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2 UNITED STATES OF AMERICA  
3 NUCLEAR REGULATORY COMMISSION

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5 UPDATE ON RESEARCH AND TEST REACTORS INITIATIVES

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7 COMMISSION BRIEFING

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9 TUESDAY

10 DECEMBER 16, 2014

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12 ROCKVILLE, MARYLAND

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14 The Commission met in the Commissioners  
15 Conference Room at the Nuclear Regulatory Commission, One White  
16 Flint North, 11555 Rockville Pike, at 9:00 a.m., Alison M. Macfarlane,  
17 Chairman, presiding.

18 COMMISSIONERS:

19 ALLISON M. MACFARLANE, Chairman

20 KRISTINE L. SVINICKI, Commissioner

21 WILLIAM C. OSTENDORFF, Commissioner

22 JEFF BARAN, Commissioner

23 STEPHEN G. BURNS, Commissioner

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EXTERNAL PANEL:

THOMAS NEWTON, PhD, The National Organization  
of Test, Research and Training Reactors, and the  
Massachusetts Institute of Technology

GREGORY PIEFER, PhD, SHINE Medical  
Technologies, Inc.

LES FOYTO, Missouri University Research Reactor

NRC STAFF:

MICHAEL JOHNSON, Acting Executive Director for  
Operations

LAWRENCE KOKAJKO, NRR

ALEXANDER ADAMS, JR., NRR

STEVE LYNCH, NRR

JOHN ADAMS, NRR

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

8:59 a.m.

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2  
3 CHAIRMAN MACFARLANE: All right, let me invite  
4 the first panel.

5 Okay, well that was fast. Nice to see you, Tom.

6 All right, well, good morning everybody. I'd like to  
7 welcome our staff, the public, industry and whomever else is watching  
8 this morning.

9 We're going to be briefed on research and test reactors  
10 and research and test reactor initiatives this morning.

11 We're going to have two panels and the briefing today  
12 is going to provide an overview of the licensing program for research  
13 and test reactors including the status of license renewals.

14 We're going to have discussions regarding the  
15 domestic production of medical isotopes and research and test reactor  
16 security initiatives as well.

17 So, the first panel is an external panel and includes  
18 three folks, Dr. Tom Newton, Chair of the National Organization of Test,  
19 Research and Training Reactors and Director of Operations and  
20 Associate Director of Reactor Engineering at the Massachusetts  
21 Institute of Technology.

22 I should say that Tom and I do go back quite a few  
23 years when I worked at MIT's research reactor. So, it's nice to see you  
24 here.

25 DR. NEWTON: And you, too.

26 CHAIRMAN MACFARLANE: Dr. Gregory Piefer,

1 Chief Executive Officer of SHINE Medical Technologies.

2 And, Mr. Les Foyto, Associate Director for Reactor and  
3 Facility Operations, Missouri University Research Reactor.

4 So, we're going to have a short break after the first  
5 panel. We're going to -- you guys are going talk for about ten or 15  
6 minutes each or whatever your allotted times are. And then we'll have  
7 questions from the Commission, then we'll have a short break, we'll  
8 hear from the staff panel as well after that. So, that's how things are  
9 going to go.

10 Let me turn to my fellow Commissioners and see if  
11 anybody has any opening remarks. No? Okay.

12 All right, well then, we will turn things over to you and  
13 Dr. Newton, you will start.

14 DR. NEWTON: Thank you.

15 Just wanted to kind of start to briefly go over our  
16 organization.

17 Next slide, please?

18 Our organization is composed of research and test  
19 reactors from the U.S. and Canada. We occasionally have folks from  
20 other nations join us depending on whatever the issues and things are.

21 Our main objective is to kind of promote the use of  
22 research and test reactors in research and education and in  
23 development of technology.

24 Next slide, please?

25 We are a very diverse group of reactors. We range  
26 from very small critical facilities up to a 20-megawatt test reactor. We

1 are mostly operating at universities.

2 We have a number of missions, we sort of compliment  
3 each other rather than compete because of our varying missions and  
4 things and so we work very well together. We're all Class 104  
5 licensees from the Atomic Energy Act.

6 Next slide, please?

7 One thing about research and test reactors is we're a  
8 fundamentally different design from a power reactor. We are a much  
9 smaller core volume, we're more interested in the radiation environment  
10 than we are in the thermal power. So, we use that for research and  
11 tests and education as well.

12 That core design is very small, as I said, much lower  
13 thermal output. We have no stored energy or very little stored energy  
14 and very little fission product inventory, so our potential for accidents is  
15 orders of magnitude lower than that of a power plant and so our risk  
16 profile is much lower as well.

17 Next slide, please?

18 We have a variety of missions in terms of what we do  
19 for research. I listed a few here in the slides. There are others as  
20 well, mostly we're interested in the radiation environment and core for  
21 materials testing for looking at development of advanced materials to  
22 see how well they behave under radiation conditions.

23 We also use neutron scattering as a very useful tool in  
24 almost every field of science, so you can look at how atoms are  
25 arranged.

26 We use neutron activation analysis for trace element

1 studies. Sometimes you can get down to the part per billion level of a  
2 sample to determine the trace elements in it.

3 There's neutrons isotope production which you're  
4 going to hear more about from my colleagues here.

5 There are also other fundamental techniques of using  
6 neutrons for different things like neutron transmutation, doping and  
7 other applications, other medical applications as well such as boron  
8 neutron capture therapy.

9 So, there's a big variety of uses of neutrons and  
10 research reactors are the predominate means of producing those  
11 neutrons in those radiation environments.

12 Next slide, please?

13 The other aspect of research and education in test  
14 reactors are that they provide a unique hands-on tool of how to operate  
15 a nuclear reactor. You can learn it in books, but there's no other place  
16 you can actually have a student do hands-on training on how to run a  
17 reactor, how they are licensed, how they, you know, look at  
18 demonstration of reactor physics and demonstration of different things  
19 in research and test reactors that you can't get anywhere else.

20 Next slide, please?

21 In terms of our interaction with NRC, we serve to  
22 provide a forum between reactor operators and users as to discuss  
23 different issues of interest of different folks. We also very much  
24 engage with the NRC Research and Test Reactor staff. We meet with  
25 them quite regularly and we very much appreciate their not only  
26 availability, but their professionalism. They're a good group of folks to

1 work with and we feel like we work well together.

2 Next slide, please?

3 A couple of issues I want to touch on before we go to  
4 licensing, first one is security issues. We all understand we live in a  
5 changing world and it's appropriate for us to occasionally assess or  
6 regularly assess our security postures and adequacy of our protection.

7 We also appreciate the opportunity NRC has provided  
8 us to interact with their recent proposed changes of Part 73. We had a  
9 meeting here in September which I think was a very good dialogue  
10 between us and the NRC and I think we both learned a lot from that  
11 meeting. And I think we left leaving a lot more comfortable with where  
12 we're headed on that.

13 But one point I want to make on security, since we are  
14 at university campuses, we provide a forum for both researches,  
15 students and educators. Any vast increase in security regulations  
16 could very much jeopardize our mission to do those things. And so we  
17 have to balance off our security needs as well as our education and  
18 training needs.

19 The next issue I want to touch on is digital  
20 instrumentation. There's another slide there.

21 Digital instrumentation we feel is developed a long  
22 way. It provides an opportunity to really improve information flow to  
23 the reactor operator. You can use it to also make it more cogent so we  
24 can filter out the more important information to go to the reactor  
25 operator.

26 There is some -- we have some growing pains in terms

1 of trying to develop the digital instrumentation needs for the reactors.  
2 There are some, I don't want to say push, but at least some possibility of  
3 using power reactor regulations for use in digital instrumentation.

4 They're very rigid and very stringent. We feel that this  
5 is a little bit beyond our needs. Our potential for accidents and  
6 potential for problems with failure of instrumentation is much lower and  
7 we don't feel this is appropriate.

8 It's also a point where a lot of the smaller research and  
9 test reactors are not able to meet those stringent requirements and so,  
10 we feel like this could ultimately discourage the use of improved  
11 instrumentation, so we want to make sure that when we work with NRC  
12 we keep those things in mind.

13 Next slide, please?

14 We also support development of guidance for digital  
15 instrumentation. We want to work with NRC on that. We want to  
16 make sure that minimal risk is taken into account as well as the  
17 requirements in the Atomic Energy Act that we keep regulations of  
18 research and test reactors at a minimum.

19 Next slide, please?

20 So, to shift to relicensing, I think a lot of our facilities  
21 have gone through relicensing or are in the middle of relicensing. We  
22 have -- feel like as a group that it's a bit more complex now than it used  
23 to be in terms of requirements for the Safety Analysis Report. Without  
24 a great improvement in safety, we appreciate the NRC working with us  
25 to alleviate the backlog that we've had before and that's also incumbent  
26 that we work together on that.



1 Next slide, please?

2 Let's shift now to MIT relicensing. We submitted our  
3 application in July of '99. Our application was no major infrastructure  
4 changes, but we did have a slight power increase from 5-megawatts to  
5 6-megawatts.

6 Next slide, please?

7 Our relicensing time line, as I said, we submitted in July  
8 of '99. We had a first round of 135 questions in the 2000/2002 time  
9 frame. There as a bit of a lull there between that and the next round of  
10 questions in 2008 and a final round 2009.

11 Our license finally got issued in November of 2010  
12 which was a total of 11.3 years in the relicensing process.

13 Next slide, please?

14 Some of the challenges we faced during that  
15 relicensing, we had September 11th happen right after we submitted  
16 things so that sort of slowed everybody down and we had to reevaluate  
17 things there.

18 There was other issues that we had some contractor  
19 changes that were reviewing the SAR and so there were a few times  
20 where we had to kind of revisit some issues we'd already visited we felt.

21 There were also a total of seven license amendments  
22 that were submitted in that 11 year time frame, so it became a bit of a  
23 challenge to keep track of which version we're talking about in terms of  
24 reviewing things, but that was part of the process.

25 And we, I think a little more pull upon on the slide was  
26 that we thought the process was a little more -- should be focused more

1 on safety issues.

2 Next slide, please?

3 And finally, to talk about our successes, we did  
4 upgrade our analytical capabilities so we feel like we're much better off  
5 in that aspect of things. Our power upgrade to 6-megawatts presented  
6 no problem from a regulatory point of view and from in actuality when  
7 we get it, it was fine.

8 We also have a mechanism in place to keep the SAR  
9 current and which we're doing now in place.

10 A couple of suggestions and this is kind of my final  
11 point, there were several minor issues that we felt could have been  
12 resolved in a less formal process, a few typos, a few kind of reordering  
13 changes and things like that we could have -- kind of felt it could have  
14 been less formal. And, again, we should simplify things, focusing on  
15 safety related issues.

16 So, with that, thank you again for allowing us to be here  
17 and I'll be happy to answer any questions.

18 CHAIRMAN MACFARLANE: Great, thank you very  
19 much.

20 All right, Dr. Piefer?

21 DR. PIEFER: I think I just turned myself off.

22 Thanks for the opportunity to come and sort of speak to  
23 you about the licensing activities for SHINE Medical. We're sort of trail  
24 blazing here in terms of building a medical isotope facility in the U.S.  
25 and I really appreciate the opportunity to come and let you know how it's  
26 going.

1           Just a quick overview, you know, this is a new  
2 technology and so I wanted to brief everybody on the very 50,000 foot  
3 view of what we're doing. Rather than using a typical research reactor  
4 to irradiate a uranium target, our technology is actually based in an  
5 accelerator driven neutron source driving a sub-critical target.

6           It's a deuterium beam hitting tritium gas. This creates  
7 neutrons that then enter an aqueous solution of uranium dissolved in  
8 water. That is the target for medical isotope production

9           It's a multiplying target, so it's not just a straight one  
10 neutron from the accelerator creates one fission in the target, but, in  
11 fact, the target neutrons themselves generated by the fission process  
12 causes significant amount of enhancement, and that's in fact needed to  
13 produce a substantial amount of medical isotopes from an accelerator  
14 driven facility.

15           Of course, there's some advantages to operating  
16 things this way. The biggest of which is if you turn the accelerator off,  
17 anything that causes power to cut immediately ceases the reaction and  
18 you're left with decay heat and decay neutrons. Very small amount, so  
19 we're talking about at full output something on the order of 100  
20 kilowatt-thermal per target and so within, you know, a few minutes,  
21 you're down to kilowatt sort of levels of decay heat.

22           So, again, very much of the scale that, you know, Dr.  
23 Newton had been talking about for research and test reactors.

24           The liquid target gives us a number of advantages  
25 including ease of separation and reuse of uranium and overall leads to  
26 the combination of that and the accelerator leads to a factor of about

1 two to three hundred reduction in radioactive byproduct generation  
2 compared to typical production in high power research reactors today.  
3 So, a lot of advantages of the technology.

4 We've done a great amount of work in sort of  
5 developing this, but also with our partners from the National Nuclear  
6 Security Administration who have been tasked with assistance to get  
7 medical isotope facilities deployed in the United States, have done a  
8 tremendous amount of technology development and sort of what we  
9 would consider de-risking on the plant.

10 We're working actually with not just the University of  
11 Wisconsin but also with Los Alamos National Lab, Oak Ridge National  
12 Lab, Savannah River National Lab and Argonne National Lab as well.

13 So, all the labs have been incredibly helpful in terms of  
14 answering some of the questions we normally couldn't answer with a  
15 new technology until the plant was up and running. They're providing  
16 data in situations that we couldn't do that.

17 So, a very strong program. We're moving really,  
18 really -- as fast as we can to get this deployed. And the reason for that  
19 is really on slide five, you know, where we see a projection.

20 The chart on slide five actually comes from a report by  
21 the Organization of Economic Cooperation and Development. Where  
22 you see moly demand in the red line, which is a, you know, sort of the  
23 market need to have moly supply with no interruptions and to be able to  
24 absorb let's say an unplanned outage by one of these very old research  
25 reactors that's currently providing the supply chain.

26 And what you see in the green line is actually moly

1 production capacity versus time assuming no new producers come  
2 online. And obviously, the biggest hit happens in 2016 when the NRU  
3 reactor shuts down in Canada.

4 That, by the way, is the only producer of medical  
5 isotopes in the Western Hemisphere, at least the only major producer.  
6 And the fundamental product there, the most important product is an  
7 isotope known as molybdenum-99 and that decays approximately one  
8 percent per hour. So, having the United States depend on sources  
9 overseas is dangerous.

10 And we've seen in fact shortages in the past when  
11 these reactors have shut down and I think, you know, that hopefully we  
12 don't again in the future, but it looks pretty grim at this point.

13 A recent study out of Canada, in fact, estimated that,  
14 you know, based on data and based on follow-up with patients from  
15 2009/2010 that another shortage in the U.S. would cost approximately  
16 \$650 million a year just due to increased health care costs. But more  
17 importantly, over 5,000 lives a year just from increased radiation dose  
18 to alternate modalities.

19 So, they haven't followed up whether people can't read  
20 the images, whether it causes poorer long term care, but just from the  
21 increased radiation dose from alternative modalities. So, it is a very  
22 important problem I guess is the point.

23 Slide six just shows the age of the major producers in  
24 the world and the location as well. Obviously, you see the NRU  
25 reactor shutting down in 2016. There is a new producer in Australia  
26 but it's just about the worst place in the world you could put one for

1 feeding, you know, the needs in the United States.

2 So, that's sort of the problem. We have been working  
3 very hard on providing a solution since around 2010 including putting  
4 together a good team to submit an application to the NRC. We're  
5 submitting a construction permit application to be followed by an  
6 operating license and we've chosen a two step process to do that,  
7 submitting the environmental report first followed by the Preliminary  
8 Safety Analysis Report.

9 And the next set of bullets are just going to give you a  
10 quick update on what we've done. And we've actually managed to  
11 accomplish quite a lot.

12 We submitted the environmental analysis in March of  
13 2013, submitted the Preliminary Safety Analysis Report in May. June  
14 24th, the NRC published an Intent to Prepare EIS and I think that was  
15 largely because it was new technology even though it's not typical for  
16 research and test reactors.

17 In June, the NRC accepted the ER. In July, the NRC  
18 followed up with an Environmental Site Audit Needs List and then had a  
19 public meeting later in July.

20 Following that, the NRC conducted the audit. We got  
21 RAIs on the environmental part in September 2013. We submitted the  
22 response to the RAIs in October, that was a very efficient process with  
23 NRC staff and we really appreciated their support on that in terms of  
24 very good communication.

25 Let's see, in December of 2013 the NRC accepted the  
26 PSAR. September 19th of 2014 we received the RAIs for the

1 construction permit on the PSAR.

2 And so, that's a long period of time and I think we  
3 started to see some of the issues associated with new technology kind  
4 of driving that time frame. We also had a short government shutdown  
5 in that window.

6 And then we just recently, very recently, submitted our  
7 responses to the questions. So, about 60 percent of them were done  
8 in October and the remainder of them in December. And 60 percent,  
9 by the way, is about 180 answers to questions.

10 So, in terms of challenges, obviously, you know, we've  
11 got a national need that's extraordinary and we've got a facility shutting  
12 down in Canada in 2016. And what we've faced so far and what we'll  
13 probably continue to face is sort of issues associated with this being the  
14 first of a kind facility and really, it's not been a staff issue so much,  
15 they've worked -- so much as an OGC issue in terms of what  
16 regulations apply to this new technology. And so, we've been working  
17 very hard on that.

18 I think on top of that, we've got multiple regulatory  
19 reviewers. It's not just a Part 50 facility as you typically think but  
20 there's also processing going on in this facility, some parts of Part 70  
21 apply. And so, I think that's a major issue.

22 And now, I think there's additional applicants that are  
23 starting to submit license applications and we want to make sure that to  
24 the extent possible, that that does not slow down. You know, the  
25 review's already in progress. It's very important that there be enough  
26 resources to keep things going.

1 From a standpoint of getting SHINE done financially,  
2 there is investor risk associated with this and the NRC's process  
3 impacts this and I know you guys don't especially care whether people  
4 make money or not, however, the investors are a necessary part to  
5 getting this facility up in the United States or it just won't happen.

6 And, you know, I think we don't have a firm schedule  
7 yet to show them that. We're currently planning on getting our  
8 construction permit in October of 2015, but the more clarity we can  
9 have around that the better.

10 As far as the licensing path forward, what we've got to  
11 do on the construction permit yet, obviously, the NRC staff are currently  
12 reviewing our answers. They've just got them, at least the final version  
13 of the answers.

14 You know, we need to complete the -- get the  
15 construction permit, hopefully again, late next year, complete final  
16 design on the facility and then submit the operating license application  
17 and go through that process.

18 Given that we go smoothly, we'll be ready to be on the  
19 market and selling commercial product in January 2018, which as you  
20 see, already leaves over a one year gap from the time the Canadian  
21 reactor shuts down, so time really is of the essence.

22 In terms of our relationship with the NRC, I think we  
23 have had an incredibly positive relationship. The staff has been very  
24 responsive to our licensing team. You know, we enjoy working with  
25 them. They obviously are very, very bright people and have grasped  
26 this technology very quickly.



1                   And I think, you know, we've been given a lot of good  
2 feedback in terms of our submissions very quickly which has provided a  
3 lot -- given us the opportunity to provide meaningful responses.

4                   So, in summary, I think we need to continue to work  
5 closely with the NRC. We need to continue to be a high priority. We  
6 have seen that but definitely need it to continue. You know, very  
7 pleased with the fact that the staff has produced specific regulatory  
8 guidance for medical isotope facilities, you know, and just need to kind  
9 of crank it through to the end here.

10                  We've worked hard to submit quality documents and  
11 believe we've had a very constructive relationship.

12                  CHAIRMAN MACFARLANE: Okay, great. Thanks.

13                  Mr. Foyto?

14                  MR. FOYTO: Thank you very much. Thank you very  
15 much for the opportunity to speak to the NRC.

16                  I'll be talking about the challenges that are associated  
17 with license renewal at the University of Missouri Research Reactor.

18                  My boss, Ralph Butler, Director at MURR was  
19 originally going to give this presentation, but he's not feeling too well, so  
20 I would stand clear of him if I were you. I usually try to.

21                  I'll give you a little -- next slide, please?

22                  A little overview of the facility, the University of Missouri  
23 Research Reactor is located on the main campus in Columbia,  
24 Missouri. It is a pressurized reflected open pool-type design, light  
25 water moderated and cooled.

26                  It is the highest powered university research reactor in

1 the United States at 10-megawatts. We are a multidisciplinary  
2 research and education facility providing a broad range of analytical  
3 and radiation services, kind of an A to Z reactor, ranging anything from  
4 archeometry down to zoology.

5 But our main focus is production of radioisotopes.  
6 And we have approximately 200 full-time and part-time staff. Out of  
7 that 200, 27 is within reactor operation, that includes licensed  
8 operators, management and administrative staff.

9 Next slide, please?

10 So, the facility was originally achieved criticality in  
11 October 13 of 1966. Originally, only licensed to operate at  
12 5-megawatts, although it was designed neutronically and thermal  
13 hydraulically to operate at 10-megawatts, at that time, they felt that  
14 operating at 10-megawatts was not necessary. They would  
15 reevaluate that at a later time as the needs of the facility increased.

16 Then in 1974, we were uprated in power at  
17 10-megawatts. In 1977, we started an operating schedule of 150  
18 hours per week. We've maintained that schedule up to this day.

19 In 2000, we submitted a request to the NRC to extend  
20 our license expiration date. This was to recapture approximately five  
21 years of the license during the construction period. So, our license  
22 was really scheduled to end in November 2001. It was extended to  
23 October of 2006.

24 And then in August 31st of 2006, we submitted our  
25 application for license renewal.

26 Next slide, please?

1 So, this is basically a time line of the Requests for  
2 Additional Information during our relicensing process. So,  
3 approximately three years after we submitted the relicense application,  
4 we had four questions regarding decommissioning and financial  
5 qualifications and one question regarding reference material. These  
6 questions were responded to within the allotted time period to respond.

7 Next slide, please?

8 Then in December, we had four questions regarding  
9 the environmental report. In April of 2010, we had six questions  
10 regarding National Historic Preservation Act. Once again, these  
11 questions were responded to in the allotted time period. So, up to this  
12 point, all the questions that the NRC had requested for relicensing had  
13 been responded to in the time period requested.

14 Then we really kind of get into the meat of the matter.

15 Next slide, please?

16 Regarding the true technical questions, in May and  
17 then in June, we received questions kind of within two categories,  
18 complex and non-complex.

19 Complex, there was never a clear explanation and  
20 what contributed a complex versus non-complex. But just by the  
21 quality of the question, you can tell that the NRC viewed that the  
22 complex just would take much longer to respond to.

23 But, when you get these questions within a month  
24 period of time, basically, it adds up to 187 total questions. So, it is  
25 quite a few questions to be asked to respond to essentially within a  
26 three month period of time.

1                   And also, and I'll discuss this a little bit later, on one of  
2 the -- there was an issue that was actually identified in responding to  
3 one of the Requests for Additional Information regarding our safety limit  
4 analysis. So, we were trying to work a license amendment on the  
5 safety limit analysis at the same time we responded to the relicensing  
6 Request for Additional Information.

7                   Next slide, please?

8                   So, that brings us up to this point. Now recently,  
9 February of 2013, we got four more questions regarding financial  
10 qualifications because, at that time, since there had been such a  
11 significant delay in relicensing, a lot of the questions that were originally  
12 asked had to be reasked just because the responses had been dated.  
13 Within financial qualification it has to be within three years.

14                  And then also, there had been a lot of kind of going  
15 back and forth with the NRC regarding the technical specifications.  
16 So, in January of 2014, we submitted what we considered essentially  
17 the revised and final version of technical specifications.

18                  Next slide, please?

19                  So, where we're currently at is all of the previous  
20 Requests for Additional Information have been responded to. Just a  
21 few days ago, we did receive another round of Requests for Additional  
22 Information regarding any facility modifications since the original  
23 submittal. Kind of like Dr. Newton alluded to, the amount of  
24 amendments since you originally applied and to the point where you are  
25 now.

26                  There has been some fairly significant modifications to

1 the facilities and a few license amendments. So, this will allow the  
2 NRC an opportunity to evaluate what has changed to the facility since  
3 the original submittal.

4 Also, in October of 2013, we submitted a revised  
5 physical security plan as part of relicensing. This incorporated the  
6 recent Part 73 changes and it also allowed us to incorporate the  
7 post-9/11 compensatory measures. And this is currently under review  
8 by the NRC.

9 So, as you can see here, we're at close to the eight  
10 year point.

11 Next slide, please?

12 So, these are mostly comments and observation  
13 throughout the licensing process. There was a -- when you added all  
14 the questions up together to this point, there were 201. We like to think  
15 that it was not so much the quality of our application but the complexity  
16 of the facility, too, because we are a one of a kind unique facility.  
17 There is no other 10-megawatt pressurized research reactor like  
18 ourselves.

19 And you do have limited resources to answer these  
20 questions in the time allotted, basically because you do have the facility  
21 that you have to run safely and reliably.

22 A lot of these questions that, because of the delay in  
23 starting the review process, many questions and basically just had to  
24 update information that was previously answered.

25 Next slide, please?

26 Many of the questions, 55 specifically referenced the

1 technical specifications. The one comment I have here is -- and this  
2 also applies to NUREG-1537 which is the format and content for a  
3 safety analysis report for research and test reactors, is they are  
4 guidance, they are not regulations.

5 But when you are being reviewed, according to these  
6 documents, specifically ANSI-15.1 which is the format for technical  
7 specifications that you're almost being forced as it is a regulation  
8 because most of the questions were basically, why did you not have  
9 this technical specification per ANSI-15.1 even though you operated 40  
10 years safety without that technical specification.

11 So, if there might have been a little bit more clarification  
12 on that in the beginning during the relicensing process that you would --  
13 we would like you to closely adhere to 15.1 and NUREG-1537, I think  
14 that would have eliminated a lot of the questions.

15 Some of the questions required significant amount of  
16 computer code work, RELAP, PARCS, MCNP, that obviously is very  
17 resource intense.

18 Some of the questions we felt were already answered  
19 in the safety analysis report and we just had to direct to them, not a big  
20 thing. But just to once again resource allocation.

21 Next slide, please?

22 We did have three site visits or at least so far during the  
23 relicensing process. One was really just more of an introductory kick  
24 off visit. The second one was a little bit more involved and the third  
25 one really had to do more so with the physical security plan.

26 And I think an increase, and obviously, this is once

1 again resource allocation, an increase in visits would definitely help  
2 because a lot of times when you submit your answers, you are kind of  
3 doing your best guess in the adequacy of the answers. Perhaps if you  
4 had more site visits before you formally submitted the answers, that  
5 might help.

6 And also, for common design features, and this really  
7 not so much for MURR because we are very unique, but a lessons  
8 learned database would be I think very beneficial to research reactor  
9 community. I mean there are nine Mark 1 trigger reactors out there,  
10 four of Mark 2 trigger reactors, three AGNs that share a lot of  
11 similarities. Perhaps they could share a lot of their experiences with  
12 each other.

13 Next slide, please?

14 As I previously stated, we did have during the review  
15 process, we did find an error within our safety limit analysis and I do  
16 appreciate the NRC working very closely with us to resolve that.

17 It did not decrease any margin of safety, however, it did  
18 require once again a considerable amount of time to put that  
19 amendment together right in the middle of a relicensing. I believe that  
20 we should have more realistic time lines to answer the Requests for  
21 Additional Information just due to the sheer number of questions.

22 And, as I previously stated, that some of the questions  
23 have to be reasked just because of the lapse in time since the original  
24 submittals, the information becomes outdated.

25 Next slide, please?

26 We were very fortunate to be able to use Argonne

1 National Lab since we are part of the fuel conversion project. A lot of  
2 their expertise was definitely supported, utilized at MURR and helped  
3 us within our safety limit analysis amendment.

4 We have always had very good support from our senior  
5 project manager during the relicensing process. And they were very  
6 understanding of our requests for additional time to respond to  
7 questions. So, that was never an issue with that. We felt pressure to  
8 answer the questions, we just worked very closely to try to resolve  
9 those.

10 Next slide?

11 Thank you very much for your attention. Any  
12 questions?

13 CHAIRMAN MACFARLANE: Okay, great. Thank  
14 you. Thank you all.

15 All right, so we're going to start off questions with  
16 Commissioner Ostendorff.

17 COMMISSIONER OSTENDORFF: Thank you,  
18 Chairman. Thank you all for being here today. This is very  
19 informative.

20 I've had the chance to visit the MIT and the University  
21 of Missouri Research Reactors. Those visits were very helpful and as  
22 with this particular community, see significant differences from one site  
23 to the next and so I think the focus on site visits and understanding that  
24 we're doing, in some cases, one of a kind technology. That point is  
25 well received, so thank you for making that today.

26 Let me start off with Dr. Newton, if I can.



1 On your slide eight that deals with security, you state  
2 that it should be recognized an increase in security requirements could  
3 substantially inhibit the research and education mission of research and  
4 test reactors.

5 I was going to ask you to perhaps expand upon that a  
6 little bit and help me understand, is that an issue with our current  
7 security requirements or what you think might be coming down in the  
8 future?

9 DR. NEWTON: No, this is more -- and this is related  
10 to the Part 73 changes. There was some initial point that they wanted  
11 to change all the HEU reactors to a Category 1 facility which makes  
12 those equivalent to a fuel fabricator.

13 That would have been very bad for all of us. I think I  
14 speak for Missouri in this as well. It would have really inhibited if not  
15 shut down our operation. And I think we made that point to the NRC  
16 folks when we were here in September, but we just -- the point you see  
17 made that, you know, we always need to have a balance between  
18 security and the mission that the reactors have. And I just don't want  
19 that point to be lost.

20 COMMISSIONER OSTENDORFF: Okay. But for  
21 the requirements that you are currently required to meet?

22 DR. NEWTON: Currently, we're okay.

23 COMMISSIONER OSTENDORFF: Okay, you're all  
24 right?

25 DR. NEWTON: Right.

26 COMMISSIONER OSTENDORFF: Okay. You're

1 concerned about further escalation?

2 DR. NEWTON: Right.

3 COMMISSIONER OSTENDORFF: Okay, I just  
4 wanted to make sure I understood that. Thank you for that  
5 clarification.

6 I'm going to stay with you Dr. Newton. On slide 11,  
7 you made a point that got my attention and it's your first bullet that says  
8 in recent years, relicensing process has become much more complex  
9 without substantive improvement in safety.

10 I think our staff may have a different opinion on that.  
11 We'll have a chance to ask them at the next panel.

12 But I want to get your -- can you give specific examples  
13 or ones that you think are --

14 DR. NEWTON: That's a bit a global concern from the  
15 TRTR group and less so from MIT. But, part of the issue with that is  
16 NUREG-1537 came into place about the time we started our  
17 relicensing.

18 And so, once that came into place, it kind of required  
19 everybody to rewrite their complete safety analysis report. And that's  
20 not at all a bad thing but going forward, there's some concern that  
21 maybe in the future once we're all set with NUREG-1537 maybe  
22 something else comes along and now we've got to redo it again. So,  
23 we're concerned about regulatory burden without an increase in safety.

24 We're just trying to follow the rules here but in terms of  
25 our risk profile, it hasn't really changed. And so we want to make sure  
26 the licensing process takes that into account.

1 COMMISSIONER OSTENDORFF: What is your  
2 understanding as to where the NRC staff is on their perspective on  
3 saying, yes, this is a safety enhancement?

4 DR. NEWTON: I mean they're reasonable. A lot of  
5 these questions that we have sometimes are just they have to be asked  
6 because there's a wording issue and things like that.

7 And it does require time both on their part and our part  
8 to answer them. It gets the feeling that, you know, why are we talking  
9 about this? This is stupid -- we need to put a comma here or whatever  
10 as opposed to, you know, we have real analysis issue that, you know,  
11 loss of coolant accident might have caused a concern or something.

12 So, we should focus our resources on the important  
13 stuff and I think we all do but sometimes the nuances and the trivia get  
14 in the way.

15 COMMISSIONER OSTENDORFF: Okay, thank you.

16 DR. NEWTON: Thank you.

17 COMMISSIONER OSTENDORFF: Dr. Piefer, thank  
18 you for your presentation. I think it's helpful for the Commission to  
19 hear the perspective on the gap you're trying to fill with the SHINE  
20 technology approach and appreciate very much your efforts.

21 I wanted to perhaps ask a big picture question and in  
22 the context of first of a kind engineering and any challenges and ask  
23 you maybe to talk about any challenges you're seeing as the CEO of  
24 your group working with NRC to deal with some technology issues that  
25 have not previously been reviewed or licensed by the NRC. Can you  
26 talk about that?

1 DR. PIEFER: Yes, sure.

2 You know, I think actually people have been very  
3 responsive on the technology. I think, again, it's been the bigger delay  
4 for us has been the sort of legal aspect of it in terms of, you know, first of  
5 all, we have a new irradiation facility that's never been licensed before.

6 And second of all, we have a processing facility the  
7 likes of which has not been licensed in this country for 50 years.

8 And so, I think in terms of finding what regulations  
9 actually apply to that or what regulations best apply is where we face  
10 the biggest challenges so far. And I think there's a path forward that's  
11 been determined there that's really helping us.

12 On the technology side, most of this has been done  
13 before, actually sort of on a piecemeal basis, not so much licensed by  
14 NRC but at the National Labs.

15 For example, irradiation of an aqueous target by an  
16 accelerator looks a lot like growing an aqueous homogeneous reactor  
17 in terms of, you know, gas generation and fission product, inventory in  
18 the liquid, et cetera.

19 But, you know, I think we, you know, it's strange to  
20 think of it, but we essentially have a liquid core moving around our plant.  
21 And so, it requires, you know, a lot of people from different parts of the  
22 NRC to really coordinate. And that's probably the biggest part of it  
23 from a technology standpoint.

24 The accelerator is fairly new but it's not particularly  
25 important to safety. You shut it off and it's done. So, it's the other  
26 elements, you know, primarily associated with the liquid target and then

1 moving that fission product inventory around the plant for processing  
2 and back to the target I think from a technology standpoint.

3 But really, I think, you know, the staff gets it and has  
4 hired the right people to help them. From a technology standpoint, I  
5 think the legal sort of aspect of where do we fit has lost more time.

6 COMMISSIONER OSTENDORFF: So, let me ask  
7 this question on the legal aspect. I recognize that my general  
8 counsel's on my left here, so I'm not going to put her on the spot.

9 But, just from our awareness, when you're discussing  
10 applicability of certain parts of the Code of Federal Regulations to the  
11 proposed SHINE technology and you're having a legalistic -- there's a  
12 legal issue that comes up. Are you dealing directly with the NRC staff  
13 and then they're going to our legal team here or are you having direct  
14 interface with our Office of General Counsel?

15 DR. PIEFER: Yes, I --

16 COMMISSIONER OSTENDORFF: I'm just curious  
17 as to how -- where the communication's flow is there.

18 DR. PIEFER: Yes, I'm actually not a 100 percent  
19 sure, but I'm almost sure that it's going through the staff and so, you  
20 know, I suspect that's what's going on based on what I've heard.

21 COMMISSIONER OSTENDORFF: Has there been  
22 any meetings where everybody sits down around the table like this one  
23 with SHINE representatives and NRC staff and legal representation  
24 and OGC staff to talk about these issues?

25 DR. PIEFER: Yes.

26 COMMISSIONER OSTENDORFF: Okay, good,

1           okay. Thank you.

2                           Okay, Mr. Foyto, thank you for being here. I wanted to  
3 ask you a question. I think you're very tactful and respectful and you're  
4 characterizations, some of your experiences, I appreciate that. It was  
5 a very professional but factually based presentation.

6                           I'm assuming you've had some opportunity and your  
7 people there in Missouri to sit down with NRC staff and perhaps have  
8 face to face discussions on the RAI process and your reactions to some  
9 of these concerns.

10                          Can you talk about that a little bit?

11                          MR. FOYTO: Yes, I mean a lot of it had to do  
12 specifically with the technical specifications portion to relicensing.

13                          It's kind of like Dr. Newton talked to about 1537 and if  
14 there's anything that I would, in going back and learning through the  
15 process, we're kind of right from the get-go because the NRC sends  
16 you out a letter saying that you're coming up for renewal application.  
17 These are the documents that you have to have and these are the  
18 documents that you're going to be reviewed by.

19                          So, you operate for 40 years safely with the current  
20 Safety Analysis Report with your current technical specifications.

21                          So, you have this feeling that you are doing everything  
22 appropriately and safely. And then all of a sudden, the technical  
23 specification that you've been operating with they want additional  
24 technical specifications in accordance with 15.1.

25                          So, you have these discussions which ones should  
26 apply, which one should not apply. A lot of the technical specifications

1 that we did not have, we had other mechanisms at the facility to either  
2 monitor them or administratively control them.

3 But really, what it comes down to is the fact that the  
4 NRC really wants you to comply with 15.1. Does it make you safer?  
5 That's subjective. But there is a lot of time and effort in that you're  
6 comply with either 15.1 or 1537.

7 A good example would be taking our current Safety  
8 Analysis Report and then you have NUREG-1537, you take out all the  
9 applicable sections of the one that we're operating under, fill in 1537  
10 then you have perhaps a 50 percent gap because there are questions  
11 within 1537 or areas that were never addressed or in the initial  
12 licensing.

13 Are some of them safety related? Perhaps but a lot of  
14 them to me and probably to the rest of the TRTR community are not safety  
15 related.

16 And that is -- it takes a lot of time in a lot of areas where  
17 we're not specialists at the reactor. You know, whether it's  
18 environmental monitoring or facilities within close vicinity to the reactor.  
19 Can they cause a problem? Things like that.

20 So, it takes quite a bit of time. But the interaction  
21 between the NRC and the facility, I think it's always been very, very  
22 good. It's trying to get to that common path to that common light at the  
23 end of the tunnel. That takes a while.

24 And, like I said previously, in fact that I think a lot of the  
25 questions could have been minimized if right from the beginning we  
26 were told that even though 1537 is a guidance document, ANSI-15.1 is

1 a guidance document, you are going to be judged by compliance with  
2 those two guidance documents.

3 COMMISSIONER OSTENDORFF: Okay. Thank  
4 you very much. Thank you, Chairman.

5 CHAIRMAN MACFARLANE: Okay. Commissioner  
6 Baran?

7 COMMISSIONER BARAN: Thank you. Thank you  
8 all for being here this morning.

9 Dr. Piefer, I wanted to start with you and ask you some  
10 questions about the SHINE technology and facility.

11 Taking a step back at the big picture and kind of place  
12 this facility in the context of the overall medical isotope issue. Can you  
13 give us a sense if licensed -- once the facility is at full capacity, how  
14 much moly-99 you anticipate producing and how that compares to  
15 domestic demand for moly-99?

16 DR. PIEFER: Sure. Yes, thank you for the question.

17 So, it's our expectation that probably within the first 18  
18 months of production, we'll be up to producing about two-thirds of the  
19 U.S. need, which is approximately one-third of global demand.

20 We've, in our license application environmental  
21 analysis, we essentially asked for approval to go up to about two-thirds  
22 of global demand, so about double that.

23 So, we do expect that as this accelerator technology  
24 matures, it's output will increase and we should be able to, if necessary,  
25 create additional isotopes going forward. We certainly see a lot of  
26 demand growth in Asia Pacific part of the world and want to make sure



1 that the U.S. continues to have ample supply going forward.

2 COMMISSIONER BARAN: And so, you talked about  
3 the kind of expected dates going forward. And so, you're hoping to get  
4 a construction permit in October 2015, the final design, you're not  
5 anticipating getting complete until April 2016. So, it's like a six month  
6 gap there where you have a construction license potentially, but work's  
7 still going with the design. How much construction do you plan on  
8 doing in that period?

9 DR. PIEFER: Yes, obviously we won't be starting the  
10 facility itself until we've got that final design complete and people, I  
11 mean contractors, set up to do that.

12 There is some early site work that we can do and plan  
13 to do in terms of bringing infrastructure to the site and also some  
14 support buildings that we can get going.

15 And I think the -- I do want to make the key point here  
16 that I think the timing of the construction permit is still essential and this  
17 goes back to, you know, getting investors and getting financial support  
18 to actually do the construction. It's going to take some time to get that  
19 lined up, probably following the issuance of the construction permit.

20 So, even though it might not look necessarily like it's on  
21 the critical path, it is absolutely time critical to move forward. So, I  
22 didn't want that to get lost in the messaging that there is a gap and that  
23 gap has been created, again, by the fact that, you know, we're a start up  
24 company and there are many things we should be doing in parallel and  
25 I would love to be doing in parallel.

26 But, you know, we've got to check off in sort of a serial

1 fashion risks in order to make sure that the financing comes to get this  
2 thing up and running.

3 So, we've got our own set of challenges there that  
4 we're working through, you know, combined with sort of the regulatory  
5 issues that we're also working on.

6 COMMISSIONER BARAN: And do you see particular  
7 challenges associated with beginning some parts of the construction  
8 before you're all the way through with the research and the design or  
9 are you going to sequence that in a way that doesn't create a lot of  
10 problems?

11 DR. PIEFER: I don't think it's going to create a lot of  
12 problems. We, you know, I think the technology we feel is pretty  
13 mature. So, what we're talking about is wiring runs and where bolt  
14 patterns or what bolt patterns look like and what type of hardware that's  
15 used to hold things down.

16 And sort of a lot of the things that, you know, would be  
17 part of a detailed design. I think in the preliminary design that we've  
18 submitted for the construction permit, we feel pretty good about the  
19 building itself and where concrete goes and where shielding goes and  
20 all of the safety related functions.

21 Now, that still does not mean we're going to start  
22 construction on the 55,000 square foot, you know, RPF as we call it,  
23 Radioisotope Production Facility, until final design's complete, we're  
24 going to have to wait.

25 COMMISSIONER BARAN: And can you give us a  
26 sense of about how much research related to the technology and the

1 facilities ongoing now and kind of the time line of that and how are the  
2 findings of that research communicated to NRC so as the NRC staff's  
3 doing its review, it's benefitting from the latest things you're learning.

4 DR. PIEFER: Yes, so, I think in terms of the  
5 technology for production, like I said, we feel like we have  
6 demonstrated everything sort of on a demonstration-ish mode which  
7 kind of means that we've shown full output in a number of ways but for  
8 short periods of time.

9 And so, for us, the concern is more, you know, what's  
10 going to happen when we run this thing pedal to the metal, you know,  
11 five and a half days a week which is our run cycle.

12 And that's where a lot of the research is actually being  
13 focused. You know, for example, Oak Ridge is doing accelerated  
14 corrosion testing. We've got a uranyl sulfate solution under irradiation  
15 and contact with zirconium, you know, real time. What does that look  
16 like in five years? You know what does look like in ten years.

17 So, as that data becomes available, we're able to  
18 communicate that to the staff.

19 But in terms of the raw technology itself, you know, I  
20 think through aqueous reactor data, we have data points at much  
21 higher power densities than we'll be generating, you know, we've got  
22 the accelerator systems producing neutrons in our shop.

23 We've got Argonne National Laboratory producing test  
24 batches of product that we can actually take all the way to our customer  
25 and for validation at this point.

26 So, there's a lot of -- it's actually pretty mature other

1 than the fact that it hasn't been built together and run again, you know,  
2 in a production environment. And of course, that'll have its own  
3 unknowns associated with it when we get there.

4 But, those are going to be the sort of non-binary risks  
5 that we should be able to work out.

6 COMMISSIONER BARAN: And recognizing this  
7 follows a little bit on Commissioner Ostendorff's question and where  
8 you all talked about the legal side of things. But I'm wondering  
9 whether, even though you kind of have a unique technology here, you  
10 are going through an initial licensing process.

11 Are there -- have you seen lessons that the NRC staff  
12 or other, you know, future applicants should be learning from your  
13 process?

14 DR. PIEFER: Well, I think so. I mean I think they're  
15 all on the record and I think, you know, for example, submitting in two  
16 parts, you know, that was a process that we had to go through and dust  
17 off. Right? That hadn't been done for a long time.

18 And you know, I think people are following sort of that  
19 advice. I think being the trail blazer and, unfortunately, you have to  
20 work a little bit harder and I think everybody is kind of watching that and  
21 learning from it. So, that's one example that comes to mind. There's  
22 many others.

23 You know, I think the communicative atmosphere has  
24 been wonderful and, you know, I think in terms of the regulations and  
25 bucketing it is probably going to help other people, too, even though,  
26 you know, I think that the definition of production facility was amended

1 specifically for our docket number due to the need to move quickly.  
2 You know, I suspect other people would follow that sort of proposed  
3 path as well.

4 COMMISSIONER BARAN: Okay, thanks.

5 Dr. Newton, can I ask -- so, you've raised some  
6 concerns about the relicensing timeliness and issues there with MIT  
7 and more generally. And so the MIT reactor, I guess you were  
8 relicensed in 2010.

9 DR. NEWTON: Correct.

10 COMMISSIONER BARAN: In the four years that  
11 have passed since then, I mean have your members of the national  
12 organization seen improvement in the speed with which, you know,  
13 relicensing's happening?

14 DR. NEWTON: Yes, it looks like there was a list when  
15 we got our license, there was, I don't know, a dozen or so reactors that  
16 were sort of in the process and I think that's down to less than that now.  
17 You can talk to the NRC guys, but it looks like it's getting better. I think  
18 they've definitely made some improvements over time.

19 COMMISSIONER BARAN: And going forward, what  
20 do you think the most important item for NRC to address is to ensure --  
21 in order to ensure timeliness of relicensing reviews?

22 DR. NEWTON: Focus on the important stuff I think is  
23 my take.

24 COMMISSIONER BARAN: Okay. It's hard to  
25 disagree with that. Great.

26 And, Mr. Foyto, do you have anything to add on that?

1 MR. FOYTO: No, I mean it's probably for the NRC to  
2 accept the feedback from the licensees based on the relicensing  
3 process and there has been quite a bit of work on streamlining  
4 relicensing.

5 COMMISSIONER BARAN: Okay. And you went  
6 through kind of the laborious process of relicensing for your reactor.  
7 After going through all that process, was there a benefit to any of that  
8 from your point of view? Do you and the folks at the reactor have a  
9 better sense -- do you think you have a better sense of, you know, the  
10 reactor, the safety basis or do we get any benefit from the years of effort  
11 that went into that?

12 MR. FOYTO: I mean based on trying to comply with  
13 1537, I would say for licensed operators, you have probably a better  
14 document to operate and even train from the accident analysis whether  
15 it's loss of flow, loss of coolant accident, are described better, without  
16 question, better in this document than they were previously.

17 Are we safer? Once again, that's somewhat  
18 subjective. I would say no. I mean I believe we were a very safe  
19 facility for 40 years and I don't think we're any safer, but then again, if  
20 the document that you're operating off of and you're training off of is  
21 improved perhaps that leaves some credence that you are doing a  
22 better job.

23 COMMISSIONER BARAN: Okay, thank you. Thank  
24 you, Chairman.

25 CHAIRMAN MACFARLANE: Okay, great. Mr.  
26 Burns?

1 COMMISSIONER BURNS: Thank you all for being  
2 here and for your presentations.

3 One of the questions to follow up on -- the license  
4 renewal term is for how long?

5 MR. FOYTO: Twenty years.

6 COMMISSIONER BURNS: Twenty years. And from  
7 the time the license is granted, it's not --

8 MR. FOYTO: Right. Not from the time you  
9 submitted.

10 COMMISSIONER BURNS: One of the questions I  
11 asked maybe Dr. Newton talked about some what I will say, minor types  
12 of things. Give me an example of something sort of you perceived as  
13 insignificant that perhaps goes to the licensing process.

14 I heard I think an example about typographical errors  
15 and things like that. Walk me through the pain, if you will.

16 DR. NEWTON: I mean our first set of questions which  
17 came in three batches, 135 questions. I think I went through there was  
18 maybe ten of them that were kind of silly. You know, it was like why is  
19 it worded this way instead of this way. Okay.

20 When you're faced with a 90-day deadline and you're  
21 looking at those things, you know, like good grief, can't we get to the  
22 meat of the problem?

23 And so, it required some effort for us to kind of go  
24 through all those. It would have probably been nicer if we'd have had,  
25 you know, here are the silly questions we have to answer at some point.  
26 But here are the really important ones that we need to address and in

1 some cases reanalyze things.

2 And so they mixed them together, it was a bit more  
3 painful, I think.

4 COMMISSIONER BURNS: Okay, okay. And I think,  
5 Mr. Foyto, in looking at your presentation, probably in some  
6 circumstances there are probably review aspects that the facility didn't  
7 have to go through 40 years so, which would have, well, 40 years ago,  
8 NEPA was in effect, but things like the environmental review.

9 I noted you had the National Historic Preservation Act  
10 review. What was that and what did that involve?

11 MR. FOYTO: That was kind of out of left field. I  
12 mean that was actually pretty interesting talking about historic sites  
13 near the facility. Actually, that was something that during licensing  
14 process, I actually thought it was kind of interesting because our project  
15 manager at the time saying hey, we're required to ask you these  
16 questions and, you know, you're a nuclear facility, you're not thinking  
17 about whether you have an Indian site located over here or something  
18 like that.

19 So, that actually was kind of interesting.

20 It wasn't too -- it was by the norm so I had to educate  
21 myself on where to look for the answer to these questions. So, I know  
22 some people who have gotten those questions have not enjoyed  
23 answering because it is out of the norm.

24 But to me, it was actually interesting. So, and it wasn't  
25 that time consuming thought, I don't remember whether it was 45 or 60  
26 days to answer it. That was sufficient, that was sufficient time to ask



1 those questions.

2 COMMISSIONER BURNS: Do either of you -- do you  
3 think there's a good understanding in the community of some of those  
4 types of what I'll say additional requirements beyond the Atomic Energy  
5 Act requirements in terms of the environmental reviews, historic  
6 presentation. There can be other things like that.

7 DR. NEWTON: That's a good question. I can't really  
8 speak for everybody. I think the licensing process is one of those  
9 eye-opening times where you start to look at, you know, airports and  
10 dams and things like that that are around you. You have to think about  
11 impact -- possible impact on your facility.

12 COMMISSIONER BURNS: Yes. Okay, thanks.

13 One other question and perhaps for you in terms of sort  
14 of representative of the organization, where do you see this community  
15 going in ten years, 20 years?

16 DR. NEWTON: Well, I think the initiative to have  
17 non-expiring licenses is a potential good step forward. As long as it  
18 makes it to where people are cognizant of the changes in the SAR  
19 whenever you upgrade your facility, keep those current, that's good.

20 But, if there's a regulatory process that is cumbersome  
21 then that's bad. So we have to make sure that we engage with NRC  
22 along that process and we are.

23 COMMISSIONER BURNS: Okay, good.

24 Mr. Piefer, again, I think it's very interesting in terms of  
25 the discussion in terms of a lot of what we focus on is sort of like legal  
26 risk which is, as I say, interesting for my colleague and for me as a

1 former general counsel as well.

2 Is there anything you see from this process -- part of  
3 that I guess part of the issue is because the nature of the technology  
4 and the design, it doesn't -- in terms of the regulatory framework that we  
5 have, doesn't fit it nicely or perhaps easily.

6 Is there anything, I mean you may have more  
7 perspective probably on the other side of the process. But is there any  
8 perspective in terms of what the framework in terms of going forward  
9 might be? Where do you see perhaps opportunities either to adjust it  
10 or the like?

11 DR. PIEFER: Well, you know, I actually have to say I  
12 think a major issue was a result just a few months ago by the  
13 Commission actually, a direct final rulemaking and that was exactly,  
14 you know, how do we fit into the regulations?

15 And I think it was good, actually, it was consistent with  
16 our expectations and with our submittal and, in fact, with the guidance  
17 documents the staff had put out for us to look at.

18 And so, you know, I think any guidance that I would  
19 give has already been sort of brought into the system. Now we need to  
20 make up some time and can we do that or not, I don't know. But, you  
21 know, certainly that's, you know, I think that other people could look at  
22 what we did there and move forward.

23 I think the Commission sort of stayed consistent with  
24 what the staff had been recommending and what we thought actually  
25 was the safest way to license this facility.

26 COMMISSIONER BURNS: Okay, good. Do you

1 also, as part of this process of bringing a facility into operation  
2 eventually, what type of interaction do you need to do with the FDA?

3 DR. PIEFER: Yes, so, you know, the FDA is not a  
4 direct regulator of SHINE, so the FDA directly regulates our customers.  
5 We're providing what's known as an active pharmaceutical ingredient to  
6 a downstream customer.

7 However, the FDA is undoubtedly curious about us  
8 and in fact, you know, we will be submitting what's called a drug master  
9 file that they will keep in their records so that when they are licensing  
10 our customers, they can understand a lot about what our process does.

11 And so, while there's no direct regulatory oversight  
12 expected and this is consistent with discussions we've had with the  
13 FDA, they will be involved. We have an active dialogue with them and  
14 through this drug master file, they should be able to understand our  
15 process and how it connects to the device that they in fact do license.

16 As far as final approval of the product goes, we expect  
17 to follow a similar path to new reactors that have been brought on  
18 particularly using new target technology. So there's a conversion from  
19 highly enriched uranium to low enriched uranium that's happened at  
20 some of the thorium reactors.

21 And the FDA established a process by which those  
22 products could be submitted to let's say our customers. They'll do  
23 three test batches where they'll gather data from elutions in making the  
24 drug kits that eventually go into the patients. Submit that to FDA and  
25 then that receives approval.

26 And that has happened fairly quickly in the past, as

1 little as a few weeks, actually, from the time the complete data was  
2 collected and the report submitted by the customers.

3 So, good coordination between us and our customers  
4 actually, we believe can get FDA approval fairly quickly as long as  
5 they're in the loop the whole way and not surprised by anything.

6 COMMISSIONER BURNS: Thanks. I think you may  
7 have mentioned, Mr. Foyto, the issue of or perhaps the advisability of a  
8 lessons learned-type of database and it might help other, you know,  
9 similar applicants recognizing there's some variability.

10 Either you or Dr. Newton, do you see any impediments  
11 to that to developing that kind of database, lessons learned database?  
12 Is that something that really say in terms of either the NRC or within the  
13 community ought to be done or can be done?

14 DR. NEWTON: I think it would take some effort to  
15 filter out the stuff that's facility specific to what is more generic. And  
16 the problem is we're very diverse in terms of our needs. So, a question  
17 that might be relevant to Missouri and MIT might not be relevant to the  
18 smaller facilities.

19 So, it would take quite of a bit of effort. I think it might  
20 be valuable to kind of let everybody know what the NRC's thinking in  
21 terms of these are the things we need to really focus on. But that  
22 would be difficult.

23 MR. FOYTO: Yes, like Dr. Newton's saying, yes,  
24 there are a number of the research reactors that are essentially one of a  
25 kind research reactors. But, you know there are quite a few trigger  
26 reactors, you know, three AGNs. So, you know to me a lot of the

1 commonalities of that could be put together in a database.

2 And also, what I found out, too, even while you're  
3 developing your technical specifications, you're following 15.1, it's still a  
4 kind of a high-level generic you need this technical specification.

5 I spent actually quite a bit of time on ADAMS going  
6 through other facilities technical specifications just trying to figure out  
7 what was accepted by the NRC to appropriately word something?  
8 Perhaps something like that putting together sectional, technical  
9 specifications would help a facility.

10 COMMISSIONER BURNS: Almost like a standard  
11 tech specs.

12 MR. FOYTO: Almost like a standard -- yes. Right.  
13 Because 15.1's very generic when you start digging into the details for  
14 each facility.

15 The way a facility's approved technical specifications is  
16 you definitely help another facility. I know it helped me but it is time  
17 consuming.

18 COMMISSIONER BURNS: Thank you, Chairman.

19 CHAIRMAN MACFARLANE: Okay, my turn.

20 So, Tom, maybe you can help me out or maybe Mr.  
21 Foyto can.

22 There are still a few reactors, research reactors in this  
23 country that use highly enriched uranium fuel.

24 DR. NEWTON: Correct.

25 CHAIRMAN MACFARLANE: Yours --

26 DR. NEWTON: Yes.

1                   CHAIRMAN MACFARLANE: -- and yours, in  
2 particular. And so, I'm interested in when you're going to convert to  
3 LEU fuel.

4                   DR. NEWTON: That's of interest to all of us. We're  
5 working the NNSA folks to develop a suitable fuel. We are eager to  
6 convert as soon as --

7                   CHAIRMAN MACFARLANE: There are high density  
8 LEU fuels out there.

9                   DR. NEWTON: There are higher density fuel but  
10 we've done quite a bit of analysis on those fuels and they would not be  
11 suitable for us. We would not have a program.

12                  CHAIRMAN MACFARLANE: Are you guys working  
13 on this?

14                  DR. NEWTON: Well, of course we are. We're  
15 working with Argonne and Idaho and all the other national labs. So  
16 we're definitely eager and we will convert as soon as the fuel is ready  
17 and approved by the Commission which is in process, it's going to be a  
18 long process because they're still trying to figure out how to make it.  
19 But it's there and we're actively engaged and we will be actively  
20 engaged.

21                  CHAIRMAN MACFARLANE: And do you guys have a  
22 similar problem?

23                  MR. FOYTO: Yes, we have very -- we probably have  
24 perhaps the most unique problem. We require density of fuel above  
25 15 grams per cc, which is ten times what we currently have.

26                  So, we have -- well, it comes down to basically the

1 density of the fuel.

2 CHAIRMAN MACFARLANE: To get the -- and this is  
3 all in aid of getting the neutron spectrum that you want?

4 MR. FOYTO: Just to achieve criticality. Not even to  
5 get the neutron spectrum, just achieve criticality.

6 CHAIRMAN MACFARLANE: Okay, so, you know,  
7 encourage you to continue those efforts.

8 But going back to the question that Commissioner  
9 Ostendorff asked about security. You know, it is different, HEU from  
10 LEU.

11 DR. NEWTON: Indeed.

12 CHAIRMAN MACFARLANE: It does require more  
13 attention and because we regulate not just safety but security. It's our  
14 job to make sure that you guys are as secure as possible.

15 So, I want to understand a little bit more, you know, so  
16 I have a little experience working at MIT's research reactor and that was  
17 before 9/11 and before, you know, there was just one guy standing by  
18 the front door when you would come in and maybe he was there and  
19 maybe he wasn't. He would check your ID going into the facility. But,  
20 that was along time ago.

21 But I want to understand how additional security  
22 requirements might actually impact some people like, you know, the  
23 person that I was going in there and working.

24 DR. NEWTON: Yes, I mean we now require  
25 background checks on everybody having unescorted access.  
26 Including FBI fingerprint checks and things like that. As required by

1 NRC, we've -- things have changed a lot since you were there.

2 And so, we are definitely cognizant of the threat  
3 environment out there. We have independent review not only from  
4 NRC but from outside agencies to look at the adequacy of our security.  
5 And everybody's come across saying we are above and beyond the  
6 requirements and we are adequate in terms of our needs and our  
7 access.

8 But, you know, that being said, we do have  
9 researchers that want to come and do things at the reactor, we have  
10 students who come in. So, they have to go through the pain of going  
11 through those checks that they used to not have to do.

12 And it's one of those --

13 CHAIRMAN MACFARLANE: Well, unfortunately --

14 DR. NEWTON: -- things that we have to achieve a  
15 balance in order to keep our mission going.

16 CHAIRMAN MACFARLANE: Right. And,  
17 unfortunately, it's the reality of the world in which we live now. You  
18 know, that's the same for power reactors. They don't have the material  
19 that you have there.

20 Okay. Let me turn to relicensing and can you guys --  
21 the two of you give me a sense of who -- of meeting deadlines.  
22 Clearly, it sounds like not that they were formal deadlines set for the  
23 NRC, but the NRC was slow in responding to your answers. Is that  
24 your sense or not? Or is your sense -- and were guys slow in  
25 responding?

26 And you used a very helpful detailed outline of your



1 experience and it sounds like most of the time, you were on time,  
2 sometimes it took you longer to respond.

3 So, I'm trying to get a sense of where the slowdown  
4 happens, whether it's that people were not meeting deadlines, whether,  
5 you know, that it was just extensive questions, you know, and that  
6 people would think up over time. What's your sense?

7 DR. NEWTON: In terms of our first round of  
8 questions, we, of the 135, we were able to answer 131 of them in the  
9 allotted time.

10 CHAIRMAN MACFARLANE: And the number, you  
11 know, I'm not so sympathetic with. I get more questions than that from  
12 Congress --

13 DR. NEWTON: I understand, I understand.

14 CHAIRMAN MACFARLANE: -- on a quarterly basis  
15 and given two weeks to answer them. So, really.

16 DR. NEWTON: I understand. But the other four  
17 required some extensive re-analysis and we asked for additional time  
18 and were granted it.

19 I would suppose that once we submitted our answers  
20 that the process at NRC didn't stop waiting for the other four questions  
21 to be answered. And if you look at the time line of how much time we  
22 took versus how much time NRC took, I think we took maybe a total of  
23 one year out of the 11.

24 But, that's very subjective because things go on in  
25 between the two. And so, was it slow? Yes. Was it -- were there  
26 other issues? Of course there were.

1 CHAIRMAN MACFARLANE: Okay.

2 MR. FOYTO: I mean, just based on, like I said, the  
3 time line that I presented, so we submitted it and approximately three  
4 years later, we got our first Request for Additional Information. So,  
5 there was a three year pause.

6 I can't speak for the NRC why it took three years to get  
7 to that point whether it's establishing a contract, to get a contractor on to  
8 do the technical review.

9 You know, I think trying to answer 180 some odd  
10 questions, and some of them ranged from very technical to simple.  
11 But even simple questions, as you know, take time when you only have  
12 maybe one or two people working on this document, most of the time,  
13 only one person working on this document.

14 So, I would say out of the time period now, eight years,  
15 it took us approximately a little over two years to answer the questions  
16 in entirety, and then some iteration back and forth with the NRC to try  
17 and finalize the technical specifications.

18 I would not point my finger at the NRC saying it was  
19 their fault because there's no question that as a licensee, we  
20 contributed to the slowdown in process. But it really comes down to  
21 resource allocation, you know, what the NRC is doing -- what other fires  
22 you have going on at the time is no different than the licensee. We  
23 have things happen at the facility, we're not a static facility, we're  
24 dynamic. We're doing facility modifications all the time.

25 So, it's hard to get a group of people set aside saying  
26 this is your lone job. That won't happen, I have 27 people within

1 reactor operations. That 27 within reactor operations is probably more  
2 staffing than 90 percent of the research reactors here. So, it's not like I  
3 don't have staff, but with that increased staff, you have a lot more going  
4 on.

5 So, I say it was a shared -- at least in MURR  
6 experience, it was a sharing of the two.

7 CHAIRMAN MACFARLANE: Okay.

8 MR. FOYTO: Yes.

9 CHAIRMAN MACFARLANE: Okay. Well, one thing  
10 I'm struck by is the extreme contrast between their experience and your  
11 experience. You are moving at light speed, although it may not feel  
12 like it, you are.

13 So, I'm very impressed by your operation for, you  
14 know, clearly how organized you are and getting back to questions, et  
15 cetera. But, I think the staff also probably deserves a fair amount  
16 credit here for their responsiveness and their speed.

17 So, I'm not sure there's much to worry about. I mean if  
18 you stay to the time line that you outlined, especially for a technology  
19 that is as complex and as new as you are presenting, I think you're  
20 probably doing pretty well.

21 So, I want to understand if there are any particular  
22 issues or challenges you see coming down in the next months, shall we  
23 say, because they're on the year's time line.

24 DR. PIEFER: You know, no, I think just in terms of  
25 getting the public hearings and everything set up and getting a calendar  
26 outlined, I think that would be really helpful for us.

1           You know, the more certainty we have around the  
2 process, the better we're going to be able to move through this. You  
3 know, I know there's a typically 180 day window for public hearings. I  
4 don't know if that's required and maybe we can move that a little faster.

5           CHAIRMAN MACFARLANE: A lot of these are legal  
6 requirements that can't be changed.

7           DR. PIEFER: Right, of course, of course. And to  
8 that, you know, to the extent that they cannot be changed, great, but to  
9 the extent that we can improve efficiencies without compromising  
10 safety, you know, we'd really ask that people do what they can to do  
11 that.

12           Because, you know, again, just to cite that Canadian  
13 study that recently came out again, every day that we're late, you know,  
14 another 15 people are dying.

15           And so, you know, obviously, we have to be safe --

16           CHAIRMAN MACFARLANE: Yes, but I'm actually  
17 really struck by one of the statistics that you mentioned and that's that  
18 the United States uses one-third of the global molybdenum supply.

19           DR. PIEFER: Half actually.

20           CHAIRMAN MACFARLANE: Half? Oh even worse.

21           DR. PIEFER: Yes.

22           CHAIRMAN MACFARLANE: So that means -- as far  
23 as I understand it, a lot of folks in Europe get a lot better health care  
24 than we do. And so, they're not using as much. And so what are we  
25 doing wrong here?

26           So, I'm not sure that there's a really strong case that

1 we, you know --

2 DR. PIEFER: Yes, and I didn't write the study, but,  
3 you know, I think these are people who do these studies.

4 CHAIRMAN MACFARLANE: And by the way, from  
5 the Canadian regulator, it's not the Canadian regulator that's forcing  
6 that facility in Canada to shut down.

7 DR. PIEFER: Understood. Of course.

8 CHAIRMAN MACFARLANE: That's a government  
9 decision.

10 DR. PIEFER: That's right.

11 CHAIRMAN MACFARLANE: So, again --

12 DR. PIEFER: That's right. Yes. Regardless, it's  
13 happening and I think it is the bottom line.

14 CHAIRMAN MACFARLANE: Right. Well, we have a  
15 job which is to make sure that --

16 DR. PIEFER: Of course.

17 CHAIRMAN MACFARLANE: -- things operate safely  
18 and securely and that's really the focus of our mission.

19 DR. PIEFER: And, in fact, I sleep very well at night  
20 knowing, you know, that you have excellent staff backing us up and  
21 backing up our operation.

22 CHAIRMAN MACFARLANE: Okay, great. Thanks.

23 Commissioner Svinicki?

24 COMMISSIONER SVINICKI: Well, I noted the same  
25 thing as Chairman Macfarlane and we really have two very discrete  
26 topics here on this panel. But, I maybe had a different reaction than

1 she did. She's seemed to have a positive draw -- a positive reaction  
2 from the contrast.

3 I think, you know, I marvel a bit that an organization  
4 that is capable of moving with some dispatch through issues for an  
5 innovative technology like SHINE. If I were the either of the gentlemen  
6 flanking the SHINE applicant, I might say, well, I'm scratching my head  
7 a bit that it takes, you know, 11, 12 years, whatever it does.

8 And you're choosing the term relicense. It is s license  
9 renewal and this has been a topic of previous Commission meetings  
10 that it is the RTR reviews are not relicensing and they may feel like it  
11 and I actually thought both of our RTR representatives here were using  
12 that on purpose to revisit that issue. It is not supposed to be a  
13 relicensing, it's a renewal.

14 But that it takes longer to move through and just certify  
15 the continued safe operation of something that's operated safely for 40  
16 years, that from an NRC staff review, the same organization that's  
17 capable of moving quickly through the innovative SHINE technology is  
18 taking the amount of time that it's taking for some of the RTR reviews.

19 So, I'm not sure I'm able to square that circle quite.  
20 So, this was a topic of high energy for the Commission when I joined  
21 this Commission three Chairmen ago, four. Soon, I'll be starting under  
22 my fourth Chairman.

23 Of course, the Chairman at that time had come from an  
24 academic background and so he had a lot of focus of RTRs.

25 I would ask both of our academic representatives, do  
26 you think that there's a long term safety implication for the United States

1 if we over time graduate generations of nuclear professionals who do  
2 not have an opportunity to do hands-on work at research and test  
3 reactors or get in reasonable proximity to nuclear materials in the  
4 course of their academic career? Do you think ultimately there's a  
5 safety implication to that?

6 DR. NEWTON: I think it certainly could be a problem.  
7 In terms of specific safety things, I don't know if I could go there, but  
8 certainly education is important and research is important and that's  
9 why we're in business and we want to continue in business to do that.  
10 So, hopefully, we can all work together to contribute to that.

11 MR. FOYTO: To me, no question. I'm also previous  
12 Navy, U.S. Navy Nuclear Power program and I would not have thought  
13 about going out to operate a nuclear powered aircraft carrier without  
14 operating a nuclear prototype first.

15 And to me, that lends a hand with individuals who are  
16 working at commercial reactors and research reactors without putting  
17 your hands on an operating facility first -- and that's just the education  
18 and training aspect of it.

19 And the amount of research that's being done at these  
20 facilities is incredible, too. It's not just a training reactor, an  
21 educational reactor, it's also, you know, true research. A lot of the  
22 research that national labs can't even do or won't do.

23 COMMISSIONER SVINICKI: Well, and it may be that  
24 I come at this with a bit of a bias formed in the time I spent working on  
25 the U.S. strategic deterrent and nuclear weapons program where we  
26 are moving now generations away from those scientists and engineers

1 who had direct involvement in the weapons testing program in the  
2 United States and we're attempting to maintain a knowledge base  
3 where we are moving away from anyone with direct experimental  
4 connection.

5 And we are building the snazziest super computers on  
6 the globe and I understand that. But as an engineer, it may just be  
7 simple engineering bias.

8 I do believe that you need to have some authentication  
9 back to the physical world. I think that that's important and I think that  
10 that is what our academic infrastructure writ large provides. And I think  
11 that having research reactors at academic institutions in the United  
12 States while no, I also can't posit any kind of near term safety  
13 implication, I am firmly convinced that over multiple generations, it's not  
14 to the benefit of the United States to have a smaller and smaller  
15 research and test reactor infrastructure. I just, I'm firmly convinced of  
16 that even in the absence maybe of hard data, it just doesn't seem to  
17 movement in the right direction.

18 On that front, is there ever any discussion in the TRTR  
19 organization or the RTR community about the interest in any academic  
20 institution of eventually building new research reactors?

21 I often think that that would be a real signal of a long  
22 term nuclear power commitment in the United States would be if there  
23 was at least on paper, consideration of building new --

24 You know, it's funny there's been discussion about the  
25 National Historic Preservation Act. When I thought about it, many of  
26 the research and test reactor in this country cover the span of the



1 atomic history of the United States. And some of these RTRs, when  
2 you go visit them, have trained the great luminaries and pioneers of not  
3 just U.S. atomic history, but all of atomic history.

4 So, but at some point, I'm wondering if anyone's willing  
5 to go to go to a university Board of Regents about 20 years from now or  
6 50 years from now building new research and test reactions. Is there  
7 ever any over the horizon talk of that?

8 DR. NEWTON: There's talk but I think at least I can't  
9 speak for the university administrations, but it's a very risky  
10 prospect. It could be a very expensive prospect. To spend  
11 \$100 million or more on a new research reactor, might not be  
12 seen as cost effective.

13 MR. FOYTO: Yes, I have the same answer. The I  
14 wouldn't say liability, but the perception sometimes as far as reactors on  
15 university campuses is kind of difficult to kind of wade through. But  
16 also, the financial investment, I just don't if there's a university out there  
17 willing to make a financial investment.

18 COMMISSIONER SVINICKI: Well, I think that takes  
19 me back to my original point, though, about if we're taking the very long  
20 term view on nuclear technology, at some point, even though in many  
21 cases having visited RTRs, they are new-old machines. There's a lot  
22 of upgrading and work that has gone on. Still in all, it doesn't kind of  
23 speak to the long term future for a renewed interest for young people to  
24 come into the field if there's never any discussion about new  
25 technologies.

26 But speaking of new technologies, we do have medical

1 isotope, we have the SHINE application and it's interesting, Chairman  
2 Macfarlane indicated that things were going well and you didn't have  
3 anything to worry about. I think you have a lot to worry about and  
4 here's why.

5 Are you aware that in the uranium recovery area, as  
6 the NRC receives new applications we actually diminish review hours  
7 and resourcing on applications that we're currently working on?

8 Now, without naming any names, depending on your  
9 success and how you proceed, as you said, everybody's watching you,  
10 there's a lot of people who are queued up who have submitted letters of  
11 interest to the NRC. Would you find it -- you said we don't care that  
12 much about people making money, and while that's true in the absolute  
13 sense, would you find it commercially punitive to you if as new  
14 applications came in yours was slowed? Are you dependent in terms  
15 of your business case on a scheme that keeps you as the first mover in  
16 this market?

17 DR. PIEFER: Yes, absolutely. You know, I think if to  
18 the extent that that would greatly slow down our application, that would  
19 greatly decrease our probability of success.

20 COMMISSIONER SVINICKI: Well, I think that in that  
21 sense, you've teed up kind of a very important issue for NRC to be  
22 thinking about for the Commission to be thinking about. Again, I've  
23 had a multi-year dialogue with the NRC staff about some of our  
24 resourcing and prioritization and the uranium recovery area which I'm  
25 not entirely comfortable with.

26 But in this instance where it a U.S. national policy

1 objective to develop domestic sources of medical isotope production  
2 and where we have another federal agency, DOE, that is engaged in  
3 actually providing incentives and encouraging this market by our  
4 inaction or action or prioritization and resourcing of these reviews, we  
5 could potentially frustrate that national policy objective.

6 So, I think that is something not to be resolved today  
7 but something that will become critically important in this area as we  
8 move forward. We could have multiple applications on a level of effort  
9 resourcing which means none of them ever get to their commercial  
10 production and in doing that, we have essentially frustrated the entire  
11 national policy objectives.

12 So, on the other hand, we can't be giving preferential  
13 treatment to anyone but it may be a case where first in needs to have  
14 significant priority in terms of the allocation of technical and staff  
15 resources. So, we're going to have to work our way through that. But  
16 we might have to depart from some of the autopilot that we've put other  
17 types of spreading of resources in other resource areas.

18 And again, I think we can look at the new reactor area  
19 to try to give us some guidelines there to how without providing  
20 preferential treatment to not at the end of the day frustrate the larger  
21 policy objectives.

22 And then I might just end with a question for our MIT  
23 representative. Do you have any idea what happened in the six year  
24 lull? I'm getting a sense now of why when I joined this Commission  
25 there was such an interest in why these RTR renewals were taking too  
26 long between 2002 and 2008. Was there any activity on your review?

1 DR. NEWTON: Not that I know of. I mean we had a  
2 few internal issues about that time. I don't think it affected --

3 COMMISSIONER SVINICKI: Were you notified that it  
4 was just tabled?

5 DR. NEWTON: No.

6 COMMISSIONER SVINICKI: Okay. Okay, well I'll  
7 ask the staff about that. Thank you.

8 CHAIRMAN MACFARLANE: All right. Any other  
9 questions? No? All right, well, thanks to the first panel and we'll now  
10 take a short five minute break for the second panel.

11 Thank you very much.

12 (Whereupon, the above-entitled matter went off the  
13 record at 10:24 a.m.)

14 CHAIRMAN MACFARLANE: All right. Everybody  
15 ready? Good. Okay, so we're going to start with the Staff Panel and  
16 hear Staff's views and analysis on research and test reactors. So, I'll  
17 turn things over to Mike Johnson, who is acting Executive Director for  
18 Operations.

19 MR. JOHNSON: Thank you, Chairman. Good morning,  
20 Chairman and Commissioners.

21 The Staff is here today to provide an update on  
22 research and test reactor activities. Lawrence Kokajko to my right is  
23 the Director of the Division of Policy and Rulemaking. Lawrence is  
24 going to provide an overview of the licensing and oversight activities  
25 within the Research and Test Reactor Licensing branches.

26 Al Adams is to my left. Al is Chief of the Research and

1 Test Reactor Licensing Branch, and he'll cover efforts to complete the  
2 research and test reactor license renewal reviews and to streamline  
3 future reviews.

4 To his left is Steve Lynch, Project Manager for the  
5 Research and Test Reactors Licensing Branch. He'll discuss the  
6 Staff's progress in developing infrastructure and conducting reviews in  
7 support of medical radioisotope production facility licensing.

8 And, finally, John Adams all the way to my right is the  
9 Senior-Level Advisor for Non-Power Reactors, and he's going to  
10 discuss security aspects of research and test reactors. So with that,  
11 Lawrence will begin our presentation.

12 MR. KOKAJKO: Thank you, Mike, and good morning.  
13 The Research and Test Reactor Licensing Oversight Branch is  
14 overseeing the operation of 31 Research and Test Reactors enabling  
15 these facilities to carry out their missions of education, research, and  
16 service. These branches are responsible for all licensing, inspection,  
17 operator licensing, and security at these licensed facilities.

18 In recent years the responsibilities of these branches  
19 have expanded to include the initial licensing reviews of proposed  
20 medical radioisotope production facilities. Additionally, these branches  
21 have provided project management for the review of the Gerald R. Ford  
22 Class aircraft carrier propulsion plant for Naval reactors and supported  
23 the effort led by the Department of Energy to convert NRC licensees  
24 from high-enriched to low-enriched uranium. Next slide, please.

25 Since beginning operation in the 1950s, Research and  
26 Test Reactors have been important in the advancement of science,

1 engineering, medicine, and education in the United States. As a result  
2 of these research-centric missions the designs of Research and Test  
3 Reactors present unique risk profiles. Accident scenarios analyzed at  
4 these facilities are primarily related to the manipulation of radioactive  
5 materials within the facility which are not expected to result in  
6 radioactive releases to the public.

7 Accounting for the unique purpose and design of  
8 Research and Test Reactor Section 104(c) of the Atomic Energy Act of  
9 1954 requires the imposition of a minimum amount of regulations that  
10 will promote security, protect safety, and permit research and  
11 development.

12 This morning we will elaborate on our  
13 accomplishments, areas of focus, and future plans with respect to  
14 maintaining safety and security at the existing Research and Test  
15 Reactors and the proposed medical radioisotope production facilities.  
16 And not to be superfluous, you're going to find out today why I like this  
17 particular job so much. With that, Al Adams will discuss Research and  
18 Test Reactor License Renewal activities.

19 MR. ALEXANDER ADAMS: Thank you, Lawrence.  
20 Good morning. I'm going to spend the next few minutes updating the  
21 Commission on the activities the Staff has performed to eliminate the  
22 backlog of Research and Test Reactor License renewal applications  
23 since our last briefing with you in March 2012.

24 First, I will briefly describe the events that created the  
25 backlog and contributed to the challenges we face. Next, I will discuss  
26 the steps that have been taken to resolve the backlog, and then I will

1 discuss some of the lessons we have learned from both completed  
2 renewal reviews and those still in progress. Finally, I will describe the  
3 steps we are taking to insure that the backlog is not repeated in the  
4 future. Next slide.

5 The backlog in Research and Test Reactor License  
6 Renewal reviews is related to several historic events. As some of the  
7 earliest facilities licensed by the Atomic Energy Commission, Research  
8 and Test Reactors were among the first to face license renewal.  
9 Initially, these licenses were extended through amendments. In 1976,  
10 the Agency expanded the scope of Research and Test Reactor License  
11 renewal review to be analogous to the reissuance of the license.

12 A large number of 20-year renewals starting expiring in  
13 the late 1990s concurrent with the expiration of 40-year original  
14 licenses. These two groups of renewals coming due in a short period of  
15 time created the seeds of today's backlog. The Staff was working on  
16 these renewals when the attacks of September 11th, 2001 occurred.

17 As the Staff's focus turned to security issues, work on  
18 license renewal stopped, which caused the backlog to grow. The timing  
19 of developing and implementing adequate licensing guidance was  
20 another contributing factor.

21 Prior to the issuance of NUREG-1537 in 1996, there  
22 was neither guidance for licensees in the format and content of renewal  
23 applications, nor for the Staff on the review of applications. This led to  
24 wide variations in the content of safety analysis reports, and in the  
25 review methods and standards applied by the Staff. The renewals and  
26 the backlog are the first developed with adequate format and content

1 guidance and the first review using the Standard Review Plan of  
2 NUREG-1537. Next slide, please.

3 In 2009 in Staff Requirements Memorandum  
4 SECY-08-0161, the Commission directed the Staff to resolve the  
5 Research and Test Reactor License renewal backlog. The Staff  
6 responded by developing a short-term streamlining plan specifically for  
7 reactors with a thermal power level under 2 megawatts which constitute  
8 the majority of Research and Test Reactors. The Staff would focus on  
9 the most significant safety aspects using reactor design, radiation  
10 protection, safety analysis, and technical specifications.

11 For these lower powered facilities this focus reviewed  
12 balances insuring continued safety with enhancing review efficiency.  
13 The five facilities with a thermal power level of 2 megawatts and greater  
14 receive a broader license renewal review following all the technical  
15 areas of the Standard Review Plan outlined in NUREG-1537. This  
16 broader review is also conducted for facilities under 2 megawatts that  
17 request a power increase at the time of renewal. Next slide, please.

18 Research and Test Reactors do not have a regulatory  
19 requirement to periodically update their safety analysis reports. The  
20 ongoing license renewal efforts are an opportunity to develop  
21 comprehensive safety analysis reports that are consistent with the  
22 guidance in NUREG-1537, and have a current NRC Staff safety  
23 evaluation report that clearly articulates why continued operation of the  
24 facility is safe.

25 Similarly, Research and Test Reactors must only  
26 submit the renewal application 30 days prior to the expiration of the



1 license; therefore, the Staff often resolves significant application  
2 deficiencies with a Request for Additional Information in lieu of rejecting  
3 incomplete applications, and potentially causing licenses to expire. Our  
4 planned rulemaking will address these issues for future license  
5 renewals. Next slide, please.

6 As we make progress on license renewals we have  
7 learned a number of lessons. Addressing these issues can add time to  
8 the review and can add to the questions we ask licensees. For  
9 example, initially Staff decided not to review the security, emergency,  
10 and operator requalification plans for facilities undergoing a streamlined  
11 review. We believe that these plans will be adequately maintained  
12 under 10 CFR 50.54 requirements. However, based on issues we  
13 identified in plans we reviewed, we have decided to review the security,  
14 emergency, and operator requalification plans for all of the remaining  
15 reviews.

16 Also, we have found substantial errors during reviews  
17 performed using NUREG-1537. For example, we discovered an error  
18 that reduced the redundancy of safety systems protecting the safety  
19 limit and technical specifications of several reactors. Recently we  
20 discovered a thermal hydraulic code issue when a licensee evaluated a  
21 high-performing bounding core. When our confirmatory calculations did  
22 not replicate the licensee's results we engaged the Office of Nuclear  
23 Regulatory Research to explore what needs to be done to insure that  
24 the codes used for thermal hydraulic analysis of Research and Test  
25 Reactors are applicable to their particular conditions. Some  
26 assumptions made in past reviews were found to be dated when

1 applying NUREG-1537. Next slide, please.

2 For example, older evaluations of accident airborne  
3 radioactive releases from confinement buildings assumed that the  
4 ventilation systems remained in operation and released all of the fission  
5 products to the environment through an elevated stack like the one  
6 pictured here. Consistent with NUREG-1537, licensees now examine  
7 releases of ventilation systems both on and off. We have found that the  
8 optimal configuration for ventilation system operation to keep public  
9 doses as low as reasonably achievable was site-specific, and often  
10 differed from the historical analysis and evaluation. Next slide, please.

11 This slide shows the timeline of license renewal. The  
12 goal is to have every Research and Test Reactor evaluated using  
13 NUREG-1537. This is essential to our long term plan for license  
14 renewal. On this chart, any application greater than two years old is  
15 considered to be in the backlog. As you can see, good progress was  
16 initially made by focusing on the easiest reviews. Some reviews were  
17 made easier by the receipt of high-quality safety analysis reports from  
18 facilities that converted from highly-enriched to low-enriched uranium  
19 fuel. The Department of Energy assisted these licensees in the  
20 conversion safety analysis. As a result, these facilities benefitted not  
21 just from a comprehensive analysis of the reactor, but also from our  
22 evaluation of the conversion analysis which reduced the scope of the  
23 license renewal work that needed to be done.

24 In addition to supporting reactor fuel conversions, the  
25 Department of Energy also assisted some licensees with technical  
26 aspects of the renewal applications. Next slide, please.

1 To summarize, the backlog exists for a number of  
2 historic events and decisions. We're using the methodology developed  
3 to work through the backlog. Our goal is for licensees to have complete  
4 safety analysis reports that are consistent with the guidance of  
5 NUREG-1537. For the Staff, the goal is to have safety evaluations  
6 conducted using the Standard Review Plan.

7 We will continue to work with licensees to insure timely  
8 and quality information is provided in response to Staff's Request for  
9 Additional Information. Our plans for the future are to insure that a  
10 backlog will not happen again.

11 To that end, we are working on a rule to streamline  
12 Research and Test Reactor regulations as directed by the Commission.  
13 We anticipate having a proposed rule completed by March 2016. We  
14 have made significant progress on resolving the backlog. There are  
15 some renewals with more challenges than others, and as you can see  
16 from our lessons learned complex issues can still appear. We will  
17 continue to update you every six months with details of our progress.

18 I will now turn the presentation over to Steve Lynch.

19 MR. LYNCH: Thank you, AI. Good morning.

20 The purpose of this part of the presentation is to  
21 provide the Commission an update on the status of the Staff's efforts to  
22 develop and implement an effective licensing framework for facilities  
23 proposing to produce molybdenum-99. The Staff first briefed the  
24 Commission on this subject in May of 2012. At that time, the Staff had  
25 interacted with a number of potential applicants but had yet to receive  
26 an application. Since then, the Staff has held numerous public

1 meetings, developed guidance for the development of applications,  
2 issued a direct Final Rule, and has received two construction permit  
3 applications. Today's discussion will demonstrate the Staff's  
4 commitment to the continuous support of an establishment of the  
5 domestic supply of molybdenum-99 in the United States by highlighting  
6 Staff accomplishments, current projects, and preparations for future  
7 licensing actions. Next slide, please.

8 Molybdenum-99 decays into technetium-99  
9 metastable which is used as a radiopharmaceutical in approximately  
10 50,000 medical imaging procedures daily in the United States  
11 accounting for about one-half of global demand. The half-life of  
12 technetium-99 metastable is only six hours, which is long enough for  
13 effective diagnosis, but also short enough to minimize patient radiation  
14 exposure. Currently, there is no domestically produced supply of  
15 molybdenum-99. Approximately half of the United States' current  
16 supply comes from the Canadian National Research Universal Reactor,  
17 which is set to cease production in 2016.

18 In recent years, domestic availability of  
19 molybdenum-99 has been disrupted due to extended maintenance  
20 shutdowns at several aging international reactors. Due to this  
21 dependence on international supply, the United States has set national  
22 policy objectives to establish a domestic supply of molybdenum-99. In  
23 support of these national policy objectives, the NRC is prepared to  
24 receive and review any application submitted in accordance with the  
25 provisions of Title 10 of the Code of Federal Regulations. Next slide,  
26 please.

1                   In preparation for and during the reviews of  
2 applications, the Staff has communicated with applicants, the public,  
3 and federal, state, and local governments. Since 2012, the NRC has  
4 held numerous public meetings with potential and current applicants.  
5 These meetings promote engagement between the NRC and  
6 applicants establishing a working relationship that supports the  
7 development and submission of high-quality applications that the Staff  
8 will be able to review in an effective and timely manner.

9                   These meetings have also served as a valuable forum  
10 for members of the public to learn more about the NRC's review  
11 process, as well as the technical details of the applicant's proposed  
12 project. Engagement with federal, state, and local governments has  
13 also been important to the success of developing a licensing  
14 infrastructure for medical radioisotope production facilities. Staff has  
15 engaged with other federal entities through the Office of Science and  
16 Technology Policy, and has also held meetings with state and local  
17 governments.

18                   Internal communication has also enhanced Staff  
19 licensing efforts. An inter-office working group meets monthly to  
20 address the technical and licensing challenges associated with new  
21 technologies requiring a breadth of technical expertise. Working group  
22 membership extends across the Agency, and includes Staff from the  
23 Offices of Nuclear Reactor Regulation, Nuclear Materials, Safety, and  
24 Safeguards, Nuclear Security and Incident Response, New Reactors,  
25 General Counsel, and Nuclear Regulatory Research, as well as  
26 Regions II and III.

1           The working group developed Interim Staff Guidance  
2           augmenting NUREG-1537 to assist applicants in preparing  
3           applications, and the working group also continues to assess the  
4           applicability of existing and proposed regulations to these new medical  
5           radioisotope production facilities. Next slide, please.

6           To date, the NRC has received 11 Letters of Intent  
7           from companies interested in producing molybdenum-99. The majority  
8           of these proposals involve the fission of low-enriched uranium and  
9           either reactor or non-reactor technologies. Designs have featured both  
10          solid clad and aqueous solution targets for use at both new and existing  
11          facilities. While there are significant variations in the methods proposed  
12          to fission uranium, all of these facilities feature hot- cell structures for  
13          the chemical separation of molybdenum-99 from other fission products.

14          The NRC may also license some natural  
15          molybdenum-based technologies using accelerators assuming that  
16          these facilities do not fall under Agreement State jurisdiction. Staff  
17          anticipates that most NRC licensed molybdenum-99 facilities would be  
18          licensed as utilization or production facilities under 10 CFR Part 50.

19          The proposed utilization facilities share many  
20          characteristics with existing non-power reactors. For example, like  
21          most existing non-power reactors the thermal power ranges at these  
22          facilities are not expected to exceed 10 megawatts. Consequently,  
23          these facilities share many similar safety and technical considerations  
24          with respect to fission heat removal and decay, and accident scenarios.

25          A few facilities could be licensed under 10 CFR Part 70  
26          or Part 30. In these cases, the Office of Nuclear Material Safety and

1 Safeguards or the Regions will assume the project management and  
2 technical lead for the reviews while the Office of Nuclear Reactor  
3 Regulation will continue to coordinate activities across the Agency.  
4 Next slide, please.

5 In 2013, SHINE Medical Technologies submitted a  
6 two-part construction permit application proposing to produce  
7 molybdenum-99 through uranium fission and eight accelerator-driven  
8 sub-critical irradiation units and three hot-cell structures. The figure on  
9 the left shows an early conceptual rendering of one of SHINE's  
10 proposed irradiation units.

11 After an initial review of SHINE's application, Staff  
12 determined that while each SHINE irradiation unit shared many  
13 characteristics of non-power reactors, they did not meet the definition of  
14 a nuclear reactor and could not be licensed as utilization facilities.

15 Subsequently, Staff recommended and the  
16 Commission published the direct Final Rule on October 17th, 2014 that  
17 adds SHINE's irradiation units to the definition of utilization facility in 10  
18 CFR Part 50. The Staff is currently reviewing SHINE's responses to  
19 Requests for Additional Information and is preparing both a draft safety  
20 evaluation report and draft environmental impact statement.

21 Northwest Medical Isotopes submitted Part One of its  
22 two-part construction permit application consisting primarily of its  
23 environmental report in November of 2014. The Staff is currently  
24 performing its acceptance review of this application.

25 Northwest Medical Isotopes proposes to fabricate  
26 low-enriched uranium targets at existing research reactors. The figure

1 on the right illustrates an example of what these targets could look like.  
2 Following irradiation, the targets will be returned to Northwest Medical  
3 Isotopes for hot-cell processing to separate out the molybdenum-99.  
4 Staff anticipates receiving the second and final portion of Northwest  
5 Medical Isotopes' construction permit application by mid-2015.

6 Oregon State University's license amendment  
7 application requests approval to place experimental medical  
8 radioisotope production targets in the Oregon State University trigger  
9 reactor for the explicit purpose of demonstrating molybdenum-99  
10 production in a small nuclear reactor. The Oregon State University  
11 reactor pool is depicted in the lower figure. Staff is currently working on  
12 the safety evaluation report for this request. Next slide, please.

13 This flow chart highlights the construction permit  
14 application review process which includes a safety review and  
15 environmental review. Ultimately, these reviews will result in the  
16 publishing of a final environmental impact statement or environmental  
17 assessment, and a safety evaluation report. In addition, the decision to  
18 issue a construction permit includes an independent review by the  
19 Advisory Committee on Reactor Safeguards and a mandatory hearing  
20 conducted by either the Commission or the Atomic Safety and  
21 Licensing Board, as determined by the Commission. There could also  
22 be a contested hearing if an intervention is granted.

23 In support of the timely establishment of a domestic  
24 supply of molybdenum-99, the Staff has prioritized these reviews. The  
25 Staff expects each review from the time of docketing to the completion  
26 of the safety and environmental evaluations to be completed within 18



1 to 24 months. The Staff based this estimate on the complexity,  
2 uniqueness, and completeness of anticipated applications. The Staff is  
3 continuously looking for efficiencies to condense review schedules.

4 The review process for an operating license will be  
5 similar; however, a hearing will not be held unless a petition to intervene  
6 is granted. Also, a narrow scoped environmental review will be  
7 performed evaluating only different and/or new information that has  
8 become available since the publication of the final environmental  
9 impact statement. Next slide, please.

10 Since last meeting with the Commission in 2012, the  
11 Staff has made significant progress in both the development of a  
12 licensing framework, including the issuance of Interim Staff Guidance  
13 and the publication of a direct Final Rule, and in the review of two  
14 construction permit applications. However, there is still a lot of work  
15 ahead. In addition to performing timely reviews of current applications,  
16 the Staff is preparing for the potential of an additional application within  
17 the next year. Furthermore, our focus on infrastructure development is  
18 expanding to include the creation of a construction inspection program  
19 and preparing for future operating license applications.

20 We look forward to updating the Commission in the  
21 future on the status of our efforts in medical radioisotope production  
22 facility licensing. I will now turn the presentation over to John Adams.

23 MR. JOHN ADAMS: Thank you, Steven. Good  
24 morning. Today, I would like to briefly describe the unique aspects of  
25 Research and Test Reactor Security. Next slide, please.

26 The Office of Nuclear Reactor Regulation holds the

1 responsibility to insure Research and Test Reactors are and remain  
2 secure. This is accomplished through the implementation of three  
3 regulatory programs and processes, the first of which is licensing  
4 process based on licensee compliance with a graded set of regulatory  
5 requirements for information, physical, and personnel security.

6 Second is the implementation of a graded security  
7 inspection program to verify continued compliance with regulatory  
8 requirements by the licensees. And third is the assessment of the threat  
9 environment and intelligence information by the Office of Nuclear  
10 Security and Incident Response.

11 The grading of Research and Test Reactor facilities is  
12 based on the severity of the regulatory consequences that could result  
13 from a theft or sabotage challenge to the facility by an adversary. The  
14 greater the potential hazards, the more robust the security  
15 requirements which must be established and maintained by the facility  
16 operators.

17 Criteria considered in grading includes type and  
18 quantity of nuclear and radioactive materials, enrichment of the nuclear  
19 materials, dose rate of irradiated and spent fuel, and the maximum  
20 licensed power level. Next slide, please.

21 Section 103 of the Atomic Energy Act authorizes the  
22 Commission to license utilization and production facilities useful in the  
23 conduct of research and development. It also directs the Commission to  
24 impose the minimum amount of regulation necessary to protect the  
25 health and safety of the public, promote the common defense and  
26 security, and permit widespread diverse research and development.

1           The expectation for minimum regulation is unique to  
2 the licensing of Research and Test Reactors. Meeting this expectation  
3 is challenging and requires significant effort on the part of the NRC  
4 Staff. The operators of Research and Test Reactors also have an  
5 awareness of Section 104(c), and share a vested interest in its  
6 application. It is important that each increase in regulation be  
7 accompanied with an adequate justification. Next slide, please.

8           Meeting Section 104(c) requires the application of a  
9 balanced regulatory approach both in the case of security and for  
10 safety. Adequate security is achieved by an accurate assessment of the  
11 threat and an implementation of appropriate protective measures to  
12 counter that threat. Considering only the threat and protections against  
13 the threat in isolation from the achievement of the mission can constrain  
14 the conduct and widespread and diverse research and development.  
15 That is why it's necessary that the Staff consider the threat, protective  
16 measures, and the Research and Test Reactors' mission in the  
17 establishment of a balanced regulatory approach. When a change in  
18 these factors occurs it can impact the establishment of the balance, as  
19 was the case following the events of 9/11. Next slide, please.

20           In addition to the Staff licensing and inspection  
21 responsibilities, the Staff has devoted significant resources to focus on  
22 security-related rulemakings, such as Part 37, and more recently with  
23 the Enhanced Security of Special Nuclear Materials Rulemaking  
24 Regulatory Basis development for Part 73. Staff focus on these  
25 rulemakings is intent in preventing unintended consequences from  
26 adversely impacting facility operations.

1                   In order to succeed in this effort it is important that the  
2 Staff receive input from the regulated community and the public. To that  
3 end, the Staff has put significant effort into outreach activities through  
4 numerous public meetings, presentations at widely attended  
5 conferences, and site visits by the NRC Staff. A good example of  
6 successful outreach effort to the regulated community and the public  
7 was the development of the Part 73 Draft Regulatory Basis. The Office  
8 of Nuclear Reactor Regulation and the Office of Nuclear Security and  
9 Incident Response held multiple public meetings, several of which were  
10 specifically focused on Research and Test Reactors to discuss in detail  
11 the proposed Part 73 changes being considered by the Staff.

12                   Outreach efforts also included a detailed technical  
13 presentation on the regulatory basis content at the National  
14 Organization of Test Research and Training Reactors annual meeting  
15 last August. This was followed by one-on-one discussions with the  
16 meeting attendees which had specific questions, comments, and  
17 concerns. The Staff also visited multiple Research and Test Reactor  
18 sites, including the three largest facilities that still operate with  
19 highly-enriched uranium fuel in order to observe firsthand how  
20 proposed changes could impact those facilities, and to gain a clear  
21 understanding of the facilities' missions.

22                   It is also important to note the active role that the  
23 regulated community has taken in reviewing the proposed changes to  
24 Part 73, assessing the potential impact on their respective facilities, and  
25 communicating comments and concerns to the Staff. Their participation  
26 has significantly contributed to the development of a Part 73 Draft

1 Regulatory Basis.

2 The Staff has also maintained an awareness of  
3 previous Commission direction as it applies to Research and Test  
4 Reactor security, including Commission direction provided in the Staff  
5 Requirements Memorandum for SECY-06-0011, Staff recommendation  
6 regarding security at research reactors, and the Staff Requirements  
7 Memorandum for SECY-09-0123, Material Categorization and future  
8 fuel cycle security-related rulemaking.

9 As you've heard earlier in this presentation, medical  
10 radioisotope production facility licensing is one of our highest priorities.  
11 Highly important to this effort is insuring that those facilities that use  
12 low-enriched uranium in the production of a radioisotope are secure. To  
13 that end, the Office of Nuclear Reactor Regulation is working closely  
14 with the Office of Nuclear Security and Incident Response and the  
15 applicants to insure an adequate regulatory framework exists for those  
16 specialized facilities and it is clearly understood by the facility designers  
17 and operators. Next slide, please.

18 I would like to conclude my remarks today with a brief  
19 summary of two security-related accomplishments applicable to the  
20 Research and Test Reactors. First, the Staff recently completed an  
21 assessment of the cyber threat for Research and Test Reactors. That  
22 assessment concluded that the licensees have implemented an  
23 adequate level of protection against a cyber security threat given the  
24 current level of use of the digital assets at those facilities.

25 Second is the successful completion of an  
26 International Atomic Energy Agency International Physical Protection

1 Advisory Service mission in October of 2013. The U.S. Government  
2 hosted the mission that included international security experts from 10  
3 countries. These experts conducted an examination of the NRC's  
4 regulatory framework for the physical protection of nuclear materials,  
5 and its implementation.

6 The NRC's preparations for this mission was led by the  
7 Office of International Programs with extensive support from the Office  
8 of Nuclear Security and Incident Response, Nuclear Reactor  
9 Regulation, and General Counsel. Nearly all the NRC organizations  
10 played an essential role in the successful completion of this mission.  
11 The mission provided international recognition that the NRC's  
12 regulatory framework for physical protection of nuclear materials met  
13 the intent of or exceeded the current international recommendations.  
14 The mission also recognized 21 good practices, a record number, many  
15 of which were related to physical protection of Research and Test  
16 Reactors.

17 This concludes my prepared remarks, and I will return  
18 the presentation back to Lawrence.

19 MR. KOKAJKO: Thank you, John. I hope you have an  
20 appreciation that the Staff is committed to eliminating the backlog of  
21 Research and Test Reactor License renewal and streamlining the  
22 regulatory framework so that this does not happen again, and that we  
23 are dedicated to supporting the national policy objective of establishing  
24 a domestic supply of molybdenum-99 by performing timely and  
25 thorough reviews of all submitted applications.

26 Finally, we look forward to continued improved

1 methods to insure adequate security at the Research and Test  
2 Reactors while maintaining the operator's ability to accomplish their  
3 research and development mission.

4 Thank you for your time this morning. We look forward  
5 to answering your questions, and I turn it back to you, Mike.

6 CHAIRMAN MACFARLANE: Thank you guys very  
7 much. Commissioner Ostendorff will again start off the questions.

8 COMMISSIONER OSTENDORFF: Thank you,  
9 Chairman. Thank you all for your presentations, very helpful.

10 I think I'm going to start out with AI. You know, you  
11 were I think in the room for the first panel presentations. Is that correct?

12 MR. ALEXANDER ADAMS: Excuse me?

13 COMMISSIONER OSTENDORFF: You heard the first  
14 panel <sub>B-</sub>

15 MR. ALEXANDER ADAMS: Yes, I did.

16 COMMISSIONER OSTENDORFF: Okay. I just want to  
17 make sure I didn't catch you by surprise on this. For the license renewal  
18 experiences at MIT and the University of Missouri we heard from two  
19 panelists earlier that expressed, you know, I think respectfully some  
20 concerns on the timing and so forth. I want to maybe just get to two  
21 specific aspects of that.

22 One of the things I think we heard from both witnesses  
23 dealt with the Request for Additional Information, RAI process. And I'm  
24 just curious, you know, has there been any adjustment or guidance that  
25 has been given to the license <sub>B-</sub> to the RTR license renewal Staff that  
26 would perhaps provide them some additional direction as to how to

1 proceed with RAIs, or from a process standpoint, or otherwise?

2 MR. ALEXANDER ADAMS: There is guidance in this  
3 area and we keep refining it, but there <sub>B</sub> - I don't think there's anything  
4 fundamentally flawed with the RAI process; that RAIs are asked  
5 because we can go back to NUREG-1537 and find out something is  
6 missing or incomplete. We do not ask RAIs for intellectual stimulation or  
7 out of curiosity. We try not to do that.

8 I think one of the best sets of RAIs I've ever seen was a  
9 set of RAIs that went to SHINE as part of their review where each RAI  
10 had a clear discussion of NUREG-1537, what NUREG-1537 was  
11 asking for, and then the question led to either something that was  
12 missing or something that was not clear from NUREG-1537. So, the  
13 direction to the Staff is that every RAI that gets asked has to have a  
14 basis that goes back to our guidance. I think that's the most important  
15 part of it.

16 COMMISSIONER OSTENDORFF: Okay. Well, one of  
17 the statements that Dr. Newton made was along the lines that the  
18 license renewal process is perhaps more complex than warranted by  
19 safety considerations, and I'm going to give you a chance to respond to  
20 that, because I think we heard from both MIT and Missouri the same  
21 message, that there are some queries by the Staff that were not rooted  
22 in a safety consideration. But please, I want to give you a chance.

23 MR. ALEXANDER ADAMS: Again, I think the RAIs go  
24 back to NUREG-1537. NUREG-1537 was developed in the '90s by the  
25 Staff at the direction of the Commission because there was a concern  
26 that there was no written guidance and everything was basically in



1 some limited number of persons' heads. So, we wrote this guidance  
2 document, which was a document that was released in draft form to the  
3 community to give us comments on, and all the comments that we  
4 received on the document were considered and changes were made to  
5 the document.

6 The other guidance that was mentioned was  
7 ANS-15.1. That's a consensus standard on what tech specs for  
8 research reactors should look like. NRC has a seat at that table, but  
9 that's mainly the community that develops that standard, that ANS  
10 Standard. That standard is addressed in NUREG-1537, and an entire  
11 chapter is looking at that standard and describing how you can put  
12 together an acceptable set of tech specs using that standard and  
13 NUREG-1537.

14 We ask RAIs for a number of reasons. And as you  
15 heard, some issues that we discovered were, you know, that had  
16 significant safety significance to them, some areas it's just where what  
17 we considered to be the basis for a modern safety evaluation report  
18 was not there. You know, you heard comments about typos. What I tell  
19 the folks working on these reviews, you know, if CAP is spelled with a K,  
20 you know, we're not going to write an RAI addressing that. However, if  
21 there's a greater than sign which looks like it was a typographical error  
22 and it actually was a less than sign appears in the SER, that we have to  
23 ask a question about because at the end of the day we want to have a  
24 document that's accurate and our evaluation that explains to the public  
25 why the document is accurate. So, there's a lot of reasons we ask  
26 questions, and I was a licensee for a number of years and, you know, I

1 can understand when you get 200 questions in the mail, it could be  
2 daunting.

3 COMMISSIONER OSTENDORFF: Well, yes, I think,  
4 you know, the experience in these two cases presented in the first  
5 panel, most people would ask some questions about why did it take so  
6 long, why was it so complex? I'm not here to criticize any Staff effort, but  
7 I think there are some hard questions that I think you probably have  
8 already asked. But I guess I would encourage you, and you've probably  
9 already done this, is to make sure that when B- you know, the first  
10 panel, two witnesses mentioned that there are issues raised outside of  
11 real safety concerns, I think it's important for us as a regulator to  
12 understand where they're coming from. I'm not going to say we have to  
13 agree with their position, we need to understand the basis for their  
14 comment.

15 I resonated and I mentioned that the B- that I support  
16 the NRC Staff having a robust site visit approach to B- rather than  
17 casting emails around from thousands of miles away, getting out there  
18 at the site and seeing facilities. And I'm curious as to what the  
19 expectation is for the license staff to actually go to the sites and sit down  
20 around the table and have a chat. Can somebody address that issue?

21 MR. JOHNSON: Well, let me just start more broadly,  
22 and then Lawrence can weigh in. And I wanted to actually as a part of  
23 the last question you asked make this statement, and it is that we have  
24 broadly taken very seriously what the RAIs do for us, and enabling us to  
25 complete the licensing process. And we've continued, I think, to look  
26 very closely at how we do that process, and continue to make

1 improvements.

2 I was coming back last week from a session where we  
3 were doing piloting training for reviewers, for example, not in the RTR  
4 community, but more broadly with respect to how we do licensing  
5 reviews, to focus on getting better, continuing to get better at the review  
6 process, including the RAI process. It's important to us that we get that  
7 right, and we're continuing to improve that.

8 We have also been very creative. In addition to RAIs,  
9 encouraging site audits. You've seen those across our business in  
10 many, many areas. For example, most recently probably at Fukushima,  
11 associated with those activities, you know that we send folks out in the  
12 field. Our reviewers are in the field looking at facilities, getting firsthand  
13 insights, and that helps us with the overall getting information that we  
14 can capture and move forward with the licensing process. So, we  
15 continue to engage in all those activities going forward.

16 Lawrence, I don't know if you want to add?

17 MR. KOKAJKO: Yes, I do. Thank you.

18 First of all on the RAIs, I'd like to sort of modify the  
19 remarks just a little bit. It's not just 1537, it's also that we have a  
20 regulatory basis that's grounded in the regulation itself, or in the act, so  
21 that when we ask a question it has some real meaning from our  
22 regulatory standpoint.

23 The other piece that I would like to say is that I can't  
24 really address the MIT history because I wasn't involved then, but at the  
25 time, if I recall correctly from listening to others, the number of Staff that  
26 were dedicated to the MIT was rather small, and we had the events of

1 9/11 that focused our attention in a different manner at the time. And I  
2 note that in the Missouri case, I believe the event in Japan also  
3 refocused our efforts there.

4 COMMISSIONER OSTENDORFF: Yes, but I  
5 understand that, and we're out of time here, but I think we have to be  
6 realistic and look at the metrics that we actually achieved, and ask  
7 ourselves some hard questions.

8 MR. KOKAJKO: And I would ask that if you were to  
9 make some comparisons, I believe the SHINE example is where we  
10 made those changes. We made the changes and improvements to the  
11 processes, and we've moved forward in I think a more meaningful way.  
12 And I believe our experience has been with the current backlog as we're  
13 reducing it shows that we made that progress.

14 COMMISSIONER OSTENDORFF: Okay. John, I'm  
15 going to ask you a quick question here. On your Slide 21, you made a  
16 comment that meeting the Atomic Energy Act expectations for B- under  
17 Section 104(c) are challenging and require significant effort on the part  
18 of the NRC Staff. Do you believe from a security perspective that we are  
19 B- that the effort for security of research and test reactors is  
20 appropriately risk-informed?

21 MR. JOHN ADAMS: Yes, I do. I believe it's  
22 risk-informed to the point that we've spent a lot of resources looking at  
23 the consequences of these facilities. As you know, there's a rather large  
24 spectrum from the smallest to the largest, and the consequences also  
25 have a very similar range. So, we've spent a lot of activity trying to  
26 quantify those consequences, and appropriately apply the graded

1 approach in our security regulations, and the higher requirements on  
2 those facilities that do present those consequences, so it's not  
3 necessarily a Probabilistic Risk Assessment type. That has not been  
4 done for safety or for security for that matter, but we B- it's more of a  
5 consequence analysis that we've completed.

6 In fact, that period of no activity that some of you have  
7 noted earlier between 2001 and 2006, there was significant security  
8 assessment work done during that period of time, and that attracted a  
9 lot of the resources that we had in the division at that time.

10 COMMISSIONER OSTENDORFF: Okay, thank you.  
11 Thank you all.

12 CHAIRMAN MACFARLANE: Okay. Commissioner  
13 Baran.

14 COMMISSIONER BARAN: Thanks. Thank you all for  
15 your presentations.

16 I wanted to start with medical isotopes and maybe talk  
17 with Al and Steve about that. So, you mentioned in your presentation, I  
18 think in Steve's presentation that NRC has received 11 Letters of Intent  
19 for facilities to produce medical isotopes. I think two of those have been  
20 suspended, but they are nine that could be reasonably anticipated. Can  
21 you walk us through how you're going to insure that we're ready to  
22 review as many as nine applications in a timely way?

23 MR. LYNCH: Yes, I'd be happy to talk about that. So,  
24 one of the things that we've done to insure that we have proper  
25 resources available is we have developed generic communications,  
26 specifically regulatory issue summaries that we've issued to the

1 community, and those B- and potential applicants saying if you're  
2 interested in coming to the NRC for a license, if you can send us letter  
3 that tells us the type of license you would like to apply for, when you  
4 think you're going to apply for it, any unique aspects of the technologies  
5 that you think might be involved in this, so that the Staff can be ready for  
6 these applications to come in.

7 We also like to emphasize the pre-application process  
8 and what that generally entails are public meetings. Public meetings  
9 have been valuable tools for us to get these applicants to come in and  
10 talk to us about their designs. And we can get an idea of how familiar  
11 they are with the NRC's regulations and expectations, and we can get a  
12 better sense of their technologies. And from these interactions we can  
13 better plan and get an idea of when these applications may come in so  
14 that we're ready for them.

15 COMMISSIONER BARAN: And do you think you have  
16 adequate resources to timely examine a number of medical isotope  
17 applications?

18 MR. KOKAJKO: Commissioner, yes, we believe for the  
19 current understanding of the applications that should come in we are  
20 sufficiently resourced in '15 and '16. And we believe that if there is a  
21 change or fact of life change, we can have the ability to come and get  
22 more, but we also have B- we think we have a robust set of skill sets  
23 that are now on the molybdenum work, and if we do need further we  
24 believe we can leverage across the Agency to gain those additional skill  
25 sets that we need.

26 MR. JOHNSON: And, of course, I guess the last part

1 of that would be B- and we propose in the budget going forward what  
2 we think is B- what will likely materialize and offer for the Commission's  
3 consideration what they will fund. As was currently answered we are  
4 appropriately funded, we believe, today.

5 MR. ALEXANDER ADAMS: Can I just make one  
6 comment?

7 COMMISSIONER BARAN: Sure.

8 MR. ALEXANDER ADAMS: The maturity of all these  
9 Letters of Intent vary widely from applications that are in house being  
10 worked on to folks that have sent us a letter and we haven't heard from  
11 them since then, folks that have come in once and talked to us. So, we  
12 encourage communication so that we know when a potential applicant  
13 has reached that point where we need to start focusing attention,  
14 resources. Do we need guidance for that particular technology? So, it's  
15 monitoring the status of the applications and being able to respond to  
16 them as they mature.

17 COMMISSIONER BARAN: And that kind of raises  
18 the question of the application acceptance process and making sure  
19 that we have a process in place so that you are reviewing high-quality  
20 applications. Can you talk a little bit about that?

21 MR. LYNCH: Yes. So, as far as the acceptance  
22 process, so when we get the application in B- so, for the two  
23 construction permits that we've got in, our starting point is  
24 NUREG-1537 and the Interim Staff Guidance that we've developed for  
25 aqueous homogeneous reactors and production facilities that will be  
26 used for chemical separation of fission products. But one of the

1 challenges with this process is the guidance we have was written for  
2 operating facilities, so it's taken the Staff a little bit of extra effort to  
3 extrapolate from all the requirements that are necessary for operation  
4 down to what do we need to know for construction? And we want to  
5 make sure that we are meeting the spirit of 10 CFR 50.34 which sets  
6 out the requirements for what's needed for a construction permit. And,  
7 generally, the regulations require preliminary data and research for  
8 issuing a construction permit, so we're trying B- we're working to scale  
9 down acceptance requirements that are in existing guidance, but that's  
10 our starting point.

11 MR. ALEXANDER ADAMS: And can I add that we go  
12 through the acceptance review, and in the case of SHINE we did find an  
13 issue where they were asked to give us additional information before  
14 we docketed the application.

15 COMMISSIONER BARAN: So, it's pretty clear at this  
16 point SHINE is kind of the first mover. They submitted their application  
17 first. We're kind of well along in that review.

18 Commissioner Svinicki raised this concern about is our  
19 review B- is the Staff's review of that application going to slow down if  
20 additional applications come in? Can you all talk about that, and  
21 whether that's something we should be concerned about?

22 MR. JOHNSON: Sure, Commissioner. As was stated  
23 in our talking points, we believe that review of the radioisotope  
24 production facilities is budgeted by the Commission, is a priority, it will  
25 remain a priority, and we would go back to the Commission before we  
26 would adjust that given something that would happen. I can't imagine



1 what, actually, in implementation year. But no, it is a priority, we are  
2 working in accordance with the direction that we've been given by the  
3 Commission to support the priorities of those reviews.

4 MR. KOKAJKO: And I might add that, as Alan said, the  
5 more mature applications or the more mature groups that are coming  
6 in, we believe we have sufficient resources to cover that right now.

7 COMMISSIONER BARAN: Good. And in terms of, you  
8 know, there was a question on the first panel from Dr. Piefer about a  
9 schedule for SHINE. Can you talk a little bit about the status of that, and  
10 what the thinking is on scheduling for SHINE?

11 MR. LYNCH: Yes. So, in terms of the schedule we're  
12 working on preparing a publicly available schedule in conjunction with  
13 the Notice for Opportunity for Hearing. The reason we hadn't issued  
14 that yet is we were waiting until we had the direct final rule that put  
15 SHINE's irradiation units under the definition of utilization facility. We  
16 wanted to make sure that they were going <sup>B</sup> - we had a firm regulatory  
17 process to go forward with before we went too far down one path and  
18 had to go back and redo work.

19 The direct final rule will go into effect at the end of this  
20 month, and we plan on having a schedule ready to go out at that time.  
21 However, while a public schedule has not been published, we are still  
22 actively working on the application. What we've communicated to  
23 SHINE is that our goal is to be at the ACRS in June for a Subcommittee  
24 meeting, and followed by Full Committee in July, and we are on the  
25 ACRS' calendar for that. So we are working to have our Draft Safety  
26 Evaluation Report ready by May of 2015.

1 COMMISSIONER BARAN: More broadly taking a step  
2 back from SHINE and just looking at the medical isotope production  
3 applications that we're expecting or that may come, what do you see as  
4 the biggest challenges associated with timely review of those  
5 applications, and what are you all doing to kind of proactively get  
6 yourself ready for that?

7 MR. LYNCH: Yes. So, I think there's three things that  
8 are the main challenges we have with reviewing these applications. I'll  
9 list them first, then talk about how we're addressing them. I think quality  
10 of applications can impact the timeliness of our reviews, timeliness of  
11 the responses to the Staff's Request for Additional Information can  
12 impact that, as well as the work that goes into developing infrastructure  
13 and ensuring that appropriate regulations apply at these facilities.

14 As far as making sure that we have high-quality  
15 applications, communication is essential. You know, we meet with  
16 applicants frequently to discuss the status of their applications, make  
17 sure that they understand our expectations, we know what's coming so  
18 that we get the best quality product when they submit it.

19 As far as timeliness of responses to RAIs, part of that's  
20 making sure that we ask good questions. I believe that if you ask a  
21 vague question you get a vague answer, and we don't want to set up  
22 any of our applicants to fail when we issue them RAIs. It's not a B - we're  
23 not testing their ability to respond to what they think we're thinking, so  
24 we're not going to ask any visceral or superfluous RAIs. We make sure  
25 that there's a clear regulatory basis for each RAI that we ask, and after  
26 we developed our first set of RAIs for SHINE, after they got them we

1 picked up the phone and had a clarification call just to say do you  
2 understand the questions we're asking? And we went one by one  
3 through them, and I think that was a very productive call. And I think we  
4 got better responses as a result of that.

5 And on the other side of that, when we got their  
6 responses to the RAIs in, we had another clarification call where the  
7 responses that we didn't quite understand what they were responding  
8 with, we thought maybe they didn't quite understand what we were  
9 asking, we clarified that and figured out what additional RAIs we need,  
10 so I think that's really pushing this process forward.

11 And then as far as addressing the regulatory approach,  
12 I think we are doing that adequately. You know, the Staff after reviewing  
13 SHINE's application initially recognized that we thought that they  
14 needed to be licensed under 10 CFR Part 50 as a utilization facility, so  
15 we worked on the rulemaking for that.

16 And we want to make sure that, you know, that the  
17 issuance of a construction permit and there isn't going to be a fortuitous  
18 design of this facility. It's going to be made on sound decisions and we  
19 don't want SHINE to have to tear down their facility after construction to  
20 go forward with the operating license. We want to make sure that Staff  
21 is confident in the designs put forward at the construction stage, that we  
22 do have processes, there are construction amendments that could be  
23 applied for if there are changes, but we want to be confident when we  
24 tell them that we've made a decision that they can go forward, that we  
25 believe that they are on the road to success.

26 COMMISSIONER BARAN: Thank you.

1 CHAIRMAN MACFARLANE: Commissioner Burns.

2 COMMISSIONER BURNS: Thank you. Let me talk  
3 about for a minute given the B- I think some of what I heard on the first  
4 panel regarding the stability of NUREG-1537, document is about 20  
5 years old. It's been some time since I've looked at it, but describe for me  
6 to what B- in effect, it's the de facto regulation. That's what you heard. I  
7 know well, and articulate well the principle that Reg Guides and  
8 NUREG documents like that are not legally binding; nonetheless, I think  
9 what you hear that, in effect, they are. In effect, that's what the Staff  
10 applies. So, what I'd like to hear is to what extent is that NUREG what I'll  
11 call stable in terms of what types of things are contemplated that might  
12 be changed in it, or those types of things that might have an impact on  
13 the regulated community?

14 MR. ALEXANDER ADAMS: Sure. So, NUREG-1537  
15 is a living document. We are doing a top to bottom review of it at this  
16 point in time related to our long-term plans for license renewal to make  
17 sure the document has incorporated the lessons we've learned. For  
18 example, right now there's a ISG for Chapter 7 which is Instrumentation  
19 and Control, which has expanded what the document says in the area  
20 of Digital I&C to help in that area.

21 When we were writing the ISG for Liquid  
22 Homogeneous Reactors, the panel that the Office of Research put  
23 together looked at the entire document and came back and told us that  
24 they thought the document had stood the test of time rather well, but the  
25 document is always open for improvements and changes. For example,  
26 one of the feedbacks we got from the licensees concerned pH and

1 conductivity measurements in open pool reactors, that relationship.  
2 When the licensees came to us with some technical information we  
3 went and we looked into the issue, we had the NRC technical experts  
4 look into this issue and the result is that we're changing our approach in  
5 that area to if certain conductivity measurements are met licensees for  
6 open pool reactors don't have to measure pH. So, it is a living document  
7 and we are looking for ways to improve it, and licensees are always  
8 welcome to come to us and say hey, you know, here's something I've  
9 seen in NUREG-1537 that you guys need to think about, for example,  
10 the pH and conductivity issue.

11 COMMISSIONER BURNS: Okay, thanks. One of the  
12 other things I heard, and I think both in the Staff presentations and the  
13 first panel was a B- I think the issue comes out that one of the  
14 challenges I think you all have for license renewal for some of the  
15 particular applications has derived from the fact that the safety analyses  
16 reports can be very old for some of the facilities and, in effect, unlike in  
17 the power reactor area where you have B- basically, you have a living  
18 FSAR, if you will, that you really B- it sounds like we really don't have  
19 that with respect to the Research and Test Reactors. So, what I'm  
20 curious as to whether you're contemplating outside of perhaps renewal,  
21 at least some update process. I'm not suggesting particularly that we're  
22 adopting a 50.59, but I mean in the power reactor area that's certainly  
23 the model where changes are made to the facility where certain new  
24 requirements are incorporated either at the licensees' behest or the  
25 NRC's behest, that the SAR is updated. Because it seemed to me from  
26 part of what I heard is some of the trouble we had was, sort of

1 recovering looking at in the year 2000 or the year 2010, what the facility  
2 looks like versus a licensing basis that might have been in the 1950s or  
3 '60s, or during the renewal period in the 1980s. So, I was curious as to  
4 whether B - what kind of contemplation you had in terms of dealing with  
5 the SAR?

6 MR. ALEXANDER ADAMS: You bring up a number  
7 of good points, and if you look at where we are historically, say analogy  
8 as to power reactors, we're where the power reactors were in the 1970s  
9 when the Standard Review Plan came into being, you know, the GDC  
10 came into being, and we looked back at the existing power plant SARs  
11 and said do they meet the Standard Review Plan? That's sort of where  
12 we are with these facilities looking back at it.

13 You know, a question was asked about what's the  
14 difference between SHINE and the license renewals? We had asked a  
15 similar question much earlier that we did six HEU-LEU conversions  
16 which are rather complex technical reviews, and all of those were done  
17 within less than a year to meet DOE's schedule to Congress for  
18 converting these reactors. And we said why did these reviews go  
19 quickly and smoothly, but yet we seem B - you know, we're struggling  
20 with the license renewals? And we looked back and it was in a lot of  
21 cases the DOE National Labs assisted the licensees in writing the  
22 SARs for conversion, and they went into NUREG-1537, and there's a  
23 particular chapter in the document that tells you how to write your SAR  
24 for conversion. And they followed that rather closely.

25 We asked a set of questions. We applied a lot of the  
26 methodologies that we use, you know, that we are using today, you

1 know, constant communication, site visits to make sure the questions  
2 are understood and make sure the answers are understood. The  
3 second round of RAIs was very abbreviated and we got to closure  
4 quickly.

5 I think part of the problem is that SHINE, these  
6 conversions we're starting from scratch. Reading NUREG-1537, writing  
7 a document following the guidance versus the difficulty of taking  
8 something that already existed that, you know, could range from 20, 30,  
9 40 years old, number of license amendments that you have to weave  
10 into that document, a number of 50.59s, a 50.59 does apply to research  
11 reactors, weave into that document. So, I think a part of it was the  
12 difficulty that you were trying to upgrade something that already existed  
13 and, you know, it represented a lot of work when you haven't really  
14 done that upgrade for 40 years. So, I think those are some of the  
15 differences in what we're seeing in the application of the guidance  
16 document. And we do emphasize to licensees it is a guidance  
17 document. You know, they always have the freedom to come in and  
18 propose to us a different way to get from Point A to Point B, and we're  
19 willing to listen.

20 MR. KOKAJKO: Could I also discuss that briefly? In  
21 terms of what we B- moving forward what we are considering, this is  
22 certainly in our mind about what we could or could not do, and we would  
23 address it through a rulemaking process. And, again, we want to try to  
24 figure out a way to balance the need, or the requirement for minimum  
25 regulation, yet also make sure that we understand what the licensing  
26 basis is for these facilities without unduly impacting their operation. So,

1 we have thought about that. We have not B- we're not yet at any  
2 conclusion as to what the path B- actual path forward should be right  
3 now.

4 COMMISSIONER BURNS: Sure. And I don't want to  
5 sort of presume in terms of what the rulemaking package might look like  
6 that's coming I guess in 2016, but besides that what other types of  
7 things do you think about that sort of focus on the effectiveness of our  
8 review process, particularly in the renewal area?

9 MR. KOKAJKO: It's still a bit unclear to me quite yet  
10 but, you know, could you have something like a 50.59 process, they  
11 could continue to amend their SAR, and then come in and seek our  
12 approval at some point. That's B- I think it's still sort of the mechanisms  
13 how it would be managed and executed by the facility and, of course,  
14 how it would be reviewed by us is still unclear.

15 COMMISSIONER BURNS: Okay. I mean, one of the  
16 issues I think AI mentioned, for example, this is just a process issue, is  
17 that currently license renewal B- for license renewal application uses  
18 the minimum period provided in the Administrative Procedure Act, 30  
19 days before expiration of the license. Are you looking at that, say  
20 pushing that earlier, because I think one of your concerns, and I think  
21 our concern is you might have an application that comes in that could  
22 be a little better, but at the same time you're trying not to B- for  
23 something that's operating safely, in the meantime you're not trying to  
24 penalize them for having maybe an application that doesn't quite look  
25 like what you'd like it to be. So, are you thinking C-

26 MR. ALEXANDER ADAMS: Sure. I mean, there's two



1 things we're looking at. One is no matter where we go with the future of  
2 license renewal, I think there's some benefit to similar power reactors  
3 having a basis for keeping the SAR up to date. I think it avoids this  
4 every 20 years your workload does this on both sides of the fence, so I  
5 think it avoids that. It, I think, produces a better document for making  
6 future 50.59 changes, and license amendments. I mean, if you don't do  
7 that, if you've got a 40-year license to figure out what your licensing  
8 basis is, you go back to your 40-year old SAR and then you have to  
9 somehow blend in all the license amendments that have occurred over  
10 40 years, all of the 50.59 changes you made over 40 years to get this  
11 licensing basis. That's why we keep coming back to the importance of  
12 the licensing basis, so I think it would allow knowledge transfer on both  
13 sides of the fence where we would keep up with the licensing basis on  
14 our side of the fence, and the licensees would put the effort in to  
15 maintaining their licensing basis. I mean, that would allow better  
16 training documents for reactor operators, a better basis for doing future  
17 50.59s, and avoiding this, you know, every 20 years this big jump in  
18 resources. And, you know, the lack of knowledge on both sides of the  
19 fence, because you go for 20, 40 years without putting a lot of thought  
20 into it.

21 COMMISSIONER BURNS: Thanks.

22 CHAIRMAN MACFARLANE: Okay. So, I appreciated  
23 the discussion that you've all had about RAIs, and Commissioner  
24 Ostendorff went into that in quite detail. I just have one additional  
25 question here, and I just want to understand some of the history that  
26 occurred a little better. And I want to understand why, especially I think

1 in MIT's case, but I think this was also the case with Missouri, that the  
2 RAIs came in so piecemeal over time, and why B- it sounds like, you  
3 know, you've corrected this now with the SHINE application and you've  
4 given them all at once. But I just don't understand why, you know, one  
5 year it was one set of RAIs, the financial ones, and then the next two  
6 years later it was another set, and three years it was another set. Why  
7 wasn't it more comprehensive?

8 MR. ALEXANDER ADAMS: I guess I'm the historian.  
9 I was a Project Manager for the MIT license renewal when it came in in  
10 1999. You know, took a period of time, six to eight months to get the  
11 contract in place, so in early 2000, RAIs were ready, and you saw MIT  
12 got RAIs, you know, relatively quick in the 1999, 2000, 2001 time frame.  
13 So, that license renewal I think was moving along at a good pace, and  
14 then 9/11 occurred.

15 There was B- the Licensing Branch was three people,  
16 myself and two other Project Managers, that at that time we probably  
17 had about 45, 50 licenses that we were handling. As we got deeper and  
18 deeper into 9/11, it became clear that we were going to have to develop  
19 a methodology for doing security evaluations of these facilities and go  
20 out and do security evaluations for 30-some facilities. I was taken off  
21 the MIT license renewal.

22 What we were doing was B- you know, as Project  
23 Manager we all pride ourselves on good communications with our  
24 licensees. The facility director and the Operations Manager knew what  
25 we were doing, that basically we were stopping work on the MIT license  
26 renewal, and also all the other license renewals that we had in

1 progress. I think if 9/11 didn't occur we probably wouldn't be sitting have  
2 this conversation right now.

3 CHAIRMAN MACFARLANE: Right, but you still  
4 haven't answered the question of why these were so piecemeal, you  
5 know, why B- I think maybe it was in the Missouri case, it was the  
6 financial ones, and then there were some B-

7 MR. ALEXANDER ADAMS: Right. So, the B- right.

8 CHAIRMAN MACFARLANE: B- typical ones, and  
9 then B-

10 MR. ALEXANDER ADAMS: So, the answer there is  
11 we tried to get RAIs in the hands of the licensees when they were ready  
12 to go versus saving them up and giving them one shot of, you know,  
13 250 RAIs at once. If we had RAIs that were ready to go, we sent them  
14 out, and that's why you saw that. It took longer to develop the technical  
15 RAIs than it did to put together a couple of RAIs B-

16 CHAIRMAN MACFARLANE: Sounding to me like  
17 there just weren't adequate resources put into this.

18 MR. JOHNSON: I'm just going to say, Chairman, I think  
19 as you look back on B- and Al did great work, did all the work we asked  
20 him to do.

21 CHAIRMAN MACFARLANE: Sure. But, you know,  
22 but if there's only three people you can only do so much work. Right?

23 MR. JOHNSON: Absolutely. There was a time when  
24 we were always impacted by resources and implementation year based  
25 on priorities. We had a priority that was higher and so we adjusted  
26 resources accordingly. As you scale out a license review it gets less

1 efficient. Honestly, candidly it does, especially if you have reviewers,  
2 new reviewers.

3 CHAIRMAN MACFARLANE: Right, because you  
4 have to, you know, sort of B-

5 MR. JOHNSON: Absolutely.

6 CHAIRMAN MACFARLANE: You have to load back  
7 up on what the particular situation of the particular facility was. Let me  
8 just go and ask then, you know, thinking then about resources in the  
9 future which is what we're doing now as an Agency. Right? It seems to  
10 me that B- and I just want to understand if I'm thinking about this  
11 correctly or not, so it seems to me that in the late '90s it was a sort of a  
12 management failure. It wasn't your fault, but there was a management  
13 failure in that, you know, if a number of these licenses were coming due  
14 for renewal and we knew that, we should have been ready with those  
15 resources in place, and we didn't. Is that correct? And just B- I think we  
16 B- I think, you know, really it's very important to understand history so  
17 you don't repeat it. And seeing how we're in the process right now of  
18 reevaluating where we are and what we're going to need in the future, I  
19 think we need to think about this.

20 MR. JOHNSON: I would simply say that looking back  
21 on what existed at that time and the resources, and the priorities, I think  
22 we made the right decision. Whether we could have been B- sort of look  
23 further looking into the future prior to that to see and better anticipate, I  
24 don't know, Chairman, honestly. We are doing a better job, I think, of  
25 continuing to try to focus resources ahead. We talked about the  
26 application review that we'll do, that we are starting on the radioisotope

1 production facilities. We think we're in the right place with respect to  
2 that. We think we have the right resources in-house today to deal with a  
3 backlog on the schedule that we've recently submitted to the  
4 Commission.

5 CHAIRMAN MACFARLANE: Right.

6 MR. JOHNSON: So, we think we're in the right place.

7 CHAIRMAN MACFARLANE: No, I B - okay.

8 MR. JOHNSON: And if resources or if priorities  
9 change, we'll have to revisit and revise.

10 CHAIRMAN MACFARLANE: So then let me just ask  
11 about the current situation, because you showed on Slide 10 I think it  
12 was, and it looks like, I think there's one application that it supposed to  
13 be completed this year. I haven't heard an update on all of this right  
14 now, and there are six that are supposed to be done by next year, that  
15 are supposed to be reviewed, okay, for renewal. So, there's one that's  
16 supposed to be done by 2014, it is the 16th of December, 2014 is  
17 rapidly coming to an end. And there are six that are supposed to be  
18 completed in 2015, according to your schedule. Are you on track?

19 MR. ALEXANDER ADAMS: I think we're basically on  
20 track. This year we finished B - the Dow license renewal was finished  
21 earlier in the year. The B -

22 CHAIRMAN MACFARLANE: There's one more that's  
23 supposed to be done this year.

24 MR. ALEXANDER ADAMS: Yes, that's B - probably  
25 will slip into early 2015 where we are at the moment.

26 CHAIRMAN MACFARLANE: Okay, and the other six

1 for 2015?

2 MR. ALEXANDER ADAMS: Right now they're B- I  
3 think they're on schedule to complete in 2015. The majority of them are  
4 pretty far along as far as the work we're doing. They're at different levels  
5 of maturity but a number of them are pretty far along, and we're getting  
6 near the end of the review. Some of them, you know, some of them  
7 we're still in the stage of going through the initial RAI process with them,  
8 but I think the schedule we had laid out to be done with the backlog by  
9 2016, and right now I see no reason why that schedule can't be met.

10 MR. JOHNSON: We update that schedule every six  
11 months and we'll give you an update, but we think we're on track.

12 MR. KOKAJKO: Yes, we have dedicated the  
13 resources, we've changed the processes. The reason the one we won't  
14 B- may not make December '14, but we don't think we're going to be  
15 particularly seriously late, and it will be B- it's better for it. In terms of the  
16 others that are in plan for throughout '15 we have a schedule for those,  
17 and they are working according to schedule. And we feel pretty  
18 confident we will meet that.

19 CHAIRMAN MACFARLANE: So, let me just ask  
20 about the Letters of Intent then. There were other questions about the  
21 Letters of Intent, I think Commissioner Baran asked about them. As far  
22 as I can tell, there are five that are active right now from the list I have.  
23 And I'm interested in understanding, you know, we get lots of Letters of  
24 Intent. We get lots of early site permits and, you know B- but I think it's  
25 really important for us to really have a bead on what's really going to  
26 happen. So, do we really understand how many of those are really

1 going to come in, and then how many of them are going to really be a  
2 challenge in terms of quality?

3 MR. LYNCH: The first steps, though, when we get a  
4 Letter of Intent in, the process we've kind of developed is immediately  
5 we respond to that with a letter that essentially sets the expectations of  
6 the NRC, and included in that we give them a project number, which is  
7 kind of like the predecessor to getting the docket so we can group all  
8 the documentation they send in, we've got in one place. We also  
9 explain to them the billing process because that's important, too, to  
10 understand the B -

11 CHAIRMAN MACFARLANE: It's not for free.

12 MR. LYNCH: B - realistic expectations. Yes. And then  
13 the third thing we say is, okay, come in for a pre-application meeting.

14 CHAIRMAN MACFARLANE: And how many of them  
15 have done the pre-application meeting?

16 MR. LYNCH: On the list, all of these listed here, all  
17 but one, all but one have come in for a pre-application meeting.

18 CHAIRMAN MACFARLANE: Okay. And of those,  
19 how many do you think are really going to go forward, and in what time  
20 frame?

21 MR. LYNCH: So, for applications that I think could  
22 come in within the next year, so we do B - we are expecting in the next  
23 year up to one additional construction permit application, and that  
24 applicant is engaged with us frequently.

25 CHAIRMAN MACFARLANE: Okay.

26 MR. LYNCH: And this is B - to me what interested

1 means is they're coming in every maybe three months for a public  
2 meeting. They're sending me emails in between those times, you're  
3 calling in between those times. To me, that's what signifies interest. We  
4 do have one Materials application in in Region III that is being reviewed,  
5 as well.

6 CHAIRMAN MACFARLANE: Right.

7 MR. LYNCH: But yes, that's where I gauge interest, is  
8 that you're picking up the phone, you're calling me, you're sending me  
9 emails. And I think everyone understands that expectation. And then for  
10 some of the other potential applicants that maybe aren't doing that,  
11 maybe I hear from them maybe once every six months just to say we're  
12 thinking about, we're not going to do anything right now, but that's just  
13 where we're at.

14 CHAIRMAN MACFARLANE: And then just very  
15 briefly, for SHINE what are the major challenges to completion?

16 MR. LYNCH: I think B - so, the major challenges right  
17 now is, I think we've set an aggressive schedule to get to the ACRS in  
18 June. And a lot of that is going to depend on how B - you know, the  
19 quality of the RAI responses that we just got in the mail last week. So,  
20 we just opened up the package, I've got a meeting with my technical  
21 reviewers this week and we're going to get some initial impressions on  
22 that.

23 Based on the first set of RAI B - I should say the first  
24 half of RAI responses we got from SHINE in October, those were very  
25 high-quality responses. We do have some follow-up RAIs, but the  
26 scope is much reduced, and I think we're preparing to issue those



1 follow-up RAIs this month. So, assuming that it's a similar case with this  
2 in these next RAIs, I think we're going to be able to put together a safety  
3 evaluation report, but I think the challenge is, you know, making sure  
4 that we can get to the ACRS in June.

5 CHAIRMAN MACFARLANE: Right. Okay. Great.

6 MR. KOKAJKO: If I might add, though, one  
7 application he said that we think is in '15. We do know that they're doing  
8 an environmental report, they're doing the environmental studies, and  
9 they've done the National Historical stuff for the site that they've  
10 chosen, so they appear to be very serious about coming in and coming  
11 in sometime later this year, next year, excuse me.

12 CHAIRMAN MACFARLANE: Right. Okay. That's  
13 helpful. Thanks. Thank you. Commissioner Svinicki.

14 COMMISSIONER SVINICKI: I think this has been an  
15 interesting meeting, and slowly but surely we've unearthed a lot of what  
16 has come before. I agree with the Chairman on the history being  
17 informative.

18 I think, though, if we want to be entirely respectful of  
19 the participation of the two panelists who spoke to the RTR experience  
20 in the first panel, you know, reflecting back on where the Commission  
21 was in 2008, and the RTR license renewals were an issue of I would  
22 say relatively high Commission attention at that time. You know, there  
23 were issues, and so there were RAIs that were asked that were relevant  
24 to power reactors, not to research reactors. And what I piece together of  
25 the history is that we had this period of suspension without using that  
26 term after 9/11, and again having served on this Commission with

1 Commissioners who were here during 9/11, I realize what an impact,  
2 that really pivoted the entire Agency to new priorities that were not  
3 previously anywhere on the radar screen, and I understand that. But I  
4 think what happened is the backlog grew because of that necessity. We  
5 did, I think, either went out to new contractors or reinvigorated because,  
6 again, we did not discuss this but these reviews are for the most part  
7 contracted out. I don't know, maybe we don't talk about that very much,  
8 so once you reinvigorate, even if it's an existing contract, if it's been in  
9 suspension for a number of years you'll probably get new technical  
10 experts assigned to it. Those people reinvigorated the RAI process I  
11 think at the time as we were getting our legs up under us again on  
12 restarting the RTR renewal reviews.

13 We probably were not as disciplined as we're being  
14 today about the RAIs that went out, so this exists. It's not just folklore,  
15 but I think that saying that there were issues that were brought to our  
16 attention. We have addressed them. We are not exhibiting the same  
17 issues today. I don't think that makes us good or bad, I think it makes us  
18 human, and I think it's fine. I do not in any way discredit what we heard  
19 from MIT and Missouri, but the truth is we've been chipping away at  
20 some of these issues, and some of them are well in the rearview mirror.  
21 So, I think that's actually a success to talk about as a large Agency to  
22 say, you know, circumstances were such, things were suspended,  
23 things were reinitiated. Restarts of things are never the cleanest, was  
24 brought to our attention, it had even the Commission's interest  
25 immediately, the Staff's interest. You know, we have done the course  
26 corrections that were needed.

1           But the curious thing here is that you've heard that  
2 phrase, everything happens for a reason. There's a reason that this  
3 unfolds this way, and it became very clear to me when the issue was  
4 first before the Commission, and it is back to what I said to the first  
5 panel, is that some of these facilities go back to the beginning of atomic  
6 history in the U.S.; therefore, they are on a cycle of renewal and  
7 reevaluation somewhat within a smeared 10 to 15-year period. So,  
8 we've been through it starting in the late '90s and going forward. Now  
9 guess what, you all will be moving on to other things, or retired, or  
10 something else, there will be different people on this side of the table,  
11 but our successors some day will encounter the next wave of these  
12 renewals. And as we also heard from the first panel in response to my  
13 question, well, in the absence of some bold university initiative with a  
14 huge endowment devoted to nuclear, probably going to be the same,  
15 some subset of these same reactors. I don't think all of them will  
16 probably sadly be here 20 years from now. Sadly I say given the  
17 diminishment of our experimental infrastructure in academic institutions  
18 in the U.S., which is one of the reasons everyone comes from around  
19 the world to study at U.S. universities, is some of this infrastructure. And  
20 if we don't have it as a country that we're not on the leading edge of  
21 innovation. But I actually think it will be different the next go around, so if  
22 you establish a rulemaking and send it up in 2017 or whenever it  
23 comes, I suspect that what you will be doing is addressing in a very tidy  
24 way all of the problems with the last set of applications, and not with the  
25 coming set of renewal applications. It will probably be different issues.

26           I don't think that you will have front and center this

1 issue of, you know, in 1965, the discipline of documenting your  
2 licensing basis probably wasn't as good as it was 40 years later. I think  
3 it will be new issues. I think it'll be things like digital I&C. I think that  
4 you're going to have issues about the absolute necessity of upgrading  
5 certain things because of obsolescence. It simply isn't going to be  
6 possible for some of these facilities to limp along and avoid some of the  
7 obsolescence issues that they've been able to deal with in the last go  
8 around starting in the '90s.

9           So, I think that B- I would ask as you think about your  
10 deliverable to the Commission in the next couple of years that you be  
11 thinking about addressing the problems of that next wave. And, you  
12 know, as painful as it was to get SARs updated, if they've done that, I  
13 think a new 50.59 process or something, or you're just fighting the last  
14 war. You're solving the problems of the last B- potentially. I don't know  
15 what should be in the content of your rulemaking to come, but you need  
16 to peer over the horizon at what the next 10 to 15 year B- I'm sorry to  
17 say every 20 years you are going to have that. I don't know what to do  
18 about that.

19           As I said, sadly, every time you encounter it, it's going  
20 to be fewer and fewer facilities, so I would ask that you think about that.  
21 So, the great thing about going last in questions is I don't really have a  
22 question on that. That's just some suggestions to you, and my  
23 diagnosis of how this is going to go.

24           I also would ask that as you look at a potential  
25 rulemaking for this that you think about this Atomic Energy Act  
26 requirement to take the lightest possible hand. You heard that the

1 reason that exists and that's not a regulatory requirement, that's statute.  
2 And the reason that exists in there is, again, was reinforced by the  
3 responses of the first panel, which is that significant expensive  
4 undertaking, no university is going to build a new research reactor. So, I  
5 think that the reason that Congress put that in in 1954 is probably going  
6 to be B - the need for it will be even more evident in the year 2020  
7 maybe than in the year 1954 when they put it forward. So, that issue  
8 isn't going anywhere, it's that these are educational assets, and if they  
9 can't come in at a reasonable cost estimate, the United States is not  
10 going to have them, and it's as simple as that.

11 I'm reflecting on one other thing, and I'm going to put  
12 Mike Johnson on the spot here. So, this is interesting when I look at this  
13 panel. We've talked about medical isotope production, and we have this  
14 odd pairing with RTRs, but on this panel we have NRR Staff, Nuclear  
15 Reactor Regulation, and we're talking about how much potential new  
16 application work we might have in medical isotope production, but we  
17 have historically been splitting this Part 50/52 thing by housing Part 50  
18 work in NRR. And it's curious to me speaking of over the horizon looks  
19 to think about a time in the future for the NRC where we might have  
20 more new reactor work going on in NRR than NRO has on its plate.  
21 We've also transferred a number of individuals from the Office of New  
22 Reactors over to NRR.

23 Again, simply as a reflection of changed  
24 circumstances. The Chairman has talked about we're looking right now  
25 at resourcing, we're trying to position ourselves for the future. Is this  
26 something, Mr. Johnson, that the senior leadership team here as they

1 work on Project Aim, as they look at future organizational  
2 responsiveness, is this something that is at least being discussed, no  
3 decisions made, but is this something that you B - my observation of the  
4 emergence of this can't be news to you.

5 MR. JOHNSON: No, Commissioner, it is not. And as  
6 you B - the elements of what you talk about in terms of where we'll need  
7 to be, for example, pulling across B - accessing the right capabilities, for  
8 example. We didn't talk about the need to B - where is the center of  
9 construction inspection, for example? Today it's in Region II. What  
10 happens when that B - when construction shrinks down, where do you  
11 put those folks organizationally? So, we are thinking about all of that,  
12 and what the future could B -

13 COMMISSIONER SVINICKI: And it's somewhat in  
14 Region II because we knew that that was the center of gravity B -

15 MR. JOHNSON: Absolutely.

16 COMMISSIONER SVINICKI: B - on new reactor  
17 construction interest for the United States.

18 MR. JOHNSON: Absolutely. As you look ahead, as  
19 we look into the future we need to think about B - continue to think about  
20 what the workload is, how does it make sense, or who B - where do the  
21 resources currently reside to do that work? How do you pull those  
22 together organizationally, and that is all a part of what we're trying to do  
23 as we look over the horizon, so your point is a good one.

24 COMMISSIONER SVINICKI: Okay. And then I will  
25 just close by saying that I know that in response to Commissioner  
26 Baran, in response to the Chairman the Staff indicated, as they have to,

1 that yes, we're looking at the medical isotope production area, and we  
2 feel that we're adequately resourced for that. I have a feeling, although  
3 I can't prove it, that in advance of the RTR submittal wave there were  
4 B- your predecessor said in response to our predecessors and said on  
5 that RTR renewal wave, we are adequately resourced. So, I do just  
6 request that you continue to status that. I think that will be necessary,  
7 and you of all people know how dynamic we need to be in that  
8 resourcing, which again feeds back into Project Aim, one of the  
9 objectives of which is greater agility.

10 MR. JOHNSON: Thank you. Commissioner, can I  
11 make just a point on that? I was sort of thinking about priorities of the  
12 radioisotope work that we will do and what could happen in the future.  
13 And I was going back thinking in my mind back to AP1000 that finished,  
14 COL was issued actually after 9/11, I'm sorry, after March 2012 after  
15 Fukushima, sort of demonstrating that even when we get high priority  
16 other activities that happen, we can keep our focus on other priority  
17 activities, so we'll look to do that, but we will need to continue to focus,  
18 and refresh, and inform the Commission about changes going forward  
19 and make sure the Commission is aware B-

20 COMMISSIONER SVINICKI: Well, and I just B- your  
21 having said that, though, I distinguish between the two. I think that 9/11  
22 was B- rocked all of the institutions in the United States to their  
23 foundations. NRC isn't different. I do fundamentally question why a  
24 nuclear reactor accident fundamentally caused a wholesale  
25 reprioritization of work in the nuclear safety regulator, so I do think that,  
26 you know, a terrorist attack, I'm going to say that would cause a

1 wholesale reordering of priorities. I do scratch my head a bit on how  
2 many organizational prophylactics and things this Agency had to do  
3 after Fukushima, so I think, again, you know, agility is key.

4 MR. JOHNSON: I understand.

5 CHAIRMAN MACFARLANE: Any further questions?  
6 No? All right. Thank you guys, thanks very much for information about  
7 what's going on now, what changes you've made. That's been very  
8 informative. I think it was really informative to hear from the regulated  
9 community, as well, earlier in the earlier panel, so we are now  
10 adjourned.

11 (Whereupon, the above-entitled matter went off the  
12 record at 12:01 p.m.)

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