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UNITED STATES NUCLEAR REGULATORY COMMISSION  
MEETING WITH ADVISORY COMMITTEE ON  
MEDICAL USES OF ISOTOPES

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THURSDAY

JUNE 25, 2009

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The Commission met at 1:30 p.m., the Honorable Gregory B. Jaczko,  
Chairman, presiding.

COMMISSIONERS PRESENT:

- GREGORY B. JACZKO, Chairman
- PETER B. LYONS, Commissioner
- DALE E. KLEIN, Commissioner
- KRISTINE L. SVINICKI, Commissioner

1     ACMUI PANEL

2             LEON MALMUD, M.D., Chairman

3             WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

4             STEVEN R. MATIMULLER, Nuclear Pharmacist Representative

5             BRUCE R. THOMADSEN, Ph.D., Medical Physicist, Radiation Therapy

6             DARRELL FISHER, PhD, Patients Rights Advocate

7             JAMES S. WELSH, M.D., Radiation Oncologist

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

2 CHAIRMAN JACZKO: Well, today is one of the good opportunities we have  
3 to get a perspective on the effects of the regulatory actions we take from the  
4 medical community. As I was going through the slides, I was certainly reminded, I  
5 think, of the breath of issues that you as a committee deal with and of the  
6 importance of these issues have, both, I think, certainly from a regulatory  
7 perspective as well as in the practice of medicine and other activities.

8 And it is certainly one of the things I'm always reminded of in these  
9 particular areas is that this is an area in which individuals are getting often times  
10 inadvertent doses. We have a lot focus and attention, I think, as a regulatory  
11 agency on the power reactors.

12 And for the most part, those issues there are really about hypothetical  
13 scenarios and potential doses. This is an area in which we are actually dealing  
14 with, on a periodic basis, unattended doses to patients, to individuals. So, it's  
15 certainly a very important program, a very important issue.

16 One of the issues I know the committee will talk about today are the events  
17 that happened at the Department of Veterans Affairs, and I think this is certainly a  
18 very important issue. Making sure we have the right regulatory program in place  
19 to oversee the VA program is extremely important.

20 And we do have an ongoing investigation right now in this area and we are  
21 continuing to get information. And it certainly will, I think, be a priority of mine and  
22 I suspect of the Commission as well to make sure that we process that properly

1 and promptly to make sure we keep the focus on protecting public health and  
2 safety.

3 So this is -- certainly the number of incidents in this areas that we deal with  
4 and all medical events is a small percentage of, I think, all the activity that goes on  
5 in the medical arena, but they certainly are important issues and ones where we  
6 want to continue to see how we can improve our programs and make them better  
7 to ensure that we bring those numbers down as small as possible.

8 So I look forward to hearing from you with your particular expertise and your  
9 experience in the field and how that can better inform our decision-making process  
10 with our regulations. So, I ask if any of my fellow Commissioners have any  
11 comments they would like to make?

12 COMMISSIONER KLEIN: I would just like to thank you for what you do on  
13 behalf of the Commission. As Greg indicated, we spend a lot of time on power  
14 reactors, but I think meetings like this remind us that there is a lot of other activities  
15 that we are involved in, that you all are involved in. So I would like to thank you for  
16 your activities for the beneficial uses of radiation that so many people depend on.  
17 So thanks for your contributions.

18 CHAIRMAN JACZKO: Dr. Malmud, I think we will begin with you.

19 DR. MALMUD: Thank you. Good afternoon Chairman Jaczko and  
20 Commissioners Svinicki, Lyons and Klein. I'm Leon Malmud. I'm professor of  
21 radiology and medicine and dean emeritus, Temple University School of Medicine.  
22 My role here is as chairman of the ACMUI. And we are pleased to have this

1 opportunity to report to you and share our thoughts on five subjects today.

2 The five include the following, which will be presented in order by Dr.

3 William Van Decker, who is the director of nuclear cardiology and associate

4 professor of medicine at Temple University School of Medicine, and that topic is

5 perspectives on the clinical benefit of diagnostic nuclear medicine.

6 The second will be Mr. Steve Mattmuller who is the chief of nuclear

7 pharmacist at Kettering Medical Center in Dayton, Ohio.

8 The third is the cesium-137 chloride irradiator subject, and Dr. Bruce

9 Thomadsen will be presenting that. He is a medical physicist and professor at the

10 University of Wisconsin, in Madison. And Dr. Thomadsen is the incoming ACMUI

11 vice chairman, who will take office in that role on October 1st.

12 The next topic will be presented by Dr. Darrell Fisher, who is a senior

13 scientist at Pacific Northwest National Laboratory in Richland, Washington. And

14 he will address the availability of cobalt-60 for gamma stereotactic radiosurgery.

15 And the last subject will be presented by Dr. James Walsh, who is medical

16 director at the University of Wisconsin Cancer Center Riverview in Wisconsin

17 Rapids and he is clinical professor of human oncology at the University of

18 Wisconsin School of Medicine and Public Health in Madison. He will address the

19 medical events involving permanent prostate brachytherapy.

20 Each of these subjects has been discussed with the full ACMUI in

21 preparation for presentation to you today. And if I may, I will pass this on to Dr.

22 Van Decker.

1 DR. VAN DECKER: Thank you, Dr. Malmud. I'm Bill Van Decker. Good  
2 afternoon, all. I'm a physician practitioner in the field of diagnostic nuclear  
3 cardiology, which is a subset of the universe of nuclear medicine testing in this  
4 nation. And it's my pleasure to speak a little bit this afternoon about the  
5 perspectives of clinical benefits of diagnostic nuclear medicine, especially in light  
6 of the recent timely report of NCRP Report 160.

7 NCRP Report 160 is actually a statistical compilation of the ionizing  
8 radiation exposure of the U.S. population in 2006. It is actually compared by the  
9 NCRP group to their last report in this arena, which is actually now about 30 years  
10 old, and quite a bit has obviously happened over that period of time.

11 It averages out ionizing radiation exposure over the entire population and  
12 points out that over the 30 years there has been about a 1.7 times increase. It  
13 points it out that on average right now average exposure is about 50 percent from  
14 ubiquitous environmental background, which obviously can vary from site to site  
15 and altitude to altitude throughout the United States, and that there is a portion of it  
16 for medical diagnostics.

17 The medical diagnostics dose has increased over 30 years about five to six  
18 times, which is a total absolute value of about 3 millisieverts, which is about the  
19 amount a commercial airline crew would get flying continental in the U.S. in a  
20 year's worth of work.

21 The increase has been shown to be due mostly to increased care utilization  
22 of CT scanning and diagnostic nuclear medicine as these technologies have

1 become more mature and useful in our patient care. I would point out that in the  
2 world of general nuclear medicine, some of those numbers have actually flattened  
3 to be decreasing somewhat over the past three or four years.

4 I would also point out that these technologies are not general screening  
5 technologies like colonoscopy or mammography. They are essentially modalities  
6 used for people with signs or symptoms of significant disease. And so, it is a  
7 subset of population that we are really testing.

8 The report does attribute the average over the entire population, and it does  
9 not take into account that this may be correctly and disproportionately performed  
10 on the elderly and those with more serious medical problems. The report does not  
11 attempt to qualify any associated health risks or specify the actions that should be  
12 taken in light of this statistical data.

13 The report also does not have time to really go into the enormous benefit of  
14 medical imaging on patient care and the intense efforts of the provider community  
15 to keep radiation dosing as low as reasonable in achieving good diagnosis and  
16 good patient care.

17 I think that, you know, if one were to say what is true healthcare outcome  
18 data on what you're doing with patients, both diagnostically and therapeutically,  
19 the real answer is how is our population doing over the past 30 years. And I would  
20 just point out that, obviously, the life expectancy over the period of time we are  
21 talking about has actually increased, which is quite good obviously.

22 And I would also point out that death rates, especially in my own field of

1 cardiovascular diseases, have actually decreased, and decreased significantly in  
2 cardiovascular diseases. And the data you seen on this slide is from the CDC and  
3 their national vital statistics publication.

4 Interestingly, deaths from neoplasms have also declined slightly and cancer  
5 incidences have taken a slight dip possibly because of some of our better  
6 screening issues, but also recognizing that we are not having increases by the  
7 modalities we are using to find these very significant issues in patients right now.

8 Just to look at an example of the clinical benefits of diagnostic nuclear  
9 medicine and using my own field of nuclear cardiology as an example, the ability  
10 to detect flow to the heart muscle is a very reliable way of trying to figure out  
11 whether blockages are present in arteries. The only real FDA way approved to do  
12 this right now is through the use of radioisotopes, although there are competitors  
13 trying to gather this data in other modalities.

14 The images are obtained both at rest flow to the heart and then after a  
15 stress test to look for differences in flow patterns in the pipes. On a risk  
16 management basis, I would point out that the patient already has a risk in being  
17 put under stress for the stress test to find the blockage. So on a clinical  
18 management basis, we are dealing with trading off risks at all points in time here to  
19 find people who are sick enough to benefit from the therapies we can offer.

20 The test itself serves as a gatekeeper for higher clinical tests downstream  
21 such as clinical angiography and catheter replace.

22 The test helps stratify for revascularization and appropriate use of stenting

1 in bypass surgery, so there is a lot of utilization issues here that this is extremely  
2 helpful for in choosing the right therapy, right patient, right time.

3 We have come to learn over the years that regardless of the amount of  
4 blockage in any artery in the heart, those people whose flow is relatively okay to  
5 the muscle, usually do relatively well with simple medical therapy.

6 We have learned that people who we can find that there are flow  
7 perturbations that are indirect evidences of their blockages, these people do worse  
8 and worse the worse that their flow to their heart muscle is, and we know we need  
9 to be more aggressive with them before natural history takes its course and  
10 reverses some of the fine work of the cardiovascular community over the last 30  
11 years.

12 This is just an example to give you a sense for things. These are three  
13 different patient scenarios. The far left is tomographic images of the heart in three  
14 planes. The top set of image in each one is under flow stress. The bottom one is  
15 under rest. The left set is equal flow throughout.

16 This is a patient that even if they had 30, 40 percent blockages in their  
17 arteries, they are going to do relatively well and can get medically managed.

18 The middle set shows unequal flow patterns, and this is indirect markers of  
19 blockages in the pipes, and we know we need to be more aggressive with.

20 And the one on the third is obviously a situation where the top set of images  
21 show very little flow to large pieces of muscle that improve at rest. This is a  
22 person who we know on a risk adjusted basis is going to do very poorly without more

1 aggressive therapies. You know, this allows us to target some of these pipe fixing  
2 type therapies.

3 In the first set of images above, you can see an old bypass graft which  
4 now has a stenosis in it and fixed by stenting.

5 The second set of images on the right is a closed artery with flow down the  
6 pipe restored after stenting.

7 The bottom two sets of images is the medical student image. This is what's  
8 called the widow maker's lesion. It's a very, very tight blockage in a big major  
9 vessel on top of the heart. These are the ones we want to be finding and being  
10 able to reestablish flow before myocardial infarction loses large pieces of muscle.

11 Having said all of that, I would point out that there is -- we have from the  
12 provider community, a strong interest in making sure that we are using ionizing  
13 radiation appropriately for the appropriate patients at the highest risks. And that  
14 we are getting the quality type of tests to make good decisions.

15 Certainly there are appropriateness criteria out there in the medical  
16 community of who should be tested and what might be the best things to do with  
17 testing results. The medical provider community has multiple sets of imaging  
18 acquisition guidelines with the help of health physicists and medical physicists in  
19 trying to fine-tune these protocols to the best possible.

20 There are new hardware on the horizon that may allow to us to use less  
21 dose and still get the same quality picture, which would obviously be a win in all  
22 worlds. But we do need good pictures to make good diagnoses. And then there

1 are lab accreditation opportunities throughout the nation in trying to help all  
2 providers improve the quality of their care in delivering quality services.

3 In conclusion for this end, I would say that NCRP Report 160 is greatly  
4 appreciated and fully noted by the full medical community, of which I'm only a  
5 small representative. We actually would prefer seeing it more than every 30  
6 years. It's a helpful reminder to relooking at things.

7 I would point out that the clinical benefits of imaging in the room with  
8 patients are incredibly great and they are driven by physician-patient discussions  
9 of what the risks of not knowing versus what the risks of knowing are and where  
10 you go from there. That is the basis of our healthcare system, that relationship  
11 and that open discussion.

12 The broad medical community across multiple subspecialties are greatly  
13 involved in assessing their use of ionizing radiation and how to use it in the  
14 smallest, most appropriate amounts.

15 And in that regard, and after discussion, the advisory committee  
16 recommends that the NRC retain its current policy where we are considering the  
17 current review.

18 And I thank you for your time.

19 DR. MALMUD: Thank you, Dr. Van Decker. We're now open to questions  
20 if you wish.

21 CHAIRMAN JACZKO: We will go through all the presentations and do  
22 questions at the end.

1 DR. MALMUD: Thank you.

2 Next presentation.

3 MR. MATTMULLER: Good afternoon, I'm Steve Mattmuller, chief  
4 pharmacist at Kettering Medical Center in Kettering, Ohio. I'll be discussing today  
5 the medical isotopes shortages, specifically Mo-99 that we are facing in our field  
6 today.

7 The four areas we will be touching on are why we need Mo-99, the causes  
8 of the shortage that we are enduring right now, the effects of the shortage on your  
9 patients, and possible solutions.

10 Very simply, we need Mo-99 for good patient care. More than 34,000  
11 nuclear medicine procedures each day in the United States depend on a reliable  
12 supply of Mo-99 for our patients. Nuclear medicine procedures are some of the  
13 most accurate methods and essential tools used by physicians to provide optimal  
14 patient care to their patients.

15 Our Technetium radiopharmaceuticals have two components: The  
16 Technetium atom and a chemical component that attaches to it. And it's the  
17 differences in the chemical component that -- based on its structure that  
18 determines where it goes into the body and how the same radionuclide with  
19 different chemical components can be used for multiple different tests.

20 For example, we can use Technetium with sestamibi for myocardial  
21 perfusion imaging much like Dr. Decker just demonstrated, or we can use  
22 Technetium with MDP for diagnostic metastatic bone disease.

1           This shows why we need Mo-99 every week. This is a graph of elution  
2 characteristics from a generator. It shows the decay of Mo-99 over time and  
3 decreasing yields of Technetium over time also. And you can see the activity of  
4 the Technetium rise and then it drops to zero. And that's when we elute the  
5 generator, when we remove the Technetium off of the generator to use with our  
6 Technetium kits to prepare for the different procedures.

7           And then, as you can see over time, in about 24 hours, the Technetium  
8 builds back up to its maximum level of Mo-99 for that day.

9           So through the week, you can see it's somewhat of a race against time  
10 where our Mo-99 is decaying and producing smaller and smaller levels of  
11 Technetium.

12           This is actually a real demo generator without the lead. This is the column  
13 that the Mo-99 would be loaded on. It would sit in it like this. Sadly today, this  
14 represents the typical generator with no Mo-99 because of the shortages.

15           This is just an example of nuclear medicine procedures. On the left shows  
16 a heart study for myocardial perfusion imaging. Approximately, 50 percent of all  
17 doses used with Technetium in nuclear medicine are for heart myocardial  
18 perfusion studies.

19           On the right is a bone study used to diagnose metastatic bone disease.  
20 This category of test represents about 30 percent of all Technetium used in the  
21 U.S. And, again, nuclear medicine images are based on the physiology of the  
22 disease versus the anatomy of disease. And CT and MRI do a terrific job of

1 creating anatomical images of the disease process, whereas nuclear medicine is  
2 complementary information based on the physiology of the disease.

3 The causes of our problem: It is due to a fragile supply chain.

4 Uranium-235 targets have to first be irradiated in a reactor. Then the targets are  
5 processed to purify Mo-99. The purified Mo-99 goes to the generator  
6 manufacturers. And those are then shipped to centralized pharmacies or to  
7 individual hospital departments, where the individual doses of Technetium can be  
8 prepared for the various studies.

9 By far and away, the weakest link in this whole chain is the small number of  
10 reactors that produce Mo-99 for us. There are four in the world that produce about  
11 90 to 95 percent of all Mo-99 in the world. The U.S. gets 100 percent of its supply  
12 from just two reactors.

13 The National Research Universal Reactor at Chalk River, Canada,  
14 produces about 60 percent of our needs. And that Mo-99 typically goes to  
15 Lantheus in the production of their generators.

16 The other reactors, the High Flux Reactor in Petten, the Netherlands, which  
17 produces about 40 percent of our needs, and that Mo-99 goes to Covidien for the  
18 production of their generators.

19 Talk about the fragility here. Our biggest problem is that our reactors are  
20 old. The NRU reactor is 52 years old and it's responsible for the current shortage  
21 that we are enduring right now that started in May of this year.

22 The High Flux Reactor in the Netherlands is 47 years old, and it was

1 responsible for a shortage that started in August of last year and that continued on  
2 to January of this year. And both of them are due to corrosion issues with various  
3 subsystems in their reactors.

4 Our current shortage is from the Canadian reactor is now inoperable. And  
5 the current estimate is three months of time that it needs to unload the fuel,  
6 complete the repairs and to reload. But that's a best-case scenario for us, and we  
7 certainly hope it turns out that way, but there is no guarantee that in three months  
8 the Canadian reactor will be back on line.

9 It's going to get worse for us very shortly. The Dutch reactor is scheduled  
10 to shut down for maintenance for a month in mid-July, which coincides at the same  
11 time that the Canadian reactor will still be down. So our two biggest reactors that  
12 we are dependent on for Mo-99 will both be down.

13 That bad outlook continues for 2010. In the beginning of next year, the  
14 Dutch reactor is scheduled for repairs, in which they estimate will take six months.  
15 So we are in the very precarious position right now.

16 So the effects of the shortages are diminished patient care. These are  
17 survey numbers collected by the Society of Nuclear Medicine. The 2008 column  
18 represents the shortage that started last year and ended the beginning of this  
19 year. The 2009 figures are very preliminary figures. This only represents about  
20 two or three weeks of actual shortages. And as you know, it continues today.

21 The shortage now is actually much more severe and probably, the worse  
22 statistic here is cancellation of a procedure. It is now almost a third are being

1 cancelled due to the lack of Mo-99.

2 The differences in these two shortages reflect which reactor is down. Last  
3 year it was the Dutch reactor, which provides Mo-99 to Covidien, but the Canadian  
4 reactor was still operable. And the Canadian reactor also has extra capacity, so  
5 they were able to ramp up their production to help cover the shortages that we  
6 were experiencing last year and into this year.

7 Sadly now that the Canadian reactor is down, there is no other reactor in  
8 the world that has extra capacity to sort of make up for the full amount that we are  
9 missing from Chalk River.

10 The diminished patient care. Referring physicians who refer to us to  
11 provide these tests are frustrated, in that they are trying to take care of their  
12 patients; that's their primary focus. And when we can't provide these procedures  
13 to them, they have to choose something else.

14 Typically, because of the nature of a nuclear medicine procedure, these  
15 other tests can be inferior in accuracy. They might be more expensive, or in some  
16 cases, the alternate procedure may actually have a higher radiation dose to the  
17 patient than our procedure. And again, this is because nuclear medicine  
18 procedures are based on physiology as opposed to anatomy, and so, it is unique  
19 information that is difficult to provide from alternate testing methods.

20 So our hope, the solutions are new Mo-99 suppliers. At Missouri University  
21 their research reactor, they are undergoing studies now on plans to produce,  
22 Mo-99. They have produced medical isotopes in other areas, and they have a

1 successful track record in that regard. But, at this point right now, they need 40 to  
2 \$50 million to build and construct a processing facility to handle the Mo-99 targets  
3 that they would irradiate in the reactor.

4 Our second best hope is with Babcock & Wilcox. They are partnering with  
5 Covidien. They are using a different reactor design, an Aqueous Homogenous  
6 Reactor. These are much -- and you are probably more familiar with these than I  
7 am, but this a modular reactor design. A modular unit, 200 kilowatts. Their facility  
8 would probably have four or five of these individual reactors.

9 But also, they have -- instead of having separate solid fuel rods and targets,  
10 it is a liquid slurry of the target fuel and the reactor fuel that then has to be -- where  
11 the Mo-99 has to be separated from. So they have some technological challenges  
12 ahead of them as this type of reactor has never been used before for medical  
13 isotope production.

14 Both of these plants have some regulatory issues facing them. And  
15 flexibility is going to be needed during the licensing process in regards to  
16 construction plans, environmental issues and radioactive waste stream issues, if  
17 these time lines of five to seven years are going to be met.

18 And finally, I wanted to finish with two of our patients for Kettering to remind  
19 us why we are here and why this is so important to us. One of these -- the lady on  
20 the left had heart disease, and the gentleman on the right had metastatic bone  
21 disease. And they are just part or two of the 34,000 people a day who rely on  
22 nuclear medicine.

1           We are in a pickle now. There are plans to get us out of it. But the next five  
2 to seven years will be very challenging for us, and we hope we can rely on the  
3 assistance from the NRC to help get us there in time. Thank you.

4           DR. MALMUD: Thank you, Mr. Mattmuller.

5           The next presentation will be made by Dr. Bruce Thomadsen, and the  
6 subject is the cesium-137 chloride Irradiators. Dr. Thomadsen.

7           DR. THOMADSEN: Thank you and good afternoon.

8           The National Research Council issued a report that suggested that  
9 Cesium-137 Chloride irradiators be eliminated. These are necessary in medicine,  
10 and the ACMUI when learning about this, looked into the issue and questioned  
11 some of the facets of that recommendation and established a subcommittee of the  
12 six people listed on the slide to look into three particular aspects of these  
13 irradiators, the need for the sources, alternatives and security of the sources.

14           Under need of the irradiators, the first and most well-known use is as blood  
15 irradiators. Around 15 to 40 percent of patients receive irradiated blood, mostly  
16 these are oncology and hematology patients who are very immune compromised.  
17 The reason for the radiation is to kill the host white blood cells that are in the  
18 blood. Otherwise they can react with the patient, and these patients can die.

19           The original report assumed about 10 percent of patients receive irradiated  
20 blood. This is probably because in their survey, the weighting that they had might  
21 have been more heavily towards trauma center, where the irradiation is not  
22 necessary.

1           Without access to the irradiated blood, the patients who do need it would  
2 either die or have very severe consequences.

3           The other use in medicine is for animal irradiation. This is for research to  
4 bring new types of therapy to light. There are two particular uses that are very  
5 dominant in this field.

6           First is to suppress the immune system of animals who are being used to  
7 test stem cell work and other types of treatments where the bone marrow needs to  
8 be suppressed.

9           The other main use is for cancer research, particularly in radiotherapy  
10 where the irradiators are necessary.

11           There are alternatives to the Cesium Chloride irradiator. Usually the most  
12 common alternatives would be x-ray units or linear accelerators. Both have been  
13 used and are used for animal irradiation, blood irradiation and material irradiation.

14           For x-ray units with blood irradiation, the FDA has only approved one unit  
15 for this use, at a cost of \$250,000 with a \$33,000 a year service contract. This is  
16 different from in the report, which specified it was \$180,000 for the machine and  
17 \$10,000 a year for the service contract. This is a lot of money for these facilities,  
18 most of whom do not operate with a large fund to replace their units.

19           Extra expenses for these x-ray machines include replacement of tubes,  
20 calibration and quality management. The calibration has to be done periodically  
21 with x-ray machines. They are not stable like the cesium machine, which is can be  
22 calibrated once and run very reliably for years. It requires some intervention on

1 the operator's part for quality management, and as I mentioned replacement of  
2 tubes.

3 With 48,000 blood units irradiated each year, a tube would have to be  
4 replaced in about 3.7 years. This is adding tremendous costs on top of the initial  
5 cost of the machine to the operators.

6 In addition, the throughput is much lower than for a Cesium machine,  
7 because the x-ray machines do not have as high of a dose rate, limiting how many  
8 units of blood a machine can process.

9 For animal irradiation, there are several machines on the market, but  
10 unfortunately, very few that operate above 200kV. The energy is very important  
11 for two reasons. One is you have to have adequate penetration to irradiate all of  
12 the bone marrow in the animals. Operating below 200 means that the skin dose is  
13 going to be very high and the penetration is not usually adequate to give good  
14 irradiation to the bone marrow.

15 The second is that radiation of different energies have different relative  
16 biological effectiveness, that is, how much damage the radiation does to different  
17 types of cells per unit dose. This varies not only with the energy but with the  
18 species and with the biological end point, which makes a very complicated matrix  
19 if you're trying to replace the historic Cesium with any of the x-ray machines.

20 The prices for these range between \$146,000 and \$250,000, with a service  
21 contract of 10 percent per year.

22 The low dose rate makes it difficult when you have an animal under

1 anesthesia, because you have to keep the animal anesthetized for a longer time  
2 than you would with a Cesium machine. All together, this is a lot of expense and  
3 trouble for institutions who usually don't have, once again, a source of revenue to  
4 replace and maintain these expensive machines.

5 For a medical linear accelerator, the price tag goes up even higher, with a  
6 typical linear accelerator, a stripped down model, costing around \$150 million a  
7 year, plus \$150,000 per year for the service contract.

8 One could use radiotherapy department's linear accelerator for the  
9 irradiations. This is done sometimes for animal irradiation. It has to be done after  
10 hours, of course, limiting the access to the machine. For blood irradiation, it would  
11 probably have to fit in between the patients during the day, causing a disruption  
12 both to the radiotherapy facility and to the blood bank.

13 Moving on to the security issue. The security of the machines has changed  
14 remarkably, since the report was issued. There are security enhancements for the  
15 users. Now, all the users for these machines have to go through background  
16 checks with fingerprints, and this has tightened the security for the users.

17 The facilities have been tightened through the directives of the NRC. The  
18 rooms in which the machines are located have to be very secure. Typically, at the  
19 University of Wisconsin where we have about five of these machines, the security  
20 enhancements cost a little bit more than \$15,000 for a typical machine, some of  
21 them a lot more. But this has greatly improved the security for those rooms.

22 And finally through a program with the Department of Energy and the

1 Department of Homeland Security, the units themselves are being hardened. With  
2 three thrusts, these have become much more secure.

3 This slide illustrates a typical machine, the Cesium sits in the middle of this  
4 machine, immobile. The sample is put in a tube on the top that slides down into  
5 the source configuration during the irradiation.

6 In order to get at the Cesium, one would need a cutting torch and a lot of  
7 tools. In order to get the machine off its pedestal, you would need also these  
8 tools, a lot of others. You also have the problem that the machine itself is on a  
9 reinforced floor, and as soon as you took it off that floor, it would be too heavy for  
10 regular floor to support. Stealing this machine would be very difficult.

11 The source material possibly could be made to a form that would be less  
12 attractive to people who might want to steal it possibly as fused glass.  
13 Unfortunately, right now, the manufacturers have no interest in making changes in  
14 the chemical form because this would be very expensive for them. We can't direct  
15 them what to do, because at the time no American manufacturer makes these  
16 sources. We import them from other countries not always who are very friendly to  
17 this country.

18 In summary, the irradiator facilities are essential for irradiating blood and for  
19 medical research. Forced replacement of the Cesium-137 Chloride units would  
20 result in great expenses to the facilities and possibly lead to facilities stopping their  
21 irradiation programs.

22 There are problems or large expenses with changing for animal irradiation

1 to x-rays. The enhanced securities for these units has mitigated much of what  
2 would have concerned people with these machines just a couple of years ago.

3 And finally, without a source, a domestic source for Cesium-137, newer and  
4 possibly safer forms of the radionuclide are not very likely. Thank you.

5 DR. MALMUD: Thank you, Dr. Thomadsen.

6 If we may, we will move on the next subject, and that will be presented by  
7 Dr. Darrell Fisher. The subject is cobalt-60 for stereotactic Gamma Knife  
8 radiosurgery systems.

9 DR. FISHER: Distinguished Commissioners, I represent patients' rights  
10 and their healthcare concerns on the committee.

11 Cobalt-60 is a critically important medical isotope, and its continued  
12 availability is a quality of healthcare issue. Today I will briefly discuss the medical  
13 need for Cbalt-60, supply and availability, transportation of sources, source  
14 security, and state fee regulation.

15 The use of Cobalt-60 in the U.S. for external beam radiation therapy has  
16 declined substantially; however, it is still used worldwide in large amounts. Today,  
17 Cobalt-60 is a highly effective isotope for radiation therapy in the newest and most  
18 advanced computer-driven stereotactic systems for treating brain tumors. These  
19 are collectively referred to as stereotactic radiosurgery or Gamma Knives.

20 The major regulatory issues impacts supply and costs of the isotopes. Most  
21 of the world supply of Cobalt-60 is produced in Canada and is distributed by MDS  
22 Nordion. It is produced in the CANDU Reactors Bruce B, Pickering A and B,

1 Gentilly and in the NRU reactor previously mentioned today.

2 High specific-activity Cobalt-60 for the Elekta Gamma Knife are produced in  
3 the U.S. by Isotopes International at the Advanced Test Reactor near Idaho Falls.

4 High specific-activity Cobalt-60 sources are used for medical therapy and cargo  
5 imaging. Two to three-year production cycles are required to produce a source.

6 Low specific-activity Cobalt-60 sources are used to in radiation sterilizers.

7 The supply and availability are currently adequate to meet international needs, as  
8 long as the ATR continues to operate and the ability to transport sources is not  
9 impeded.

10 According to industry representatives, the major Cobalt-60 supply issues  
11 are availability of approved transport containers and casks, source security, the  
12 costly import/export licensing requirements for U.S. licensees, and excessive state  
13 transportation permit fees. These issues impact availability and the ability to move  
14 Cobalt-60 from the reactor to the cancer treatment systems.

15 When we increase the difficulty of transporting sources, we also decrease  
16 availability and increase the ultimate cost of cancer treatment to patients.

17 Shipping containers is the next subject. The U.S. Department of  
18 Transportation withdrew approval of all specification packages in October 2008  
19 after a four-year transition period.

20 The availability of replacement package designs has not kept up with the  
21 need to make shipments.

22 Approval of new replacement package designs can take 18 to 24 months

1 and can cost up to \$750,000 per design.

2 The NRC, in the interim, is working with industry and has approved the use  
3 of discontinued packages on a case-by-case basis. This is appreciated by  
4 industry.

5 However, the major issue seems to be that packages approved by foreign  
6 regulators are not equally recognized by U.S. regulators. This situation makes it  
7 more difficult to transport category one sources inside the United States. Some  
8 strategies have involved exporting sources, and then reimporting them to make  
9 deliveries within the United States.

10 The container revalidation process is burdensome to industry. Industry  
11 recommends a process to improve the approval of shipping containers already  
12 approved by foreign regulators according to well-defined international standards.

13 In the area of source security, industry supports the concept of increased  
14 source security. Fundamentally source tracking is a very good idea, but industry  
15 reports that the current NRC system is not working well in practice.

16 For example, under current requirements, the 200 sources shipped to  
17 replace aging Cobalt-60 sources for a single Gamma Knife unit have to be tracked  
18 individually rather than as a unit. This has required, for example, the transmitting  
19 of 200 individual faxes to track those sources for a single shipment.

20 If Category 3 sources are also tracked, the current system will not be able  
21 to handle the large number of individual sources.

22 Import authorization should be included in the possession and use license

1 to reduce the financial burden on industry.

2 Export license fees and expirations should be based on the U.S. licensee  
3 and not on the importing country, which is a fee uniformity issue.

4 U.S. companies should not be required to list all possible customers on the  
5 import/export license. These are recommendations from industry representatives.

6 Also for your information there are two other issues that may be mentioned.

7 Under state fee regulation, some states require excessive fees to transport  
8 Cobalt-60 within state boundaries. Therefore, shippers and carriers often bypass  
9 these states whenever it is possible which increases transportation costs and  
10 in-route times. One example is the high fees charged in the State of Iowa.

11 The NRC does not have preemptive authority over the states for  
12 transportation to help make fees uniform from one state to another.

13 On the positive side, there is the good news that the recovery and recycling  
14 program is working very well.

15 In summary, Cobalt-60 availability is very good but always subject to  
16 ongoing reactor operations.

17 Approved container shortages, the complex transportation regulations, and  
18 costly import/export licensing requirements have made it extremely difficult and  
19 costly to supply cancer therapy devices with Cobalt-60. These costs are  
20 eventually borne by our healthcare system. Further efforts are needed to  
21 streamline the approval of shipping containers. And I thank you.

22 DR. MALMUD: Thank you. And we will move on to our next presentation,

1 which will be made by James Welsh, who is a physician and a radiation  
2 oncologist, and who will present the ACMUI's observations regarding multiple  
3 medical events involving permanent prostate brachytherapy within the Department  
4 of Veterans Affairs Medical System.

5 Dr. Welsh.

6 DR. WELSH: Distinguished Commissioners, good afternoon, and thank  
7 you for the opportunity to speak before you today.

8 There has been a good deal of publicity surrounding this sensitive matter  
9 recently, and thus, I have prepared this introductory statement.

10 ACMUI joins with the Commissioners and the NRC staff in our concern  
11 regarding the reported number of incidents at the VA Philadelphia. Due to recent  
12 public awareness, I have refocused my presentation slightly. NRC has confirmed  
13 that there is an ongoing inspection and has committed to keeping the ACMUI  
14 informed of its progress. The ACMUI remains intensely interested in this issue  
15 and will offer advice, as requested.

16 I have followed the recent coverage closely, and I would like to offer today  
17 the perspective of a radiation oncologist who is concerned with patient outcomes.  
18 If the ongoing inspection by the NRC should conclude that there has been  
19 substandard patient care, I would join with my colleagues in encouraging  
20 appropriate corrective action. We acknowledge that the VA understands the  
21 gravity of the situation and is moving on this matter.

22 Some of the reported events may prove to be clinically significant, others

1 may not. For example, there have been criticisms that post-implant dosimetry was  
2 not uniformly performed. Is post-implant dosimetry strongly recommended? Is it  
3 considered by many to be standard of care? Yes. But is it mandatory? No.  
4 However, even a single event which does not comply with radiation and patient  
5 standards of care, is of great concern to me, as well as to all members of the  
6 ACMUI.

7 I hope that in this brief presentation today, we can maintain objectivity in  
8 what appears to be a very serious situation. We look forward to hearing more of  
9 the results from the NRC, and, in the interim, we should not rush to judgment. At  
10 the end of the day, we must ensure that our veterans and all patients, receive what  
11 they deserve, that is, the very finest in medical care.

12 So with that introduction, I move to the first slide, which is simply a synopsis  
13 of the events.

14 The NRC received reports from VA Medical Center, Philadelphia of multiple  
15 medical events involving prostate brachytherapy.

16 NRC inspected 13 medical facilities of the same permittee. Numerous  
17 medical events were identified at multiple locations.

18 Prostate brachytherapy at the VA Philadelphia has been suspended along  
19 with three other programs.

20 Corrective actions have been taken, which I will describe a little bit today.

21 The VA will not start its suspended cancer programs until these  
22 commitments have been met. Several have appropriately asked where our

1 veterans will be going to receive their prostate brachytherapy should they so  
2 desire it, and this is an important question.

3 So before I talk about additional actions taken beyond the corrective  
4 actions, I want to make a brief comment about the corrective actions themselves.

5 One of them, which I wouldn't detail here explicitly, mentions the ordering of  
6 an external review of the prostate brachytherapy program by an Administrative  
7 Board of Investigation or ABI. One would hope and expect that this ABI includes  
8 some of the true experts in our field.

9 Additional actions taken are on the slide here for patients care concerns at  
10 one facility, the licensee performed verification CT scans on all patients,  
11 reevaluated the dose, and reimplanted some patients at a different facility.

12 The question that arises immediately is can one really trust these  
13 verification CTs if they were done long after the fact, which appears to have been  
14 the case in some situations?

15 This is a schematic diagram of what is considered to be a good implant.  
16 Note the dose of 144 Gray and note also that the bladder in this case is partially  
17 anterior to the prostate; in other words, at the top of the screen here.

18 Among the caveats and pitfalls of this matter is the question about whether  
19 our criteria for medical events could possibly be too low? In other words, are our  
20 criteria too sensitive but not specific enough? Perhaps not,, based on the  
21 statistics, which there were approximately 100 medical events out of 50,000  
22 procedures, suggesting that that large denominator -- that large denominator

1 suggesting that this is not a huge pervasive problem in the United States.

2 But, one has to ask if there are too many medical events being reported  
3 that are not truly of a clinical significance? This is a general question, but may be  
4 of great relevance here as we attempt to answer the important question of whether  
5 there were many bad implants conducted, or are they so labeled because of our  
6 current definitions?

7 Let's look at the definitions, or the definitions that were used in the VA  
8 medical events. Twenty percent -- greater than 20 percent of the prescribed dose.  
9 No one can fault someone for using this, because it comes straight from 10 CFR  
10 35.3045. But one does have to ask how is the dose actually determined?

11 If we say that not all the patients underwent post-implant dosimetry, where  
12 is the data coming from? Get this from a CT scan that was done a year later?  
13 That is an important question that remains to be answered. Or the D90s and  
14 B100s calculated, these are parameters that are used to define a quality implant  
15 and assess the technical quality event procedure. We don't have any information  
16 on that yet.

17 One important topic that I would like to touch on in this slide here is  
18 regarding the external tissue. In the analysis, five or more seeds located beyond 1  
19 centimeter exterior and inferior to the surface of the prostate was one of the  
20 criteria for a medical event.

21 Recall that one of the treatment planning goals in prostate brachytherapy is  
22 to cover the prostate, the prostate gross target volume or GTV, the prostate itself,

1 plus a margin of 3 to 5 millimeters to cover potential extra capsular extension of  
2 disease; in other words, the clinical target volume or the CTV.

3 In order do to achieve this, one must frequently implant seeds intentionally  
4 beyond the prostate capsule. Thus, some might contend that the definition used in  
5 this context was a bit too strict.

6 This brings up the other important point, which is that there is a new rule  
7 being contemplated regarding medical events for prostate brachytherapy. The  
8 current criteria of determining medical events was used in this analysis.

9 But the proposed criteria put forth by experts from national organizations  
10 such as ASTRO and ACRO and discussed by the ACMUI is 20 percent or more of  
11 the seeds implanted beyond 3 centimeters from the boundary of the treatment site.  
12 Treatment site could be a planning target volume or PTV.

13 This is significantly different from the criteria used in the analysis, and one  
14 has to wonder whether the medical events in question would still be so classified if  
15 one used the proposed new rule that was proposed by some of the experts.

16 Normal practice is to have a post-implant CT scan to determine seed  
17 placement. We know that this was not done routinely because of the faulty  
18 software. Comparisons, therefore, could not uniformly be made.

19 One of the corrective actions was instruction to the Radiation Safety Officer  
20 and quality management staff to immediately report all deviations that exceed 10  
21 percent of the prescribed dose or dose fraction. This raises the question about  
22 whether an RS0 or medical physicist or any nonphysician member of the quality

1 management staff can make this call. Some might, some certainly could not.

2 I would submit that only a trained specialist M.D. who is fluent in male  
3 urogenital anatomy can really make this call reliably.

4 I would like you to take a look at this particular slide and I call to your  
5 attention first that this schematic is based on a CT that was done after the fact and  
6 the prostate is in red. But as I said, the prostate is very difficult to define at its  
7 inferior most border. Thus, the seeds in green here in this diagram to be well  
8 below the inferior border.

9 But what if the inferior border is not correctly contoured here? You can't tell  
10 from this diagram if the physician who put those green seeds way down towards  
11 the right side inferiorly in this patient was making the right call or if the person who  
12 created this diagram for us today made the correct call and has the prostate in red  
13 significantly in a different location. It is not very easy to reconstruct this  
14 afterwards.

15 So can we determine this late if a medical event has truly happened? For  
16 patient care, the licensee performed verification CTs on all patients between 2002  
17 and 2008, re-evaluated the dose and re-implanted some of these patients.

18 I personally have a little problem with this. First of all, I, as you can sense,  
19 I'm not convinced that one can use a CT scan done months or years after the fact  
20 to ascertain where the seeds were originally placed when the seeds were first put  
21 in there. Seeds can migrate, the prostate can enlarge, the prostate can shrink, the  
22 prostate can change shape. So I do not believe that one can reliably determine

1 medical event using this methodology.

2 Secondly, I would not recommend reimplantation solely based on late after  
3 the fact CT data. Other clinical data such as the PSA and digital rectal exam  
4 would be far more important, and I suspect that they were used in the cases that  
5 were reimplanted.

6 I have already mentioned that it is known that the prostate may shrink  
7 following prostate brachytherapy, but long after the fact, the prostate can grow,  
8 seeds can migrate, the prostate can change shape, leading one to question the  
9 reliability of post-implant dosimetry that is done long after the implant.

10 ACMUI is concerned about determination of medical events based on CTs  
11 that were done a year after implantation, and in some cases perhaps longer.

12 So, of course, the goal is to prevent such events from ever happening  
13 again.

14 The licensee instituted a medical center peer-review system for radiation  
15 oncology services and post-treatment evaluations. ACMUI fully supports the idea  
16 of performing peer reviews for permanent prostate brachytherapy procedures.

17 Another question on the table is, should an authorized medical physicist  
18 participate in the procedure?

19 A third question is, should post-implant dosimetry recommended move from  
20 strongly recommended and endorsed by professional societies to become  
21 mandated? I have my opinion on that.

22 The answers to these questions by the ACMUI formally awaits further

1 information from NRC before any definite recommendations are made.

2 So I would like to thank the following individuals for allowing me to use  
3 some of their slides and for their presentation at the recent ACMUI meeting.

4 Thank you very much again for my opportunity to speak with you today.

5 DR. MALMUD: Thank you, Dr. Welsh.

6 CHAIRMAN JACZKO: Thank you. Appreciate the presentations. We will  
7 start our questions with Commissioner Lyons?

8 COMMISSIONER LYONS: Well, first I would like to thank all of you for a  
9 really very informative presentations, and each one of you spoke to an area that I  
10 think is of very substantial interest to the agency and to the Commission.

11 Dr. Malmud, I have appreciated a number of opportunities to work with you  
12 and other members of ACMUI. Over my tenure here, I have just greatly  
13 appreciated the opportunity that I have had to interact with you and your team and  
14 contributions of ACMUI going well beyond the discussions that are ongoing today.  
15 You certainly have my great appreciation, all of you.

16 DR. MALMUD: Thank you.

17 COMMISSIONER LYONS: I could start with questions, I think, for almost  
18 any one of you where I have a very strong interest. But, perhaps starting with  
19 Dr. Welsh first.

20 Certainly very much appreciated your comments on the current concerns at  
21 the Philadelphia VA, and those are concerns that I know are shared throughout  
22 the agency. And I also appreciated your discussion of possible reevaluation of the

1 criteria for reporting of medical events.

2 But even with the uncertainty that you expressed in whether we have the  
3 best definitions, I guess every morning as I come in and review the incident  
4 reports and see the types of medical events that are reported, I keep wishing that  
5 we could find better ways of encouraging far fewer such events.

6 We have talked at the Commission and staff level about trying to instill a  
7 greater safety culture, more attention to the different attributes of safety culture  
8 within the medical community, but in general among material licensees. I just  
9 would be curious in any thoughts you might have or any other members of your  
10 team here today on actions that the Commission and the agency might take to try  
11 to reduce events in the future, including specifically, whether you see any potential  
12 for trying to instill a greater focus on safety culture.

13 DR. WELSH: Well, I did briefly mention that I think that in general within the  
14 radiation oncology community, the safety culture is there. The reason I can say  
15 that is because even including the events at the VA Medical Center, there were  
16 approximately 100 out of 50,000 medical events in 2008, which amounts to 0.2  
17 percent. Meaning that, in general, it appears that most radiation oncology  
18 programs and practitioners do have a safety culture already in place.

19 However, it is alarming whenever you see 92 or more medical events from  
20 a single institution, and therefore, one does have to really wonder if that particular  
21 institution was lacking in safety culture. The analysis thus far appears that safety  
22 culture may have been lacking.

1           But I have to say that I and ACMUI have relatively limited data on this, and  
2           that therefore, I cannot make a definitive statement on how lacking the safety  
3           culture might have been, nor can I make a statement on just how severe the  
4           medical events truly were, based on the limited data that I have before me.

5           Thus, my discussion today did seem to focus a bit on the question of  
6           whether these events which are labeled as medical events and do meet the  
7           criteria as defined, are they of clinical significance. They may very well be, but I  
8           do not have that detailed information.

9           So, our recommendations such as making sure that all prostate  
10          brachytherapy programs have a peer review done on a regular basis, that this  
11          peer review is mandatory might be one suggestion to make sure that medical  
12          events do not happen in such large succession at another facility ever again.

13          Post-implant dosimetry was done in some cases here but not all cases.  
14          Perhaps it's time that we make that mandatory, and this would improve the quality  
15          assurance. And if after one or two cases we see that the post-implant dosimetry is  
16          indicating that the implants were suboptimal, corrective actions can be taken there  
17          and then before you have something like 90 in a row.

18          COMMISSIONER LYONS: Would any other of you like to comment on  
19          safety culture and medical event frequency in general?

20          DR. MALMUD: Dr. Fisher.

21          DR. FISHER: I agree with Dr. Welsh, improved quality assurance, quality  
22          control is important. Second person checks, particularly in dosimetry, but also in

1 the surgical placement of seeds and improve training, and as Dr. Welsh  
2 mentioned, better peer oversight all could have really helped in this case.

3 DR. MALMUD: Other members of the committee?

4 I think that the concept of peer review is critical. The physician is the  
5 individual who identifies the anatomy prior to the treatment. The dose calculation  
6 is done jointly by the physician and the physicist.

7 Then, when the procedure is ongoing, the anatomy of the prostate changes.  
8 As it is injected with the seeds, it swells, becomes distorted slightly until the  
9 process is completed.

10 So at the end of the procedure, the organ is larger than it was before the  
11 installation of the seeds, and not necessarily in the same location. So that a  
12 second calculation is performed at the time of the procedure.

13 And then my understanding is that it is routine to do a post therapy  
14 recalculation after it is known to where the seeds migrate. And the seeds do  
15 migrate because of the swelling and shrinking of the prostate.

16 Also, my understanding, though I'm not a radiotherapist, is that it is within  
17 the range of normal procedure for a certain number of these seeds to be  
18 misplaced at the time of the installation of the seeds. And perhaps the term  
19 "misplaced" is incorrect, but to be a placed outside of the gland for several  
20 reasons.

21 One is that if we think of the prostate as being a lemon-sized organ through  
22 which a sipping straw runs right through the center of it, when the seeds are

1 placed in, they are placed so that they emit the radioactivity to the tissue of the  
2 lemon. That means that they have to be scattered about. Some of that tissue is at  
3 the edge of the lemon, and therefore, some of the radiation will penetrate and go  
4 to the adjacent organ. That's calculated by the radiotherapist and physicist  
5 together.

6 But occasionally, in trying to achieve closeness to the edge of lemon, it will  
7 go into the adjacent organs. The two adjacent organs are the rectum and the  
8 bladder. So a certain number of these will migrate or may be placed at the  
9 periphery or may be actually outside.

10 And my understanding is, having learned a lot about this recently, but still  
11 not being an expert in the area, that a one-centimeter perimeter was considered a  
12 reasonable margin, because within the centimeter, that seed would still be treating  
13 some of the tissue at the margin of the prostate.

14 It is essential, though, in whatever we do in medicine that there be some  
15 peer review, particularly when it's an invasive procedure or therapeutic procedure.  
16 And it's common in radiology for us to reread each other's scans and X-rays.

17 And the ACR has a program in which after a study has been read by one of  
18 my colleagues, a certain number of those are randomly accessed by myself, and  
19 then I check and see whether I agree or disagree and grade these, and these are  
20 then scored. And if there is a significant discrepancy, we review the individual  
21 case.

22 And that helps to prevent the same error from recurring, if perhaps I had

1 read something incorrectly, and my colleague points it out to me or vice versa.

2 So that the peer review process that Dr. Welsh addressed is a critical  
3 process and should be performed by another expert in the area. In this case it  
4 would be a physician, because it is the physician who has the anatomy. The  
5 physicist has the skill with the calculation. It is the physician who would identify  
6 the anatomy.

7 COMMISSIONER LYONS: You used the word "mandatory peer review."  
8 Are you suggesting that NRC should mandate, or that that should be mandated  
9 through -- I don't know all the right words here -- the procedures at the hospital,  
10 different clinical boards who should do this mandating?

11 DR. MALMUD: That is an excellent question because as you know, we try  
12 to not become involved in the practice of medicine and leave that, in this case, to  
13 ASTRO, the professional society for radiation oncology. But it is reasonable to  
14 review the dosimetry in the peer review process.

15 And if the feeling at the end of this investigation is that the current system is  
16 not sufficient, it may be sufficient. This may just be a lapse at one institution. But  
17 if it is felt that it is not sufficient, then, it may be that the -- may have to be a  
18 requirement of the NRC as well.

19 We need to see the database first, though. And that database is still being  
20 aggressively collected by NRC investigators staff.

21 COMMISSIONER LYONS: Darrell and James, I'm well over my time, but  
22 would you concur with that statement that perhaps NRC should be the one

1 mandating? Which probably is not what I would have first suggested, but it very  
2 much appreciate that point of view. But would you share that view?

3 DR. FISHER: I think that it's more important for the individual scientist  
4 physician involved to oversee the quality assurance and make sure that it is  
5 practice -- it's part of common practice, at least for the treatment plans that I'm  
6 responsible for, I always involve a second medical physicist as part of the check.  
7 And in brachytherapy, I do review seed orders and find mistakes, and I think that a  
8 voluntary QA/QC program might be more effective than one that is mandated by  
9 regulation.

10 COMMISSIONER LYONS: I'm done -- I'll stop now, but I don't know if  
11 Dr. Welsh wanted to respond too.

12 CHAIRMAN JACZKO: Did you want to add any additional information, Dr.  
13 Welsh?

14 DR. WELSH: I could just say that I concur that this is a challenging  
15 question, challenging situation about who can impose this regulation. It is a  
16 recommendation already, but it is not enforceable. Only if it becomes enforceable  
17 would all conform to this recommendation.

18 I also like Dr. Malmud's lemon and straw analogy, although it has ruined  
19 forever my taste for lemonade, but I would like to point out that the rind is also part  
20 of a treatment target. And in order to treat that rind, seeds will occasionally have  
21 to be placed outside there. And when you are withdrawing that straw, inevitably in  
22 some cases, that straw will suck out a seed or two as part of the process. And this

1 is something that is acknowledged to happen in the process.

2 CHAIRMAN JACZKO: We will turn to Dr. Klein next for questions.

3 COMMISSIONER KLEIN: Thanks. Again, thank all of you for a very  
4 informative presentation, and I think we oftentimes forget the value of the medical  
5 applications of radiation and the positive effects that it has, and it is a good  
6 reminder when we have these kind of presentations.

7 Let me start with the order -- my questions usually go by the presentations,  
8 and so, I get to start with Dr. Van Decker first.

9 On your slide six, you showed some healthcare outcomes. And I think  
10 when we looked at the increased medical exposures, we tend not to hear the  
11 decreased death rates. You know, we only hear one side of that. We don't hear  
12 the positive aspects.

13 I guess, is there any cause/effect relationship that you all can show to the  
14 fact that while the average exposures are going up, that this directly correlates to  
15 these decreased death rates?

16 DR. VAN DECKER: I think that, obviously, this is a multi-factorial thing, and  
17 there are certain testing and therapeutic paradigms in place now that utilize this on  
18 an everyday basis. And so, I think we have to say that the process of our current  
19 thought process in therapeutics has made a difference here.

20 And obviously, you know, on non-population studies if you looked at --  
21 supplied some literature on outcomes data for following individual patient  
22 populations in different risk groups, how they did with intervening or not

1 intervening, that certainly made a difference in those smaller populations as  
2 opposed the population in general.

3           So, I think we have data on select populations that shows that appropriate  
4 testing utility leading to appropriate therapeutics is helpful. And I think that, you  
5 know, we certainly can say that if the concern was, is there an underlying negative  
6 effect for the positive effect we are following in those studies, we don't see  
7 dramatic negative effect here from what we are doing and we are doing on a fairly  
8 widespread basis right now on the realm of, you know, diagnostics, obviously,  
9 though, targeted to appropriate patients at appropriate times who are mostly older  
10 and mostly having symptoms and getting sicker.

11           DR. MALMUD: Mr. Klein, Dr. Van Decker is much too modest being a  
12 cardiologist.

13           Fifty years ago, if a man had a heart attack and made it by ambulance to  
14 the hospital before dying of an arrhythmia, the treatment was oxygen, bed rest,  
15 something for pain, a primitive pill to remove water and mercurial diuretic and  
16 prayer. If the man recovered from myocardial infarction after a six or eight-week  
17 period of bed rest, he was a cardiac cripple from that point on and did not return to  
18 gainful employment in many situations.

19           Today, the same man, with the same degree of heart disease is seen in the  
20 emergency -- is first of all, maintained in the emergency vehicle with cardiac  
21 monitoring, if necessary, gets to the emergency department, is whisked into a  
22 cardiac cath lab, has a catheter inserted in the groin up into the heart. The blood

1 vessel that is affected is opened -- reopened. That man is healthier 48 hours later  
2 than he had been for months before the heart attack and returns to work within a  
3 matter of two weeks.

4 The price of that man's altered lifestyle and productivity following  
5 myocardial infarction is way beyond the extremely high cost of having treated him  
6 that way.

7 Now, what techniques were used in being able to do this? Not a chest  
8 X-ray, which only gave 30 millirem, and that was done 50 years ago, but an  
9 intensive radiologic procedure in which the patient is under a fluoroscopy unit  
10 while the vessel is opened up or a stent placed in. So the radiation burden is  
11 much higher, but the man is now alive and back to work and back with his family,  
12 or a woman, because women now have increasing incidents of heart disease,  
13 thanks to their larger use of tobacco.

14 It is very difficult -- and I agree with Dr. Van Decker, it is very difficult to  
15 attribute the greater longevity and survivability to one particular technique. It may  
16 be the statin drugs. It may be the reduced use of tobacco. It may be our greater  
17 awareness of lifestyle, though, our body habitus does not say that that's true. But  
18 at any rate, it may be any of those.

19 But the contribution of radiologic techniques in the hands of cardiologists  
20 and radiologists has been enormous and has revolutionized the healthcare of  
21 heart disease. So that when we look at the long-term effects of the slight increase  
22 in radiation exposure and compare it with flying a jet plane for a year as a pilot or

1 living in Denver at mile high with a greater exposure, it becomes the risk is much  
2 less than the gain, as far as we can measure it today.

3 COMMISSIONER KLEIN: Thank you very much. That is a good analogy.  
4 Certainly the risk benefit for that person to survive was very high.

5 Steve, I have got a question for you. We met yesterday with the head  
6 regulator from Canada, Mr. Michael Binder, and he made an interesting comment,  
7 and I'd like your thoughts on this as well. He says when you look at the shortage  
8 of medical isotopes, that you are really impacting people's lives, you know, it's  
9 cancer, cancer treatment, and so forth.

10 And so, he asked a question, where is outrage, where is the incentive from  
11 Congress, where is the incentive from the medical community? In other words,  
12 you don't pick up a newspaper and read about this. It is only those of us that are  
13 sort of in the business that really are aware of this.

14 Can you comment on why there is no outreach?

15 MR. MATTMULLER: Perhaps that would be a better question for the media  
16 who is in this room. I'm certainly frustrated by that, and even within our own  
17 community for those who -- and for example, at this point, we have a Covidien  
18 generator at our facility, so we're relatively, unaffected for the moment. But in a  
19 month or so, we are going to be in significant trouble.

20 In talking with other colleagues we struggle with that, too. We don't quite  
21 understand how this has remained under the radar, so-to-speak, and more people  
22 are not concerned about it.

1 DR. VAN DECKER: You know, we have gone through these bumps over  
2 the last couple of years, and it has always bounced back so far, so I think that  
3 there is a lot of belief in the trenches that this is maybe a short-term thing and it  
4 will go away. You know, this is a type of that is going to take several months to  
5 really begin to go to enough people that they are buying dramatically,  
6 disadvantaged – to learn more about it, that's for sure.

7 COMMISSIONER KLEIN: It certainly puts us as a regulator in a unique  
8 position because we are not really the advocate for the production. You know, we  
9 into protecting people and the environment. But, yet, the NRC and our fellow  
10 regulators have been raising this issue for quite a while and it has not really gotten  
11 a lot of attention. And it really does need, I think, more emphasize.

12 And it was a good question that he brought up, because he feels in a  
13 difficult position as the Canadian regulator of having to make some difficult choices  
14 of people's lives versus operating a very old facility that has need of repair. So I'm  
15 sure -- hopefully, we will get on to some paths for long-term sustainability.

16 Well, I had a question for you on your -- I was enlightened at your  
17 comments about some of the assumptions that the national academy made in their  
18 Cesium activities. Some of those were pretty dramatic in terms of missing some  
19 data. I guess the questions is, how did that happen and is there any corrective  
20 actions that we can take to get the better assumptions out there?

21 DR. THOMADSEN: If you're asking me how could the committee that wrote  
22 the initial recommendations miss that, I can't address that, and it would be best to

1 talk with them directly. How to get the information out there is a much more  
2 difficult question, and it is very related to the one you had just asked.

3 There is a lot of things that are going on under the radar in the medical  
4 radiation community mostly because the population does not know much about  
5 radiation. They don't understand much about it and how it factors into their health  
6 and well-being.

7 The professional organizations bring up that issue frequently, how can we  
8 make this more appealing for the general population to look into and to  
9 understand? So far, it does not seem to have been an initiative that brings such  
10 things to the general population's light. I'm sorry I can't be of more help.

11 COMMISSIONER KLEIN: That is helpful.

12 Well, Dr. Fisher, I had a question for you in terms of you look at some of the  
13 issues that you brought up, are there any actions that you think the NRC should be  
14 taking that we're not taking?

15 DR. FISHER: Well, I did mention that NRC is doing some good things with  
16 industry. I think the main thing I have heard in my survey with industry is that  
17 some of their concerns are not being heard adequately. In particular, the issue on  
18 recognizing foreign approved containers. I think that was the main issue.

19 One thing to keep in mind, this is a relatively safe industry. The Cobalt-60  
20 industry have produced over a billion curries of Cobalt-60 since 1950. Hundreds  
21 of thousands of high-level sources have been produced, shipped safely with  
22 relatively few incidents over many, many years.

1           The difficult part today is transporting sources according to regulation. And  
2 I think from what I have heard from -- and I have talked to many industry  
3 representatives, some of the regulations are very, very burdensome and make the  
4 transportation of these sources maybe more difficult than they need to be.

5           COMMISSIONER KLEIN: Thank you.

6           CHAIRMAN JACZKO: Commissioner Svinicki.

7           COMMISSIONER SVINICKI: Thank you all. I would like to add my voice to  
8 the commendation and thanks that you have received from my colleagues. I don't  
9 think I can adequately convey how important and beneficial I think it is to sit here  
10 as an individual Commissioner and hear your perspectives, and I have heard the  
11 NRC staff also compliment your work.

12           And, Dr. Malmud, thank you for your willingness to serve as chairman which  
13 is an added service that you take on. I think it is important.

14           We have gotten a bit off cycle, as I understand it. We used to convene with  
15 you when eight more of your members might be here in town. And my hope is that  
16 we can rejoin the schedule so that we will -- and I appreciate your willingness to  
17 support this meeting on a schedule off of your normal cycle where more of your  
18 member might be able to attend.

19           And again, as was noted, your contributions go well beyond the topics that  
20 we have addressed today.

21           I want to start with something that I did not want to interrupt my colleagues  
22 question, but I want to turn to the lemon. But it is important, because Dr. Welsh

1 had talked about these imaging diagrams and they been in the newspapers as  
2 well. So I want to be certain of my understanding of what we are seeing there.

3 Dr. Welsh, you had a diagram of a successful placement of the seeds, and  
4 then you also had a diagram where the seeds appeared to not be placed in the  
5 prostate. And Dr. Malmud was explaining the physiological response of swelling  
6 of the prostate as the seeds are in place.

7 So if I understand correctly, after the seed placement if that swelling  
8 diminishes, would the prostate eject seeds, or would the seeds move with the -- as  
9 the prostate got smaller so that that image then, I guess -- and I'm not speaking to  
10 the specifics of the incident under investigation.

11 I'm trying to understand the phenomenology generally, so I'm not taking  
12 your statement to specifically go to any of the incidents in Philadelphia. But just  
13 generally as it reduced in size, would the seeds be carried along with it?

14 DR. MALMUD: Dr. Welsh.

15 DR. WELSH: In general, the prostate may expand or shrink and the seeds  
16 will go along with that expansion or shrinkage. They will not stay in place and so  
17 migrate. They generally maintain their relative positions.

18 But if edema occurs or swelling occurs, although their relative positions may  
19 remain stable, their absolute difference in distances between each other may  
20 increase. Therefore, the dose between seeds can be slightly lower if edema is  
21 pronounced and prolonged, which happens to be one of the reasons why I like the  
22 longer half life isotopes but not all my colleagues are in full agreement with that.

1           But the prostate does expands, and if it expands and the seeds remain  
2 separated from each other, there could be areas of under dosing. More of a  
3 concern with the short half life isotope than a long half life isotope.

4           COMMISSIONER SVINICKI: The reason I'm pursuing this and want to be  
5 certain of my understanding is that one of the themes that I took from your  
6 presentation is it is very hard a year later to have great clarity on exactly what kind  
7 of dose would have been delivered where. And I'm taking from the discussion  
8 about the edema and then its duration, which again, you couldn't establish a year  
9 later, I'm assuming. So it becomes very difficult to reconstruct exactly what  
10 occurred.

11           Is that accurate?

12           DR. WELSH: I should point out that what I just stated is relative to what  
13 happens within the first month or so. That expansion through edema and that  
14 subsequent contraction is well known, well studied.

15           What happens, months, years -- several years later is not as well  
16 characterized and there could be changes, asymmetrical changes in the prostate  
17 shape or size as opposed to the generally symmetrical changes that occur acutely.  
18 So, try to ascertain what happened years later can be far more challenging  
19 because of this asymmetrical change in shape and size.

20           COMMISSIONER SVINICKI: Okay. And again, without the specific  
21 expertise, what I'm drawing from this is that these are the types of complications  
22 again which as we think about any particular medical event, there are all these

1 layers of complexity in terms of the medical significance that are -- can be difficult  
2 to establish patient by patient, particularly if a number -- a certain amount of time  
3 has passed.

4 So, I appreciate you bringing that forward. Again, it does not speak to any  
5 of these specific incidents, but just I think it helps me to understand the complexity  
6 of what we are talking about when you see one image and it looks like none of the  
7 seeds were placed where they should have been. It is not quite as simple as just  
8 that one image. Thank you for that. I appreciate that.

9 Dr. Fisher, I would ask, could you address -- you talked lot about the  
10 transportation issues, and beyond the case-by-case exception for expired  
11 packaging, would you assess generally that progress is being made on the  
12 development of new packages to be certified?

13 I didn't take a sense that there was a lot of focus in your presentation on  
14 dealing with the day-to-day, but as you look out over longer time periods, do you  
15 see that transportation package manufacturers are in development in licensing of  
16 new packages? Are you encouraged or discouraged?

17 DR. FISHER: Personally I don't qualify as an expert in the package design  
18 area. That's not what I do. But it has been my perception that finding qualified  
19 packages is very difficult. And, having previously qualified package disqualified  
20 exacerbates the situation. Trying to find good packaging is extremely difficult in  
21 today's world, and I'm not encouraged that the process is moving along very  
22 quickly.

1           COMMISSIONER SVINICKI: Thank you. And, again, I realize you don't  
2 speak for that segment. But just generally as you canvas for availability, it sounds  
3 like at least you're not aware of groundswell of development of new packages to  
4 be available. So, it is something to keep our eye on, I think.

5           And Dr. Thomadsen, you were asked question about the report and why  
6 were estimates in the report different. I might come at it a little differently and ask  
7 you for the cost estimates that you provided, and you had some specific costs, I  
8 think, for x-ray units. Where did you derive those? I'm assuming when I read that,  
9 that that's perhaps a manufacturer's price or something, that that number that you  
10 used in your presentation was derived from manufacturer's literature or list price  
11 for a device?

12          DR. FISHER: Not necessarily. List price, that is the prices that people  
13 have received on quotes very recently.

14          COMMISSIONER SVINICKI: Would that also be true when you gave cost  
15 for annual service contract, is that bid prices --

16          DR. FISHER: That is correct.

17          COMMISSIONER SVINICKI: -- that various facilities have received?

18          DR. FISHER: That is correct.

19          COMMISSIONER SVINICKI: So, that's the source for your estimates, and I  
20 won't question any of the estimates that were used by others.

21          Mr. Mattmuller, I wanted to be certain I understood on slide number 21,  
22 where you talked about diminished patient care and you talked about preliminary

1 survey results for 2009. This has to do with postponed procedures or canceled or  
2 changed procedures. And I'm trying to project forward in an answer, I think, to Dr.  
3 Klein, you talked about facilities that were not yet feeling the full effect of the NRU  
4 shutdown.

5 And so, drawing from that, that the 2009 numbers as the effect is felt more  
6 fully would be even more pronounced than is listed here, up to and including -- if  
7 Chalk River were in a position never to restart, would we reach a point on this  
8 statistics that are listed here for postponing and canceling procedures, would we  
9 reach a kind of steady state if we only had Petten available and then obviously, it  
10 would be altered during the time period when Petten would not be available for  
11 four or five years? I guess I'm asking us to think about a worst case scenario  
12 there.

13 MR. MATTMULLER: Well, I think the worst case scenario would be upon  
14 us in about a month when the Petten reactor does go down. And then the typical  
15 suppliers that supply 100 percent of Mo-99 to the US will both be down.

16 COMMISSIONER SVINICKI: Okay. Because at that point in terms of  
17 availability, it is just we are at the lowest availability, we just don't know the  
18 duration, because if NRU comes up in three or four months, it is a different  
19 circumstance than if they don't?

20 MR. MATTMULLER: Right. And that's a big wildcard as far as how long  
21 the NRU at Chalk River is going to be down. Hopefully, no more than three  
22 months, but there is no guarantee on that.

1 I mean, at this point there is still -- it's my understanding from a recent visit  
2 up there that they are still evaluating the reactor. So they don't -- at this point, they  
3 are making their predictions based on what they know is wrong and what they  
4 anticipate would be wrong, but they are there is still more discovery -- the  
5 discovery process has not been completed yet.

6 COMMISSIONER SVINICKI: And I'm aware of the significant uncertainty  
7 around that three-month estimate, as you are mentioning here. The statistics as  
8 they are, even the preliminary results are obviously very sobering, and I'm  
9 speaking only to my own reaction here, and I'm no fan of melodrama and  
10 hyperbole. But I think this is a factual based conclusion that I'm drawing, given the  
11 number of procedures that are done, and you have mentioned a figure. And we're  
12 talking a very large patient population.

13 And I know that the substitutes have their drawbacks, so if we look at  
14 postponing and cancellation and those statistics become more pronounced. Even  
15 in changing a procedure, I guess there is an alteration of the potential medical  
16 outcome there.

17 So given the patient population affected, I think it is safe to conclude that in  
18 a prolonged unavailability, there are patients who will die as a result because of --  
19 and it's hard to know exactly who they are. But I think it's merely factual to  
20 conclude that given a large number of procedures that might be postponed or  
21 cancelled, that there will be patients who will suffer a horrible outcome as a result  
22 of that.

1           And so, I appreciate that you're frustrated. I might use a stronger word than  
2 that, but it's obviously, a national -- and you did use the term "crisis," I appreciate  
3 that. I do think it is a national crisis.

4           I know I'm over my time. Thank you.

5           CHAIRMAN JACZKO: Thank you, Commissioner Svinicki.

6           I wanted to -- I don't want to go into too much depth, we have talked a lot  
7 about the VA issue. But I didn't want to leave, I think, the impression, that the  
8 NRC doesn't view this as a very serious incident. I just wanted to read from the -- I  
9 think, Dr. Welsh, you talked a little bit about the lack of the CT scan, I guess, to do  
10 the dose assessment post incident --

11          DR. WELSH: Post implant.

12          CHAIRMAN JACZKO: Post implant. And I think that certainly is an  
13 important factor. As the NRC developed -- as we developed this, we did a  
14 inspection. And I just wanted to read from this again.

15          The NRC is finishing up an investigation on this, and so I don't want to get  
16 into too much detail beyond this. But I thought it was useful just to read the  
17 assessment from that inspection report and -- which, I think, puts a slightly  
18 different character, perhaps, on this incident than maybe has been conveyed to  
19 this point.

20          And that says that, "The NRC contracted a medical consultant to review a  
21 selected number of medical events and determine if any health consequences to  
22 the patients were expected" -- and I think this is the important sentence. "The

1 consultant noted that the seed placement in the cases reviewed was quite erratic  
2 and not consistent with current medical standards.”

3           So again, I think we are not necessarily talking here about a disagreement  
4 in terms of very vagaries of a difficult procedure, which I think every since I come  
5 to the Commission I have learned about brachytherapy, and in particular, in  
6 prostate seed implantation. And it is difficult because the -- as I understand it, the  
7 prostate is not a well defined -- and when you're injecting straws into the lemon,  
8 that is not a precision process. There is a lot of vagaries here.

9           But I just wanted to put that statement on the record, because again, that  
10 was one of the findings of the contractor that we had contracted with in order to do  
11 the inspection. And it certainly does indicate some challenges. As I understand it  
12 the inability to have the CT scans was the inability, I guess, of the dose  
13 reconstruction software to read the CT images, but they, in fact, took the CT  
14 scans, had the information.

15           So it was not that they were not taking the -- they were not doing the CT  
16 scan the following day, they were do the CT scans, however, they never corrected  
17 the software errors to allow them to then use those CT scans to do dose  
18 reconstruction the day following.

19           So, I just wanted to make sure we have factually a lot of the information  
20 correct on this particular issue, because I think it certainly is an issue that I think  
21 we take very seriously as an agency, and I think one that we will continue to  
22 pursue the investigation.

1           Dr. Fisher, you raised an issue on the Cobalt-60, which I think is an  
2 interesting one and I recall -- I don't think Mike Webber is here. I wish he were  
3 here. I asked him a question about the transportation issue a while ago, and  
4 perhaps you can answer this question as well for me.

5           The issue with transportation packages is an issue that goes back, I think,  
6 to 2004. That is when the NRC initially implemented the new regulations to  
7 conform ultimately with international standards. The whole purpose of our change  
8 to the package designs was really to conform with the new International Atomic  
9 Energy Agency standard PSR, whichever it was, 1 -- I get the cues from the back.

10          We did a variety of communication tools to let people know that they had  
11 four years to get new packages in place. In August of last year, we put in place --  
12 we made another announcement, sent it out to the industry explaining that these  
13 packages were going to expire in October of 2008, that there was -- we outlined, I  
14 think, five criteria that they needed to come in and satisfy for an exemption  
15 request. The agency has approved number of exemption requests for certain  
16 packages to be used beyond their expiration date.

17          What do you think we could do beyond that, because it seems that for some  
18 reason, we have not communicated in that four-year time, well, our expectations --  
19 or maybe we did communicate and the industry just ignored it. I don't know if you  
20 can shed some light on what you think happened with that?

21          DR. FISHER: Each of the things that you have mentioned are correct, and  
22 industry has had time to respond. But I think there's -- there is a disconnect

1 between the manufacturers of these casks and the suppliers of isotopes. They are  
2 not always the same organizations.

3 And what happens is, if progress is slow in cask design and approval, that  
4 does impact on the manufacturers of the isotopes, and they are kind of caught  
5 without a package.

6 I know that, at least back at the laboratory where I work, the containers that  
7 we have been relying on for a number of years are no longer available to us to  
8 use, and we don't have a replacement. There are some new containers available  
9 that are very, very expensive to lease -- impossible to purchase but expensive to  
10 lease. And finding the packages for specific applications is still very difficult.

11 What the NRC can do, I think, number one, listen to the industry concerns.  
12 Hear what they are saying. They met before the Commission in the past.

13 CHAIRMAN JACZKO: To some extent, that was 2004. We made the rule  
14 change. And I think we had a good process. That largely -- again, part of the  
15 reason we did this -- is it interesting. There is one area where we adopt  
16 international standards by regulation, and that is in the transportation area. That is  
17 precisely, I think, to address industry concerns of consistency and uniformity as  
18 packages move from country to country.

19 So in that process, we did go through a rule-making process at that time. I  
20 was not around at that time, so I'm assuming we did get industry feedback and  
21 tried to incorporate that as best we could within the constraints of the IAEA  
22 guidelines.

1 I guess what -- I guess what I'm trying to find out, how can we communicate  
2 better so that people could prepare properly and that we don't find ourselves in a  
3 situation five years later where people are without casks, as you just indicated, or  
4 unable to ship material. Absent a rule change that's the situation we have. And a  
5 rule change will not solve the problem any time quickly.

6 DR. FISHER: But I think the approval of already approved foreign made  
7 casks would help the most. I recognize that a lot of these issues are created by  
8 another agency, the Department of Transportation and not the Nuclear Regulatory  
9 Commission, but working effectively with DOT is also helpful.

10 There is also some issues that I have heard that are very difficult, and that's  
11 transporting sources between the U.S. and Mexico are very problematic right now,  
12 because U.S. carriers are not allowed to transport in Mexico. There are some  
13 issues there that your staff have probably been working on already.

14 CHAIRMAN JACZKO: Well, I appreciate that. And there are other issues  
15 too as we meet subsequently to continue to, I think, improve the communication  
16 and dialogue that we have there. I think that will be helpful as we go forward.

17 This is a question, I think, for you, Dr. Mattmuller. Many have touched on  
18 the medical isotope issue, and I guess sometimes we take off our regulatory hats  
19 and we have human being hats that we put on, believe it or not. And certainly  
20 medical isotopes is an important issue.

21 It does not seem to be an important issue for the nation, which I think  
22 everyone has highlighted the disconnect that that presents.

1           Certainly, my interest and I think the focus for this agency as we go forward  
2   is on making sure that we play our role in whatever solutions may develop which is  
3   in the regulatory arena and being prepared to review licenses to deal with any  
4   applications that might come forward in this five to seven-year period or in the  
5   short term.

6           The question I had on this, and I think it really goes to something you  
7   touched on very briefly, I think, at the end of your presentation, you talked about, I  
8   think, for the NRC to look at flexibilities and other issues in the regulatory process.  
9   One of the things I have done in the last two weeks is ask the staff to look at the  
10  regulatory issues.

11           Now, the B&W approach may have issues. Those are probably statutory  
12  issues and not really regulatory issues. They don't manifest themselves as  
13  regulatory issues, but they are inherently statutory issues in how we define waste,  
14  and that we may have limited flexibility in what we can do there.

15           But I'm not aware in the other areas -- I mean, these are relatively routine  
16  kinds of licensing actions, whether it is looking at targets, whether it is looking at --  
17  really, ultimately, that would be the main issue, imports/exports, which we do on a  
18  routine basis.

19           Are there were specific issues that you were concerned about when you  
20  said that we should have flexibilities? Are there particular issues that you can  
21  point to in our regulations where you think that there will be inappropriate choke  
22  points that we would need to look at?

1 MR. MATTMULLER: Some of the choke points that exist now, for example,  
2 for the Missouri reactor is powered by HEU fuel, and they are undergoing steps to  
3 convert to LEU fuel. That's my understanding in order to have an appropriate  
4 neutron flux for bombardment of the targets, they will need to raise the power limit  
5 of their reactor from ten megawatts, which is the current limit for that type of  
6 research reactor to 12 megawatts.

7 So, in essence, they need a new license for a category that does not exist  
8 right now. And I don't know if that would need to go through the complete  
9 regulatory process --

10 CHAIRMAN JACZKO: So, there is nothing -- you're not aware of any  
11 specific problem with that regulatory -- just that it would require a regulatory  
12 review?

13 MR. MATTMULLER: Yes. Well, I guess the issue would be that there is  
14 not a category -- there is nowhere for them to go into the regulations to get a  
15 license right now. It is going to be something new, is my understanding.

16 And similarly, for the Babcock & Wilcox reactor, in that it won't be a test  
17 reactor, it won't be a research reactor. It is going to be 100 percent for the  
18 production of medical isotopes. And it is my understanding there is not a category  
19 like that for reactors in the current regulations.

20 CHAIRMAN JACZKO: Well, I thank you. I don't know if any of the staff  
21 wanted to comment on the first point in particular, if there is an issue.

22 The second issue is, again, I'm not sure -- certainly there are categories. I

1 think we have just never licensed facilities of that nature. So, there certainly are  
2 categories to do it, and I think we have just never done it before.

3 George, I don't know if you have any comments.

4 MR. PANGBURN: Just this week, a couple of us were at Missouri, Eric  
5 Leads, Tim McGinty, myself and a few others. And at that point, you know, we  
6 talked with the folks at Missouri. I think they are well aware of the need for an  
7 amendment to their Part 50 license.

8 We had some discussions about other types of licensing and how you might  
9 work that within the Part 50, whether there would need to be a separate Part 70 or  
10 Part 30 license, because they are looking at making a production facility a  
11 processing facility, might be the more appropriate term here. And they have done  
12 an awful lot of planning.

13 So I think they are thinking ahead on it, as you know we have received from  
14 B&W, they are thinking ahead. The staff is looking at the issues to try and make  
15 sure we were clear with Missouri this week that the agency did not want to be in a  
16 position where we were on the regulatory hold point toward the national solution  
17 towards the medical isotope issue. And I think both Missouri and B&W are moving  
18 ahead with some speed on this.

19 CHAIRMAN JACZKO: I appreciate your answers.

20 Commissioner Lyons, did you have additional questions.

21 COMMISSIONER LYONS: Just couple of additional questions.

22 Steve, if I could continue the line of questions that Greg was just on,

1 perhaps a question that really is not directly within the NRC's purview. But in your  
2 slides, you had the statement that it is four to five years to any of the solutions on  
3 Mo-99.

4 What determines that time?

5 MR. MATTMULLER: Those are the estimates that Missouri and Babcock &  
6 Wilcox have given us. And sometimes -- and even Babcock & Wilcox might be  
7 more appropriate five to seven years as far as the time they think they need to  
8 pursue licensing to pursue construction and to become operational.

9 So, those are coming directly from those two producers.

10 COMMISSIONER LYONS: Well, I guess speaking just for myself, I would  
11 hope that as the importance of this crisis becomes more visible, that -- and again,  
12 this is not an NRC -- it is not directly an NRC issue -- I would hope that, perhaps,  
13 Congress would be moved to step in, and to the extent dollars can address -- can  
14 shorten any of those times, I think it is simply vital to the country that that happen.

15 A question for Bruce, if I may. You, in talking about the national academy  
16 report, made a number of comparisons more from a cost or a dose rate issue if  
17 one moved from Cesium-137 to some of the X-ray options. You didn't talk,  
18 however, about the efficacy of moving to such irradiators.

19 And I have had at least some folks in the medical community suggest to me  
20 that with the currently available end point -- I don't remember the number, I think it  
21 is 180 kilovolts or so -- on existing x-ray machines, that there is a real question on  
22 whether you have the same efficacy in terms of the medical effect that you're

1 desiring.

2           Could you comment at all on that? Are you aware of work to try to better  
3 address that? I'm more than willing to believe that as you go up in energy,  
4 eventually, they will be the same but you also increase the complexity of the x-ray  
5 system substantially?

6           DR. THOMADSEN: Yes. This is a confusing issue based on what data is  
7 available. There are facilities that do use the lower energy x-ray sources for blood  
8 irradiation. They seem to be able to do it just fine. They are subject to the  
9 complications that we mentioned in the report, but the doses do seem to be able to  
10 serve to inactivate the white blood cells.

11           There is always the question with those lower energies of what price you're  
12 paying due to the fact that you have to give much higher doses to some parts of  
13 the blood product. And what is that going to do to the blood products that you  
14 want to use and not inactivate? That is not well documented at the moment and  
15 not well researched at the moment.

16           In the reports that we have seen, they do not have long-term data to  
17 follow-up on that. We just don't have an answer to that question at the moment.

18           COMMISSIONER LYONS: I appreciate that it is still viewed as an open  
19 question. It strikes me as a very, very important question. And if there is more of  
20 a shift towards the lower energy x-ray systems, I certainly hope that that gets the  
21 research focus that I think it deserves.

22           And the only other comment I would have made, Mr. Chairman, I certainly

1 appreciated Dr. Fisher's remarks on a National Source Tracking System and  
2 deficiencies therein as of today.

3 I just wanted to make the point that the deficiencies that you highlighted,  
4 and others, I think are very, very well understood at the staff level. They are well --  
5 we are well on the path towards addressing each of the issues that you raised.  
6 And certainly, the staff intent is to vastly improve the operation of the National  
7 Source Tracking System.

8 COMMISSIONER KLEIN: One follow-up question, a question probably for  
9 Dr. Welsh.

10 Based on what you know of the NRC's response to the VA situation, are  
11 there any actions that we should have taken that we didn't? Do you think our  
12 actions were sufficient for what you know to date?

13 DR. WELSH: From what I know, it appears that there the NRC has acted  
14 appropriately and things are moving in the correct direction.

15 COMMISSIONER KLEIN: Thanks.

16 COMMISSIONER SVINICKI: Before you turn off your mike, Dr. Welsh, I  
17 will follow-up and say that your presentation talked about a number of questions  
18 that you indicated were important questions. As an advisory committee, is there a  
19 plan for you, again on these more general themes, to take up those questions and  
20 be arriving at a consensus recommendation or any recommendations that might  
21 come out of your deliberations of those questions?

22 DR. WELSH: I don't know if there is a plan for further specific meeting and

1 discussion between NRC staff and ACMUI on this individual topic. But I am told  
2 that there will certainly be more information relayed to us in general, and we look  
3 forward to having that information, interpreting it, and providing advice and input  
4 as requested.

5 DR. MALMUD: Commissioner, what usually happens is the NRC  
6 completes its investigation, which is, as you know, aggressively ongoing now.

7 At the completion of the investigation, they prepare a report. They will then  
8 brief us on the report and recommendations that they may have made internally  
9 with NRC staff. And then ask us for our opinion with regard to the outcome of  
10 actions that might be taken and perhaps even unintended consequences of what  
11 might occur.

12 Then we render our advice. They take that advice and then, if necessary,  
13 incorporate it into the recommendation.

14 So, they know that we intensely interested in this. We and the NRC staff  
15 both have great concern for the well-being not only of our veterans but of all  
16 patients who are being treated. And therefore, we know we will continue to be  
17 informed, because that's been the pattern of NRC staff in dealing with us.

18 And we will happily review the material and offer any constructive advice  
19 that can be forthcoming from this group which represents radiation oncology,  
20 radiation physics, radiochemistry, patient advocacy, each of the elements that's  
21 necessary to deal with this.

22 COMMISSIONER SVINICKI: And I appreciate that. It is really a

1 two-pronged response, as I think you're indicating here, there is the reaction to the  
2 specific event, but then there are the improvements to our processes that could  
3 potentially be recommended as an outgrowth of examining the one specific event.

4 So I, of course, appreciate and I'm certain that the agency will benefit from  
5 the application of all of your expertise to both of those prongs of response to this  
6 event.

7 And I would just close with a comment that the topics that we have heard  
8 about today are very dynamic, they are very active issues and a lot is going on, so  
9 I would encourage the ACMUI to not hold back.

10 And again, given the unfortunate infrequency with which we have an  
11 opportunity to have the kind of meeting we had today, there are other vehicles for  
12 the committee to make if they feel there is any urgent recommendations or issues  
13 that need to be brought to the agency or Commission's attention. I would  
14 encourage you, speaking only for myself, to avail yourself of other types of  
15 communications that would get thing of urgent importance or developments you  
16 feel need to be brought to your attention, please do so, and thank you again.

17 DR. MALMUD: The Chairman has already transmitted that message to us  
18 long before this particular issue arose, so we know that we have access, and we  
19 will take advantage of it at the right moment. Thank you.

20 COMMISSIONER SVINICKI: Thank you.

21 Thank you, Mr. Chairman.

22 CHAIRMAN JACZKO: Thank you for your presentations. I know the staff

1 certainly appreciates your interactions and your dialogue. ACMUI is a unique  
2 committee. As a staff advisory committee you do play that unique role in  
3 interacting with the staff in providing them with helpful guidance as you go forward.

4 It is certainly I think, periodically useful for us to hear from you directly, but I  
5 hope that you will continue to have your interactions with the staff. I think that is  
6 certainly a helpful role and some thing that is important as we go forward. And I  
7 thank you for your presentation.

8 We are adjourned.

9 (Whereupon, at 3:33 p.m., the meeting was adjourned.)

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