

UNITED STATES

NUCLEAR REGULATORY COMMISSION

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STRATEGIC PROGRAMMATIC OVERVIEW OF THE
FUEL FACILITIES AND THE NUCLEAR MATERIALS USERS

BUSINESS LINES (PUBLIC MEETING)

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THURSDAY,

APRIL 26, 2018

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ROCKVILLE, MARYLAND

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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

STEPHEN G. BURNS, Commissioner

ALSO PRESENT:

ANNETTE VIETTI-COOK, Secretary of the Commission

MARGARET DOANE, General Counsel

NRC STAFF:

VICTOR McCREE, Executive Director for Operations

MARC DAPAS, Director, Office of Nuclear Material Safety and
Safeguards (NMSS)

CRAIG ERLANGER, Director, Division of Fuel Cycle Safety, Safeguards and
Environmental Review, NMSS

LINDA HOWELL, Acting Deputy Director, Division of Materials Safety,
Security, State and Tribal Programs, NMSS

AARON McCRAW, Chief, Materials Inspection Branch Division of Nuclear
Materials Safety, Region II

ERIC MICHEL, Chief, Projects Branch 2, Division of Fuel Facility Inspection,
Region II

BRIAN SMITH, Deputy Director, Division of Fuel Cycle Safety

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

1 PROCEEDINGS

2 9:07 a.m.

3 CHAIRMAN SVINICKI: Well good morning, everyone and
4 welcome to the Commission meeting this morning.5 We convene in public session today to receive a briefing
6 from the NRC staff on what we call a business line meeting or programmatic
7 overview of the Fuel Facilities and the Nuclear Materials Users Business
8 Line. And this is always a very content-rich meeting because there's a
9 strong diversity and a lot of discrete set of activities going on but we will hear
10 about the two business lines in two separate panels and we will take a brief
11 break in-between but we will begin with the Fuel Facilities Business Line.12 And I would ask if my colleagues have any opening
13 remarks to make.14 Hearing none, I suggest we just dive right in. And the
15 staff's presentation will be led off by our Executive Director for Operations,
16 Victor McCree.

17 Vic, please proceed when you're ready.

18 MR. McCREE: Thank you, Chairman. Good morning
19 and good morning, Commissioners.20 We appreciate the opportunity, again, to provide you with
21 an update on the strategic considerations associated with the Fuel Facilities
22 and Nuclear Materials Users Business Lines, including current activities,
23 business line priorities, emerging focus areas, and challenges, and the
24 changing environment in which these programs are executed.25 Today's briefings will be provided in two panels, beginning
26 with the Fuel Facilities Business Line. Both business lines are led by the
27 Office of Nuclear Material Safety and Safeguards, or NMSS. These

1 business lines are working on complex issues that involve significant
2 stakeholder engagement.

3 With respect to the Fuel Facilities Business Line, several
4 NRC offices have a role in carrying out its functions. These partners include
5 Region II, the Office of Nuclear Security and Incident Response,
6 Enforcement, International Programs, New Reactors, Nuclear Reactor
7 Regulation, the Chief Financial Officer, and the General Counsel.

8 As will be discussed during the first panel, the work within
9 the business line is diverse and challenging. The strong relationships
10 between the business line partners are essential to achieving success and
11 addressing challenges in a changing environment.

12 Within the Fuel Facilities Business Line, we are proactively
13 planning and prioritizing activities to respond to an uncertain external
14 environment. Over the past year, there have been substantive changes
15 within both the domestic and international fuel cycle industry. These
16 changes include Honey Well Metropolis' decision to idle production, Centrus'
17 lead cascade facility entering decommissioning, Westinghouse's declaration
18 of bankruptcy, the restructuring of AREVA to Framatome and an overall
19 decrease in the demand for uranium.

20 We've been effective and timely in responding to these
21 changes in the industry. Examples include adjustments to the Core
22 Inspection Program and optimizing efficiencies in our licensing reviews.

23 We also embraced the concept of being a matrixed
24 organization within the Fuel Facilities Business Line with both Headquarters
25 and Regional staff supporting one another in a variety of regulatory activities.

26 This approach has allowed us to adjust to changes in the Fuel Cycle
27 Program and respond to emergent issues.

1 Our future work within the business line is also changing.
2 In addition, the traditional core licensing and inspection activities will
3 continue to work on reviews of medical isotope facilities, and
4 accident-tolerant fuel, as well as advanced reactors.

5 The business line also has significant challenges related to
6 the topic of fair and equal -- equitable fees for fuel cycle facilities. This topic
7 will be discussed in the next presentation.

8 Next slide, please.

9 Our first speaker is Marc Dapas, to my right, the Office
10 Director of NMSS, who will provide an overview of the Fuel Facilities
11 Business Line. Following Marc's presentation, we'll hear from Craig
12 Erlanger, to Marc's left, Director the Division of Fuel Cycle Safety,
13 Safeguards, and Environmental Review, or FCSE, who will discuss the
14 current Fuel Cycle Program environment.

15 After Craig, Eric Michel, to my far left, the Chief of the
16 Projects Branch 2 and the Division of Fuel Facility Inspection in Region II,
17 will discuss Fuel Cycle Inspection Program activities.

18 We'll end the first panel with Brian Smith, to my immediate
19 left, the Deputy Director of FCSE. Brian will provide an update on the fee
20 billing project being conducted by NMSS in the Office of the Chief Financial
21 Officer.

22 With that brief introduction, I'll now turn the presentation
23 over to Marc Dapas. Marc.

24 Next slide, please.

25 MR. DAPAS: Thank you, Vic. Good morning, Chairman
26 and Commissioners.

27 As Vic noted during his remarks, I will begin with an

1 overview of the Fuel Facilities Business Line. Next slide, please.

2 The Fuel Facilities Business Line is responsible for
3 ensuring the safety and security of fuel cycle in greater than critical mass
4 facilities. The business line leads the licensing and oversight of these
5 facilities, as well as domestic material control and accounting, and
6 international safeguards implementation activities for the NRC.

7 Additionally, the business line supports rulemaking and
8 environmental review activities.

9 The business line priorities influence the work performed
10 on a day-to-day basis, as well as long-term planning and agency budget
11 execution and formulation processes.

12 Our current priorities are, first, ensuring safety, security,
13 and environmental protection through effective oversight of operating fuel
14 facilities and facilities under construction, and through effective management
15 of licensing actions. This includes maintaining a focus on nuclear safety
16 culture with outreach and education, as directed by the Commission.

17 Second, supporting U.S. nonproliferation activities through
18 implementation of international safeguards agreements and domestic
19 material control and accounting, or MC&A programs.

20 Our third priority is maintaining effective communications
21 with stakeholders on our approaches to emergent issues, rulemaking,
22 guidance development, and other regulatory activities specific to the Fuel
23 Facilities Business Line.

24 Next slide, please.

25 The scope of activities in this business line includes the
26 licensing and oversight for 13 licensed fuel cycle facilities in the United
27 States, six of which are operating, one of which is currently under

1 construction, four that are licensed with construction pending, one facility
2 that is in the process of decommissioning, and one facility that has idled
3 production.

4 We also provide licensing and oversight for a number of
5 Part 70 licensees that possess greater than critical mass quantities of
6 special nuclear material, such as universities, research, and test facilities.

7 From a budget perspective, the Fuel Facilities Business
8 Line is comprised of 114 full-time equivalent or FTE and \$5.3 million in
9 contract support and travel, including corporate -- excluding corporate
10 support resources. This represents about 2.7 percent of the agency's FTE
11 budget for fiscal year 2018. The majority of the resources reside in the
12 oversight, licensing, and international activities product lines.

13 Next slide, please.

14 As Vic mentioned in his opening remarks, we are
15 proactively addressing fees for the Fuel Facilities Business Line and in
16 response to the changing environment. As discussed in the
17 decommissioning and low-level waste, and spent fuel storage and
18 transportation business lines Commission meeting in January, ensuring
19 equitable and transparent fees for all fee classes is a top priority for us.

20 In February 2018, we delivered to the Commission a paper
21 with the results of our evaluation of the Nuclear Materials and Waste Safety
22 Programs and fee classes, which included options for restructuring selected
23 programs and for addressing the uranium recovery fee class issue. It also
24 provided the Commission with an update regarding our plan for continuing to
25 engage industry and public stakeholders on potential improvements to the
26 fuel facilities fee class annual fee calculation methodology. We are
27 exploring changes to the calculation methodology to address concerns that

1 some fuel facility licensee have expressed about the fairness and equity of
2 their annual fees. To support this effort, we are engaging industry and
3 public stakeholders on potential improvements to the fee calculation
4 methodology.

5 On December 13, 2017, we conducted a public meeting to
6 describe the current method for calculating annual fees for the fuel facilities
7 fee class. In this meeting, we provided an overview of the existing Effort
8 Factors Matrix and three proposed alternatives to the methodology used to
9 calculate annual fees. We sought feedback on that method and discussed
10 options for improvement.

11 During this meeting, we requested written comments from
12 stakeholders and, in response to our request, we received eight comment
13 letters. In short, comments were mixed as to whether we should continue
14 working on changes to the methodology for calculating annual fees at this
15 time. Some stakeholders indicated that we should continue with this effort,
16 while others stated that we should consider alternatives, such as a reduction
17 of budgeted resources before changing the current Fuel Facility Effort
18 Factors Matrix.

19 On March 27th of this year, we held a second meeting on
20 this topic. In this meeting, based in part on feedback we previously
21 received from stakeholders, we provided an overview of the Fuel Facilities
22 Business Line budget and how that budget is formulated and executed. We
23 also discussed revisions to the Fuel Facility Effort Factors Matrix. Lastly,
24 we provided feedback on the written comments that we received after the
25 December 13th meeting and requested comments on the proposed options
26 by April 27th, 2018.

27 Upon completion of our planned stakeholder engagement

1 activities, we intend to provide the Commission with the recommendation on
2 how best to determine the annual fee for fuel facilities as part of the
3 recommended policy and administrative changes for the fiscal year 2019
4 proposed fee rule. We anticipate that the associated paper will be
5 submitted to the Commission this summer.

6 Next slide, please.

7 Over the past decade, the work within the Fuel Facilities
8 Business Line has significantly changed. We experienced a period of
9 significant workload increase leading up to 2012 and a significant workload
10 decrease from fiscal year 2013 to fiscal year 2018. As a result, we made
11 corresponding budget adjustments to align resources with the changing
12 workload.

13 The graph on this slide provides an historical overview on
14 a biannual basis of the Fuel Facilities Business Line enacted budget since
15 2008. Some of the reasons for the increased workload and corresponding
16 budget leading up to 2012 include the review of four major license
17 applications, including associated mandatory and contested hearings.
18 These reviews were for the AREVA Eagle Rock, Global Laser Enrichment,
19 International Isotopes, and Mixed Oxide or MOX fuel fabrication facilities;
20 oversight of the construction of the Louisiana Energy Services and MOX
21 facilities; the completion of license renewals for five major fuel cycle facilities
22 and five greater than critical mass licensees. We also reviewed three new
23 greater than critical mass license applications during this time period.

24 Additionally, the events that occurred involving Fukushima
25 reactors in 2011 had a direct impact on the work within the Fuel Facilities
26 Business Line. For example, we conducted additional inspection activities
27 at each of the major fuel cycle facilities, issued a generic letter related to

1 natural phenomena hazards, and issued a specific confirmatory order for
2 one licensee.

3 Lastly, we received an unexpected and significant amount
4 of licensing actions by Louisiana Energy Services, as the facility was
5 constructed.

6 Some of the reasons for the workload and corresponding
7 budget decreases since 2012 include an overall reduction in the number of
8 licensing actions and construction inspections. Additionally, the majority of
9 the major license renewals were completed during this time period and the
10 total number of operating fuel cycle facilities decreased.

11 We have made corresponding budget adjustments to align
12 resources with changes in the workload. The FY2019 budget request,
13 which was made public on February 12th of this year, represents a
14 significant resource reduction when compared to recent years. Even with
15 these reductions, we continue to look for efficiencies in our program.

16 Lastly, we considered the changing nature of the work
17 within the business line during the development of our FY2020 proposed
18 budget.

19 In response to these changes, we recently initiated an
20 effort to restructure FCSE to optimally accommodate the current and
21 anticipated workload within the Fuel Facilities Business Line. Specifically,
22 we will restructure the division from a five- to a four-branch model this fiscal
23 year. Similarly, the workload for the Division of Fuel Facility Inspection, or
24 DFFI, in Region II has decreased over the last several years due to the
25 completion of expansion activities at the Louisiana Energy Services Facility,
26 the Paducah Gaseous Diffusion Plant decertification, delays in facilities
27 transitioning from construction to operation, the transfer of inspection

1 function for the lead cascade facility from DFFI to the Division of Nuclear
2 Material Safety in the NRC's Region III office, and efficiencies gained
3 through Project Aim. DFFI is currently evaluating options for reorganization
4 consistent with proposed resource reductions for the fiscal year 2020
5 budget, as reflected in the Nuclear Materials and Waste Safety and Fee
6 Class Evaluation Report submitted to the Office of the Executive Director for
7 Operations on October 6, 2017.

8 Next slide, please.

9 I would now like to highlight a significant accomplishment
10 pertaining to the Fuel Facilities Business Line. We have completed all
11 activities involving the complex technical issues associated with Generic
12 Letter 2015-01, entitled Treatment of Natural Phenomena Hazards at Fuel
13 Cycle Facilities. The completion of this activity involves significant
14 interaction with industry and internal stakeholders. Through closure of the
15 generic letter, we were able to conclude that the licensees performed
16 appropriate natural phenomena hazards evaluations for their facilities and
17 are in compliance with their licensing basis and our regulatory requirements.

18 The following examples highlight some of the safety and
19 regulatory improvements achieved through this effort. We issued an
20 information notice to inform addressees of recent inspection findings
21 regarding programs and procedures for determining and implementing
22 management measures for isolation controls. These controls are required
23 to be available and reliable to perform specified safety functions to prevent
24 or mitigate accident sequences. A licensee made significant seismic and
25 missile protection modifications to its facility to meet the applicable
26 regulatory requirements and to provide reasonable assurance of adequate
27 protection for public health and safety.

1 Licensees updated their integrated safety analyses
2 documentation to accurately reflect design and safety information for natural
3 phenomena hazards. These updates resulted in better clarity of the
4 facility's licensing basis, as they relate to natural phenomena hazards.

5 Additionally, licensees updated their safety programs to
6 require further evaluation of facility and design changes, as well as the
7 impacts to the natural phenomena hazards licensing basis.

8 Lastly, many licensees modified internal equipment to
9 improve the resiliency of their sites against seismic hazards.

10 Next slide, please.

11 We continue to effectively implement the Commission's
12 direction regarding safety culture within the context of this business line. In
13 our continuing efforts to keep licensees focused on the importance of
14 maintaining a healthy safety culture, we provided a presentation on nuclear
15 safety culture during the fuel cycle information exchange, which was held in
16 June of last year.

17 With respect to educational tools, the Safety Culture
18 Educational Resource Workbook is a comprehensive tool, which includes all
19 nine safety culture trait talks, a safety case study and journeys document, as
20 well as the Federal Register notice outlining our safety culture policy
21 statement.

22 All tools are available for licensees on our Safety Culture
23 web page.

24 Programmatically, one way to address safety culture
25 issues is through the Alternative Dispute Resolution or ADR Program.
26 During fiscal year 2017, we conducted two ADR sessions that involved
27 safety culture elements. For one licensee, a confirmatory order was issued

1 that required it to conduct a safety culture survey. For the other licensee, a
2 safety culture assessment was initiated by the licensee as a corrective
3 action.

4 Thank you. And I will now turn the presentation over to
5 Craig Erlanger.

6 Next slide, please.

7 MR. ERLANGER: Thank you, Marc. Good morning
8 Chairman, Commissioners.

9 My presentation will focus on the current fuel cycle
10 environment. The Fuel Facilities Business Line supports a number of
11 activities involving a broad range of stakeholders. In my presentation I will
12 highlight several accomplishments, ongoing activities, and focused areas for
13 the business line.

14 Next slide, please.

15 Our last Commission briefing for this business line was in
16 March of 2017. Since that time, we have realized many accomplishments
17 and made significant progress on several important initiatives.

18 For example, in the area of rulemaking, we made
19 considerable progress on the fuel cycle cyber security rulemaking effort,
20 which included extensive stakeholder interactions. A total of 12 public
21 meetings were held in connection with this rulemaking initiative. Through
22 our interactions with licensees, other federal agencies, and members of the
23 public, we obtained important information, as well as different views and
24 opinions that informed the development of the proposed rule package and
25 the draft regulatory guide.

26 As part of the proposed rule package, we developed draft
27 regulatory and backfit analyses that aligned with Commission direction

1 regarding cost considerations and the applicability of the compliance
2 exception to the backfit rule.

3 Last summer, we briefed the Advisory Committee on
4 Reactor Safeguards, or ACRS, and the Committee to Review Generic
5 Requirements, or CRGR, regarding the proposed rule package and draft
6 regulatory guide. Both the ACRS and CRGR endorsed proceeding with
7 formal comment on the proposed rule package and the associated guidance
8 document. We have provided the proposed rule package to the
9 Commission in the fall of 2017.

10 Another example of significant progress is the completion
11 of the modified small quantities protocol rulemaking, which represents a
12 multi-year effort. The purpose of this rulemaking activity was to extend
13 certain reporting requirements for licensees that possess source and special
14 nuclear material in Puerto Rico and other U.S. Caribbean territories through
15 a revision to 10 CFR Part 75. During the past year, the Commission
16 approved amendments to 10 CFR Part 75.

17 On Monday of this week, we received the information
18 collection and review approval for these amendments from the Office of
19 Management and Budget. With this approval, we are moving forward with
20 the publication of a Federal Register notice. These amendments will then
21 go into effect 30 days after publication of this notification.

22 The Small Quantities Protocol will enter into force following
23 notification to the International Atomic Energy Agency, or IAEA, that the
24 United States has gathered all the necessary inventory information and is
25 able to implement the reporting requirements.

26 The Department of State then sends the official notification
27 on behalf of the U.S. Government. Following notification, the next action is

1 the submittal of the initial inventory reports for material located in the U.S.
2 Caribbean territories to the IAEA.

3 Another activity where we have made significant progress
4 this past year is the Westinghouse Lessons Learned Initiative. As you may
5 recall from our presentation to the Commission back in June of last year on
6 the Westinghouse scrubber condition that was reported to the NRC in July of
7 2016, we initiated a lessons learned effort as part of the agency's focus on
8 continuous improvement. In the resulting report, which was issued on
9 January 30th, 2017, we identified areas needing further evaluation,
10 specifically in licensing, inspection, operating experience, roles and
11 responsibilities, and knowledge management.

12 We also issued a non-publicly available report on May
13 31st, 2017, which provides recommendations to improve our internal
14 processes and communications. These recommendations are not directly
15 associated with the cause of the event but are, nevertheless, important in
16 the context of better organizational effectiveness.

17 These two reports contain 25 recommendations, 7 of
18 which are prioritized as high, 13 as medium, and 5 as low. To date, we
19 have completed three of the seven high-priority recommendations and four
20 medium-priority recommendations. The remaining actions are on track to
21 be completed this summer.

22 Of note, we developed inspection guidance to ensure that
23 all systems that present a high or an intermediate consequence hazard,
24 albeit the probability of occurrence is low, are inspected at least once every
25 five calendar years.

26 We also revised our inspection procedures to ensure that
27 the effects of multiple plant modifications are considered in inspection

1 planning.

2 I'd like to note that the associated action items are
3 summarized on a chart on the NRC's public web page. Next slide, please.

4 This graph provides both an historical overview of the
5 number of licensing actions completed by the Fuel Facilities Business Line,
6 as well as to project the number of licensing activities. As Marc previously
7 discussed, there's been an overall decrease in fuel facilities-related work in
8 recent years, specifically in the area of licensing.

9 In fiscal year 2017, we completed a total of 58 licensing
10 actions. Examples of licensing actions recently completed include a
11 transfer of control review for AREVA and a threshold determination as part of
12 the initial step in the proposed Westinghouse transfer of control, both of
13 which met the respective licensees' emergent needs.

14 Additionally, we are leading the review of the special
15 nuclear material license application for the Johns Hopkins Applied Physics
16 Laboratory. Moving forward, based on the known, and anticipated
17 workload, we expect a number of licensing actions will be approximately 50
18 per year.

19 In the past year, we have also completed the license
20 renewals for the GE Vallecitos Nuclear Center, the Massachusetts Institute
21 of Technology, and the Pennsylvania State University.

22 Additionally, we supported the Operating Reactors
23 Business Line in the review of the Northwest Medical Isotope construction
24 permit and we are preparing for the SHINE operating license review.

25 We will continue to support the agency's efforts to engage
26 the Department of Energy and industry in anticipation of reviews of fuel types
27 for existing and advanced reactors. Lastly, we do not expect any major

1 license applications for new facilities until fiscal year 2021.

2 Next slide, please.

3 We continue to effectively implement the licensing and
4 oversight programs for fuel cycle facilities by performing high-quality and
5 timely licensing reviews and oversight activities consistent with the current
6 environment. I'd like to highlight a few significant programmatic activities
7 that have resulted in enhancements to these programs.

8 In the area of licensing, over the past two years, we have
9 performed internal process reviews to improve the efficiency and
10 effectiveness of our program and initiated actions to implement identified
11 enhancements.

12 First, we performed a self-assessment of the safety
13 evaluation report or SER development process. This effort involved
14 benchmarking our process against existing procedures used by other NRC
15 organizations. We evaluated SERs that were developed during the last
16 three years. As a result, we identified opportunities to improve the
17 consistency of SER format and content by developing new templates,
18 improve guidance for requesting assistance from technical staff, and improve
19 documentation of meeting outcomes that inform the development of SERs.

20 Second, we performed an assessment of our request for
21 additional information or RAI process. We conducted training with the staff
22 in the summer of 2017 to address the results of this self-assessment and to
23 provide for continued improvement in the effectiveness and efficiency of the
24 RAI process.

25 Third, we transitioned to a Web-Based Licensing System,
26 or WBL, to effectively track and manage licensing actions. This system
27 enables the tracking of submittal status, metric due dates, and related

1 documents, as well as provides a high-level template of the activities that
2 need to be considered during licensing reviews. This system also provides
3 a useful and effective knowledge management tool that can be used to
4 understand the current and past licensing activities for the various fuel cycle
5 dockets.

6 Lastly, we recently issued guidance to the staff on
7 expectations for developing and communicating hours estimates for our
8 licensing reviews. After this approach is piloted, this guidance will be
9 incorporated into a future licensing review handbook update.

10 We also actively participate in the NRC Licensing Process
11 Commonalities Steering Committee. This steering committee is composed
12 of representatives from OGC and several program offices. The main
13 objective of the committee is to align on appropriate licensing strategies and
14 assist in evaluating options for efficient and effective implementation of
15 licensing processes.

16 The committee is currently performing evaluations in the
17 areas of pre-application meetings, expectations for project management,
18 oversight of hours charged in connection with licensing actions, and
19 transparency of plans scheduled for licensing actions.

20 Lastly, to promote continuous improvement within the
21 Licensing Program and enhance knowledge of management and transfer
22 within the business line, we conducted several licensing seminars on a
23 number of important licensing topics, including RAIs, Web-Based Licensing,
24 the budget process, annual fees collection, document quality, and a
25 Westinghouse Lessons Learned update.

26 In the area of oversight, we continue to make
27 improvements by evaluating events through our Operating Experience

1 Program. We recently completed a Fuel Cycle Operating Experience
2 Report that provides the results of our analysis of events over the past ten
3 years. A public version of this report will be made available to support the
4 2018 Agency Action Review Commission meeting.

5 As part of the Operating Experience Program, we
6 developed a screening process to categorize, analyze, and identify recurring
7 issues of safety significance that would merit consideration of changes to our
8 Inspection Program.

9 We continue to share information with the Department of
10 Energy through quarterly briefings and with our international counterparts via
11 participation in the Fuel Incident Notification Analysis System, better known
12 as FINAS. We are also continuing to engage in information exchange
13 activities with the Nuclear Regulatory Authority of Japan and the Canadian
14 Nuclear Safety Commission.

15 Next slide, please.

16 We recently revised three Inspection Manual chapters, or
17 IMCs, in six inspection procedures, including a revision to IMC 1246, which
18 describes the training and qualification requirements for technical reviewers
19 and project managers in the NMSS. These most recent updates eliminate
20 the backlog of inspection procedures and IMCs that needed to be revised.

21 Recently, the Office of Nuclear Security and Incident
22 Response, in coordination with staff from NMSS in Region II, completed a
23 significant enhancement to the Security Core Inspection Program for
24 Category 1 fuel cycle facilities. This effort was initiated in 2015 by
25 conducting extensive analysis of the Inspection Program, the applicable
26 regulations, and orders culminating in the consolidation of the program from
27 24 inspection procedures into eight.

1 Lastly, our business line provides the agency's expertise in
2 material control and counting, or MC&A, for fuel cycle facilities, reactors, and
3 other NRC licensees authorized to possess special nuclear material.
4 Activities in the MC&A area include supporting inspections through close
5 cooperation with regional inspectors, updating MC&A guidance and
6 qualification documents, supporting reviews and providing consultations
7 related to MC&A for advanced reactor designs, medical isotope facilities,
8 and other licensing actions.

9 Finally, in the past year, we have made progress on the 10
10 CFR Part 74 rulemaking pertaining to MC&A requirements and plan to
11 deliver that rule to the Commission by January of 2019.

12 Next slide, please.

13 In addition to focusing on our Licensing and Oversight
14 Programs, we continue to support regulatory activities through stakeholder
15 outreach. The Fuel Cycle Information Exchange, for FCIX, which was last
16 held in June of 2017, provides a forum for NRC staff, industry
17 representatives, and other stakeholders to discuss regulatory issues of
18 mutual interest related to the nuclear fuel cycle. Over 100 attendees
19 attended last year's conference. Examples of topics discussed include
20 improvements to the fee billing process, cyber security, and lessons learned
21 from the Westinghouse scrubber condition.

22 We also successfully piloted a session at the 2018
23 Regulatory Information Conference on the current environment and future
24 trends in the fuel cycle industry. The panel consisted of NRC, government,
25 and industry executives. Panels discussed trends in the fuel cycle industry,
26 regulatory oversight, and licensing initiatives, as well as the future
27 challenges facing the fuel cycle industry.

1 We continue to manage the cumulative effects of
2 regulation through the use of an integrated schedule and regular meetings
3 with licensees and other stakeholders. The integrated schedule lists the
4 current regulatory activities, the major milestones, public interaction dates,
5 and the drivers for the actions. We use it to more effectively coordinate
6 activities to avoid scheduling conflicts and to assure that we are focused on
7 the most important topics.

8 Public meetings on the cumulative effects of regulation are
9 scheduled biannually. In these meetings, we provide updates on the
10 integrated schedule, as well as seek feedback from stakeholders. The most
11 recent meeting was held on April 11th, 2018.

12 Overall, we have received feedback that these interactions
13 continue to be an effective way to keep stakeholders aware of ongoing
14 initiatives, as well as help prioritize activities and resources.

15 Next slide, please.

16 Consistent with our business line priorities, we continue to
17 support the United State Government activities related to international
18 safeguards. This involves continuing to lead the implementation of
19 international safeguards treaties and agreements at NRC-licensed facilities
20 in order to fulfill the United States' obligations under agreements with the
21 IAEA.

22 Activities pertaining to the international safeguards include
23 reporting for source and special nuclear material through the Nuclear
24 Materials Management Safeguard System, or NMMSS, operated by the
25 Department of Energy with NRC support, reporting under the additional
26 protocol for other nuclear materials and equipment, coordinating information
27 with IAEA on NRC-licensed facilities, including producing the annual updates

1 for the NRC's licensees on the eligible facilities list, and coordinating and
2 participating in interagency groups within the United States Government on
3 safeguards and nonproliferation, including chairing the subgroup on IAEA
4 Safeguards in the United States, known as SISUS.

5 We also participate in the U.S. Safeguards Support
6 Program for IAEA and support the annual meeting of the Quad Group that
7 includes the U.S., Canada, Australia, and Euratom, for tracking obligations
8 of source and special nuclear material.

9 Lastly, we provide technical support to the Office of
10 International Programs on import and export licensing reviews, reviews of
11 technology transfers under Part 810, and the review of bilateral agreements
12 for nuclear cooperation or 123 Agreements.

13 Some specific activities we conducted in the past year
14 include organizing and leading with the Department of Energy the annual
15 NMMS users training meeting, working with two licensees to update their
16 IEAE design information questionnaires, and successfully submit them to the
17 IAEA, and working with two licensees to update their transitional facility
18 attachments, submit them to the IAEA, and implement them as license
19 conditions.

20 Next slide, please.

21 We are focused on ensuring the safety and security of fuel
22 facilities through effective licensing and oversight and by supporting U.S.
23 non-proliferation activities. We will continue to implement strategies to
24 address current business line challenges and focus on future opportunities.
25 Moving forward, this entails implementing strategies to improve the accuracy
26 of fee billing, continuing engagement with external stakeholders on the Fuel
27 Facilities Effort Factors Matrix, ensuring the effective and timely

1 reorganization of FCSE, supporting medical isotope accident-tolerant fuel
2 and advanced reactors licensing activities, and ensuring effective
3 implementation of the current Licensing and Oversight Programs.

4 This concludes my part of the presentation. And I will now
5 turn it over to Eric Michel, who will discuss the Fuel Cycle Oversight
6 Program.

7 MR. MICHEL: Good morning Chairman, and
8 Commissioners. My name is Eric Michel and I am the Branch Chief for
9 Projects Branch 2 within the Division of Fuel Facility Inspection in Region II.

10 Our Fuel Facility Oversight Program plays a key role in
11 ensuring the safe and secure operation of fuel cycle facilities through
12 effective implementation of comprehensive safety and security inspections.

13 Next slide, please.

14 Our inspection and enforcement activities contribute to
15 safe and secure licensee performance. Fuel facility oversight
16 accomplishments include completing approximately 89 core inspections at
17 eight operating facilities in calendar year 2017 to ensure they operated
18 within the established safety basis. We chartered one reactive special
19 inspection team in response to an event at the BWXT Nuclear Operations
20 Group and which a significant, unanticipated accumulation of uranium was
21 discovered in two desiccant vessels servicing a glove box line in the
22 research and test reactors area.

23 We also completed approximately 15 additional
24 plant-specific inspections, including follow-up to a confirmatory action letter,
25 follow-up to a confirmatory order, completion of the temporary instruction for
26 natural phenomena hazards at four facilities, and completion of several
27 information security-related inspections.

1 Lastly, we successfully completed two Alternative Dispute
2 Resolution sessions, one with the Westinghouse Columbia Fuel Fabrication
3 Facility and one with Global Nuclear Fuels America, and subsequently
4 issued the associated confirmatory orders.

5 Next slide, please.

6 We continue to seek opportunities to innervate and thereby
7 improve the efficiency and effectiveness of the Fuel Facility Inspection
8 Program.

9 We have evaluated and plan to shift inspection hours from
10 regional inspection staff to the senior resident inspectors at the Category 1
11 fuel cycle facilities in two areas: operational safety and fire protection. In
12 the operations area, we evaluated and plan shifting 24 hours of inspection
13 and in the fire protection area, an additional 32 hours, for a total of 56 hours.

14 The senior resident inspector is well-positioned to take on
15 these additional hours from an efficiency standpoint. Moving the hours will
16 give complete ownership of the operations area to the senior resident
17 inspector, permitting deeper looks into samples and will increase efficiency
18 by reducing regional travel expenses, as well as inspection preparation and
19 documentation time.

20 Driven by recent events that have resulted in escalated
21 enforcement action, we conducted a gap analysis between our current
22 Inspection Program and four years' worth of violations and events that were
23 reportable to the NRC. The purpose of this analysis was to identify areas
24 where our program could be better positioned to identify those issues before
25 they became self-revealing events. Overall, we confirm that the Inspection
26 Program, as implemented, provides adequate oversight of fuel cycle
27 facilities. However, we identified some areas for improvement. For

1 example, verification of licensee's categorization of components as
2 like-for-like during replacements was identified as one area needing
3 additional inspection effort.

4 Finally, all DFFI inspectors have completed the initial
5 phase of backfit reset training and we are sensitive to backfit concerns.
6 Next slide, please.

7 I would like to spend just a few minutes on inspection
8 oversight of the Mixed Oxide Fuel Fabrication Facility in Aiken, South
9 Carolina. In 2017, we expended over 1700 hours inspecting the principal
10 systems, structure, and components, or PSSCs, as well as the quality
11 assurance, corrective action, and change process programs. We have
12 continued to inspect construction activities on many PSSCs. Today, MOX
13 Services has certified that five of the 53 PSSCs are complete, two of which
14 have been verified by the NRC.

15 At least year's business line Commission meeting, we
16 discussed an issue associated with the undersized welds and floor and
17 ceiling supports within the aqueous polisher building. We issued a severity
18 level 3 violation for this issue. As a result of the undersized welds, MOX
19 Services could not ensure that all accredited safety functions could be
20 performed for all event scenarios, including seismic motion.

21 This severity level 3 violation resulted in MOX Services
22 being moved into column 2 of the Construction Action Matrix described in
23 Inspection Manual Chapter 2630, Mixed Oxide Fuel Fabrication Facility
24 Construction Inspection Program. Column 2 requires additional regulatory
25 oversight in the form of inspection review of the associated root cause
26 investigation and a regulatory performance meeting.

27 Following our inspection of the licensee's corrective

1 actions to restore compliance with the design basis, the facility was returned
2 to column 1 of the Construction Action Matrix in the third quarter of 2017.

3 Next slide, please.

4 Inspection oversight activities at the Westinghouse
5 Columbia Fuel Fabrication Facility continue in 2018 as a result of the July
6 2016 event, where the mass limit for uranium was exceeded in a ventilation
7 scrubber. The scrubber collects and filters off gas from several different
8 pieces of equipment in the uranium conversion process prior to release to
9 the environment. Following notification of the event, we initiated a reactive
10 augmented inspection.

11 On August 11, 2016, we issued a confirmatory action letter
12 documenting the licensee's corrective action commitments needed to restore
13 compliance prior to resuming operations. All short-term restart items in the
14 confirmatory action letter were completed and inspected and a recovery area
15 of restart was authorized in October 2016.

16 Long-term actions were transferred to a confirmatory order
17 that I will be discussing later in my presentation.

18 In March 2017, we reviewed the performance of the
19 Westinghouse Columbia Fuel Fabrication Facility per the requirements of
20 Inspection Manual Chapter 2604, Licensee Performance Review. In light of
21 the scrubber condition, an area needing improvement was identified. We
22 scheduled three supplemental inspections as part of our increased
23 oversight, two related to management measures and criticality safety
24 evaluations, and one related to nuclear safety culture.

25 In February of 2018, the licensee's performance was again
26 reviewed and the area needing improvement remains in place.

27 As part of our enforcement process, Westinghouse

1 requested to participate in our Alternative Dispute Resolution, or ADR,
2 process and in May of 2017, a successful mediation was conducted. This
3 was followed by the issuance of a confirmatory order in August 2017, which
4 documented the agreed-upon additional corrective actions the licensee
5 planned to take to further enhance safety. This includes the completion of a
6 second nuclear safety culture survey within two years, the design and
7 implementation of hardware enhancements to reduce uranium carryover
8 from systems upstream of the S-1030 scrubber, and development of a
9 system to monitor for and alert operators of the early accumulation of
10 uranium in the S-1030 scrubber.

11 Additionally, the previously mentioned long-term
12 confirmatory action letter items were transferred to this confirmatory order
13 and the confirmatory action letter was closed.

14 We have maintained additional inspection oversight of the
15 Westinghouse Columbia Fuel Facility. All cleanout activities and licensing
16 inspections of the S-1030 scrubber have been observed since the July 2016
17 event. Additionally, we conducted two inspections in 2017 to verify aspects
18 of the confirmatory action letter and two supplemental inspections were
19 conducted to follow-up on the area needing improvement and confirmatory
20 order items.

21 During these inspections, we observed safety culture
22 behaviors in order to additionally assess the licensee's progress in this area.

23 Finally, in February of this year, Westinghouse management participated in
24 a public meeting held in Atlanta to discuss their recovery actions.

25 Based on the results of our inspection activities, we
26 concluded that the licensee has shown progress in the areas of safety
27 culture, management measures, and criticality safety evaluations. I would

1 note that, per the confirmatory order, the licensee is required to implement
2 additional actions with respect to safety culture which we will subsequently
3 inspect.

4 Next slide, please.

5 We maintain a strong connection with both NMSS and
6 NSIR through periodic counterpart meetings, regular phone calls, and a joint
7 approach to issue resolution. In addition, we have collaborated closely in
8 addressing the Westinghouse Scrubber Lessons Learned recommendations
9 and DFFI inspectors are actively involved in the working groups that support
10 this effort.

11 Additionally, we've recently developed -- we've recently
12 supported development of two information notices, one related to the
13 determination of adequate management measures for process isolation
14 controls designated as items relied on for safety and the other addressing
15 long-term fissile material accumulation due to unanalyzed or improperly
16 analyzed conditions at fuel cycle facilities.

17 We continue to leverage our communities of practice as a
18 vehicle to promote knowledge management. Effective implementation of
19 Fuel Cycle Inspection Program requires expert operational knowledge at
20 several different types of facilities and several technical areas, such as
21 criticality safety, material control and accounting, and information security,
22 which forms some of our communities of practice.

23 The communities of practice provide opportunities for
24 inspectors and Headquarters staff with a wide range of backgrounds and
25 experience to share knowledge within their specialized technical discipline.

26 Lastly, continuing an initiative that we began eight years
27 ago to enhance organizational agility, we continue to encourage and support

1 inspector cross-qualification in several areas of the Fuel Facility Inspection
2 Program, as well other areas involving other business lines. Roughly 70
3 percent of fully qualified inspectors in the Division of Fuel Facility Inspection
4 are cross-qualified in at least one additional specialty area. While there is
5 no formally prescribed matrix approach, DFFI inspectors with significant
6 reactor experience have been qualified to support the Division of Reactor
7 Projects, Reactor Safety, and Construction Oversight. As their work
8 schedules permit and needs arise, they have conducted problem
9 identification and resolution inspections, provided hurricane coverage, and
10 are qualified to conduct inspections as limited operating examiners.

11 This concludes my portion of the presentation. I will now
12 turn it over to Brian Smith, who will provide an update on the NMSS and
13 OCFO fee billing project.

14 Next slide, please.

15 MR. SMITH: Good morning, Chairman, Commissioners.

16 Next slide, please.

17 Over the past few years, billing errors have been identified
18 across all the Nuclear Materials and Waste Safety Program Business Lines.
19 These errors included both over and under billings to licensees as a result of
20 data integrity and accuracy issues. Although these errors have been
21 addressed individually as they were identified, their prevalence has
22 underscored the need to increase the focus on preventing fee billing issues
23 and improve the overall billing processes.

24 In order to address the challenges related to accurate fee
25 billing, a joint NMSS and OCFO team was established in November 2016,
26 consistent with a tasking memorandum signed by the NMSS and OCFO
27 Office Directors.

1 While the errors routinely manifest as data integrity issues,
2 it became clear that underlying root causes spanned a broad spectrum of
3 areas. Contributing factors included miscommunication, a loss of
4 institutional knowledge, outdated documentation, inadequate training,
5 insufficient data input controls, a lack of internal controls, and antiquated
6 data exchange methods. With the support from OCFO and regional staff,
7 we developed a project plan to address the issues involving a collaborative,
8 comprehensive approach.

9 Task completion was further structured into three phases,
10 according to the relative priority of the various tasks, with the most urgent
11 tasks targeted for completion during Phase 1. Task prioritization focused
12 on the activities that most directly affect fee billing aspects and are critical to
13 ensuring sufficient and timely information collection, population, system
14 interfaces, and quality control of data.

15 Many high-priority tasks in Phase 1 have been completed
16 and the lower priority actions in Phases 2 and 3 are underway. This
17 initiative will be completed this fiscal year.

18 Next slide, please.

19 Through our dedicated efforts, we have completed a
20 number of high-priority tasks. These include completion of the initial phase
21 of the Web-Based Licensing, or WBL, system license data review in fiscal
22 year 2017. This initial review phase focused on the licenses with the
23 highest potential for billing errors because of their higher level of complexity.

24 A total of 771 licenses across all business lines were reviewed during this
25 phase, requiring involved staff to verify information in 19 critical data fields
26 necessary for fee billing.

27 As a result of the review, we identified errors that resulted

1 in fee changes for 24 licensees involving a fee increase to begin in fiscal
2 year 2018 and 14 licensees with a fee decrease from their fiscal year 2017
3 annual fees.

4 Data changes which affected fees were related to incorrect
5 program code assignments. Improvements have since been made to
6 improve guidance, increase staff awareness, and institute enhancements to
7 database system architecture to increase internal controls.

8 We have approximately 2,000 remaining licenses which
9 are expected to have a low probability of billing errors, since these licenses
10 are of lower complexity, are currently under review.

11 We also consolidated the majority of licenses within the
12 Nuclear Materials and Waste Safety Program in WBL. The billing data for
13 these licenses were previously maintained in different IT systems, primarily
14 serving licensing purposes only. This consolidation ensures consistency in
15 fee billing data elements and enhances data transfers to the Financial
16 Accounting and Integrated Management Information System or FAIMIS.

17 Other significant IT-related tasks include the completion of
18 interface enhancements to the FAIMIS and WBL systems to support
19 integration with the new agency Master Data Management System
20 Initiatives. At the same time, we enhance system features to provide
21 additional functionality and internal controls necessary to further advance the
22 accuracy and timeliness of licensee fee billing. Examples include additional
23 data fields, role-specific access controls, automated transfers, and automatic
24 notification generations.

25 Next slide, please.

26 We issued a Memorandum of Understanding between
27 NMSS, OCFO, and the Office of the Chief Information Officer. Although this

1 Memorandum of Understanding addressed the information technology
2 aspects of the interface between WBL, FAIMIS, and the Master Data
3 Management System, we included roles and responsibilities related to fee
4 billing activities specific to OCFO and NMSS. To support the
5 implementation of this Memorandum of Understanding, an NMSS office
6 procedure was created that includes these roles and responsibilities and
7 contains other activities that support the fee billing process.

8 We also initiated a significant action to establish a
9 decommissioning status change process that clearly delineates the point in
10 time that licensees enter decommissioning and the resultant fee billing
11 changes. This process addresses many different types of decommissioning
12 scenarios. We are making changes in the WBL system now, a desk guide
13 is being developed, and staff training is planned for later this summer.

14 Finally, we have conducted both internal and external
15 stakeholder outreach activities to increase awareness of what we are doing
16 in this area. These include publishing articles in our NMSS Newsletter,
17 discussing the fee billing process and associated enhancements during
18 division at office-level all-hands meetings, providing discussions during
19 sessions at the 2017 SCIX, and conducting a poster session at the 2018
20 Regulatory Information Conference.

21 Next slide, please.

22 As we progress towards completion of this initiative by the
23 end of this fiscal year, we are focusing on wrapping up the remaining tasks.
24 These include completing the review of the remaining license data in WBL
25 and system interface improvements, completing the tax identification number
26 and billing address collection process for new licensees, as well as
27 completing collection of this information for existing licensees where it is

1 needed, and conducting training across our office and in the regions to
2 ensure that roles and responsibilities and fees fundamentals are clearly
3 understood, as well as to ensure that changes in WBL and in guidance
4 documents are communicated to our staff.

5 Throughout this project, there has been great cooperation
6 between OCFO, NMSS, and the regions. We have made significant
7 progress in addressing our highest priority items, such as reviewing
8 fee-related data within WBL, and establishing information technology and
9 administrative controls to maintain the data.

10 We will continue to collaborate with our partners to
11 complete implementation of the remaining actions that will enhance the
12 accuracy of the licensee fee billing process that affects all Nuclear Materials
13 and Waste Safety program business lines.

14 Thank you. And with that, I turn it back to Vic.

15 MR. McCREE: Thanks, Brian. Chairman,
16 Commissioners, that concludes our presentation on the Fuel Facility Nuclear
17 Material Users Business Line and we're ready for your questions.

18 CHAIRMAN SVINICKI: Well, thank you for those
19 presentations. We will begin the Q and A today with my questions. And as
20 is typical with me, I'll share some thoughts as well.

21 I do appreciate -- again, I mentioned there's a broad
22 amount of work of different activities that are described at this business line
23 meeting and this second panel, which we have some knowledge of, will
24 continue this same general theme.

25 We always kind of show up where we are. So at this
26 festive budget time of year, one of the new things I get to do as chairman,
27 which my colleague, the colleague to my left probably does not miss at all, is

1 I spend a lot of time studying the budget so that I am readily conversant. I
2 mean the Commission, obviously, formulates the budget request so they're
3 very aware of it, but you have to be very readily conversant in a lot of kind of
4 budget execution matters and the budget request itself that I think I was able
5 to skirt along with a little bit less depth on these issues.

6 So at this time of year when we've been discussing the
7 budget with those who will decide on our future budgets in the U.S.
8 Congress, I received this information and think a lot about the efforts that are
9 being made to right-size, and get the right process, and the right people in
10 the right organizational structure to be able to carry out this work. One of
11 the themes of the hearing that our Commission appeared at yesterday was
12 how dynamic the nuclear industry is in the United States. And I extract from
13 your presentations that you're keeping an eye on that and you're being very
14 mindful. And that segues very well into Brian's description and presentation
15 about all you are doing on the analysis for the fee setting algorithms and
16 trying to map that to anticipated work.

17 But you know I note that Craig presented that the forecast
18 is that we do not expect any major license applications until 2021. We
19 completed 58 licensing actions. And when I scrub that against Marc's slide
20 8, which is this historic slide of FTE over the years for work -- I'm kind of a
21 numbers and analysis person -- so, by itself that graph does not and cannot
22 make the case for absolute right-sizing because there's not enough data
23 there. I mean it is a necessary analysis.

24 And so as I prepare for our congressional hearings and
25 think of, candidly, questions much, much tougher than anyone else would
26 ask you, you know you always think of the very, very toughest questions,
27 one of the questions is how do you make the case that the resourcing that

1 you have is mapped to the work that you have.

2 And historic data is interesting but ten years ago, which is I
3 think that graph started at fiscal year 2008, well in theory, that's before the
4 efficiency improvements of Project Aim. It's before a lot of organizational
5 thrusts and initiatives that we've had. Also, our reliance on various
6 automation tools and things, in theory.

7 I mean I don't know. I haven't looked at it discretely for
8 this set of activities. But in theory, most kind of corporate business
9 organizations have had some efficiency improvements just because we have
10 access to more technology now that, in theory, is making us more efficient,
11 in addition to NRC's very purposeful work to improve processes and become
12 more efficient and effective in what we do.

13 So as you have gone out for public comment on these fee
14 issues, you -- I guess this came in to Craig and came in yesterday, but
15 you're received a letter with industry perspectives from the Nuclear Energy
16 Institute making the point -- I'm sure you're read it but for the benefit of
17 everyone, I'll just read this. It's a multi-page letter but it notes while the total
18 business line FTE has decreased -- this is for Fuel Cycle Facility Business
19 Line -- has decreased since FY2014, the annual fee recovery amounts
20 stayed essentially the same, while the number of licensees responsible for
21 paying these fees decreased from ten to seven, which is 30 percent but it's
22 going from a small number to an even smaller number, during this period.

23 It says the current NRC FTE per operating fuel facility ratio
24 of 16-to-one is disproportionately large when considering the low risk of the
25 facilities and historically safe and secure operations.

26 It goes on to say later on, a related note, there are no new
27 license renewals, major amendments, or new applications on the horizon for

1 this class of licensees.

2 It's interesting to me because the questions we've been
3 getting externally are on the reactor side because we do have a number of
4 reactors that are terminating their operations prior to the cessation of their
5 license, some with more notification to us than others, some it may be much
6 more abrupt. And so we're trying to stay agile, given that changing
7 landscape.

8 And when I read ten facilities, you know spreading the cost
9 across ten facilities versus seven, at first I was like well that doesn't seem
10 very dramatic. But if that were occurring on the reactor side and it were 30
11 reactors, I think that we would be receiving a lot of questions about how it is
12 that we're proving the sustainability of the 90 percent fee recovery that we
13 have.

14 And I've been asked directly, or on behalf of the
15 Commission, in some of our hearings about well when is that tipping point for
16 you. And it occurs to me, I don't know. Maybe it's already happening in
17 the fuel cycle side.

18 So we're making a lot of efforts. I'm just -- I have a
19 lingering concern, though, that this is a little more dramatic than we realize.
20 The vectors, again, which were described I thought very accurately by
21 Senator Feinstein in the hearing we had yesterday, of the trends of
22 consolidation and shutdown or suspension of operations in various sectors
23 of the nuclear industry, this fees piece I think is something that is going to
24 come more squarely to the forefront because -- and by tipping point I mean a
25 point at which the mandate to recover 90 percent of fees over smaller and
26 smaller groups of regulated entities, at some point it goes from being a
27 difficulty for those facilities to being something that actually causes more of

1 them to shut down. And not so much on the reactor side because the
2 overall dollar amounts are much larger in terms of their revenues and
3 operating costs.

4 But here, I'm just wondering if we can confront this well
5 here, maybe we can carry that over on the reactor side, should the day come
6 that we need to understand that a little bit better.

7 So then I tried to think about how do you create a case for
8 right-sizing. Even if we were to try to benchmark against NRR, and I think
9 many people think NRR probably isn't perfectly right-sized, but would that be
10 meaningful? Could we even do that? This point about you know NRC FTE
11 per operating fuel facility ratio of 16-to-one, I don't know what that would look
12 like on the reactor side.

13 And is it even a meaningful comparison? I don't know
14 because there's like the licensing actions over on NRR are tremendous.

15 It's a multi-variable equation and, as I've admitted, I'm a
16 numbers person. But at some point, I think we're going to be asked to show
17 our work papers on this and we're going to be asked to make a really
18 meaningful case.

19 And the other thing is that I think that the material side has
20 not been the pointy tip of the spear on risk-informing. I don't say that as a
21 criticism. I say it because well, there's multiple contributing factors for that.
22 Some are really obvious like reactors have -- there's more homogeneity
23 there so we can extract the data points to do better risk-informing on the
24 operating reactors side. Here, as I was just noting, you have a small
25 number of facilities. And even amongst themselves in a category, there is
26 like a lot of -- well, there's enough diversity there that risk insights are not as
27 readily extracted.

1 So when I couple the notion of you know we need to make
2 the case that this is -- we are right-sized for the level of activity, we have not
3 in 2008 but in 2018 and '19, and 2020. And then we've got more you know
4 heterogeneity here. The facilities are more different. So, we've got more
5 challenges here.

6 But the other thing that we haven't talked about is
7 Wyoming becoming an Agreement State when you know we'll have like two
8 people left for a whole program -- I mean two regulated entities.

9 And so I just -- I'm feeling -- I don't mean to like infect
10 everyone with my anxiety but I think that this is a really novel and
11 challenging issue. And I think that if at the end of the day we needed relief
12 as an agency and that 90 percent, again, that's our work to do. It's for us to
13 make a case one way or another. Maybe we would get relief and maybe we
14 wouldn't from the Congress but this is, again, the U.S., as I understand it, as
15 a policy, wants to have a nuclear program. And, therefore, we regulate it.

16 And if this 90 percent recovery thing, at some point,
17 becomes such a barrier that certain aspects of the industry can't sustain the
18 90 percent fee recovery, we're the experts in that. So we need to be ahead
19 of that issue and not behind it.

20 So, I spent a lot of time talking about it. I did have a
21 question, which is, is it time to combine the RIC with the, what is it -- FCIX?

22 I know you did a segment of the RIC. Was that -- but I'm
23 wondering the fact that the RIC is, in theory, reactor-centric, is that kind of
24 archaic and should we just combine those? Because again, to take the
25 point that all of the reactor industry is affected by everything we're talking
26 about today.

27 MR. McCREE: Might I start and --

1 CHAIRMAN SVINICKI: Yes.

2 MR. McCREE: -- Marc can finish. And I would also like
3 to speak to your first point.

4 On the second question, is it time? The answer is yes, as
5 far as I'm concerned. In fact, I asked that question ten years ago and Mike
6 Weber and I --

7 CHAIRMAN SVINICKI: So maybe it's past time.

8 MR. McCREE: No, Mike Weber and I met at a restaurant
9 just north of here and we asked that. There are a number of things that
10 have pushed against that but Marc knows that I socialized that with him as
11 recently as a little over two years ago.

12 I believe it's time. I believe we can do it. We may have
13 to modify the length of the RIC to do it more in a more fulsome way. But
14 given the participants in the Regulatory Information Conference which, as
15 you know, includes a number of people from the fuel cycle industry senior
16 leaders who are synergizing with other -- with the rest of the fuel cycle, I
17 think it's an opportune time.

18 CHAIRMAN SVINICKI: Well, and as we're discovering
19 with advanced reactors, you know what, you've got to have fuel.

20 MR. McCREE: All of the above, right.

21 CHAIRMAN SVINICKI: Okay, fuel is not a thing you think
22 about later.

23 MR. McCREE: Right. So Marc has a tasking to work
24 with Mike and to work with Brian to enable that in 2019. So that's the short
25 answer. There's no direction yet but again --

26 CHAIRMAN SVINICKI: Well, of course the Commission
27 would have to be supportive of it but I'm just asking the question.

1 MR. McCREE: Indeed. Indeed. But to begin to work to
2 strategize around what it would look like, what the implications would be.

3 Chairman, on next Wednesday, the senior leaders will hold
4 a strategic leadership meeting. Your first topic area, it is indeed
5 challenging. It's novel but it's also timely that we engage that. So we have
6 about a two-hour session scheduled in the afternoon for the senior
7 leadership team to engage in a philosophical conversation.

8 I think it's an actionable conversation about what we would
9 do about this impending challenge. So I look forward to briefing you on the
10 results of that.

11 CHAIRMAN SVINICKI: Well and I think it helps that we
12 are being asked this by the body that would have to be a part of making a
13 change, which is the United States Congress. And I appreciate your looking
14 at it.

15 I was asked just that question in one of our hearings last
16 month. They said, well is it time to engage the Congress on this? And I
17 said in my individual view, yes, it probably is. But we do have some
18 analysis to do first. So I appreciate that you're thinking about that.

19 I'm over my time. Thank you.

20 And next we will hear from Commissioner Baran.

21 COMMISSIONER BARAN: Thanks. Thanks for your
22 presentations.

23 I'd like to ask about the proposed rule on cyber security for
24 fuel cycle facilities, which the Commission is currently considering.

25 In March 2015, the Commission decided that this
26 high-priority rulemaking should be completed in an expeditious manner.
27 The draft proposed rule would require fuel cycle facilities to implement a

1 cyber security program capable of detecting, protecting against, and
2 responding to cyber-attacks that could cause consequences of concern.

3 Craig, I want to start by asking about the basic need for
4 this rulemaking. NRC does not currently have specific cyber security
5 requirements for fuel cycle facilities. Is that right?

6 MR. ERLANGER: Commissioner, yes, that is correct.

7 Currently, there are two requirements in place. One is the
8 Interim Compensatory Measures Orders of 2002. That was general, as it
9 spoke to cyber. It focused more on emergency planning and offsite
10 communications. There was no specific guidance that accompanied that
11 ICM order related to cyber.

12 The other rulemaking -- the other regulatory requirement in
13 place is the Design Basis Threat Rule. And that has aspects that apply to
14 our Category 1 fuel cycle facilities. However, again, it's not comprehensive
15 in that it doesn't consider the scope of the proposed rule as it relates to
16 safety, security, and safeguards functions.

17 COMMISSIONER BARAN: Instead, licensees have
18 implemented voluntary measures. The NRC staff has previously
19 characterized these voluntary measures as limited and ad hoc. Is that still
20 the staff's assessment?

21 MR. ERLANGER: I'll begin this answer and if any of my
22 colleagues have anything more to offer -- based upon our site visits, the
23 implementation of cyber security varied site-by-site.

24 Our overall analysis and it would be a generalization is,
25 depending on the site you went to, there was varying degrees of
26 implementation of the voluntary initiatives.

27 Additionally, I think the staff would say that they were not

1 comprehensive in nature in that they did not consider all of the elements that
2 were presented in the proposed rule and draft regulatory guide.

3 MR. DAPAS: I just would offer the perspective that, given
4 there was that variability, the staff felt there was vulnerability to a cyber
5 attack vector, given that those measures were not comprehensive.

6 But I will offer the industry has indicated that they think the
7 measures they have in place are sufficient. They don't challenge whether a
8 cyber threat needs to be addressed. I think it's more a function of what the
9 licensees in place they feel is sufficient and a comprehensive requirement as
10 reflected in the proposed rule is not necessary.

11 COMMISSIONER BARAN: So I just want to be clear
12 about what the staff's view is on this. Based on your evaluation, are these
13 fuel cycle facilities still vulnerable to cyber security threats?

14 MR. ERLANGER: So from my perspective is anywhere
15 there is the use of digital technology, the potential exists for vulnerability.

16 We, over the development of the proposed rule package,
17 and in the development of our guidance, and our site visits, we identified
18 digital systems that were in use at these facilities.

19 From the information that we've received from the
20 interagency, vulnerabilities do exist in both hardened and non-hardened
21 digital systems.

22 MR. DAPAS: The only thing I would offer, Commissioner,
23 is I've been extensively involved in the preparation of the proposed rule and I
24 would offer, based on the briefings that I have received from the staff, and an
25 opportunity to talk to licensee management when I visited the facilities, from
26 my perspective there is a vulnerability that exists, notwithstanding the
27 measures that the licensee has implemented to date.

1 COMMISSIONER BARAN: Has the staff actually
2 observed potentially exploitable vulnerabilities during site visits?

3 MR. ERLANGER: I will emphasize the word potential
4 because of the use of digital systems, yes. What we lack, though, is absent
5 the comprehensive analysis and the approach that was provided in the rule,
6 you only know what you know. So potentially by the fact that the digital
7 systems are in use at facilities, the potential does exist.

8 COMMISSIONER BARAN: So the steps identified
9 specific systems and networks necessary for safety and security that are not
10 hardened against a cyber attack?

11 MR. ERLANGER: I would charac -- I would answer the
12 question as looking at it from a vital digital asset and system level. There
13 were systems that were identified that could warrant further protection.

14 I would point to Appendix B of the proposed rule, Appendix
15 B of the draft regulatory analysis. In that -- and I believe the title was
16 Vulnerability of Fuel Cycle Facilities, and that's publicly available -- what the
17 staff did in there was spoke to the case made by the interagency but also
18 provide illustrative examples of cyber attacks outside of the fuel cycle but
19 analogies could be drawn based upon the methods that were employed in
20 those instances.

21 COMMISSIONER BARAN: Does the NRC staff currently
22 have any oversight inspection or enforcement authority to ensure that the
23 voluntary cyber security measures taken by fuel cycle facilities are
24 adequate?

25 MR. ERLANGER: Not for the voluntary measures. We
26 do not.

27 COMMISSIONER BARAN: Are the consequences of

1 cyber attacks on fuel cycle facilities potentially significant in terms of safety
2 and security?

3 MR. ERLANGER: Yes, we structured the rule to focus on
4 safety, security, and safeguards functions. The consequences we directly
5 tied to the requirements in Part 70. We did that, based in part, on some of
6 our learnings from the reactor rulemaking related to cyber security about
7 having specific consequences.

8 What I'm referencing is the limits that appear in Subpart H
9 of the Part 70 requirements.

10 COMMISSIONER BARAN: Are fuel cycle facilities
11 currently required to consider potential radiological and chemical
12 consequences of cyber attacks in their integrated safety analyses?

13 MR. ERLANGER: I'll take this one as well. No, because
14 of the fact that cyber security is predicated on a bad -- an actor, a malevolent
15 actor and not safety. They do not.

16 COMMISSIONER BARAN: NRC initiated this rulemaking
17 three years ago. Would you say the cyber security threats to fuel cycle
18 facilities have increased, decreased, or stayed the same since that time?

19 MR. ERLANGER: My perspective and based upon just
20 my reading of what's in the news and participation in the interagency is the
21 threat to cyber just globally continues to increase.

22 COMMISSIONER BARAN: Given all that, I think it's pretty
23 clear that we need to move forward with this rulemaking so, I'm working on
24 this now.

25 Let me ask a couple of aspects -- about a couple of
26 aspects of the proposed rule or the draft proposed rule.

27 The safety consequences of concern in the draft proposed

1 rule include events that may impact only on-site personnel and not the
2 broader public. What was the thinking behind that?

3 MR. ERLANGER: I can start this and I'll ask Brian, if you
4 could, jump in and support me on this one.

5 In taking the example of criticality, that is likely to have an
6 on-site consequence, an impact on a worker. If you transition to the topic of
7 chemical hazards, chemical safety, while there may be both an on-site and
8 an offsite consequence.

9 So part of our thinking was to align this rulemaking with
10 some of the foundation principals that are found in Part 70.

11 MR. SMITH: I's just have to echo what Craig said. It
12 kind of parallels what we did with the ISA requirements in Subpart H of Part
13 70, where we have the performance requirements related to consequences
14 for members of the public who are offsite but also the workers who are
15 on-site.

16 COMMISSIONER BARAN: So just to boil that down to
17 make sure I understand it, so the staff's view is that fuel cycle facilities
18 should be able to defend against a cyber attack that could cause a criticality
19 event or acute chemical exposure to workers. That's the staff's view.

20 MR. ERLANGER: Yes, and we would tie it back to the
21 performance objectives in Part 70 about what those limits are.

22 COMMISSIONER BARAN: Makes sense to me.

23 The draft proposed rule also requires a licensee to have a
24 cyber security program, even if the facility doesn't currently have any vital
25 digital assets. What was the thinking behind that?

26 MR. ERLANGER: Brian, again, you want to start this one
27 or I can --

1 MR. SMITH: Yes, we have the requirement in the
2 proposed rule to establish a plan. And as part of that plan is a methodology
3 to determine if you have any vital digital assets. So we believe that the plan
4 is necessary so that they can make that determination themselves and going
5 forward.

6 Part of the plan and the requirements includes the
7 configuration of management program aspects, such that if they make
8 changes to controls, safety/security controls in the future, that they would
9 evaluate that against the vital digital asset determination.

10 COMMISSIONER BARAN: So even if they don't have any
11 vital digital assets now, they may have in the future. And if they did, they
12 would need to take steps to protect from a cyber point of view.

13 MR. SMITH: That's correct.

14 MR. DAPAS: Just one point to add. There's been a fair
15 amount of discussion with the industry about a facility. If you don't have any
16 vital digital assets why do you need to maintain the infrastructure, especially
17 with the cyber security team?

18 I would offer, in response to public comments that may be
19 offered if the proposed rule is published, that's an area that we need to
20 continue to look at there. You know what exactly would be required of a
21 licensee if they don't have any vital digital assets?

22 What expertise do you need to maintain or can you
23 contract that expertise, such that if you introduce digital assets in a process
24 system, how would they be evaluated to determine whether that digital asset
25 is in fact a vital digital assets, or whether there is an alternative means that
26 can be credited to ensure the function is maintained?

27 COMMISSIONER BARAN: Well, thank you. Thank you

1 all for your hard work on this important rule. I appreciate it. Thanks.

2 CHAIRMAN SVINICKI: Thank you, Commissioner Baran.

3 Commissioner Burns.

4 COMMISSIONER BURNS: Thank you for the
5 presentations this morning.

6 I'm going to probably hop around a number of areas
7 versus focusing on a particular one.

8 One of the things I'm interested in sort of leading off I think
9 from where the Chairman started in her remarks is this question of what the
10 things look like. Now you said in 2021 -- what is it that we expect in 2021?
11 Is it a new facility?

12 MR. SMITH: X-Energy, a new reactor designer for a
13 pebble bed reactor.

14 COMMISSIONER BURNS: Okay.

15 MR. SMITH: They're interested in fabricating -- or in
16 building -- a fabrication facility.

17 COMMISSIONER BURNS: A fabrication type facility.

18 MR. SMITH: For TRISO fuel, yes, sir.

19 COMMISSIONER BURNS: And we talked about now that
20 there are estimates for the number of license actions. And what I want you
21 to do for me is also define what a licensing action is because I think
22 sometimes, as a lawyer, I think of it as something different than the staff
23 actually uses it in terminology.

24 This number of 50, so tell me what a licensing action is
25 and tell me how many, as we are halfway through the fiscal year, where are
26 we with respect to that estimate of 50?

27 MR. ERLANGER: So a licensing action can be

1 determined as an amendment, say a triennial requirement, where a
2 decommissioning funding plan needs to be submitted.

3 It's virtually everything absent a license renewal. And why
4 I separate the two is based upon the complexity of rules -- renewals in our
5 metrics, we have chosen to treat them as licensing actions but not count
6 them in our number of licensing actions on an annual basis, if that makes
7 sense.

8 So the 58 number for this year includes amendments,
9 whether it's triennial submissions, administrative changes at the facility,
10 updates to physical security plans, those would be what we're talking about
11 when we talk about licensing actions.

12 While license renewals are licensing actions, we're just not
13 counting them in that 58.

14 COMMISSIONER BURNS: Because they are more
15 complex.

16 MR. ERLANGER: Correct, and the time associated.

17 COMMISSIONER BURNS: Okay. So where are we
18 halfway through this fiscal year?

19 MR. ERLANGER: Brian, do you happen to know a
20 number offhand?

21 MR. SMITH: I do not. The last time we were briefed was
22 about a month or so ago and we were on track to complete about that many,
23 around 50.

24 COMMISSIONER BURNS: Okay.

25 MR. ERLANGER: Commissioner, what I will offer is that
26 as we developed the slides, we did extrapolate out based upon what has
27 occurred and what we anticipate coming in. So when we came up with the

1 number, there was some thought behind it.

2 COMMISSIONER BURNS: Okay. Well, maybe you can
3 get that number for me after the meeting.

4 One other thing, there was a lot of description of process
5 reviews, looking at things like -- you know some of the things which, quite
6 honestly, have been a focus for or in areas of refocus the last few years, not
7 only in this area but in the reactor area, how we use RAIs, how we
8 implement the backfitting rule, sort of resetting and things like this.

9 And I think, Craig, you described a number of initiatives.

10 Another one was this licensing process commonalities and
11 I didn't get so far to write down the last piece of it. Is that a cross-office
12 organization?

13 MR. ERLANGER: Yes, it is. It was an initiative that was
14 started by NRR.

15 COMMISSIONER BURNS: Okay.

16 MR. ERLANGER: And we participated in it. We found a
17 lot of benefit in sharing practices across the agency and the offices. And
18 we're learning a lot from one another. And we've picked a few topical areas
19 that we want to work on together moving forward.

20 COMMISSIONER BURNS: Okay. And so give me some
21 specific accomplishments and implementations from these various what I will
22 call reform efforts. Where have we seen actual results in application?

23 We may have identified, for example, being better about
24 RAIs. I remember my question in front of the Senate EPW and fortunately, I
25 had had a heads up that that was coming about why we're asking whether
26 the United States Geologic Service was a non-foreign dominated
27 organization, although go into the Russian -- stuff.

1 So but for example, where are -- what are specific
2 accomplishments, a specific thing, areas where we think we have made an
3 improvement and can show an improvement?

4 MR. ERLANGER: Sure, I can start and Brian, if you have
5 any to add in, please do.

6 First, in the development of safety evaluation reports, in
7 the past week we issued the license renewal for the Pennsylvania State
8 University. This is after the Massachusetts Institute of Technology renewal
9 which occurred earlier this year.

10 We learned a lot about SER format and content and we
11 were able to pay that forward and that is representative in the Penn State
12 renewal that went out last week, earlier this week. So that was one
13 example where we did a self-assessment, we learned things, and we have
14 already begun to implement changes.

15 Another on that I'll point out deals with hourly estimates,
16 cost estimates. It was brought to -- we were aware of bit but it was also a
17 conversation we had with the industry about the benefits of providing cost
18 estimates when we put out our acceptance review letters. We've
19 implemented that with one licensee recently and we've formalized and put
20 out guidance to project managers regarding expectations for hourly
21 estimates.

22 So that's two that I'd point to where we've actually
23 identified it and implemented the fixes.

24 COMMISSIONER BURNS: Okay, Brian did you --

25 MR. SMITH: In the area of RAIs analysis that we did
26 previously, I think we determined that the guidance that we had in place was
27 fairly robust.

1 We did identify a tool I believe that NRO utilized that we
2 wanted to take advantage of and kind of modify for our own use. So we're
3 in the process of doing that now.

4 We did do a training session on RAIs to reinforce that
5 guidance this past summer. And so we're moving forward with
6 development.

7 MR. DAPAS: One other thing I'd offer, Commissioner, is
8 we have a graded approach regarding the level of supervisory review and
9 involvement there.

10 If you're going out with a second round of requests for
11 additional information, that requires a higher level of management review.
12 And the focus there is to ensure that the questions are associated with
13 specific gaps in information that are necessary in order to make a safety
14 conclusion versus not exercising a sufficient level of discipline where a
15 reviewer may be of the view I'd like to know this. Well, explain the nexus to
16 the gap in information that exists in this submittal such that you need that
17 information in order to be able to make a conclusion regarding reasonable
18 assurance of adequate protection.

19 And then the other thing that we're doing where I think
20 there's tangible results is other offices have conducted self-assessments
21 regarding the RAI process and shared the results of those self-assessments.

22 I think I've mentioned that in previous business line Commission meetings
23 and that has been particularly valuable. And it reinforces that community of
24 practice, sharing lessons learned as part of any agency collective effort to be
25 more disciplined in the RAI process because we recognize that that has an
26 impact on the licensee in preparing responses and the timing of the licensing
27 review.

1 And if I could just offer one quick perspective, while we are
2 looking at how to be more efficient in the licensing review process, one of
3 the challenge is while there has been a 38 percent reduction in the FTE of
4 between 2012 and 2018, the challenge is that the Part 170 services fees
5 associated with licensing actions or inspections has decreased and it's
6 decreased at a greater rate than the budget has decreased, if you will. So
7 the percentage of hourly fees associated with the budget is less. Therefore,
8 the annual fee hasn't had the corresponding same decrease.

9 And I just point that out because that is one of the -- you
10 mentioned, Chairman, the multi-variables that come into play. That is one
11 factor.

12 COMMISSIONER BURNS: Yes, I understand. That's I
13 think we have a consciousness of. So, I appreciate that, Marc.

14 One of the things, as I recall either talking to Marc or
15 others on this, one sort of challenge we have, and I just am interested where
16 that might stand is the question of how we report under the INES scale on
17 international events. And that's -- it's been a little fragile. Maybe that's the
18 way it is.

19 I will say, personally, I am not one who is -- I think we
20 should meet our international obligations but I am not obsessed with the
21 reporting system because it really should be -- it's a backward looking
22 system. But I know, in talking with you, Marc, is there have been some
23 issues with that. And if you could just update me on what -- you know
24 where we sort of tried to maybe normalize or get things on what you would
25 see as the right track in that regard.

26 MR. DAPAS: Well, thank you for that question. I know
27 we've had a fair amount of discussion on that subject matter.

1 And from my perspective, I think it's important that when
2 we make a report, it's as accurate as it can be. You know we don't want to
3 be unnecessarily alarmists in the fog of war, if you will. If we subsequently
4 learn information, it may indicate that reportability thresholds were in fact not
5 met.

6 So while there are timeliness requirements, we really are
7 trying to strike the right balance to ensure that we have sufficient information
8 to make a fully-informed assessment whether the criteria been met, yet not
9 be overly or spend an inordinate amount of time there trying to obtain as
10 much information. You know there is a balance that we strike there.

11 And I think that we have had discussions with the
12 individuals that would be involved in determining whether an event is
13 reportable. We've, of course, engaged with NSIR. And Trish Mulligan that
14 plays a significant role as kind of the owner of the INES reporting system.

15 And I think that we have made progress there. I will offer,
16 you know it's part of the changed management. There are some staff that
17 feel you communicate what you have within what -- is it 24 hours or 72 -- I
18 don't remember the exact time frame. And if you have to update, you have
19 to update. I'll just offer I am of the view it may be prudent to spend a bit
20 more time to ensure that we have a solid basis for making a report.

21 COMMISSIONER BURNS: Yes, I tend to be with you
22 because I think you know reflecting on the Fukushima Daiichi accident, I
23 think my view of what, frankly, Japan did in terms of reporting it at certain
24 levels and then increasing the level, and then increasing as the event was
25 progressing was, frankly, counterproductive on that. But that's my opinion.

26 I'm over my time. Thanks, Chairman.

27 CHAIRMAN SVINICKI: Well, again, I thank this panel for

1 their presentations.

2 We will take a short break until 10:40 and we will
3 reconvene for Panel 2.

4 Thank you.

5 (Whereupon, the above-entitled matter went off the record
6 at 10:32 a.m. and resumed at 10:39 a.m.)

7 CHAIRMAN SVINICKI: Well, thank you, everyone. Let's
8 -- if we can come to order and people can retake their seats.

9 Now, we will proceed with the second panel where the
10 staff will present on the Nuclear Materials Users Business Line.

11 And, once again, Vic, if you will lead off the staff's
12 presentation? Thank you.

13 MR. MCCREE: Okay, good morning again, Chairman and
14 Commissioners.

15 Let's pivot to slide 33, please? Very good, thank you.

16 With me at the table again is Marc Dapas who will provide
17 a strategic overview of the Nuclear Material Users Business Line.

18 He'll be followed by Kevin Williams, Acting Director of the
19 Division of Material Safety Security State and Tribal Programs, MSST, who
20 will discuss the Current National Materials Program environment.

21 Next, Aaron McCraw, on my left, Chief of the Materials
22 Inspection Branch Division of Nuclear Materials Safety in Region III will
23 discuss the Regional Materials Licensing and Inspection Program Activities.

24 And, lastly, Linda Howell, to Aaron's left, the Acting Deputy
25 Director of the Division of Materials Safety Security State and Tribal
26 Programs will discuss the status of NRC activities regarding emerging
27 medical activities.

1 Similar to the presentation of the fuel facilities business
2 line, you'll hear examples of where we've taken actions to improve the
3 efficiencies and effectiveness of our programs.

4 In addition, we'll make mention of the Office of the
5 Inspector General Audits related to Tribal outreach and consultation and the
6 National Materials Program.

7 Additionally, the Government Accountability Office, or
8 GAO, conducted an audit of Tribal Consultation for Infrastructure Projects
9 and there's one ongoing GAO audit of Part 37 effectiveness.

10 So, with that brief introduction, I'll turn the presentation
11 over to Marc.

12 Next slide, please?

13 MR. DAPAS: Thank you.

14 Again, good morning, Chairman and Commissioners.

15 One quick thing before I start with my formal presentation.
16 During the question and answer session previously, I think I made reference
17 to Trish Milligan instead of Trish Mulligan.

18 I'm traveling Saturday to Myrtle Beach for a golf vacation.
19 I think I have golf on my mind.

20 (LAUGHTER)

21 MR. DAPAS: So, my apology to Trish.

22 Next slide, please?

23 The work within the Nuclear Materials Users Business Line
24 is significant in terms of its breadth and scope. It includes the materials
25 licensing, inspection, security and Agreement State program oversight in the
26 context of the National Materials Program as well as federal, state, and
27 Tribal programs.

1 Given the broad range of activities and interests in this
2 business line, we continue to communicate and coordinate with stakeholders
3 to ensure external factors that may affect the business line are identified
4 early and that strategies are adopted to mitigate the potential uncertainties
5 and disruptions to the business line activities.

6 We continue to focus on effectively managing the current
7 work load as well as preparing for future workload changes and potential
8 challenges.

9 For fiscal year 2018, the Nuclear Materials Users Business
10 Line consists of 223 full-time equivalent, of FTE, and \$22.7 million in
11 contract support and travel, excluding corporate support resources which is
12 about 6.6 percent of the Agency's FTE budget for fiscal year 2018.

13 The majority of the resources reside in the oversight,
14 generic homeland security and licensing product lines.

15 Next slide, please?

16 We have completed several activities and are actively
17 working on a number of high priority items. For example, as Vic mentioned,
18 we are supporting GAO's engagement to assess the effectiveness of 10
19 CFR Part 37 for NRC and Agreement State licensees.

20 This engagement was mandated by legislation and the
21 results will be reported to Congress in December of this year.

22 On a related note, we completed our review of the
23 effectiveness of Part 37 back in December of 2016 and we are working to
24 address recommendations deriving from that effort.

25 You will hear more about this during Kevin Williams'
26 presentation.

27 In addition, the NRC's Office of the Inspector General, or

1 OIG, initiated an audit of the National Materials Program on July 31st 2017.

2 The objective of the audit was to determine if the National
3 Materials Program is an effective and efficient framework for carrying out the
4 NRC and Agreement State regulatory programs.

5 The OIG provided its audit findings and recommendations
6 on April 4th of this year.

7 The third high priority item for us is the review of Draft
8 Agreement submitted by the States of Vermont and Wyoming to assume
9 regulatory authority for byproduct and/or source material.

10 The two submittals are different in that Vermont is seeking
11 regulatory authority for a spectrum of programs and materials that the NRC
12 currently regulates while Wyoming is seeking only limited regulatory
13 authority.

14 Vermont's draft application to enter into an agreement with
15 the NRC to assume regulatory authority covers byproduct material, source
16 material and special nuclear material in quantities not sufficient to form a
17 critical mass.

18 The draft application was submitted on September 15t,
19 2017. Currently, there are approximately 36 specific licenses in the State of
20 Vermont that would be transferred from the NRC.

21 Only seven of these licensees are inspected at a
22 frequency of three years or less, specifically for medical centers, two mobile
23 medical units and one nuclear pharmacy.

24 Unlike other states seeking agreements in the last 20
25 years, the State of Vermont does not have an established licensing or an
26 inspection program for radioactive materials such as naturally occurring
27 radioactive material, or NORM, as a starting point for an agreement

1 program.

2 We are completing our assessment of the draft agreement
3 application and working closely with the Vermont Department of Health to
4 facilitate the timely completion of the agreement.

5 Kevin Williams will discuss the status of our review of the
6 draft agreement submitted by the State of Wyoming during his presentation.

7 Next slide, please?

8 Another high priority item that we have been working on
9 involves Native American Tribes. We are implementing the Commission's
10 direction in the Tribal Policy Statement regarding engagement of Native
11 American Tribes.

12 We have revised the Tribal Protocol Manual to reflect the
13 six overarching principles in the Tribal Policy Statement and are currently
14 updating Management Directive 5.1 entitled Intergovernmental Consultation.

15 We conducted outreach with Tribal organizations to
16 increase their awareness of the Tribal Policy Statement, the Revised Tribal
17 Protocol Manual and our activities of interest to the Tribes.

18 We supported the GAO's engagement on Tribal
19 consultation for infrastructure projects which was initiated in March of last
20 year.

21 This engagement focused on several federal agencies
22 involved in the Federal Permitting Improvement Steering Council including
23 the NRC.

24 The GAO conducted an exit briefing with us on March 26,
25 2018 and has indicated that its findings and recommendations will be
26 provided in the near future.

27 As previously mentioned, the OIG initiated an audit of our

1 Tribal outreach and consultation activities on August 1st, 2017. The
2 objective of the audit was to determine if our Tribal outreach and
3 consultation efforts are efficient and effective.

4 The OIG conducted an exit and providing its audit findings
5 and recommendations on April of this month on April 4th.

6 Another priority item is the State Liaison Officers, or SLO,
7 program activities. On September 26th through 27th, 2017, we hosted the
8 National SLO Conference to deliver timely information on our activities and
9 to enhance communication with state stakeholders.

10 Forty SLOs attended the event. Topics discussed
11 included spent fuel management, transportation of radioactive materials,
12 reactor decommissioning, source security and accountability, non-Military
13 radium, reactor emergency preparedness, and cybersecurity.

14 Additionally, we offered optional training sessions on topics
15 such as Small Modular Reactors, emergency preparedness rulemaking
16 associated with advanced reactors as well as core damage assessment
17 training.

18 With that, let me know turn the presentation over to Kevin
19 Williams.

20 Next slide, please?

21 MR. WILLIAMS: Thank you, Marc.

22 Good morning, Chairman and Commissioners. My
23 presentation will focus on the National Materials Program and the NMU
24 Business Lines accomplishments and ongoing activities.

25 I will discuss certain aspects of the National Materials
26 Program with a focus on engagement, partnering, and outreach.

27 Our last Commission briefing with respect to the NMU

1 Business Line was in March of 2017. Since that time, we have realized a
2 number of accomplishments and made significant progress on some
3 important initiatives.

4 First, let me provide some general background on the
5 National Materials Program and the NMU Business Line.

6 Next slide?

7 The National Materials Program is a broad, collective
8 framework within which both the NRC and the Agreement States function in
9 ensuring the safe and secure use of radioactive materials.

10 Between the Agreement States and the NRC, we regulate
11 licensees that range from companies that utilize well logging sources to
12 large medical users.

13 About one-third of all materials, licensees are engaged in
14 diagnostic or therapeutic medical activities.

15 A small number are academic or research users and a
16 majority of the remaining licensees use radioactive materials for commercial
17 or industrial purposes such as radiography, soil density testing using
18 portable gauges and sterilization of material using irradiators.

19 On this are some pictures depicting different applications
20 of the use of nuclear materials.

21 The number of materials licensees remain relatively stable
22 in providing for an effective national materials program, it is essential that
23 NRC and Agreement States work collaboratively to provide oversight for the
24 wide variety of licensees.

25 Next slide?

26 We continue to effectively engage the Agreement States
27 as our regulatory partners in a variety of activities.

1 These activities include participation in working groups for
2 guidance development and Agency evaluations of regulatory approaches
3 that directly impact Agreement State program.

4 Agreement States are currently supporting 18 working
5 groups. Our interactions with Agreement States also include the monthly
6 conference calls with the Organization of Agreement States, or OAS, and the
7 Conference of Radiation Control Program Directors, or CRCPD.

8 These monthly calls cover a wide range of regulatory
9 topics and include non-military radium related activities as a standing topic.

10 With respect to OAS, just last month, I attended the OAS
11 annual Board meeting which provided me the opportunity to coordinate our
12 shared effort to enhance oversight of the National Materials Program.

13 The timing of this was particularly important in light of the
14 recent OIG audit of the National Materials Programs.

15 In the past year, we have collaborated with Agreement
16 States on a number of non-military radium related oversight activities.

17 The Agreement States are actively addressing potential
18 contamination and developing our implementing plans to address potential
19 historical non-military radium use based on the site information that we
20 provided the states or that they obtained through their own evaluation.

21 In July of 2017, we collaborated with our Agreement State
22 partners on a webinar to discuss non-military radium related activities. The
23 webinar included presentations from Nevada, Ohio, Pennsylvania,
24 Washington, and the NRC on how sites with potential historical non-military
25 radium use are being dispositioned including descriptions of specific
26 challenging cases and lessons learned.

27 In August of 2017, we participated along with staff from

1 Massachusetts, New Jersey, and Ohio in a panel discussion on non-military
2 radium use, I mean, radium, during the OAS annual meeting.

3 Over the past year, Agreement States have shared with us
4 the results of their site investigations. At this time, 13 Agreement States
5 have completed their respective site investigations and do not plan any
6 further actions.

7 Moving forward, we will maintain non-military radium
8 activities as a standing discussion item on the OAS and CRCPD monthly
9 teleconferences, continue our collaboration and related activities and provide
10 status updates to the Commission.

11 Next slide, please?

12 We are fully engaged with the State of Wyoming on its
13 Agreement State application and we continue to work closely with the
14 Wyoming Department of Environmental Quality to facilitate the timely
15 completion of the agreement.

16 By way of background, of February 27th of 2015, Governor
17 Mead of Wyoming submitted a Letter of Intent for the State of Wyoming to
18 become an Agreement State, a limited agreement to regulate source and
19 byproduct material as defined 11(e)(2) of the Atomic Energy Act.

20 11(e)(2) byproduct material is defined as the tailings or
21 waste produced by the extraction or concentration of uranium and thorium
22 from any ore processed primarily from -- for its source material content.

23 The Commission approved Wyoming's proposed approach
24 to enter into a limited agreement in August of 2016.

25 The limited agreement would include 14 uranium mill sites
26 and excludes the American Nuclear Corporate site which would remain
27 under NRC jurisdiction.

1 On October 28th or 2016, the State of Wyoming submitted
2 a draft application for a limited agreement and we are continuing our
3 assessment of the state's formal request.

4 We plan to ask for Commission approval to publish the
5 results of our assessment as well as the draft agreement for public comment
6 next month.

7 Next slide, please?

8 We continue to enhance our outreach activities with Native
9 American Tribes. I will discuss two examples of our successful efforts in
10 that regard.

11 The first example involves engagement with the Catawba
12 Nation of Indians whose reservation is situated within 55 miles of Summer,
13 McGuire, and Robinson Nuclear Power Plants.

14 Through our outreach activities, we have established a
15 cooperative relationship with the Catawba Indian Nation. We have
16 discussed a number of activities such as consultation, outreach, training,
17 and the NRC's licensing process.

18 Because of it's close proximity to the Catawba Nuclear
19 Power Plant, 12.5 miles, the Tribe has expressed interest in expanding the
20 emergency planning zone to include the Tribal reservations.

21 Our outreach activities involved NRC staff from NMSS
22 Region II and the Technical Training Center and it included a government to
23 government meeting hosted by the Tribe at the Catawba Nation
24 Reservations in South Carolina.

25 Over 20 individuals from the Catawba Nation, including
26 members of the Tribal Counsel, the Catawba Environmental Services
27 Department, and the Catawba Department of Transportation participated in

1 the government to government meeting.

2 During the meeting, we provided training on the NRC's
3 mission, the environmental review process and associated legislation, health
4 physics, the reactor oversight process, and emergency preparedness.

5 A second example of our successful outreach activities are
6 those involving the Navajo Nation.

7 With respect to the Navajo Nation, the NRC is one of six
8 federal agencies supporting uranium contamination cleanup. As part of the
9 federal five-year plan to address uranium contamination in the Navajo
10 Nation, each agency is contributing to community education and knowledge
11 development.

12 In the 2014 and 2015 time frame, we provided training at
13 two Navajo Nation colleges, Navajo Technical University and Dine College
14 on basic health physics and radiation safety.

15 In response to requests to provide more of this type of
16 training, we have been working collaborative with the Navajo Technical
17 University and Dine College to provide them with the NRC's fundamental
18 health physics course material.

19 Making this online course material available at the Navajo
20 colleges will facilitate access for students as well as community members
21 who may want to increase their knowledge in this area.

22 Navajo Technical University has adopted the course
23 material and is using it this semester. Dine College is currently evaluating
24 the course for future implementation.

25 Next slide, please?

26 We continue to work actively with our federal partners to
27 ensure that the infrastructure for the security of risk significant radioactive

1 sources provide for the secure use of radioactive materials.

2 One area of collaboration is participation in the Radiation
3 Source Protection and Security Task Force which was established by the
4 Energy Policy Act of 2005 to provide recommendations relating to the
5 security of radioactive sources in the United States from potential terrorist
6 threats, including acts of sabotage, theft or use of a radiation source in
7 radiological dispersal device or radiation exposure device.

8 We have worked diligently to achieve alignment among the
9 task force member agencies on the status of existing recommendations as
10 well as the development of new recommendations related to alternative
11 technologies, end of life management for risk significant or Category 1 and
12 Category 2 sealed sources, and ultimate disposition of sealed sources.

13 In August, the NRC will submit to the President and
14 Congress the fourth report of the task force.

15 Next slide, please?

16 With regard to the area of cybersecurity, in October of
17 2017, we completed our evaluation of cybersecurity for byproduct materials
18 licensees and determined that the current threat environment does not
19 warrant developing new regulations relating to the protection of risk
20 significant radioactive materials against cyber threats.

21 This conclusion was based, in part, on the fact that risk
22 significant radioactive materials licensees do not rely solely on digital
23 systems to ensure safety or physical protection.

24 Nevertheless, we determined that it would be prudent to
25 develop an information notice to communicate effective practices for
26 cybersecurity for licensees that possess risk significant radioactive materials.

27 The information notice will provide licensees with a better

1 understanding of contemporary cybersecurity issues and enable licensees to
2 consider strategies for protection to protect digital assets, for example,
3 computers and digital alarm systems including those assets used to facilitate
4 compliance with physical security requirements in 10 CFR Part 37.

5 In the interest of openness and transparency, we
6 communicated the results of our evaluation and the associated path forward
7 on the NRC public website.

8 Next slide, please?

9 With regard to source security and accountability, we are
10 making significant progress in our effort to address recommendations for the
11 program review of 10 CFR Part 37.

12 In early 2018, we issued RIS 2018-01. This RIS provided
13 information concerning common violations identified in the first two years of
14 the NRC licensee implementation of Part 37 and reminded licensees of
15 resources available to effectively implement requirements of the rule.

16 Next slide, please?

17 We also developed a draft revision to NUREG-2155 which
18 pertains to physical protection requirements of Part 37 to incorporate
19 numerous clarifications and enhancements aimed at improving licensee
20 understanding and implementation of the rule.

21 The NUREG is in its final stage of development, and once
22 finalized, it will be issued for public comment.

23 In addition, we are in the early stages of preparing a
24 rulemaking plan to address recommendations stemming from Part 37
25 program review and petition for rulemaking from the Nuclear Energy Institute
26 to amend Part 37 to address larger components and robust structures.

27 In the interest of efficiency and effectiveness, we plan to

1 integrate rulemaking activities associated with Part 37 with other rulemaking
2 activities pertaining to material licensees.

3 This concludes my remarks. I'll now turn the presentation
4 over to Aaron McCraw.

5 Next slide, please?

6 MR. MCCRAW: Thank you, Kevin.

7 Good morning, Chairman Svinicki, Commissioner Baran
8 and Commissioner Burns. I am honored to be here this morning to provide
9 you with a brief overview of some activities of interest pertaining to the
10 Regional Materials Licensing and Inspection Programs.

11 Traditionally, the regional representative presents
12 information on the number of activities such as licensing actions and
13 inspections completed in the previous fiscal year.

14 I'm happy to report that the workload in our licensing and
15 inspection programs continues to be stable as it has been for the last several
16 years and is projected to remain stable for the foreseeable future.

17 A regional materials programs are mature and provide for
18 robust oversight of materials licensees. This robustness is in large part due
19 to our qualified and capable license reviewers and inspectors, some of
20 whom I will highlight during the presentation.

21 My presentation will focus on how the regional materials
22 programs are contributing to the Agency's overall goals to become more
23 effective, efficient, and agile and to identify ways to transform how we do
24 business to be better prepared to adapt to advancements in technology.

25 Next slide, please?

26 On January 31st, 2016, we submitted to the Commission
27 SECY-16-0009, recommendations resulting from the integrated prioritization

1 and re-baselining of Agency activities.

2 Enclosure 1 to the SECY included a list of 151 work
3 activities that could be shed, deprioritized, or completed with fewer
4 resources.

5 This list is also referred to as the C List. On April 13th,
6 2016, the Commission issued a staff requirements memorandum for the
7 aforementioned SECY approving the vast majority of the staff's
8 recommendations for these work activities.

9 Several of the C List items pertain to the Nuclear Materials
10 Users Business Line.

11 I would like to highlight three specific areas where we
12 proactively identified opportunities to be more efficient. We included these
13 items on the C List and have implemented these innovations since the last
14 Commission briefing.

15 First, we completed a revision to Inspection Manual
16 Chapter 2800 in May -- excuse me, September 2017. The purpose of this
17 limited scope revision was to allow for more flexibility and logical extensions
18 to the inspection intervals for selected materials licensees that will not
19 diminish the protection of public health and safety or the security of licensed
20 material.

21 A team of regional and Agreement State inspectors
22 incorporated flexibilities into the revised IMC by changing the current 25
23 percent allowable time extension for the inspection interval to 50 percent,
24 extending the initial inspection period if licensees are not yet in possession
25 of licensed material and allowing for extension of inspection intervals based
26 on good performance on a case by case basis.

27 These flexibilities enable our materials inspectors to more

1 efficiently plan inspection trips, especially to more remote areas of NRC
2 jurisdiction such as the North Slope of Alaska, the Caribbean Islands, and
3 the upper peninsula of Michigan.

4 Second, we extended the materials license renewal
5 periods from 10 to 15 years which will save resources spent on licensing
6 work by regional staff.

7 We established the methodology and approach to
8 implement the 15-year term for license renewals and new license
9 applications and are in the process of communicating this change to NRC
10 materials license holders.

11 The sufficiency allows us to more effectively address
12 safety significant license amendment requests.

13 Finally, I'd like to highlight the centralization of bankruptcy
14 reviews at NMSS.

15 On October 6th, 2017, we issued a procedure designating
16 NMSS as the lead for materials license bankruptcy reviews.

17 The consolidation of bankruptcy reviews in NMSS reduces
18 the burden on our regional licensing staff, enabling them to maintain their
19 focus on safety significant licensing actions.

20 While the exact savings and resources from these three
21 innovations have yet to be fully realized, we expect to see appreciable
22 returns over the next several years.

23 Next slide, please?

24 However, we do not intend to stop there. We anticipate
25 identifying additional efficiencies when we conduct a more comprehensive
26 review of IMC-2800 starting this spring.

27 This will also be a collaborative effort with our Agreement

1 State partners and will include, as one example, a review of inspection
2 frequencies in IMC-2800 to ensure that they are risk informed.

3 Next slide, please?

4 I'd like to use the next few slides to show you some of our
5 regional material staff in action.

6 This slide depicts our staff doing some of the bread and
7 butter work of our licensing and inspection programs.

8 And, the picture on the top left, you see Region III
9 materials license reviewer Sarah Forster providing a presentation to Region
10 III material staff on pre-licensing guidance enhancements during a seminar.

11 In the top right picture, you see Region IV Deputy Regional
12 Administrator, Scott Morris, on left facing us, and Region IV Senior Materials
13 License Reviewer, Jackie Cook on right facing us.

14 Speaking with licensee representatives as part of a site
15 visit during a panoramic irradiator reloading which is a truly fascinating
16 process if you ever get the opportunity to see it.

17 In the photo on the bottom, you see Region I Senior Health
18 Physicist, Randy Ragland, taking a survey of a blood irradiator package for
19 transport and ultimate disposal.

20 Next slide, please?

21 On this slide, I'd like to highlight some of the more unique
22 and challenging situation our staff may encounter.

23 In the top left picture, you see Region IV Senior Materials
24 Inspector, James Thompson who's the second from the left, suited for
25 helicopter underwater escape training which is required to fly on helicopters
26 out to inspect radioactive materials on offshore rigs, a daunting task that is
27 thankfully unique to Region IV.

1 In the picture on the top right, you see Region III Senior
2 Materials Inspector Jeff Warren center and Region III Senior Materials
3 License Reviewer Brian Parker, right gowned up to conduct an initial
4 inspection of a licensee's new radium-223 dichloride production and
5 distribution facility.

6 In the photo on the bottom, you see Region IV Senior
7 Health Physicist Roberto Torres on the left on site at a mining operation that
8 uses radioactive materials in a fixed gauge.

9 A fixed gauge at a site like this could be used to monitor
10 process flow or determine the mineral content of the material being mined.

11 More importantly, this picture illustrates one of the many
12 safety hazards that our materials staff may encounter in the field, heavy
13 machinery.

14 Next slide, please?

15 Next, I would like to highlight a couple of areas where we
16 have proactively identified some opportunities to transform how we do
17 business in the materials arena.

18 These two areas are related to enforcement and were
19 identified through our efforts to track any trends. Overall, I will note that the
20 workload in the areas of allegations and enforcement has also been stable
21 over the last several years.

22 While we did not identify any notable trends with respect to
23 allegations, we noted that a number of escalated enforcement cases
24 involved the security of portable gauges and the NRC security requirements
25 in 10 CFR Part 37 for risk significant quantities of radioactive material.

26 I will touch on each of these areas separately in the
27 coming slides.

1 Next slide, please?

2 In regard to enforcement for violations involving the
3 security of portable gauges, we are further risk informing our
4 characterization of these violations.

5 Historically, almost all violations involving the security of
6 portable gauges were immediately considered for escalated enforcement
7 action.

8 However, a working group with representation from NMSS,
9 the Regions, the Office of Enforcement, and OGC was chartered to explore
10 factors that could mitigate the severity of violations where there is little
11 potential for impact to public health and safety.

12 The case that prompted this review involved an event
13 where a portable gauge user stepped away from a gauge to check on his
14 next test site for approximately eight seconds.

15 During that time, a construction vehicle working in the area
16 backed up and contacted the gauge. The gauge sustained minimal
17 cosmetic damage with no impact to the radioactive materials in the device.

18 The gauge user quarantined the immediate area which
19 was on a construction site inaccessible to the general public until the
20 licensee's radiation safety officer could survey the gauge to ensure that there
21 was no damage to the radioactive sources and that it was safe to transport
22 the gauge, as is, back to the licensee's facility.

23 While the gauge user's failure to maintain constant
24 surveillance of the gauge constituted a violation of general security
25 requirements during the time the gauge was unattended, the duration was
26 short, the gauge sustained cosmetic damage only. And it occurred in active
27 construction site that was secured from the general public.

1 Overall, this event and its resulting violation had little to no
2 impact on public health and safety.

3 This violation was dispositioned at severity Level 3 in
4 accordance with our enforcement policy and past precedent.

5 However, it provided a real life example of an opportunity
6 to evaluate our existing guidance and past precedent to better risk inform
7 our enforcement practices.

8 Once we finalize the guidance on how similar violations
9 should be dispositioned in the future, we will provide that guidance to our
10 inspectors.

11 In the picture, you see Region III Materials Inspector Ed
12 Harvey observing a gauge user prepare for a soil compaction test using a
13 portable gauge at a temporary job site.

14 This picture is not of the event I just described, but it does
15 illustrate how different our assessment could have been.

16 You'll notice in the background that there is a private
17 residence in the vicinity of where this gauge is being used.

18 Next slide, please?

19 In regard to Part 37 violations, we continue to gain
20 valuable operating experience through our inspection findings.

21 As Kevin mentioned, we recently published a generic
22 communication on our first two years of inspection experience with Part 37 to
23 share those experiences with licensees.

24 Our inspections also give us an opportunity to observe
25 new security technologies and equipment being used in the field as well as
26 the advances in commercial security service provider offerings that many of
27 our Part 37 licenses have pursued.

1 These new technologies present new challenges to ensure
2 that our regulations enable the use of more advanced technologies.

3 When developing the requirements of Part 37, our staff
4 could not anticipate every possible scenario or predict the advancements in
5 technology.

6 Therefore, we rely on our regional materials inspectors to
7 share their observations and findings from the field regarding potential
8 challenges between the use of new technologies and our regulatory
9 requirements with the Part 37 implementation working group.

10 So, the working group can determine a path forward
11 involving rulemaking, developing guidance, or issuing generic
12 communications.

13 One example of where our regional inspectors have
14 shared their observations and findings with the Part 37 Implementation
15 working group involves 10 CFR 37.49(c)(2) which requires licensees to have
16 an alternative means of data transmission that is not subject to the same
17 failure mechanism.

18 Generally, the most common way for licensees to meet this
19 requirement is to have two traditional means of data transmission such as a
20 cellular primary means and a landline backup means or vice versa.

21 The following findings are three examples where more
22 advanced technologies have been employed, providing us with opportunities
23 to examine how our regulations can accommodate advancements in
24 technology.

25 One recent finding involved a licensee that had a
26 commercial security system that used two cellular transmitters, one primary,
27 and one backup.

1 While not employing a method we originally envisioned,
2 the system did meet the overall intent of that requirement with a redundant
3 means of communication.

4 Another recent finding involved a licensee that had a
5 custom security system with a single supervised landline that alarmed at an
6 onsite, central alarm station staffed by deputized security officers.

7 This system also did not employ a method we originally
8 envisioned. However, the system was capable of summoning an armed
9 response as fast as, if not faster, than a minimally complaint system, thereby
10 meeting an overall objection of Part 37, timely assessment and response to
11 an alarm.

12 Lastly, a licensee received a security upgrade to its
13 security panel from its commercial security service provider.

14 The service provider was replacing the old panel that
15 operated on an outdated 2G network with a newer one that operated on the
16 more reliable 4G LTE network.

17 However, the new panel did not include a landline backup
18 like the old panel did and was, therefore, not compliant.

19 While it is ultimately the licensee's responsibility to ensure
20 compliance with Part 37, the evolving security industry continues to create
21 opportunities for us to ensure our regulations are flexible enough to meet the
22 evolving needs while continuing to provide for adequate security of risk
23 significant quantities of radioactive material.

24 We must keep in mind that commercial security service
25 providers and telecommunications companies are every evolving to meet
26 their primary customers' demands and we will need to transform our
27 processes, procedures and regulations to proactively enable the use of

1 advancement in technology.

2 And, now, I will turn the presentation over to Linda Howell
3 who will speak on emerging technologies in the medical field.

4 Next slide, please.

5 MS. HOWELL: Thank you, Aaron.

6 Good morning, Chairman Svinicki and Commissioners.
7 Today, I'm going to discuss emerging medical technologies including some
8 recent medical events.

9 I'll highlight the process used by the staff to maintain
10 awareness of new technologies and radiopharmaceuticals that are being
11 developed for use and discuss a few of the technologies and products that
12 we have recently reviewed and anticipate reviewing in the near future.

13 I'll also discuss one type of treatment or procedure which is
14 relatively new that the staff has recently reviewed in greater depth following
15 several reported medical events.

16 Our review of data related to this type of procedure is part
17 of the staff's efforts to look for opportunities to enhance our inspection and
18 licensing programs through continuous assessment of trends and event
19 reporting and assessment of licensee performance.

20 Next slide, please?

21 We frequently engage our stakeholders including the
22 Advisory Committee on Medical Uses of Isotopes, or ACMUI, medical
23 professional organization, the U.S. Food and Drug Administration, or FDA,
24 medical product manufacturers and our Agreement State partners to
25 maintain awareness of any emerging medical technology that would require
26 licensing by the NRC or the Agreement States.

27 With respect to emerging medical technologies, ongoing

1 interactions with their stakeholders enable us to plan accordingly in terms of
2 resources needed for technical evaluations and reviews as well as guidance
3 document -- development, excuse me -- for new medical technologies.

4 As we become aware of a new technology or
5 radiopharmaceutical we reach out to our stakeholders to gather information
6 in order to determine whether new technology can be licensed under 10
7 CFR Part 35 regulations.

8 I want to note, that for this discussion, the technology may
9 be a device, a sealed source, or unsealed byproduct material such as a
10 radiopharmaceutical.

11 We review the specifications and proposed use of the
12 technology and then evaluate the subsections of Part 35 to determine
13 whether it can be licensed under existing regulations.

14 As part of this review process, we may coordinate with
15 OGC as appropriate.

16 If we determine that the new technology can be licensed
17 under Part 35 requirements, we review the technology for radiation safety
18 aspects, waste disposal considerations and other safety related attributes.

19 The information is shared with the regions and the
20 Agreement States to inform licensing and inspection activities.

21 If additional guidance is warranted for either licensing or
22 inspection activities, we develop that guidance in coordination with the
23 regions and the Agreement States as part of the guidance development
24 process.

25 If we determine that the technology is not covered under
26 existing subsections of Part 35, we will develop specific licensing guidance
27 under the provisions of Part 35.1000 which can be used to create specific

1 license conditions that are incorporated indirectly by reference or directly in a
2 materials license.

3 The process for developing licensing guidance for
4 technologies to be used under Part 35.1000 addresses all radiation safety
5 aspects of the new technology and may reference the need to ensure
6 commitments from the licensee for implementing specific subsections of Part
7 35 as appropriate.

8 The process may also involve evaluation of whether
9 license conditions are needed to address aspects such as training and
10 experience of authorized users of the technology or medical event reporting
11 requirements.

12 Guidance development typically takes 6 to 12 months
13 depending on the complexity of the technology and information required in
14 the guidance.

15 We coordinate with the Food and Drug Administration to
16 maintain awareness of that Agency's progress in conducting its review of
17 any new technology or radiopharmaceutical.

18 Pertinent information that the FDA shares with us in
19 accordance with our Memorandum of Understanding informs our guidance
20 development efforts and resource planning.

21 Information from manufactures of a new technology is also
22 used in license guidance development process.

23 Upon drafting licensing guidance, we coordinate with the
24 ACMUI to have the Committee perform a review of the guidance so that we
25 can obtain their perspectives on the guidance and any recommendations for
26 changes based on the Committee's expertise.

27 The licensing guidance is then reviewed by OGC and a

1 determination is made as to whether the guidance needs to be provided to
2 the Office of Management and Budget for evaluation under the
3 Congressional Review Act.

4 Once we approve the guidance, it's shared with the
5 regions, the Agreement States and is made available on our public
6 webpage.

7 Next slide, please?

8 We submitted a SECY paper in March of this year on the
9 topic of emerging medical technologies. That SECY paper provided an
10 estimate of staff resources needed in the next few years to develop licensing
11 guidance for emerging medical technologies based on similar resource
12 utilization in the past five years.

13 In the SECY paper, we identified technologies that have
14 been reviewed during recent few years as well as technologies and
15 applications that may be forwarded as to review in fiscal year 2020.

16 Next slide, please?

17 Some future emerging medical technologies that we're
18 aware of are identified on this slide. They include phosphorus-32
19 microparticles which will be used to treat advanced pancreatic cancer, the
20 MASEP Inifini Cobalt-60 Stereotactic Radio Surgery Unit for treating brain
21 tumors and lesions, the GammaPod Cobalt-60 Stereotactic Radiotherapy
22 unit for treating breast cancer which was just approved by the FDA and
23 iodine-131 radiolabeled nonocolonal antibody which will be used in
24 preparation for hematopoetic stem cell transplantation in certain cancer
25 indications and radiopharmaceuticals involving thorium that has been
26 processed into lead-212 for targets alpha therapies.

27 Our recent reviews of emerging technologies have

1 included Lutetium-177 dotatate which was approved by the FDA on January
2 26th of this year for treatment of neuroendocrine tumors of the gut and the
3 Radiogenix automated molybdenum-99/technetium-99m generator which
4 was approved by the FDA for use on February 9th, 2018.

5 Next slide, please?

6 I'd now like to discuss the staff's recent evaluation of
7 certain reported medical events. Some events that we've taken a deeper
8 look at recently involved yttrium-90 microsphere brachytherapy which is a
9 palliative treatment for liver cancer.

10 From a review of our routine inspection results and the
11 event reporting review process for fiscal year 2017, we suspected that an
12 increase in yttrium-90 microsphere brachytherapy medical events was
13 occurring.

14 This raised questions, prompting additional review of
15 information related to these procedures.

16 We evaluated three areas to better understand the
17 possible cause for the suspected increase in reported medical events for
18 these treatments. Specifically, we looked at the regulatory requirements for
19 using yttrium-90 microspheres, the use of post-treatment imaging to
20 determine the dose delivery to the intended treatment site and potential
21 licensee performance trends through a review of all medical events involving
22 yttrium-90 microspheres.

23 Next slide, please?

24 Specific license conditions for the use of yttrium-90
25 microspheres which derived from our guidance in Part 35.1000 require
26 pre-treatment imaging to verify proper catheter placement which is what you
27 see on this slide. You can see the arrow that's pointing to the placement of

1 the catheter in the hepatic vasculature.

2 This is an important step in ensuring delivery of the
3 microspheres to the intended treatment site.

4 A licensee may also perform pre-treatment lung-shunt
5 evaluation to assist in determining where the microspheres may potentially
6 be delivered during treatment.

7 A physician may use this information to decide whether or
8 not to proceed with treatment using yttrium-90 microspheres.

9 These actions together give high confidence that each
10 treatment is in accordance with the Authorized Users written directive.

11 Of note, while some stakeholders consider it a prudent
12 practice, post-treatment imaging to verify the measured does is not required
13 by NRC regulations.

14 The ACMUI reviewed our licensing guidance in 2014. As
15 part of its review, the ACMUI examined some of the challenges in
16 administering yttrium-90 microsphere treatments.

17 Specifically, once yttrium-90 microspheres are injected into
18 the vascular pathway toward the target tissue, the flow of the microsphere is,
19 and the final site of implantation are entirely dependent on the patient's
20 unique anatomy and blood flow dynamic.

21 The ACMUI agreed based on its review the pre-treatment
22 imaging to verify catheter placement and the elective pre-treatment
23 lung-shunting evaluation are all that is within the control of the licensee to
24 ensure proper treatment Administration.

25 The ACMUI has considered both the benefits and the
26 challenges of conducting post-treatment imaging.

27 One of the challenges proposed treatment imaging is the

1 limitations in performing accurate dose assessment which was what it's
2 typically used for given the available post-treatment imaging technology and
3 dosimetry software.

4 Based on current post-treatment imaging technologies and
5 capabilities, the ACMUI did not make a recommendation to include that in
6 early yttrium-90 licensing guidance.

7 Next slide, please?

8 The images on this slide are examples of post-treatment
9 images following administration of yttrium-90 microspheres. As you can see
10 the detail in the images varies widely, depending on the technology used to
11 create the images and the information provided by the images also varies.

12 Although the ACMUI did not recommend incorporating
13 post-treatment imaging in our licensing guidance, as I noted earlier, recent
14 medical events raised questions with some of our staff.

15 In particular, the staff noted through inspection efforts to
16 follow up on reported medical events that some of the events were actually
17 identified during the post-treatment imaging. Had the post-treatment
18 imaging not been done, the licensees may not have identified the medical
19 event.

20 We considered, again, whether yttrium-90 licensing
21 guidance should be updated and to further inform our actions, we conducted
22 a more detailed evaluation of reported medical events involving this form of
23 treatment.

24 Next slide, please?

25 We asked Idaho National Laboratory, or INL to conduct the
26 case study on yttrium-90 microsphere medical events recorded in the
27 Nuclear Materials Events Database.

1 Since yttrium-90 microsphere treatments began in the
2 United States approximately 15 years ago, the number of reported medical
3 events has increased over time.

4 However, there has not been an appreciable increase in
5 the number of reported events in the past five years.

6 Based on our review and the case review conducted by
7 INL, we concluded that the increase in reported medical events over the past
8 15 years is consistent with the increase in use of the yttrium-90
9 microspheres over that time period based on data that the staff obtained
10 from the product manufacturer.

11 Next slide, please?

12 Based upon our review of INL case study report and an
13 analysis of all trending data from the Nuclear Materials Event Database, we
14 did not find a negative performance trend or gaps in our regulations.

15 However, we will continue to evaluate our regulations and
16 requirements to verify that our requirements remain adequate to ensure the
17 safe use of medical technologies and radiopharmaceuticals.

18 We've concluded that the current requirements do give
19 high confidence that each treatment is in accordance with the written
20 directive and that there is not a need to update further the licensing guidance
21 to require post-treatment imaging in corresponding licensing conditions.

22 Thank you. That concludes my discussion. And, with
23 that, I'll turn it back Vic.

24 MR. MCCREE: Thank you, Linda.

25 Chairman, Commissioners, we appreciate your attention.
26 That concludes our presentation of the NMU Business Line and we're ready
27 to respond to your questions.

1 CHAIRMAN SVINICKI: Well, thank you each for your
2 presentations and for all the staff that have worked on the topics that you
3 discussed today. I will begin the Q&A once again.

4 Something that we heard mentioned on various topics from
5 the previous panel and this panel is references to, you know, mandatory time
6 frames to update inspection procedures, inspection manual chapters,
7 guidance document.

8 In the Agency as a whole, have we looked at in some ways
9 risk informing those frequencies for routine revisiting of the whole body of
10 documents that we have? Looking at whether or not they need to be
11 revised?

12 Some, I imagine are in more dynamic areas and they
13 benefit from ore frequent looks for revision. But others are probably fairly
14 static.

15 And, I know the management directives dictates some of
16 these procedures by the staff. But, is that something that's been looked at
17 in terms of eliminating areas that if there's not value added in looking at
18 these documents so frequently for revision and update?

19 MR. MCCREE: So, Chairman, thank you for your
20 question and you're correct. We have guidance both in -- for the reactor
21 oversight process and the fuel cycle facility oversight process of the material,
22 oversight process that guide the frequency of our reviews, of our inspection
23 procedures.

24 We have not, to my knowledge, quote, risk informed the
25 frequency of those reviews or informed them based on their safety and
26 security impact. That's something that we can certainly consider that the
27 merits of. So, I'll just leave that.

1 CHAIRMAN SVINICKI: Okay. Well, I appreciate that.
2 And, again, when you look at the tiered document hierarchy we have below
3 regulations themselves, there's a lot of documentation there.

4 And, like I said, it seems likely that there's variability in the
5 value of revisiting, like I said, some may be very dynamic, others could have
6 I think a diminished frequency of revisiting.

7 And, I just -- I kind of teed up -- I'm a little surprised at
8 what's in it. It's the kind of thing I thought might have been done as part of
9 Project AIM.

10 But, I guess the irony here is that because if there are
11 management directives that dictate the frequency of update, you have to
12 update the management directives then in order to diminish the frequencies
13 or if you have a body that has to be done.

14 In any event, Marc, did you want to say something about
15 that?

16 MR. DAPAS: Yes, just one comment, you know, similar to
17 the concept of just in time training, if there is an event or an issue that's
18 identified and we need to communicate guidance, for example, to the
19 Agreement States, we can use the state and Tribal communication letter to
20 address a more contemporaneous matter.

21 And then, you know, codify that, if you will, when we do
22 end up updating the management directive or associated procedures.

23 CHAIRMAN SVINICKI: Okay. I just, again, I don't have
24 specific knowledge of any particular thing that I would propose that we look
25 at diminishing the frequency of updating, but like any large organization, I
26 think some of these procedures are probably somewhat just on autopilot and
27 we just look at them on a certain frequency because we've always done that.

1 But, I know as part of our innovation and transformation,
2 we've challenging some of those assumptions. So, I'll leave that topic there
3 and see what the staff elects to do with it.

4 Regarding the Wyoming and Vermont Agreement State
5 processes, a couple of things were noted.

6 The first is that next month, the staff will ask to publish the
7 -- it's evaluation of the Wyoming Agreement State agreement, oh that
8 sounds very redundant, but that's the way we say that, I guess, the
9 Agreement State agreement.

10 Has the staff since it previously informed the Commission
11 on other matters related to the Wyoming Agreement, State Agreement, have
12 they unearthed any new novelty or challenges that need to be resolved?

13 MR. WILLIAMS; No, the issues that the staff had identified
14 originally were consistent with what we communicated to the Commission
15 and we're at a point where we're ready to move forward and we don't have --
16 we do not articulate any new challenges.

17 CHAIRMAN SVINICKI: Okay, thank you for that. Well,
18 we look -- I'm sure the Commission looks forward to seeing the next
19 engagement that we have with the staff on that.

20 With respect to the Vermont Agreement, the staff noted
21 that Vermont, unlike some other states that had requested to enter the
22 Agreement State process did not have an existing licensing or inspection
23 program for radiological materials. And, I guess that makes sense because
24 you don't need it until you become an agreement.

25 But, some states do have for state regulated materials,
26 they have something that they can kind of put into utility for once they
27 become an Agreement State.

1 How does the staff approach that and what novelties does
2 that pose for you in moving forward with the Vermont request?

3 MR. DAPAS: We -- thank you, Chairman for that
4 question. We recently issued a Request for Additional information and the
5 nature of that is focused on inspection licensing allegation program, incident
6 response, staffing, and training.

7 And, we are asking for the state to more fully describe
8 those programs because it's the first time that they've engaged. They don't
9 have, if you will, a baseline, for example, if they were regulating a naturally
10 occurring radioactive material or a NORM. So, that is a unique aspect.

11 But, based on the engagement that we've had with the
12 states and the discussions with the Vermont Department of Health, we don't
13 see any challenges there. It's just a matter of providing a greater level of
14 detail to describe the programs that are in place.

15 And, we've had three rounds of questions and we expect a
16 response to the most recent Request for Additional Information in three to
17 four months. And, that's consistent with the time frame that we've laid out to
18 complete the agreement by March 30th of 2019.

19 CHAIRMAN SVINICKI: Okay, thank you very much. I'm
20 certain that, if anything changes on those, you'll keep the Commission
21 promptly informed. I appreciate that.

22 Aaron, your presentation, I thought, was a really wonderful
23 demonstration of a message that the Agency as a whole has been trying to
24 bring forward ever since there was an enhanced, an inappropriately
25 enhanced focus on radiological source security in the United States after
26 9/11, but particularly after the Government Accountability Office had done
27 some investigatory work and what is referred to as stings where they

1 attempted to acquire materials.

2 The GAO has put forward since those events in I think
3 2007 recommendations which I think that they consider remain open, that
4 they would have the Agency put forward more prescriptive regulations in this
5 area like how many alarms should you have, things like that.

6 You made the point in your presentation as we watched
7 security technologies continue to evolved, and I'm putting -- I'm paraphrasing
8 but I think you were concluding that our performance based security
9 regulations serves well because we do find that technology evolves in ways
10 that surrogate technologies provide the same level of security performance
11 that we require.

12 And, if we had the more prescriptive regulations,
13 consequently, we would have to then be modifying those or we would be
14 basically constraining facilities to have outdated security technologies simply
15 because that's what the regulation prescribed.

16 So, I appreciate that that's the point, the general point that
17 the Agency has advanced on that topic that you're finding in the field things
18 that verify the performance based serves us well and allows us to require the
19 requisite levels of security and also allow new technologies for security
20 alarms and things to be adopted.

21 I did have a specific question for you. You'd said that
22 there's an ongoing review of inspection frequencies in some areas to ensure
23 that these frequencies are risk informed.

24 Can you just generally describe the process that we use to
25 risk inform an inspection frequency?

26 MR. MCGRAW: Sure, great question.

27 I think it's probably a little early to determine the exact

1 process that we're going to use. We're still developing the charter for our
2 working group.

3 That might be leaning a little too far forward to say risk
4 informed, more like reevaluate. It's been 15 years since we've looked at our
5 inspection frequencies. We've had a number of regulatory updates as well
6 as just the regulatory environment has evolved in that time frame as well.

7 So, we really just want to look at them from top to bottom.
8 Are they still where they need to be as far as what we know from things that
9 we might look at would be like compliance history.

10 What kind of enforcement actions have been taken against
11 certain program codes, types, and quantities of materials that they're using?

12 What kind of events could happen? You know, there are
13 some small users of radioactive materials that are using mill curie or micro
14 curie quantities of material and they can't get a medical event.

15 So, things of that nature for --

16 CHAIRMAN SVINICKI: Well, I appreciate that and, if it's
17 early, I'm not trying to force the staff's hand. And, I think you're talking point
18 might have mentioned risk informed because I don't -- it might be that the
19 Commission sees your talking points ahead of time. So, I didn't mean to
20 hang you up on that.

21 But, I appreciate your point that you were making about
22 looking at what can happen. Because I think consequence has to be a part
23 of risk informing. As a matter of a fact, it might be foundational to risk
24 informing.

25 If you look only at the frequency of finding violations and
26 things, you're not getting to -- you may say, okay, well, we need to inspect
27 that area more frequently because we tend to have findings in that area.

1 But, if the consequences are low, that has to be part of the
2 overall equation of risk informing.

3 So, I look forward to hearing more from the staff as they
4 proceed through that process and develop the insights.

5 And, I think, potentially, that work then could be something
6 that's kind of case study for other areas. So, I wish and those conducting
7 that, I wish you well in that endeavor.

8 And, Marc, did you want to say something?

9 MR. DAPAS: Yes, thank you, Chairman.

10 Just a quick perspective. I think when we say risk
11 informed, it's in the qualitative context and you're looking at what can wrong?
12 How like is it and what is the consequence, the risk triplet.

13 And you look at radiography events, we current inspect
14 those licensees on a yearly basis given the source strength and the potential
15 risk should there be an exposure because the procedures weren't followed.

16 So, it's that type of assessment looking at the findings and
17 determining is the current frequency of inspection appropriate? You know,
18 it's been some time since we did that evaluation.

19 In fact, George Pangburn led a working group back when I
20 was in Region III.

21 CHAIRMAN SVINICKI: Gosh, that's a name I've not
22 heard in a number of years.

23 MR. DAPAS: Yes, yes, ma'am.

24 But, it's time to revisit that in terms of ensuring that our
25 inspection frequency and the scope of inspection is appropriate through the
26 risk significance, if you will, of the activity we regulate.

27 CHAIRMAN SVINICKI: Well, thank you for that. And, I'll

1 just close by saying, of course, that doesn't mean that in all cases there's a
2 diminishment. And, I'm not trying to set that expectation.

3 It may well be that it would allow us to shift our focus from
4 area to another area. And so, that's also why this is such an important
5 undertaking for safety. So, I do appreciate that you're re-looking at those
6 frequencies.

7 And, with that, I will turn it over to Commissioner Baran.

8 COMMISSIONER BARAN: Thanks.

9 I was actually also going to ask about that, and that's a
10 very interesting discussion.

11 In terms of the discussion there on performance history or
12 compliance history, is the idea that, as part of this, you would look across the
13 universe of licensees and say, well, we've found that a certain area is of
14 more or less concern?

15 Or, are you looking more licensee specific on that? What
16 are you contemplating with that there?

17 MR. DAPAS: I would offer we're looking at both. And,
18 I'm sharing a perspective in that I've not had a detailed discussion with the
19 staff, so you're hearing some of my thinking and --

20 COMMISSIONER BARAN: This is dangerous. Keep
21 going.

22 MR. DAPAS: So, the staff may move me to a different
23 place. But, I would offer that it's both. And, I think we need to consider
24 both aspects.

25 MR. MCCRAW: Yes, I would concur with that. We're
26 going to look across the program codes as a whole and see what kind of
27 violations we've seen in the past, what kind of violations could happen.

1 Again, I'll just reiterate that it's very early on. I've got to
2 consult with my team members on how we're going to go about that.

3 COMMISSIONER BARAN: How does that compare with
4 how we -- how it works under ROP? I know that there's the annual
5 reevaluation there.

6 MR. MCCREE: The short answer, it -- philosophically, it
7 compares very favorably to --

8 (Off microphone comments)

9 MR. MCCREE: Not really. Actually the frequency under
10 the ROP is it's part of our biannual review of reassessment of the oversight
11 process.

12 And, in fuel cycle facilities when we risk informed to the
13 extent that we were able to do it because the revised fuel cycle load
14 oversight process wasn't supported by the Commission, but we did the same
15 thing. We looked at -- it was a risk informed performance based
16 assessment.

17 How is our licensees performing? Recognizing the
18 diversity among fuel cycle facilities. Where can we right size and
19 restructure our inspection program.

20 As the last panel alluded to, we're in the implementation
21 phase of that. But, very analogous.

22 COMMISSIONER BARAN: I wanted to --

23 MS. HOWELL: Yes.

24 COMMISSIONER BARAN: Yes?

25 MS. HOWELL: If I could add to Vic's comments. To a
26 certain extent some of that risk assessment occurs as part of the annual
27 NMEDS database review and report where we are actually looking at the

1 number of events that occur across the spectrum of materials licensees.

2 And, that would include Agreement State licensees as well
3 as NRC licensees.

4 And, that permits us to take a look at frequency of events,
5 consequences of events and that really helps us make a determination of
6 whether we want to look further into a particular type of activity such as what
7 we did with the yttrium-90 microsphere study.

8 So, we accomplished some of that at a somewhat more
9 frequent interval, but it's typically, it's been some time since we had
10 assessed inspection intervals based on that review.

11 COMMISSIONER BARAN: That's very interesting.

12 I also wanted to ask about a couple of the recent IG
13 reports that were mentioned during the presentations.

14 And, in one of the audits, the Inspector General looked at
15 NRC's Tribal consultation practices. And, one of the key findings there was
16 that there was a lack of or inadequate management attention to Tribal
17 outreach and consultation practices.

18 What was the staff's reaction to that finding and what is the
19 staff doing to address that concern?

20 MR. DAPAS: You know, I noted the same thing in reading
21 the audit report and that was of particular concern or attention to me.

22 I would offer that any time you identify gaps or
23 opportunities for improvement in a program, you can -- one school of thought
24 is that's a reflection on the degree of management engagement there has
25 been.

26 And, if there is a sufficient degree of engagement, those
27 gaps would not exist.

1 But, there were five recommendations that were proposed
2 by the OIG. You know, and one of them really focused on lack of detailed
3 staff guidance on how to coordinate with the Federal, State and Tribal liaison
4 branch, or FSTB, and work with Tribes.

5 So, we do need to update the Management Directive 5.1
6 that I mentioned earlier, to more fully carve out roles and responsibilities.

7 There was some feedback provided by the IG based on
8 the interviews they conducted that there is some confusion regarding how
9 that branch can be leveraged to support consultation activities.

10 You know, there was a comment about we need to require
11 staff and management that may interact with Tribes to take a Tribal
12 Relations training.

13 There was a thought that expressed by the IG that we
14 need to have a detailed qualification program for FSTB staff.

15 And, we are aligned with those recommendations. I do
16 think there's been sufficient management engagement. I would highlight,
17 albeit on the last page of the IG report, there was a statement, while there
18 are areas for improvements, NRC has completed many successful activities
19 in recent years related to Tribal outreach and consultation.

20 NRC has excellent working relationships with certain
21 Tribes such as the Prairie Island Indian community, Catawba Nation, and
22 Seneca Nation.

23 FSTB leads an internal Tribal working group that includes
24 representatives from several different NRC offices in the regions.

25 FSTB, in coordination with staff from other offices continues to
26 update the Tribal Protocol Manual and completed in 2017, NRC's Tribal
27 Policy Statement, FSTB created an online mapping system to help identify

1 Tribes more easily.

2 My point is that is, those are some successful
3 accomplishments that I would offer would reflect on an appropriate degree of
4 management engagement.

5 With that being said, our plan going forward, we need to
6 address the recommendations. There are opportunities for improvement
7 there to ensure that the staff that'll be involved in Tribal consultations fully
8 understand the resource we have in FSTB and how that can be leveraged
9 for productive outcomes.

10 COMMISSIONER BARAN: And, that was, I thought an
11 interesting recommendation or finding of the report was the concept of that
12 branch is kind of the Agency's experts in this area. And, if you're a program
13 manager working on something where this could be an issue, you should
14 check in with them as a resource and as a concept that makes sense to
15 you?

16 MR. DAPAS: Yes, I believe that it's appropriate to have a,
17 if you will, center of expertise that can be used as a resource and
18 understanding how best to approach Tribal consultations.

19 You know, the cultural sensitivities, training and
20 engagement with those individuals in the branch that have expertise, I think
21 helps position folks that are going to be involved for success.

22 Now, there are various degrees of interactions. There's
23 outreach and then there's consultations. So, I wouldn't offer that every
24 individual that might be involved in a meeting with a Tribe needs to have
25 detailed consultation skill set training.

26 But, those that are going to play a more substantive role
27 certainly should. And, the IG mentioned training that we conducted back in

1 2016 and there were 138 employees that received the training and not all
2 senior managers did attend the training or received the training, it was online
3 training.

4 And, the point is, there's been quite a bit of turnover so it's
5 time to ensure that newer staff that might be involved have received the
6 appropriate training.

7 COMMISSIONER BARAN: Okay. The other IG audit
8 focused on NRC's oversight of the National Materials Program.

9 And, as part of this audit, OIG basically polled the
10 Agreement States on their level of satisfaction on their influence on the
11 program.

12 And of the 31 Agreement States that responded, 45
13 percent said that they were dissatisfied with their influence on the program.

14 To be honest, based on my interactions with the
15 Agreement States over the years, I was surprised by that.

16 Was the staff surprised by that level of dissatisfaction and
17 what is the staff looking to do to try to address that concern?

18 MR. DAPAS: I would offer that we were surprised by that.
19 The statement was, level of influence on NRC decisions.

20 And, my experience, having been the Office Director for
21 NMSS over the last 21 months and reinforced with my experience in three
22 Regions is, we, as an Agency, can do a better job of explaining the basis for
23 a decision.

24 If we have an NRC Agreement State working group and
25 input is provided on a regulatory initiative and we decide to go forward, how
26 do we communicate the decision? How do we communicate the degree to
27 which the input provided by the Agreement State was considered?

1 There have been some occasions where communicating
2 information to the Commission is how some of the Agreement States learned
3 about the NRC proposed position going forward.

4 So, I would offer doing a better job of explaining how we
5 arrive at decisions and how the Agreement State input was factored into the
6 decision making forum.

7 But, there will be cases where we will agree to disagree
8 here. And, we experienced some of that when we were going through the
9 source security reevaluation, source security and accountability. And there
10 are different views and we need to fully consider those views and then
11 communicate the basis for a decision going forward.

12 So, I think there's room for improvement in that regard.
13 And, I'll let Kevin speak to some of the interactions he's had more recently
14 with the organization of Agreement States and the accounts for radiation
15 control program directors.

16 MR. WILLIAMS: Yes, so some of the things that we
17 shared with them is focusing not necessarily treating them as stakeholders
18 but more as partners. And, taking time to let them get involved in our
19 processes more.

20 For example, at the OIS Board meeting, they said, hey, we
21 would not like to have to submit, petitions for rulemaking. Is there some
22 way that we can be treated more as a co-regulator?

23 One of the things that we have done is, we have added
24 OIS to our, you know, to our panel as we're going through development of
25 rulemaking.

26 So, we're taking steps and initiating things to treat them
27 more as partners, treat them as co-regulators. You know, and we do

1 recognize that the subtlety in terms of it may not necessarily be the same
2 level, but we are engaging more as partners and we're doing that at a lot of
3 levels.

4 MR. DAPAS: And, I would offer looking -- what learnings
5 can we derive from various initiative where we think that partnership is
6 working well.

7 Like, I would offer the Management Review Board and the
8 Integrated Materials Performance Evaluation Program process is something
9 where we really are partners in terms of assessing another Agreement
10 State's performance or regional performance.

11 And, you know, are there learnings there in terms of how
12 we interacted that we could leverage in other forums and venues?

13 MR. WILLIAMS: And, the only other thing I'd offer is that,
14 in some of the issues that they talked about is, are you interfacing from a
15 management perspective with our Boards?

16 We are taking that seriously and we're making sure, for
17 example, we have CRC meeting coming -- CRCPD meeting coming up in
18 May. We are going to attend the Board meeting so that we can discuss
19 issues of mutual interest prior to the meeting and as we go forward, we'll be
20 in a better position to be treated -- you know, treating them more as partners.

21 We'll do the same thing in the OIS meeting.

22 COMMISSIONER BARAN: Okay. One last question I
23 had, I'm over on time, but I just wanted to quickly hear.

24 Kevin, you talked about the staff efforts or plans to address
25 the Part 37 program review recommendations.

26 And, it sounds like one element of that is a potential
27 rulemaking. Can you talk just a little bit more about what the staff has in

1 mind there?

2 MR. WILLIAMS: Sure, so one of the things that we've had
3 is, you know, there's been probably at least two working groups that have
4 actively been associated with Part 37.

5 And, then, we've received a petition from rulemaking from
6 NEI. And so, some of the initial thoughts, and I do have to caveat this
7 because we haven't really had the time to discuss with Marc at all.

8 But, one of the things that we're looking at is, you know,
9 the unintended consequences from the, you know, the large components or
10 how is Category 1 and 2 materials stored in robust structures.

11 We're going to talk about how do you engage the local law
12 enforcement for when you're doing, you know, an alternate job site? How
13 can we clarify some of the definitions? You know, when you meet biannual,
14 is it 365 days? Is it 12 months? Is it some combination of both?

15 We're looking at things such as, you know, direct
16 surveillance, continuous surveillance or, you know, things of that nature.
17 How can we improve those things such that people understand what we
18 meant by those terms?

19 MR. DAPAS: I would offer that largely in the area of
20 guidance development, et cetera.

21 In terms of rulemaking, one of the recommendations that
22 derived from the working group was, and this is as well associated with the
23 working group involved in the reevaluation of the Category 3 source security
24 and accountability, should we, as an Agency, require that safety and security
25 equipment be in place before a license is issued?

26 And so, the staff's made a recommendation and if the
27 Commission directs us to go forward with that, we would include that along

1 with any Part 37 program review related rulemaking in an integrated
2 rulemaking plan.

3 Because it's the same stakeholder population that would
4 be affected and interested in providing comments.

5 And, that's another opportunity to work closely with the
6 Agreement State partners as we go through that very, I would offer, public
7 and transparent rulemaking process should the Commission endorse the
8 staff's recommendation to move forward in that regard.

9 COMMISSIONER BARAN: Okay, thank you.

10 CHAIRMAN SVINICKI: Thank you.

11 Commissioner Burns?

12 COMMISSIONER BURNS: Well, thank you.

13 Thank you for the presentations. I think just following up
14 on the two IG reports that have been mentioned, and I appreciate Marc and
15 others saying I think taking it under advisement, looking at areas for
16 improvement.

17 Because, I -- at my own reading of them, I see no major,
18 you know, faults in the system. These are ways of, you know, ways of
19 improvement.

20 You know, as with many IG reports, the lack of a specific
21 process, procedure defined in a thing isn't an outcome. But, you know, I
22 appreciate you're taking it seriously.

23 And, there are ways to do it, you know, there are ways of --
24 particularly, a lot of this is not what I would say sort of process, churn out
25 the, you know, going down the assembly line.

26 It is about the engagement with others who are involved,
27 whether it's the Tribal governments or the Agreement States.

1 I mean, I -- Kevin talked a lot -- talked a bit about some of
2 our engagement, for example, with the Catawba Nation. And, I know they
3 drop by, I happen to see them, the Chief and some other officials from the
4 Tribe come by when they were in town for another I think Tribal
5 organizations meeting and were very complimentary of Region II and the
6 staff.

7 And so, those are -- I think those are a success, we just,
8 we build on that. So, I appreciate how you're reacting to that.

9 One of the things, and this might be, I think prompted by
10 Kevin's discussion, but you talked about the number of sources in the United
11 States in both under our jurisdiction and Agreement State being fairly stable.

12 One of the questions I have, do we have a sense of, is the
13 type of source or the types of sources, has that changed? The overall
14 number seems stable, but the types of things that are being used, is that
15 different at all? Do you have any sense of that, Linda?

16 MS. HOWELL: I'll respond with a qualitative response
17 and not quantitative.

18 COMMISSIONER BURNS: Okay, sure, sure.

19 MS. HOWELL: I do think that we are seeing some
20 changes. We are seeing new medical devices in radiopharmaceuticals
21 coming out. And so, technology is advancing in the medical area.

22 At the same time that we're observing technological
23 advances, we are observing some decrease in the number of smaller
24 community hospitals. And, that's just driven by the economy and, you
25 know, what's happening in healthcare and whether it's insurance or other
26 reasons.

27 We're seeing some shifts in the well-logging area as

1 technological advances occur and where you can detect natural gas and oil
2 deposits. We're seeing different types of technology being used. We still
3 have many old sealed sources out there because people may not be able to
4 dispose of them. But, you are seeing shifts in technology.

5 And then, another area that the staff has been made
6 aware of is some shifts in nondestructive testing.

7 There is, and this is industry driven, a trend towards use of
8 ultrasound techniques because there have been advancements in that
9 technology over the traditional industrial radiography using sealed sources.

10 So, we are seeing some shifts and that, too, may influence
11 where we end up with modifying the inspection intervals and frequencies.

12 COMMISSIONER BURNS: Yes, yes, that's an interesting
13 observation because it would seem, you know, depending if you have lots of
14 little sources of low, you know, low radiation content or low radioactivity that
15 moved to a larger sources that, you know, you said they were from a risk
16 informed perspective. That's potentially different. But, that's a good
17 observation.

18 And, what Aaron's working on will deal with that.

19 One other things, let me sort of follow up on that question.

20 We talked about source security violations as being an
21 areas. I mean, I go way back on this and if I -- you ask me in the first five
22 years I worked at the NRC, what was I dealing with, it was failure to secure
23 sources. It was failure to survey.

24 And then, I had one case out of Region -- it was out of
25 Region IV, failure to register appropriately with cross, I'll call it cross border
26 use, meaning going from an Agreement State to, I mean, well, either way, go
27 in an Agreement State to an NRC State or vice versa.

1 So, can you give me an idea of sort of what are the big
2 three or five in terms of violations? Are they still sort of that similar type of
3 profile?

4 MR. MCCRAW: Well, the two that I highlighted are really
5 the two that Region III in particular, but I think all the regions could concur,
6 kind of chasing the 30.34(I) violations reportable gauge security.

7 COMMISSIONER BURNS: Okay.

8 MR. MCCRAW: As well as the general security
9 requirements. We kind of go both ways on those.

10 Part 37 certainly as we've transitioned from the increased
11 controls to Part 37, there's some subtle changes in there that not all of our
12 licensees picked up on.

13 COMMISSIONER BURNS: Okay.

14 MR. MCCRAW: As well as some of the wording changes
15 that we made presents some challenges in implementing them.

16 And then, reciprocity continues to be an issue. It's just the
17 awareness of licensees of do they know which states are Agreement States?
18 Do they know which areas are NRC jurisdiction?

19 COMMISSIONER BURNS: Yes, and the case I was
20 thinking about, the guy knew where he should have been keeping the thing.
21 So we whacked with a civil fine.

22 MR. DAPAS: Just one point of clarification.

23 COMMISSIONER BURNS: Yes.

24 MR. DAPAS: Because I think Kevin has a couple
25 thoughts. And, I apologize, Aaron, I wouldn't call them subtle changes in
26 terms of the different between the orders in Part 37.

27 Licensees thought that Part 37 simply codified the

1 requirements in the orders and there were addition requirements. And so,
2 they did not -- were not sufficiently familiar with the Part 37 to know they
3 needed to implement additional measures. So, that was a factor.

4 And, that's why we issued the regulatory information
5 summary to alert the licensee community to the fact that there are
6 differences. And, despite an extensive effort to outreach and ensure full
7 awareness, we were not fully successful in that regard.

8 COMMISSIONER BURNS: Yes.

9 MR. DAPAS: But, that's where a number of violations
10 stemmed from.

11 COMMISSIONER BURNS: Yes. Kevin, did you want to
12 say something? Add something?

13 MR. WILLIAMS: That's what I was going to say.

14 COMMISSIONER BURNS: Okay.

15 MR. WILLIAMS: Yes.

16 COMMISSIONER BURNS: Well, let me go back, actually,
17 let me stay with you.

18 The interesting -- I think one of the things that I want to
19 compliment the staff on because it was an area, quite frankly, I think Marc
20 knows I had some concerns when we proceeded with the evaluation on the
21 radium, you know, the legacy radium issue.

22 And, I think the staff's done a good job. I was up in
23 Region I earlier this year and I got a good, interesting briefing on a number
24 of the places, particularly in Connecticut, the old watch factories and, you
25 know, some, you know, the differences between, you know, some of these
26 buildings are long abandoned. But, some want to be attractive new condos
27 that they've wanted, I understand.

1 But, having to work through some of those issues.

2 So, Kevin, you mentioned 13 Agreement States have sort
3 of closed that. I presume what, for the most part, they were, in terms of the
4 list of potential sites of interest, they sort of were able to clear those out. Is
5 that essentially --

6 MR. WILLIAMS: Yes.

7 COMMISSIONER BURNS: -- what it is? Okay.

8 How much more work, I may have missed what you said?

9 MR. WILLIAMS: Well, I think what we were trying to say
10 was that, you know, we share the information with the states.

11 COMMISSIONER BURNS: Yes.

12 MR. WILLIAMS: You know, some states are still doing a
13 little more work, a little more looking at it. But, 13 of those states have said,
14 hey, we looked at it, we've completed it. We're not going to take any further
15 action.

16 And, then others will continue to look at it.

17 COMMISSIONER BURNS: Okay, okay.

18 MR. DAPAS: My understanding is that each of the states
19 prioritized their review of the sites based on the most risk significant sites.

20 And so, for the other I guess it would be 12 states of the
21 35, I would offer, as I understand it, some of those lower priority sites have
22 not been fully evaluated yet.

23 But, it sounds like, from across the 35 states, the more risk
24 significant sites have been evaluated by the agreement states.

25 COMMISSIONER BURNS: Okay, good, good. I'm going
26 go back to Linda's discussion on the increase in or the emerging medical
27 technologies.

1 happened to be one of these and we talk about refreshing Management
2 Directives and things like this, and this may be one that isn't an anachronism
3 or not. I just don't -- I don't know.

4 And, the final thing, I would go to this issue on the
5 yttrium-90. And, that's a tough issue. I appreciate, Linda, your description
6 of some of the thinking or what's gone into it.

7 I mean, one of the things is I think you said, is that the
8 trend and -- sort of increased medical events. There's a correlation with the
9 increased usage of it.

10 And, some of the difficulties, you know, this is on some of
11 the -- with some of the technology, some of the difficulties that makes exact
12 --

13 MS. HOWELL: One of the subtleties and a unique
14 elements of doing the yttrium-90 microsphere treatments is that, you can --
15 the licensee can do everything possible to place the catheter exactly where it
16 needs to go to get -- deliver the microspheres to the intended tissue site.

17 But, something as subtle as the patient's breathing can
18 move that catheter.

19 COMMISSIONER BURNS: Yes.

20 MS. HOWELL: And so, even though they're doing this
21 imaging, relatively close in time to the time that they initiate injection of the
22 microspheres, the patient is -- something is -- monitors the patient's
23 breathing, beyond their control can actually cause the catheter to move.

24 And, when we looked at the medical events and we did
25 scrub them fairly closely, we had some events where imaging might have
26 been 15 minutes in advance of the procedure.

27 There were some medical events that occurred when

1 imaging was only a couple of minutes in front of the procedures.

2 So, there are many factors about this form of treatment
3 that is beyond the licensee's control no matter how good of a job they do to,
4 you know, try and protect any risk so to speak.

5 But, again, it's -- that's taken under consideration by the
6 patient's physician and the authorized user who's performing the treatment.

7 COMMISSIONER BURNS: And, is there, I mean, is there
8 a focus on understanding some of the difficulties in terms of the delivery and
9 all. Is the medical community looking at or trying to think about ways that
10 maybe can reduce that --

11 MS. HOWELL: I don't know that I have --

12 COMMISSIONER BURNS: -- those type events?

13 MS. HOWELL: -- a clear personal firsthand knowledge of
14 that to provide to you. But we could certainly elicit some of that information
15 perhaps from the ACMUI Committee.

16 COMMISSIONER BURNS: Okay.

17 MS. HOWELL: And, return that answer to you.

18 COMMISSIONER BURNS: All right.

19 MR. DAPAS: Just one quick perspective I'd offer and I'm
20 recalling from the presentation that ACMUI and I think we assessed that the
21 things that are clearly within the licensee's control there, they've done to
22 ensure that the intended dose is delivered to the treatment site.

23 Perhaps as post-imaging advances in terms of the state of
24 the art technology. But, if a patient, you know, due top breathing shifts, you
25 know, what can you do to try and alleviate that concern or prevent that. I
26 think that presents a particular challenge.

27 So, from a regulatory perspective, are we ensuring the

1 licensee is doing all they can to preclude, if you will, a medical event from
2 occurring?

3 And then, if one does occur, you have to look at the
4 significance here.

5 So, it is a challenging issue. But, you know, ACMUI did
6 conclude and it was consistent with our conclusion that the pre-treatment
7 imaging and the shunting is the licensees are doing what they can to --

8 COMMISSIONER BURNS: Okay.

9 MR. DAPAS: -- ensure the delivery is in accordance with
10 the written directive.

11 COMMISSIONER BURNS: Okay, thanks, thanks.

12 CHAIRMAN SVINICKI: I have no medical training, Marc,
13 but, in general if the patient stops breathing that is a bad medical outcome.

14 (LAUGHTER)

15 CHAIRMAN SVINICKI: So, that much I do know.

16 Well, again, and the other -- to the other point about a
17 policy statement needing to be updated, I could say something glib about the
18 wisdom of our predecessors and forebearers but, much like the Atomic
19 Energy Act which I have remarked to lawmakers that as much as the nuclear
20 has changed over the course of time, that there's a lot of resiliency in the
21 way they wrote the Atomic Energy Act.

22 Because, so, my point about the policy statement would
23 be, done right and kept at a high level, it should be able to accommodate a
24 whole range of possible futures. And, that is what both lawmakers,
25 regulation drafter, and policy statement issuers hope that that's their
26 objective, is to accommodate a range of possible futures.

27 COMMISSIONER BURNS: Yes, we hope, but we don't

1 always acknowledge it. I mean, we, you know, I, you know, I would agree
2 but, you know, this is like you sometimes.

3 And, I don't criticize this particular policy statement, I just
4 happened to come across it and wondered whether it is.

5 But, you know, the -- it's the type of thing, you know, in the
6 State of Vermont used to have a law that required you pack all covered
7 bridges with snow during -- that was so sleds could go through it.

8 Well, I hope we don't do that today.

9 (Laughter)

10 COMMISSIONER BURNS: Anyway.

11 CHAIRMAN SVINICKI: All right, well, again, thank you all
12 for your presentations and we're adjourned.

13 (Whereupon, the above-entitled matter went off the record
14 at 12:05 p.m.)

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16