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NUCLEAR REGULATORY COMMISSION

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33RD REGULATORY INFORMATION CONFERENCE (RIC)

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TECHNICAL SESSION - T14

MAKING AN IMPACT: INNOVATION IN THE PRODUCTION OF MEDICAL RADIOISOTOPES

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TUESDAY,

MARCH 9, 2021

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The RIC session convened via Video Teleconference, at 1:30 p.m. EST, Brian Smith, Deputy Director, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, presiding.

PRESENT:

BRIAN SMITH, Deputy Director, Division of Advanced Reactors and Non-Power Production and Utilization Facilities, NRR/NRC

ROY BROWN, Vice President, Government Affairs and Strategic Alliances, Curium Pharma

JOANIE DIX, Deputy Director, Office of Conversion, U.S Department of Energy-National Nuclear Security Administration

JAMES HARVEY, Senior Vice President and Chief Science Officer, NorthStar Medical Technologies, LLC

GREG PIEFER, Chief Executive Officer and Founder, SHINE Medical Technologies, LLC

JOHN WITKOWSKI, President, United Pharmacy Partners, Inc.

C O N T E N T S

P R O C E E D I N G S

1:30 p.m.

MR. SMITH: Good afternoon everyone. Or should I say good morning or even good evening, depending on where you are in the world today.

Welcome to RIC Session T14. Otherwise known as Making an Impact: Innovation in the Production of Medical Radioisotopes.

Over the next hour, we will focus on applications of nuclear technology beyond energy production. Millions of people each year rely on the production of radioisotopes for medical, diagnostic, and therapeutic treatments.

Among these radioisotopes is molybdenum-99, or moly-99, and its daughter product, technetium-99m. Of which there is no widely available domestic production capability in the U.S.

The nuclear industry is currently preparing and submitting applications for new technologies dedicated to producing moly-99 and other medical radioisotopes, supporting patient care in the U.S. and around the world.

The NRC staff is committed to supporting national policy objectives of establishing a domestic

supply of moly-99 by licensing nuclear reactors, subcritical operating assemblies, target processing facilities, target manufacturing facilities and the medical use of nuclear material. If we could go to the next slide, please?

For our panel today, we welcome experts with diverse perspectives on the medical radioisotope supply chain, including representatives of the federal government and industry.

But first, my name is Brian Smith. And I am the Deputy Director of the Division of Advanced Reactors and Non-Power Production and Utilization Facilities. Our division is responsible for the licensing of moly-99 production facilities.

We have five panelists during our session today. And I'll introduce those now. The first is Roy Brown.

And Roy is the Vice President of Government Affairs and Strategic Alliances at Curium Pharma. His principal responsibility is assuring the long term supply of moly-99 and other radionuclides by working with research and test reactors around the world, and partnering with groups developing new technologies in nuclear medicine.

He has more than 30 years of experience in the nuclear medicine industry. Mr. Brown holds a BS in Radiation Biophysics, and a Master's in Business Administration.

Our next panelist is Joanie Dix. And Joanie is the Deputy Director of the Office of Conversion within the Department of Energy's National Nuclear Security Administration.

Ms. Dix oversees the office's programs on converting reactors from highly enriched uranium to low enriched uranium, qualifying new low enriched uranium fuels, optimizing proliferation resistance in reactor designs, and supporting non-HEU based medical isotope production.

Ms. Dix holds a Master's degree in nonproliferation and counter terrorism from the Monterey Institute of International Studies, and a Bachelors degree in International Relations from the University of San Diego.

Our next panelist is Dr. James Harvey. Dr. Harvey is the Senior Vice President and Chief Science Officer of NorthStar Medical Radioisotopes. And has been with the company since its inception 16 years ago.

Dr. Harvey has almost 50 years of experience in the area of scientific development and business operations.

He has managed company activities to ensure compliance with federal and state regulations, and managed major government contracts involving federal research and development. Dr. Harvey has also provided his expertise to various Department of Energy operational programs.

The next panelist is John Witkowski. John was the Operations Manager at United Pharmacy Partners before becoming its President in 2013.

Since 1984, his experience in nuclear medicine and radiopharmacy has crossed many functional areas, including sales, marketing, business operations, and the network distribution channel at Amersham and GE Healthcare.

Prior to Amersham, Mr. Witkowski was Marketing Director at Nuclear Pharmacy, Inc. And was Adjunct Professor with the Mercer University Nuclear Pharmacist Authorized User Training Program for radiation safety and quality control.

Our last panelist is Dr. Greg Piefer. Dr. Piefer is the founder and Chief Executive Officer

of SHINE Medical Technologies.

He has more than 13 years of executive management experience at growth stage technology companies. Before founding SHINE, Dr. Piefer founded and served as the President of Phoenix Nuclear Labs, where he managed the development of high output particle sources.

He also served as the Chief Technical Officer at Gillware, Inc., a leading data recovery and backup company. Dr. Piefer holds a Ph.D. in Nuclear Engineering, and BS degrees in Physics and Electrical and Computer Engineering from the University of Wisconsin Madison.

Welcome panelists. Thank you for being here today. In this session, our guests we'll share their experience and knowledge on a variety of topics, ranging from the importance of our collective effort to establish a reliable domestic supply of moly-99, challenges to establishing supply and importance of technology innovation, and the other applications of medical radioisotope technologies in the nuclear industry.

As we cover these topics, we invite the audience to participate in our live polling feature,

to select the questions they are most interested in hearing about from our panelists.

Audience members may also submit freeform questions that will be addressed by panelists during our Q&A period at the end of our session.

We will start each topic with a question for one or two of our panelists. That will be followed by the question selected from our polling feature, which can be answered by any of our panelists.

So, if you could go to the next slide, please? All right. Our first topic is significance of reliable medical radioisotope supply.

The traditional process of producing moly-99 includes the following steps: enriched uranium or molybdenum targets are irradiated to produce moly-99.

The moly-99 is then processed and purified before being sent to a generator or manufacturer, and ultimately distributed to radiopharmacies and hospitals, where Tc-99m is diluted and delivered to patients as a radiopharmaceutical.

Approximately 40 thousand procedures are

performed daily in the U.S. using Tc-99m, ranging from cardiac perfusion testing to bone scans.

If we could have the first polling question put up please? All right.

So, our first lead in question for this topic, or the lead in question is for John Witkowski. Recognizing the importance of supply chain and resilience for moly-99 to provide needed medical care, could you describe how the COVID-19 pandemic has impacted the supply, distribution, and demand for medical procedures involving Tc-99m?

MR. WITKOWSKI: Thank you, Brian. I'm very happy to speak on the subject. The nuclear pharmacies are in the part of the supply chain that is the point where we receive the --

(Audio interference)

MR. WITKOWSKI: -- moly-99 and Tc-99m generators, and our reagent tip.

If we roll back the calendar for a year, the great concern with supply chain and disruption and resilience, is the use of (audio interference) the breaks.

But, what I'm happy to say is, because the moly supply chain (audio interference) but

experience this type of disruption years before.

But the monitor during the part of that was because the reactor's opportunity to (audio interference) it evoked COVID protocols. It is non-operating (audio interference)

Additionally, the FDA had approved NorthStar as a third supplier of moly to the marketplace. And so that was a great addition into the --

(Audio interference)

MR. WITKOWSKI: During the time of the lock down, we actually (audio interference) air transportation (audio interference).

During the initial lock down and air transportation was disrupted (audio interference) by COVID-19 that they had provisions in place to use other means to get the material from the reactors and processors to the (audio interference) generator facilities.

So, these --

MR. SMITH: Okay. Hey, hey, John? I'm sorry to -- John, I'm sorry to interrupt. But, we're having a lot of issues with your feed breaking up.

Sorry about that. So, I think we may

look at the results of the polling questions now. Hopefully it will improve as we go along.

MR. BROWN: Hey Brian, I might suggest, if John kills his video, that might improve his audio feed.

MR. SMITH: Okay.

MR. WITKOWSKI: Does that happen to sound better?

MR. SMITH: It does. It does.

MR. WITKOWSKI: Okay.

MR. SMITH: Do you want to go ahead and finish your answer then?

MR. WITKOWSKI: Yeah, yeah. So, I would like to say that we saw a great decline during the lock down, of procedures being ordered.

The radio pharmacies had to actually adopt, and every hospital had security and COVID protocols. So, we had to do the same so that we could make the delivery of the final unit doses for the patient use at those facilities.

And we have now seen in this time frame, from June forward, a resurgence in the imaging procedures. And so those procedures are coming back. And supply is adequate for the procedures that are

being ordered today.

Thank you.

MR. SMITH: All right. Thank you, John. And glad that worked out a lot better.

Okay. When we look at the, at the polling question, it looks like the third one there has the most response. So, we'll go with that.

What coordination is there among companies in the various stages of the supply chain? Would one of our panelists like to --

(Simultaneous speaking)

MR. BROWN: This is Roy. I'd be glad to take the first shot at the, at this question. I'm from Curium. We're both a moly producer and a technetium-99 generator producer.

So, we're really at two different phases of this operation. What we've done on the reactor level, all the research reactors around the world that currently irradiate targets for moly production, coordinate schedules.

This is done through a trade association based in Europe, called Nuclear Medicine Europe. Where each of the reactors give their schedule for the coming years.

So, we have a pretty good indication of when these research reactors, when they'll be up, when they'll be down. So, there's a great deal of coordination and when one reactor is down, we make sure that at least two other major reactors are up, and can take care of that.

The other back up arrangement we have is on their generator line. Both Curium and Lantheus, who produce conventional generators, we're very good at comparing notes.

And a lot of times when Lantheus can't supply a generator, Curium will step in and supply that customer with a generator and vice versa.

So, there's coordination both on the reactor side, on the -- and on the technetium generator side.

MR. SMITH: All right. Great. Does anyone else like to respond to that question?

DR. HARVEY: Yeah, I would. Yeah Brian, it's Jim. NorthStar's flexible production allows us to step in now into the market when need be.

And it helps a lot having another supplier that can also supply material.

DR. PIEFER: Okay. And I would -- I

would say as a potential new entrant here, you know, we're -- we've been pretty blessed to be able to work with certain parts of the supply chain in terms of validating our product.

And it's been, you know, we've tried to set up our supply chain so that the end product doesn't look any different than what people are used to getting from reactors.

So, we'll supply them test batches. Get feedback on those test batches. And then also developing just interfaces for things like shipping containers, et cetera.

So, when they need to sort of access the moly, when it's ultimately shipped to them, you know, we know that will be seamless and we won't lose a lot of time there.

So, kind of having an integrated schedule with potential, I guess, customers for us have been really nice. And it's good to see that people are -- have been willing to engage with us in sort of development of that, despite the fact that we're, you know, still a couple of years out from really ramping up production.

MR. SMITH: Okay.

MS. DIX: And I also just had one thing to add. From our side, this is Joanie, I'm at the Department of Energy.

Certainly we're a little bit further separated then the actual producers and prospective producers that are coming into the market. But, we do like to provide opportunities for the entire industry to meet, discuss ongoing issues.

So, COVID has obviously thrown a wrench into everyone's efforts over the past year. But, typically we hold a stakeholder's meeting for the moly-99 community, as well as some sort of kind of broader symposium or topical meeting focused on the subject.

So, we like to offer those up so that the community can engage, talk through upcoming issues, ongoing efforts to establish the production in the United States.

And we also participate with CORAR, which is an industry trade group for moly that often meets. And we engage with usually once or twice a year from the government side.

MR. SMITH: Okay. Great. Thanks for, thanks for all the responses. I would like to ask

one of the other questions from the poll.

How will a reliable supply of moly-99 change patient care? Would one of you like to respond to that?

How -- how might that better change things?

DR. HARVEY: Brian, I'll take off. I'll get us started on that with a couple of points that I think will -- you'll see in the future.

First of all, if a reliable supply will help the existing SPECT infrastructure be used more efficiently. SPECT is the technology, the cameras that are being used.

And a reliable supply may encourage development of more SPEC related procedures in the future. So, I can see two places where a reliable supply could assist the market in the future.

MR. SMITH: Okay. Great. Anybody else like to respond?

MR. WITKOWSKI: Yes.

MR. SMITH: John, go ahead.

MR. WITKOWSKI: (audio interference)

MR. SMITH: Unfortunately, John, now your voice is -- your audio is not coming through

very clear either.

So, I think we'll -- we'll move onto the next topic. So, if we could have the next slide, please? There we go.

So, Challenges to Establishing Supply. Since 2008 there have been significant supply chain interruptions and shortages of moly-99 due to extended maintenance shutdowns of international reactors.

Additionally, in 2018, the National Research Universal Reactor in Canada, the primary supplier of moly-99 into the U.S., permanently ceased operations.

As part of establishing domestic supply capabilities, the National Nuclear Security Administration has established call sharing cooperative agreements with potential producers, such as SHINE Medical Technologies, Northwest Medical Isotopes, NorthStar Medical Radioisotopes, and Niowave.

NRC staff has supported U.S. government efforts by issuing construction permits to SHINE and Northwest Medical Isotopes. Issued material licenses to Niowave. And issued guidance for use of

NorthStar Radiogenix generator.

If we could have the next polling question put up, please? And for -- for this topic, we're going to have two lead in questions.

And the first goes to Roy Brown. Given that Curium is involved in the development, manufacturing, and distribution of radiopharmaceutical products throughout the world, what do you see as the current biggest challenge to a stable moly-99 supply chain? And what can be done to address this?

MR. BROWN: Thanks, Brian. There were some significant outages at the largest research reactors making moly back in 2009 and 2010.

Those two reactors were the HFR reactor in the Netherlands, and the NRU reactor up in Canada that you just mentioned. What happened when those two outages went down, there were major disruptions in both the supply of moly-99 and technetium-99m generators around the world.

The U.S. wasn't as bad as some countries. But, globally there was quite a shortage of moly and technetium for quite a while.

The industry did quite a few, took quite

a few steps to improve things since that time. And I'd like to discuss a couple of those things that have been done.

First of all, there are a couple of reactors that have been added to the supply chain that significantly have improved the supply situation. The first reactor added was the Maria reactor in Poland.

Also added, was the LVR-15 reactor in the Czech Republic. As well as the Missouri University Research Reactor in Columbia, that's doing production for NorthStar that I'm sure Jim will talk about in a little while.

Also, there are a couple of other reactors that are being planned. The FRM II reactor that has been up and running for about 10 or 12 years now, that are shortly going to go into moly production.

As well as the Jules Horowitz reactor in France. That will be added in a couple of years too. That will help significantly to the European supply.

So, the European reactors that were added helped both Curium and IRE with the European supply. And the majority of the moly coming into the U.S.

comes from Europe at this point.

Also, all the reactors as well as the technetium generator producers have come up with a concept called outage reserve capacity.

And that is, where we'll have excess capacity for both production of moly and for production of generators, if one of the generator manufacturers goes down, or if one of the other reactors has another outage.

So, that outage reserve capacity has also helped significantly with the -- with shoring up the supply of moly.

And lastly, it's the addition of domestic production of both moly and technetium-99m generators. NorthStar, as I'm sure Jim will talk about in a few minutes, has been approved by the FDA since 2018.

That has helped significantly where we have a deficit supply of technetium generators in the U.S. Also at SHINE, there's just right around the corner to being able to produce moly to supply the more conventional generator manufacturers at Curium and Lantheus.

So, we're quite excited about SHINE and

some of the other new entities that are coming onto the market. So, we feel like the industry has done quite a bit to shore up our supply in the last couple of years.

Brian, you're on mute.

MR. SMITH: It had to happen at least once. Thank you, Roy for that answer. Appreciate that. The next question goes to Joanie Dix.

NNSA is involved in international efforts to convert moly-99 production to non-HEU methods, as well as domestic efforts supporting research and development for new technologies in providing financial cost sharing assistance for potential producers.

Could you describe any research and development challenges that NNSA is supporting industry in resolving that are of particular importance to establishing a reliable supply of moly-99?

MS. DIX: Yeah. Thank you, Brian. There's a couple of questions here that I want to make sure to address both sides of.

The first part is that we continue to provide technical support to international producers

as they need it, as they convert to non-HEU moly-99 production.

We worked very closely with Curium during their conversation, as well as NTP Radioisotopes. And we continue to provide technical assistance to Belgium's IRE in their efforts to succeed in the full conversation to LEU production.

Regarding the domestic efforts that we have to help establish non-HEU production, technologies here in the United States in which, you know, Greg and Jim are very well equipped to talk about, I don't think that I would say there is one particular area that we're supporting.

For all of our cooperative agreement partners, there's a lot of different technology approaches that each company is pursuing. So, really what we're pleased to provide is that our national labs have a lot of very unique capabilities.

And, we like to make those available to not only our cooperative agreement partners, but also other entities that might be pursuing non-HEU based moly-99 production in the United States.

So, with these different technologies, we try to make sure that we address technical areas, or

provide facilities that will help these partners be successful in their objectives to establish production.

A couple of examples, we recently, one of our national labs recently completed a 60 curie production run at their low energy accelerator facility. They then shipped about 30 curies of this over to NorthStar to do some testing on their accelerator project.

So, we support a lot of different activities throughout the year. We do this every year where we discuss with the labs, with the cooperative agreement partners and other interested parties, and do our best to identify and support whatever the most pressing and technical areas are that need to be addressed.

And I think that's it.

MR. SMITH: Great. Thank you for the, for the response. So, we have the polling responses up on the screen now. And it looks like the third one by a wide, wide majority is the most responded to.

What challenges have policy regulation and licensing posed?

DR. PIEFER: Yeah, happy to take a first crack at that. You know, I think policy has been really helpful. And you know, Joanie talked a little bit about the NNSA's role in this.

But, I think this has been a priority for pretty high levels in the government now for a long time. The nonproliferation agenda that NNSA is supporting, and obviously the healthcare agenda that they're also supporting, by getting a more, let's say, domestic supply chain up and running.

I think, you know, the time of COVID certainly is, maybe even more emphasized the importance of having a domestic supply chain here for medical products.

And so, the policy agenda from my view, has certainly filtered down. It's obviously filtered down into NNSA. And there's direct funding support there.

But, we see it, I think, in the NRC as well, in terms of really maybe providing a prioritization of some of these reviews. And making sure that they get addressed and get the right resources applied to them very, very quickly.

And so, I think that, from a policy

standpoint, has been really helpful. I think that the nation recognizes the importance of establishing this supply chain.

And it's been a big deal. What we're trying to do is no joke. It's very hard. It's very expensive.

And you know, I think, when I looked at raising money early on, one of the biggest threats that I always got sort of back from investors, potential investors, were, you know, this is an unknown regulatory paradigm essentially that you're walking into.

And I think that the national focus on this has helped to blunt that criticism a little bit. I think from a regulatory standpoint, look, I mean, we're building new irradiation capacity as well as processing capacity.

And, you know, really focusing on sort of fission moly, which is, you know, the sort of present gold standard for moly production. For a facility like that, and you're essentially licensed as a reactor.

And, you know, it's -- there's a lot of requirements, I guess, that go along with that. And

it's a big deal.

But, at the end of the day, it's still driven really simply by, you know, one GS spike, which is safety. And regulations are designed around safety.

But, we've always tried to really make a safe design. And then, you know, try to communicate, I think, to you guys, you know, Brian at the NRC, why it's a safe design.

And you know, I think we've had really early engagement with you guys. And that that sort of back and forth has been really productive for us.

You know, I think getting new technology through the NRC is recognized as a -- I think almost falsely recognized as a barrier for new technologies coming to market.

But, certainly in medicine we've seen that, you know, where -- where a staff are absolutely willing to engage and talk about things.

And there's the current regulatory framework where we try and make things fit when we can, because otherwise you're -- you're getting into a legal set of complexity too.

But, let's start from the first

principles. And I'll probably say more about this later, but, make it safe. You know, and then explain why you think you've done that.

And so far, I think because it's a priority, you know, we've had really good, I guess, back and forth on that with the NRC.

DR. HARVEY: And Brian, let me add and support what Greg has just said. But NorthStar has had the -- is in the unique position that not only do we work with the NRC, but we work with the Organization of Agreement States.

And we've also worked even more closely with the FDA. And these agencies and entities have been extremely supportive of what NorthStar's doing, and bringing alternative technologies to market.

The COVID situation has been both a blessing and a curse. There are situations where we've, you know, the agencies have responded very quickly.

And there have been other agent situations where the time lag is still there. And it just takes time to get things done.

And I think more important long term, is that, you know, many of these time related endeavors

that are needed to get a license or permit in place, if we could find ways to streamline those, that would really be helpful. Recognizing that COVID has impacted some of those.

But, nevertheless, we still see some time delays related to just the process that has always been in place, the way we've always done it. And we need to start thinking out of the box a little bit.

MR. BROWN: And Brian, I'd also like to weigh in on this. Kind of echoing what both Jim and Greg have said.

Rather than see the policy, government policy and regulations as a hindrance, we've really seen the government agencies really do all they can to embrace this new technology.

Between DOE funding domestic production, which we absolutely support, and NRC obviously embracing this new technology, and doing all they can to staff up to review some of these new applications, but also with FDA.

We had a conversation, as was mentioned earlier, from high enriched uranium to low enriched uranium targets. Really, the FDA was wonderful to work with.

They realized the importance of converting from HEU to LEU. And they really did all they could to do a rapid review of our application and this new process for making moly.

So, we really appreciate all the work at both DOE, NRC, and FDA as well.

MR. SMITH: All right. Thank you for all the responses. And from an NRC perspective, we treat the moly-99 license applications or construction permit applications as a high priority for us, recognizing the policy position of the -- that the U.S. has taken on this.

And so, we do dedicate necessary resources to it. And as you stated, our main purpose is to -- is for the safety, security, and the protection of the environment from this proposed facility.

And so, it is a challenge. It is a new type of facility for us to type -- for our review. We do have staff involved that are from the research and test reactor regime as well as the operating fleet, as well as some of the fuel facility folks, because of the different hazards involved in the facility.

And so, there is a mix of -- of technical staff here. And getting them to take -- take on the review from a risk-informed perspective is what we're trying to do.

And we have laid out like a two-year schedule to complete the review for the SHINE operating license application. And we are striving to meet that schedule.

So, we're working as best we can with SHINE on all the responses. And getting through the review of the application.

So, great. If we could have the next slide, please? All right.

We felt because the importance of technology innovation in addition to traditional reactor production methods, potential moly-99 producers, excuse me, producers, propose subcritical operating assemblies for the irradiation of aqueous and solid uranium targets such as those proposed by SHINE and Niowave.

There has also been innovation in the development of new generator technology by NorthStar, which can produce high specific activity Tc-99m from low specific activity moly-99.

To support these new technologies, the NRC staff has adapted its review procedures and developed guidance to facilitate timely completion of reviews in commercial production of radioisotopes.

If we could have the polling question for this topic, please? All right, thank you. Our leading question for this topic goes to Dr. Harvey.

In November 2018, NorthStar began the first limited commercial production of moly-99 in the U.S. since 1989. While most prosp -- while most prospective producers are developing technologies to produce moly-99 through uranium fission, NorthStar elected to develop a new generator technology to produce irradiated molybdenum targets.

What motivated NorthStar to take this different approach? Also, what are the next steps necessary for NorthStar to expand its production capabilities?

DR. HARVEY: Thank you, Brian. A good two part question. And I'll answer, hopefully, very succinctly here for you.

We recognized back as in last 2007 when there was the first extended shutdown of the NRU reactor that we have the ability to bring a unique

solution to the market.

We had been working with some intellectual property that we had licensed for a number of years that was a platform technology for a generation of parent -- daug -- parent/daughter re -- new class, daughter new class of nuclide in the nuclear medicine market from their parent.

We were already looking at electronic accelerator technology to produce various medical related radioisotopes.

So, combining these two technologies together allowed us to produce moly-99 using a stable moly target without the use of uranium, and bring a new generating system to this market that could use low specific activity moly and produce high activity concentration, USP compliant, technetium-99m.

So, we feel like that -- we felt like we could see a future. And then that was borne out even more importantly in the 2009/2010 market shortages that occurred when NRU went down for an extended period of time.

So, we felt like we had a technology that we could bring to market. And we worked very strongly on both the electron accelerator, and the

neutron capture portion of producing material.

But, the second half of that question, of what are we doing to expand this technology, we've expanded our production capabilities with both new infrastructure, and related FDA approvals at our Columbia, Missouri facility. And that we work with our Missouri University research reactor partners.

In early January of this year, we also, with another approval from the FDA, we replaced our initial six curie offering with seven and a half, 12, 15, and 19 curie source offerings to our customers.

By mid-2021, we'll have the capacity to provide more the 100 of these sources for each -- for delivery every Tuesday morning to customers.

We also have major expansions underway in our Beloit, Wisconsin facility. We're commissioning new state of the art hot cells and fill lines, along with the completion of a new electron accelerator facility, the first two of which accelerators, arrive onsite next month. And will start being installed in April of next year.

So, over the next year or so, you're going to see a lot of announcements out of NorthStar, and how we're continuing to expand this production

program. And they'll be related to multiple FDA approvals in the future, we believe.

So Brian, that's kind of a summary of answering both questions in one quick answer.

MR. SMITH: Okay. Thank you very much, Dr. Harvey. Let's see, we have the polling responses up on the screen.

It's like the first one is the most. That question is, why have companies elected to develop new technologies, rather than utilize proven production methods?

DR. PIEFER: So, I can weigh in on why we did. You know, we -- ours is sort of a combination of a couple of factors.

I mean, I got into this frankly, wanting to make fusion energy in the beginning. And see medical isotopes as sort of a stepping stone to getting there.

So, you know, this was -- this was a neat thing, I thought, for fusion to play a role in, on the path too hopefully someday producing energy.

I think the other sort of challenges, when you look at the economics of investing in a reactor, and the payback time associated with a

return on investment in a new reactor, it gets pretty challenging pretty fast.

Investing in sort of a reactor-based production method, you know, I think the JHR reactor is still coming online, and still not producing isotopes.

And I think the all in cost on that is probably estimated to be around $2, $2.5 billion now, right? That's very expensive when you look at how much money there is to be made in the moly-99 supply chain.

You know, I think that the new PALLAS reactor in the Netherlands, the most recent estimate jumped to over $1 billion on that. And it's pretty early stage.

So, you know, we know that these costs tend to not come down as you get more and more detail in the amounts of design. So, when you look at actually making an investable proposition, you know, for us a new reactor is sort of not on the table. It doesn't -- it doesn't make money.

Now, you know, there's varying views on that. And I think there's other people who might disagree with that.

But, that's sort of our perspective on it. So, you know, given when the supply chain is, you know, you needed to come up with a way that was -- if you were going to include a radiation capacity, at least in your proposal, you know, you needed to come up with a way to do that more cost effectively.

And for us that pointed as, you know, directly at new technology. And then on top of that, you know, when you're using a source like SHINE's, we have a more defused sort of neutron flux then you would typically find in a reactor.

And so that -- that necessitated new technology as well. How do you -- how do you take advantage of a lower flux then you would typically find in a reactor and still make the same amount or even more moly-99?

You know, we believe that the factory we're building in the U.S. will be one of the largest, probably eventually, the largest medical isotope producer in the world. Despite the fact that it's a lower target.

Our license with the NRC actually goes up all the way to about 82 hundred, six-day curies per week. So, you know, it's going to be a really big

factory.

But, we had to -- we had to invent new technology essentially, to make that low flux usable in a way that would produce moly that the current supply chain -- our goal was to produce moly that the current supply chain couldn't differentiate from reactor produced moly.

So, you know, in order to make a cost-effective solution that was scalable, for us, we came to the conclusion that new technology was needed.

DR. HARVEY: And Brian, let me add a quick sentence here. To sort of go along with what Greg has just said.

New technologies assist in DOE's goal of nuclear nonproliferation, because they've helped move the market away from HEU. They assist in the reduction of overall waste in the production of medical radioisotopes.

And they augment the infrastructure that already exists in the market, by providing more ways to produce material, increasing the reliability of production of moly worldwide.

MR. BROWN: Well Brian, let me also add, as a conventional moly producer, and a conventional

technetium generator producer, we are constantly working on ways at improving conventional production of moly.

When we convert it from HEU to LEU, we added some target efficiencies. So, we made our production operation more efficient and more cost effective.

But also, looking to the future, I mean, we welcome new entries. We welcome SHINE to the market. They're making -- they're going to make moly that we can use in our generators.

So, if they can make it reliably, and in a cost-effective process, we'll be more than happy to use that type of moly in our generator system.

So, we're improving on old technologies. At the same time, looking forward to these new technologies.

MR. SMITH: Okay. Great. Thanks. I'd like to ask another one of the questions from the poll.

What additional tools or resources would facilitate developing new technologies, and getting those to market?

Is there --

DR. PIEFER: I can -- I can offer some. You know, I think new technology in nuclear is really hard. It's really difficult to get private capital invested in it.

You know, it's -- and I think it's just there's time frames involved that are very long, compared to what, I think, typical venture investors look for in terms of returns.

You know, you know of need somebody who's patient -- a patient capital that's really willing to go forward. I, you know, and the NNSA program is cost share, and it's really awesome.

But, you know, that -- if you don't have the up-front cost share, that doesn't -- that doesn't get you very far.

And I think that created, at least for us, you know, despite NNSA's patience and good will over the years, you know, that slowed us down quite a bit, in fact, in the beginning.

So, you know, I think there is an R&D role to be played in nuclear in general, where there's more grant type assistance for really neat projects. I think that's increasing.

You know, I think we are seeing more of

that. We are also seeing the private sector put up more money for nuclear. But, so our grants are a big deal.

One of the barriers for us, just was, you know, cost straight. The NRC reimbursement fees are a big deal for new entrants in pre-revenue companies, right? And that's just a mandate of how the NRC is structured to work with, you know, I think 90 percent cost recovery.

But, I don't know if there would be a way for future entrants developing new technologies to do a shortened review that would help them convince investors that they were on the right path.

And maybe it's not a full review, but it's some sort of engagement with the NRC that -- that would be less expensive. And allow them to evaluate the regulatory path they're proposing.

The type of system they're proposing, in such a way that they'd have more confidence when they were trying to pitch their ideas to the private sector, that there was a good regulatory path. And that there was some certainty.

You know, we were lucky enough that the NRC had a focus on medical isotopes as we -- as we

sort of emerged. And you know, there was new interim staff guidance being drafted as we emerged, and so the SHINE approach was included in that interim staff guidance.

That was useful for us. I think if that hadn't been there, you know, that might have been the end of the road.

So, you know, that's just something to think about. Is how do you get new innovative companies to get some confidence at least, in the regulatory path, which is long and expensive overall, and is going to require some patience.

MR. SMITH: Yeah. I'll respond to that a little bit. There are a lot of parallels to what you're just talking about, to the new advanced reactors that are being developed today.

And like medical isotopes, we have one license application in with us now for an advanced reactor design. And we're kind of in the process of developing guidance for these new advanced reactors, as well as similar to what -- what we did for medical isotope facilities back a while ago now.

So, one thing that we would encourage, as a way to kind of address what you said there Greg,

about some type of early review. For the advanced reactors, and we're -- when we have discussions with other potential applicants, we really encourage pre-application engagement with us.

So, before you submit an application, you can submit what we call, topical reports, or white papers on various topics. Things that you're going to have to address as part of your application.

If it's a white paper, we can give you like verbal or written feedback on our initial review of that topic. If it's what we consider a topical report, we can actually write a safety evaluation on that.

Such that if the information stays consistent at the time you submit your application, we can utilize that previous review as part of the full review of that application. Kind of you get credit for what you did previously.

And so, so those that you do, the more confidence you can give your investors that the application will proceed through.

DR. HARVEY: And Brian, can I have a shout out to both the NRC and the FDA? The agencies have a -- have a very significant role in the future

of nuclear medicine.

In that many of these alternative technologies require approvals from one or both agencies. The joint FDA/NRC panel last October that was put together, was a very, very good first step.

The two agencies that are most directly involved, coming together, and listening to what's out there in the future that those agencies need to be aware of is coming. So they can be prepared.

And I would strongly endorse that that type of a forum becomes a regular forum so that the two most important agencies, NRC and FDA stay abreast of what is coming in the future of nuclear medicine.

MR. SMITH: Great. Good point. Another aspect is that there are other parts within the NRC that are involved in this whole process.

We -- my group, my division does the licensing of the production facilities. Another group within another office handles the use of that material in medical uses.

So, -- so, there is other coordination going on within the, within the agencies. So, good responses everyone.

So, if we could have the next slide,

please? We'll move onto our final topic. Which is the impact of medical radioisotope production on the future of the nuclear industry.

The drive to establish a reliable supply of medical radioisotopes has encouraged the development of new technologies that may be used for other commercial research and military applications.

The NRC's review of medical radioisotope applications has also demonstrated an ability to effectively license new technologies.

So, if we could have the polling question? And you can see on the slide there, it's just some of the uses of the materials, including in the veterinary space.

So, I want to mention real quick before we get into the lead in question. I just want to remind all the people that are logged into this session, that you can submit questions off to the right.

And once we finish this topic, we are going to go into the Q&A session. So, if you have any outstanding questions, and if we have enough time, we'll try to get to as many as we can.

All right. So, the first question, or

the lead in question for this topic goes to Dr. Piefer, Greg.

SHINE is currently constructing its medical isotope production facility in Janesville, Wisconsin, while the NRC reviews its operating license application for eight subcritical operating assemblies and one production facility.

What lessons has SHINE learned from its experience with designing, licensing, and constructing this facility that it intends to apply to its future efforts to build a second facility in Europe, and produce lutetium-177 at its planned therapeutics facility?

Also, what influence do you think SHINE has had on the development of other new nuclear technologies?

DR. PIEFER: Yeah. So, cool. This is a fun question for me actually. Because learning and getting more efficient has been really important to our company's evolution since it was formed.

And you know, I think one of the things that we sort of struggled with really early on is, there is a, there is a status quo in nuclear.

And it's not, from my opinion, it doesn't

have anything to do necessarily at the regulatory framework. It's just sort of the way business has been done.

And nuclear power has a certain way of doing business that for various reasons in my view, may not be as efficient as it could be. You know, whether it's due to decades of cost-plus contracts, just incentivizing maybe some of their own behaviors or what.

But, you know, I think for us -- and it goes back to what I was saying a little bit of earlier, you know, you always just need to ask yourself if the path you're on makes sense.

And so, you know, just like first principles does -- does the path you're going down, or does the path somebody's recommending to you make sense?

And you know, that comes down to, from the interface with the NRC for example, is it safe? Right? It's a sample question.

Do we do it like a power reactor did, even though this process looks totally different than a power reactor, and its hazards maybe totally different then a power reactor?

Sometimes the answer is yes. Sometimes there are really good methods that have been developed there. And they're applicable. And we use them.

But, you know, sometimes no. And sometimes those methods just don't make any sense. And no matter how loud somebody shouts at you that that's the only way you can do it, you're going to ask yourself, does -- is that required to make it safe?

Is that actually the best way to make it safe? And you know, do you have to do it the way it's been done? Well, I don't know. Let's go ask the NRC for example, and see what they think about, you know, our approach.

I think there's a lot of trust been built up, because I think people at the NRC know that like safety is sort of really, really core to our company's operating philosophies. But, we're not necessarily married to the traditional way of doing things.

And so, I think that's something that new -- I would encourage any new company in nuclear, or any even old company in nuclear, to really consider going forward.

The way things are done, you know, there's a lot of reasons why they're done that way. But, they don't necessarily tie back to the regulations.

And they don't necessarily tie back to legal requirements. And in many cases, the way things are done, don't tie back as it turns out.

I mean, I can't tell you, during the early days how many times I had to ask the question, show me the regulation that says we must do it this way. And you know, nine times out of ten, it comes back that, well, okay, maybe it's not -- it's not really a regulation, right.

So, you know, I think that questioning attitude and sort of always, you know, asking yourself, does an approach make sense? Is this the safest thing we can actually do?

I tend to prefer simplicity. You know, I tend to think that the simplest solutions tend to be the safest and the most practical to implement.

And so, you know, that's sort of probably the biggest lesson, I guess, I've learned, and that we intend to apply going forward. And I think that's really probably very foundational to our efforts to

produce lutetium-177 for example.

You know, in terms of what -- what influence we've had on others, I hope we've had an influence on others.

You know, I think building a, you know, a commercial scale facility that is licensed under the regulatory framework of a reactor, you know, hasn't been done, I think, in a long time for -- certainly for medicine, and you know, using this process even for power, for a long time.

And being really focused on having to make money and having to have a business case that can be successful while meeting all the requirements, you know, from a safety and regulatory perspective, hasn't really been done in a long time.

So, you know, I think the at -- you know, it's great. I love -- we use it all the time, the little sound bites.

When folks at the NRC refer people to look at our license application if they want to see how to do things, you know, that's great. And I hope people do that.

You know, it took us a long time to build the team and the culture that we have now. And that's

something that I hope people can do more quickly in the future.

Sorry about my little friend here. I'll move him off. But, yeah, that would be the biggest thing, I think, it would be nice if people could take that away from our experience.

MR. SMITH: All right, great. Great. I see the, your friend's play area there in the background as well. It looks really nice.

My cats would love that.

DR. PIEFER: One of many. They're spoiled.

(Laughter)

MR. SMITH: All right. We have our polling results up now. Four questions this time. And the third one is the one with the most response.

So, what is the next challenge that needs to be addressed once a stable supply of moly-99 is established?

Anybody want to take a shot?

DR. HARVEY: I'll take a shot at it, Brian.

MR. SMITH: Okay.

DR. HARVEY: I think that, you know, you

-- with a stable supply, you need to get sustainability and reinter -- re-energize this energy, this industry.

And we're going to need to start making sure that individuals are trained on all the new technologies, new approaches, innovative things that are being done in this industry.

So, sustainability, reliability, training, are the things that we see necessary in the future.

MS. DIX: I can jump in here a little bit as well. You know, I think from the NNSA's perspective and the government's perspective, one of the main things that we want to make sure we pay attention to, and that we address as we need to going forward, is noting any issues relating to either the front or back end of the supply chain.

So, you know, for any of these technologies, everybody has source material that they need to receive. Whether that's enriched uranium, or whether that's enriched molybdenum.

So, I think, you know, making sure that the supply chain on all ends, not just, you know, following the moly after irradiation and getting it

to the generators, and to the hospitals, and to the patients. In order to make sure that that happens, I think paying attention to the sufficient source material on the front end.

And then addressing waste on the back end. Each process is going to have a different waste stream, a different disposition pathway.

But, I think those are two very important areas that we at least need to pay attention to as we're going forward for the supply chain to be stable and sustainable in the long term.

MR. BROWN: Well, and I'd also like to look into the future and talk really about the future of nuclear medicine.

In the past, nuclear medicine has largely been diagnostic. To go in and diagnose disease, or to look at the function of an organ to see how well it's operating.

But really, the new direction of nuclear medicine is in the therapeutic end. And the research reactors have played a large role in this in producing some of the isotopes.

I mean, for years and years, the research reactors have produced the majority of the

radionuclides in nuclear medicine.

But, some of the nuclear power plants are starting to get involved too. I mean, we have nuclear power plants globally that are already producing cesium-137, cobalt-60, even a moly-99 production effort at a commercial power plant in Canada.

But, I think not only the commercial power plants, in addition to the research reactors, can play a role in the future. I mean, we're going to have a lot of need for things like lutetium-177 that's going to need a lot of reactor space.

So, not only -- not only can the research reactors play a role, but I also think that commercial nuclear power plants will play a role in the future of therapeutic nuclear medicine.

MR. SMITH: Great. Great. Good answers there. We have -- we have some more time. So, one of the other questions that got a lot of responses was, are there other areas of nuclear medicine that will benefit from establishing new medical radioisotope approaches?

And I think Roy, you touched on some of that from a therapeutic approach. But, any other

specifics that anyone can think of? Okay.

DR. PIEFER: Yeah. I mean, therapeutics is the biggest -- the big up and coming. Roy was exactly right about that.

And the reimbursement for therapeutics is substantially higher than it is for diagnostics. And so, it's a more investable business case for a lot of players.

But, you know, the therapeutic supply chain isn't great either. You know, Roy mentioned lutetium-177 as a really exciting isotope.

And I think there's a lot of drug trials out there for that. And we've got a focus on it at SHINE as well.

But, you know, the raw material supply chain's not great for that either. Enriched Ytterbium-176, which is, you know, required for that primarily source of thing, pretty much only made in Russia and primarily sourced from Russia these days.

So, you know, there's -- there's -- applications of technology, you know, that may apply to that, right. We actually believe we can use the SHINE radiation facility for any medical isotope that's produced with a neutron capture that is

followed by a transmutation. Right.

So, where you have elemental separation between the parent nucleus and the daughter nucleus. That allows us to use chemical separation to get back up to high specific activity, even if there's a -- even if there's a lower flux.

You know, the particle beam technology that we've developed for driving the fusion reactor is ideal essentially in some ways for enriching isotopes, of certain types of isotopes.

So, you know, if we want to make our own Yuttribum-176, for example, that's actually something we're planning on doing. And so, you know, there's new spin off applications of this.

We also see, you know, what we're doing at least on the fusion side, in generating these high energy neutron sources, fusion neutrons are, you know, around 14 MeV, sort of average output energy.

This sort of puts them in an ideal range of the cross section for things that could be really important long term. Like for example, transmutation of nuclear waste.

When we look at handling the waste problem that's been building up from power reactors,

and power reactors are an awesome source of low carbon energy, zero carbon energy effectively. You know, the one thing people complain about the most is the long-lived waste isotopes.

Well, if you can separate those and concentrate them and put them into a high energy neutron flux, you get a large number of, it's 14 MeVs, right, in the peak of the cross section for N-2 and N-3 on reactions for just about everything.

And so you can transmute these things down to be much shorter lived half life. So, we actually expect that, you know, as our medical facilities come online, and sort of the engineering time we've needed to dedicate to that, frees up a little bit, that we're going to move into waste transmutation sort of over the next few years.

So, I think there's a lot of neat sort of spinoff applications that will come out of this. I'm sure Jim can talk about some of those that will come out of the NorthStar technology as well.

But, for us, you know, we see really neat spinoff applications.

MR. SMITH: Okay. All right. Okay, if we could have the -- well, before we go to the next

slide, John was able to join us via phone, as opposed to his internet connection.

John, if you're able to -- we can unmute John. John, is there anything you want to add to any of the previous topics?

MR. WITKOWSKI: Yes, Brian.

MR. SMITH: Go ahead.

MR. WITKOWSKI: It's -- okay, are you able to hear me?

MR. SMITH: Yes.

MR. WITKOWSKI: Okay. Thank you. One of the things that's very exciting is the development of gallium-68 chemistry. Which is a metal chemistry.

And one of the future products to come to the market will be gallium-68, labeled PSMA, for imaging prostate cancer.

But, at the same time, as the metal chemistry is developing for the gallium products, it's also rejuvenating interest in technetium chemistry for the same product, for PSMA for prostate imaging.

And that opens up, instead of positron emission tomography cameras being use, going back to the single photon emission commuted tomography

cameras, or SPECT cameras.

And that can bring more opportunity for hospitals and imaging centers to provide services for a very large population that will need to be investigated for prostate cancer and its advanced stages later on.

So, that opens up with prostate cancer. I do believe that products that are being developed for breast imaging will open up more opportunities for technetium imaging in breast cancer and colon cancer or lung cancer can follow as well, all this related to solid tumor imaging.

And then following on with the therapies. The only reason these products would be developed just to have a concomitant therapy that could effectively treat soft tissue and bone disease and prostate, lung, breast, or colon cancer.

Thank you.

MR. SMITH: All right. Okay. Glad you're able to reconnect and come through clearly. So, all right. If we could have the last slide?

So, now that we've explored our prepared topics, we'll now turn to questions from the audience. If we run out of time before your

question, please feel free to reach out to any of the NRC contacts listed on the slide, and we will follow up with you to get you the information that you're looking for.

We have a couple of questions. And I will go through a couple of those.

And one of them is, the NRC staff has a final rule before the commission that would make innovated changes, innovative changes to NPUF licensing, including medical radioisotope licensing. What is the status of that rulemaking?

That rulemaking is still before the commission. So, we're still waiting to get the final votes on that. And then the direction from the commission.

If you have any questions, feel free to submit those at any time. We have two more here.

One of the U.S. goals was to have international full cost recovery for moly-99 production. Given the number of new projects, both under construction, and being planned internationally with government support, can that goal be reached?

That goal being full cost recovery for moly-99 production. Joanie you want to take a shot

at that?

MS. DIX: Yeah. I'll start off. And then see if anyone else wants to jump in.

The full cost recovery effort was really kind of spearheaded and led by the OECD. They established a high level group on the security and supply of medical radioisotopes.

And two of the main things to come out of that, one, Roy has already mentioned, which is the outage reserve capacity. And the other was focused very much on full cost recovery.

I think, you know, the group has shrunk a little bit. Yeah, Roy?

MR. BROWN: Go ahead, Joanie.

MS. DIX: Okay. The group has shrunk a little bit in the past few years. COVID has made meetings harder still.

But the full cost recovery portion of those discussions, I think it's something that everyone has struggled with, and continues to do so.

I'm not sure, you know, that I can definitively say one way or the other that will be successful. But, it's certainly something that the OECD group and certainly the U.S. government

continues to pay attention to in terms of trying to find what that balance is.

How you can support the industry so that it is able to be stable, while making sure that you are not putting so much money in that you are unintentionally making it unstable in the long term.

Roy, over to you.

MR. BROWN: Yeah, thanks Joanie. Yeah, I can address the conventional production of moly. We've been working with that same high level working group that Joanie mentioned at OECD in Paris.

And they have been pushing for full cost recovery for quite a few years now. What we've seen with the research reactors we use to irradiate moly targets, we have seen a loss of government support for those research reactors.

And what those research reactors have done, is they've systematically increased the irradiation charges for all the moly production. All the uranium targets are going to the reactors for moly production.

So we've seen increased costs on our end. They'll go up year after year in the name of full cost recovery. We understand that.

We think that has stabilized the market some. We think we have gotten to a point where full cost recovery, if it's not -- if we're not there yet, we're very, very close.

So, from a conventional moly-99 production standpoint, I think we're very close to full cost recovery now.

DR. HARVEY: And Brian, I can add from the new technology side that especially those that have accepted federal support, we're required to be full cost recovery.

So, we look forward to the day that the entire market is completely full cost recovery, because if not, those of us that have implemented full cost recovery programs, could be at a disadvantage in the market. And that means the market is potentially unsustainable.

MR. SMITH: Okay. Thank you. We have one other question that's been submitted.

What does the future of alpha emitting radiopharmaceuticals look like?

DR. HARVEY: I can provide some information that, because NorthStar's got an active program in producing Actinium-225 as we speak.

If you -- if you look at the history of the alpha immunotherapy landscape, there's a conference that occurs every other year. It's -- it was in Kanawaza, Japan in 2017. There were slightly over two hundred participants.

In Ottawa, Canada two years later, there were 435 participants. The amount of work, the amount of research, the amount of money that's going into therapeutic radionuclides, in particular alpha emitting radionuclides, is significant.

And I do believe that the future is bright for approvals with alpha emitting radionuclides.

MR. SMITH: Roy?

MR. BROWN: Yeah, thanks Brian. I have to agree with Jim. We think the future for alpha emitters is very, very bright.

With the advent of isotopes like Actinium-225, as Jim mentioned, but also lead-212, thorium-228, there are a lot -- there's a lot of work being done by Curium and other companies looking at therapeutic alpha emitters.

So, we think there's quite a future here. The conventional therapy or the current therapy out

there right now, and probably for the next few years, will involve more beta emitters.

But, there's some clear advantages with the LET radiation from alphas. We think there's a clear future for alpha emitters in nuclear medicine.

MR. SMITH: All right. We do have another question that came in.

When do you expect the U.S. to be self sufficient in developing or producing moly-99? What about other radioisotopes?

Joanie?

MS. DIX: I'll start off here. I mean, it's certainly a complicated question. And I think, you know, one thing that I want to make sure to highlight is that this question is rather complex.

And ensuring that the United States has a reliable supply, will probably be a blend of both domestic and international producers. You know, we are supporting our domestic entities here in the U.S. to try to get them up to the capacity that they can be a, you know, stable sufficient supplier.

But, ultimately that's -- it's a commercial market. And it will -- it'll vary depending on how that goes between both international

and domestic producers.

From the NNSA side, the one thing that I wanted to add, is that we released a funding opportunity announcement in July of last year. And are proceeding through that process.

And one of the key parts of this funding opportunity announcement for the domestic producers, was that they have an established production capability by the end of 2023.

So, we are really driving hard from the NNSA side, to be able to provide financial support to companies that can be up and running in the U.S. by the end of -- at least by the end of 2023, if not sooner.

So, we are hoping that 2023 will be a bright year for the U.S., and seeing additional suppliers come online by that point.

MR. SMITH: All right. Great. We have a little less, probably around four, three or four minutes left.

If you would like to make some closing remarks before we go, I'm open to doing that. Both, Dr. Harvey, any final remarks you want to make real quick?

DR. HARVEY: Yes. Just first of all, an appreciation for the commission having this type of a session, and bringing industry together and making it a -- and making the comments and those of us on the panel available to people who have questions.

Secondly, I want to just repeat what I said a few minutes ago. The joint session between -- or conference between NRC with -- NRC and FDA last October, was extremely valuable in understanding, getting the agencies to understand what's coming for the future of nuclear medicine and the new radioisotopes that are going to support the future of nuclear medicine.

I strongly recommend that these types of interactions become regular, rather than just occasional.

MR. SMITH: Great. Great. Roy?

MR. BROWN: Thanks, Brian. Yeah, I want to thank the NRC for including the medical community in this session for the RIC.

We recognize that the RIC is very well attended. It's always highly anticipated by the nuclear community, both nationally and internationally.

So, I just want to recognize NRC and thank you for adding this medical panel.

MR. SMITH: Sure. Greg, any final remarks?

DR. PIEFER: Yeah. No, I think it's actually a really exciting time for nuclear technology. And I do want to applaud, you know, some of the efforts being taken to make nuclear more accessible. Particularly the innovative start up companies. And I think that's really awesome.

You know, and I think piggybacking on what Joanie said, you know, we really are looking forward to playing our role in helping the U.S., you know, reestablish. I know NorthStar's already there.

We're really looking forward to playing a major role in shoring up U.S. production, and frankly, becoming a leader in production of isotopes globally. And even exporting, right.

So, producing a robust enough supply that we can sell some overseas. I think there will always be a component coming in, and I think that's a good thing.

I think it's -- it's good to have diverse sour -- diversity of sources, and a supply chain that

can exist in multiple places.

So, I think that the -- I think there's a light at the end of the tunnel. I think the existing producers have done an awesome job, you know, managing the supply chain.

I think there's some tough situations. But, you know, hopefully going forward, the U.S. returns to a position of leadership in isotope production.

MR. SMITH: Great John, do you?

MR. WITKOWSKI: All right. Yes. I really appreciate what the NRC has been doing. And it's actually expanded over to looking at the training and experience of authorized users, those physicians that can inject alpha emitters, beta emitters, even do diagnostic imaging.

And so the NRC is far reaching, and looking at training criteria and authorized user criteria, as well as the new and emerging radiopharmaceuticals. How they will license such things as Y-90 solid tumor products and other lutetium products, actinium products, and such.

So, the NRC is definitely looking at an expanding marketplace in medical isotopes. Thank

you.

MR. SMITH: Great. Thanks a lot, John. Joanie? Right before we end here.

MS. DIX: Yeah. I'll just -- just a few quick things. I think, you know, I really appreciate the NRC pulling together this panel, as, you know, both Roy and Jim said.

But, I think it's particularly important not only from the medical isotope industry side of things but also that, you know, from a licensing perspective, you know, medical -- moly-99 and medical technologies has certainly resulted in some new and interesting engagements with the NRC, I think from -- from all of the domestic companies for sure.

And as you mentioned earlier, I think there's a lot of parallels that can be drawn for some of the work that's going on with advanced reactors in new other upcoming areas.

So, I think that hopefully this was beneficial not only just for the medical side, but also for kind of new nuclear regulatory industries.

MR. SMITH: All right. Great. I just want to thank all my panelists for participating today. It's been a wonderful session.

I really appreciate all the -- all the good dialog that we've had and the participation by the -- by the public as well in responding to our polling questions.

So, I look forward to continuing these discussions in the future, and the future of medical radioisotopes. So, thank you once again.

And this ends our panel session. Thank you.

(Whereupon, the above-entitled matter went off the record at 2:46 p.m.)