UNITED STATES

NUCLEAR REGULATORY COMMISSION

+ + + + +

STRATEGIC PROGRAMMATIC OVERVIEW OF THE DECOMMISSIONING AND LOW-LEVEL WASTE AND NUCLEAR MATERIALS USERS BUSINESS LINES

+ + + + +

THURSDAY,

NOVEMBER 5, 2020

+ + + + +

The Commission met in the Commissioners' Hearing Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 9:00 a.m., Kristine L. Svinicki, Chairman, presiding.

COMMISSION MEMBERS:

KRISTINE L. SVINICKI, Chairman

JEFF BARAN, Commissioner

ANNIE CAPUTO, Commissioner

DAVID A. WRIGHT, Commissioner

CHRISTOPHER T. HANSON, Commissioner

NRC STAFF:

MARGARET DOANE, Executive Director for Operations

PATRICIA HOLAHAN, Director, Division of Decommissioning, Uranium Recovery and Waste Programs

JOHN LUBINSKI, Director, Office of Nuclear Material Safety and Safeguards

TIMOTHY MOSSMAN, Chief, Source Management and Protection Branch

MARY MUESSLE, Director, Division of Nuclear Material Safety, Region IV

DAVID PELTON, Director, Division of Nuclear Materials Safety, Region III

KEVIN WILLIAMS, Director, Division of Materials Safety, Security, State and Tribal Programs

P R O C E E D I N G S

9:01 a.m.

CHAIRMAN SVINICKI: Well, good morning everyone. I call to order the Commission's meeting on the strategic programmatic overview of the decommissioning and low-level waste and nuclear materials users business lines, which is quite a mouthful, but this is a recurring meeting of the Commission in a series of examinations, or what we call business line meetings, to examine parts of the Agency's program of work. And today, we will consider the two lines of work that I have mentioned.

We will hear from two panels of NRC staff. We will take a very short break in between. And then reconvene and hear the second panel.

After each panel, the Commissioners will be recognized for any questions that they would like to ask that panel.

And, again, I think that I have derived great value from these meetings because it provides for a systematic look at activities in the Agency and allows the staff to bring forward to the Commission's attention progress that it is making on things that may be falling not in our clear, high visibility at the moment, but are still very, very important pieces of work.

So, before we begin, would any member of the Commission like to make any opening comments?

(Pause.)

CHAIRMAN SVINICKI: And I am not seeing that the staff would like to do that, so, again, the first of the two business lines that we will hear from the staff about is the decommissioning and low-level waste business line.

And as is typical for us, we will be led off by our Executive Director for Operations Margie Doane, and then presenters on the NRC staff panel will turn the presentation over to each other.

So, with that, I ask that we turn things over to EDO Doane.

MS. DOANE: Okay. Slide 2, please. Good morning, Chairman Svinicki and Commissioners.

CHAIRMAN SVINICKI: Good morning.

MS. DOANE: We appreciate the opportunity to provide you with an update on the strategic considerations associated with the decommissioning and low-level waste and the nuclear materials users business lines, including current activities and accomplishments, business line priorities, challenges and emerging focus areas.

These business lines are directed by the Office of Nuclear Materials Safety and Safeguards, or NMSS.

Both business lines continue to risk-inform and transform their processes ensuring that they have the right people, the right places at the right time with the right training as we continue to work as modern risk-informed regulators.

The business lines also continue to leverage the strategic workforce plan to ensure that both staff and management are well-prepared for future challenges in an uncertain external environment.

We accomplish our mission with our partners in the regions, the Office of Nuclear Regulatory Research, Nuclear Reactor Regulation, Nuclear Security and Incident Response, International Programs, Enforcement, Investigations and the Office of the General Counsel, as well as

our corporate office partners who provide us with crucial infrastructure support for our programs.

Today, you will hear how the business lines, with the support of our partners, have accomplished much since the last business line briefing and have developed effective strategies to address the challenges and opportunities before us.

Before we begin, I would like to commend the staff for their hard work, diligence and commitment.

They maintained an impressive level of public outreach, communication with external stakeholders, and a general amount of work that has been accomplished in all these areas during the past seven months when almost all of these interactions have had to take place remotely.

The staff was able to adapt to rapidly changing realities of the COVID-19 public health emergency and leveraged new technologies and techniques that continue to make progress in these diverse, and often complicated, areas with minimal impact on the associated scheduled.

Along with the rest of the Agency, the staff in decommissioning and low-level waste and nuclear materials users business lines continue to achieve the NRC's mission despite the many recent challenges placed before them.

Today's briefing will be provided by two panels, which I'll introduce separately. Today's briefing begins with the decommissioning and low-level waste business line.

The decommissioning and low-level waste business lines ensure regulation of the decommissioning, low-level waste and uranium

recovery functional areas.

It also receives decommissioning and cleanup of -- I'm sorry -- of contaminated sites, space management and disposal of low-level waste and uranium recovery activities.

Several significant accomplishments for the decommissioning and low-level waste business lines are examples of successful coordination between offices across business lines and in concert with our fellow regulators and federal agencies, as well as other external stakeholders.

These wide-spanning accomplishments include completion of a memorandum of understanding with the Environmental Protection Agency on in situ uranium recovery activities, issuance of an updated guidance for alternative disposal processes for low-level radioactive waste, progress in several rulemaking areas related to radiological waste disposal and completion, or progress toward completion, of decommissioning at numerous power reactors and materials facilities. These topics will be discussed further during the upcoming presentation.

Next slide, please. Our first speaker is John Lubinski, the director of NMSS, who will provide an overview of the decommissioning and low-level waste business line.

Following John's presentation, we will hear from Trish Holahan, director of the Division of Decommissioning, Uranium Recovery and Waste Programs, who will discuss the current programmatic environment and ongoing activities in these areas.

We'll end the first panel with Mary Muessle, director of the

Division of Nuclear Material Safety in Region IV, who will discuss the ongoing efforts to further risk inform uranium recovery and decommissioning oversight activity.

I'll now turn the presentation over to John to kick us off for the decommissioning and low-level waste business lines activity.

MR. LUBINSKI: Thank you, Margie. And good morning, Chairman and commissioners.

As noted, I will provide an overview of the decommissioning and low-level waste business line, which, for simplicity, I will just refer to as the "business line" this morning.

The business line is charged with ensuring effective licensing and oversight of reactor and material sites undergoing decommissioning, and regulation and oversight of uranium recovery sites, and the safe use and handling and disposal of low-level radioactive waste.

The business line also oversees waste incidental to reprocessing, or WIR, and provide support to the Department of Energy for activities related to the West Valley Demonstration Project Act.

The business line manages these programs in close coordination with other federal agencies, states and Native American Tribal governments, as well as licensees and the public.

The business line is comprised of 84 full-time equivalent, or FTE, and $5 million in contracts supporting tribal. Most of these resources support direct mission core activities.

Next slide, please. Today's presentation will cover several of the significant business line activities and achievements with a special focus

on the innovative approaches being taken to accomplish our mission.

Among its many activities, the business line oversees a diverse decommissioning portfolio which includes 25 decommissioning reactors. Three of which are in active decom, and 12 of which are in SAFSTOR.

Also, we oversee four research and test reactors, ten complex material sites, and five Uranium Mill Tailings Radiation Control Act, or UMTRCA, Title II uranium recovery sites.

The business line also coordinates decommissioning efforts related to both military and nonmilitary uranium sites and provides support to the naval reactors' decommissioning efforts related to the Surface Ship Support Barge.

We continue to effectively implement strategies to address the increase in power plants transitioning to decommissioning.

Five power reactors have shut down in the last five years and licensees for an additional eight reactors have notified us they plan to shut down those reactors by 2025.

We continue to work closely with our partners in the Office of Nuclear Reactor Regulation to ensure the effective transition of resources between business lines as a result of this changing environment.

We are also ensuring that our infrastructure surrounding decommissioning, such as licensing and inspection guidance, is consistently updated to support this workload.

Specifically, we have used the lessons learned from the effective decommissioning of 12 power reactors and more than 50 material

sites to make our regulatory and oversight tools more effective.

Next slide, please. The staff has completed many significant accomplishments over the last two years. A few of these recent activities are noted on the slide.

We've provided two reports to the U.S. Congress on activities identified in the Nuclear Energy Innovation and Modernization Act, or NEIMA.

The first report described recommendations to improve effectiveness, efficiency and transparency of uranium recovery licensing reviews and was provided to Congress in April of 2019.

This report supports ongoing interactions between the NRC and agreement states to align best practices and share knowledge to prepare for future uranium recovery applications.

In July of this year, we provided a second NEIMA report identifying best practices for establishing and operating local community advisory boards related to the decommissioning of nuclear power reactors.

In order to develop the report, the staff sought extensive stakeholder input. We requested written comments, posted 11 public meetings across the country in under four months and conducted two nationwide webinars.

The public meetings ensured effective consultation with those states, communities near decommissioning power reactors and existing community advisory boards.

As a result, we received over 1200 public comments on the best practices for decommissioning power reactors that were effectively

incorporated into the report. This report was well-received by Congress as well as our external stakeholders.

Meanwhile, in the uranium recovery world, the NRC effectively worked with Wyoming to become the 38th agreement state at the end of 2018.

The staff supported significant milestones in this area, including the finalization of the agreement with the State and conducting the first integrated Materials Performance Evaluation Program, or MPEP, review of the State.

In addition, we worked with the agreement states that have oversight of uranium recovery facilities to develop streamlined licensing processes.

These activities were being accomplished in parallel to the government-wide activities associated with the Nuclear Fuels Working Group.

This resulted in the collaborative development of a standard licensing review schedule that will better position our program to respond to future changes to the uranium recovery market by supporting a more efficient review of new applications by both NRC and agreement state staff.

Finally, after years of outreach and development, we finalized guidance related to alternative low-level waste disposal requests.

The updated guidance provides clarification on the information to be provided by applicants and describes the NRC process for documenting, reviewing and improving, on a case-by-case basis, requests for alternate disposal under the regulations in 10 CFR 20.2002 and 10 CFR 40.13.

These are only a few of the accomplishments of the business line and other activities and accomplishments will be discussed during the remainder of this presentation.

So, now, I would like to turn the presentation to Trish Holahan. Next slide, please.

MS. HOLAHAN: Thank you. Good morning, Chairman and Commissioners. I'm now going to share the results of several significant innovations and other achievements attributed to the DLLW business line since the last Commission meeting, as well as provide additional details on improvements to the process for transitioning power reactors from operation to decommissioning.

Next slide, please. As Margie mentioned, one of our program's recent accomplishments was the finalization of a memorandum of understanding, or MOU, with the Environmental Protection Agency in July of 2020 to clarify jurisdictional issues surrounding the in-situ uranium recovery process, or just ISR.

This MOU establishes a framework for implementing the individual steps toward responsibilities of the NRC and EPA with respect to the regulation of ISR activities and was an innovative step in the effort to streamline the NRC's ISR rulemaking in an expedited manner.

As a result, we have now implemented an accelerated schedule for this rulemaking to include engaging the agreement states along with innovative project development approaches, concurrence improvements and proactive steps to establish and maintain alignment on expectations.

So, the rulemaking will affect some agreement states.

We've already engaged with the Organization of Agreement States, or OAS, for representation during the rulemaking efforts.

The OAS has identified representatives in Texas and Wyoming to ensure that the ISR rulemaking meets the needs of a national materials program.

Specifically, we intend that the ISR rulemaking will improve the regulatory infrastructure surrounding uranium recovery by increasing consistency and transparency and licensing reviews between the NRC and agreement states and will clarify the applicability of existing requirements to ISR activities in Part 40.

Next slide, please. Now, to some of our ongoing initiatives. This year, we completed the depleted uranium, or DU, implementation plan, which used a graded approach strategy based on risk and involved an extensive review of our own historical records, as well as reviews performed by the military.

The staff verified the current military possession of DU is authorized by an NRC license or is being addressed through the MOU between the NRC and Department of Defense.

The development of the DU implementation plan incorporated lessons learned from the efforts surrounding the military and nonmilitary uranium programs that were implemented over the past several years.

As part of our oversight of unlicensed radioactive material at DoD sites, which is addressed through the MOU, the staff continued implementing the stay-informed approach for remediation by DoD at sites

listed on the EPA's National Priorities List and plants' continuous reliance on EPA oversight at these sites.

We also continued monitoring activities at DoD cleanup sites not listed on the National Priorities List.

Specifically, in FY 2020, we completed reviews of cleanup reports for the Treasure Island Naval Station and the Dugway Proving Ground.

The staff has regular communication with DoD to ensure that implementation of the MOU is going well at these sites and that the DoD's remedies will meet the NRC's dose criterion for sites that will be released for unrestricted use or are consistent with NRC requirements for sites that will be released for restricted use.

Similarly, we continue monitoring activities under the MOU with the National Park Service for sites in New York.

Upon learning of confirmed unlicensed radioactivity in an additional site, Dead Horse Bay, the staff amended the MOU with NPS.

Lastly, we've continued working with site owners at the five nonmilitary uranium sites that need additional cleanup to protect public health and safety.

To date, two of the five sites are being remediated. Through these efforts we continue to effectively address uranium cleanup at military and nonmilitary sites.

Another area we continue to risk inform is our WIR, Waste Incidental to Reprocessing evaluations. In May 2020, we issued a technical evaluation report documenting the staff review of the DOE WIR evaluation for the Hanford Waste Management Area C.

The review was conducted under an interagency agreement as part of the DOE's process for determining whether the waste meets DOE's criteria for management as low-level waste.

In a related effort, we've begun an evaluation of DOE's draft WIR determination for the vitrified low-activity waste that will be produced by Hanford's waste treatment and immobilization plant.

All these reviews are being conducted using information gained from the site-specific risk assessments performed for each area.

In addition, we are currently monitoring the performance and disposal actions by DOE at three of its WIR facilities, are monitoring strategy for each of these sites as risk-informed and performance-based, and we continue to make progress in monitoring DOE disposal actions related to waste incidental to reprocessing.

Based on our review of the site-specific assessments to ensure consistency with the performance objectives of 10 CFR Part 61, we are focusing monitoring efforts on those aspects that are most risk-significant to the performance of the site.

The results of these activities have been used -- have also been used to update the DOE's site-specific risk assessments, and we've monitored our monitoring plans accordingly in a risk-informed, performance-based manner.

Next slide, please. Another area that has seen progress in recent months are the rulemaking activities associated with Greater-Than-Class C, or GTCC, waste and proposed changes to the 10 CFR Part 61 low-level radioactive waste disposal requirements.

We were recently able to collect comments on a draft regulatory basis to support rulemaking in the future.

We hope to address the feedback and reflect the extensive outreach that has been ongoing throughout this effort.

The comment period for the draft regulatory basis for the GTCC rulemaking closed in November 2019.

The staff used this time to evaluate the comments received. The NRC received over 70 individual comment submissions from members of the public, environmental groups, industry stakeholders, a tribal nation, various state agencies and DOE, as well as approximately 7,000 form letters from environmental groups.

Some commenters supported the near-surface disposal Greater-Than-Class C waste, whereas the majority of public comments stated that GTCC waste should be -- only be disposed of in a deep geological repository.

Based on a technical and regulatory review related to the disposal of GTCC, as well as an examination of the comments received, the staff determined that most of the GTCC waste streams analyzed in the draft regulatory basis are potentially suitable for near-surface disposal provided appropriate controls are implemented and a sufficient site-specific analysis is conducted to ensure protection to inadvertent intruders and outside individuals.

Site-specific analyses and refinement in the waste stream inventories could also result in a different quantity of GTCC waste potentially acceptable for near-surface disposal than was determined in the NRC's

generic analysis.

In addition, the staff determined that most GTCC waste could be regulated by an agreement state from a safety perspective.

A recent SECY paper was issued providing the staff conclusions and recommendations. The near-surface disposal of GTCC could be approved under the current regulations on a case-by-case basis using technical information developed to support the regulatory basis.

The paper recommends that rulemaking could improve clarity and consistency in their requirements, which would provide applicants for the near-surface disposal of GTCC waste with greater regulatory uncertainty.

If addressed or rulemaking, the GTCC and transuranic waste efforts could be combined with the ongoing 10 CFR Part 61-related rulemaking activities.

As part of the rulemaking, staff recommends that agreement states could regulate disposal of GTCC waste.

An alternative view regarding agreement state authority and jurisdiction over GTCC, including special nuclear material, is included in the paper.

We appreciate the incorporation of this alternative view as it helps enhance the process and make the final decision well-rounded.

The staff took this well-articulated alternative view into consideration, but did not modify their overall recommendation.

Next slide, please. Recently, we proposed a new interpretation of authorized recipient, under 10 CFR 20.2001, that would allow

certain very low-level waste to be transferred to no licensed disposal sites using a regulatory process that is both innovative and risk informed.

The proposed interpretive rule would clarify the meaning of authorized recipient such the persons who hold specific exemptions would be considered authorized recipients and eligible for disposal transfers.

My staff conducted multiple outreach activities via public meetings, notices for public comment, and specific communication with our regulatory partners at the agreement states, EPA, the Association of State and Territorial Solid Waste Management officials, and among the waste compacts, to obtain feedback on the proposal.

The comment collection process concluded on October 1st and we're evaluating the options to address this issue.

Regardless of the outcome, the lessons learned from this effort will be leveraged into another ongoing low-level waste program initiative, the NRC's 2018 very low-level waste scoping study, as well as possibly being considered as part of the evaluation of overall radiological waste classification.

The scoping study was conducted to identify the actions that the NRC could take to strengthen its regulatory framework for very low-level radioactive waste.

Many of the recent accomplishments in the business line such as updating the guidance for alternative disposal requests and using rulemaking where appropriate to update waste disposal pathways were conducted in parallel to the scoping study and will be factored into our analysis of the feedback received on the study.

The staff intends to formally close out the scoping study by

providing a paper to the Commission in FY 2021 that will capture the results of the study.

We will continue to evaluate the long-term efforts associated with the scoping study, as well as leverage the lessons learned in all of our low-level waste regulation and oversight activities, to keep moving forward in being a more efficient risk-informed regulatory program.

Next slide, please. An area of continuing growth and focus for the business line is the efficient transition of power reactors from operations to decommissioning, and a specific subject of increased interest involves a recent uptick in power reactor licensees adopting new business models for accomplishing decommissioning.

These new business models include both temporary and permanent license transfers to specialized decommissioning companies for the purpose of expedited dismantlement and decontamination.

In response to these developments, my division evaluated whether there are any potential risks to the new business models.

One item identified resulted in a self-initiated assessment to address concerns regarding the current funding requirements and mechanisms that form part of the basis for the license transfers.

These concerns were raised given the significant acceleration of decommissioning schedules and withdrawals from decommissioning trust funds that accompany transfers for the purpose of expedited completion of decommissioning.

To address these concerns, an Interoffice Reactor Decommissioning Financial Assurance Working Group was assigned to

comprehensively document and evaluate whether the existing Reactor Decommissioning Financial Assurance Program remains adequate under the new decommissioning business models.

In May, we issued the final report of the working group, which represents the completion of a staff-initiated, short-turnaround, enterprise risk management project to work across business lines and ensure a robust financial assurance process for power reactors.

The report included nine recommended program enhancements encompassing guidance revisions and a training program to ensure more consistent and efficient financial assurance process for power reactors undergoing decommissioning, which will improve the efficiency, effectiveness and transparency of the program going forward.

In addition, we recently updated internal guidance documents to address the new decommissioning license transfer business models and incorporate other lessons learned from recent decommissioning activities.

The goal of this guidance was to incorporate overall efficiencies and improvements to the process based on the decommissioning transitions completed to date and help clarify the expectations and requirements related to the new decommissioning business models.

Training on this new guidance is being conducted for all NRR and NMSS reactor program managers.

Next slide, please. Another effort currently underway is to develop enhancements to our Reactor Decommissioning Inspection Manual, as well as the associated inspection procedures, to risk-inform the oversight

guidance and incorporate recent changes related to the decommissioning business models and the surrounding financial assurance mechanisms.

In recent months, the Decommissioning Power Reactor Inspection Manual, which is IMC 2561, was revised holistically in an effort to further risk-inform the inspections of permanently shut down reactors.

This revision, along with updates to the associated core inspection procedures, will become effective in January 2021.

There have also been several recent updates to major decommissioning guidance, including issuing NUREG-1507, a significant health physics guidance document, soliciting comments on a volume of NUREG-1757, which covers site characterization and radiological surveys, and finalization of another volume of NUREG-1757, which covers the decommissioning process for materials licensees.

All these revisions represent significant updates to incorporate best practices and lessons learned from recent decommissioning experience.

Each revision was done in concert with many of our industry and regulatory partners and the staff will continue to engage industry on future updates to these documents.

To this end, we recently met with members of industry and other stakeholders to discuss potential areas to further use risk insights and the decommissioning power reactor license termination process.

This meeting will be one of many as we continue to enhance the decommissioning reactor program.

I will now turn the presentation over to Mary Muessle to take

us through the risk-informed approaches being adopted in the decommissioning and uranium recovery oversight area.

Next slide, please.

MS. MUESSLE: Thanks, Trish, and good morning, Chairman Svinicki and Commissioners.

Today, I will have two initiatives to transition uranium recovery and decommissioning oversight guidance to a more risk-informed, performance-based approach.

Next slide, please. Uranium is --

CHAIRMAN SVINICKI: I'm sorry, Mary. This is Chairman Svinicki. Before you proceed, I've been asked to please remind other presenters to mute while Mary is presenting. Thank you.

MS. MUESSLE: Thank you.

Uranium recovery operations include construction, operation and decommissioning of uranium mills and 11e.(2) byproduct material disposal facilities as well as in situ recovery facilities.

At present, the NRC regulates eight of these sites. One is currently operating, two are authorized, and five are in decommissioning.

Agreement states also regulate 34 sites. 11 of these are active or in standby, five are authorized, and 15 are in decommissioning.

The current oversight guidance for these operations are included in Inspection Manual Chapters 2801 and 2641.

Next slide, please. The current inspection programs date back to calendar year 2000 and do not reflect performance-based concepts or changes in industry technology.

Last April, with travel restrictions in place due to the COVID-19 public health emergency, Region IV began to revise the current guidance to incorporate risk insight and combine construction and operational program components into one Inspection Manual Chapter.

Since there are no existing probabilistic risk or integrated safety analysis for uranium recovery facilities, determining risk-significant activities in this area is qualitative.

To address this, we use risk insights and the existing NRC guidance and first-hand experience to focus inspection activities on risk-significant ones.

Examples of the areas of greatest concern are spill response, radiological emergencies, yellowcake dryer operations, and accidents and groundwater contamination.

The revisions also enhance the oversight program by adding more performance-based concepts to the inspection guidance and providing more direction to inspectors on where to focus their time.

The updated guidance specifies core and discretionary inspection procedures. Core procedures are mandatory and encompass risk-significant activities, including disposal cell construction, radiation protection, groundwater and water management programs, and radioactive waste disposal.

Discretionary procedures, in contrast, are performed only if warranted by weaknesses in licensee performance.

The discretionary procedures include areas such as management and organization and administrative control. For example, the

review of established procedures and programs.

Next slide, please. Each core inspection procedure identifies high-risk activities. For example, the groundwater and water management program.

Risk-significant areas include monitoring and preventing spills, excursions, aquifer contaminations, ponding, and other releases to the environment.

This approach improves the quality of NRC oversight by focusing resources on license activities that pose the greatest risk to workers, the public and the environment.

As you can see in this slide, inspectors encounter a variety of locations, conditions and activities of interest while performing their oversight activities.

The revised guidance takes a turn from previous compliance-based approaches and moves towards performance-based inspections.

Fundamentally, inspectors will now conduct SAFSTORs of their critical license activities, perform independent radiation surveys and conduct only a limited records review.

Returning to the example of groundwater and water management program, inspections will include observing the physical condition of the equipment, discussing system health with the operators, and adjusting the effectiveness of the system.

The revisions to these core inspection procedures are currently under broader Agency review. We will partner with agreement

states for input and will inform other audiences such as the National Mining Association, state governmental organizations and tribes, once the changes are close to completion next year.

To ensure successful implementation, impacted staff will receive training with particular focus on implementing risk-informed, performance-based inspections.

Next slide, please. The Materials Decommissioning Program focuses on determination of licensees for uranium recovery facilities, fuel site facilities and sites involving more complex decommissioning activities.

These facilities typically were manufacturing or industrial sites that process uranium, radium or thorium or were former military uses.

There are currently 17 of these large decommissioning projects being overseen by the NRC as well as several shorter duration projects.

Decommissioning oversight at fuel facilities and complex materials facilities is conducted in accordance with Inspection Manual Chapter 2602.

Adopting the approach described for updating uranium recovery guidance, Region IV will lead a working group to revise IMC 2602 through the Materials Decommissioning Program and will incorporate uranium recovery decommissioning guidance enhancements into the update.

We anticipate the scope of the project and level of effort will be much larger than the uranium recovery project given a broader range of facility types with significant activities, radiological concerns and larger

number of licensees.

For these facilities, common major risks include groundwater plumes and soil contamination. Other significant risks will be dictated by the different types of radioactive materials released at each facility.

The major difference between the risks in uranium recovery operations and in decommissioning is who is impacted. For operations, the primary safety concern lies with radiation dose to the workers. For decommissioning, the primary concern is radiation dose to members of the public and radiological contamination of the environment.

In both cases, the impact to workers, the public and the environment are all considered risk significant.

Radiological protection practices and regulatory requirements for decommissioning activities for different facilities are fairly consistent.

The NRC's decommissioning inspector qualifications often focuses on health physics as insight for decommissioning.

Specific activities conducted by the facility during operations affect where and what radiological hazards are present and the level of inspection effort that will be required.

The manual chapter and inspection procedures serve to provide specific guidance on where to focus inspection efforts using risk-informed approach.

The working group for the update to IMC 2602 will include representatives from each region, headquarters and agreement states.

In addition, the working group will reach out to inspectors

and subject matter experts to validate the risk significance and clearly define specific areas of interest for each type of facility.

Stakeholder involvement will be critical to the success of this project. The working group will meet with industry and other external stakeholders at public meetings.

We are looking at innovative ways to engage inspectors and other interested parties to crowd sourcing, and we are exploring the potential to do scenario-based risk exercises and/or to pilot proposed inspection changes in the field.

This concludes my portion of the presentation and I now turn it back over to Margie to close out this part of the briefing.

Next slide, please.

MS. DOANE: Thank you, Mary.

In closing, it is clear a significant amount of work has been accomplished under the decommissioning and low-level waste business line, and innovative approaches and tools employed by staff will help ensure we continue to be effective while incorporating efficiencies, lessons learned and other enhancements while adapting to changes in the external environment.

I'd like to thank all of the panelists for their presentations and all of the NRC headquarters and regional staff, as well as the agreement state staff and other co-regulators that support and make the decommissioning, low-level waste and uranium recovery programs a success, and of course the staff that has helped us put these presentations together and helped us organize all of this.

So, this concludes our presentation on the

decommissioning and low-level waste business line and we look forward to addressing those questions that you may have for us.

CHAIRMAN SVINICKI: Well, thank you very much for those presentations. I will be going first in the recognition of members of the Commission to ask questions today.

I have -- I share your observation, Margie. There is clearly a lot of work going on and moreover staff is really embracing our kind of modernizing and re-looking at areas and seeing what we've learned maybe in the past number of years since we last looked at a process or procedure.

And they're really looking for opportunities there to incorporate the knowledge we have today, not just the knowledge that we had years ago.

And it's very -- a lot of work is in progress, but I think it's very exciting and I wanted to begin by offering that comment.

I was going to touch on a couple of things that Trish raised, but I know that the structure of this panel is such that Margie or John may want to respond.

So, although they are things that Trish mentioned in her presentation, she doesn't have to be the one to offer a response depending on what you all decide amongst yourselves.

One of the things that Trish talked about was the recent SECY paper on near-surface disposal of GTCC.

And I think if I have my history right, Commissioner Baran and I have the most direct awareness. We were members of -- we're still members of the Commission, but we were here when this matter was briefed

to the Commission.

And for me, you know, the paper that we recently got is kind of a -- it's a follow-on progression from previous works that the staff laid in front of the Commission.

And as a part of the paper that's laid in front of us to combine some rulemaking activity stuff, recommends that, in their view, agreement states could regulate the disposal of GTCC waste and that builds off of some taskings that the Commission previously gave to the staff.

Also noted, however, is that a differing view accompanies the paper and I agree with. I think Trish's term was very well-articulated. I agree with that.

I have read the differing view and it does quote extensively from Commissioner Baran's votes, which are also very well-articulated on that previous work, but that was -- the interpretations and structure advanced by Commissioner Baran was not ultimately central to what the Commission majority on a bipartisan basis had adopted at that time.

So, I noted that the paper, although the differing view accompanies it, there's not kind of a staff response or anything, not that that's mandated in terms of the paper structure.

And part of me was trying to figure out, you know, if you're laying one view in front of the Commission, but you recommend something else, shouldn't you have something that kind of briefs the other side of the question.

And what occurred to me is that maybe the staff is a little bit in a bind here because other than revisiting the previous SECY paper decision

and the Commission's outcome in that case, the staff would be in a position of kind of saying the Commission's previous policy decision was either wrongly decided or the staff would have to then re-articulate the Commission's outcome, which really isn't its role to do.

It doesn't need to write long articulations of what the Commission decided years ago. So, I didn't -- my question is twofold.

It is, first of all, was that part of the reasoning why the paper doesn't have a section that really addresses the differing view and why the staff continued to recommend something other than the differing view?

Or if that's not accurate and there are other elements that the staff considered with the different view, as Trish said, do you intend to provide something to the Commission along those lines?

And with that question, I don't know if that's a Margie question or John or Trish herself.

MR. LUBINSKI: Thank you, Chairman. John Lubinski here, if I can start, and of course Trish and Margie can follow.

So, as you noted, it's a follow-on paper to the previous SRM where the Commission did ask us to do an evaluation not only of whether or not this near-surface disposal could be accomplished in a safe manner, but asked us if the states could have that authority to regulate that disposal as well.

So, the staff did go on that premise in developing the regulatory basis from a safety perspective.

It was very clear, when we came out, that we believe that the states do have the ability to do that.

They currently, with respect to Greater-Than-Class-C, do regulate storage handling and transportation.

They do currently regulate disposal of non-Greater-Than-Class-C waste, but we see that expertise there.

From the standpoint of the options, we believe that that was the best recommended option to ensure consistency of the implementation of a program if it were approved to go forward with the disposal of Greater-Than-Class-C waste and shallow burial.

We believe the benefits of that, from a safety perspective, again, you know, a policy issue that we're talking about here from a safety perspective would be that it would ensure consistency as we -- consistency in accordance with our other programs for disposal.

And also, it would eliminate the need for any dual regulation of these sites. If the disposal would be regulated within an agreement state, that the NRC would not dual regulate that site with respect to the other wastes.

So, we were really going forward on that premise that this was our recommendation going forward and following the previous SRM.

We coordinated with the Office of General Counsel to make sure it was a legally acceptable position going forward.

They agreed. So, therefore, that was the logic we used in providing that back to the Commission.

Again, with having alternate views of the staff, we strongly encourage folks to raise those. I appreciate the view being raised and I appreciate the time that one individual took to explain the detail with that view with me to help inform the decision.

But in the end, I believe that the recommendation from a safety standpoint and policy standpoint is sound.

And the answer to the second part of your question is, so we don't see right now that we'd be providing any additional information to the Commission.

We believe it's a policy issue right now in front of the Commission about whether to go forward with our recommendation and we believe you have the information to do that.

CHAIRMAN SVINICKI: Okay. Thank you.

That's helpful and I think a good suggestion that I take on board is embedded in that for me, which is to -- although I was here for the work on SECY 1594, I should reacquaint myself with some of the Commission's deliberations with both Commissioner Baran's views and other things that were articulated at the time. So, I'm not all the way through my consideration of the matter.

And I do share your expression of appreciation for the differing view. It is extremely thoughtfully laid out and I will spend additional time with that as well as I consider these really foundational and important issues on the topic of GTCC disposal.

And I've made no final determination, so I appreciate the differing view being part of the mix here and obviously great care and attention was taken in its preparation.

So, the other -- just quickly, I think another ongoing area, the work is not completed yet, but really caught my eye, is the working group that has been established on reactor decommissioning financial assurance.

I think that, as Trish gave an update of the status, it may be that the Commission would receive a paper on this in 2021.

So, the work is, by that statement, obviously still ongoing, but at bottom, the staff is looking at some of the new models for how decommissioning both is being conducted now and will be conducted, some of the new business models and frameworks for doing it.

And as the staff's charter or purpose for the activity notes, the working group has been assigned to comprehensively document and evaluate whether the existing reactor decommissioning financial assurance program remains adequate in alignment with how decommissioning is being approached now and going forward.

So, is there anything -- it got a glancing blow, I think, in Trish's presentation. Is there anything more that the staff can talk about there? That's a pretty broad charter to the group.

I don't know if that's another John question.

MR. LUBINSKI: Actually, I believe I'll ask Trish to start the response.

Trish.

MS. HOLAHAN: Yeah. The working group has finished their efforts and we sent a CA note up on the results of the working group with the report.

We didn't identify any regulatory gaps, but they did recommend enhancements to the guidance and procedures implementing the program to improve its effectiveness, efficiency and transparency.

Things like we're revising the inspection procedures to make

sure that the inspectors are not put in a position that they have to do a financial analysis, but, you know, send something back to the programmatic people in the financial assurance branch, developing a spot-check program for reactors in decommissioning, and then training the inspectors with the financial assurance people as well as the decommissioning PMs.

CHAIRMAN SVINICKI: So, it sounds like, Trish, I might have had that a little bit wrong then. I apologize.

So, is it some of this revised guidance that will be developed in 2021? Is that what's kind of the ongoing activity?

MS. HOLAHAN: Yes, that's the ongoing activity.

CHAIRMAN SVINICKI: Okay. Thank you for that clarification and I -- in preparing for today's meeting I didn't get all the way through the working group report and maybe I thought that there was further determinations that you all were making. That's very -- actually, that's very helpful. Thank you.

And I'm sure that the staff, I would just close on this note, will be coordinating closely with the Commission to make sure that any changes to guidance don't establish new requirements because, of course, we would do that through rulemaking.

So, I know the staff will work to navigate those guideposts very carefully. And with that, I'm over my time, Commissioner Baran.

COMMISSIONER BARAN: Thank you.

Well, I'd also like to start by asking about the potential Part 61 low-level waste and Greater-Than-Class-C waste rulemaking.

The staff is recommending that we handle both topics in one

re-proposed rule. The staff presented a second option of not addressing Greater-Than-Class-C waste issues in a rulemaking.

If we went that route, the current regulations still would allow NRC to issue a license for near-surface disposal of GTCC on a case-by-case basis.

My understanding is that there is one potential GTCC waste applicant -- waste disposal applicant in Texas, and that that applicant favors a case-by-case application; however, the State of Texas is apparently unwilling to accept GTCC waste at this time.

That raises the question about whether it makes sense to do a GTCC rulemaking. We could potentially spend a lot of time developing standards and then have no applicant.

Could someone walk us through the staff's thinking on the question of whether to proceed with rulemaking on Greater-Than-Class-C waste disposal?

MS. HOLAHAN: Thank you for that question.

The staff was thinking that there are overlapping requirements, including site-specific analyses and intruder assessment. So, that's why we recommended combining the two rulemakings.

There would be some benefits of not combining the two rulemakings. It would allow for the current Part 61 to be completed sooner if it's re-posted with a narrow scope combining -- if it's re-posted.

Then the most significant benefit of completing the Part 61 rulemaking would be to provide clear and consistent requirements to current disposal facilities on safe disposal of large quantities of DU.

Also, the definition of "low-level waste" could be revised to remove the exclusion of true waste in that rulemaking, but the recommendation was to combine them because we thought that besides the overlapping technical requirements, there wouldn't be that much in terms of resource savings and it would allow enhanced coordination outreach.

So, the staff expects that consolidating the rulemaking activities will involve additional time, but then there's no significant downside to that because operating sites are effectively meeting what would be the safety requirements proposed in the Part 61 rule.

So -- and I recognize that only one potential applicant has expressed interest in Greater-Than-Class-C waste.

MR. LUBINSKI: If I could add to that also, Commissioner -- Trish, thank you -- from a benefit of rulemaking versus the case-by-case basis, the staff does see that there are benefits to both.

And so, while we did recommend rulemaking, we believe we could effectively implement the case-by-case.

The key benefit to doing rulemaking with respect to Greater-Than-Class-C is to provide a more fulsome review and analysis of the requirements through a formal established process under the Administrative Procedures Act that would allow for further input.

We believe, from a safety basis, the reg basis did a very good job of determining the type of waste.

And the additional requirements, as Trish talked about, such as intruders, that would be -- those types of issues, we think, having a fulsome discussion publicly as part of the rulemaking process would provide a benefit

in making those final decisions.

COMMISSIONER BARAN: Thanks.

You know, thinking through the pros and cons of that, one thing that wasn't totally clear from the paper, to me, is whether the GTCC rulemaking element and the staff's view is only really worth it if it is combined with the Part 61 rulemaking.

So, I guess the question is if it were -- if GTCC were a separate standalone rulemaking not combined with Part 61, would the staff still view that as worthwhile?

MR. LUBINSKI: I think the short answer would be yes to that, Commissioner. We did make the recommendation because, again, from the benefit standpoint of the Greater-Than-Class-C rulemaking it wasn't just the efficiency of combining the two. It was really the benefit of getting more fulsome public engagement on the issues associated with what would go into the rule to have that codified.

And as you said today, there is only one applicant, but, from a rulemaking standpoint, it would codify for the future if there were future applicants.

COMMISSIONER BARAN: Okay. And if we didn't proceed with the GTCC rulemaking, if we went with, I guess, the second option, would it make sense to develop guidance on how NRC would review a case-by-case application for near-surface disposal?

MS. HOLAHAN: Thank you for that question.

The staff would, first of all, finalize the draft regulatory basis for GTCC and use it as a technical basis for any licensing decision.

And then we'd probably work with the -- well, we'd work with the agreement states to develop licensing guidance.

And the short answer to your question is, yes, we still think it would be advisable to look at a case-by-case basis.

COMMISSIONER BARAN: Okay. Thanks.

Well, I don't think it's a straightforward issue. As the Chairman mentioned, I think there were four of us on the Commission last time we looked at this.

It was the only one, one, one, and one vote I've been here for. Four commissioners, four different positions.

So, it wasn't easy, but, you know, we did work --

CHAIRMAN SVINICKI: And I stand by my comment that your votes were very well-articulated.

COMMISSIONER BARAN: Everyone had a very well-articulated totally different view last time we looked at this. So, I look forward to reengaging on this issue.

Let me also ask about very low-level waste. As Trish mentioned, the staff took public comment on a proposal to authorize a transfer of what the staff is calling very low-level waste to entities who hold specific exemptions for land disposal without a case-by-case review or approval of the transfers.

The basic idea is that solid waste landfills could be allowed to accept and dispose of this waste.

Based on the number of comments received and the substance of those comments, it looks like this potential reinterpretation of an

existing NRC regulation is quite controversial. At a Commission meeting a few weeks ago, agreement states were also raising concerns about it.

What can you tell us about the staff's plans on this issue?

MS. HOLAHAN: We are currently -- thanks for the question.

We're currently looking at all those comments and we're looking at possible ways to close it out.

We're possibly considering, you know, if we don't go forward with the proposed interpretive rule, we factor that into the scoping study and possibly the waste classification relook when it's done. So --

MR. LUBINSKI: Trish, if you don't mind?

MS. HOLAHAN: Yes.

MR. LUBINSKI: So, thank you, you know, Commissioner, as Trish said, in looking at those comments, and, as you said, there are a large number of comments and some strong views from the states.

We expect to make a decision shortly on whether to move forward or not move forward with that interpretive rule and we will be informing the Commission of that decision before it's made public.

In going forward, whether or not the rule becomes final or not, we will be taking the information and the large diverse set of comments that we received and, as Trish said earlier, factoring those into future decisions with respect to very low-level waste.

But the short answer to the Federal Register Notice is we will make a decision shortly and we'll inform the Commission before we issue a Federal Register Notice either finalizing or withdrawing.

COMMISSIONER BARAN: Okay. Well, thanks for that and

I know you're still digesting comments and thinking it through.

Do you see any scenario in which the staff decides to go ahead and finalize the proposed interpretation without coming to the Commission for a vote?

MR. LUBINSKI: At this point, as I said, we would be informing the Commission of our decision, whether to go forward or not.

And if we were to decide to go forward with that, we would be evaluating that decision whether or not it would require a commission vote or not.

COMMISSIONER BARAN: Okay. Thanks so much. That's all I had, Chairman.

CHAIRMAN SVINICKI: Thank you, Commissioner Baran.

Next, we will hear from Commissioner Caputo.

COMMISSIONER CAPUTO: Good morning.

I'd like to start out by saying I really commend the staff for its work on uranium recovery this year.

Successfully negotiating the EPA MOU, resuming rulemaking, enhancing decommissioning guidance and transitioning oversight to a more performance-based approach, all reflect a considerable level of effort and teamwork. So, I'd like to start by just saying "well done."

However, the Commission recently issued decisions in both the Crow Butte and Powertech ISR licensing proceedings.

The Powertech decision wrapped up a near decade-long process questioning what effort is sufficient for the staff to meet its National Historic Preservation Act and NEPA responsibilities.

The Commission's decision in Crow Butte has now placed that proceeding on a similar trajectory.

Our principle of clarity states that Agency positions should be readily understood and easily applied.

Our reliability principle states regulatory actions should be -- always be fully consistent with written regulations and should be promptly, fairly and decisively administered. These recent proceedings certainly fail to meet those principles.

We've created a situation without clarity, predictability or decisiveness. Neither the staff, nor future applicants, will have a clear understanding of what constitutes a reasonable effort to meet these requirements.

Either there will be rounds of litigation until a board finally determines whether or not they have found the right rock or their effort has exhausted all practical options.

Given that the staff has spent considerable work trying to improve the licensing process, does the staff have any innovative ideas under consideration on how to simplify this regulatory gauntlet?

And I don't know if that's John or Patricia.

MR. LUBINSKI: Thank you. I will start and ask -- John Lubinski here -- and then I will ask Patricia to chime in if she has any additional thoughts.

So, as you said, Commissioner, these were recent Commission decisions that came to us. In moving forward, we're specifically looking at Crow Butte working with the Licensing Board, as well as the

applicant, as well as the people who filed the contentions, on what's the best way to move forward from that.

In doing that, as you know, it's not the safety aspect of that. It's the environmental and the national Historic Preservation Act.

We are looking at those right now to determine how do we continue to move forward in a better way.

So, I tell you it's a dual path right here where we're looking at NHPA, National Historic Preservation Act, and how can we do a more effective job in meeting the Act and doing that coordination with the interested parties.

And specifically working on Crow Butte, to take any lessons learned how we move forward in that case both in the past, as well as continuing to move forward, to develop those changes.

So, that is the plan we have right now, but I'll tell you it's too early to say that we have a clear plan laid out of what a success path looks like.

COMMISSIONER CAPUTO: Thank you.

Dr. Holahan, in reviewing the background material for the meeting, I noted that NMSS issued interim guidance to the staff on reactor decommissioning transition process with regard to reactors transitioning from operations oversight by NRR into decommissioning under NMSS.

That guidance contained a knowledge management checklist which appears to help manage the transition more smoothly.

In addition to those guidance, there were two other nearly identical office procedures, one from NRR and one from NMSS, that also

contained this knowledge management guidance on the transition of decommissioning activities.

In your view, wouldn't it be more transformational to have one set of office instructions covering this topical area rather than two nearly identical sets of internal office procedures amounting to more than a hundred pages referencing the knowledge management decommissioning checklist and associated activities?

MS. HOLAHAN: Thank you for the question.

You mentioned the interim guidance and that was superseded by the NMSS guidance. Now, you asked about the duplication of the NRR procedures and the NMSS procedures.

What the NRR procedures were to cover more than just interactions on decommissioning. It was to cover a lot of activities with environmental, with financial assurance.

And so -- and we wanted to make sure that we were saying the same thing in each because they wanted to keep the transition for decommissioning in there as well.

So, we ensured there was consistency, but theirs was more than just the reactor decommissioning whereas ours was specific to reactor decommissioning.

And we can look at it again and ensure that, in the future, we don't duplicate efforts.

COMMISSIONER CAPUTO: Okay. Thank you for that.

I just want to go back for a little bit more clarity on financial assurance requirements for reactor decommissioning.

Can you just give me a little clarity on where you think the new -- our current requirements are not necessarily -- well, how does the new business model really present differing challenges for our existing framework as opposed to current financial assurance, which, as near as I recall, is basically -- handle all of our decommissioning reactors sufficiently so far.

MS. HOLAHAN: Thanks for that question.

The new business models are more expedited decommissioning. We haven't experienced that until the new business models came up with people purchasing -- or transferring licenses to decommission more rapidly and it doesn't allow the time.

It -- sites are in SAFSTOR. They have a certain amount of time for that decommissioning trust fund to grow. And so, we were concerned that that wouldn't be able to happen.

But we looked at it and we were satisfied that there were no gaps or regulatory -- regulation changes necessary.

COMMISSIONER CAPUTO: Okay. Because with that, if there's a concern about a fund potentially coming up short, there's room for a company to utilize a parent company guarantee, correct?

MS. HOLAHAN: Yes. And so, we have -- you know, certain companies have parent company guarantees. And so, that's why we felt that there were no gaps.

So, we just wanted to make sure that in this current environment with sites decommissioning faster, it was still the same.

COMMISSIONER CAPUTO: Okay. Thank you. That's all I have.

CHAIRMAN SVINICKI: Thank you, Commissioner Caputo.

Next, we will hear from Commissioner Wright.

COMMISSIONER WRIGHT: Thank you, Chairman, and thanks for bringing up the topic of the paper this morning.

You know, I -- and, Trish, I appreciate the staff including the different views in the paper, but I haven't had time to digest it yet.

So, I don't have -- I need time to kind of formulate where I'm going and even thinking about what questions I would have, if I had any. So, with that, I'm just -- I won't be referencing that again today.

Thank you for your presentations across the board today. So, you've been doing great work. Continue to do that during this public health emergency or pandemic and you're continuing to effectively regulate in every area, you know, while adapting to what's going on and how things are evolving.

So, I really appreciate what you're doing and the way you're trying to stay in touch and keep us informed.

John, you mentioned before that NMSS is invested in risk-informing across program areas. We've heard a bit about that on this panel and I believe we're going to hear more in the second panel.

Can you expand a little bit on how these efforts fit together and do they fit together to create a unified vision of how NMSS will be using risk insights going forward?

MR. LUBINSKI: Yes. Thank you, Commissioner.

You know, as you know, today we're talking about the decommissioning and low-level waste business lines. And even within that

business line there is diversity. And then when you go across NMSS, there's a lot of diversity in the business lines.

Even with that said, though, the overall philosophy of taking a risk-informed -- look in a risk-informed approach is being treated consistent across the board.

We are using, as part of our transformation tools, the BeRiskSMART model in moving forward.

We are trying to take lessons learned in the oversight programs. We did make some changes to our spent fuel storage -- interim spent fuel storage facilities as well as our fuel cycle facilities.

And one of the biggest lessons learned from that was making sure that we're bringing the correct people to the table that have the most expertise on looking at risk, because in NMSS business lines you're not dealing with PRAs the way you are in reactors and you're using a lot of qualitative information to develop those risks.

So, bringing the right people back to the table, which includes the inspectors who have been doing this for years, that they have the experience in looking onsite of what's to be done, getting their insights on determining what's the most risk-significant activities, and, most importantly, what makes those activities the most risk-significant so that that can be put into the procedures as knowledge management and going forward to say these are the types of -- or type of qualities that make these activities more high-risk and require further attention and it's being able to re-baseline those programs. So, it's a philosophy across the entire group.

We're looking at it from the standpoint of our oversight

programs, also our licensing programs, and then with respect to regulations as well.

So, it is a unified effort across the office. With that said, each division is taking its own leadership role.

Trish mentioned this morning two efforts where we looked at oversight of operating reactors -- the oversight of operating reactors.

Mary talked a bit about what she's starting to just kick off right now in the -- for the materials decommissioning sites.

Later in the presentation you'll hear about what we're doing for the nuclear materials users in that same area, and all the groups have been consistently discussing what the best practices are in moving forward in those areas.

COMMISSIONER WRIGHT: Thank you.

Trish, I guess this will maybe come for you and maybe, Mary, you might want to kick in if you have any thoughts on it as well.

So, go back to the business model. The decommissioning business model discussion, you know, has evolved over the last decade and we've seen the use of fleet models for decommissioning multiple sites and some innovation in these approaches, too.

So, you mentioned that we made some changes to our licensing and oversight guidance and training to address these changes.

Can you provide me maybe some examples of how we've updated our guidance or training?

MS. HOLAHAN: Yeah. I'll start and then Mary can chime in if she wants.

What we did with our inspection guidance is the inspectors were feeling that they had to assess whether the financial qualifications -- or basically do an audit of the financial situation.

And so, we revised the guidance to ensure that the inspectors were looking at what was being done in terms of decommissioning, and then the annual reports are reviewed by the financial assurance group.

And so, the inspectors would be communicating with the financial assurance group if they identified something that was said to be done, but wasn't.

But basically, we were giving the inspectors the opportunity to just inspect the activities at the site, not do a financial audit.

COMMISSIONER WRIGHT: Okay. Mary, do you have anything?

MS. MUESSLE: Sure. I mean just that, as John mentioned, we're very early at looking at procedures and doing the updates, but the type of things that we're talking about are in the past when we might have gone in and done a compliance-based records review of effluent releases and exposures and even in terms of personnel monitoring, radiation monitoring.

Now, we would be actually going out onsite and really doing direct observations as to how people are actually conducting activities, how they're recording that, you know, moving through the process it wouldn't go back to those records review unless we saw that there was an issue.

COMMISSIONER WRIGHT: Okay. Thank you.

So, we've completed -- or I guess we're nearing completion of license terminations for several licensees that decommissioned their plants

using the licensee model.

And then you have the decommissioning contract model and the temporary license transfer model. We've also had several years of experience with the permanent license transfer model.

Are there any significant differences between how decommissioning progresses or the types of licensing actions required based on the model used? Anybody?

MS. HOLAHAN: Sorry. The permanent license transfer model is the newest model. And so, we don't really have a lot of experience with it. We have experience with the licensee model and the decommissioning contract model.

But in terms of the temporary license transfer or permanent license transfer, we're working with the industry to identify places we can communicate, and we are encouraging them to share lessons learned from the decommissioning activities across the industry.

Does that answer your question?

COMMISSIONER WRIGHT: Well, I just wonder were there any significant differences between how decommissioning progresses or the types, you know, of licensing actions required?

MR. LUBINSKI: Maybe if I could add, Commissioner, thank you. John Lubinski here.

As you said, are there differences, right, and you've already quoted what some of the difference are.

But from the standpoint of our oversight, right, we're still using the same principles of what's important, right?

It's release of the site. It's ensuring safety of the workers at the site. It's ensuring that any material that goes offsite is handled appropriately. It's ensuring that there's appropriate cleanup.

And then it's also ensuring that you have the funding available and it's used appropriately in going forward.

What we're seeing as some of the differences is really the business cases that they're using, whether or not you're shipping large components offsite or whether or not they're trying to decon many of those onsite and ship clean components offsite.

So, it's where the focus that you --

COMMISSIONER WRIGHT: Hello? You lost your sound.

MR. LUBINSKI: Sorry. Thank you. The -- sorry, I think I lost the sound and forgot what I was saying.

So, the activities may be a little bit different where they're making business decisions on volume of material that's going offsite, how much they're cleaning up onsite, what they're trying to recover as clean material.

But from our standpoint, we're still using the same criteria to determine what goes offsite, is it safe, does it meet our standards, and onsite is it the same?

And I think it's a good point here to make now that we've talked a lot about the new business model.

When we're doing this analysis, there is not -- there's not any judgment on whether or not the new model is good or bad.

Really, we're looking at the model to say are our oversight

programs appropriate in going forward based on these differences?

And the first one that jumped at us was the decommissioning fund. And we're going to continue, as we go forward, to ask these questions as we would in any other program.

So, more so to your question, as we're moving forward in implementing this model with a shorter time frame for decommissioning, if we're noting changes in their business programs that require us to change our oversight or the way we're doing licensing, we will definitely be engaging with them to make those changes.

COMMISSIONER WRIGHT: Thank you.

CHAIRMAN SVINICKI: Thank you, Commissioner Wright.

Next, we will turn to Commissioner Hanson for any questions he may have. Thank you.

COMMISSIONER HANSON: Thank you, Chairman Svinicki, and thank you all for being here this morning. I found the presentations very helpful and informative.

I want to join my colleagues in kind of drilling down a little bit on this issue of the decommissioning business models.

Licensees are required to submit annual decommissioning trust fund reports. Are our evaluations of those reports based solely on whether sufficient funds remain for decommissioning activities covered under regulations, or do we evaluate at all the reasonableness or prudency of the expenses incurred by the licensee?

MS. HOLAHAN: Thank you for that question.

The annual decommissioning trust fund report reviews for

reactor -- evaluate whether a licensee is demonstrating reasonable assurance, that a licensee has adequate funds to complete decommissioning of the facility and terminate its Part 50 license.

When a licensee permanently ceases operations, there's a regulatory requirement to provide a post-shutdown decommissioning activities report that includes the decommissioning cost estimate.

While staff does not approve the decommissioning cost estimate, they -- the staff does evaluate the reasonableness of that.

The annual -- and then the annual analysis considered to decommissioning trust funds remaining that are dedicated to radiological decommissioning compared to the estimated remaining amount needed to complete the project, but we really don't get into levels of detail as to how they're spending the money.

COMMISSIONER HANSON: Okay. Thank you.

You mentioned the PSDAR that's submitted, and the PSDAR must contain a discussion that provides the reasons for concluding that the environmental impacts associated with site-specific decommissioning activities will be bounded by appropriate previously issued environmental impact statements.

Given that the current decommissioning business models have evolved over the last decade, do you think that the environmental impacts for the associated decommissioning activities are still bounded for most of these facilities by the existing EISs?

MS. HOLAHAN: Yes, I do. Because, as John mentioned, we're just -- the new decommissioning model just looks at -- with the new

decommissioning models we're just looking at how it's done safely and the site is cleaned up.

So, I think the environmental impacts are the same.

COMMISSIONER HANSON: Okay. Thank you.

On slide 12 you mentioned that you're proactively identifying and addressing any potential risk associated with implementation of the new decommissioning business models.

What emerging important risks have you identified and how are we managing those?

MS. HOLAHAN: We have identified -- right now, we really don't have any information to make a determination that there is an issue with the new business models, but we have it as a risk and we're monitoring it as an enterprise risk to make sure that those continue to work.

COMMISSIONER HANSON: Okay. You mentioned, Trish, that the staff's recently revised and issued several guidance documents to support the effect of transition of operating reactors to decommissioning. My colleagues have asked about this as well.

My question is, really, what indicators are you monitoring to make sure that you were getting the desired outcomes or achieved from these activities?

MS. HOLAHAN: Um.

COMMISSIONER HANSON: So, we've issued guidance documents and then kind of what are we -- how do we know that those guidance documents are being implemented effectively, that we're getting the desired performance out of licensees, et cetera --

MS. HOLAHAN: Well, we're monitoring --

COMMISSIONER HANSON: -- and out of the staff?

MS. HOLAHAN: We're monitoring the licensees and inspection program overall and we're doing a self-evaluation.

We just are issuing the guidance now. So, we'll do a self-evaluation in another year to figure out if it's meeting the metric.

COMMISSIONER HANSON: Okay. That's helpful. So, in a year you'll put things in place to monitor the progress on that and in a year we'll get some results on that then.

MS. HOLAHAN: Yes. And we're doing the same thing with the reactor decommissioning business models. We've issued the guidance and we're going to self-evaluate it in a year.

COMMISSIONER HANSON: Okay. Thank you.

My final question will just be on the Nuclear Energy Innovation and Modernization Act, Section 108, report on community advisory boards for decommissioning.

I want to express, first of all, on this subject, my gratitude to the staff for conducting the 11 Category 3 public meetings in really a pretty expedited time frame and getting that report out to the public and to Congress.

And, you know, I appreciate your efforts to promote the meetings in media outlets and, you know, all over the country, in-person and virtual participation.

I do feel that these public meetings help to increase transparency and build public trust and allowed us to hear views from local communities.

And I understand the repot was also well-received in Congress and was considered well-written and very informative. So, thank you all for your efforts on that. And I found that -- I personally found the report informative as well.

But one of the things I'm curious about, you know, given that NRC's, I think, public communications efforts are often one of our strong points particularly for such a technical agency, we really make a great effort to involve the public and communicate well on complicated topics about the efforts, did you identify best practices for NRC in interaction with some of these community advisory boards?

I know the report kind of focused more on activities the advisory boards themselves, how they can be successful, but what can NRC do in our interactions or do better in our interactions with those boards?

MS. HOLAHAN: Thanks for that question.

And we have been invited to citizens advisory boards and make a presentation on how the decommissioning process works.

So -- and we find those very useful as well as holding all those public meetings for the citizens advisory boards' best practices, but we find one of the things we can do is interact with the citizens' advisory boards or other organizations and explain the decommissioning process.

And we either do that in person or virtually.

COMMISSIONER HANSON: Okay. Thank you.

Thank you, Chairman Svinicki.

CHAIRMAN SVINICKI: Well, thank you all again for your presentations. We will take a short break until 10:30. So, we will reconvene

at 10:30.

During the break period if the presenters for the next panel would just confirm that they have silenced their Outlook chime for incoming email, if you know how to do that, that would be helpful.

Thank you and we will reconvene in seven minutes.

(Whereupon, the above-titled matter went off the record at 10:24 a.m. and resumed at 10:33 a.m.)

CHAIRMAN SVINICKI: Okay, welcome back everyone. We've had our break and now we will hear NRC Staff presentations for the Nuclear Materials Users Business Line. And we will begin, again, with Executive Director for Operations, Margie Doane.

MS. DOANE: All right, Chairman, I was making sure I was taking myself off mute. Okay.

So, hello again. We'll now transition to provide our strategic overview of the Nuclear Materials Users Business Line.

The business line is focused on transformation, innovation and risk-informing the national materials program. The business line also continues to increase the use of technology in the materials program through expansion and modernization of the integrated source management portfolio. And has made communicating and coordinating with external stakeholders a key focus area.

The Nuclear Materials Users Business Line continues to risk-inform and transform their processes while ensuring adequate protection of public health and safety. The results, in part, have been demonstrated in the enhanced engagement and robust relationships with the agreement states

and other external stakeholders through routine and transparent interactions.

During the presentations you'll hear about the successes and accomplishments, such as innovations in the medical area related to emerging medical technologies, innovations in rulemaking and the appointment of the National Materials Program co-champion, who are now hosting periodic champion chats.

Next slide please. The presenters for today's panel are, again, John Lubinski. He'll provide an overview of the business line.

Kevin Williams, the Director of the Division of Materials Safety, Security State and Tribal Programs, will provide an update on ongoing transformation and innovative activities in the materials program. And will show a video describing the National Materials Program and the unique partnership between the NRC and the agreement state.

Tim Mossman, Chief of the Source Management and Protection Branch, will discuss the use of technology and data analytics to enhance the materials program processes.

Finally, David Pelton, Director of the Division of Nuclear Material Safety in the region, in Region III, will discuss regional perspective in coordination and communication with external stakeholders.

So this concludes my opening remarks and I'll now turn it over to John.

MR. LUBINSKI: Thank you, Margie. And good morning again, Chairman and Commissioners.

As noted, I'll provide an overview of the Nuclear Materials Users Business Line. And as I did earlier, I'll just refer to this as the business

line.

Next slide please. The business line receives and implements the National Materials Program to enable the safe and secure use of radioactive materials in medical, industrial and academic applications for beneficial civilian uses.

The business line active support the licensing and oversight of users of radioactive materials in a matter that adequately protects public health and safety and promotes the common defense of security.

We establish and maintain effective communications and working relationships between NRC and the agreement states, local governments, other federal agencies and Native American Tribal Governments to promote greater awareness and mutual understanding of policies and activities.

The business line is comprised of 201 full-time equivalent, or FTE, and almost $17 million in contract support and travel. The business line oversees approximately 2,200 specific licensees.

In Fiscal Year 2020 we completed over 1,350 licensing actions. These included review of new license applications, amendments, changes of control and ownership, renewals of licenses and sealed source and device registrations.

We also conducted over 370 inspections of licensed activities. The divisions of nuclear material safety in Regions I, III and IV implement the majority of the materials licensing activities. And they perform all of the materials inspection activities for the NRC.

The business line is also responsible for the agreement

states program. Including, developing policies and procedures, managing the Integrated Materials Performance Evaluation Program, or IMPEP, coordinating and completing compatibility reviews of agreement state regulations and serving as NRC's liaison for communications between NRC agreement states, state and local governments and other federal agencies.

Next slide please. During Fiscal Year 2020 we implemented and completed activities related to transformation and innovation, along with incorporating well manage risk-insights into our materials licensing and oversight programs.

We issued a direct final rule to allow modern, digital, personnel dosimetry for industrial radiography, irradiator and wall logging licensees. These devices can be read onsite, enhancing safety by allowing licensee and personnel to identify doses sooner and make appropriate adjustments to work activities.

The licensees also benefit by allowing workers to return to work sooner. The use of the direct final work process allow the significant change to be implemented sooner.

In March of this year we issued the second major revision to the Inspection Manual Chapter, IMC 2800, to enhance the effectiveness and efficiency of, and to further risk-inform, the materials inspection program.

The revision enhances coordination and communication among the NRC regions, and the agreement states, streamlines documentation for materials inspection, allows flexibility for in-office reviews and enhances reciprocity inspection information.

Next slide please. The Nuclear Materials Program is a

collaborative effort between the NRC and the agreement states. It involves close coordination with the Organization or Agreement States, or OAS, and the Conference of Radiation Control Program Directors, or CRCPD.

You heard from both of these outside organizations at a commission briefing on October 8th.

While NRC regulates about 12 percent of materials licenses in the United States, our implementation to the Nuclear Materials Program means we provide substantial support and periodically review the agreement states, and the actions taken by states, to ensure that the states remain adequate and compatible.

We conduct training courses and workshops, we evaluate licensing and inspection issues, we review states rule changes, we participate in CRCPD activities. And we perform outreach to the states on new and ongoing rulemaking and other regulatory efforts.

Since the last business briefing in April of 2019, Vermont entered into an agreement with the NRC that was effective at the end of 2019. Approximately 33 NRC licenses for byproduct source or special nuclear materials were transferred to the State of Vermont.

NRC held its first periodic meeting with Vermont in July of 2020 to discuss initial program implementation. The first IMPEP review for Vermont is scheduled to take place next March.

As part of our continued transformation process, and our continued partnership with the agreement states, we made a decision to evaluate the Nuclear Materials User Program of the NRC as one consolidated program under IMPEP, rather than individual regions and offices, as we did in

the past. This will treat NRC similar to larger agreement states and should result in program efficiencies.

The first consolidated NRC IMPEP review is scheduled for the summer of 2021.

We also finished updating 13 state agreement procedures. And this was a real team effort with NRC and the agreement states. Nineteen agreement state participants from 11 different agreement states, and 21 NRC personnel from the three region headquarters collaborated on the development and completion of the revised procedures.

There are many more activities that we'll discuss today, including innovation and risk-informing. And with that, I'll turn to Kevin Williams to continue the presentation.

MR. WILLIAMS: Thank you, John. Good morning, Chairman and Commissioners.

I will discuss how we have been incorporating transformation, innovation and risk information into our processes.

Next slide please. We are focused on our people, our behaviors and our mind sets as we transform into a modern risk-informed regulator.

We are partnering with the agreement states to share how the NRC is incorporating risk into our work products. In our continuing efforts to keep licensees focused on the importance of maintaining a healthy safety culture, we provided training to medical licensees at the IAEA consultancy meeting this past January.

Next slide please. An example of transforming our

processes and modernizing our decision-making was a Staff review and approval of Exubrion Therapeutics proposed license application template for the use of Tin-117m metastable to treat osteoarthritis in large dogs.

This was transformative for NMSS in that once approved, future licensees can use a template for approval by NRC and agreement states. This was a first of a kind review of NMSS because the Staff adopted aspects of the specification, taskforce travelers process.

In addition, the Staff carefully balanced the safety and risk to pet's families, as well as the broader public.

Next slide please. In January we submitted to the Commission a rulemaking plan that discussed our reevaluation of Training and Experience, or T&E, in our subsequent recommendations.

We engaged stakeholders, such as the public, ACMUI, OAS, and specialty boards, to ensure we obtain and reflected the bearing views on T&E before recommending less prescriptive and more performance-based criteria for authorized user credentialing.

Under our recommended approach, physicians would need to be certified by an NRC recognized, or an agreement state recognized, medical specialty board to become an authorized user. This transformative approach would better position the Nuclear Materials Program for a projected increase in the use of new and diverse radiopharmaceuticals in medicine.

This is a good place to highlight ACMUI's input to the NRC. The ACMUI advises the NRC on policy and technical issues that arise in regulation of the medical use of radioactive material in diagnosis and therapy. You will hear from ACMUI in their upcoming November 18th Commission

meeting.

With regards to T&E, the ACMUI perform their own evaluations of the NRC's training and experience requirements and made suggestions to the staff regarding the need for a re-look.

We built upon ACMUI's efforts and conducted our own evaluation of our T&E requirements, which prompted this additional engagement with stakeholders. This effort culminated in the paper that is now before the Commission.

Next slide please. To further streamline our processes and increase efficiencies, we are looking at how we license emerging medical technologies under Part 35.

We formed a new standing committee to obtain stakeholder feedback earlier in the process. Guidance will be developed in the streamlined approach. And we developed a rulemaking plan for a broader look at how the 35-1000 process is used.

Another item we are addressing in the medical area is in relation to medical event reporting is extravasations. There is congressional interests, a petition for rulemaking.

And ACMUI performed a re-look of the 1980 NRC medical policy statement. Currently, we do not classify extravasations as medical events and thus do not require them to be reported to the Agency.

However, considering the recent and anticipated advancements in nuclear medicine, the Staff is reevaluating this position. This will provide an opportunity for the Staff to use risk insights in evaluating medical event reporting.

The Staff will complete its evaluation in the spring and will prepare recommendation for the Commission thereafter as appropriate.

Next slide please. Continuing with our discussion of innovation and modernizing decision-making, we are employing strategic thinking in other areas of the material program.

Specifically, as a result of the COVID-19 public health emergency, we developed a temporary instruction to address IMPEP reviews of programs impacted by the public health emergency. This temporary instruction ensures adequate protection of public health and safety and effective oversight by communicating effectively with the agreement states.

Staff developed a risk-informed approach for the IMPEP teams to ensure that radiation control programs are reviewed consistently under IMPEP. And has described specific considerations to be given under each performance indicator.

Next slide please. The NRC and the agreement states continue to focus on developing and strengthening relationships and partnerships across the National Materials Program.

In the following video, you will hear from NRC and agreement state staff as they reflect on the need for flexibility, open communications and partnerships in the implementation of the Nuclear Materials Program. If we could play the video.

(Video played.)

PARTICIPANT: Today, there has been broad acceptance in all levels of the NRC as the importance of the partnership with the agreement states. It wasn't until a joint NRC agreement state working group

was established --

(Video ended.)

CHAIRMAN SVINICKI: While you're hearing silence, for the information of people, at least in the Commission meeting room we cannot see the video, we can hear the audio. So let's pause for one moment, but we may have to move beyond it. I will let you know if we make that decision.

(Video played.)

PARTICIPANT: Today, there has been broad acceptance in all levels of the NRC as the importance of the partnership with the agreement states. It wasn't until a joint NRC agreement state working group was established in 2000 to address the impacts of the increasing number of agreement states that the NMP had an initial framework.

Implementation of this working groups recommendations resulted in process changes and expansion of existing programs. NRC Staff agreed with the Inspector General recommendations and worked with the Organization of Agreement States and their membership to develop a formal framework for the NMP with an emphasis on enhanced communications.

The adoption of SA-10 in May 2019 and the naming of NRC and agreement state champions was the start of a new era for the NMP.

PARTICIPANT: The Nuclear Materials Program is built around five objectives that guide the efforts to achieve its goals and priorities. These objectives address the need for flexibility, open communication, partnership and predictability in the implementation of the NMP.

In the following segments you will hear from NRC and agreement state staff as they reflect on each of the objectives.

PARTICIPANT: Risk-informing our future regulatory efforts will be vital to the success of the Nuclear Materials Program. Everyone, states and NRC alike, are feeling more pressures on budget, staffing and overall resources.

PARTICIPANT: First informing for the state of Minnesota's perspective is about looking at risks and consequences associated with the use of radioactive materials through a public health lens.

When we create regulations or perform regulatory activities, we have to consider how those actions will influence public health and safety and tie into the agency's mission of protecting and maintaining the health of all Minnesotans.

PARTICIPANT: Most of the noteworthy accomplishments that I have been a part of with our co-regulator atmosphere with the NRC has centered around the more complex issues that we've had within our state.

In each case we've been able to reach out to the NRC. Whether it's the NRC region or headquarters, to talk through with them the guidance or the regulation that we're trying to apply.

PARTICIPANT: Agreement states should keep in mind that the NRC does actually consider you in its decision-making process. Conversely, the NRC should recognize that agreement states do not have the same amount of resources, including staffing, compared to the NRC's four regions and headquarters' offices.

PARTICIPANT: As the NMP takes home more emerging technologies and revises existing regulations, the regulatory framework must have a balanced risk-informed posture. Risk-informed cannot be viewed as

less regulation and therefore less public health and safety.

PARTICIPANT: In many cases, novel uses of radioactive material arrive in agreement states before they arrive in NRC jurisdiction. And agreement states develop licensing and inspection experience with these technologies.

PARTICIPANT: Staff is planning to develop regulatory guidance in a risk-informed manner for the release of animals following other veterinary procedures. And we will need the support of the agreement states for this endeavor.

PARTICIPANT: I think there is good communication between the NRC and agreement states. NRC, and the organization of agreement states, regularly send out important information to the agreement states.

There are regular conference calls with the NRC and agreement states. There is the annual OAS meeting with the NRC.

Also, specific questions or concerns can be discussed with the NRC through the regional state and agreement officers.

PARTICIPANT: NMP co-champion partnership has been a good driver for information sharing. One area for improvement is how to match programs facing emerging technical issues with NMP partners who have experience with those same issues.

PARTICIPANT: During the COVID-19 public health emergency there was a tremendous amount of information sharing that record. We can learn from what work and didn't work in that regard to shape the expectations on how we're going to communicate in the future.

PARTICIPANT: Two noteworthy accomplishments that I have been a part of are, when the Commonwealth of Virginia and the State of Vermont became agreement states. I was able to assist these states as they built their radioactive materials programs from the ground up. And today, they are successful partners in the Nation Materials Program.

PARTICIPANT: Conversations have evolved significantly over the past two years as NMP partners continue to refine radiation safety priorities. We have become increasingly open to innovative training and experience approaches.

And in fact, we, including myself, are now championing these ideas.

PARTICIPANT: The most recent was being part of one of the working groups updating the SA procedures for IMPEP. The members of this working group are fully engaged. We have thoughtful discussions that lead to, I believe, a product that was meaningful for both the NRC and the agreement states.

PARTICIPANT: I think to continue the growth of this partnership there first needs to be universal acceptance of the idea that we are in fact partners. We need to hear one another and actually listen to each other's ideas or concerns and offer the support like we would hope to receive it.

Though we strive for consistency and compatibility, realize that we are 40 different regulators, and it is okay to have differences of opinion or methods from time-to-time.

PARTICIPANT: In 1959 Congress recognized state's

interest in regulating the peaceful uses of byproduct, source and special nuclear material and acknowledged that as the states improved their capabilities to regulate effectively such materials. Additional state responsibilities may be desirable.

Over the years, Congress expanded agreement state responsibilities through the passage of legislation, like UMTRCA and the Energy Policy Act of 2005.

The NRC and agreement states have continued to use and strengthen their synergistic partnership to meet the regulatory challenges of the 21st century and to stay true to our core mission for the protection of public health and safety.

After more than 60 years, the NMP framework remains unique and evolving with the NRC agreement states well position to meet any challenges collectively.

(Video ended.)

MR. WILLIAMS: This is Kevin Williams. I don't know if you got to the video, it got stuck or locked up, but we couldn't see the rest of it and we do apologize for that.

CHAIRMAN SVINICKI: Kevin, we were able to see it. Thank you.

MR. WILLIAMS: Oh, great. Wonderful. So, this concludes my remarks and now I will turn it over to Tim Mossman.

MR. MOSSMAN: Thank you, Kevin. Good morning, Chairman and Commissioners.

I will be presenting how we will be using technology to

enhance our workflow management and our use of data.

Next slide please. The business line has long made use of technology to facilitate our work. And we continue to push to keep our tools consistent with modern standards.

The systems that comprise the Integrated Source Management Portfolio, or ISMP, are at the core of how we use modern technology to better enable us to perform our mission effectively and efficiently.

In September, we successfully awarded the follow-on contract for ISMP support services. We regularly use the data from ISMP to collaborate with internal and external stakeholders to ensure consistency with respect to materials, safety and security.

The National Source Tracking System, or NSTS data, is shared with the HOOs and regional offices for situational awareness, exercises and emergency situations, such as response to natural events. The data is also shared with the FBI, Department of Energy, Department of Homeland Security and Customs and Border Patrol for their situational awareness.

Availability of these systems has been essential to us being able to conduct our work remotely in 2020 during the COVID-19 public health emergency.

During the June NMU champions chat, the representative from the State of Tennessee indicated that they had transitioned to using NRC's Web-based Licensing, or WBL system, in November of 2019. Using WBL meant they had access to all of their licensing and process information

during COVID, such that they were function "business as usual."

The aforementioned National Source Tracking System, NSTS, is the United States source registry that tracks Category 1 and Category 2 byproduct material sources. The system currently tracks over 75,000 sources and handles as many as 10,000 transactions per month.

The WBL system is an application that manages all aspects of nuclear material licensing in the United States. WBL allows Regulatory Staff to manage the licensing lifecycle from initial application through license termination. The WBL system also permits other related functions, such as inspection planning and tracking.

The License Verification System, or LVS, brokers information from WBL and NSTS and provides a way for licensees nationwide to confirm a license is valid and that the licensee is authorized to acquire the radioactive materials being requested before those materials are sent to preclude material landing in the hands of individuals who are not authorized to possess it.

The portfolio enrolment module enables staff to credential users and manage access to the ISMP systems.

Next slide please. We have over 2,000 users for the various ISMP systems. Roughly a quarter of the users are NRC employees, and another 15 percent belong to agreement state regulatory staff.

Over half our users are from our licensee community. Most of these are materials licensees.

A handful of our users' hail from our federal partners, such as the Department of Homeland Security and Customs and Border Patrol.

We have made the web-based licensing system available to agreement states, and we continue to reach out to agreement states to facilitate its further adoption. To date, seven agreement states fully use WBL. And we have six more in the process of transitioning to use the system.

Next slide please. MSST and regional staff use this suite of systems for a variety of licensing and inspection tasks. We have been, and continue, to evolve the system to streamline our work.

We are currently integrating WBL with ADAMS and will be developing online application capability where licensees cannot only submit licensing material, via a Turbo Tax like interface, but also track the status of their applications.

In late 2019 we released a significant upgrade to our inspection support capability. The following video depicts features now available to inspectors who are now closer to being able to work entirely remotely.

I will turn it over to --

(Video played.)

PARTICIPANT: The integrated source management portfolio is now, more than ever, transforming and modernizing the way regulators, as well as licensees, conduct day-to-day operations in an efficient, secure and safe manner.

We continue to modernize applications because of the importance to be able to do work wherever and whenever while ensuring that the use of radioactive materials can be conducted safely and securely. Specifically, with regard to the web-based licensing system, or WBL, we are

streamlining our workload.

For inspections, WBL supports the inspector from the planning phase through inspection completion. The new inspection trip planning feature uses GPS data for licensee inspectable sites and Google Maps to enable inspectors to visit licensees within a geographic area on the same trip optimizing their time in the field.

To allow inspectors to work as remotely as possible, they can now access inspection forms and complete an inspection report in the field from a mobile device.

Work is underway to integrate agency systems, such a ADAMS, into WBL. Agency staff will have the ability to digitally sign documents, profile, and submit final documents to ADAMS and retrieve these documents all from within WBL.

Modernization efforts are not exclusive to the benefit of the NRC and the growing number of agreement state regulators using the system. But also for the licensee community. In Fiscal Year 2021 licensees will be able to submit applications online and track the review status via WBL.

(Video ended.)

MR. MOSSMAN: Thank you. Next slide please. The ISMP systems already have a wealth of licensing and inspection data related to byproduct material sources in the U.S.

A planned system upgrade to add a non-casework tracking capability will capture much of our operating data not directly associated with licensing the inspection. Although we are relatively early in our efforts to develop dashboards for data analytics, we have been collaborating with other

NRC offices, learning from their experiences.

We are currently exporting a portion of our ISMP data to the OCIO data warehouse to build proof of concept dashboards that are automatically refreshed using the data warehouse as its source of data.

As we expand our dashboard development, the ISMP information that is sent to the data warehouse will be modified and increased accordingly. Two of our early dashboard efforts are depicted on this slide.

The first is a workload tracking tool developed by Celimar Valentin that we use in MSST to keep up with significant actions within the division.

The second is a materials license tracker, built by Adelaide Giantelli, based upon a need expressed by our regional counterparts to have an easier way to identify licensees with expiring licensees.

This concludes my remarks and I will now turn it over to David Pelton. Thank you.

CHAIRMAN SVINICKI: Dave, we're not hearing you, are you muted?

MR. PELTON: Yes, Chairman, I'm still struggling to unmute in a timely way, so thank you for that prompt.

(Laughter.)

MR. PELTON: Modern and risk-informed indeed. So thank you for your patience.

Thank you, Tim, again. And good morning, Chairman and Commissioners. Today I'm pleased to be talking with you about the role of regional staff in our stakeholder outreach and coordination efforts across the

Nuclear Materials Users Business Line.

Next slide please. In terms of our regional coordination and communication with the National Materials Program, I'd first like to discuss agreement and non-agreement state engagement.

The Regional State Agreements Officers, or RSAOs, play a critical role with supporting the NRC and OAS champions with establishing and maintaining effective co-regulator relationships between the NRC and agreement states.

They also provide an important conduit for the opened exchange of information between the NRC and agreement state programs, including follow-up discussions stemming from states response to material events.

The RSAOs often partner with their Regional State Liaison Officer, or RSLO counterparts, to provide a unified approach to communicating with both agreement and non-agreement states. They often leverage joint government-to-government meetings where they provide perspectives and insights into the NRC's oversight of nuclear materials and operating reactors.

They also partner effectively to engage with non-agreement officials, again, in response to materials events.

We also actively nurture our relationships with the states by having regional staff engage in joint NRC and OAS collaborations, to build relationships with their agreement state peers, share a collective experience and best practices. And to jointly consider risk smart alternatives to existing oversight and communication practices.

For example, we are modernizing, and risk-informing inspection manual Chapter 2800 and the associated inspection procedures led by our working group that includes NRC regional inspection staff and agreement state inspection staff.

The third phase of this revision is currently underway. Where we are adding risk-informed insights to materials inspection program, incorporating strategies to address low safety significant issues and are evaluating possible adjustments to inspection scopes and frequencies for several types of materials licensees.

So as far as our coordination with the regulated community, our staff gave valuable insights through feedback from licensee staff and management during our routine licensing and inspection interactions. We're looking into ways to capture this feedback more efficiently and share them with other regional and headquarter staff.

Finally, I just want to mention that we've had a lot of recent success in revising the materials license exemption process to include more modern technics to rapidly process COVID related license exemptions, such as leveraging IT and applying risk insights during the review. We held virtual meetings to seek licensee and other stakeholder feedback as we revise this process.

Our stakeholder engagement and innovative processes support the timely issuance of exemptions that preserve safety and security while minimizing unnecessary regulatory burden during the pandemic.

Next slide please. When we work with other federal agencies and international organizations, we often develop mutually

beneficially regulatory relationships, we gain unique insights into other regulatory approaches and take the opportunity to share best practices. I'll mention just a few examples of each.

Regional staff coordinated with federal agencies and congressional staff as they conduct the oversight in coordination of the Veteran's Affairs Air Force and Navy Master Materials Licenses, or MMLs, ensuring the effectiveness of a program that provides the NRC with a broad licensing inspection footprint using fewer resources while providing MMLs with NRC developed inspection and licensing procedures, guidance and training.

Our staff also coordinated with congressional staff and provided several briefings with the support of the Office of Congressional Affairs on inspection follow-up of materials events, answering questions and highlighting the important safety and security role played by the inspectors.

Such events included a low-level waste railcar fire in the State of Illinois, flooding in the State of Michigan that affected multiple materials licensees, and an explosion in a hot cell at Curium Pharma in Indiana.

Regional staff also worked with the OIP, Office of International Programs that is, and successfully engaged with international partners, or stakeholders, on a variety of materials related topics that include a presentation through the Department of Energy. And NNSA, and a large international audience on the recruitment and training of reactor and materials inspectors.

And our staff supported the Ibero-American Forum of Radiological and Nuclear Regulatory Agencies, or FORO, in cooperation with

IAEA, by developing and presenting Spanish versions of NRC's licensing and inspection requirements for radiopharmacies.

This concludes my part of the presentation and I'll turn the meeting back over to Margie.

MS. DOANE: Okay, thanks, Dave. This concludes the Staff's remarks. And we'll now turn it over to the Commission.

I usually take this opportunity to thank all of the Staff. I see we're running a few minutes over. We are very thankful for everyone who has helped to put these presentations together, of course. And the entire programs that aren't represented at the table.

CHAIRMAN SVINICKI: Thank you, Margie. Again, I'll begin the round of questions from Members of the Commission.

I appreciated the update on the National Materials Program. And it's clear that it's continuing to evolve as a collaborative effort between NRC and the agreement states.

Of course, under the current public health emergency, which has been going on for some time, and looks like it will span into the future, we know that our agreement state partners are under unique challenges and stresses, as are a lot of public health officials across the country to deal with all that's going on.

And many of the agreement state partner agencies have responsibilities under the state structure that are different. And they have other parts of the public health emergency that they're dealing with.

The Commission did have an opportunity to hear from the Organization of Agreement States on this topic. And others recently.

But how would the NRC Staff describe any of the unique stressors that might be on our agreement state partners due to just enhanced demands on them due to the COVID-19 public health emergency?

MR. WILLIAMS: This is Kevin. I can address that.

I would say, we've had a significant amount, level of engagement with the agreement states. And where we have focused is, just as the demands of the NRC on our inspection activities, we recognize they have the same thing.

So what we have done is we have shared all of the guidance that we put out. Whether that was exemption guidance or inspection guidance, our inspection recovery plans.

And we've stayed in locked stepp with them in terms of some of the challenges that they've had in terms of their budgets. But through it all, they have maintained the posture that we will do what needs to be done to protect the public health and safety.

So while they maybe have been impacted with not the inability to travel, and they've had some restrictions on going to their offices, they would offer that they've maintained their programs, just as similarly as the NRC has maintained its program.

CHAIRMAN SVINICKI: Thanks for that, Kevin. And that's in general what I was wanting to hear someone on the Panel address.

And I know also that states have had some restriction in entering various medical settings because of the very limited allowance of letting non-medical personnel or patients into a lot of medical facilities. So they've had that complication for carrying out some inspection programs.

I appreciate that we continue to collaborate and share our experiences as regulators. Again, there are a diminishing number of NRC direct licensees, but we do still have a relatively significant number.

And on that point of maybe challenges in budget and resources, I appreciate very much the video on web-based licensing. I have quite a long history spanning to the early days of the rollout of components of the national source tracking system and web-based licensing for NRC.

And in that time of over ten years, of course, information, technology modernizes very, very quickly. And a sensitivity there, of course, is although we have states that have adopted web-based licensing others are transitioning.

We can't fundamentally impose it as a, or mandate it as a system, that would be an unfunded mandate on the state agencies. That being said, as the video makes clear, web-based licensing offers a lot of capability.

And I'm sure that a number of state regulators, agreement state regulators, probably desire to be able to adopt it.

Have we worked at all to make it less resource intensive?

I know some states ten years ago were almost entirely, I mean, this respectfully in kind of paper systems. I'm assuming that they've come along, but let me say, there were a lot of legacy to systems in the agreement states for tracking these types of materials.

So, is there anything that we can do as NRC, with the resources that we have at the federal level, to maybe make it more approachable from a resource standpoint for states, agreement states, to

adopt web-based licensing?

MR. MOSSMAN: I can answer that. Yes, it has actually been a point of emphasis of ours in the last couple of years to try to make the system more available to agreement states, as we recognized.

There's been a lot of investment by the NRC in this system. It offers a lot of value for agreement states.

That we offer the system free of charge. It's something that I think they would be hard pressed to afford, just even the operation and maintenance, which we take care of for them. Given that it's now a web-based, cloud-based system, there is no hardware required on their part to adopt the system.

We've been trying to reach out. We recently got some really good help from our RSAOs to identify additional agreement states that are interested.

We've had a couple that we've been working with a little while. Occasionally they will get stuck in process given workloads on their end. We've been trying to reach out, again, over the last year or so to help them as much as we can.

There is a little more work on their part that's required to get the data in the system, but we're trying to minimize what it takes to get them up and running. And of course, we can't impose it, it's just something we offer.

CHAIRMAN SVINICKI: I think those are really promising measures, Tim, and I appreciate you going over some of those.

Again, we can't, for the pure transition costs, that's

something we can't really insert ourselves into. But I think that the measures we described are very meaningful.

And hopefully, as we move into the future, given the capacity that is offered by web-based licensing, we would see more states finding value in adoption of it. Even if it does require resource investment on their part.

And then, Tim, maybe sticking with you. Appreciate that you had use of data analytics as a growing emphasis. And movement of data sets into the OCIO data warehouse.

As you look across programs though, beyond NMSS, do you see opportunity space around moving towards cross-agency development of dashboards and other tools that would help us maybe in budgeting and resourcing and other things that extend beyond the reactor safety program or the materials safety program?

MR. MOSSMAN: Yes. I think we've looked at kind of dashboards from two different directions. There are definitely kind of strategic level dashboards that I think would probably have broad application across the agency that take a broad picture of resource utilization. And those kind of big picture snapshots of how we're doing work.

And then I think some of our early efforts within the NMU business line are more tailored, kind of operational dashboards, aimed at very specific needs of the business line.

So, we definitely are keeping tabs with what our colleagues and NRR and OCIO are up to. Trying to learn from them. Trying to make the best use of resources we can.

And I know John and Rob, when we've talked to them about this, they are very focused on what we do in this area. Being an office level approach not just even unique to our business line, trying to make best use of our resources.

CHAIRMAN SVINICKI: Thanks for that, Tim. And I ask it, I guess, a bit selfishly because at a level like member of the Commission or the EDO or ADEDO, our ability to look across the agency's processes and resourcing is something that has a direct benefit to informing our decision-making.

And I know it needs to start at business line, product line, office level, but hopefully at some point we'll be kind of rolling these up.

And I don't want to say that in any way that discourages smaller workgroups from developing data analytic tools that really serve their needs at a very granular level. So I think we can do both. And I think we can succeed at both, so thank you for that.

And, Kevin, I might pivot to you just quickly. You addressed a slide of modernizing the IMPEP strategy.

And I know that something that has been worked on by NRC Staff, I think with involvement of agreement states, is a fundamentally pivoted approach to the IMPEP reviews of the NRC's own programs in the regions and otherwise. And I think we sometimes forget that we're not just, states are not the only ones who undergo an IMPEP review.

NRCs work in this area with our licensees. Gets equivalent to kind of peer review through the IMPEP process.

What can you say about that change that is, that changed

approach to NRC's IMPEP review that we're thinking about or maybe we've implemented it?

MR. WILLIAMS: So, yes. Back in December of 2019 we, DEDO at the time, Steve West, agreed that we would treat the NRC as one IMPEP.

And the genesis behind that was, we looked at how we, if you take the State of New York, they have several different programs, several different factions out there, and we treat them as one. So the impact on one has the same impact on the other.

And we did an independent self-assessment and we said, hey, you know what, maybe we should look at how we look at the NRC as a program, as a whole. We're all doing the same thing, our processes are similar. We should be able to take advantage of some efficiencies.

There is ability to do some work that's from headquarters, but there is a better opportunity to align with the agreement states and treat the program more as a, you know, we talk about the co-regulator aspect of it but we're, we drove for consistency across the program. And I think we will achieve that as we do the NRC as one.

CHAIRMAN SVINICKI: Thanks, Kevin. And next we will turn to Commissioner Baran.

COMMISSIONER BARAN: Thanks. This has obviously been a very challenging year with the pandemic.

The toughest balance for NRC to strike has been on inspections. For the few months of the pandemic NRC was conducting very few in-person safety and security inspections.

I note that on the reactor side the Staff has focused on getting back to in-person safety inspections. The Staff set a goal of meeting the minimum samples for the reactor oversight process based on inspections this year. And it looks like we're mostly on track to meet that important goal.

Dave, how is it going on the materials side, are we able to get most of the plant inspections done, and if not, what challenges are you seeing?

MR. PELTON: Thank you for that question, Commissioner. Yes, the regions are managing the conduct of inspections very well.

Let me first say that, when we think about the conduct of inspections, given the COVID circumstances, our first focus is on the safety of our staff. And then of course we look at the continuity of an effective oversight of the nuclear material users.

So with that in mind we've been able to really coordinate well across the regions and with headquarters. We've applied some risk smart and COVID consequence approaches to planning our inspections, to preserve staff safety and to manage and to plan for our inspections.

And for any inspections that perhaps needed to be delayed or deferred because of COVID conditions, we have effectively tracked those and partnershipped with headquarters to make sure that we document the challenges or delays or deferrals, and that we have a plan for completing those in the future as conditions allow.

Kevin, maybe some program level perspectives?

MR. WILLIAMS: Sure. So, we looked at the inspections.

We developed a strategy. There is some things that we could do remotely. Things that we could do with remote onsite follow-up. Or onsite itself.

And we looked at the health of the program, we looked at engaging our licensees to make sure that we had reasonable assurance of adequate protection to public health and safety. And we focused on our long-term efforts to address any challenges.

You know, we looked across the regions, we partnered with the regions, we partnered with the agreement states. And we developed some good strategies to look at this from a long-term approach. And that has worked well for us.

And we're continuing to move forward in looking at the health of the program. And I think we've been extremely successful in this effort.

MR. PELTON: Yes. And, Commissioner, I'll just add. I think what part of your question was, onsite inspection versus perhaps virtual.

Our Staff have made, I think tremendous strides with the leveraging of virtual tools to be able to conduct our, the appropriate portions of our inspections. Trust that we still believe that an onsite presence, when appropriate, is an important element of what we do. Both from completing the program perspective and a public confidence perspective.

But we now recognize that there are elements of inspections that can be efficiently conducted virtually, sharing of documents, using video and other means, in partnership with our onsite portions to satisfy all of our inspection requirements.

COMMISSIONER BARAN: Great. Well, thanks.

MR. LUBINSKI: Commissioner, if I can just add one last comment in response to your question. And I appreciate Dave and Kevin's response.

One thing. The Nuclear Materials Oversight Program is a bit different than the Reactor Oversight Program as far as time frames for when inspections are completed.

But from a current status standpoint, during FY 2020 there were some overdue inspections that were performed late, that have been completed. There are a few more that are currently late, but we do have plans in place to complete those by the end of the year. And we have made telephone contact with those licensees.

The goal was not necessarily to have it done by the end of the year because, again, the way the program is setup. We're looking at each class of licensees and making our determination.

So, we'll continue to do that as we move forward. And the goal is to try to get back on track where we have no late inspections.

COMMISSIONER BARAN: Great. Well, thank you for the update, that sounds encouraging.

Dave, you mentioned that the Staff is working on Phase 3 of the effort to update and risk-inform the materials inspection procedures. What is the working group contemplating in terms of changes in inspection scope and inspection frequency?

MR. PELTON: Yes, thank you, Commissioner. I'll just be frank. It's a little early in the process to have, paint the vision for you of any changes.

Certainly, I'll just offer, we are blessed with a strong team on the working group who is made up of regional inspectors, headquarter staff, and agreement state staff, so that we can hear best practices and past challenges.

And also, they help us strike a really appropriate balance between being efficient and our safety and security mission. But the, frankly, the project, at least at this point, we have not made specific recommendations.

A matter of fact, currently we are developing an initial model of an inspection procedure that we believe would represent a risk-informed modern procedure. And then we will seek a broad range of stakeholder feedback on that procedure.

That will help us build a framework to shape the remainder of procedure changes as we go forward.

COMMISSIONER BARAN: Okay. Well, I look forward to following that process as it moves along.

I also want to ask about the staff's ongoing evaluation of whether extravasation should be reported as medical events. Kevin, you mentioned this topic.

How is the NRC team going to go about determining whether extravasations are preventable and whether the dose consequences of extravasations are significant?

MR. WILLIAMS: Yes, thank you. There has been a significant amount of interest in this area.

Back in 2019 we worked with ACMUI to look at the 1980 policy statement. And took a re-look at that in terms of how, should

extravasations been reported.

So, coming out of that the Staff said, hey, we're going to do another evaluation of that. And what we're going to focus on is, are extravasations preventable using technology.

And we also focused on, is it a practice of medicine or is a regulatory area that we want to focus on. And then we need to look at and appreciate the dose consequences.

Are the doses high enough that would warrant a, some change to the policy or a re-look to take some additional regulatory action.

And in that regard we have looked at, we've initially conducted some reviews of how you would approach this from a diagnosis perspective where there is a little bit of use of radioactive material to then that of therapeutic. And analyzing the potential for where the doses could be higher.

So, we're initially starting this evaluation. We've engaged in a number of public meetings with stakeholders. And we have a subsequent meeting in December to engage the medical community on this as well.

COMMISSIONER BARAN: Does the Staff have sufficient in-house expertise to make these determinations or are there objective medical experts, perhaps at other agencies, with whom the Staff can consult?

MR. WILLIAMS: So, I would offer that we do have a medical expertise. We have a number of people that have advance degrees.

And all of the congressional briefings that we've had to date, you know, it has been NRC Staff addressing this issue of extravasations. We

can do the historical research.

We do benefit from people such as ACMUI. But those inputs are just to inform our process. We do have a significant number of people that understand what an extravasation is and are well suited to make this determination.

COMMISSIONER BARAN: Well, thanks, I appreciate that. I think that's good.

I mean, ACMUI is a great resource of course. Most of its members are licensees though and so they naturally bring a certain perspective to the question of whether NRC and agreement states should require licensees to report something they aren't currently reporting.

The NRC Staff needs to be able to reach independent, technically supported judgements. And I would encourage that you think we, we have the expertise to do that. So thank you. That's all I had, Chairman.

CHAIRMAN SVINICKI: Thank you, Commissioner Baran. Next we turn to Commissioner Caputo.

COMMISSIONER CAPUTO: Good morning. I would like to start off with David.

I have a few questions about the regional staff partnering with the FBI to look at concerns over whether a member of the public might possess nuclear materials without a license.

The assessment found no regulatory or safety concerns existed, but could you just describe this activity on a little more detail?

MR. PELTON: Yes, Commissioner. It was a bit of an interesting one. And we used a cross-organizational approach to look at this.

An individual had actually, and I'll try to be brief, an individual had actually filed a patent for a process for processing of uranium that they had successfully submitted. They wanted to make changes to the control of the information from a safety, from a security perspective.

When they weren't satisfied with the response from the U.S. Patent Office they engaged with the State of Illinois, and with the Region III Office, to try to seek a remedy to provide additional controls. But in doing so, they made statements that led us to believe that perhaps they already were in possession of some available yellow cake or other form of uranium.

We partnered with our Office of Investigation, and with the State of Illinois, frankly, to seek to understand better what they actually had in possession and what they're intentions were with both comments made and the need for a change in the security of the language in their patent. And that's really what we went after.

So, in consultation with headquarter staff, State of Illinois and the FBI, we actually reached out to the individual, discussed the matter with them. Were able to talk through NRC regulatory possible concerns, FBI possible concerns and to ultimately conclude that there was no public or environment impact.

So, in a nutshell, that's essentially what happened. And that was the outcome.

COMMISSIONER CAPUTO: Wonderful. It sounds like a very effective partnership.

MR. PELTON: Thank you.

COMMISSIONER CAPUTO: So, I appreciate your focus

on that.

I also have a question for Kevin on Exubrion. I really do think the way the staff approached this is a good start in modernizing decision making. It sounds like a very transformational effort.

Can you just tell me how long did this initial review take and how long do you anticipate future reviews taking given that you are following the task force travelers process?

MR. WILLIAMS: Sure. This was a rather novel opportunity and approach for the NRC, but it was an opportunity for us to, for NMSS within itself, you know, to be open and receptive to new ideas, to new ways of doing things, and seeing, you know, could we learn from, you know, NRR, could we learn from advanced reactors, and could we take those same approaches and apply them here.

And so I would say about a year ago, you know, Exubrion had approached us in regards to looking at this effort and as a result of that effort we have spent some time in numerous public meetings in terms of scoping out what, you know, how this would be a good approach to do it with a clear focus on, you know, some of the aspects of be risk smart, identifying what the risk was, appropriately managing that risk, and then walking through with Exubrion to get to, you know, what we thought would be protective of public health and safety and also would share as a template and a model to build on to the future such that we wouldn't have to spend a year to do conduct a review.

I will tell you we did the lay work up front and, you know, we may have had some growing pains in that regard, but I think we are in a

position where we have developed clear expectations, clear license commitments, and information to license reviewers such that this could be done in a, and I don't have a, you know, I couldn't say like three months or six months, but it certainly would be done in less than a year.

I am being a little forward-leaning, but I think the process itself will dictate now that we can do these things, you know, we can do this in a smarter stepwise fashion.

COMMISSIONER CAPUTO: And do you think this is a model for future therapeutics to follow?

MR. WILLIAMS: I think it is. I mean because what we did is we took the, you know, we took a vendor's process, and it wasn't a licensing process, and we were able to apply similar type of activities that we have done in other, you know, entities or other offices and it's something that we can build upon.

I think it really showed that, you know,

when we take the time to focus on the right stuff, get the right people onboard, that we can get these things done in a very timely fashion.

I think as we continue to move forward we are learning how to do things, you know, differently and we are getting feedback, you know, from the vendors and from the stakeholders on how these processes work.

But the ultimate goal is to make sure that we do maintain public health and safety as we are moving through these type of evolutions.

COMMISSIONER CAPUTO: Wonderful. Thank you. Timothy, I would just like to associate myself with the Chairman's remarks. I really appreciate how the office is embracing data analytics.

It's a huge step forward toward data-driven decision making whether it's in our regulatory work or managing just the operations of the agency itself, so I do really appreciate that step forward. Thank you for that.

MR. MOSSMAN: Thank you.

COMMISSIONER CAPUTO: I have one last question for Kevin. I did notice on one of the slides it says NMSS issued 13 state agreements dealing primarily with the review of common performance indicators in the agreement state program.

When I look at the NMSS website there are 40 other such procedures. So we've got 50 years of experience in this area and with transformation in mind is it possible for the staff to streamline or transform some of these procedures into a more straightforward and accessible process?

MR. WILLIAMS: So one of the things that we were doing initially is, you know, with the implementation of Management Directive 5.6 we turn our initial focus of what do we need to do now, how do we need to communicate effectively to maintain the health of the program, and so we focused our efforts there.

There is a recognition that, you know, as a learning organization we can always go back and look and see as we are trying to streamline our processes where there is some redundancy in the processes, where we need to effectively engage our stakeholders to get a good feel on as we are trying to better and position the National Materials Program how can we streamline our processes.

So we are engaging at all levels across the National

Materials Program to look at our messages, to streamline our processes, and to make sure that we are focused on the right activities at the right time.

COMMISSIONER CAPUTO: So does that mean you have actually reviewed the 40 and looked to see whether they are all still relevant or maybe some of them are overtaken by events?

MR. WILLIAMS: So I think our initial focus was on the 13. We will now, you know, start turning our focus on to the other procedures to see where we can improve our processes.

COMMISSIONER CAPUTO: Wonderful. Thank you. That's all I have.

CHAIRMAN SVINICKI: Thank you, Commissioner Caputo. Next we turn to Commissioner Wright.

COMMISSIONER WRIGHT: Thank you, Chair. I want to just chime in here and again say how much I appreciate all of you and your presentations today.

A lot has happened since our last meeting in April of 2019 and that's when we really just started talking about the National Materials Program, so I really appreciate the way that you have reached out again and tried to keep us updated and informed.

Last month we heard from the OAS and also from the CRCPD and how the enhancements to the program helped them and the NRC coordinate and navigate our responses to and during the pandemic.

OAS and CRCPD spoke highly of our communication efforts, which I think has been something that we have really strived to improve over the last couple of years.

So I wanted to thank you again for that because that's been important and I think that they acknowledged that they feel more like a co-regulator today than maybe they did before, so I really appreciate again how you all followed through on that.

Kevin, thank you for your presentation and it's always nice to hear how we're going and putting, hear how specific things are happening in the transformation process and to that end I want to follow up on Commissioner Caputo's question about Exubrion.

So I know that this is a new process but I am really interested maybe in you giving me a little bit more background on how you decided on this model and that how you had to adapt if you had to adapt it at all.

MR. WILLIAMS: Sure. So when we looked at Exubrion we recognized that they are not a licensee and we looked across the organization and we've seen where we have been successful, you know, taking the new and novel approaches to our work.

And so with Exubrion we looked at, one, we identified what's the risk, and what the risk was was focusing on solely relying on instructions as a means of meeting the guidance and if we are going to do that what type of activities can we put in place that will give us a level of assurance and where have we done that.

So if you look at it, and it's not one-for-one, but if you look at how we use ITAAC as a means to establishing a level of comfort, we came up with licensing commitments.

And so when you look across the process itself here is

things that we can do for the NRC staff to give them a level of appreciation to that when they review this there is clear goals, a clear focus on meeting the safety mission, and then when you look at Exubrion is there a clear path forward at the end.

In looking at these processes this was a natural fit in terms of it because we would have placeholders on there that would at the end of it would give us, you know, we would still have reasonable assurance of adequate protection if we put certain measures in place, such as, you know, requiring the veterinarian to follow up a week after treatment, pre-stream screening criteria.

So a lot of this was consistent with our programs and approaches to maintaining a level of safety and security, you know, in the process while using new ways of doing something.

COMMISSIONER WRIGHT: Thank you. I am going to stay with you with one more question. So last month, you know -- Let's talk about the temporary instruction that you brought up and talked about.

Can you provide maybe a little bit more detail on the types of issues that will be evaluated using this temporary instruction, and I guess to build on that, you know, have similar issues been identified in IMPEP's already performed to date during this public health emergency?

MR. WILLIAMS: Yes. So early on, you know, when the NRC was looking at its process, you know, we were trying to get the help of the state inspection programs as well as the help of our programs.

And we quickly recognized that there may be some things that when we look at it from a safety perspective, you know, and looking at

what can we do to, you know, some licensees want some sort of regulatory relief.

We looked at it in terms of an exemption perspective while maintaining safety. And so we looked at things such as, you know, leak tests or annual reviews, you know that status or status of where licensees were, were they open, were they closed, and we looked at three different areas.

We focused on the medical area, we focused on licensing, we focused on, you know, Part 37 type activities, and where would we still have a level of assurance and reasonable assurance that these activities could be performed.

We shared all that information with the states because they are looking at the same type of activities that we are looking at and what types of things should we do.

Early on in the process we informed the states, hey, you need to document what you are doing. We looked at it from a 5-year perspective. You know, some licensees or agreement states will not be impacted, it could be after to five years, so how could we document that thinking.

And so we developed this temporary instruction and we engaged the agreement states, we worked with them to say, okay, what types of activity should we be focusing on and what type of activities will maintain reasonable assurance of adequate protection.

So when we developed that TI, you know, that was what we were thinking. We just recently used that TI in the Virginia IMPEP and the --

(Audio interference.)

CHAIRMAN SVINICKI: Oh. Kevin, we have lost your audio.

COMMISSIONER WRIGHT: He doesn't hear us. Kevin, we lost your audio. He must be on -- I'll just go to one more question to --

CHAIRMAN SVINICKI: Yes, if you would, Commissioner Wright.

COMMISSIONER WRIGHT: Yes, while we are getting him back up. Tim, I am going to come over to you. Can you hear me?

OPERATOR: Welcome to the audio conferencing center. Please enter a conference ID followed by pound. If you are the meeting organizer press star now. You are now joining the meeting.

CHAIRMAN SVINICKI: Kevin, do we have you back?

OPERATOR: Please wait for the -- You are now joining the meeting.

COMMISSIONER WRIGHT: There's the music.

CHAIRMAN SVINICKI: Okay, Kevin.

MR. WILLIAMS: Everybody is telling me they lost -- Yes?

CHAIRMAN SVINICKI: Okay. So we lost you I think three-quarters of the way through your response to the last question. I know it's probably hard to remember exactly where you were.

I don't know, Commissioner Wright, do you want to refresh or another question, what would you like to do?

COMMISSIONER WRIGHT: I'll probably just go to another question. He answered most of it as he was going through, at least he got the high points in.

Tim, I was going to come to you to just follow along with Commissioner Caputo's comments. I really as well appreciate the use of data analytics and how you are using that and adopting technologies within the program.

I am interested in how these products can be used in the staff's day-to-day work. So you demonstrated how an inspector could use WBL and I do share the Chairman's concern about resources at the state level because this really is something the states would be able to benefit from, so if we could find a way to plug more of them in all the better.

So you did demonstrate how an inspector could use WBL. Could you walk me through how the NRC or how an NRC staff member doing a licensing review could use it to simplify the review process and how it differs from what they would have done a few years ago?

MR. MOSSMAN: So, good question. So we are building now and hopefully in Fiscal Year 21 we'll roll out an online application submission so licensees can submit all their material online and that will be able to come straight to us.

We will be able to route that to the staff member who will be able to access all those files straight through WBL. With our integration with ADAMS you won't have to go to multiple systems to get your documents, you'll be able to get all your documents through WBL.

You know, our goal is to be able to, you know, track and keep tabs on the entire licensing activity through WBL and then the license gets generated and issued from WBL.

We have a wide variety of templates in WBL and form letters

that will auto populate depending on what the user selects and just we're continuing enhancing the system to kind of cut down on the manual repetitive work that a license reviewer needs to do and just keep all the flow within web-based licensing for them.

COMMISSIONER WRIGHT: Thank you so much.

MR. MOSSMAN: I hope that helps.

COMMISSIONER WRIGHT: Mm-hmm. Appreciate it.

MS. DOANE: Commissioner, I would also add -- This is Margie. I would also add that it has been very useful in situations for security purposes where there is a lost source.

The information in the web-based licensing database is very specific. You can tell, you know, where it was manufactured, what kind of source it is, and a lot of other information.

It has also been very helpful with respect to export and import licensing if there is ever an issue, so it is also used in our oversight not just by the inspectors but at Headquarters when we are trying to understand the scope of the impact of a lost source or the security issues associated with a lost source, or safety, too.

COMMISSIONER WRIGHT: Thank you for that, Margie.

CHAIRMAN SVINICKI: Okay. Thank you very much, Commissioner Wright. Next we will turn to Commissioner Hanson.

COMMISSIONER HANSON: Thank you, Chairman Svinicki. Thank you all for being here this morning. As earlier, this is very helpful.

I want to start off with a couple of questions about training

and experience requirements or administration of radiopharmaceuticals.

In the SECY paper that the staff sent up on this subject the staff indicated that if their recommended approach is approved, they would evaluate the board recognition criteria and determine if less prescriptive criteria could provide equivalent radiation safety competency as the current criteria.

Some stakeholders have indicated that the current criteria are not over burdensome and are actually pretty reasonable.

So, for example, under the current approach the work experience has to involve several different areas, for example, receiving and unpacking radioactive material safely, performing quality controls, preparing patients, how to handle spills, et cetera, as described in 10 CFR Part 35.

So could you provide specific examples where less a prescriptive criteria would be appropriate?

MR. WILLIAMS: So one of the things that we were looking at is, you know, initially when we embarked on this process it was 700 hours that somebody would need to be an authorized user.

And so we were initially tasked with, hey, are there any carve-outs, is there anything that you guys could look at to where this could be, you know, it wouldn't take 700 hours to be qualified as an authorized user.

And so in some of the regards if you take the doctors who don't perform a lot of this, all of these types of tasks, and they want to look at a smaller subset of the task that could maybe require 80 hours of training.

And then if they could get, you know, become an authorized user by a medical board to do this particular evolution versus trying to get the

qualification at 700 hours then they see there is some benefits to that.

So it's not having to go through the whole gamut of it, but focusing on a smaller subset of criteria.

COMMISSIONER HANSON: So what would be a specific example though for something that would maybe require only 80 hours?

MR. WILLIAMS: I don't have that specific item, but I could say it's more tailored training and experience but I don't know the specifics on that aspect of it.

COMMISSIONER HANSON: Okay.

MR. LUBINSKI: If I could maybe add, Kevin. This is John Lubinski, Commissioner. As you mentioned a lot of the requirements handling materials coming in the door would be if you are dealing with many different types of isotopes.

Where you could look at streamlining this, as Kevin said as far as training, would be to really look at what are the limited amount of activities that you are going to do and if you are buying, you know, unit doses from a radiopharmaceutical manufacturer where you are not doing measuring, separating, the handling is already in a unit dose, then the type of training that you would need to do those kind of activities would be much less and, therefore, a lot of the additional training that would be part of the 700 hours would not be necessary for that limited activity.

So if we were looking at these boards we would think that the majority of these activities would be very limited to certain types of technologies that would very much be more along the line of unit dose based.

But the other advantage to this is as the market continues

to grow we don't know what the new technologies are going to come up with and as those new technologies come out if they, again, lend themselves to saying that the radiopharmaceutical manufacturers are limiting the type of activities that need to be done by an authorized user that would also limit the amount of training that was needed.

COMMISSIONER HANSON: Okay. Thank you. That is helpful. You know, one of the pieces of feedback we got from outside stakeholders, including some members of the organization agreement states, they are concerned about confusion and chaos, not chaos, but just confusion among agreement states if each state's medical specialty board designated kind of different requirements.

So let's say a physician is certified by a specialty board in Texas but then they move to New Mexico and they still want to work as an authorized user, you know, how are we kind of accounting for that?

Would that physician need to get re-certified by a specialty board in the new state of residence or would they need to kind of start all over or would there be some kind of reciprocity and how are you guys kind of incorporating some of that feedback?

MR. WILLIAMS: So my thought would be, and, you know, that's why we kind of said it that way in terms of at the end of the paper is, hey, there is recognition that we need to work across the board with all the agreement states to figure out what this would look and issues such as reciprocity in terms of if I was in one state and I moved to another state does it follow me or follow with me.

These are all things that I think we would have to consider

and that's one of the reasons why we would engage other stakeholders. As we go down this path to develop what that would look like we want to start engaging the medical community as well.

We would engage the agreement states such that we could make an informed decision on what activities we need to do, what is the scope of it, what is the depth of it, what is the breadth of it in terms of what we would recommend and how this would be fully implemented.

COMMISSIONER HANSON: Okay, thanks. So one of the things I think as I look at this paper I am trying to balance here is kind of training and experience requirements that protect patients and adequately train authorized users but also kind of accommodate emerging medical technologies, right, that we're not stifling innovation.

And you mentioned I think, Kevin, in the slide presentation about streamlining the review process for emerging medical technologies, but could you get into some kind of specific examples of how you all are doing that?

MR. WILLIAMS: Yes. So I think we have been very successful in 10 CFR 35.1000. We have been able to take an emerging technology and be in a position to develop the guidance, develop, you know, the associated activities that need to occur in order for the medical community to use this particular radioactive material or isotope in a very, what we would call a timely fashion.

And so because we have had some run time with that we need to look at, hey, can we take this process and streamline it such that we are able to -- Right now it takes about 14 months to process these things.

If we can get to a point where we have a better understanding up front quicker that we can look at streamlining the process to get input ahead of time, develop the guidance quicker, such that we can be in a position to make a recommendation on the safety and, you know, security aspects of this type of isotope, we are trying to do that.

And we have two right now, you know, in the queue that we are trying to focus that on. We just stood up our standing committee, it will include agreement states, and we are trying to do this earlier in the process.

We have a meeting next week to where we are trying to implement this process. In that process we believe that we could probably trim maybe six months off of the review process.

We are now able to do this in an 8-month timeframe. So that's some of the things that we are trying to do.

COMMISSIONER HANSON: Okay. Interesting. Thank you. I look forward to the results of that. I am going to -- In the minute and 45 seconds I have left here I am going to squeeze in one last question. I think this is for Dave Pelton on the Inspection Manual Chapter 2800.

We had just released I think pretty significant revisions to that back in March and it may be too early to tell kind of the impacts of those, but particularly over the last few months as we have been doing things like remote inspection or enhanced guidance on conducting reciprocity inspections, et cetera, do we have any kind of early stage lessons learned on the implementation of IMC 2800?

MR. PELTON: Yes. Great question, Commissioner. I think we do have a few early returns. One is that, you know, we revised 2800

in our Phase 2 effort to try to set the table for our Phase 3, the bed is the modernizing and risk informing of the individual procedures.

In doing so, as you suggested, we identified some streamlining, including some additional flexibilities with inspector planning and scheduling of inspections that through the COVID process have been incredibly valuable in helping us to prioritize and make sure that we have a keen eye on the continuity of inspection and oversight, so that has been very positive.

The reciprocity enhancements we have made I will offer we are actually still streamlining because the Phase 2 of 2800 painted a fairly broad brush on when and how to conduct reciprocity inspections that we are finding based on feedback from our agreement states and internally by our own inspectors perhaps a bit more clarity is needed.

So we are actually developing some internal guidance, you know, in concert with the organization of agreement states to provide a little more clarity on predictably how to engage and when to engage on reciprocity, you know, based on both historical experience, operating experience, as well as risk insights.

So those are two elements that right away struck me as, one, being a ready-to-leverage enhancement in terms of scheduling the other, a bit of a challenge going forward but we probably need to provide the staff with a bit more clarity.

So those are my initial thoughts, Commissioner.

COMMISSIONER HANSON: Okay. Thank you very much. Thank you, Chairman Svinicki.

CHAIRMAN SVINICKI: Well, again, on behalf of the Commission I thank all of the staff who presented, who answered our questions, and among the five of us we covered an awful lot of ground today, so I thank my colleagues as well and all those who helped the staff presenters to prepare for today thank you for your efforts.

And with that we are adjourned. Thank you. Have a nice day.

(Whereupon, the above-entitled matter went off the record at 12:00 p.m.)