UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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UPDATE ON RESEARCH AND TEST REACTORS INITIATIVES

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COMMISSION BRIEFING

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TUESDAY

DECEMBER 16, 2014

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ROCKVILLE, MARYLAND

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

COMMISSIONERS:

ALLISON M. MACFARLANE, Chairman

KRISTINE L. SVINICKI, Commissioner

WILLIAM C. OSTENDORFF, Commissioner

JEFF BARAN, Commissioner

STEPHEN G. BURNS, Commissioner

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.

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

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

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

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

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

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

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

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

DR. NEWTON: And you, too.

CHAIRMAN MACFARLANE: Dr. Gregory Piefer,

Chief Executive Officer of SHINE Medical Technologies.

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

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

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

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

DR. NEWTON: Thank you.

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

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

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

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

are mostly operating at universities.

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

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

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

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

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

We use neutron activation analysis for trace element

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

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

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

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

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

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

work with and we feel like we work well together.

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

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

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

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

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

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

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

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

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

Next slide, please?

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

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

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

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

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

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

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

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

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

on safety issues.

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

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

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

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

CHAIRMAN MACFARLANE: Great, thank you very much.

All right, Dr. Piefer?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And what you see in the green line is actually moly

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

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

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

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

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

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

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

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

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

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

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

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

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

construction permit on the PSAR.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN MACFARLANE: Okay, great. Thanks.

Mr. Foyto?

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

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

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

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

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

It is the highest powered university research reactor in

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

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

Next slide, please?

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

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

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

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

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

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

Then we really kind of get into the meat of the matter. Next slide, please?

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

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

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

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

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

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

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

There has been some fairly significant modifications to

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

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

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

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

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

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

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Many of the questions, 55 specifically referenced the

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

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

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

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

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

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

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

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

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

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

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

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

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We were very fortunate to be able to use Argonne

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

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

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Thank you very much for your attention. Any questions?

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

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

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

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

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

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

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

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

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

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

DR. NEWTON: Currently, we're okay.

COMMISSIONER OSTENDORFF: Okay, you're all right?

DR. NEWTON: Right.

COMMISSIONER OSTENDORFF: Okay. You're

concerned about further escalation?

DR. NEWTON: Right.

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

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

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

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

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

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

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

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

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

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

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

COMMISSIONER OSTENDORFF: Okay, thank you.

DR. NEWTON: Thank you.

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

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

DR. PIEFER: Yes, sure.

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

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

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

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

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

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

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

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

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

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

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

DR. PIEFER: Yes, I --

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

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

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

DR. PIEFER: Yes.

COMMISSIONER OSTENDORFF: Okay, good,

okay. Thank you.

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

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

Can you talk about that a little bit?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN MACFARLANE: Okay. Commissioner Baran?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMISSIONER BARAN: Okay, thanks.

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

DR. NEWTON: Correct.

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN MACFARLANE: Okay, great. Mr. Burns?

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

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

MR. FOYTO: Twenty years.

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

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

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

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

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

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

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

some cases reanalyze things.

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

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

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

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

So, that actually was kind of interesting.

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

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

those questions.

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

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

COMMISSIONER BURNS: Yes. Okay, thanks.

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

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

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

COMMISSIONER BURNS: Okay, good.

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

former general counsel as well.

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

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

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

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

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

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

COMMISSIONER BURNS: Okay, good. Do you

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

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

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

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

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

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

And that has happened fairly quickly in the past, as

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

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

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

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

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

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

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

commonalities of that could be put together in a database.

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

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

COMMISSIONER BURNS: Almost like a standard tech specs.

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

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

COMMISSIONER BURNS: Thank you, Chairman.

CHAIRMAN MACFARLANE: Okay, my turn.

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

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

DR. NEWTON: Correct.

CHAIRMAN MACFARLANE: Yours --

DR. NEWTON: Yes.

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

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

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

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

CHAIRMAN MACFARLANE: Are you guys working on this?

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

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

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

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

density of the fuel.

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

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

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

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

DR. NEWTON: Indeed.

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

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

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

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

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

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

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

And it's one of those --

CHAIRMAN MACFARLANE: Well, unfortunately --

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

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

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

And you used a very helpful detailed outline of your

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

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

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

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

DR. NEWTON: I understand, I understand.

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

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

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

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

CHAIRMAN MACFARLANE: Okay.

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

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

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

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

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

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

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

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

CHAIRMAN MACFARLANE: Okay.

MR. FOYTO: Yes.

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

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

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

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

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

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

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

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

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

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

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

DR. PIEFER: Half actually.

CHAIRMAN MACFARLANE: Half? Oh even worse.

DR. PIEFER: Yes.

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

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

we, you know --

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

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

DR. PIEFER: Understood. Of course.

CHAIRMAN MACFARLANE: That's a government decision.

DR. PIEFER: That's right.

CHAIRMAN MACFARLANE: So, again --

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

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

DR. PIEFER: Of course.

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

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

CHAIRMAN MACFARLANE: Okay, great. Thanks.

Commissioner Svinicki?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But speaking of new technologies, we do have medical

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. NEWTON: No.

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

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

Thank you very much.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

applying NUREG-1537. Next slide, please.

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

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

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

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

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

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

I will now turn the presentation over to Steve Lynch.

MR. LYNCH: Thank you, Al. Good morning.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Office of Nuclear Reactor Regulation holds the

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

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

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

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

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

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

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

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

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

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

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

Regulatory Basis.

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

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

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

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

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

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

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

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

Finally, we look forward to continued improved

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

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

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

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

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

MR. ALEXANDER ADAMS: Excuse me?

COMMISSIONER OSTENDORFF: You heard the first panel B-

MR. ALEXANDER ADAMS: Yes, I did.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

improvements.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN MACFARLANE: Okay. Commissioner Baran.

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

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

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

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

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

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

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

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

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

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

COMMISSIONER BARAN: Sure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMISSIONER BARAN: Thank you.

CHAIRMAN MACFARLANE: Commissioner Burns.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMISSIONER BURNS: Thanks.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. JOHNSON: Absolutely.

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

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

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

CHAIRMAN MACFARLANE: Right.

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

CHAIRMAN MACFARLANE: No, I B- okay.

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

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

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

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

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

CHAIRMAN MACFARLANE: Okay, and the other six

for 2015?

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

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

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

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

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

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

CHAIRMAN MACFARLANE: It's not for free.

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

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

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

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

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

CHAIRMAN MACFARLANE: Okay.

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

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

CHAIRMAN MACFARLANE: Right.

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

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

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

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

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

CHAIRMAN MACFARLANE: Right. Okay. Great.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. JOHNSON: Absolutely.

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

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

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

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

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

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

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

MR. JOHNSON: I understand.

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

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