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BRIEFING ON POTENTIAL MEDICAL ISOTOPE PRODUCTION LICENSING ACTIONS

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TRANSCRIPT OF PROCEEDINGS

Public Meeting

Before the U.S. Nuclear Regulatory Commission:

Gregory B. Jaczko, Chairman

Kristine L. Svinicki, Commissioner

William D. Magwood, IV, Commissioner

William C. Ostendorff, Commissioner

APPEARANCES

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DOE/NNSA

Potential Producer Representatives:

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Vice President of Corporate Development
Babcock & Wilcox Technical Services Group, Inc.

Carmen I. Bigles
President and Chief Executive Officer
Coqui Radiopharmaceuticals Corporation

Gregory Piefer
Chief Executive Officer
SHINE Medical Technologies, Inc.

NRC Staff Panel:

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P R O C E E D I N G S

CHAIRMAN JACZKO: This morning we're here to discuss the status of potential licensing actions for new medical isotope production facilities. I'm pleased that we're joined by such a diverse panel of experts. The staff has received a number of expressions of interest to license production facilities for Molybdenum-99. Preparing for these license activities will be a challenge given the novel and complex designs under consideration, some that have never been -- before been licensed by the NRC, but we'll hear today, and I hopefully feel, well, I hopefully will hear today, and I feel confident that we'll hear that the staff is prepared to address this work as it comes forward. So I will start with our -- if any of my colleagues would like to make any remarks? Okay, we'll begin with Parrish Staples, who is the director of the Office of European and African Threat Reduction at DOE. If it's orange, you're good.

PARRISH STAPLES: It is orange.

CHAIRMAN JACZKO: Yeah.

PARRIST STAPLES: Thank you. Chairman, Commissioners, thank you very much for the opportunity to present the DOE/NNSA efforts to support the domestic production of Mo-99. I also have the distinct pleasure to, in some respects, present this for the entire U.S. inner agency that is working on this issue. There's a very large group of us that includes staff from the White House, Department of Energy, all the way through to the NRC and many of the other agencies that are involved in this. So it's a coordinated effort, and we appreciate everyone's response to support this for the purposes of HEU minimization and threat reduction activities, as well as developing reliable domestic supply of Mo-99.

On Slide Number 2, you can see we have the basic Mo-99 policy objectives, and this actually is an excerpt from an Office of Science and Technology policy presentation from the White House in a December 2011 topical meeting that we had on this subject in Santa Fe, New Mexico. The three main policy objectives that we have for this program is to ensure a reliable supply of Mo-99 for the 30 million patients worldwide that use this on an annual basis. We also are working to eliminate the use of HEU in Mo-99 production, and the third objection that has really driven this industry into the situation that it currently is in is the subsidies that do take place. So we're working with the Organization Economic Cooperation Development Nuclear Energy Agency to end subsidies, and to establish an economically sound industry for the future viability of the medical community.

On Slide Number 3, it describes the global threat reduction initiative mission and program goals. We were originally involved in this effort primarily because we have the mission to reduce the use of highly enriched uranium in the civilian sector. We have done that by incorporating three diverse programs under the GTRI umbrella of converting research reactors and medical isotope production processes to the use of low-enriched uranium, to remove and dispose of excess nuclear and radiological materials once they are no longer needed for use in the civilian sector, and in an interim period, we will support the physical protection at these sites for both nuclear and radiological materials.

On Slide Number 4, it discusses the balance that we have between our international and our domestic program. Under our long-standing HEU minimization mission that literally goes back to its origins in 1978, GTRI provides assistance to research reactors and isotope production facilities to convert from

HEU to LEU. We do through developing technology, and to support the licensing actions that will be required to implement that technology at the respective facilities.

Recently, with the shortages that occurred over the past several years due to the closure and/or long maintenance outages of several of the large production facilities for Mo-99, our mission has now included accelerating the establishment of a reliable U.S. domestic supply of Mo-99 that is produced without the use of HEU so it is consistent with our other mission mandate. However, it requires a very careful balance between our international and our U.S. domestic efforts.

On our international efforts we are working with existing Mo-99 producers to convert their facilities to LEU, and we work in a manner such that we will not support the increased production of their facilities, that is their commercial obligation. We simply work to minimize the use of HEU in those facilities. However, domestically, we are working to accelerate the establishment of commercial non-HEU-based Mo-99 production in the United States and I think there are some of our cooperative agreement partners here around the table, and they will give you some more information on their programs, and there are also other entities that are working independently of our support program, but also have very viable production capability to support this need for the medical community.

Slide Number 5 demonstrates our basic overall strategy for a reliable, non-HEU-based Mo-99 supply. The top bar that's shown in both blue and red, where blue indicates the use of LEU or non-HEU-based production, red indicates the use of HEU-based production. The top slide bar demonstrates the

current situation. The NTP radioisotopes in South Africa is partially converted to LEU production, and still has full LEU production, and the other three producers in the Netherlands, Belgium, and Canada are all currently using HEU targets for medical isotope production. We expect by the 2015 timeframe, or in that transition, that we will completely have converted the South African facility to LEU production, and through the recent Nuclear Security Summit, we have commitments from both the Netherlands and Belgium to convert their facilities over to LEU production. We have a significant number of indicators from Canada that they will cease large-scale isotope production at the NRU facility in the 2016 timeframe. That will cause a significant gap in the production capacity for the global medical isotope supply market, and that's where we envision that we will have a number of domestic projects that will fill that gap to be assured of a reliable supply into the future. All of those domestic projects will be a non-HEU-based production, some of which will use LEU, and others that will use other techniques that do not include uranium at all.

Slide Number 6 goes over the projects that we currently have active. And there our objective domestically is to accelerate their production to meet at least 100 percent of the U.S. demand of the Mo-99 produced without HEU. We've looked at a number of different technologies to ensure that we do not have a single point of failure in the technology or distribution network as we identified that was one of the causes of shortages that occurred recently, was the dependence and reliance upon one large producer using a single technology.

So we have been supporting a neutron capture program with General Electric-Hitachi, however due to the market conditions that they've identified, they suspended their project on February 7th, 2012.

There is also LEU solution reactor technology that will be presented by Babcock and Wilcox today, and I won't discuss that any more. On accelerator technologies, we have two programs. One of which is with NorthStar Medical Radioisotopes, and they use a gamma-N reaction, they do not using any uranium in their system, so therefore I think that's not context of discussion today.

Our second cooperative agreement partner under accelerator technology is with Morgridge Institute for Research and again, we will be hearing a presentation from them in just a little bit, so I do not want to take any of their presentation space away from them. But our basic program objective of how we implement this with these cooperative agreements is that they're currently limited to a $25 million cap under a 50/50 cost share agreement. It's expected that the magnitude of their projects are much larger than that, but this is the amount of funding that we are providing to help accelerate the production of these respective technologies.

On the final slide is also an overview of the U.S. National Laboratories support that we provide to the industry in general, where we make this expertise, and we have made this expertise available to support the technical development for each of the Mo-99 pathways that are being supported, and we also ensure that this technical expertise at the National Laboratories is available to support the acceleration of those projects using non-HEU technologies. Now, all of the work packages that we fund in this respect are outside the cooperative agreement, and are open-sourced, non-proprietary, but also non-critical-path activities. We really do consider it to be the obligation of the respective commercial entities to implement their programs as rapidly as possible. So -- and if requested, some work conducted at the laboratories outside of the

cooperative agreements is available to help inform the NRC in regulatory decisions. So thank you very much for your attention.

CHAIRMAN JACZKO: Thank you. We'll now hear from Randy Spickard, who is the vice-president of the Corporate Development at Babcock & Wilcox Technical Services Group.

RANDY SPICKARD: Thank you Mr. Chairman, Commissioners. I'm pleased to be here on behalf of the Babcock and Wilcox Company. As you know, we've got a long history in the nuclear industry supporting lots of different things, and we're very pleased to be involved in this program. As everyone knows, it's vitally important that we develop a reliable domestic supply of Mo-99, and particularly one that meets the NNSA's non-proliferation goals, and we've got an approach to potentially do that.

On Slide 2 here, just a little bit about the B&W Company, I won't go into much detail, but we're a large company, $3 billion a year company involved from -- all the way from SMRs to running the MNOs at the DOE sites around the country. We have a long history, for over 60 years, of doing that. So won't go into that, and we're in partnership in this project with Covidien which one of the leading suppliers in the nuclear medicine industry, and we believe the two of us together form a very good partnership, in order to move forward on a project of this size, and magnitude, and scope, so it's a good partnership we have with them.

Our project is called the medical isotope production system, or MIPS for short. And it's an AHR, an Aqueous Homogeneous Reactor. We developed it, and have intellectual property on it that we developed in the 90's. Market conditions and otherwise, we really didn't move forward with it until 2007

or so. We reached an agreement with Covidien in 2009 where we would work together to both develop the technology, and to -- for them to take the supply from the plant. We entered into an agreement with NNSA in 2009 to help in the non-proliferation mission and to develop a domestic supply, and that's worked very well. It's certainly one of the things that kick started our program was getting that cooperative agreement with NNSA.

The next slide, just briefly on what our technology is. It'll be a single license for both the reactor and the production processing cells. So it's an AHR reactor, 240 kilowatts per reactor, if you will, and then a purification and processing facility. From there it goes to a generator facility at Covidien, and then to end users. The only thing I would note, a couple things is the, you know, the solution is reused every time, so we minimize the waste, we have -- we believe the once every five years or so we would need to replace the solution, and that would -- has currently been designated as high-level waste, and we have means to store that in our plans until a final disposition path is developed.

The next slide, kind of where we stand, we've been working with the National Laboratories a lot, as Parrish said they're certainly a resource we utilize here. We've worked with Argonne and Los Alamos, we've worked at Purdue University, we've done some work at INVAP, and it's run the gamut from doing studies on purification methods to absorbent columns to the reactor studies, and all over we've used their expertise in order to push this forward. At INVAP we actually ran a little mini loop of the actual reactor system, and got product out of it which was sent to Covidien, and actually put in a generator, which generated some product which met purification requirements, and gave us some confidence that we're on the right path.

The next slide, so where we're going. It's our intention to submit a single license under 10 CFR 50. MIPS is both a reactor and a processing plant, so it's a utilization and a production plant. Considered non-power reactors, so we need a construction permit, and an operating permit. The vast majority of the waste, as I just described, is low-level waste, has a clear disposition path. We need to continue and complete preliminary design, which would lead to an environmental report in our construction application, and then from there we need to complete final design and submit the operating application, and then obviously move into construction and commissioning. And then from there we need FDA approval, obviously, as well, which is a different path that we need to go down as well.

So in summary, we believe the MIPS system is one that's very viable for moving forward to develop a domestic supply. Its increased efficiency significantly reduces waste byproduct out of this, there's no proliferation concerns, it's a very safe operation and it allows us to have a stable domestic supply of Mo-99 in the United States, which is a very important goal, so thank you.

CHAIRMAN JACZKO: Thank you, we will not hear from Carmen Bigles.

CARMEN BIGLES: Bigles.

CHAIRMAN JACZKO: Bigles, who is the president, chief executive officer at Coqui Radiopharmaceutical.

CARMEN BIGLES: Good morning, Mr. Chairman, and members of the Commission. Thank you for inviting me to participate in this meeting today. My name is Carmen Irene Bigles, and as you said, I am the president and CEO

of Coqui Radiopharmaceuticals Corp. I am pleased to have this opportunity to discuss our status for the production of Mo-99. I would also like to thank Mr. Parrish Staples from the DOE/NNSA, Mr. Brian McManus from the Office of Honorable Governor Rick Scott of Florida, our engineers project manager Ernesto DeLaurenzo from INVAP, and Jill Lockhart from Gretchen Smith and Partners, and our advisors, board members, and all present. Also, good morning to our fellow panelists, who are also pursuing to solve the Mo-99 crisis. Randy Spickard from Babcock and Wilcox, and Gregory Piefer from SHINE Medical Technologies.

Next slide. Slide, begin. Okay, actually Slide 3, it would be. There you go. Okay, Coqui Radiopharmaceuticals Corp. was incorporated on September 10th, 2009 with a specific goal of establishing the first commercial dedicated medical isotope production facility in the United States in order to ensure a continuous flow of the radioisotope Molybdenum-99 for medical use, and to create an advanced nuclear medicine research facility in the field of nuclear medicine. Coqui's medical isotope production facility consists of twin research levels, small nuclear reactors, and radiochemical production lines, as well as a waste storage facility. Coqui will contribute to society by developing and operating the first U.S. commercially dedicated Mo-99 pharmaceutical production facility utilizing low-enriched uranium.

Sorry, next Slide, 4. Thus providing a continued source of Mo-99 for the world's nuclear medicine industry, advancing nuclear medicine by establishing a state-of-the-art production research facility contributing to national security by reducing the need of the exports of weapon-grade uranium, ensuring national health for U.S. patients, and bringing much-needed employment and

economic development. Coqui will supply 100 percent of the U.S. market for Mo-99. Coqui has analyzed the prospect of the Mo-99 market and in the near future, supply chain outages and the commissioning of 16 reactors are expected to occur. Demand for Mo-99 in the U.S. is expected to continue to increase at the current rate of 3 to 5 percent. The product shortages are expected to substantially increase the price of Mo-99 as supply constraints pressure international producers that supply the U.S. market. These price increases will set the stage for a transition from government to private sector production. Without -- next slide. Please.

Without the prompt implementation of current technologies in the U.S., private sector commercial-scale production of Mo-99 could be substantially delayed. The strain on supply and demand is expected to cause substantial increase in the price of Molly as current facilities are decommissioned without replacement. Coqui has the proven technology required to meet the current and future market demand of the U.S. Next slide please.

Coqui offers a clear path and solution to the U.S. Molybdenum problems. Coqui's facility will use proven technology using low-enriched uranium in compliance with the global threat reduction initiative. Our facility is a turn-key product delivered by INVAP who are the world's leading designers of low-enriched Molybdenum production facilities. They built the OPAL research reactor in Australia, which is a research reactor built to function using LEU.

Its Mo-99 manufacturing processes are used in facilities across the world. Their production and processing technologies are mature and currently available, thus minimizing design construction, commissioning, and operation uncertainties. Moreover, our end product is the same already approved by the

FDA that is subsequently imported to the U.S. for patient use. Our NRC -- Slide 8 please.

Our NRC status: on March 15, 2010, Coqui submitted its letter of intent to the NRC for an application to license our medical isotope production facility. Subsequently, we held some pre-application meetings, and in May 2010, Coqui submitted its first licensing strategy document to the NRC, indicating what class of license it intends to apply for. On June 2010, Coqui submitted its second licensing strategy document to the NRC. The NRC responded to these submittals in September 2010 providing Coqui with important information on preparing its application. On October 2010, Coqui held its first public hearing at the NRC, and today, May 11th, 2010, we're at the NRC updating our status.

At this time Coqui would like to inform the NRC that it has selected the site for our facility. Phase one of environmental report is complete. A significant amount of the technical portion of the application has already been prepared through our contractor INVAP and we're arduously working on negotiating the financing in order to prepare application submittal to the NRC. Slide 11, please.

On the yellow portion of the site, on the conceptual site, the slide shows a conceptual site layout for the 40 acre area where the facility will be built in Progress Corporate Park in Alachua, Florida. Thanks to the efforts of Enterprise Florida and the University of Florida Foundation a site has been chosen which has been offered to Coqui by the Foundation. This site is NUREG-1537 compliant. As we have discussed Coqui expects demand worldwide to continue to increase and supply will be worsened by the production shortfalls and decommissionings. Consequently, the price increase will benefit the investment

situation of proven Mo-99 manufacturing methods such as those that will be employed by Coqui. Being the only tried, tested and commercially scalable method of supplying Mo-99, Coqui low enriched uranium reactor based facility is the solution for the current crisis situation.

Coqui RadioPharmaceutical Corp. is engaged in negotiations with investors to finance the licensing of the construction of our medical isotope production facility. Enterprise Florida also provided Coqui with a tax and workforce incentive packages to establish the facility. With that being said, the application, locating a site, and proving our technology is not a hurdle. We've already done all that, what we're still negotiating is the financing. Once we have that lined up, Coqui would like to reaffirm for both the NRC staff and the Commissioners that we will aggressively complete our NRC submittal pursuant to the schedule explained herein for the NRC's review.

This timeline is a condensed summary of our project schedule. The first test is a licensing submittal and the second is the submittal of the environmental report. You can appreciate an overlapping of the beginning of the review and the license submittal on construction. These efforts account for approval by NRC and beginning of civil construction, meaning roadways, bringing electricity, water, et cetera, to the actual site. So I don't want it to be interpreted as the, basically we're beginning construction without the approval of the NRC, it's just that there's other types of construction. Also at the end the same thing. The beginning of the commissioning for the operating license it occurs the same way. We would be since our -- we have to build the reactor halls and we have the processing plants and the waste facility building we will be beginning once completed begin the operating license of that one and subsequently we might still

be constructing maybe part of the administrative areas or finishing with the waste while one of them is being licensed.

Okay, well, this concludes the current status of our project and application. We would like to take this opportunity to thank the NRC staff for how helpful they have been in assisting us in getting to this point. The staff has been responsive to our questions and overall very receptive to meeting with us to provide input as we pull together our NRC submittal, and for that we thank them. And, yes, Coqui RadioPharmaceuticals Corp., sustainable design, proven technology, plus finance equals saving lives, and saving lives plus global threat reduction equals a better world. Again I thank you and then happy Mother's Day to all of you Moms.

[laughter]

CHAIRMAN JACZKO: We will not turn to Gregory Piefer --

GREGORY PIEFER: Piefer.

CHAIRMAN JACZKO: Piefer, who is Chief Executive Officer SHINE Medical Technologies.

GREGORY PIEFER: Thank you Mr. Chairman, Commissioners for holding this briefing. I think it's very forward thinking of you to address this problem early and get insight from the producers, so thank you very much for doing that.

Probably none of you have heard of SHINE Medical Technologies before now, so I'd like to give you a little bit of an introduction to who we are and what we're trying to do. And also wanted to give as quick explanation of Parrish said the NNSA Award was to the Morgridge Institute for Research, yet I'm here and I say SHINE Medical Technologies. We've partnered with the Morgridge

Institute for Research, it's a new institute and one of their primary missions is commercializing promising technologies, and so they were the applicant for the NNSA Grant, but we're working very closely with them to use that money to develop a production facility. So, hopefully that helps explain why my label says SHINE Medical and the DOE Award is to Morgridge Institute for Research.

I wanted to give a little explanation of our values and culture, and I think we share a lot of common values with the NRC. The safety of our workers and the health of the environment around our plant is essential for our business to operate successfully. This is not only a medical business, it's also a nuclear business and we know that we cannot operate a business without sharing the same values. So, we look forward to working with the staff to provide a very safe operation.

I think going on to the company background, SHINE was also formed recently. It was created in 2010, to pursue the production of medical isotopes with an accelerator based technology. Its basis is in an accelerator that had been developed for other applications, but really the loss of the MAPLE reactors which were the future for world production, especially in North America, and really stimulated us to enter this market and that's why the timing is so recent. It was really motivated by this accelerator technology which is very eco-friendly. It's got a lot of the advantages of the B&W system that we heard about in terms of very low waste production, and it's, you know, it's really the market opportunity again that drove us due to the failure of the MAPLE reactors.

We do plan to be a world leader in the supply of medical isotopes. This facility should be capable of generating large quantities of isotopes, up to half the U.S. demand initially and it's going to produce vision-based isotopes. So

Mo-99, but also very important isotopes for medicine including Iodine-131, which is essential for the treatment of thyroid disorders, and Xenon-133, which is a lung imaging agent. Next slide, please.

Just give a quick introduction to the technology. The core of this is that we're producing neutrons with a particle accelerator and then those neutrons are passing into an LEU solution. In that LEU solution they multiply and create medical isotopes causing fission. After irradiation the isotopes of interest are chemically separated. So we would run probably something like a five and a half day cycle with the accelerator on; turn off the accelerator and run the solution to chemical process where we separate out Mo-99, Iodine-131, Xenon and anything else of medical use.

Slide 5 shows a picture which I'm hoping will help give you a little bit of a feel for, a cartoon of how this would work. So you see in the center is the particle accelerator and the beam starts at the top, that five and a half meter picture, and it shoots downward and it ends up in that silvery cylinder at the bottom, and that's where the neutrons are produced. It's a deuterium/tritium reaction, so deuterium beam hitting tritium gas creating neutrons. The neutrons shoot out in all directions, it's isotropic, and enter this LEU solution which is sort of the blue annulus, it's an annular chamber that's, I don't know, maybe, maybe about this big in diameter. The whole thing is contained in a big light water pool, looks kind of like a TRIGA core buried under water. So then we'd run that system for five and a half days. Going on to Slide 6.

The facility would have multiple of these units. We're planning on right now six to eight units. That's a cost benefit tradeoff that we're considering right now. Each unit can supply about 10 percent of the U.S. need for Mo-99, a

much greater percentage of the need for I-131 and Xenon. The fission thermopower equivalent of this system, so the amount of fission going on, is about 100 kilowatts in this design. So at six units the total facility power would be something like 600 kilowatts thermo fission power. They're isolated from each other, each in a separate, completely separate system, so one can be down while the others are operating.

This is what I wanted to spend the most time on is Slide 7. And just to give you guys, you asked for an update on project status and so that's what I'd like to do. A lot of the technology proof of concept is done. We've got a prototype accelerator in our lab that, you know, makes neutrons. This is all good. But really we've got a very strong team. We've got about 60 FTEs working on this effort right now. We've spent over $8 million and are planning to spend in the next year another $20, on this project. So it's moving very, very aggressively. The team includes experts at National Laboratories such as Los Alamos, Argonne, Savannah River. It includes help from the NNSA, and it also includes experienced NRC contractors such as Sargent & Lundy, MachTech, well, A-Mach now, formerly MachTech, and others that are helping us write the environmental report and the safety applications. Our Chief Operations Officer is a former Lab Director from Los Alamos so he has a tremendous amount of experience with facilities and nuclear safety. So we've put a great investment in building the team.

Our preliminary design work is under way and we are expecting to submit, planning toward to do everything we can to submit at least our environmental report in late 2012, our preliminary safety analysis report around the end of the year as well. Some of that is dependent on additional feedback

that we might get due to the fact that our guidance is in draft form at this time.

So I wanted to say just a little bit in my remaining minutes some of the challenges that we see, and obviously like I said, the guidance that we're working from is in draft form so it's safe to say that it's not mature. This could lead to delays in both our application preparation and approval. But at the same time we've got this other national objective that Parrish spoke about, where we've got a fairly short window of time before the NRU reactor in Canada stops producing isotopes, and that'll be around 2016. So there needs to be some sort of reserve capacity established by then to prevent patient shortages.

There's also the possibility that shortages or a market collapse could drive certain players in the market back towards HEU, and I think there's some concern that Russian reactors that use HEU could come online and not go away. So we do have a window of time to really push this LEU transition I think through. So that's really the national challenges that are faced by this.

I do want to take the time to thank everybody, essentially, at the national federal level who has recognized this and helped with the project so far. The NNSA program I think is very visionary. I think they found something that they could get in place that could help programs, be relatively noncontroversial and move it and it has been a huge accelerant for our program. And I think the NRC staff has also seen this coming and I want to thank the NRC staff for being forward thinking and preparing this draft guidance. It was good to see that they've already done a lot of work on this and investigated what would be involved in licensing medical isotope facilities. And there are some really, really productive interagency working groups that are going on that involve multiple organizations from NNSA, from NRC, FDA, and even CMS. So it's a wonderful

interagency working group that been put together to help.

I do want to say that we need that to continue if we're going to meet this Federal priority of 2016, in particular since I'm talking to you, I, you guys I would like to ask that to the extent possible the priority for medical isotope applications is elevated. This will help accomplish these Federal goals of preventing the failure of the health care system with regard to medical isotopes. It'll support the HEU minimization efforts that are under way by NNSA, and it'll help establish a domestic supply rather than a foreign supply reverting to the primary source for U.S. radioisotopes.

Also I want to ensure that the NRC staff that is performing the review has the resources that they need are required to do an expeditious but complete review and, so, I just ask that the staff be listened to. I'm not suggesting that they aren't, I'm sure they are, but wanted to make sure that that is there.

Just parting thoughts, our perspective, just to leave you with our system. It's not a nuclear reactor by definition but it is in terms of radioisotope inventory comparable to what we would think is a very small research reactor. It's much smaller, in fact, than many campus reactors in terms of thermopower and the environmental impacts of a system like this are insignificant compared to power reactors. It still, obviously, need to be considered, addressed and studied but wanted to leave you with those parting thoughts on small systems that produce medical isotopes. So thank you very much for the chance to speak.

CHAIRMAN JACZKO: Appreciate everybody's presentations. We'll start with Commissioner Ostendorff with questions.

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman, and

thank you all for being here today. This is very interesting and before getting ready for this meeting I'd not really spent much time looking at this particular area. I was pretty familiar with the HEU to LEU conversion process when I worked at the NNSA a few years ago, but I was less familiar with some of the private sector efforts that were underway.

Parrish I appreciate your being here and I think it's significant that you're representing the interagency group in this particular area. And I wanted to -- it's kind of interesting to have a, you have a global nonproliferation program that has an overlay interaction with plans for moving forward domestically here in the United States. And one of your slides that dealt with the HEU, non-HEU, the red and blue colored schematic, it would seem to me that the ability of the people to your left to predict future supply and demand curves in the United States and worldwide is absolutely essential in order to make -- for investors and looking, responding to kind of the requirements discussion about the understanding is, what is the financial risk of investing in these programs? And I was just curious, you mentioned you think the Canadian reactor will shut down permanently in 2016. I know that's a projection, but how do you feel about the predictability of the rest of the worldwide supply of Moly as it might interface with strategic planning and investment decisions by potential producers in the United States?

PARRISH STAPLES: Actually it's a very good question, very relevant. Through the OECD working group that we have we've evaluated and projected what the future supply should look like. And on Slide 5, which you're referring to for the audience, looking at any one of those bars as we go across, the average age of four of those five facilities are roughly 45 to 50 years. So recognizing that they're reaching the end of their lifetime, they've gone through

numerous lifetime extension programs. The only one that's a relatively new reactor is the ANSTO facility, that was recently commissioned less than about five years ago in timeframe. They can only produce roughly about 10 percent, maybe 15 percent of the global supply. So it's very easy to project that at some point in time in the next five to 10 years there will be significant shortages from these facilities' inability to produce. Both the Dutch and the Canadian facility shut down for about a period of a year, several years ago, which really spurned the inner agency process because those two combined facilities produced well over 50 percent of the medical supply. The reserve capacity from the Belgian and the South African facility was not sufficient to meet the global demand so it really caused significant issues.

COMMISSIONER OSTENDORFF: From your current position in the Department of Energy and with respect to the White House involvement in this effort, is it, am I correct in assuming that the Federal government policy is such that you have, I guess the question I'm having is you're assuming that the companies that might potentially produce Molly in the United States would also be perhaps exporting this overseas?

PARRISH STAPLES: That is correct, yes. The current market as these facilities operate and as you're probably aware, power reactors have very high duty cycle, many research reactors do not, and the best example perhaps is the Belgian reactor which operates roughly two-thirds of the year at best. So there's numerous production gaps in any one of these facilities. The current market, in some cases, supply will go from the North American continent to Europe and other cases during other facilities that are operating the supply chain will operate in the reverse direction. We assume in the future as any U.S.

entities come on line with their production that the market forces would continue to operate in that. It really is a boutique industry and they need to cover the supply net needs for the respective continents.

COMMISSIONER OSTENDORFF: Those are very helpful answers to the feedback. I appreciate that, those were very comprehensive. Anybody to Parrish's left want to provide any comments or any concerns on your ability from your private sector positions as to being able to project supply that might influence your decision to go forward? Any, that's okay if you don't.

RANDY SPICKARD: I'd agree with Parrish. I think that we're reasonably comfortable that the supply and demand is sufficient to support a business case.

COMMISSIONER OSTENDORFF: Okay. Let me ask a, I want to ask Randy, and Carmen, and Greg the same question here. And I'm kind of picking up from Greg, on one of his last slides where you raised tactfully some perhaps concerns on regulatory -- on draft guidance from NRC, and I guess I'd ask each of you if you have any concerns to give you the opportunity to provide those to this group. Concerns or challenges or obstacles that you see moving forward with what you understand to be the NRC's current positions on various issues that might affect licensing of your facilities.

CARMEN BIGLES: In my case our license is a103, regular research, non-power reactor license approach which is the one that the NRC's used before and they have worked on before. So we're not – ours is very clear and straightforward approach and we're very comfortable with it and, like I said, we're very comfortable with the staff and everything that, how we're moving around.

COMMISSIONER OSTENDORFF: Okay.

GREGORY PIEFER: I would just add and I think the staff has been absolutely wonderful to work with. I think they do have competing priorities. There is a number of applications that they're working on at one time. It's a fairly small staff in the non-power reactors area and, you know, they're very, very hard working. But, you know, my ask was, you know, that the priority of medical isotope projects just take into account this short window of time that we may have before either patient shortages occur again or before the market returns to HEU in order to protect itself from shortages. So that's really my only.

COMMISSIONER OSTENDORFF: Let me ask you this. My personal opinion is we've had some analogous issues raised in the small modular reactor arena and, you know, there's, the staff, my personal view has done a great job of trying to develop policy positions from a whole host of issues controlling staffing, EP, security issues, et cetera, but our staff can only go so far until they receive the national license application.

GREGORY PIEFER: Of course.

COMMISSIONER OSTENDORFF: So there's a certain amount that can be done but the devil is in the details as we all know.

GREGORY PIEFER: Yep.

COMMISSIONER OSTENDORFF: Are there any particular substantive areas, Greg, that concern your potential application?

GREGORY PIEFER: Not at this --

COMMISSIONER OSTENDORFF: As far as a gap as to where you think our work might not be?

GREGORY PIEFER: Not at this time. The staff has been very

cooperative in offering to schedule a series of pre-application meetings and I hope in those meetings that we can get with them, talk to them about our strategy for submitting an application and through that process either recover, uncover where there may be weaknesses or where we might work together to make sure we submit a complete application. I think that is just as important as elevating the priority if not more important. So, you know, I think at this point we've been very happy with the staff. I think the -- whether or not the guidance will change sort of in the final hour from the draft guidance is something that we wonder about, you know, and I think that's something that we keep our eyes on. But, you know, so far, no.

COMMISSIONER OSTENDORFF: Okay. One last question, Randy, I'm turning to B&W just for a minute.

RANDY SPICKARD: Sure.

COMMISSIONER OSTENDORFF: Obviously you guys have been active in the SMR arena. Are you seeing significant synergies between your Molly proposal and existing work that B&W has in the SMR area?

RANDY SPICKARD: We do. I mean we share some of the same staff, you know, there are certainly skill sets within our company in the design and licensing area where we're trying to leverage that as a company and it certainly is helping us as we go forward.

COMMISSIONER OSTENDORFF: Okay. Again thank you all for being here today. Thank you Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Svinicki.

COMMISSIONER SVINICKI: Thank you. Good morning to each of you. I want to thank you for your presentations and also for your involvement in

this really important topic. I think the Chairman has mentioned previously, I know the Commission has focused on, that most Americans will at some point in their lives have some sort of nuclear medicine technique for themselves and members of their family. So I appreciate a lot of the coordinated work that's going on, Parrish, that you've talked about for this important national priority and it's, of course, why we're gathered here today.

I appreciated the questions asked by my colleague, Commissioner Ostendorff. I try not to be redundant with that. I did have a few other things that I was curious about both in the presentations and also through presentations that I think each of you have made to the staff or information that you've provided. I have some awareness of the development of some of your efforts over the course of the years.

Parrish I wanted to start with you. You made reference to the work that NNSA has led I think with involvement of the DOE National Laboratories. Argonne, if I understand correctly, has been very involved in developing for the LEU transitions and conversions. Where those have taken place, do we continue to monitor the effectiveness of what's been designed and converted and installed, and what kind of early lessons are we learning about how particularly the LEU target conversions have gone?

PARRISH STAPLES: In the specifics and perhaps the best reference to go back to is the National Academy study that came out of the 2005 Energy Policy Act which evaluated the status of the Argonne work for developing the new targets. Our efforts with Argonne, or I should say Argonne's efforts that we've been supportive of have been in the production of foil targets that would actually be a direct replacement for the targets that are currently used which are

dispersion target.

And to describe the difference very briefly, dispersion target would have a certain density of uranium. The foil target, as the name implies, would be a metallic foil that would replace the powder target and maintain the Uranium 235 density while being low enriched uranium, so that for each target you could maintain the production capacity. Australia who started production still uses a dispersion target. South Africa, when they converted, they had the advantages that they were using 45 percent enriched powder targets or dispersion targets. They converted over to a 20 percent or 19.75 percent dispersion target also. So no one has actually implemented at a production scale the Argonne technology.

However, in support of both the Belgian and the Dutch processes, we are continuing the work with Argonne, that's part of our legal obligation to ensure that we develop the technologies that would be sufficient for the conversion of those producers. We also believe that it is a very efficient technology in terms of production capacity because of the high density foil that would be used for Mo-99 production.

COMMISSIONER SVINICKI: Okay, thank you for though, that's very helpful. Like others I have been following the development process over the years, so it's helpful to have that status update. Thank you for that.

Turning to our other participants in the panel, a few of you have made reference to FDA approval kind of in your timeline and sequence of activities. So, it occurs to me in hearing that, that I'm not as cognizant of how that fits into your planning. Is it at the very end that you get approval of the products you produce after you've constructed the whole facility or are there preliminary engagements with the FDA? Or are you designing your process to

produce something so equivalent to what is already FDA approved that you can have some confidence as you're moving along that other than perhaps doing a product qualification at the end, there's a good degree of certainly in that FDA approval process? Could anyone just comment on that just for my own education?

CARMEN BIGLES: Well, in my case, the ones that come from ANSTO is basically, is the same technology. So it would be -- we would work with either the suppliers who are the ones that get the end product FDA approved and go through that path. But since it's the same technology that's been brought already for patient use, our path is pretty straightforward.

COMMISSIONER SVINICKI: Okay, great. Randy or Parrish?

RANDY SPICKARD: Yeah, I would say it actually is at the very end and it does pose a risk. I don't know if I'd categorize it as a significant risk in that we need to get the NRC license first, run it for a period of time, a significant length of time, in order to establish what we need to get FDA approval. So, one, we're operating a facility without generating revenue. So we're full of operating costs or nearly of operating costs for a period of time before we can generate revenue. So it does pose a risk but it's one that we understand and it's pretty well laid out what we have to do.

COMMISSIONER SVINICKI: Okay, and is that, I think it was in your presentation that you had mentioned producing some scale, at a scale level producing some product equivalent to.

RANDY SPICKARD: Correct.

COMMISSIONER SVINICKI: So it's kind of concept.

RANDY SPICKARD: Absolutely.

COMMISSIONER SVINICKI: Thank you, okay, refer to it that way. Greg?

GREGORY PIEFER: Yeah, and I'll just add, you know, our thoughts are very similar to Randy's and I think involvement of the FDA early in the process through the early submission of a drug master file is helpful so that they understand what's going on and they understand how the Molly's being made. But at the same time, you know, what they're really, I mean the FDA doesn't actually directly license Molybdenum-99, they license the technetium-99, and that comes off the generators. However, our customers will demand a certain purity spec from us.

COMMISSIONER SVINICKI: Okay.

GREGORY PIEFER: And that needs to be compliant with what the FDA has licensed them to put in their technetium generators. So there's an FDA requirement, essentially indirectly through our customers. And we need to show after we're in production that we can repeatedly hit that.

COMMISSIONER SVINICKI: Okay.

GREGORY PIEFER: Without variation so that they start to trust it. And, so, early involvement is good but I think you do need to get the system up and running before they'll be okay with it.

COMMISSIONER SVINICKI: Okay, and Greg, I think on your Slide 8 you had talked about making sure all aspects of the licensing framework that will need to be addressed are in place for, you know, timely deployment and certainty kind of in know what the requirements will be. But I took in your response to Commissioner Ostendorff that you, and please correct me if I misunderstood this, that you really feel that we are at least cognizant in trying to

work towards all of those aspects? There weren't any, I think you said, any gaps or anything that we truly just weren't working on it all?

GREGORY PIEFER: We've seen a tremendous amount of cooperation, been very happy with it so far.

COMMISSIONER SVINICKI: Okay, thank you. And I was going to ask Carmen, your slides had emphasized that the INVAP technology is a proven technology in other places. Are there, though, adaptations or modifications that you would be making to that for your?

CARMEN BIGLES: Yes. Each of the INVAP designs is custom made for each of the places where it's being built. OPAL, for example, was originally for the supply of Australia plus some research that the government was doing, or does with nuclear medicine. In our case ours is directed for nuclear medicine and producing the Mo-99 and the subsequent iodine and other radio chemicals that come from the radioisotopes that come from the process, but ours is specifically designed for the twin research so that the supply chain just keeps on going. We don't have to shut down for an, and shut down the entire supply chain in order to do maintenance on one of the reactors and not the other three of the twins and the spare processing lines and then goes to a facility, so.

COMMISSIONER SVINICKI: Okay, thank you for that -- for that information. And I think I would just generally provide an opportunity, this is really the last topic that I wanted to touch on. I think all of you have mentioned the efforts of the interim staff guidance. All of your organizations have had the opportunity to comment on that and in looking at some of that I thematically drew, I won't attribute this to any one of you particularly, but some of the themes I took from comments that the NRC staff received on the interim staff guidance was

that the NRC should be mindful of the hazards of these facilities. I think Greg, you spoke to that pretty directly in your presentation, some of the suggestion of requiring that there be an analysis for 50 miles of, you know, all other hazards or considerations, that that seems to be drawn from NRC's requirements for large power reactors and that ingestion pathway planning for 50 miles. And so, I think there was some commentary on that. Is there anything to the extent that you prepared or are very familiar with your company's comments or feedback on the interim staff guidance? Is there anything beyond what I've commented to say that, you know, the suggestion of the requirements should be cognizant of the actual facilities themselves and the hazards in consider, environmental considerations they pose? Is there, I would give you an opportunity to just -- is there anything else as a broad theme that you would emphasize out of the comments?

RANDY SPICKARD: No.

CARMEN BIGLES: No, I -- and I just want to say this and I'm going to -- every time I've had a concern, or a comment, or a question, or do not -- within our advice or something, you know, it's debated between our engineers as well. The staff has always been very helpful in guiding us in the right direction, so.

COMMISSIONER SVINICKI: Okay, thank you. Greg, did you?

GREGORY PIEFER: Yeah, and I, well I think you captured ours and, you know, some of that probably came from our response. You know, I think everyone's doing the best they can to get something in place quickly and we recognize that's a challenge and we appreciate the chance to give feedback like this. And I think, you know, just be mindful of what the facility is and, you

know, the hazards it poses. I think you've summed it up, my thoughts exactly, so...

COMMISSIONER SVINICKI: Okay, thank you. Thank you Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Magwood.

COMMISSIONER MAGWOOD: Good morning to all of you, and let me repeat the thanks for your presentations this morning. The, it's always, when you're around long enough you get to graduate to become a curmudgeon.

[laughter]

So let me look curmudgeonly this morning. You know the, and I'm sure Parrish you're aware that there were attempts in the recent past, about a decade ago, to try to deal with the Mo-99 problem. And we made some progress, but the government kind of lost interest along the way the last time. And we could -- and I look at this in some great frustration because I've visited some hospitals in the last year or so and found that, you know, that, you know, the threat of the shortage isn't just a threat, it's happening today. There are patients who are going without technetium analysis and having to go to different isotopes that give them higher exposures. So, you know, the government's lack of vision a decade ago led to this situation.

So let me congratulate NNSA on staying the course on this so far, and let me just also congratulate you for working with the interagency group which hopefully will sustain the government's interest in this and hopefully congressional interest in this issue so that we don't let this fall off the scope again and be revisiting this crisis five or 10 years from now. That's it.

It's interesting that NNSA is leading this because it's a little bit

almost sort of the tail wagging the dog a bit, because you're interest in this as an organization is to reduce the HEU. However, that does seem to be the reason the government is involved in this. So that's a good thing, I guess. But it -- when you're working with the interagency, I just want to get your -- I haven't talked to anybody in the interagency group. So I wanted to get some perspective on this. Does the interagency group look at this as a nonproliferation issue, or do they look as a medical issue? How does, how does the group as a whole look at this issue?

PARRISH STAPLES: Okay, actually you're touching on a lot of history and maybe I'll go through that slightly as I, let's say the, you refer to the, in the mid-90s the U.S. government was trying to develop a supply at Sandia National Laboratory with the ACRR, among other options that were investigated. The reason I think the government lost interest at that point in time is because we were assured that the commercial industry would actually be developing a supply. The supply that we were contemplating was actually on Federal facilities and it was a government activity, so we can't compete with commercial activities if there is sufficient supply.

However, the MAPLEs never succeeded, which was the main advocate for who would be developing that commercial supply. So we generated the vision now to actually support the development of commercial industry, so I think we took lessons learned very well and are applying them appropriately. And, as you mentioned, the entire interagency is very committed. We're actually led by the Office of Science Technology Policy of the White House. That was the group, the organization that brought us together several years ago when the shortages occurred that we evaluated if it was possible in an interim basis to

implement any emergency production methodologies.

We did actually come up with a solution that could be implemented; however, it was extremely expensive. It required weekly mill air shipments to the production facility in Canada from reactors in the United States. In the interim, we were also working with the international community to try to develop alternative emergency actions and to great credit to the Belgian facility they implemented an additional cycle out of the norm that was able to make up some of the shortage and get us through the interim period until the Dutch facility came back online.

The NNSA role in this definitely is the, from the HEU minimization standpoint is how we got involved. But when OSTP solicited the interagency a few years ago who had experience and expertise in it, it was our organization because of the HEU minimization effort that we knew who the international community was and we understood many of the issues. And we also, through the reactor conversion program, knew what the capabilities and capacities were each of the research reactors that could be utilized for the interim production.

We've a very close, cooperative relationship with the isotopes program in DOE. The DOE isotopes program has a responsibility for support of isotopes where there is not commercial capability. Again, we are differentiating very close between our HEU minimization mission and commercial capability.

I think what really demonstrates the vision that the interagency has on this, however, to close your question, is that we view it as both an HEU minimization, a threat reduction standpoint and a medical issue. Our co-representatives at the OECD are Health and Human Services, FDA, and the Centers for Medicaid and Medicare Services. So that definitely, I think,

demonstrates that both OSTP and the NSC, who's significantly involved in this, has the vision that it's a medical supply issue as much as a threat reduction standpoint in terms of HEU minimization. So, and quite honestly we don't feel that we could resolve the situation unless CMS in particular is involved also due to the reimbursement aspect that they play for the insurance system of how we can transition this industry from a heavily subsidized industry, which is part of what led to the current failure, to a full cost recovery truly commercial activity that's taking place without government intervention other than from a regulatory standpoint from both FDA and --

OPERATOR: Please pardon the interruption. You're conference contains less than three participants at this time. If you would like to continue, press star one now or the conference will be terminated.

PARRISH STAPLES: So, that was the perfect interruption.

[laughter]

COMMISSIONER MAGWOOD: I hope Apostolakis wasn't calling from long distance. Well, appreciate your views on that. We'll have to talk off line about the history a little bit. I think there's a little skew there, but I'll let that sit for now. But, again, appreciate what you're doing here. It certainly seems to me that you've got some expertise and commitment to this personally, so I appreciate that. You're an excellent representative of the interagency on this. Keep up the good work and, you know, let us know if there's anything we can do to be of assistance.

For the panel, just a couple of questions. Of the three of you I think Carmen has in some ways the least challenging outlook because the technology is well proven. For the others, you have some work to do in the technology

development side and in a nuclear area, as everyone can certainly testify who's been in this business for any time, usually the hard part is waste in some fashion or other. And I think that Randy, in your presentation you mentioned that I think every five years you've had to change your liquid fuel. What final form does your waste take?

RANDY SPICKARD: Well, what'll be described there, what would be categorized as high level waste, it will still be in a solution. So our plan in the interim is to solidify it and store it on site.

COMMISSIONER MAGWOOD: Solidify as, in what form, how, doing?

RANDY SPICKARD: We're still developing that. Still, I mean that's one of the things we're certainly working through now. And there are solutions that we're working with the DOE on to have a disposition path for that, and we're confident that between our interim storage and a long term solution that, that won't be an impediment to us moving forward.

COMMISSIONER MAGWOOD: Same question to you Gregory. What's the final form and what type of waste do you think you'll be dealing with?

GREGORY PIEFER: Yeah, and it's a very good question, and it's similar I think in character, although according to definitions it's not high level waste. The way the definition is codified is, is essentially if you follow the chain it goes back to basically, it has to be produced in a reactor to be high level waste although the character, again, is similar.

You know, part of it depends a lot on what happens with this S.99 Act that's presently being considered by the Congress, which includes a lease and take back of uranium by the Department of Energy. In which case, we would

never own the uranium nor the waste products and so we'd have to work with the Department of Energy to give them a form that's suitable for disposal. Their other options are to solidify in some form of concrete or plasticize waste and then, in our case, there may be some Class C waste disposal options now that we have at the Texas site recently opening. So, we're again still kind of waiting to see how S.99 plays out. That's obviously the preferred mechanism for us. And, I think it would really help all of our operations if S.99 were to go through and give us a disposal path.

COMMISSIONER MAGWOOD: It's interesting, because that -- because it sounds like those decisions are going to have a pretty big impact on your eventual applications, so that may become the pacing item in this entire program. So, that's something we'll have to watch very closely.

Again, Carmen, I think you're -- like I said, I think your job is a little bit of the easiest from that perspective, but one quick question for you, not to leave you out. The -- what kind of experience have we had overseas with the Argentine reactors? Have there been any issues that have, that were worth pursuing?-

CARMEN BIGLES: The one issue that -- and actually I spoke with some people from ANSTO at the beginning when they were, they had to change the kind of -- the processing in order to be able to distribute it to the U.S. and keep it there in that amount, and that had to change some of the things. But, they were able to modify them, and we get the Molly there now.

And I did want to mention, we do, I did begin through -- because of a patient's, and, or cancer patients that needed the technetium in order to get the bone scans and get the -- to see where they were done, and, you know, the

amount of radiation that the children were receiving as well due to not having the technetium is not, it's not healthy at all. It's creating more tumors, and, you know, not good, basically.

COMMISSIONER MAGWOOD: Yeah. I appreciate that and agree with you. I thank all of you for your presentations and, you know, best of luck with your projects. Thank you, Mr. Chairman.

CARMEN BIGLES: Thank you

CHAIRMAN JACZKO: Well, thank you. I had a couple of questions. Parrish, maybe you could just give me a sense, we, you know, I appreciate the part of the dual goals here is one is to reduce the use of LEU, the use of HEU. We don't currently, of course, have any specific prohibition on use of HEU in U.S. reactors, research reactors or things like that. Well, we have an effort to reduce, but, if we were to get an application that came in, you know, let's say we -- I mean, because originally I think we were looking at 2013. I think the original goal was to have reactors online in 2013. Now, we're looking at 2016, so that's a little bit longer. You could put in the skeptical camp that 2016 is achievable with some of the work we have left to do. We don't have applications. I mean, so, we're looking at four years, which should be, you know, doable timeframe if we get applications soon. But, certainly, for review, and maybe construction, and I don't know if actually get to production, and then you have FDA issues to deal with. So, you know, maybe 2016 is not real reasonable.

If somebody came in with, you know, they wanted to use an HEU-based process, what should we do, do you think, and they could do it faster? I'm not saying that there's anybody out there.

PARRISH STAPLES: I understand, yeah. No. It's kind of a

complicated question. Let me actually start at first, this, the slide that I showed where the Canadian reactor ceases production, according to all indications, and which has come from the government of Canada in 2016 -- that's not a programmatic objective. Our programmatic objective actually is by, and our contractual objective with our cooperative agreement partners is at the end of 2014. We figure that gives us the appropriate contingency to ensure --

CHAIRMAN JACZKO: So in 2014, you'd like supply?

PARRISH STAPLES: That is our contractual objective with our cooperative agreement partners, and this also is commiserate with language that we've provided to Congress for our budget approvals in terms of --

CHAIRMAN JACZKO: Now, you realize that that's not possible to have supply by 2014?

PARRISH STAPLES: That's when we would actually -- that's our contractual objective with our cooperative agreement partners for initiating production. We do realize that's an extremely aggressive goal. The rationale for that is that the Canadian reactor will cease production in 2016, so we're pushing to as aggressive objective as possible so that we have some contingency in the system. That is also the same rationale that we have four cooperative agreement partners, each that we are working towards a 3,000 six day curie. The global supply or demand is approximately 12,000 six day curies, so the simplistic algebra indicates that the U.S. producers that we are supporting would actually dominate the global industry.

In all due respect, that's probably not how it will work. We've never, you know, we realize that some projects will fail. Quite honestly, we're also supporting these commercial entities to develop their program. It's their

obligation --

CHAIRMAN JACZKO: All right, so, tell me, so what -- I mean, from a policy perspective, I mean, do we need something in our requirements that would favor? I mean, I'm just looking at that, I mean, obviously, if 2014, that's an even more aggressive than what I was thinking, and I think that is a real challenge. So, if we had somebody who came in and was going to at least maybe on an interim basis say take a currently HEU-fueled research reactor and put a source in and even if they wanted to use an HEU source, should we do that or should we not do that?

PARRISH STAPLES: We should not do that, and I think that we would have the legal obligation to not support that part of the language. And I'll probably be misquoting it here, but the essence is that if there is alternate LEU technology available, we are obligated to support the implementation of that LEU technology.

CHAIRMAN JACZKO: I don't know. Maybe, is that -- does that apply to us? I mean, I was as aware that that was more of an export, HEU export, but not on a domestic use perspective. I mean, we have prohibitions on exporting HEU to Canada, for instance, but I don't think there's anything that prohibits, I mean, obviously, in the U.S.

MARIAN ZOBLER: Not aware of anything, no.

CHAIRMAN JACZKO: Well, I mean, I know it's putting you on a spot. It's probably not a question that you can answer. But, you know, it is something that we'll -- I don't know that anybody who's out there wants to do that, but I think, you know, I mean, it still seems like most of all of you have some work to do. I mean, we don't have applications yet. So, you know, doing these things

by 2014 is going to be difficult.

PARRISH STAPLES: That would also be counter to presidential level commitments, say, at the Nuclear Security Summit, that we should minimize the use of HEU. So, at a minimum, it's a policy of the United States government not to support the development of civilian applications that are utilizing HEU.

CHAIRMAN JACZKO: Okay. Well, I appreciate your thoughts on that, and I don't know that it's going to matter, because I don't know that anybody's going to come forward in that category. But, the -- let's see, sorry. I have another question for you. Parrish, this is also a question for you -- the -- you talked about in your slides the work that's being done in the national labs on the, on, you know, some of the research in these areas, and that this would be available to the NRC staff if we requested it. Is that -- was that in the formal sense? Do you need a formal request from us for that, or is that just more in the kind of friendliness sense, if we want it, it's there, or are you looking specifically, is there a need for a formal request?

GREGORY PIEFER: There's not a need for a formal request. We've worked with the NRC in numerous, you know, undertakings in both informally and formally. Obviously, we respect very much your independence, and we will operate within your bounds and requirements of how we can support applications I think, as Commissioner Magwood indicates, I think goes back in the 2005 timeframe with his office, when he was in NE, we put together a program that then also partnered with the NRC to convert all of the U.S. research reactors to LEU fuel that could convert, and it was a fabulous collaboration, and we're trying to follow that same type of a model as we go through this effort here, that we work with the other offices within DOE, and support the NRC as legally

able in terms of technical support or informational support.

CHAIRMAN JACZKO: Well, I appreciate that and I'll probably ask the staff too if there's anything that they feel that they need, they can mention it then. On the – Mr. Piefer, you talked a little bit about, I think you mentioned that you would be licensed under Part 70, have you gotten that from the staff or that's just, right now, your view on your facility?

GREGORY PIEFER: I would actually appreciate the chance to clear that up, actually. It was in our earlier -- some of our earlier documentation that we thought we might be able to license this under Part 70. Subsequent discussions with the staff, in review of the regulations, suggest to us that the easiest way to license it will be to go through Part 50.

CHAIRMAN JACZKO: Part 50, Okay, good. What is the K effect of your process of --

GREGORY PIEFER: The multiplication factors are between 50 and 100. So, we're talking about sort of that ballpark range. I don't want to get into a long technical argument here, but what we would define as the physical margin from critical is much greater than that. So, the out of spec, let's say the solution height would have to be, for example, which is one of the things we do when we're filling the system is a significantly greater margin than that. So, that's one of the things we're going -- one of the conversations we're going to try to be having, you know, with staff, is to see if that argument makes sense.

CHAIRMAN JACZKO: Okay. Well, I certainly encourage you to bring those issues up. You know, those seem to be the ones that could be challenging as we go forward. So, I'm trying to figure out -- I don't know if we've ever licensed a facility like that, that ---

GREGORY PIEFER: I don't think so.

CHAIRMAN JACZKO: -- has that kind of unique characteristic, so I'm sure it'll be lots of new things for us to go through as we do that, so -- well, again, I appreciate all of you being here, and your statements, and encourage you to continue to interact with the staff, and, you know, as you do go forward, the thing that we found that is most effective is if you have applications that you interact extensively, the better your application is, the better the process will be, and the more you interact ahead of time, the better your application will likely be. As issues can be addressed and you can send us an application that is, you know, addresses issues ahead of time, I think that's better, so I encourage you to continue to do that, and I look forward to any submittals we get. Thank you.

CARMEN BIGLES: Thank you.

GREGORY PIEFER: Thanks.

RANDY SPICKARD: Thank you.

CHAIRMAN JACZKO: Thank you. We'll take a quick break. Okay.

[break]

CHAIRMAN JACZKO: Okay, Mike.

MIKE WEBER: Good morning Chairman, Commissioners. It's a pleasure to be appearing before you today to address this important topic. I apologize for the little delay. As you know there are some constraints that we operate under during those kinds of breaks. As we heard from the first panel, the NRC staff recognizes the need for both a reliable and a safe domestic supply of medical isotopes. We also recognize the importance of producing these isotopes, using low enriched uranium, both targets and fuel.

For many years, we've coordinated our regulatory approach with

the Department of Energy, to reduce the reliance on the use of high enriched uranium, including the conversion of research and test reactors in the United States, to use a low enriched fuel. If a domestic supply of medical isotopes is developed in the United States, our role as the regulator is to ensure that the supply is accomplished safely, securely, and in a manner that protects the environment, and as you will hear from our presentation today, we are cooperating within the federal government to prepare for the review of a diverse range of potential licensed applications. This diversity adds complexity to our preparations and you'll hear about that in our presentation. However, we are ready to review a license application in both a high quality and in a timely manner.

Now, I'll turn over the staff's presentation to Tim McGinty. Tim is the director of the Division of Policy and Rulemaking at NRC's Office of Nuclear Reactor Regulation. Tim.

TIMOTHY MCGINTY: Thanks, Mike. Good morning. I'd like to start today by describing some of the background driving activities towards the domestic production of Mo-99, using LEU targets. You actually already explored that extensively, and with Commissioner Magwood, your dialogue with Parrish even in more detail than I'll present.

Following that, Mr. Jesse Quichocho will provide information on NRC's interactions with potential applicants. Following Jesse will be Patty -- Ms. Patty Silva providing information on licensing and technical review processes of medical isotope activities, and then I'll be returning for a summary.

The fragility of the domestic supply of Mo-99 most recently become apparent to us in 2007, and that's when there was a two month shutdown of the

National Research Universal Reactor in Canada. We had our first letter of intent within a couple of months of that shutdown, in December of 2007. At the time, the NRU facility was responsible for 40 percent of the worldwide supply and 60 percent of the U.S. supply of Mo-99.

Spurred by the additional shutdowns that later occurred at both the NRU facility as well as the high flux reactor in the Netherlands, in 2009 and 2010, significant interest in establishing a domestic supply of Mo-99 grew. For example, we briefed congressional staffers in 2009, and DOE began establishing the cooperative agreements.

At this point, I'm going to ask Mr. Jesse Quichocho to present his information on NRC's interactions with the potential applicants.

JESSE QUICHOCHO: Thank you, Tim. Good morning. As mentioned earlier, the 2007 shortage of medical isotopes led to a significant interest in creating a domestic Mo-99 supply. Starting in 2008, the Nuclear Regulatory Commission staff held discussions with B&W in identifying potential licensing and technical issues to their design of a medical isotope production facility, as you heard earlier today.

In 2009, we were contacted by Coqui, GE Hitachi, University of Missouri Research Reactor, and SHINE Medical Technologies, through a letter of interest, and partnership with Morgridge Institute for Research, as you've heard earlier today. Each sent in a letter of intent to produce a domestic supply of Mo-99, using different proposed technologies and designs. As you heard earlier today, the broad spectrum, you're looking at a research and test reactor to an aqueous homogeneous reactor.

In 2010, the staff started to identify the regulatory framework and

develop technical guidance based on the proposed technologies and designs. Because of the large number of interested applicants and potential for licensing facilities with new and varying degrees of technologies, the NRC needed to communicate the need for potential applicants to engage with the NRC early and frequently, in the development of the application to assist in submission of a high quality and complete application. To accomplish this, the NRC issued a Regulatory Issue Summary 2011-06, in July of 2011.

Further, the regulatory issue summary requested potential applicants to provide updated scheduling information, to allow the NRC staff to allocate resources for the review of license applications, and for timely completion of these reviews. The NRC staff received four responses to the Regulatory Issues Summary. They were from B&W, Coqui, SHINE, and GE Hitachi, who, as Mr. Staples pointed out earlier, suspended their activities.

NRC's response to the information obtained from the Regulatory Issue Summary included identifying skill sets needed to support the NRC technical reviews, determining proper licensing approaches to each specific technology and facility posed, coordinating efforts for an efficient and effective review process. Next slide, please.

Since 2011, the NRC staff has interacted with potential applicants in numerous venues. The NRC staff has held over 10 public meetings with potential applicants, and responded by letter to licensing and technical questions, to identify the appropriate regulatory framework, for each proposed facility and to address numerous licensing and technical issues associated with each proposed design. In our public meetings, the NRC staff discussed the applicability of NRC regulations to what the applicants propose to do, and how they propose to do it.

As you heard earlier from the first panel, the multiple designs presented, the NRC had to devise a licensing approach for each specific one. Additionally, the NRC staff has discussed technical attributes to the proposed designs and technologies, to better understand the methodologies used -- we did this to establish a more efficient review process for both the applicant and the NRC, by helping ensure complete applications.

The NRC also responded to letters from potential applicants, which raised specific questions, including the types of licenses the NRC issues, whether the NRC would consider issuing a combined construction permit and operating license under Part 2, and clarification of guidance. The NRC has communicated to the applicants that these types of interactions are strongly encouraged by the NRC, and the NRC staff appreciates the frequent and early engagement it has received to facilitate the understanding, thoroughness, and completeness of these applications. The NRC has also communicated to applicants that there is an existing regulatory framework available for each proposed technologies. I will now turn the presentation over to Ms. Silva.

PATRICIA SILVA: Thank you and good morning. The licensing of any medical isotope facility will depend on the configuration, the proposed configurations for reducing, separating, and processing the Mo-99. Part 50 and Part 70 would be used as applicable to the licensing of the proposed facilities. In addition, the NRC has the authority to issue orders, exemptions, and license conditions. These regulatory tools will be used as warranted. Based on what we know of the proposed facilities, the extraction and purification systems would be defined as production facilities. Part 50 defines a production facility as any facility designed or used for processing of irradiated materials containing special

nuclear material.

The safety aspects of the proposed facilities would be evaluated using existing regulations and guidance based upon the configuration and operation of the proposed facility. Licensing could be either a two step process consisting of a construction authorization and an operating license, or orders could be issued allowing for a combined license.

In preparation for potential applications, the NRC established the Mo-99 working group. This working group consists of representatives from NRR, NMSS, FSME, NSIR, Research, the Office of General Counsel, the Office of Congressional Affairs, and the Office of International Programs. The working group was established in late 2009, to address the regulatory issues related to the production, transportation, and security of Mo-99. The working group meets on a regular basis to discuss licensing process and development of interim staff guidance. I'll discuss the interim staff guidance a little more on the next slide. The working group continues to review the need to adapt its plans for licensing processes based on what's known from the potential applicants pending an actual submission of an application. Next slide.

The interim staff guidance augments NUREG-1537, which is the current guidance for non-power reactors. The guidance follows a format of the NUREG, which contains two parts. Part one contains the guidelines for the format and content of an application for a non-power reactor. Part two contains the standard review plan and acceptance criteria to be used by the NRC reviewers in the licensing review.

The interim staff guidance augments the NUREG by including the guidelines for preparation and review of applications for aqueous homogeneous

reactors and production facilities. The interim staff guidance has been issued for public comment. Comments received are currently being addressed. The ISG will be finalized in late 2012, and will include disposition of the comments that we receive.

Because granting a construction permit or operating license for these proposed facilities is considered a major federal action under the National Environmental Policy Act, the licensing reviews will require either an environmental assessment or an environmental impact statement. The Department of Energy is also responsible for preparing an EA or EIS for those applicants receiving DOE funds. The NRC is coordinating with DOE to ensure environmental reviews are completed as efficiently as possible, such as potentially producing a joint EA or EIS. Tim.

TIMOTHY MCGINTY: Thanks, Patty. So, in summary, the staff recognizes that there is a diversity of proposed designs contributing to a unique licensing pathway for each of these designs. The staff is confident that with continued and frequent engagement with the potential applicants, these challenges will be overcome through advanced preparation. By seeking public input to the interim staff guidance as well as our acceptance review process for these applications, the staff will be better able to support potential applicants in development of a thorough and complete application, as well as we will be better performed to perform our own review. The staff is coordinating with the Department of Energy and NNSA, and we're developing efficiencies for the environmental reviews that are required by NEPA.

We'll also continue to identify efficiencies as we review the first application or each application that we receive. We'll learn from the experience.

We've anticipated having applications since 2010. We've planned for that, at least one application since then. We've had, obviously, we've had some uncertainty as to when we'll receive an actual application. I think what we've heard earlier today, that's reduced my uncertainty, but we've been experiencing, obviously, delays in receiving an application; nonetheless, the staff will be prepared and ready to perform the reviews of applications when the NRC receives them. This concludes our prepared remarks and we look forward to your questions.

CHAIRMAN JACZKO: I have to say, I think this was the shortest staff presentation ever.

[laughter]

MIKE WEBER: We knew that the first panel would do such a good job covering the topic that we had little to add.

CHAIRMAN JACZKO: We'll start with Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman. Let me start out with a question, maybe I guess I'll direct it towards Jesse and Patty, but if you want to direct elsewhere, it's your call. There's a lot of people here and I think you all are the right ones. Recognize that we typically have licensing guidance that's fairly general, and yet we're talking about very specific different technologies that are likely to be seen by the NRC in potential applications, and I know that you don't have an application submitted as of yet, but can you give me an example or two whether it's a hypothetical or based in a projected sense on how we might adapt our general licensing guidance approach to reflect a specific technology if it comes in, and I'm trying to understand how that might happen.

JESSE QUICHOCHO: That's exactly what we did with the interim

staff guidance, is that --

COMMISSIONER OSTENDORFF: Please tell me something specific and not general, very specific here.

JESSE QUICHOCHO: We took -- what we did was we looked across the agency. We looked at all of the staff guidance that are available, power reactors, NUREG-0800. We looked at research and test reactors, NUREG-1537. I believe we also even looked at NMSS and some of their regulatory guidance, and what we did was, looking at it as a whole and looking at -- we didn't know what the actual designs or technologies were until, I believe, late 2009 and 2010, and so at that point, once we honed in, focused on the aqueous homogeneous reactor and the production facility, that we then started applying, evaluating all the different guidance that we had, and what we ultimately did was identify NUREG-1537 as the governing document that had the majority of the content and format for these types of applications. And so what we did was we used that as our basis. In all, I totally agree with you, with let's not reinvent the wheel. Let's find something that's similar and close to it, and designed to these facilities.

MIKE WEBER: Okay. Can you give an example of, like, criticality control?

JESSE QUICHOCHO: Some of those -- okay, so when we looked at, for example, and I think Patty may be able to answer some of those specific ones.

PATRICIA SILVA: All right --

COMMISSIONER OSTENDORFF: Yeah, I'm looking at specific -- I want to hear some technical application of how we've adapted our general

approach to what we think might be a Mo-99 application. So, as specific example as possible would be very helpful.

PATRICIA SILVA: Okay. So, like Jesse said, we took NUREG-1537 to start with, and so if you have a reactor based technology, then you're going to have the non-power reactor piece of it with that, and then we added the aqueous homogeneous reactor into that, and then on the production facility side was a lot more like a fuel cycle facility, where we have chemical hazards. You have criticality safety issues, and so that's the part where we integrated in our NUREG-1520, where we reference back to there. So, we see it being, you know, a Part 50 license, but we're going to have a lot of applicability of Part 70 methods, methodologies.

COMMISSIONER OSTENDORFF: Okay. I'm looking for -- and I'm sorry.

PATRICIA SILVA: I don't know how specific I can get.

COMMISSIONER OSTENDORFF: No, no. I want to hear -- and it can be a hypothetical example. I'd be fine with that, but not necessarily associated with any of the three potential applicants of the previous panel. I'd just like to hear an example. You know, are we talking about, you know, a different approach to criticality control, as a good example, or radiation shielding, or waste? I'm just trying to hear something specific, so I can get a --

MIKE WEBER: Marcus, You're more technically familiar. Would you like to address? State your name, please.

MARCUS VOTH: Yes. I'm Marcus Voth and I'm a member of Jesse's branch. I was involved with a project from the beginning, and I might try another approach at your question, Commissioner. The first thing we did, when

we looked at 1537 and the schemes that we were attempting to license was to see what was applicable and what was not. One of the obvious shortcomings was that the existing document did not address aqueous reactors. So, we convened -- we -- through a research user need, Research convened a panel, and they addressed the entire subject of aqueous reactors, and there were other parts of the NUREG guidance document that we said didn't need any significant changes, for example, sighting, financial qualifications, and so forth. So, we identified these items and we really added a section for aqueous reactors.

COMMISSIONER OSTENDORFF: Okay. Well, I'm sorry. What I'm looking at -- and if you want to get back later on after the meeting, that's fine. I'm looking at a specific example or two of where, let's say, the aqueous reactors have a different design than what the guidance was originally developed for. So, how is that general guidance been tailored in a technical example or two, to deal with an AHR reactor?

MIKE WEBER: Can you address that or should we just get back --

COMMISSIONER OSTENDORFF: If you want to get back, that's fine. I'm just trying to -- I think the responses have all been so conceptual and theoretical, it's not -- I'm trying to get a real pragmatic context for what kind of deltas we're dealing with here.

BRUCE BOGER: Like an accident analysis of the maximum --

PATRICIA SILVA: Right, but like --

BRUCE BOGER: -- critical accidents different in these --

PATRICIA SILVA: We would expect the processes and hazards to look a lot like a fuel cycle facility. So, we were going to use -- we expect for the applicants to come in with an integrated safety analysis, to look at those hazards

and to identify items relied on for safety, and to develop management measures. So, we're looking at it a lot like fuel cycle. If you don't -- like in the SHINE, where there are going to be sub-critical, most of that would be, I believe, reviewed under the excepting criteria and methodologies more like Part 70, because there is no reactor.

COMMISSIONER OSTENDORFF: Okay.

AL ADAMS: Al Adams, from the Research Reactor Licensing Group. I can give you two examples. NUREG 1537 requires applicants to discuss the attributes of the fuel. With the liquid fuel, there's attributes you don't see in solid fuel. For example, we asked the licensees to discuss how they would control the pH of the fuel, because that's important in keeping the fuel in solution. Another example of reactivity control, liquid reactors produce a lot of gases. That produces churning of the liquid. We asked, in the guidance, we ask licensees to describe how that accounts into their modeling of thermo hydraulics, how that accounts into their modeling of the reactor control, and how the reactor control system will react to the fact that now, instead of a set of solid fuel elements, you now have a churning liquid. So, there's two examples where we took the guidance from 1537. That was written for the existing reactors and tailored it specifically to the technology of liquid homogenous reactors.

COMMISSIONER OSTENDORFF: Thank you. That's very helpful. Let me follow it up with a kind of related question, and, Jesse, I'm going to stay with you, I think, and Patty. Based on what you know today, what are the unresolved policy issues, if any, that NRC may face with respect to licensing of a Mo-99 facility? Are there any unresolved policy issues?

JESSE QUICHOCHO: As of today, I don't know of any unresolved

policy issues.

COMMISSIONER OSTENDORFF: Okay. Agree? Okay. Thank you all. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Svinicki.

COMMISSIONER SVINICKI: Well, thank you for your presentations and I appreciate your responses. Tim, I might start with you. In terms of -- was there a point at which the staff looked at whether, you know, any rulemaking was necessary? We've approached this through the interim staff guidance, was there, you know, a fulsome look at whether rulemaking would provide efficiencies, and again, I think I have a sense of this after the first panel, is that because there's a lot of uniqueness, it would be hard, I think, in rulemaking space to have a really applicable generic approach, but could you talk a little bit in the reasoning about going with the staff guidance modification versus any type of rulemaking?

TIMOTHY MCGINTY: Yes, and that's related to my initial response, and we've been anticipating an application since 2010, and as you know, rulemaking takes periods of time that's a very deliberative process, that includes public interaction. So, it takes time, and so, the staff actually had direction from the Commission to consider methodologies to develop efficiencies, to conduct our review, including evaluating rulemaking, and in part, because of the pending, what we believe we were going to be receiving pending applications soon. That was one of the elements that led us to conclude that our existing regulatory framework supports the ability to perform our licensing reviews. There are plenty of options available, including the use of orders and exemptions that licensees could apply for, as well as the existing process that is, I would say,

mature and time tested.

COMMISSIONER SVINICKI: And having put a version of interim staff guidance out for comment, do you, reflecting on it at this point and time, feel that our decision to pursue the guidance modification was appropriate, would not run into anything that we didn't anticipate there?

TIMOTHY MCGINTY: Yes, I do.

COMMISSIONER SVINICKI: Okay. Thank you. I don't know -- I don't -- this isn't really intended to be the same question as posed by Commissioner Ostendorff, but I was going to pose this very generally. The previous panel talked about comparisons of the technology that they're proposing as similar to a research and test reactor. I think somebody said it would be like a small university reactor. When you think about the hazards posed, not about the specific technology, but about hazards and safety considerations, or environmental considerations, do you think that that generalized comparison to research and test reactors or university reactors, do you think that it's apt or appropriate, and if not, where do you think the big departures are? Anyone.

JESSE QUICHOCHO: I believe so. I believe they are, and when you look at the hazards comparable to research and test reactors.

COMMISSIONER SVINICKI: Would you draw any comparison or do you think there's, again from a hazard standpoint, with maybe source manufacturers, or something like that? Do you think that's also somewhat parallel in terms of a comparison of hazards?

JESSE QUICHOCHO: I didn't hear the first piece or before --

COMMISSIONER SVINICKI: Instead of comparison to RTRs, if you were doing a comparison in the materials area, to maybe like a large source

manufacturer, distributor, something like that, do you think that the hazards comparison is also -- there's some parallels there?

PATRICIA SILVA: I think there's some parallels with the fuel cycle processing.

COMMISSIONER SVINICKI: Okay, and the other thing that occurred to me, as I listened, maybe mostly to NNSA's presentation, but a little bit also of the potential applicants, as we look at these technologies which are unique, and maybe novel in some aspects, or there may be in some aspects where things we simply have not worked with in many decades in this country. So, we may be going back to the past on some things, but I got to thinking about the kind of the human capital side of this, and there aren't that many experts in some of these technologies, and while I appreciate that NNSA said that it is, you know, very energetically working with the experts that we can find at DOE National Laboratories, I don't know, maybe some are at universities as well. I always kind of flip that over and say, but the NRC's independence, of course, requires that we have access to experts, free of any conflict of having worked with applicants or helping to prepare their applications.

As you look down the road, and if you have, let's say you even had more than one application in front of you, with technology, with unique and novel characteristics, are you at all concerned about access to experts that won't have had any involvement in preparing any of the underlying support for the applications?

JESSE QUICHOCHO: I understand that we did hire, and in fact, I think Marcus Voth, who just spoke earlier --

COMMISSIONER SVINICKI: Okay.

JESSE QUICHOCHO: -- he was part of --

COMMISSIONER SVINICKI: Raced out to you at one conflict free expert, okay.

JESSE QUICHOCHO: -- and we did hire someone, Jim McGovern years ago, to help develop the interim staff guidance for the aqueous homogeneous reactors. We do look at that and we are getting folks out to visit some other facilities. We just had, you heard Al Adams, we had him have a tour, at the INVAP reactor in South America, we're planning on looking at other facilities that we can tour and observe. I think we did a tour at B&W, down in Lynchburg, similar facilities. So, we are performing activities to gather that knowledge, and maintain that.

COMMISSIONER SVINICKI: Okay. Very good. Did anyone else want to add anything on that?

MIKE WEBER: Well, I was going to say that that's one of the benefits of having two branch chiefs here at the table, because we count on our branch chiefs to look at the critical staffing skills that they need to have, and then feed that up through an agency role up, so that we maintain our focus on ensuring that we have the kind of critical skills that we need to perform these kinds of reviews, and that's especially the case where you have novel technologies that are not widely distributed. So, part of what we do is focus on ensuring that we use all means at our disposal, to gain those kinds of capabilities.

COMMISSIONER SVINICKI: Okay, thank you. Thank you all. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Magwood.

COMMISSIONER MAGWOOD: Back to the curmudgeon. In his questioning, the Chairman expressed his skepticism about the dates, and while I didn't express, I have similar skepticism about making these dates, especially in the context of the 2016 closure of the reactors in Canada, and probably the area that gives me the most pause when I think about that, or what Commissioner Svinicki just talked about, which are these novel technologies, and I recognize you had people going out and looking at the history, and I know that National Labs built aqueous homogeneous reactors back in antiquity. Don't think we've ever licensed one. Is that correct? Have we licensed an aqueous homogeneous reactor?

JESSE QUICHOCHO: Yes, we did one.

COMMISSIONER MAGWOOD: What timeframe was that?

JESSE QUICHOCHO: Back, I believe in the 80's. Al Adams could help --

AL ADAMS: Al Adams again. Over the years, the NRC has licensed 12 liquid homogenous reactors. The last one went out of operation in the early 80's.

COMMISSIONER MAGWOOD: What applications were those?

AL ADAMS: They were mainly universities, L77s, L54s they were called. The largest powered one was at Walter Reed, in Washington, D.C. They had a kilowatt scale liquid homogeneous reactor, but it's true. They -- time wise, came and went, and by the early 80's, they were all shut down.

COMMISSIONER MAGWOOD: So, were those Part 50 facilities under 103 or 104?

AL ADAMS: 104(C).

COMMISSIONER MAGWOOD: These were 104(C), so these would be 103s, right?

JESSE QUICHOCHO: That's correct.

COMMISSIONER MAGWOOD: So, does that create a higher level of analysis than what we've had in the past? What does that mean in terms of the type of analysis you'll have to do, in a sense, in terms of the safety analysis?

JESSE QUICHOCHO: I think Al can help me answer that. I believe that the 103 analysis is a little bit more descriptive. Al, do you have any more details on that?

AL ADAMS: As far as what a licensee, the information they would have to give us, that's the same that's governed by 50.33, 50.34. The difference, the primary difference between a 103 and a 104(C) is our processes. For example, a 103 license would go past the ACRS. A 103 process would have a mandatory hearing at the construction permit stage, versus a 104 would be, if an intervener would ask for a hearing. The 103 process is that these reactors would go through licensing similar to power reactor process. So, that's the main differences -- it is a more complex process which has more steps.

COMMISSIONER MAGWOOD: Okay. So, that means a mandatory hearing and the whole -- okay. On the accelerator based system, has -- I know we haven't licensed one of those. So, let me ask a couple of questions about that one. First, it's an interesting system, I mean, it's an accelerator -- there are a lot of accelerators, small accelerators used for a variety of purposes. We don't license all of them. The states license some of them. Where do you see the breakdown between state and federal licensing with a system that's been proposed? Do you see a state role in this at all or is it entirely a federal

licensing?

JESSE QUICHOCHO: From our look on the proposed applications, it would -- I believe it would be, if it was in an Agreement State, the Agreement State would license the accelerator with the licensing of a production facility. We would propose license conditions on the Part 50 license for licensing the production facility based on the operations and how they want to accomplish their work.

COMMISSIONER MAGWOOD: Okay. Let me make sure I understand what you just said. So, you're saying the accelerator itself would be licensed separately from the, I'm not sure what to call it, the production unit. Is that what you just said?

JESSE QUICHOCHO: Right.

COMMISSIONER MAGWOOD: So, you actually could have two separate licenses for the same machine?

JESSE QUICHOCHO: An applicant could have two separate licenses, one from an Agreement State --

COMMISSIONER MAGWOOD: For the accelerator?

JESSE QUICHOCHO: -- for the accelerator, and one from the NRC for the Part 50 production facility.

COMMISSIONER MAGWOOD: Does OGC want to comment on that?

MARIAN ZOBLER: If I may clarify, Commissioner. My understanding is that the answer is it depends, and that, of course, is whether the accelerator is an integral part of the reactor that, in that case, the NRC could license the entire facility. So, it depends on the integration of the technology.

CHAIRMAN JACZKO: That's what we were doing for SHINE.

MARIAN ZOBLER: Is that -- yeah. Yeah, it's correct.

COMMISSIONER MAGWOOD: Could. NRC could, okay. I remember once, I was talking to a person in novel technologies, talking about briefing the NRC, and he asked my immediate reaction, and this was before I came here. So, please take into that context. I said, "Be afraid. Be very afraid." So, these aren't straightforward in my eyes. I see a lot of decisions that will have to be made along the way, and I think if I were an applicant, I'd be a little daunted by that. So, I encourage the staff to find ways to define these questions, and give answers as much as you can. I know you've engaged, so I appreciate that. So, just keep doing that.

MIKE WEBER: I was just going to say, that's the whole reason why we've been engaging and why we've been encouraging the potential applicants to step forward early and think through the problem, identify the strategies that they tend to employ, and raise those, so that that will help us frame those issues, and if there are policy issues, or regulatory issues, or legal issues that have to be addressed, to the extent we can, we want to get them addressed early, and get them out of the way, because we don't want to slow down once the application comes in. We want to be focused on the safety, and the environmental review, and the security review, and do what we need to do to support a licensing decision.

COMMISSIONER MAGWOOD: Appreciate that. Patricia mentioned earlier that she saw ISAs being used for some of these facilities. Can you tell me where you don't see the ISAs? Obviously, you're not going to use ISAs for the research reactors, but beyond that, where do you not see ISAs being

applicable?

PATRICIA SILVA: Actually, I think I see it for pretty much the entire facility, with the exception of the reactor, because after the reactor, then you have a lot of processing with chemicals, and uranium, and you have to worry about criticality safety. You have to worry about chemical hazards. So, that's what we primarily came in for under the Part 70.

COMMISSIONER MAGWOOD: Do you see ISAs being used for the entire accelerator facility

PATRICIA SILVA: I'm sorry?

COMMISSIONER MAGWOOD: The accelerator based facility, would an ISA be used for that entire facility?

PATRICIA SILVA: I think there would be application for the entire facility.

COMMISSIONER MAGWOOD: Okay. We talked a little bit about waste, the last panel. Maybe I'll look to the leadership here, Kathy and Mike. Can you walk me through this a little bit? What's -- explain the waste in the accelerator facility to me. You know, it seems to me you've used the deuterium reaction to make neutrons to cause fission. The fission is happening in the uranium solution and you're going to get, you know, you're going to get plutonium. You're going to get all kinds of actinides, you're going to get fission products, and then you're going to solidify this to keep it as a waste form in some fashion, and explain to me why that's not high level waste, and I recognize it's not coming out of a reactor, but explain to me, you know, if it walks like a duck, quacks like a duck, you know. Explain to me why that's not high level waste and why we don't treat it like high level waste. Is it simply the legal definition? Is that

clear that we've --

MIKE WEBER: That's the primary driver, the legal definitions are laid out in the law, and they're tied to how the waste is generated. Of course, we would ensure that the hazards are appropriately addressed in all cases. So, despite the fact that you may have plutonium, or mixed fission products, or actinides in there, you know, it'll have to be handled in such a way that the waste will be safely dispositioned. However it goes, whatever we call it, so…

COMMISSIONER MAGWOOD: So, we could see this called Class C or greater than Class C low level waste, whatever is actually in it. That's essentially where we would be ending up with, is that correct?

MIKE WEBER: Yeah, but in all cases, you'd have to ensure the public's going to be protected and it's going to be handled appropriately, and it's got to be dispositioned in accordance with existing legal framework.

COMMISSIONER MAGWOOD: Just a final -- I appreciate your presentation. It was short, but it was actually quite informative. I appreciate that. One comment that was also conversation at the end of the Chairman's question about HEU, this sort of occurred to me while that was going on, that whatever the -- however one interprets the policy and law, the practicality is I don't think you can get HEU from anywhere. I mean DOE has been the source for HEU generally in the United States, and I don't think you can get it from them for these applications now, and I don't know how you would import it from someplace else. So, as a practical matter, I don't think you could do it anyway. So, it's just observation. Thank you very much. Thank you, Chairman.

CHAIRMAN JACZKO: Sure. Tim, you all did the RIS and, I think it was June of 2011 --

TIMOTHY MCGINTY: 2011.

CHAIRMAN JACZKO: -- you got, I guess, responses back from three people or --

TIM MCGINTY: I think from four.

CHAIRMAN JACZKO: -- four people.

TIMOTHY MCGINTY: Four, including GE Hitachi.

CHAIRMAN JACZKO: So, they've dropped out. So, it's the three, well just all three of the people -- it was the three people we had here at the table that responded?

TIMOTHY MCGINTY: That's correct.

CHAIRMAN JACZKO: Part of what that RIS was intended to do was to highlight, you know, to get feedback now on what the issues are, the technical issues, the licensing strategies of licensing approaches. As you look at the RIS responses, are there any errors in which right now you don't feel like you've accommodated or can accommodate the responses in the RIS?

TIMOTHY MCGINTY: Not from a RIS perspective. What we're really interested in is working on the comments that we've received for the interim staff guidance and the last comment period just closed yesterday, but from a RIS perspective, no. It was designed to encourage as much early interaction on potential applications as possible, and more is always going to be better in terms of overall preparedness.

CHAIRMAN JACZKO: So, if you look at the interim staff guidance responses, are they significant, or again, do you see issues in there that are going to be difficult to resolve?

TIMOTHY MCGINTY: I don't see difficult issues to resolve, but

again, as we've mentioned, we've got a number of different licensing processes, different types of designs. There is, in many respects, we're going to -- they are relatively unique issues for the staff to address, and so it's a high quality application is probably the best driver for timeliness and completion of an overall review, and the staff is really going to have to -- like the things that we've learned in doing the RTR license renewals, where we, in order to move along more crisply, we focused our reviews. We developed a graded approach. We need to ask the questions and get the answers that we absolutely need to make the licensing decisions, to make it move along fastest, and we'll be focusing in that arena.

JESSE QUICHOCHO: I'd just like to add, you know, just a little bit, is that we recognized back in 2010, 2011, that there are varying designs, and so we took it upon ourselves to put the RIS out, and engage with these folks, and let them understand what the licensing process is, the approach, and how they can benefit, per se, in hearing us and hearing the questions that we ask of their design, so that they can submit a complete application, as well as allowing us to understand what they're going to do with these facilities, and so we can identify that licensing approach that we have to licensees, and so…

CHAIRMAN JACZKO: Well, I appreciate that and I think -- I certainly appreciate Commissioner Ostendorff's line of questioning, and I think certainly what I was listening for from your responses to his questions was some kind of certainty to us that you've identified those issues, that because clearly, you know, if what the guidance says is, you know, due an accident of, you know, loss of coolant scenario, we have something where -- particular in mind, if we're thinking of researching test reactors, and what that means. I mean some

research and test reactors don't even have backup cooling systems, or whatever.

So, you know, what we don't want is for an applicant to come in and have, you know, written 200 pages of doing that, and they're exactly the wrong thing, because they were trying to follow guidance that wasn't written for them. So, you know, looking back and looking at the interim staff guidance, I mean it seems like you went through and specifically in the draft, you put out to identify what those were, and I think through his questions, I think he was trying to get some -- certainly, I was hoping to get some certainty that you'd actually done that, and I think there's probably more there than you communicated in this meeting. So, we can probably figure out a way for you to maybe send something up, just to kind of go through that, maybe at a higher level, and just highlight what those are, you know, without repeating the entire interim staff guidance.

But, you know, I think that this is a difficult issue for us. We are a regulatory body. It's not our job to develop a Mo-99 capacity in this country, but I certainly have watched for years as we have -- others have tried and failed, and it will come a time in which we will be up to bat, so to speak, and we just need to be ready when that time comes, and be ready to hit all the pitches, and so, you know, I think that's, as I look forward that's just staff work, and we've had more time, and I think, unfortunately, part of the problem is we've had more time than we expected. So, since we've had more time, we've had more time to do and, redo, and ask, and re-ask, and but in the end, that should hopefully pay off.

Back to the RIS, one difference, I think, Missouri did not submit a response on the RIS. This time around, they submitted a letter of intent. Are they no longer interested or they just didn't submit a response to the 2011 --

TIMOTHY MCGINTY: I'd have to ask Jesse, if I could.

JESSE QUICHOCHO: They didn't -- they did not respond to the RIS. The only thing we had interactions with them, was they sent a letter of intent, and then we had a public meeting with them.

COMMISSIONER JACZKO: So, effectively at this point, are we planning to receive an application from them?

JESSE QUICHOCHO: At this point, we're not planning on receiving an application from the University of Missouri Research Reactor.

COMMISSIONER JACZKO: Okay. Great. Well, again, as I think you've heard from many people here, you know, we want to be ready and make sure we're prepared, and so keep doing what you are doing. Keep interacting with the applicants, so that if we do see some applications, we'll be ready to process those in the most efficient way. I mean, of course, you know, in the end, we have to make a safety call, and it's important that we do that in a good way, but, you know, the more we're prepared, I think, the more effective that process will be. Any other questions or comments?

COMMISSIONER MAGWOOD: Thank you, Chairman. Just a resource question, how are you resourced to go forward with this? How many applications are you resourced to receive and can you get us an idea of what's --

CHAIRMAN JACZKO: I think just remind people we don't discuss beyond 2013, in terms of the budget.

TIMOTHY MCGINTY: Okay. So, in the green book for 2013, you'll see that we are resourced, budgeted for -- to conduct one application, a review on one application. With that said, as with any process that the -- that we go through here at the agency to do licensing, when we get -- when high priority activities are presented before us, we assess it in an agency way across all of

our product lines to determine whether or not it would be more efficient for the agency to apply resources to a particular area than another. We have a lot of technical expertise and capability to be able to address multiple applications, should they arrive, but at this point in time, for 2013, we've planned for one, and we need to do that responsibly, and part of that goes back to we've been expecting an application for quite some time, and so it's not necessarily efficient to plan for things that don't come in.

CHAIRMAN JACZKO: Sure.

COMMISSIONER OSTENDORFF: I wanted to piggyback on your comment and I appreciate you raising this. I still like -- I agree. I'd like to have more information provided back to the Commission, that tries to answer my question a little more fully, or you can suggest a different question I can ask, that would get this thing thought process, because I still don't have a good enough feel for what we're talking about here.

CHAIRMAN JACZKO: Any other comments? Questions? Sure.

ERIC LEEDS: Can I just respond to Commissioner Ostendorff? Commissioner, I think what you're asking for and what we need to provide you are what are the staff's safety concerns with each one of these technologies? Let's go to the heart of the review and provide you those kinds of detailed items. You heard Al Adams come up here and talk to you about criticality safety for the liquid homogeneous reactor. You know, that's a concern, you know, the different interactions, that sort of thing. I think that's what you're asking for. I think that's what we should give you. I think that scratches your itch.

CHAIRMAN JACZKO: Let me, in the interest of time, let me say I'm not -- well, if you want to respond

COMMISSIONER OSTENDORFF: No, I appreciate Eric coming up --

CHAIRMAN JACZKO: I think we -- Commissioner Ostendorff has asked this question. I think it's incumbent upon you to provide a good answer to the question. Let's not try and negotiate that in this particular meeting, but send some information. If it's not sufficient, we'll go back and we'll keep working it until we make sure we get it, but I think, you know, I think it's pretty clear we asked for some very specific things and we'll get some of those up, and then go from there. Anything else? Okay, thank you.

[Whereupon, the proceedings were concluded]