations for this generator as it has been  
20 approved with a -- as it has a drug master file.

21 But that does not mean that the NRC is  
22 recommending that this is the only generator that can  
23 be used. Generators that are used by broad scope  
24 licensees that are not this generator can be used in

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1           accordance with regulations.

2                       The only reason that we are focusing on the  
3           Eckert and Ziegler Generator is that was what the NRC  
4           was reviewing with this working group, that's what we  
5           had to work with at the time.

6                       We can open up another working group in the  
7           future if manufacturers are notified that there are  
8           future generators coming down the pike as we are  
9           becoming aware.

10                      I would like to turn it over now to Dr.  
11           Daibes for his talk about the financial assurance.

12                      DR. DAIBES:   First of all thank you for the  
13           opportunity.   First of all let me express our gratitude  
14           to Steve Mattmuller for his support in making sure that  
15           information became available.

16                      Thanks to ACMUI for your support in  
17           providing guidance and for the guidance and expedient  
18           review from OGC and making sure that we were able to  
19           deliver.

20                      At our last meeting we said we were going  
21           to provide something and we have made something.   We  
22           have provided progress and today we are going to provide  
23           you some information on it.

24                      So do we need to provide background on

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1 gallium, I think everybody is pretty familiar on -- So  
2 do we not go there?

3 Okay, so let's go directly to the point.  
4 We in the past had an issue, people have raised concerns  
5 in the past with respect to the DFP requirement that we  
6 had and we still have in place.

7 We provided multiple options or regulatory  
8 options as potential options. One of them was this  
9 license specific exception that we -- oh, my apologies  
10 -- so that we in our last meeting provided as the plan  
11 forward and our progress towards that initiative is that  
12 we indeed have provided that exemption to the regions.

13 It was provided on July 29 and an SCC letter  
14 was provided to Agreement States as well on August 18th.  
15 So having that aligned and concurrent to that we were  
16 working on a direct final rule which the -- I was today  
17 provided a question on, well, why a direct final rule.

18 Well in order for the exemption to proceed  
19 we had to demonstrate that we had a rulemaking process  
20 aligned or in process in order to provide a path forward,  
21 and we went ahead and provided a direct final rule plan  
22 to OGC and as of today OGC is still reviewing that  
23 package.

24 And the intent of the direct final rule was

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1 to provide a potential footnote, I had to clarify this  
2 that it was not to work on the actual table itself it  
3 was to provide a footnote in order to accommodate the  
4 isotope that we were pursuing, and another question was  
5 raised today on that same issue.

6 The DFP exemption basically was providing  
7 a short term option to licensees in order to provide  
8 access to the needed isotopes. Another question that  
9 has been raised is do we need financial assurance. I  
10 want to clarify this.

11 Indeed, we need financial assurance. In  
12 this case why do we need financial assurance? Well, the  
13 exemption, and I need to clarify, financial assurance  
14 if the exemption is requested. So why do we need  
15 financial assurance?

16 Well there has to be a guarantee that there  
17 is a mechanism in place to allow for if something that  
18 is not planned happens and we have a mechanism to  
19 accommodate that, right.

20 So that financial assurance is very  
21 explicit in that exemption in the enclosure and I am  
22 going to refer back to that enclosure to provide you more  
23 details on it, but the summary of that financial  
24 assurance is here on the screen and it's basically any

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1 licensee possessing one or two medical generators or  
2 Germanium/Gallium-68 generators will need financial  
3 assurance in accordance to \$225,000 minimum of  
4 financial assurance.

5 And licensees having or possessing more  
6 than two, up to 20, will need \$1.125 million in financial  
7 assurance. I need to clarify that because, again,  
8 another question was raised.

9 So I am going to refer you back to that  
10 exemption, or the enclosure, that will provide you  
11 further information with respect to this. We can  
12 proceed. Do we have any questions?

13 CHAIRMAN ALDERSON: Questions for Dr.  
14 Daibes? Mr. Green?

15 MR. GREEN: The current strength, the size  
16 of the GalliaPharm generator is 50 millicuries of model  
17 activity, plus or minus 15 percent, so with the luck of  
18 the draw you can receive a unit that's 57-1/2  
19 millicuries or 42-1/2, and that's today's strength.

20 They are looking at manufacturing and  
21 licensing a larger, more potent generator, so you may  
22 want to look at the one or two or look at the 50 to 100,  
23 because if you possess two brand new ones you may be at  
24 114 millicuries. So just a caveat.

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1 DR. DAIBES: Thank you. We spoke to the  
2 company and we were provided that info, that there is  
3 a potential down the road for that to be implemented,  
4 but thank you for that.

5 CHAIRMAN ALDERSON: Other questions for  
6 either of our panelists? From the audience? No.  
7 Anyone on the phone would like to comment, operator?

8 OPERATOR: If you'd like to share a comment  
9 please press star 1.

10 MEMBER LANGHORST: While we are waiting --

11 CHAIRMAN ALDERSON: Yes?

12 MEMBER LANGHORST: -- I would just like to  
13 express gratitude to the NRC --

14 CHAIRMAN ALDERSON: In getting through it  
15 all.

16 MEMBER LANGHORST: -- in getting through  
17 all this and providing this exemption. It's not the way  
18 we like to regulate, I understand, but it is going to  
19 impact so many patients and make this available to them  
20 and it was based on a rule that's an old rule that didn't  
21 get updated when other parts of the regulations did and  
22 so thank you, thank you, thank you.

23 CHAIRMAN ALDERSON: Well said.

24 OPERATOR: And I am showing no comments

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1 from the phones.

2 CHAIRMAN ALDERSON: No comments, that ends  
3 this particular session. Thank you very much.

4 DR. DAIBES: Thank you.

5 DR. TAPP: Thank you.

6 CHAIRMAN ALDERSON: You can be the  
7 moderator.

8 VICE CHAIR ZANZONICO: Okay. So I'm just  
9 going to step into this last presentation to serve as  
10 moderator since our Chair, Dr. Alderson, will be making  
11 a presentation and he will be presenting on ongoing  
12 efforts and strategies for enhancing communication with  
13 the medical community. Dr. Alderson, the floor is  
14 yours.

15 CHAIRMAN ALDERSON: Yes, thank you, thank  
16 you. So this will be an update on the discussion we had  
17 at a previous meeting about the importance of  
18 establishing stronger and more regular communications  
19 between the ACMUI and the user community.

20 And so it was decided after a discussion  
21 that the most cost effective way to do this would be to  
22 have our members at the meetings that they typically  
23 attend and offer to their respective societies the  
24 opportunity to have a session with the representatives

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1 of the NRC and we have gone on in trying to set that up  
2 and a number of the members of the ACMUI did agree at  
3 that time to approach their respective societies and to  
4 determine if there was interest in actually setting up  
5 such a session.

6 This was not the only thing that was  
7 recommended, there were some other recommendations that  
8 could foster a society outreach. Well, we talked about  
9 the first one just now, that is a regularly scheduled  
10 presentation by one of you, an ACMUI member, at the  
11 annual Society meeting.

12 There was also the suggestion that we  
13 should consider an NRC booth at these meetings in the  
14 exhibit area, that perhaps we would offer to write a  
15 regular NRC column in the respective Society  
16 newsletter, or that we would potentially pay to have  
17 other people travel to come to us, and that's what a  
18 reverse outreach means here.

19 The last note on this slide would be that  
20 one of the societies would be nominated at each  
21 particular meeting, the Society of Nuclear Medicine and  
22 Molecular Imaging at one, the American College of  
23 Radiology at another, to actually be here and sit at this  
24 table and make a presentation about their concerns.

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1           But when it was all said and done we came  
2 around to the fact that the most cost effective and the  
3 most efficient way to get things going in a hurry was  
4 to have our respective members who are out in these  
5 Society meetings, because of their own professional  
6 interests, to actually make presentations on behalf of  
7 the ACMUI at those meetings.

8           So I am happy to say that in the last several  
9 months a number of you have actually done this and have  
10 set up meetings of this type, so I will go on down the  
11 last couple of slides to talk about that, the Ask the  
12 Regulator Q&A session.

13           Some sort of overview slides that sort of  
14 tell generally what the important issues are in front  
15 of the ACMUI and then a Q&A so that the audience can  
16 actually stand up and those people can say exactly what  
17 their concerns are so that we can get that communication  
18 and work on putting those things together.

19           Now we did find out in the course of these  
20 approaches to various Societies that a number of them  
21 believe that they have open communications and exchange  
22 with the NRC ACMUI already and that perhaps additional  
23 things weren't necessary and well that's fine.

24           The idea of the approach is to increase

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1 communication and if communication is already fine and  
2 they are happy with it, and many of those are like people  
3 that you see frequently at these meetings in the  
4 audience who step up and make comments at the  
5 microphone. Well that's fine, no need to change  
6 something like that.

7 But here some ideas of some of the things  
8 that we hope will happen where these sorts of  
9 discussions have already led to tentative plans to have  
10 an ACMUI session.

11 So the American College of Radiology will  
12 consider holding such a session as part of the  
13 continuing medical education program in May of 2017, and  
14 that's Dr. Metter who has made that contact, is that  
15 correct?

16 (No audible response)

17 CHAIRMAN ALDERSON: Great, excellent.  
18 The Society of Nuclear Medicine and Molecular Imaging  
19 seems like they would like to hold such a session at  
20 their next meeting in June of '17. Was that you, Chris,  
21 who --

22 MEMBER PALESTRO: Yes.

23 CHAIRMAN ALDERSON: Chris Palestro made  
24 that particular contact. ASTRO, that's the Society for

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1 Radiation Oncology, therapeutic and radiation oncology  
2 fields, that they have a good communication with us  
3 already, but they are talking about a formal session at  
4 the September meeting next year, is that right, John  
5 Suh?

6 MEMBER SUH: Yes, this is something Ron  
7 Ennis --

8 CHAIRMAN ALDERSON: Right, Ron is the one  
9 who is -- and Ron had to leave early so Ron isn't here  
10 to make a comment on that.

11 And the Association of Residents in  
12 Radiation Oncology, ARRO, also seems to be supportive  
13 of this meeting, and was that you, John?

14 MEMBER SUH: Yes.

15 CHAIRMAN ALDERSON: Yes, very good. So  
16 you can see that a number of our people have reached out.  
17 The Association of Physicists in Medicine and the  
18 Brachytherapy Society are interested in maintaining  
19 efforts that are already existing in communication  
20 between our organizations.

21 And the Health Physics Society was  
22 receptive to an outreach program and their mid-year  
23 meeting is scheduled for January of '17 in North  
24 Bethesda, which is where we are now, this is North

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1 Bethesda.

2 Obviously, they are not meeting here at the  
3 NRC, but they are meeting at a hotel nearby I presume,  
4 and they would like to invite an NRC representative to  
5 be the speaker.

6 Well, Sue, was it you who made that contact?

7 MEMBER LANGHORST: Well Pat and I and we  
8 have, we are going to be working with the medical  
9 committees, medical section on that, to I hope involve  
10 NRC staff that aren't necessarily medical team staff,  
11 but other NRC staff to kind of broaden the understanding  
12 and opportunity to learn that medical use is different.

13 I will also point out that I have been  
14 stomping for my replacement and so if you go to the  
15 Health Physics Society webpage you can look at the HPS  
16 Newsletter and my article is there, questions and  
17 answers of serving on ACMUI, and not only asking for  
18 people to consider being my replacement but to encourage  
19 people how they interact with ACMUI and how they can be  
20 part of the discussions.

21 CHAIRMAN ALDERSON: Well, we certainly  
22 appreciate that outreach and at the same time we  
23 appreciate the context that you are virtually  
24 irreplaceable.

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1 MEMBER LANGHORST: Thank you.

2 CHAIRMAN ALDERSON: Are there questions or  
3 comments about this? That was the end of my brief  
4 report and I thank everyone who has reached out to their  
5 respective societies and they are starting to set up  
6 these communication links.

7 Questions or comments? I see none in the  
8 audience.

9 VICE CHAIR ZANZONICO: Any on the phone?

10 OPERATOR: Yes, we do have a question from  
11 the phone, it comes from Cindy Tomlinson, your line is  
12 open.

13 MS. TOMLINSON: Thank you. This is Cindy  
14 Tomlinson from ASTRO. I just wanted to let you know  
15 that we are trying to figure out how to engage with the  
16 NRC and the ACMUI at our annual meeting, but just know  
17 that nothing is firmly in place.

18 We just finished our last one at the 2016  
19 annual meeting, so we are still trying to figure out how  
20 we can do some things in 2017.

21 CHAIRMAN ALDERSON: Well, thank you for  
22 that update.

23 VICE CHAIR ZANZONICO: Thank you. If  
24 there is no one else on the phone then that brings this

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1 session to a -- well not this session, but this  
2 presentation to a close.

3 CHAIRMAN ALDERSON: All right. So that  
4 brings us to the administrative closing and Michelle  
5 Smethers will do that for us.

6 MS. SMETHERS: Thank you. As part of the  
7 administrative closing we are going to discuss possible  
8 potential future dates for our Spring ACMUI meeting.

9 This is typically in March or April and  
10 subject to the Commission's availability. We try and  
11 couple it with the Commission meetings.

12 I sent out a doodle a few weeks back and we  
13 got a number of dates that actually seem to work for the  
14 Committee, so we are just going to talk through those  
15 and make sure those still work.

16 It appeared that the first choice that  
17 worked for everyone was March 20th through 21st, that  
18 was a Monday/Tuesday. Please confirm if this still  
19 works for everyone, or let me know if that does not work  
20 for someone rather.

21 MEMBER LANGHORST: Dr. Alderson?

22 CHAIRMAN ALDERSON: Yes? Oh, I'm sorry.

23 MS. FAIROBENT: Dr. Alderson, Lynn  
24 Fairobent with AAPM. I just want to note that the AAPM

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1 Spring meeting is that week.

2 MS. SMETHERS: Okay, thank you for letting  
3 us know.

4 CHAIRMAN ALDERSON: Other comments? No.

5 MS. SMETHERS: We did try and check the  
6 different professional organizations, but I appreciate  
7 the information. April 25th through 26th, that was a  
8 Tuesday/Wednesday, that seemed to work for all members.  
9 I believe there was a preference by one not to have that  
10 date.

11 VICE CHAIR ZANZONICO: I'm sorry, which  
12 date?

13 MS. SMETHERS: I'm sorry, say that --

14 VICE CHAIR ZANZONICO: The dates again you  
15 just said.

16 MS. SMETHERS: That was April 25th through  
17 26th, that is a Tuesday/Wednesday. Dr. Palestro, I  
18 believe you had a preference not to do that date, is that  
19 still the case?

20 MEMBER PALESTRO: It's a preference, but I  
21 can certainly attend.

22 MS. SMETHERS: Okay, thank you. Okay, the  
23 second one for other backup dates was April 26th through  
24 27th, that will be a Wednesday/Thursday. Are there any

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1 conflicts for that date?

2 (No audible response)

3 MS. SMETHERS: Again, I think it was a  
4 preference by Dr. Palestro not to have that one if we  
5 can avoid it. Okay, a third choice was April 27th  
6 through 28th. That appeared to work for all members,  
7 is that still the case?

8 (No audible response)

9 MS. SMETHERS: Okay, is there anyone who it  
10 doesn't work for?

11 (No audible response)

12 MS. SMETHERS: Okay, I'll keep that one on  
13 there. And then the last one was April 20th through  
14 21st, that was a Thursday/Friday. It appeared to work  
15 for all members. I believe there was a preference not  
16 to pick that date, but it seemed to work for everyone.

17 Okay, do we want to pick a first choice  
18 date, should we -- So our first choice date was March  
19 20th through 21st, would we like to remove that as our  
20 first choice since that seems to be in conflict with the  
21 other meeting?

22 CHAIRMAN ALDERSON: Sure. Yes, if that  
23 seems reasonable. We have several other choices here  
24 in April.

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1 MS. SMETHERS: Okay.

2 MS. HOLIDAY: Dr. Alderson, this is  
3 Sophie. As Michelle stated earlier we try to have the  
4 Spring meeting in alignment with the Commission  
5 meeting. I can tell you that the Commission has  
6 tentatively held March 21st as a possible Commission  
7 Spring meeting date.

8 However, they have not started looking at  
9 their April calendars yet since that's another month in  
10 advance from that, but I just wanted to make you guys  
11 all aware that you are nailing down your first and second  
12 choice of dates that March 21st is something that they  
13 are holding.

14 CHAIRMAN ALDERSON: I think that -- Yes,  
15 Mr. Fuller?

16 MR. FULLER: I hate to be talking across  
17 the ACMUI but I would ask Sophie, Sophie based upon your  
18 experience with the Commission would you advise, in  
19 trying to get these States scheduled over the years,  
20 would you advise that we jump on this opportunity that  
21 the Commission has provided us so that we can sort of  
22 nail down, in other words what is your, why don't you  
23 just go ahead and tell us what you think we should do  
24 with regards to that date.

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1 MS. HOLIDAY: My advice would be for March  
2 20th and 21st to be your first choice and then from there  
3 you can select your alternative second and third backup  
4 choices.

5 CHAIRMAN ALDERSON: So I think, to the  
6 ACMUI members, that we have felt it to be quite important  
7 to be in front of the Commission if we can get there on  
8 an annual basis.

9 So that would suggest that these two dates  
10 in March would be the first alternate, the first choice.  
11 Is anyone opposed to that?

12 MEMBER LANGHORST: Not opposed, my  
13 question is is if there is a Commission date in April  
14 that coincides with these other ones that that could  
15 then become the first choice.

16 CHAIRMAN ALDERSON: Yes.

17 MEMBER LANGHORST: Okay. I would suggest  
18 that.

19 CHAIRMAN ALDERSON: Right. Yes, that's  
20 the idea.

21 MS. HOLIDAY: As you are aware the dates  
22 that you are planning now are tentative.

23 CHAIRMAN ALDERSON: Yes.

24 MS. HOLIDAY: We actually don't confirm it

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1 until possibly in December or January, so when this  
2 meeting ends we will alerting our technical assistant  
3 staff as well as the EEO and SECY staff to tell them what  
4 ACMUI choices are and after that they will come back to  
5 us and tell us which dates the Commission has chosen.

6 CHAIRMAN ALDERSON: Yes, all right. So I  
7 think we have just agreed that the first choice will  
8 certainly to be with the Commission and that will be  
9 these March dates at the current time.

10 MS. SMETHERS: Okay. And we can  
11 definitely let them know --

12 CHAIRMAN ALDERSON: Right.

13 MS. SMETHERS: -- our various choices.

14 CHAIRMAN ALDERSON: And it looks like the  
15 April options then we have no idea of what they might  
16 be considering in April, Sophie, we don't?

17 MS. HOLIDAY: No.

18 CHAIRMAN ALDERSON: We do not. Well there  
19 is a whole group of these that sort of run together in  
20 one particular week, running from Tuesday the 25th  
21 through Friday the 28th --

22 MS. SMETHERS: Right.

23 CHAIRMAN ALDERSON: -- so my suggestion  
24 would be sort of as a broad thing just kind of keep those

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1 dates as a reserve date, the dates that week, and then  
2 we'll -- if they decide to meet in late April, I think  
3 that would be unusual for them, then we would try to flex  
4 within whatever they decide so that we coincided with  
5 one of their days.

6 MS. SMETHERS: Okay. Do we want to pick a  
7 second choice from that group or should we let them know  
8 we have this range of dates available?

9 CHAIRMAN ALDERSON: That's what I just  
10 suggested, that we have the range of dates for the April  
11 second choice.

12 MS. SMETHERS: Okay, sorry.

13 CHAIRMAN ALDERSON: Now because we just  
14 discussed that and no one said I can't do any of them.  
15 Chris had some dates that he felt he could make, but  
16 weren't probably ideal, but none of the dates were  
17 excluded in that particular week.

18 MS. SMETHERS: Okay.

19 CHAIRMAN ALDERSON: If we missed someone  
20 who has an exclusion that week then please speak now.

21 (Off mic comment)

22 CHAIRMAN ALDERSON: My suggestion is that  
23 we were just going to consider holding the 25th through  
24 the 28th, those dates, all in the same week the last week

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1 in April.

2 MS. SMETHERS: Okay. And then not to  
3 include the 20th and 21st?

4 CHAIRMAN ALDERSON: Not include the 20th  
5 and 21st, yes.

6 MS. SMETHERS: Okay.

7 CHAIRMAN ALDERSON: Obviously, if the  
8 Commission makes a decision that we don't expect we can  
9 reconsider all of this.

10 MS. SMETHERS: Okay, sounds good. Okay,  
11 so to confirm, we have our first choice as March 20th  
12 through 21st, which is a Monday and Tuesday, and our  
13 second choice would be to provide to the Commission the  
14 range of dates between April 25th through 28th for  
15 availability.

16 CHAIRMAN ALDERSON: Yes.

17 MS. SMETHERS: Okay, excellent, thank you.  
18 At this time I would like to go over the new  
19 recommendations and actions, which are in red. Each  
20 member of the ACMUI should have the hard copy in front  
21 of them and we will be sending out an electronic version  
22 as well after this meeting.

23 Beginning with Item 38, Dr. Alderson  
24 requested that the ACMUI discuss the Nursing Mothers

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1 Guidelines during the Spring 2017 ACMUI meeting. Are  
2 there any updates to that item?

3 (No audible response)

4 MS. SMETHERS: Okay.

5 CHAIRMAN ALDERSON: I did make that  
6 suggestion, yes, I --

7 MS. SMETHERS: Yes. Okay, Item 39, the  
8 Committee recommended that staff issue a generic  
9 communication in the form of an information notice  
10 regarding tubing issues, such as kinking, connection,  
11 hub, et cetera, during the administration of Y-90  
12 microspheres brachytherapy.

13 Item 40, for the medical event reporting  
14 for all modalities, excluding Permanent Implant  
15 Brachytherapy Subcommittee, Dr. Alderson removed Dr.  
16 Pat Zanzonico and appointed Mr. Frank Costello.

17 The Subcommittee membership includes Mr.  
18 Costello, Dr. Dilsizian, Dr. Ennis, Dr. Palestro, and  
19 Dr. Suh as Chair. Mr. Ouhib will be added to the  
20 Subcommittee once he receives full voting rights and Dr.  
21 Katie Tapp is the NRC resource.

22 CHAIRMAN ALDERSON: I actually think that  
23 it's way more proper to say that Dr. Zanzonico agreed  
24 to step aside so that Frank Costello could be appointed.

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1 It sounds very dictatorial, like saying you're out.

2 MS. SMETHERS: We can make that update of  
3 my -- excellent, okay. Item 41, Dr. Alderson  
4 reestablished the Patient Intervention Subcommittee.  
5 The Subcommittee's new charge is to make a  
6 recommendation on what the definition of what patient  
7 intervention should be.

8 Subcommittee membership includes Mr.  
9 Costello, Dr. Dilsizian as Chair, Dr. Ennis, Dr. Suh,  
10 and Ms. Weil. Ms. Maryann Abogunde is the NRC resource.

11 CHAIRMAN ALDERSON: Yes. So this was to  
12 resolve some ongoing lack of clarity. Thanks to the  
13 Committee for being willing to tackle this a little  
14 longer.

15 MS. SMETHERS: Item 42, the Committee  
16 recommended that the Pathway 2 remain. The NRC and OAS  
17 Working Group should determine what the requirements  
18 should be for the proctoring of cases by the  
19 manufacturer.

20 VICE CHAIR ZANZONICO: Just to clarify,  
21 this is specifically for the Yttrium-90 microspheres?

22 MS. SMETHERS: Yes.

23 VICE CHAIR ZANZONICO: Okay.

24 CHAIRMAN ALDERSON: I think that should

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1 actually be in what's written.

2 VICE CHAIR ZANZONICO: In that, yes.

3 MS. SMETHERS: We will add that in. Item  
4 43, the Committee recommended to support the update to  
5 the waste disposal section and the review of the Y-90  
6 radiation safety issues in autopsy and cremation. Now  
7 -- yes, Mr. Green?

8 MR. GREEN: I think it's worth being  
9 specific, Y-90 could be broadly assumed to include  
10 Zevalin. We are really talking about the spheres here.

11 MS. SMETHERS: Just adding that word would  
12 make it --

13 PARTICIPANT: Yes, we're adding it.

14 CHAIRMAN ALDERSON: Yes.

15 MS. SMETHERS: Excellent. Oh, I am seeing  
16 it now, thank you, Ms. Holiday. Okay, for Items 44  
17 through 52, so Item Numbers 44 through 52 are  
18 recommendations which were contained in the NorthStar  
19 Mo-99 Tc-99m Generator Licensing Guidance Subcommittee  
20 report and were endorsed by the Committee today as  
21 stated in Item 53. Are there any questions, comments?

22 CHAIRMAN ALDERSON: Langhorst?

23 MEMBER LANGHORST: I know that this, this  
24 has bothered me with all of these lists, but actually

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1 if you could have a little something up there at the  
2 beginning that says exactly what you just said, that  
3 these numbers refer to that licensing guidance then you  
4 know what you are reading, you know, but each one you  
5 don't want to have to say oh, it's with the licensing  
6 guidance.

7 We all know it today, but when you go back  
8 and read it in 2020, whoever is still here, you may not  
9 remember that's what all those refer to, so I just, it's  
10 confusing sometimes.

11 So I don't know if there is anything to be  
12 done to help kind of clump those together so that you  
13 can say this is what these refer to.

14 MS. SMETHERS: I think we could put a  
15 simple note, like a little header on the paper, yes.

16 MR. GREEN: Yes, parentheses LG.

17 MS. SMETHERS: Yes.

18 MR. GREEN: We can do that.

19 MS. SMETHERS: Okay, so those are the  
20 items, the new items. Are there any other  
21 questions/comments/updates?

22 MR. OUHIB: Sophie, this is Zoubir.

23 CHAIRMAN ALDERSON: Yes, speak up so that

24 --

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1 MR. OUHIB: Yes. I'm sorry, I was trying  
2 to communicate earlier but the whole afternoon I was  
3 unable to communicate with you, I was totally on a  
4 different line.

5 But at any rate, for the Spring meeting,  
6 April 20th through the 22nd is the American  
7 Brachytherapy Society Meeting, so just to note that for  
8 us.

9 MS. SMETHERS: Okay.

10 CHAIRMAN ALDERSON: Thank you.

11 MS. SMETHERS: Thank you.

12 (Off the record comments)

13 CHAIRMAN ALDERSON: Laura, did you have a  
14 question?

15 MEMBER WEIL: No.

16 CHAIRMAN ALDERSON: It's been resolved?  
17 Thank you. Other comments?

18 (No audible response)

19 CHAIRMAN ALDERSON: Hearing none, is there  
20 further business to be brought before the ACMUI?

21 MR. BOLLOCK: No. At this time we don't  
22 have any other business unless there is anything that  
23 you or the Committee would like to discuss or bring up.

24 CHAIRMAN ALDERSON: Does anyone wish to

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1 make a final statement? Hearing none I --

2 MR. BOLLOCK: Or any questions for staff  
3 that I could answer?

4 CHAIRMAN ALDERSON: Yes.  
5 Comments/Questions?

6 (No audible response)

7 CHAIRMAN ALDERSON: Hearing none I think  
8 that we stand adjourned.

9 MR. BOLLOCK: Thank you.

10 (Whereupon, the above-entitled matter went  
11 off the record at 3:35 p.m.)

12

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