

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE ADVISORY COMMITTEE ON THE MEDICAL  
USES OF ISOTOPES

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PUBLIC MEETING

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TUESDAY,

APRIL 14, 2015

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The Commission met in the  
Commissioners' Conference Room, 1st Floor, 11555  
Rockville Pike, Rockville, Maryland, at 9:30 a.m.,  
Stephen G. Burns, Chairman, presiding.

PRESENT

STEPHEN G. BURNS, Chairman

KRISTINE L. SVINICKI, Commissioner

WILLIAM C. OSTENDORFF, Commissioner

JEFF BARAN, Commissioner

ALSO PRESENT

BRUCE THOMADSEN, ACMUI Chair

FRANCIS COSTELLO, ACMUI Member

VASKEN DILSIZIAN, ACMUI Member

CHRISTOPHER PALESTRO, ACMUI Member

LAURA WEIL, ACMUI Member

MARGARET M. DOANE, OGC

ANNETTE L. VIETTI-COOK, SECY

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

9:35 a.m.

CHAIRMAN BURNS: Okay. I want to welcome our ACMUI members here today, and we're holding this meeting with the Advisory Committee on the Medical Use of Isotopes. This is an opportunity for the members of the Committee to provide their views on significant issues that have come before the Committee.

Before we begin, on behalf of the Commission I would like to take this opportunity to congratulate Dr. Bruce Thomadsen, Chairman of the Advisory Committee, on his recent honor of being presented with the Ulrich Henschke Award by the American Brachytherapy Society. I understand this is the highest honor that the Society can bestow on a practitioner in the area, and so we're very fortunate here at the NRC to have someone whose achievements are well recognized serving as the Chair of the Committee and providing guidance to the Staff.

DR. THOMADSEN: Thank you very much.

CHAIRMAN BURNS: You're welcome. You're welcome.

We're going to be briefed today by several of the Committee members on various topics.

1 Chairman Thomadsen will provide an overview of the  
2 Committee's work since our last meeting, and the  
3 work that remains ahead. Ms. Laura Weil will discuss  
4 Patient Rights issues before the Committee. Dr.  
5 Vasken Dilsizian will discuss the Committee's  
6 comments on the Advance Notice of Proposed  
7 Rulemaking for 10 CFR Part 20. Dr. Christopher  
8 Palestro will discuss molybdenum-99 production and  
9 impacts on the medical community. And Mr. Francis  
10 Costello will discuss the Committee's views on  
11 yttrium-90 microsphere brachytherapy, and I want  
12 to say hi to Frank who I worked with many years on  
13 the Staff when I was an attorney here, an earlier  
14 NRC career.

15 The presentations will be followed by  
16 a Question and Answer session with the Commission.  
17 Before I begin --- before we begin, would any of  
18 my Commissioner colleagues like to make any remarks?  
19 And is Commissioner Svinicki on the phone pending  
20 her ---

21 MS. VIETTI-COOK: I don't know.  
22 Commissioner Svinicki, are you still on the phone?

23 CHAIRMAN BURNS: No, okay. Hopefully,  
24 the traffic will clear.

25 So again, Chairman Thomadsen, would you  
26 please begin your presentation.

1 DR. THOMADSEN: Thank you very much, Mr.  
2 Chairman. It's a pleasure to be able to come and  
3 tell the Commission exactly what we've been up to,  
4 and we've been up to an awful lot lately.

5 The ACMUI exists to advise the NRC Staff  
6 and that way you, the Commission, on policies of  
7 medical uses of radionuclides. Also, to provide  
8 technical assistance and serve as consultants to  
9 the Commission. Next slide, please.

10 We have members of the Committee that  
11 represent various stakeholders in the medical  
12 radiation arena, including health care  
13 administrators, nuclear medicine physician and a  
14 physicist, two radiation oncologists, and a medical  
15 physicist, nuclear cardiologist, diagnostic  
16 radiologist, nuclear pharmacist, radiation safety  
17 officer, patient right advocate, Agreement State  
18 Representative, and a U.S. FDA representative  
19 giving a wide range of viewpoints to all of the  
20 issues that we discuss.

21 Some of the topics --- next slide,  
22 please. Some of the topics addressed by the ACMUI  
23 in the last six months have been refining some of  
24 the aspects of the 10 CFR Part 35 rulemaking, issues  
25 involved with patient release following iodine-131  
26 therapy -- next slide, please --- NRC's Medical

1 Policy Statement, the ACMUI bylaws,  
2 inconsistencies in the tables in regulations  
3 leading to problems with decommissioning  
4 germanium-68 gallium generators --- next slide,  
5 please --- medical events for all medical  
6 applications with particular attention to those  
7 involving yttrium-90 labeled microspheres, medical  
8 event databases --- next slide, please --- the  
9 physical presence requirement for gamma  
10 stereotactic radiosurgical units, safety culture  
11 and the relationship between the Nuclear Regulatory  
12 Commission and the medical community, issues  
13 concerning the supply of molybdenum-99 and the  
14 Advance Notice of the Proposed Rulemaking for  
15 CFR Part 20. Next slide.

16 Our current topics, what we're  
17 currently talking about in the Committee include  
18 continuing discussions of patient release, the  
19 germanium-gallium decommissioning funding plan  
20 issue, review of the medical events, compatibility  
21 categories for medical events, continuing  
22 discussions of physical presence requirements for  
23 gamma stereotactic radiosurgery units, Part 35  
24 rulemaking status, abnormal occurrence status,  
25 radioactive seed localization guidance, patient  
26 intervention definition and guidance for handling

1 bodies of the deceased containing yttrium-90  
2 microspheres. Also, the possibility of  
3 establishing a periodic stakeholder's topical  
4 meeting on an annual or biannual basis.

5 The present and future of the Committee  
6 is discussing a number of issues that have come up  
7 very recently, and the number seems to be  
8 increasing. Our workload is remaining quite heavy,  
9 not overwhelming, but the issues are very  
10 interesting, and the possibility that it may be  
11 increasing is very likely, particularly if we do  
12 have stakeholder meetings.

13 And with that, I will conclude. That's  
14 what the Committee has been doing, and is likely  
15 to be doing. And I will now turn the presentations  
16 over to Ms. Laura Weil, who is our Patient Rights  
17 Advocate.

18 MS. WEIL: Thank you for the opportunity  
19 to talk about some aspects of patient advocacy in  
20 the context of the ACMUI.

21 The welfare of patients is the central  
22 component of all ACMUI deliberations, and we are  
23 quite earnest about our professional and ethical  
24 responsibility to protect patients and patient's  
25 rights.

26 Members of the ACMUI are distinguished

1 by particular fields and expertise in medical arenas  
2 that use radiopharmaceuticals, and as the  
3 Designated Patient's Rights Advocate on the  
4 Committee, I have a dedicated responsibility to  
5 represent a constituency comprised only of  
6 patients, and I have no dual accountability to any  
7 other clinical or regulatory sphere. Next slide.

8 So, I would like to explore briefly three  
9 broad categories of issues that have recently been  
10 discussed and mentioned by Dr. Thomadsen. Each has  
11 a significant patient advocacy component. I'll  
12 illustrate each category with specific examples.

13 The broad issues include medical event  
14 and abnormal occurrence reporting, public health  
15 implications of regulatory decisions, and  
16 licensing-related access considerations. Each of  
17 these issues has an underlying common thread; the  
18 regulation's potential for unintentional creation  
19 of barriers to care limiting patient's access to  
20 needed medical treatment. Next slide, please.

21 The ACMUI was asked to participate in  
22 fine tuning the definitions of medical event and  
23 abnormal occurrence. The definitions of these  
24 reportable events have to be carefully crafted so  
25 that they're used as an effective tool for improving  
26 patient safety and licensee accountability.



1 Definitions should facilitate capture of those  
2 incidents that represent opportunities for  
3 identifying and correcting problematic issues, or  
4 processes, or individuals that cause preventable  
5 harm.

6           Microspheres infusions and permanent  
7 implant brachytherapy have a disproportionate  
8 number of reportable events. The challenge is to  
9 develop regulatory language where licensee  
10 failures in proficiency and due diligence can be  
11 identified without unnecessarily censoring  
12 licensees whose patients experience negative  
13 unanticipated outcomes unrelated to preventable  
14 factors.

15           Unclear regulatory language should not  
16 result in making clinicians shy away from offering  
17 patients useful therapy like microsphere infusions  
18 and permanent implant brachytherapy simply because  
19 each has a disproportionate incidence of  
20 unreasonably defined reportable events. Next  
21 slide, please.

22           The ACMUI has been asked on several  
23 occasions to comment on the Patient Release Rule  
24 of 1997. At issue has been whether or not patient  
25 release is safe. While all members of the ACMUI  
26 believe that patient release from licensee control

1 after administration of iodine-131 can be in the  
2 vast majority of cases a safe and cost-effective  
3 way to manage the post-treatment period. There's  
4 been much discussion, and some concern about how  
5 this is actually being managed in real practice  
6 across a wide range of treatment facilities.

7 When the 1997 iodine-131 Patient  
8 Release Rule was put into practice, health care  
9 insurers were given solid grounds for refusing to  
10 cover even a short hospital isolation for any  
11 patient treated with iodine-131. The public health  
12 issue is to balance the tension between two  
13 competing realities; the first being the  
14 unnecessary health care resource use in hospital  
15 stays for all patients, and the second being  
16 preserving the right to a hospital stay for those  
17 few patients who are truly unable to appropriately  
18 isolate themselves during the post-treatment  
19 period.

20 The repercussions of patient release  
21 range from the mundane to the truly sobering.  
22 There's ample anecdotal evidence of households that  
23 have been banned or fined by refuse carting and  
24 disposal services because iodine-131 patients in  
25 those homes were not adequately instructed  
26 regarding trash isolation after their treatment.

1 Their household trash sets off radiation detector  
2 alarms when it's collected, and this causes burdens  
3 for the householder, for the carting company, and  
4 for the municipality that has to investigate the  
5 radiation alarm.

6 This, of course, could be prevented with  
7 proper instruction prior to iodine-131 treatment.  
8 And more sobering, young children in the household  
9 of an iodine-131 patient can be exposed to radiation  
10 if the patient has not been adequately instructed  
11 about the need for isolation.

12 These patients are predominantly women  
13 at an age when they could have children at home,  
14 and the cause of the problem, this poor instruction  
15 problem can be complex. It can be housing-related,  
16 a single bathroom in the home for use by everyone,  
17 including the patient. Bathrooms are the most  
18 significantly contaminated room in the environment  
19 of the patient who has received iodine-131. They  
20 can be language-related. The instruction for  
21 isolation was, perhaps, not provided in a language  
22 that the patient and the family easily understand,  
23 or simply that the licensee did not provide adequate  
24 instruction about the post-treatment isolation  
25 period at all, or did not provide instruction in  
26 a way that allowed the patient time to make a

1 realistic plan for several days of isolation.  
2 There's ample anecdotal evidence that patients are  
3 not uniformly well informed about the realities of  
4 the post-treatment isolation period. Next slide,  
5 please.

6           Creating and managing regulations to  
7 promote patient safety and licensee accountability  
8 has to be balanced against compromising a patient's  
9 right to reasonable access to treatment with  
10 radiopharmaceuticals.

11 The ACMUI was asked to advise the NRC regarding how  
12 users of radium-223 dichloride, which is an  
13 injectable alpha emitting radiopharmaceutical,  
14 should be licensed. This was the first of  
15 potentially many injectable alpha emitters to be  
16 approved for therapeutic use.

17           The regulatory goal is to provide  
18 licensees with appropriate guidelines for safe  
19 administration of the drug and to allow regulators  
20 to monitor such safe use with clear and enforceable  
21 standards. The ACMUI did not want to recommend  
22 something that would create unreasonable  
23 roadblocks to patient's timely access to this highly  
24 effective palliative therapy.

25           The ultimate decision to recommend  
26 licensing radium-223 dichloride under 10 CFR Part

1 35.300 was made with the above considerations in  
2 mind. We hoped this recommendation would facilitate  
3 safe access for patients without unduly burdensome  
4 licensing requirements for clinicians.

5 Another recent example of ACMUI  
6 discussion involves the use of the new gallium-68  
7 drugs for diagnostic PET imaging for neuroendocrine  
8 tumors. These new gallium-68 drugs provide many  
9 benefits to patients. They provide vastly superior  
10 diagnostic images, and require only one day versus  
11 two days to image. They have a lower radiation  
12 burden, and are less expensive compared to the  
13 spectra currently in use today.

14 They have been used for several years  
15 in Europe to manage --- to image this diverse class  
16 of neuroendocrine tumors, and the PET gallium-68  
17 drugs have been granted orphan drug status by the  
18 FDA. Currently, drug sponsors and the FDA are  
19 working together to gain approval for these  
20 important diagnostic radiopharmaceuticals.  
21 However, an NRC regulation has created an almost  
22 insurmountable and likely unintentional roadblock  
23 to broad patient access to these new diagnostic  
24 isotopes.

25 The gallium-68 has a short half-life of  
26 68 minutes, and is produced via a small

1 shoebox-sized generator from its parent isotope,  
2 germanium-68. The short half-life precludes the  
3 possibility of transporting the drug from central  
4 pharmacies for wider distribution and use.

5 The problem lies in the fact that  
6 currently a decommissioning funding plan is  
7 required for the use of a 50 millicurie gallium-68  
8 generator due to the small regulatory limit of 10  
9 millicuries. The outcome of the small regulatory  
10 limit is that licensees find themselves responsible  
11 for an extremely expensive and time-consuming  
12 decommissioning funding plan requirement, to the  
13 extent that health care institutions will be  
14 reluctant to include the gallium-68 generators in  
15 their radiopharmaceutical arsenal.

16 Our concern is that patients who suffer  
17 from neuroendocrine disorders, many of whom are  
18 children, will be in danger of being regulated to  
19 inferior and more physically burdensome  
20 alternative treatments all caused by a regulatory  
21 quirk that requires a decommissioning funding plan  
22 for a gallium-68 generator. Next slide, please.

23 In summary, it would be safe to say that  
24 any given deliberation of the ACMUI has embedded  
25 patient advocacy components. We strive to recommend  
26 balancing regulatory imperatives and patient

1 safety without creating unreasonable barriers to  
2 medical care.

3 Thank you. I'll now introduce Dr. Vasken  
4 Dilsizian.

5 DR. DILSIZIAN: Thank you, Laura. It's  
6 a pleasure to represent the Committee, and we were  
7 charged to make recommendations in answers to  
8 specific issues and questions that were brought to  
9 us by the NRC on the Advance Notice of Proposed  
10 Rulemaking for 10 CFR Part 20. Next slide, please.

11 There were six issues that were  
12 identified by the NRC, and we'll address all six  
13 of them briefly. We will be supporting three issues,  
14 one, two, and five, and will not be supporting issues  
15 three, four, and six. Next slide, please.

16 So briefly, issue number one is  
17 regarding updating the 10 CFR Part 20 to align with  
18 ICRP-103 methodology and terminology. The ACMUI  
19 supports replacing the terminology total effective  
20 dose equivalent with effective dose. Total  
21 effective dose equivalent is an outdated term and  
22 no longer used other than in NRC's regulatory  
23 literature. Total effective dose equivalent while  
24 similar in concept to effective dose differs largely  
25 in technical detail. It uses quality factor rather  
26 than radiation-weighting factor, and different

1 tabulations of the tissue-weighting factor which  
2 does not include all the tissues and organs. Next  
3 slide, please.

4 Issue number two relates to the  
5 occupational dose limit for events of the eye. The  
6 ACMUI supports changing the occupational dose limit  
7 of the lens of the eye from 15 rem to 5 rem. And  
8 this is based on recent human epidemiological  
9 studies which have suggested that reduced  
10 transparency of the lens of the eye may occur at  
11 significantly lower doses of radiation, ionizing  
12 radiation than previously estimated, which is  
13 termed radiation cataract. And this radiation  
14 cataract has actually distinct anatomical location  
15 which is posterior subcapsular region of the lens  
16 of the eye, which differs from age-related nuclear  
17 location of the cataract or in diabetic patients  
18 with cortical location, so we have a thumb print  
19 or a roadmap where there's a specific radiation  
20 cataract. Next slide, please.

21 And the personnel exposed to byproducts  
22 material include repair or maintenance of  
23 cyclotrons. From the medical perspective, those who  
24 are involved in fluoroscopic x-ray procedures, such  
25 as intervention radiologists performing yttrium-98  
26 microsphere therapies, cardiologist performing



1 intravascular brachytherapy, and all the  
2 associated x-ray personnel in the room.

3 So, in a relatively busy interventional  
4 suite, the estimated annual dose to lens of the eye  
5 ranges from 4 to 8 rem. And, therefore, this is a  
6 reasonable range regarding regulation to request  
7 that the regulatory dose be down to 5 rem. Next  
8 slide, please.

9 There are three broad categories of  
10 shielding by which this can be accomplished. Number  
11 one, protective leaded eyewear glasses which can  
12 be prescriptive eyeglasses, as well;  
13 portable/moveable transparent scatter-shielding  
14 screen. And the third, which is a more expensive  
15 option but it's very effective, is wearing a  
16 personal protection whole body suit with 1  
17 millimeter lead-equivalent acrylic face shield and  
18 apron. And all of these have been shown to  
19 effectively decrease the dose to the lens. The  
20 leaded eyewear reduces the lens dose by a factor  
21 of 5 to 10. The scatter-shield screen will reduce  
22 the lens dose by a factor of 5 to 25, and if you  
23 use both together it will reduce the dose by 25-folds  
24 or higher.

25 What are the implications of the change  
26 from 15 rem to 5 rem? Well, this will certainly

1 require changes in the fluoroscopic x-ray safety  
2 programs making the use of personal leaded glasses  
3 or eye protective shield, we recommend it to be  
4 mandatory for those physicians and trainees who are  
5 practicing exactly at the table with the patient.  
6 And, of course, the ancillary staff, as long as  
7 they're about 3-feet away from the fluoroscopic  
8 table, it's been shown that the radiation exposure  
9 will be 10-fold reduced to those ancillary staff.  
10 And, therefore, we would recommend that those  
11 ancillary staff be wearing eye shield, but it's not  
12 mandatory.

13 Now, of course, if there is any procedure  
14 that has significant non-uniformity in the  
15 radiation field in terms of body versus the eye,  
16 those personnel may need to utilize eye-specific  
17 dosimeters which can be worn directly above the  
18 eyebrows with a head strap.

19 Issue number three, that relates to  
20 limiting the dose of the embryo and fetus of a  
21 declared pregnant occupational worker. The ACMUI  
22 does not support reducing the dose to the embryo,  
23 fetus, or declared pregnant woman from 5  
24 millisieverts to 1 millisievert, or 500 millirem  
25 to 100 millirem.

26 Unlike the data that I presented to you

1 regarding to the dose to lens of the eye where  
2 there's plenty of scientific epidemiological data,  
3 the risk of cancer from in utero radiation exposure  
4 is a controversial subject. While the dose limit  
5 to the embryo or fetus should certainly be kept as  
6 low as reasonable, we all agree with that, there  
7 is no scientific data, however, that there's  
8 increased risk in declared pregnant occupational  
9 women with the current 500 millirem dose limit. Next  
10 slide, please.

11 The ACMUI does not know of a source of  
12 data other than that gathered by the vendors  
13 providing individual monitoring devices. And based  
14 on our collaborative knowledge, deep effective dose  
15 equivalent measurements from individual monitoring  
16 devices assigned to these declared pregnant women  
17 remain well below 500 millirem over the gestational  
18 period, and the latest NCRP report continues to  
19 recommend dose limit of 50 rem per gestation month,  
20 which would be similar to the recommended dose of  
21 500 millirem per year.

22 Now, I would like to add at this point  
23 that the additional potential recommendation on  
24 changing the regulatory dose to 100 millirem would  
25 be that it is equivalent to the variability of the  
26 background radiation dose that is currently present

1 across the United States among the states. So, if  
2 we're going to have a regulatory rule, it will be  
3 tough to control that and maintain that because it  
4 would be difficult to differentiate the incremental  
5 dose of 100 millirem in a pregnant woman beyond that  
6 is already variable with the background dose. That  
7 would be extremely difficult to regulate.

8 So, based on these findings, the other  
9 potential --- next slide. The other potential  
10 negative impacts of lowering the dose limit would  
11 be that a more restrictive limit could result in  
12 an increase in individuals choosing not to declare  
13 their pregnancy, particularly in the early  
14 gestational period in order to insure their  
15 continued employment.

16 The other potential possibility would  
17 be that there would be non-compliance of wearing  
18 proper dosimetry in order to keep their occupational  
19 dose within the lower limit to maintain their  
20 employment. And this, of course, would result in  
21 an inappropriate bias in potentially selecting  
22 female applicants for these ionizing  
23 radiation-dependent jobs.

24 Issue number four relates to individual  
25 protection, ALARA planning. The ACMUI does not  
26 support having specific ALARA planning and

1 implementation requirements to 10 CFR Part 20  
2 regulations. The current Part 20 requires ALARA  
3 programs, but does not provide specific ALARA  
4 planning and implementation requirements, and so  
5 allowed licensees to design the ALARA requirement  
6 that are most appropriate for their own activities.

7 The medical users of radioactive  
8 materials rarely experience situations where  
9 workers' doses approach regulatory limits. Many of  
10 them already utilize administrative control levels  
11 to maintain doses as low as possible.

12 The risks --- next slide, please. The  
13 risk and safety cultures of different industries  
14 and different licensees within the same industry  
15 differ so much that providing the same  
16 compliance-based requirements on all licensees  
17 will not be effective. And, moreover, defining what  
18 may be reasonably achievable is an inherently  
19 subjective process. So, the best methodology would  
20 be to maintain the status quo and not impose any  
21 further prescriptive requirements. Next slide,  
22 please.

23 Issue number five relates to  
24 metrication, units of radiation exposure and dose.  
25 The ACMUI does support the change to use  
26 international system of units in radiation

1 protection regulations. The use of both  
2 international and traditional units should be used  
3 consistently throughout the regulation with the  
4 emphasis on the international unit first as a  
5 regulatory standard followed by the conventional  
6 unit in parenthesis. This should be done as a means  
7 to effect a transition to the sole use of  
8 international units in the future. This should not  
9 cause undue burden or hardship upon any licensee  
10 or class of licensees as all nations other than the  
11 United States have already accomplished this  
12 transition to the international units. Next slide,  
13 please.

14 Issue number six relates to reporting  
15 of occupational exposure. The ACMUI does not support  
16 expanding additional categories of licensees that  
17 should be required to submit annual occupational  
18 exposure reports under 10 CFR 20.2206(a).

19 The ACMUI does not believe that the NRC  
20 should act as the nation's repository for  
21 occupational radiation exposure data, particularly  
22 since NRC does not have regulatory authority over  
23 all ionizing radiation sources. It also does not  
24 make sense to collect national data for only one  
25 area of occupational radiation exposure  
26 considering that the more extensive exposure is from

1 x-rays. Next slide, please.

2 Occupational doses have low averages  
3 for medical use licensees and licensees which  
4 support them. Accordingly, many of these workers  
5 are not even assigned personal dosimetry; thus,  
6 requiring national occupational dose tracking of  
7 those radiation workers who do require  
8 individualized monitoring would lead to  
9 unrealistically high estimates of average  
10 occupational dose for medical licensees. In  
11 essence, the data would be unintentionally biased  
12 towards higher doses since most of the low-dose  
13 individuals will not be even monitoring with  
14 personal dosimetry.

15 Moreover, occupational dose does not  
16 include doses received from background radiation,  
17 medical administration of diagnostic or  
18 therapeutic doses in these individuals, or some  
19 voluntary participation in medical research  
20 programs which will not be captured in the  
21 dosimetry. Next slide, please.

22 And NRC does not, of course, regulate  
23 all use of radioactive materials. Most are regulated  
24 by Agreement States. If the purpose of a central  
25 database is to assess total annual occupational  
26 exposure for radiation workers, the NRC's limited

1 regulatory authority would not make an ideal federal  
2 entity to manage such a central database. Next  
3 slide.

4 So, in conclusion, the ACMUI recommends  
5 NRC use a similar implementation plan that was used  
6 for the latest significant change of 10 CFR Part  
7 20, 1991 where the licensee could choose to  
8 implement the regulatory change any time within a  
9 given time frame, and the ACMUI recommends a time  
10 frame of at least three years to allow  
11 implementation of procedure, training, hardware,  
12 and software changes needed to comply with the new  
13 regulatory requirements.

14 Thank you very much for your attention,  
15 and I would like to present Dr. Palestro to present  
16 his topic on molybdenum-99.

17 DR. PALESTRO: Thank you. In the next few  
18 minutes, I'm going to address molybdenum-99  
19 production and its impact on the medical community.  
20 Can I have the next slide, please?

21 Molybdenum-99 is the parent of  
22 technetium-99m, and technetium-99m is the modern  
23 nuclear medicine imaging workhorse. Worldwide,  
24 technetium-99m is used in approximately 80 percent  
25 of the 30 million diagnostic nuclear medicine  
26 procedures that are performed annually. And



1 technetium-99m studies in the United States,  
2 approximately 50,000 of these are performed on a  
3 daily basis. Next slide, please.

4 North America, nearly 50 percent of the  
5 30 million procedures using technetium-99m  
6 annually are performed. In Europe, approximately  
7 20 to 23 percent of these procedures are performed,  
8 and Asia and the Pacific regions account for another  
9 20 to 27 percent. It is estimated that  
10 technetium-99m nuclear medicine procedures  
11 worldwide will increase by about 1 to 2 percent  
12 annually through 2020. Next slide, please.

13 The European Union produces  
14 approximately 45 percent of the world's  
15 molybdenum-99, and consumes about 22 percent of the  
16 molybdenum-99. Canada produces about 40 percent of  
17 the world's molybdenum-99, and uses about 4 percent  
18 of the total world production. The United States,  
19 which produces no molybdenum-99, consumes nearly  
20 50 percent of the world's molybdenum-99. Next slide,  
21 please.

22 Now, in getting from molybdenum to  $^{99m}\text{Tc}$   
23 and its use in nuclear medicine and for patients,  
24 there's a supply chain. It has several different  
25 components. The first component is a nuclear  
26 reactor. We have neutron bombardment of uranium

1 target produces daughter isotopes which include  
2 molybdenum-99. Then the second component is isotope  
3 production which consists of both the extraction  
4 and purification of molybdenum-99. Third is the  
5 manufacture of the molybdenum-99 technetium-99m  
6 generator, and fourth is the distribution of these  
7 generators. And each of these components typically  
8 are organized and controlled by different  
9 organizations, different corporations. Finally,  
10 the distribution of these generators goes in some  
11 cases to hospitals, but in the United States  
12 primarily to radiopharmacies. Next slide, please.

13 It's important for us to be cognizant  
14 of the fact that the molybdenum-technetium supply  
15 chain is fragile, and there are several reasons why  
16 it is fragile. Number one, the entire worldwide  
17 production of molybdenum-99 takes place at fewer  
18 than 10 sites, none of which are in the United  
19 States. So, the impact of any one of these sites,  
20 particularly the larger ones, going down for a  
21 protracted period of time can be quite significant,  
22 as we learned a few years ago.

23 Complicating matters is the fact that  
24 many of these reactors, including several that I've  
25 listed here, the NRU in Canada, the HFR, the Osiris  
26 BR2 in Europe, and Safari in South Africa, which

1 account for about 95 percent of the total world's  
2 production of molybdenum-99 are more than 45 years  
3 old. Several of these reactors are scheduled or have  
4 been scheduled for decommissioning over the next  
5 several years. And, admittedly, while the  
6 decommissioning dates have continued to be  
7 postponed, and likely will continue to be postponed  
8 for the foreseeable future, their age alone is cause  
9 for concern. They can have extensive down time, as  
10 we learned in 2008 to 2010 when the NRU in Canada,  
11 and the HFR in the Netherlands, which together  
12 account for nearly 70 percent of the world's  
13 molybdenum-99 production, were out of service for  
14 15 and 13 months respectively.

15 Finally, the United States produces  
16 more than 90 percent of the world's highly enriched  
17 uranium. And the U.S. has decided for security  
18 reasons at some point in the not too distant future  
19 to stop exporting highly enriched uranium. Next  
20 slide, please.

21 What are the consequences of  
22 interrupting the molybdenum-technetium-99m supply  
23 chain? Well, we had a chance to experience that and  
24 come to understand some of these problems during  
25 those interruptions of 2008 to 2010. And,  
26 ultimately, it potentially can and did wreak havoc

1 on patient care.

2 For example, some of the effects on  
3 diagnostic testing include postponed or cancelled  
4 studies, the use of alternative less desirable  
5 radiopharmaceuticals, the use of alternative more  
6 expensive and not necessarily more accurate  
7 procedures. The effects on patient care? Well, there  
8 were delays in diagnosis, delays in treatment, and  
9 in the United States alone from 2008 to 2012, there  
10 was nearly a 10 percent decrease in the number of  
11 nuclear medicine studies performed. Next slide,  
12 please.

13 So, how did we cope, or how can we cope  
14 with the molybdenum-technetium supply chain  
15 interruptions? Well, what we developed, what we  
16 learned for that period of 2008 to 2010 was that  
17 the solutions were really short term, or perhaps  
18 better described as stopgap. One solution is  
19 certainly to more frequently elute the generator.  
20 The technetium activity is there, elute it, remove  
21 it from the generator, use it. That works provided  
22 you have a generator, but if the generator is not  
23 available, you can't elute it. Revised examination  
24 schedules, increasing the work day so it could elute  
25 the generator more frequently, scheduling cases on  
26 Saturdays and sometimes Sundays because the

1 technetium is available at that time, make use of  
2 it. It certainly provides greater access to the  
3 patients in most need. And we also grouped studies  
4 together, like studies. Instead of doing a bone scan  
5 today, and a bone scan tomorrow, consolidate them  
6 all, or try to, on one day.

7 Well, that works to some extent, but it  
8 also results in canceled studies. When studies need  
9 to be performed immediately, the referring service  
10 feels that they can't wait, they go to seek  
11 alternative studies. Next slide, please.

12 Another option for coping with these  
13 interruptions, decrease the amount of administered  
14 activity. Give less radioactivity to each patient  
15 so that we can image more patients. And, you know,  
16 on the surface that sounds quite good, and certainly  
17 is viable. The downside is that it requires a longer  
18 imaging time to have a satisfactory or comparable  
19 image quality. And, unfortunately, the vast  
20 majority of the patients that we image are ill.  
21 They're often in pain making it difficult for them  
22 to lie still for longer time periods.

23 In the case of the children, what is a  
24 20-minute scan turns into a 30-minute scan or a  
25 35-minute scan. And for the 20-minute scan perhaps  
26 they could lie still, for the 35-minute scan maybe

1 now we have to go to sedation. So, there are  
2 significant ramifications to decreasing  
3 administered activity.

4 What about alternative  
5 radiopharmaceuticals? Nuclear cardiology accounts  
6 for about 60 percent of all technetium-based  
7 studies, and during the interruptions of 2008 to  
8 2010, it wasn't uncommon to switch from  
9 technetium-based agents back to thallium-201,  
10 which is really a throwback. Thallium-201 offers  
11 inferior image quality, increased patient  
12 radiation exposure, and in some cases an increased  
13 downstream testing and increased cost. Next slide,  
14 please.

15 There are other radiopharmaceuticals  
16 for nuclear cardiology, nitrogen-13, rubidium-82,  
17 positron emitters, excellent  
18 radiopharmaceuticals, but here we were confronted  
19 with a relatively limited number of PET imaging  
20 systems versus the conventional gamma camera SPECT  
21 imaging systems. Bone scintigraphy accounts for  
22 about 20 percent of technetium-based studies, and  
23 there certainly is an excellent alternative to the  
24 bone scan, fluorine-18. Unfortunately, again,  
25 fluorine-18 is a positron emitter so we are limited  
26 --- have to deal with limited availability. And

1 further complicating matters is fluorine-18 is not  
2 yet reimbursable. Next slide, please.

3 So, while these measures certainly  
4 enabled us to get by in the short run, they're not  
5 long term solutions. What, in fact, then is needed?  
6 Well, what is needed is a readily available  
7 consistent supply of molybdenum-99m so that we'll  
8 --- molybdenum-99 so the technetium-99m will be  
9 available to facilitate the performance of nuclear  
10 medicine procedures that are necessary for patient  
11 care. Next slide, please.

12 Long-term solutions, what are they?  
13 Well, certainly, one long-term solution would be  
14 to decentralize molybdenum-99 production. As I said  
15 previously, the entire worldwide production is  
16 accomplished at fewer than 10 sites. If there were  
17 15 sites, if there 20 or 25 sites, then the impact  
18 of one, or two, or three sites going down at any  
19 given time would be of far less magnitude than what  
20 we experienced in 2008 to 2010. For a lot of reasons,  
21 that's probably not likely to happen.

22 I think a more realistic and probably  
23 a better solution, certainly for the United States,  
24 is to develop a reliable domestic supply of  
25 molybdenum-99. At least under these circumstances  
26 we will be in control of our own destiny. Next slide,

1 please.

2 At the moment, there are two companies  
3 that are seeking or in the process, I should say,  
4 of developing molybdenum-99. One is NorthStar  
5 Medical Technologies which makes use of a neutron  
6 capture technology. They had planned to be  
7 operational in 2015, although, it looks like 2016  
8 is probably a better estimate of when they might  
9 be operational. Initially, they would anticipate  
10 being able to provide about 5 percent of the United  
11 States molybdenum-99 needs. When they are fully  
12 operational at some time in the future they expect  
13 to supply about 50 percent of our country's needs.

14 Shine Medical Technologies is the other  
15 company. They make use of a low enriched uranium  
16 technology, and they say that when they are fully  
17 operational they will be able to supply perhaps as  
18 much as one-third of the world's molybdenum-99  
19 needs. They originally had hoped to be operational  
20 by the end of 2017, but now it appears that they're  
21 not likely to be operational until sometime in about  
22 mid-2018.

23 So, in summary, we have made some strides  
24 towards coping with interruptions in the  
25 molybdenum-99 supply, but we still have a way to  
26 go. Thank you, and now I'll turn the session over



1 to Mr. Francis Costello.

2 MR. COSTELLO: Thank you. As Chairman  
3 Burns mentioned, both he and I had a previous NRC  
4 career, and mine was for 30-1/2 years, and during  
5 that time I never had the opportunity to brief the  
6 Commission, so I'm very honored to be able to be  
7 here today.

8 About a year ago, you know, I work in  
9 Pennsylvania, we had an event involving  
10 microspheres where they were shunting to the GI  
11 tract. And we'd never seen one of those events  
12 before, so I did a little literature research and  
13 looked in EDMED and another Agreement State, Ohio,  
14 had a couple of events like that. And then I looked  
15 further in the literature, which indicate that  
16 actually this was a recognized risk of the  
17 treatment, and might be expected to happen a couple  
18 of percent of the time.

19 So, I talked to some of the RSOs at our  
20 larger institutions, mostly in Philadelphia, and  
21 they indicated that it may very well be that this  
22 was -- it may be that many of the uses were not  
23 consider to be medical event then -- if they did  
24 everything right themselves. And despite that, the  
25 spheres went to the GI tract. So, having just been  
26 appointed to the ACMUI, I brought it up at the ACMUI

1 spring meeting, and they set up a subcommittee to  
2 look into this. So, I'm reporting back to you today  
3 as to what the subcommittee did, and make a few  
4 comments on what the implications are. Next slide,  
5 please.

6 A little bit about the treatment itself.  
7 For the most part, these treatments are done as a  
8 palliative treatment. There's some evidence it can  
9 improve survival, and it perhaps in fortunate cases  
10 it could enable the patient to become ready for a  
11 transplant. But mostly, this is done as a palliative  
12 treatment. Next slide, please.

13 The procedure, and there's an image I'll  
14 show you in a second, the microspheres go through  
15 a catheter, go to the hepatic artery, the branches,  
16 and the microspheres themselves are too large to  
17 pass through the capillaries and become permanently  
18 implanted in the tumor, and they then irradiate the  
19 tumor with a therapeutic dose. Next slide, please.

20 You can see an image of this there, and  
21 if you note, in a couple of places there is  
22 blockages, and those are there to prevent the  
23 microspheres from going to places they shouldn't  
24 go; prevent them to be shunting to the lung, and  
25 prevent shunting to the GI tract. So, there's  
26 mapping that's done in advance of the treatment to

1 make --- to do the very best they can to make sure  
2 that these spheres only go to the liver and don't  
3 go to the GI, or go to the lung. Next slide, please.

4 So, each patient must meet strict  
5 selection criteria. And each procedure is  
6 meticulously individualized for the patient to make  
7 sure that the right dose is given, of course, and  
8 to make sure that the spheres will not go to places  
9 they shouldn't go. And the idea is to eliminate or  
10 minimize the known risk of activity deposit,  
11 non-target tissues, particularly into the lung, and  
12 into the GI tract, which is what we had in  
13 Pennsylvania, and it also happened in Ohio. Next  
14 slide, please.

15 So, a subcommittee was formed at the  
16 spring ACMUI meeting to determine well, what  
17 conditions should be a reportable medical event,  
18 because it was apparent that there are practitioners  
19 who are doing this, and because they put the spheres  
20 exactly where they wanted them to go and they blocked  
21 the vessels off the best they could, may not have  
22 been reporting these because the procedure had gone  
23 well despite that the spheres wound up, perhaps,  
24 in the GI tract. So, the Committee was looking into  
25 well, what can do about that? What's the right thing,  
26 and what's the right thing for the guidance to be

1 done? As I'm sure you know, this treatment is done  
2 under 35.1000, so most of the requirements are found  
3 in the guidance which is on the website which has  
4 been changed quite a few times since the first time  
5 this was placed under 35.1000. Next slide, please.

6 So, our charge was recommendations for  
7 relevant changes to the guidance. And the guidance,  
8 most recent guidance was in 2012. next slide,  
9 please.

10 However, we were also given an expanded  
11 charge at the discretion of the subcommittee, we  
12 could determine whether additional medical event  
13 issues related to --- unrelated to GI deposition  
14 also require considerations. And we were to offer  
15 specific recommendations to the Staff on related  
16 regulatory guide changes. Next slide, please.

17 So, the Committee met on this over  
18 several months over the summer of 2014, and we voted  
19 unanimously that the current guidance needs to be  
20 modified in order to align with the new  
21 characteristics of Y-90 microsphere brachytherapy.  
22 The advances and improvements that have occurred  
23 over time to basically decrease the likelihood of  
24 these spheres winding in non-target areas. And,  
25 actually, to reflect the current medical practice  
26 of authorized users and medical teams across the

1 country. Next slide, please.

2 The conclusion was, basically, that the  
3 most appropriate metric for regulatory purposes is  
4 what was the prescribed activity in the directive,  
5 and what was the actual activity infused into the  
6 patient? The medical event report criteria should  
7 be based on a readily determined difference between  
8 the prescribed activity in a written directive and  
9 the actual activity put into the patient. Next  
10 slide, please.

11 You may recall, there's some similarity  
12 here between what we did in permanent brachytherapy,  
13 the same issue came up there. Specification of an  
14 acceptable GI tract and lung dose in the written  
15 directive should not be required because,  
16 basically, the goal here is that there not be  
17 shunting. Not that we're trying to set an acceptable  
18 level of shunting, but with proper mapping and  
19 proper blocking of vessels, that there will not be  
20 shunting, or significant shunting to the GI tract,  
21 or to the lung. So, the total treatment activity  
22 to be administered should require compliance  
23 measures for organs and tissues other than the  
24 treatment site.

25 A written --- a medical event in this  
26 case would be if there's a difference between the

1 actual infused activity and the activity written  
2 in the written directive. That would be the goal;  
3 except, there are some cases where stasis occurs,  
4 and it's not possible to safely infuse any more  
5 activity, and that then simply becomes a new  
6 prescribed activity. Except in the case of stasis,  
7 you compare the prescribed activity to the infused  
8 activity, and if it differs by more than 20 percent,  
9 that would be a medical event.

10 We recommended that the Staff  
11 incorporate these considerations into the  
12 guidance, and that they share this with the  
13 Agreement States and the licensees so they can  
14 implement it. Last fall, at the fall meeting, we  
15 provided the recommendations to the Staff, and Staff  
16 currently has them under consideration. I expect  
17 we'll be hearing from them at our next meeting.

18 A few points I would like to make about  
19 this. As I mentioned before, this modality is  
20 regulated under 35.1000, which gives us the  
21 flexibility of essentially changing the  
22 requirement without a rule change. I would also  
23 point out that the --- it shows how operational  
24 experience coming from Agreement States, Ohio and  
25 Pennsylvania, can be of great benefit to the NRC,  
26 to the Staff. You know, most of the licensees, those

1 medical licensees now are regulated by Agreement  
2 States, and getting that operational experience to  
3 the NRC is of great value to them.

4 In addition, the ACMUI's advice to the  
5 Staff on an issue like this is a frequent and  
6 integral part of the process for developing  
7 guidance, and it provides yet another example of  
8 the value-added by the ACMUI. Thank you.

9 CHAIRMAN BURNS: Thank you, Mr.  
10 Costello. And with that, I think that's it, and we'll  
11 begin with Commissioners question. Commissioner  
12 Ostendorff.

13 COMMISSIONER OSTENDORFF: Thank you,  
14 Chairman, and thank you all for being here.  
15 Congratulations.

16 DR. THOMADSEN: Thank you.

17 COMMISSIONER OSTENDORFF: And I just  
18 think --- I've been here --- I guess I'm the  
19 second-longest serving Commissioner after  
20 Commissioner Svinicki, but I know that after five  
21 years of being at these meetings, I continue to be  
22 amazed at what I learn and just the highlights of  
23 value that you provide to the NRC when it comes to  
24 the intersection between what we regulate and how  
25 medicine is practiced in this country, so I'm just  
26 very grateful for what all of you do.

1           Dr. Thomadsen, let me start off with you,  
2 please. On your Slide 7 you talk about some of the  
3 topics in your overview, and I found that very  
4 helpful. But could you just comment maybe in a little  
5 more detail, the bullet on the relationship between  
6 the NRC and the medical community? Are there any  
7 particular concerns there, or any high-level points  
8 you'd like to make?

9           DR. THOMADSEN: Yes. We've talked about  
10 that at a previous Commissioner's briefing, that  
11 the relation between the Commission's Staff and the  
12 facilities is very critical to try to improve the  
13 safety at those facilities. The punitive effect of  
14 some of the inspections and the way that the  
15 inspectors may characterize problems that are found  
16 can itself provide a chilling effect on the  
17 reporting of problems from a facility. And sometimes  
18 this may be intentional, and sometimes it may not.  
19 It may be that the facility may understand some  
20 things about problems they have, but they just don't  
21 want to share for fear that they may be punished  
22 in some way.

23           So, the safety culture that the NRC  
24 suggests for facilities to try to be open and  
25 non-punitive also could be beneficial to apply for  
26 the NRC working with the facilities, the goal being



1 to improve safety, not necessarily to punish those  
2 who have accidents and commit errors.

3 COMMISSIONER OSTENDORFF: In your  
4 communications between the Committee and the NRC  
5 Staff, does our Staff have the benefit of the  
6 knowledge of some of these specific examples where  
7 you believe there's been a chilling effect, or a  
8 punitive approach from the eyes of the inspected  
9 facility?

10 DR. THOMADSEN: At the briefing last  
11 time, I did use an example that was presented by  
12 an NRC Staff person at the Health Physics Society  
13 meeting last year, not this --- the one that was  
14 in Madison, where the inspect --- or the person  
15 reporting on the inspection was talking about the  
16 chilling effect at the institution of the workers  
17 who did not want to report things that would make  
18 their facility look bad, and made the assumption  
19 that that was due to the managerial policy;  
20 although, that was not clear in the presentation.  
21 What was clear in the presentation was that the NRC's  
22 Staff during the inspection and the report was  
23 definitely making statements about the facility  
24 that possibly could exacerbate any chilling effect  
25 that there might be at the facility.

26 COMMISSIONER OSTENDORFF: Okay, thank

1       you.

2                     DR. THOMADSEN: You're welcome.

3                     COMMISSIONER OSTENDORFF: I'm going to  
4 shift now to Mr. Costello, but I'm kind of looking  
5 at the very last slide you have, and the last bullet  
6 about, you know, the example, the benefit of ACMUI's  
7 input into the Staff. I thought that was really an  
8 effective summary of your presentation.

9                     I guess one thing that I wanted to ask  
10 you about, but others may have an opinion here to  
11 --- and you'll have a chance to provide that. You  
12 know, as a regulatory body we, obviously, deal with  
13 rulemaking under the Administrative Procedures  
14 Act. There's a very somewhat bureaucratic process  
15 we go through to look at regulatory issues, and even  
16 with respect to promulgation of guidance. And I was  
17 just trying to think about the yttrium-90  
18 microsphere piece and the notion of palliative care  
19 is why that's being administered in many of the cases  
20 of treatment. And do you feel like our system is  
21 sufficiently responsive time-wise to incorporate  
22 this type of feedback, and to change the guidance,  
23 or do you have any perspective on that having worked  
24 at the NRC, and being in your current position? I  
25 worry about, you know, because medicine --- I know  
26 the practice of medicine, this as a lay person,

1 changes every day. And practices, it's a very  
2 dynamic environment, and so --- but we're not  
3 necessarily set up to be as dynamic as the practice  
4 of medicine is. Do you want to comment on that?

5 MR. COSTELLO: Absolutely, sir.  
6 Modalities are covered by 35.1000, enables the NRC  
7 to be fairly nimble in changing it as they become  
8 more knowledgeable what's going on out there in the  
9 community. And this is a very good example here.  
10 I mean, the Staff can change the guidance in the  
11 website fairly easily, and I think you'll find all  
12 the Agreement States pretty much follow what's on  
13 the websites.

14 Changes, however, that require  
15 regulatory changes. We talked about the  
16 germanium-gallium generator, for example, changes  
17 that would seem very simple can take an inordinate  
18 amount of time because the rulemaking process is  
19 what it is. So, I'll say that the -- with regard  
20 to things in 35.1000, I think the NRC should be proud  
21 how quickly it can change the guidance and improve  
22 things. With regard to things that are in black  
23 letter regulation, it's much slower, much more  
24 difficult.

25 COMMISSIONER OSTENDORFF: Do you see  
26 --- you know, from your experience over your career,

1 do you have any suggestions on how we might be able  
2 to be a bit more responsive in this area? Again,  
3 noting that this is the practice of medicine, as  
4 opposed to perhaps some other topical areas we  
5 regulate?

6 DR. THOMADSEN: Yes. There's a downside  
7 of 35.1000, and the downside, it doesn't have the  
8 public comment, the public input that you have for  
9 regulations. There's a reason why rulemaking takes  
10 as long as it does, because more opportunity for  
11 the public to get involved in the process, and I  
12 understand that.

13 In addition, things under 35.1000 are  
14 supposedly there temporarily. And the goal of  
15 35.1000 was to --- for new modalities until the  
16 Agency gets experience to regulate them that way,  
17 that perhaps later are incorporated in the  
18 regulations.

19 In all honesty, I have never understood  
20 why the simplest rulemaking takes as long as it does.  
21 You will know way better than I do. I imagine you  
22 must be as frustrated as many people are that the  
23 simplest rulemaking can take years.

24 My only advice would be if there's some  
25 way to, you know, make things go through the direct  
26 rulemaking process more simply for things that are

1 non-controversial. Again, the example of the  
2 germanium decommissioning requirements, changing  
3 them, there would be no --- no one would complain.  
4 It's an obvious change that one would want to make,  
5 if you knew the situation. But when one talks about  
6 it, it talks well, this could take years. It is  
7 incomprehensible to the outside. States are slow,  
8 but not that slow.

9 COMMISSIONER OSTENDORFF: Okay. I'm  
10 going to allow our Patient Rights Advocate. Perhaps,  
11 I think you maybe wanted to say something, Laura?

12 MS. WEIL: I just --- I think Mr.  
13 Costello has said it well. The time lag to be able  
14 to make changes that would benefit patients and  
15 clinicians, it's just such an unwieldy process. And  
16 there must be something that can be done to give  
17 relief in those situations where there's clearly  
18 a need, and no downside.

19 MR. COSTELLO: Can I make one more  
20 comment on that?

21 COMMISSIONER OSTENDORFF: Yes.

22 MR. COSTELLO: In 2005, the Commission  
23 which did not include anyone here, recommended that  
24 the requirements for permanent brachytherapy  
25 change from a dose-based rule to an activity-based  
26 rule. This is in 2005. It is now 2015, and the current

1 requirement for permanent brachytherapy is a  
2 dose-based rule. And the Chairman and I discussed  
3 this over breakfast this morning, the U.S.  
4 Constitution was written faster than that. Thank  
5 you.

6 COMMISSIONER OSTENDORFF: Thank you for  
7 that helpful example. Thank you all.

8 CHAIRMAN BURNS: Commissioner Baran.

9 COMMISSIONER BARAN: Well, thanks for  
10 being here, and to all of you for your service on  
11 the Advisory Committee.

12 Just to follow-up on the yttrium-90  
13 microsphere issue. I wanted to get a better sense  
14 of how common is it that non-targeted organs are  
15 affected, and how avoidable is that? Is it something  
16 that's just unavoidable in certain cases, or are  
17 there practices that can improve the issue?

18 MR. COSTELLO: The medical practice has  
19 learned a lot over the last seven or eight years,  
20 in terms of doing the mapping in advance to prevent  
21 these spheres from going to the lung, or going to  
22 the GI tract. This is a very personalized treatment,  
23 but sometimes the body can resist what you're trying  
24 to do. And it could create new pathways after you've  
25 blocked the previous pathways.

26 I don't think we know how common it is.

1 It is rarely reported, which is the first thing that  
2 called it to my attention. It happened in  
3 Pennsylvania, it happened in Ohio, looked at the  
4 literature and you look at the package insert on  
5 this and it indicates this is an expected, you know,  
6 risk of this procedure. And it's hardly ever  
7 reported, I think because the practitioners who when  
8 they do everything properly to the best of their  
9 knowledge, don't see this as a medical event.

10 I really do not know how often this  
11 happens. I know that it's rarely reported in  
12 Pennsylvania. In the eight years we've been an  
13 Agreement State, I think it happened once, but I  
14 think some states have never had it reported. But  
15 you read the literature, it should happen a certain  
16 number of times.

17 DR. DILSIZIAN: Could I add to that?

18 COMMISSIONER BARAN: Please.

19 DR. DILSIZIAN: We do a lot of yttrium-90  
20 therapies at the University of Maryland, and the  
21 two areas is the gastric reflux, which the physician  
22 should be able to coil the artery so that they avoid  
23 the reflux. And it's rare, it's very rare for us.  
24 We do several of these a week, and we're one of the  
25 largest centers that do these therapies.

26 Regarding the shunt, the lung shunt that

1 we're talking about, it can't be prevented by  
2 coiling the arteries. The shunt itself is a  
3 physiological shunt. The tumor itself has AV  
4 malformation so you give the microspheres, it just  
5 goes to the lung, and we can understand that before  
6 the therapy by giving MAAs and you calculate what  
7 the percent shunt is to the lung. And, accordingly,  
8 you give lower dose to prevent subsequent  
9 radiation-induced pulmonary fibrosis, if you will.  
10 And so the two --- I don't want to mix those two  
11 up.

12 The gastric reflux is something that you  
13 can prevent by coiling. The lung shunt is a  
14 physiological shunt induced by the tumor, which you  
15 can assess ahead of time, and then change your  
16 dosimetry accordingly. Does that help?

17 COMMISSIONER BARAN: That does help. And  
18 just so that I have a better understanding of this,  
19 so tie that a little bit to the guidance and what  
20 that looks like now. So, walk us through a little  
21 bit what's the essential concern with the current  
22 guidance? Is it unclear, or is it implementation  
23 too difficult, or is there another issue there?

24 MR. COSTELLO: I think they think that  
25 it's clear but it's not good.

26 COMMISSIONER BARAN: Okay.



1                   MR. COSTELLO: The guidance would ask  
2 you to estimate the dose to the GI tract. And,  
3 basically, the medical team is trying to prevent  
4 any dose to the GI tract. It's not a matter of what's  
5 acceptable. The idea is to have none. And as you  
6 indicate, as far as the lung goes, I believe there's  
7 some situations where via the mapping, if they think  
8 the dose to the lung is too high, they reduce the  
9 dose along to the treatment. Okay? I think I've  
10 answered the question.

11                   COMMISSIONER BARAN: Okay. Did you want  
12 to add anything, Dr. Dilsizian?

13                   DR. DILSIZIAN: No, that's fine.

14                   COMMISSIONER BARAN: Okay. And I take it  
15 most of you were on the Subcommittee that looked  
16 at this issue. Ms. Weil, were you on the  
17 Subcommittee, also, or no? Do you have a view on  
18 this?

19                   MS. WEIL: Well, I think, you know, from  
20 a patient's perspective, I think the problem is,  
21 is that this is a therapy which is not I would say  
22 common, but it is of great value, and is a last resort  
23 to folks who have these intractable tumors, and who  
24 perhaps need to just survive while they're on the  
25 transplant list to get something curative. But  
26 institutions become less and less willing to provide

1 this particular therapy because they get reported,  
2 because there is a high incidence of reportable  
3 events associated with microsphere infusions. And  
4 that's --- you know, it creates something that is  
5 not beneficial to patients when the reportable  
6 events impede treatment in a way that isn't related  
7 to protecting patients, because it should be patient  
8 protection, it should be to identify preventable  
9 problems, and that's kind of not how it's playing  
10 out.

11 COMMISSIONER BARAN: So, let me ask you  
12 this, and this is for anyone who wants to weigh into  
13 this. I mean, what's your sense of whether there  
14 would be any controversial about changing the  
15 guidance in this way? Is this something that there  
16 are folks who are going to be really concerned about  
17 this, or is this one of those cases where there's  
18 going to be kind of universal agreement that this  
19 is a good idea?

20 DR. THOMADSEN: I'll take a stab at that  
21 one.

22 COMMISSIONER BARAN: Okay.

23 DR. THOMADSEN: And I don't think so. I  
24 think this is --- this would be a change that would  
25 not be controversial, and particularly the people  
26 who do the procedure understand that this is a

1 problem with physiology. It's not a problem with  
2 what they do, and so they would be in favor of it.  
3 The Patient Advocate, as you've just heard, would  
4 not want to see this limit the number of places that  
5 could do this just because of fear of having to  
6 report an event. The number of occasions in which  
7 this is a --- has detriment to the patient is few.  
8 There are some, and it is a known toxicity of the  
9 procedure. Being a known toxicity and one that is  
10 just part of having the procedure done, there seems  
11 little reason to call that an event.

12 COMMISSIONER BARAN: Talking more about  
13 a side effect.

14 DR. THOMADSEN: Yes.

15 COMMISSIONER BARAN: A known side  
16 effect.

17 DR. THOMADSEN: Yes. I'm sorry. The  
18 terminology that most lay people would have would  
19 be side effect.

20 COMMISSIONER BARAN: Which I ---

21 DR. THOMADSEN: Right, we use toxicity.  
22 Sorry.

23 COMMISSIONER BARAN: Right. No, that's  
24 fine. Anything else on that topic before we turn  
25 to someone else? Yes?

26 DR. PALESTRO: Yes. We do a fair number

1 of these procedures, approximately 100 per year,  
2 and I would just echo Dr. Thomadsen's comments about  
3 a lack of opposition to changing the guidance.

4 One of the big issues is there's no  
5 reliable way to accurately determine the dose to  
6 the gastrointestinal tract given current  
7 techniques that we have. And while I can't quote  
8 you the frequency with which these side effects  
9 occur, I think there's ample documentation in the  
10 literature, and certainly our own personal  
11 experience that the more of these that are done,  
12 the more experience that one has, the fewer --- the  
13 lower the frequency of these sorts of events.

14 We had one or two cases early on, and  
15 have not had any cases of GI toxicity over the past  
16 couple of years. So at our institution, at least,  
17 it would be well under 1 percent.

18 COMMISSIONER BARAN: Okay, thank you.

19 MR. COSTELLO: Just one thing.

20 COMMISSIONER BARAN: Yes.

21 MR. COSTELLO: The one thing I would  
22 remind you, of course, is we have not heard back  
23 from the Staff yet. These are recommendations that  
24 we gave the Staff at the fall meeting, and I'm hoping  
25 to hear the Staff's response to this at next fall's  
26 meeting.

1                   COMMISSIONER BARAN: Okay. Maybe we  
2 could turn to the proposed changes to Part 20 for  
3 just a minute, or for the last couple of minutes  
4 of my time. Thank you for your comments on that.

5                   Can you talk a little bit more about how  
6 the Advisory Committee weighed the pros and cons  
7 of the proposed change to the occupational dose  
8 limit for the lens of the eye from 15 rem to 5 rem?

9                   DR. DILSIZIAN: Yes. Thanks. The two  
10 major areas is that there was significant  
11 epidemiological scientific data to suggest that  
12 radiation does induce cataract, number one. And that  
13 there was a fingerprint area of the lens of the eye  
14 posterior subcapsular which was related to that.

15                   The next thing we did is to say okay,  
16 now that we do know. Now, unlike other aspects of  
17 radiation, fortunately, cataracts are easily  
18 replaceable with another lens surgically.  
19 Obviously, we need to work on the prevention rather  
20 than the therapy aspect of it.

21                   The next was the data on what is a busy  
22 interventional laboratory, what was the annual  
23 exposure in those individuals? And I provided the  
24 data, it was before 4 and 8 rem. So, that's assuming  
25 that we're not doing all these protective measures.  
26 Now, I would admit that most radiologists and

1 cardiologists are wearing lead eyeglasses, but I'm  
2 not sure --- I don't think that they're wearing lead  
3 eyeglasses plus the shield, so you can actually  
4 reduce by 25-folds if you do the two combinations.  
5 So, given that the range was within that 5 rem, it  
6 wasn't too far away, we felt that it would be  
7 important for us to not just recommend but mandate  
8 prevention for cataract at these folks who are at  
9 the table, and make it a recommendation for those  
10 who are in the room, but 3-feet away from the table.

11 COMMISSIONER BARAN: And it sounds like  
12 the steps you take there are actually pretty  
13 straightforward, if it's just kind of the glasses  
14 and stand behind a screen.

15 DR. DILSIZIAN: Yes. And, again, some of  
16 these are already in place in that sense. The shield  
17 in the CAT lab, it's there. The glasses some people  
18 use. It's just that it's not used -- it would be nicer  
19 to make the recommendation more firm rather than  
20 voluntarily, if you will.

21 COMMISSIONER BARAN: Okay, thank you.  
22 Thanks, again.

23 CHAIRMAN BURNS: Thank you all, again,  
24 for your presentations. Good to get the briefings  
25 on the various aspects of the work of the Committee.

26 One question I have, maybe start going

1 back to this area that Mr. Costello and Ms. Weil  
2 were talking about, and anyone can sort of respond  
3 to this. But, I mean, I remember --- I mean, I  
4 started to work here at the time when we called these  
5 medical events misadministrations. And I forget  
6 and, Frank, you'll have to remind me when that rule  
7 change, I think that may have been in the '90s. And  
8 I understand, and I appreciate that, but --- and  
9 this is maybe in part --- it's not really a  
10 rhetorical question, but the question, what's the  
11 effect --- and maybe those from the medical  
12 --- what's the effect of identifying something as  
13 a reportable event? And when I started saying is  
14 not from the standpoint of the NRC, because I think  
15 I understand from the NRC, but under --- I think  
16 behind your comments there's a question of there's  
17 an impact of labeling something as a reportable  
18 event. So, I'd appreciate actually anyone's  
19 comments or reflections on that.

20 MS. WEIL: I think even a little further  
21 upstream what's the purpose of collecting this data?  
22 And the purpose of the collection should be to  
23 improve patient safety, to improve clinical  
24 outcomes, but that's not how it works out,  
25 necessarily, because the definitions of these  
26 reportable events does not --- it doesn't

1 necessarily relate to something that can be  
2 corrected. And it's those two pots that we have to  
3 reconcile, the preventable stuff, and the  
4 unpreventable stuff.

5 Certainly, reporting preventable stuff  
6 and fixing the procedures and the processes, the  
7 institutional processes that lead to them would be  
8 a wonderful outcome, but the unpreventable stuff  
9 is different, and those need to be teased apart.

10 CHAIRMAN BURNS: Yes, Frank?

11 MR. COSTELLO: I can't tell you how many  
12 times in speaking to licensees either individually  
13 or sometimes as a group, I will say medical events  
14 are not violations. I mean, sometimes we follow-up  
15 on a medical event, it's a clear inspection. And  
16 we actually will praise the licensee for having  
17 identified and take corrective actions for this  
18 medical event. However, I recognize that --- and  
19 they will tell me that sometimes they think that  
20 I'm naive; that these things are public, that their  
21 management is unhappy, patients may hear about it.  
22 You may recall the fellow at the VA a number of years  
23 ago, and they'll tell me stories of other inspectors  
24 or other regulatory agencies other than  
25 Pennsylvania coming down very hard on licensees for  
26 having reported a medical event even though they



1 may have done everything right.

2           It's up to us, speaking now as a  
3 regulator, it's up to us to treat these things as  
4 they're supposed to be treated; that the simple  
5 reporting of them is something as a licensee is a  
6 good thing. They identified it, and reported it,  
7 and took corrective actions. There may be times  
8 where the causes of something is another story, but  
9 yes, I think there are licensees who when told that  
10 a medical event is not a violation think that the  
11 person telling them that is naive. They don't  
12 understand the real environment that these people  
13 work in.

14           CHAIRMAN BURNS: Okay. Anyone else? Dr.  
15 Dilsizian, I've got a couple of questions on the  
16 proposed Part 20. Actually, I saw the one  
17 recommendation with respect to the conversion to  
18 international units sort of somewhat bemused  
19 because I just came from OECD Nuclear Energy Agency  
20 and my colleagues in radiation protection were very  
21 amused at the Americans and their practices. I said  
22 well, I'm here now. I said I'm here for legal advice,  
23 not for whatever, but anyway, so it's interesting.

24           Is there perhaps --- is there a  
25 resistance, perhaps, other than it's always  
26 difficult, you know, making --- you know,

1 relabeling things or something like that. Where do  
2 you see the potential resistance to that  
3 recommendation?

4 DR. DILSIZIAN: I suspect it won't  
5 --there won't be a lot of resistance. It's just,  
6 you know, it's human nature. You're used to certain  
7 terminologies, you're resistant of change. But I  
8 guess in our investigation we found out that a lot  
9 of the --- even in the United States, a lot of these  
10 treating doses have already switched to  
11 international doses.

12 CHAIRMAN BURNS: Okay.

13 DR. DILSIZIAN: So, there is already a  
14 large adaptation when it comes to exporting and  
15 importing. And all that we need to do now is within  
16 the United States kind of move that into that  
17 direction.

18 I just think that it's just a matter of  
19 a few years, a period of time just getting used to  
20 the reporting both, and at some point to just give  
21 up.

22 CHAIRMAN BURNS: Okay. As I say, I was  
23 constantly sort of poked by colleagues at NEA over  
24 this issue. One other thing to make sure I understand  
25 the question on ALARA, or ALARA programs. I take  
26 it, and I haven't looked at the particular

1 recommendations, ANPR, in particular. But I take  
2 it the concern is that the description that would  
3 be --- there are more precise guidelines or criteria  
4 for particular ALARA programs. Is it that the nature  
5 of it?

6 DR. DILSIZIAN: Yes, because there's  
7 such different applications with this equipment,  
8 machinery versus medical use, to have one  
9 prescription which is relatively subjective to kind  
10 of guide all of them would be difficult. And I also  
11 understand that the ones that we would be concerned  
12 with that would approach the ALARA limit, the large  
13 machines are actually under Agreement States more  
14 than under NRC's, so it seems like we're not --- we  
15 don't have the jurisdiction to even make that  
16 happen, even if we were to prescribe them,  
17 specifically.

18 MR. COSTELLO: If I may. Most of  
19 occupational dose in medical institutions result  
20 from x-rays. Even the lens of the eye is from x-rays.  
21 The amount of dose from byproduct material at  
22 medical institutions is pretty near ALARA right now.  
23 To me, it's fixing a problem that's not there, at  
24 least in the medical arena, anyway.

25 CHAIRMAN BURNS: Thanks. Dr. Palestro,  
26 I was interested in the comments in terms of the

1 supply of isotopes. I know this is another issue  
2 that's gotten the attention of the international  
3 community, been providing legal support at NEA for  
4 joint declaration on the supply. But as sort of a  
5 bottom line given what you showed, I thought it was  
6 a very interesting chart in terms of production and  
7 use, or production and consumption. Ultimately, it  
8 looks like biggest solution in terms of long term  
9 is some sort of, you know, isotope producer in the  
10 United States, or the ability to do that. Would you  
11 agree?

12 DR. PALESTRO: No, absolutely, because  
13 as I had said, it would allow us to control our own  
14 destiny, that we're not dependent on outside sources  
15 for the molybdenum.

16 CHAIRMAN BURNS: Yes. At this point as  
17 you note, that there are significantly older  
18 facilities. And I guess NRU they've extended for  
19 another three years. I think originally it was  
20 supposed to be, they had announced before, shut down  
21 this year and have extended for three years. And  
22 I know they have the same issue in terms of the  
23 reactors in Europe themselves in terms of it. So,  
24 the bottom line, you say there is a lot of work in  
25 terms of sort of international cooperation on  
26 improving the isotope production of --- I think

1 it's, in effect, the full cost --- and one of the  
2 issues I think internationally has been this issue  
3 of full cost recovery, and all.

4 DR. PALESTRO: Yes.

5 CHAIRMAN BURNS: But, ultimately, it's  
6 about facilities that are able to produce the  
7 isotope. Okay. Well, thank you very much.  
8 Commissioner Svinicki.

9 COMMISSIONER SVINICKI: Good morning,  
10 and thank you all. I have had the opportunity for  
11 a number of years now to participate in the  
12 Commission's engagement with your Committee, and  
13 I thank all of you and your colleagues who aren't  
14 maybe here in the room today for the work that you  
15 do.

16 It's curious to me, I look around the  
17 audience today, and I was thinking to myself, I think  
18 it's at the end of this month our Commission will  
19 hold a meeting on our Fukushima activities, which  
20 are very important. I predict that there will be  
21 almost no empty seats in the room and, yet, for  
22 something that affects all of us, and certainly if  
23 you include our close loved ones on a day to day  
24 basis, we do not have as many people present. And  
25 I hope you don't take it as a sign that there isn't  
26 a strong interest, and I'll go beyond that to say

1 a very essential quality to having the kind of  
2 medical and patient advocacy and Agreement State  
3 input that the Committee's structure provides to  
4 us.

5 All matters related to nuclear medicine  
6 with which I've been involved in time as a  
7 Commissioner, I approach as very, very perilous  
8 matters because of the fact that there is a real  
9 life safety patient outcome element here that I  
10 think given the strong defense-in-depth in many  
11 other aspects of our regulatory structure are not  
12 as keenly present as they are in the medical uses  
13 of nuclear technologies.

14 So, I think that our overall charter to  
15 ourselves as the Nuclear Regulatory Commission not  
16 to unnecessarily impede, and frustrate, and  
17 obstruct the practice of medicine regarding these  
18 modalities, and the diagnostic and therapeutic  
19 techniques is something that over the course of the  
20 years that I've been on the Commission, I think to  
21 a person, all members of our Commission have taken  
22 very, very seriously. And I think I'll just state  
23 that my sense from the NRC Staff is that they have  
24 a similar posture on these issues because very  
25 consciously we do not attempt to replicate the types  
26 of practitioner and patient advocacy expertise that

1 the Committee provides.

2 So, I'll just react to a few things. I  
3 might have a couple of questions, but since this  
4 has been a multi-year dialogue for me, I've  
5 developed some decided views on these issues.

6 Again, I've been reading the medical  
7 events reports now for a long time. I read the  
8 abnormal occurrence report then that we send forward  
9 to the Congress. It is weighted almost exclusively  
10 with medical events because we simply do not see  
11 the health significant in other aspects of our  
12 regulatory framework. We don't see the same  
13 thresholds, and so it's interesting to me as a lay  
14 person, I read the, you know, one of two paragraph  
15 description of these things that again have met the  
16 triggers and thresholds to be reported. And then  
17 as a lay person I'm reading it, and I say well, it  
18 was maybe a dose to the non-treatment site, or  
19 something else. It seems so significant to me, and  
20 then often I get all the way to the end of the  
21 description and what's stated there is the medical  
22 assessment is that there is not likely to be an  
23 adverse outcome for the patient. And so, if I  
24 struggle with that being this much closer to these  
25 types of --- of reading this type of reporting, I  
26 sometimes think to myself as we forward this on to

1 the Congress what must they be thinking about the  
2 quality of the administration of these various  
3 techniques? And I think it's very skewed, and I think  
4 it's not accurate, and I regret that. So, when we  
5 look at the yttrium-90 microspheres, I appreciate  
6 that what we're trying to do there is begin with  
7 the end in mind, and not have a whole body of  
8 reportable events.

9           You know, the other aspect is, of course,  
10 for a patient. How traumatizing it is for a patient  
11 and family to hear that there's something  
12 reportable. And then I'm sure they do hear the  
13 statement of but we don't assess --- frankly, when  
14 there is an adverse outcome expects, it's more  
15 likely that it's because we didn't get the treatment  
16 to the site where we wanted it, and so I think that's  
17 probably remedied in the care going forward. But  
18 in any event, great anguish, I think, is created,  
19 so there's a real --- there's a global inaccuracy.  
20 There is a patient by patient, family by family  
21 --- you know, I think a negative consequence that  
22 is unneeded, so I think that's something that I  
23 appreciate that we continue to try to look at that,  
24 and approach that in a more informed way.

25           Also, the presentation on molybdenum-99  
26 and the tech-99m. You know, I'm reaching a point



1 where I have been on the fringes of hearing about  
2 the impact of this fragile supply chain for so long  
3 that's developing beyond an awareness into, I'll  
4 confess, a bit of a frustration; particularly, when  
5 we look at from the time of the supply interruption.  
6 You know, the statistics are compelling in the  
7 abstract, and when you think about real patients  
8 and real families, and the fact that, you know, maybe  
9 --- we had to prioritize, and I'll use this word,  
10 ration the delivery of certain things in our country  
11 when we are so innovative, so prosperous, have the  
12 quality of medical care that we have. I just am  
13 frustrated with our national tolerance to be so  
14 vulnerable to that kind of supply chain. It is  
15 unnecessary. We should view it as intolerable. I  
16 know there are financial and other reasons, but I  
17 have sat here year by year as I've watched the plans  
18 to have U.S. capacity come.

19 I'm actually not bothered by a foreign  
20 dependency, frankly, across our economy, the U.S.  
21 You know, we can tolerate being dependent on foreign  
22 suppliers, it's true, of rare isotope, you know,  
23 the elements and things. And I think as hopefully  
24 someday we continue as a nation to explore the  
25 promise of radiopharmaceuticals even much more  
26 broadly than we have them now, and need to produce

1 kind of boutique quantities of things, I think  
2 having a good global supply chain is perfectly  
3 supportable. The problem is that it isn't robust  
4 globally, and so I --- you know, at some point you  
5 just want to take a deep breath and say I can't  
6 believe that we keep allowing this to be this way.

7           And moly-99, and the tech-99m, and I've  
8 had a chance to visit manufacturer, distributors,  
9 and so I know about the elution, and I have some  
10 very rudimentary understanding of how you milk them,  
11 you know, for what you need. Again, we are  
12 innovative, in that time of shortfall, I appreciate  
13 the slide about all of the innovative ways we came  
14 up, but I still don't think it's something that we  
15 need to have going on.

16           I mean, I appreciate that we were  
17 innovative about it, but if even one patient was  
18 affected by that, my personal view, it's one too  
19 many. So, appreciate that someday, some future  
20 Commission, some future ACMUI members are going to  
21 sit here and be able to talk about this as something  
22 that we conquered and put to rest. And I really look  
23 forward to that day. I'll be --- if I'm not in the  
24 room, I'll be somewhere tuning in cheering that  
25 quietly because we need to get on with that.

26           And then on the input that you provided,

1 and you I read your written comments on Part 20,  
2 which were even more detailed than what was  
3 discussed here today, there's a lot of competing  
4 things that need to be balanced there. And on the  
5 whole, I want to compliment the Committee. I felt  
6 that you balanced competing concerns and interests  
7 there.

8 I know that ACMUI, it's difficult to our  
9 regulated practitioners of this, and so one could  
10 view your input on regulatory changes as being maybe  
11 too heavily weighted towards your day to day routine  
12 as practitioners. I don't view it that way because  
13 of this uniqueness about the delivery of medicine.  
14 We heard about recently, it was either in the  
15 Washington Post or the New York Times, a long profile  
16 critical of FDA, and I have sympathy as fellow  
17 regulators for --- I think it was about ALS and some  
18 new --- you know, where do they make --- when people  
19 are just wanting to kind of manage their illness  
20 and prolong their life. How do you balance risk,  
21 and making things available? You know, you don't  
22 want it to be snake oil about which there's just  
23 no good science at all, but on the other hand, if  
24 you're a patient or the loved one of a patient your  
25 view is I want to weight it towards riskier --- or  
26 why can't I make that decision, and why does FDA

1 get to be the one deciding that? If my loved one  
2 could get one more month, he or she wants that, so  
3 I appreciate, you know, your sensitivity, because  
4 I view your comments as trying to balance that risk,  
5 which is different than the power reactor side. And  
6 we need to keep our sensitivity tuned very high on  
7 that.

8 I also appreciate your sensitivity to  
9 the needs of women working in this field when it  
10 came to the embryo and fetus. I think you have a  
11 euphemistic statement in there of it's an area of  
12 controversy. It's difficult, but there are a lot  
13 of competing things to try to balance there. And  
14 in instances where we could be more prescriptive  
15 or intrusive, I took your comment document to state  
16 that what you're trying to do is say what is the  
17 benefit to be gained from this? And you're balancing  
18 that burden and these other downsides with that.  
19 So, I appreciate that.

20 So, maybe stepping back really  
21 generally, one thing that I would be interested in  
22 understanding from the Committee, we had an  
23 editorial in some trade press a few weeks ago about  
24 NRC speaking of the media being critical. In this  
25 instance in Energy Daily, there was an opinion piece  
26 that NRC's very, very complex regulatory framework

1 is likely impeding the rollout of new nuclear  
2 power-related technologies.

3 Your Committee provides input to us on  
4 I think it's every year or every other year about  
5 the effectiveness of the Committee structure, the  
6 composition, and things like that. One of the things  
7 that you provide feedback on is whether or not you  
8 feel the Commission, and I don't know if in answering  
9 that question you mean the individual members of  
10 the Commission, or the Agency as a whole, has a good  
11 understanding of what --- of the practice of nuclear  
12 medicine and what it means to deliver that every  
13 day, again, through the prism of, you know, patient  
14 care and patient outcomes, which is really what's  
15 driving you.

16 If there was something that we could  
17 understand better in the --- you know, we can't  
18 become you, and we have a lot of other things we're  
19 working on, but what would be --- if we had an extra  
20 hour each week to get smarter on these issues, if  
21 any of you just want to chime in. I'm a little over  
22 my time, but I'd like to know since I'm doing wrap-up  
23 on the Q&A. What do you think is the keenest gap  
24 in terms of what --- the ways you've engaged with  
25 NRC or this Commission over the years?

26 DR. THOMADSEN: I would look at two

1 issues, and I'm not sure that you can deal with one  
2 of them, and that is the issue that came up dealing  
3 with the ability to adapt regulations as quickly  
4 as needed to deal with the issues that are raised  
5 in the community. The changes in regulations have  
6 to be transparent, and certainly the NRC works very  
7 hard at doing that. You have to get the input from  
8 all of the stakeholders, and the NRC works very hard  
9 at doing that. I think you do a commendable job at  
10 trying to bring in all of the various viewpoints.

11 The problem is it still takes an awfully  
12 long time. The rules for changing regulations do  
13 not provide for rapid changes. They probably should  
14 not allow changes too rapidly, but there should be  
15 some way to address the issues more quickly than  
16 what they are now.

17 The other one, I think in general for  
18 the --- from our point of view, our interactions  
19 with the NRC Staff have actually been stellar. The  
20 NRC Staff that we work with are incredibly sensitive  
21 to the issues that we're dealing with, and are trying  
22 to deal with them as expeditiously and effectively  
23 as possible. That is not always true for all of the  
24 people in the field, as we've mentioned. And I think  
25 the issue that we were discussing earlier of trying  
26 to establish a way to help facilities improve what

1 they do, particularly when they have the opportunity  
2 to see their weaknesses through an event, could  
3 certainly be improved and make life less  
4 adversarial. That does not usually help the facility  
5 in trying to grapple with the issues. They need  
6 people who can help them, and they aren't afraid  
7 to deal with.

8 Those would be my two takes on what might  
9 be issues that the NRC should consider thinking  
10 about.

11 COMMISSIONER SVINICKI: Thank you.  
12 Would anyone else like to offer anything?

13 MR. COSTELLO: On the rulemaking, have  
14 to bring that up again and the germanium. I just  
15 call to your attention why I think that should be  
16 a simple change. There's a table in Part 20 which  
17 gives the quantities of material requiring  
18 labeling. There's a table in Part 30 which provides  
19 the quantities of material requiring labeling.  
20 They're titled exactly the same.

21 The requirement for decommissioning in  
22 Part 30 refers to the table at Part 30.  
23 Unfortunately, the table in Part 30 was really not  
24 changed after the 2005 Atomic Energy Act revisions,  
25 so it doesn't have a quantity for germanium-68. So,  
26 you have to use the default quantity. In Part 20,

1 there is a quantity for germanium-68, and if you  
2 could use that quantity there would be no problem  
3 with decommissioning. So, you have two regulations,  
4 Part 20 and Part 30, with identical tables with  
5 different values. One would think that would be a  
6 regulatory change that would be easy to make. It  
7 almost could be well, we made a mistake. They should  
8 be the same. But I don't believe that that, like  
9 any regulatory change, can be made inside a year.

10 COMMISSIONER SVINICKI: Well, I'm over  
11 my time, but I'll just close with this. I didn't  
12 speak to rulemaking, specifically. Just so you know,  
13 this is not unique to the nuclear medicine parts  
14 of our regulation. We have over the course of decades  
15 now been attempting to embed in our regulations a  
16 risk-informed performance-based standard, and what  
17 that allows you to do is to have in guidance  
18 appropriate, you know, procedures, methodologies,  
19 compliance pathways so that the regulations  
20 themselves can be robust. But as I sometimes tell  
21 the NRC Staff, in my view, the easiest regulation  
22 or regulation change to draft is the most  
23 prescriptive. To make things robust enough to just  
24 be a performance-based or a risk-informed outcome,  
25 that's I think the nuanced work. And it's harder  
26 to do. We do try to do it. It's a principle espoused,



1 again, of long standing for NRC, but that allows  
2 us as modalities, you know, changes, as techniques  
3 evolve, you can simply have it accommodated and not  
4 need to make a rule change. We do try on the reactor  
5 side, we've been trying to have a technology-neutral  
6 framework for a long time, but it's just --- it's  
7 hard work. But that's why we embrace that principle,  
8 but thank you all, again.

9 CHAIRMAN BURNS: Thank you,  
10 Commissioner. Before we close, anything else?

11 I want to, again, thank members of the  
12 Committee for appearing today and providing very  
13 interesting briefing on the various topics related  
14 to medical uses of isotopes. I think it's important  
15 to hear these views as we look at our regulatory  
16 program to hear areas where we may need to focus,  
17 and to not have unintended effects in terms of the  
18 safe use of radiomedicine. And I, again, also  
19 appreciate the participation of all of you, and Ms.  
20 Weil in terms of as a Patient Advocate, because it's  
21 also important to hear those views and that side  
22 of the story, as well.

23 So, again, thank you, and with that we're  
24 adjourned.

25 (Whereupon, the above-entitled matter  
26 went off the record at 11:14 a.m.)