UNITED STATES OF AMERICA U.S. NUCLEAR REGULATORY COMMISSION

BRIEFING ON RESULTS OF THE AGENCY ACTION REVIEW MEETING (AARM)

MAY 27, 2011 9:00 A.M.

TRANSCRIPT OF PROCEEDINGS Public Meeting

Before the U.S. Nuclear Regulatory Commission:

Gregory B. Jaczko, Chairman

Kristine L. Svinicki, Commissioner

George Apostolakis, Commissioner

William D. Magwood, IV, Commissioner

William C. Ostendorff, Commissioner

APPEARANCES

Licensees:

Joseph Henry Retired Admiral and President, Nuclear Fuel Services

Frank Miles Associate Chief Patient Care Services Officer, Department of Veterans Affairs

NRC Staff:

Bill Borchardt Executive Director for Operations

Fred Brown Director, Division of Inspection and Regional Support, NRR

Scott Moore Acting Director, Office of Federal and State Materials and Environmental Management Programs

Victor McCree Regional Administrator, RII

Mark Satorius Regional Administrator, RIII

PROCEEDINGS

CHAIRMAN JACZKO: Good morning. Today we are meeting to
receive a briefing on the results of the Agency Action Review Meeting. This is
certainly one of our most important meetings that the Commission holds every
year. It provides us the opportunity to publicly review licensee safety
performance over the previous year and to focus on the most significant safety
challenges that licensees experienced. The issues we will be discussing today
are at the heart of our public health and safety mission. In 2010, both reactor
and material licensees demonstrated good overall performance. We did,
however, identify some significant issues at certain facilities. This, for me, will be
I think the fourth consecutive year in which we've had representatives from
Nuclear Fuel Services here to discuss their facility. It certainly raises interesting
questions and concerns about why we continue to have NFS appear before us
today. And so I'll be very intent to hear what kind of concrete steps NFS plans to
take to address the safety issues that they've been experiencing, and to ensure
that ultimately they improve their safety and don't appear at next year's AARM.
The Commission will also hear from representatives from the
Department of Veterans Affairs about the steps they've taken since last year's
meeting to address the issues that led to multiple events at the VA Medical
Center in Philadelphia. While no reactor licensees met the criteria for
participating in this year's AARM meeting, we did identify some concerning
issues at certain plants over the past year. Right now there are three reactor
licensees in column three of the Reactor Oversight Process Action matrix. And
one plant, Browns Ferry, is currently in column four after experiencing an issue of
high safety significance late last year.

1	It's clear that both the agency and its licensees need to continue to
2	maintain a strong safety focus to avoid these types of challenges. So during
3	today's meeting, the Commission will first hear presentations from the NRC staff,
4	and then from two panels of representatives from the Nuclear Fuel Services and
5	the Department of Veterans Affairs. Before we begin, I'd like to offer my
6	colleagues an opportunity to make any opening remarks. Okay, Bill, you want to
7	get started?
8	MR. BORCHARDT: Good morning. Thank you. Go to the second
9	slide, please. The objectives of the Agency Action Review Meeting, there's four
10	of them, are to review the agency actions that have been taken for the nuclear
11	power reactors, nuclear materials licensees, including fuel cycle facilities that
12	have experienced significant performance problems, and to identify any
13	additional actions that are warranted.
14	Second, it's to ensure that the coordinated course of action have
15	been developed by the staff and are being implemented.
16	Third, to review the results of the staff assessment of ROP
17	effectiveness. And fourth, to ensure that the trends in industry and licensee
18	performance are recognized and appropriately addressed.
19	The next two slides in your package show the agenda for the staff
20	briefing this morning. Using the criteria, as defined in our management
21	directives, there are two facilities that warrant discussion today. And those are
22	Nuclear Fuel Services and the U.S. Department of Veterans Affairs. So I'll now
23	turn the presentation over to Fred Brown.
24	MR. BROWN: Thank you. Good morning, Mr. Chairman,
25	Commissioners. Starting on slide six. The Industry Trends Program assesses

1 performance across the entire fleet of operating reactors and provides

2 predetermined thresholds or limits. If a threshold is crossed, the staff must

3 assess the effectiveness of the reactor oversight process and the need for

4 additional agency action. Next slide please.

As you are aware, the staff concluded that no action thresholds were crossed in calendar year 2010, based on the information that was available to us in March of this year. Having said that, there were two items that were noted in our information paper on this topic, and that also generated discussion at the Agency Action Review Meeting. Next slide please.

The first issue that was discussed involved the number of significant events that were recorded in 2010. The number of events calculated on a per unit basis increased from zero in 2009 to nine in 2010. While on its face this appears to be a very significant increase, it did not cross the short-term prediction limit, which is shown as the red line on this graph. And it also did not result in an increasing trend over time, as calculated and shown with the black line on this graph. Staff responded to each of these events within the ROP process. Each of these particular events resulted in a very thorough 95-002 supplemental inspection to assess the effectiveness of the licensee's corrective actions for the underlying performance deficiencies.

Prior to the AARM, the staff had looked at each of these events and concluded that they were different enough that there were not required changes to the ROP process. As a result of the discussion at the Agency Action Review Meeting, the operating experience staff in the Office of NRR are going to go one step further and perform a high level review of the significant events to see if there are any common root causes or themes that will give us additional insights.

The second issue that came up in discussion was the HP Robinson complicated trip that occurred in March of 2010. As you know, the event included a fire, a reactor trip, plant equipment that did not respond as expected, plant operator errors, and a reignition, subsequently, of the fire. Ultimately, the plant was placed in a safe condition. But multiple performance deficiencies were identified in the augmented inspection team effort. A loss of defense-in-depth that occurred resulted in meeting the level two reporting criteria on the International Nuclear Event Scale. In the eight years that NRC has been rating all nuclear events, this was only the second level two event that we've reported for operating reactors. It was at Kewaunee for internal flooding issues, affecting multiple systems, sir.

The event also contributed to a white performance indicator for SCRAMS, and resulted in two white findings in the Mitigating Systems

Cornerstone of the ROP. The licensee undertook substantial corrective actions as a result of this event, including actions such as an Independent Safety Culture Assessment that are typically only performed by licensees in column four of the action matrix. As you know, the staff continues to refine the ASP evaluation for this event. We are currently performing internal reviews, and have shared the draft report with the licensee for their review.

If the ASP results indicate that this was a significant precursor event, it will be the first since the Davis-Besse vessel head degradation. With respect to discussion at the AARM, the staff concluded that the licensee and agency response under the ROP were appropriate. But we also identified an improvement opportunity within the ROP and will establish a new procedural requirement for cases where multiple performance deficiencies overlap in plant

1 performance. In these cases, the staff will evaluate conditional core damage

2 probability insights to determine whether a deviation from the ROP is

3 appropriate. Next slide.

As you are aware from our annual information paper on ROP effectiveness, the staff concluded that the ROP is an effective and open process. We did, however, identify opportunities for improvement. In concluding that the ROP was effective, we evaluated 45 aspects of the program that have pre-identified metrics. The great majority of the metrics were met. And we performed evaluations of the circumstances associated with the few metrics that were not met. One missed metric involved a number of ROP deviations that were opened last year. And I'll address that in just a moment.

Before I do that, though, let me turn to the metrics for resident inspector demographics. The Commission has provided the staff with tools for improved recruitment and retention of resident inspectors. And these tools helped arrest the very significant problem that we had as recently as three years ago in retaining residents. We will be sending you a separate paper on the topic of these tools later this year. With respect to the most recent data, the experience levels were very stable last year. The only decrease was in non-NRC experience for resident inspectors. And we think that reflects the entry of the Nuclear Safety Professional Development Program graduates into the ranks of the residents, which is a good thing. And overall most importantly, we continue to staff the resident ranks with very qualified, very high performing individuals. Next slide please.

With respect to ROP deviations, we did miss our metric this year because of an increase in the number of new deviations that were issued. But

three deviations involved increased resources for Vermont Yankee related to
onsite groundwater contamination issues and to review a demand for information
associated with inaccurate information provided to non-NRC officials. We also
used increased resources for San Onofre related to longstanding human
performance and problem identification and resolution problems, and the large
increase in the number of allegations. The San Onofre and Browns Ferry
deviations have been closed. The Vermont Yankee deviation is open pending
final information from the licensee, but the region is using only baseline
resources at this time. In reviewing these deviations, we did not identify any
common threads that would require program changes. However, the Vermont
Yankee deviation did contribute to a policy issue that I'll discuss in my final two
slides. Next slide.

The first policy issue involves a security cornerstone of the ROP. At its inception, the ROP treated all seven cornerstones as equal inputs into an integrated assessment process. After several years of this fully integrated approach, the security cornerstone was split out, and it's now standalone and separate. This occurred as part of a process to protect information that could be exploitable to potential adversaries. At the time of the change, the staff did not release any information on the existence of Greater than Green security findings, the very existence of which was considered potentially exploitable.

In the policy paper that you should see today or on Tuesday, the staff discusses the advantage of reintegrating the cornerstone into a comprehensive assessment process. Staff does not believe that this change will have a net impact on information security at this time, because we're already releasing information on the existence of Greater than Green security findings

that have been identified and corrected.

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The second policy issue involves unintentional radioactive effluents, most typically seen in the form of underground leaks of contaminated water. This issue is identified as a result of multiple staff activities over the last couple years, including a gap analysis of existing ROP processes, a review of ROP deviations, and an assessment of internal and external feedback on the consistency or reliability of staff response to groundwater contamination events. Staff does not have a specific change in mind, but sees opportunities to identify process improvements in the area of defining and protecting defense-in-depth principles for effluents. The Commission should see the staff's paper on this issue within the next two weeks. And I personally apologize for how long it's taken to get this to you. That concludes my remarks, and I'll turn it over to Scott. MR. MOORE: Good morning. For the Materials Performance Evaluation Program, NRC and the agreement states collect, monitor, and evaluate industry data on an ongoing and periodic basis. We use this process to identify significant licensee performance issues, or NRC issues and gaps warranting management attention and awareness at the AARM. The AARM review is part of a broader oversight process that includes licensing, inspection, and licensee performance reviews and routine enforcement. It deals with a large number of licensees, specifically 22,600, of which 3,000 are NRC licensees and 19,600 are agreement state licensees; so roughly 13 percent or so are our licensees. And we're getting the data on all the rest from the agreement states. More importantly, we're dealing with a wide variety of types of materials licensees, industrial, medical, academic, when we're looking at this data and information. The criteria target the most critical issues, involving various serious

- 1 events, those triggering the strategic level measures, significant licensee
- 2 performance or program issues, and the NRC program gaps or failures that are
- 3 identified. Can I have the next slide please?
- 4 These are the goals and criteria against which we monitor. We use
- 5 a graded approach, from higher level, higher consequence, including strategic
- 6 outcomes and performance measures and abnormal occurrences that are
- 7 reported to Congress, to lower level precursor monitoring that are reported within
- 8 NRC. This graded approach provides us with the ability to focus management
- 9 attention on the higher level items, while providing an early indication of any
- 10 programmatic issues and allowing for early action on our part with the lower level
- 11 issues. Can I have the next slide?

significant sources in FY10.

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In FY10, all of the strategic outcomes were realized, and our performance measures were within the established goals for the agency. In particular, and this is important, there were no unrecovered, lost, or stolen risk

With regard to abnormal occurrences, our third performance criteria that we look at, there were 15 abnormal occurrences in FY10. Actually, six of them occurred within the FY, the fiscal year, and nine of them were reported and we determined the results during the fiscal year. But they actually occurred in previous fiscal years. All 15 of those were medical related events. Eight of them were in NRC states, and seven of them were in agreement states. Three of the AOs included dose-to-embryo on fetuses. For the past 10 years, it's typical for medical related events to generally dominate the total number of AOs for a given year. Possible reasons why medical related events dominate the number of AOs are that there are a large number of medical procedures performed. For

- 1 instance, the Society of Nuclear Medicine, in a 2008 annual report, indicated that
- 2 there are more than 20 million molecular imaging procedures performed each
- 3 year. Another possible reason medical events dominate the total numbers of
- 4 AOs are that intentional uses of radioactive materials are performed on
- 5 individuals. Over the past year, in comparison to this 20 million number by the
- 6 Society of Nuclear Medicine, there have been an average of 40 reported medical
- 7 events per year. And then, for comparison, we have the 15 AOs in FY2010. So
- 8 you're talking about a total small number of events out of a large denominator,
- 9 basically. Not that any number is acceptable. But overall, it's a very small
- 10 number.

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Human error continues to be a primary contributor to the root cause for these AOs. The causes themselves include not following procedures, improper equipment setup, and incorrect radioactive material or dose to a patient, or things like failure to take pregnancy tests, or not knowing that the patient was pregnant. There's no discernable trend in the total number of AOs from year to year. But the number of AOs is small, as I mentioned, compared to the number and diversity of uses.

We also have identified an additional 15 events that took place during 2006 to 2010 that are potential AOs, for which additional information about the event is still required. And the reason we still require that information is because they're ongoing enforcement cases, either NRC or agreement state, or we just don't have the information yet and we're still acquiring, or the agreement states are still acquiring that information. And so they may later turn out to be an AO, or not. And they would be included in later reports. Next slide.

With regard to licensee and NRC program performance, this part of

1	our process identifies licensee performance issues or NRC program issues or
2	gaps that warrant the attention and awareness of NRC senior management using
3	the AARM criteria. In FY2010, there were two nuclear materials licensees: NFS,
4	which the Chairman mentioned, and the Department of Veterans Affairs, that met
5	the significance performance issue criteria. We also issued, in the Federal
6	Register last fall, a proposed revision to the criteria that we're going through and
7	about to finalize. And so that would address whether licensees had met their
8	prior year, if they've come up in the past, whether they've met their prior year
9	criteria and whether it was effective. And so we're going through now and
10	changing the criteria for being addressed at the AARM. After review and so

those two licensees will be addressed by Mark and presentations after mine.

After review and analysis of the data, we did not identify any significant trending issues with materials and waste programs. We discussed the last 10 years of event data reports to NMED. And in FY10, we had about 421 significant events posted and reported to NMED. We didn't identify trend issues with those. They were consistent with prior year events that were reported to NMED. Also, there were no NRC program gaps or failures that were identified and discussed at the AARM. So that concludes my presentation. And with that I turn it over to Vic.

MR. MCCREE: Good morning, Mr. Chairman, Commissioners. I want to begin with a brief background discussion of the performance of Nuclear Fuel Services, NFS. I'll then provide an overview of NFS's more recent and current performance. And finally, I'll describe the actions that we plan to take, looking forward. Next slide please.

In late 2009, NFS experienced an unexpected chemical reaction in

1 the uranium-aluminum line of the Blended Low-Enriched Uranium, or BLEU.

2 Preparation Facility. They also experienced the next month, that would be in

3 November 2009, a glove box fire in the commercial development line. These

4 events, and insights from the subsequent NRC reactive inspections, prompted us

to conduct an interim performance assessment in December of 2009. This

assessment resulted in the identification of the following concerns: inadequate

NFS management oversight of facility process changes; perceived production

pressures; an apparent lack of a questioning attitude on the part of workers and

management; poor communications on the part of NFS staff; a lack of significant

progress in improving safety culture on site; weaknesses in design control in

configuration management processes; and NFS's inability to perform thorough

introspective evaluations and then apply the results of those in their decision-

13 making.

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Based on this interim performance assessment and subsequent dialogue with NFS management, the NRC issued a confirmatory action letter in January 2010 that documented NFS's commitment to maintain suspended operations of the main process lines and implement corrective actions for the underlying causes of the issues I just described. NFS's performance is being discussed at this Commission meeting because it met the Agency Action Review Meeting's screening criteria of multiple and repetitive program issues that warranted additional NRC oversight. Next slide, please.

To verify NFS's commitments in the confirmatory action letter, we conducted a series of inspections to assess NFS's corrective actions, readiness to sequentially restart each process line. All process lines were subjected to an NRC restart readiness inspection in 2010. And we formally authorized four of the

five processes to restart. NFS has since successfully restarted each of the four
processes. The uranium hexafluoride line, which is the last process line that
would be restarted, was inspected earlier this month. We're still evaluating the
issues, but I expect to make a decision soon regarding authorization to restart
this process. In the area of safety culture, NFS issued a second independent
safety culture assessment report in June of last year. This report, which was
required by the confirmatory order of February 2007, stated, and I quote, "That
NFS has made only nominal progress in improving the safety culture at NFS
since 2007."

Finally, in November 2010 we issued a second confirmatory order to NFS to document their commitments and response to violations associated with the willful falsification of fire damper inspections, and a lack of progress in the area of safety culture. In addition to implementing corrective actions for the specific fire protection violations, the order requires NFS to develop and implement a safety culture improvement plan to address the findings identified in this second safety culture assessment, requires NFS to perform an integrated, independent safety culture assessment to an accepted nuclear industry standard by June 2013 and at least every 24 months thereafter. It also requires NFS to assess its current corrective action program against the program requirements of the ASME NQA1 standard, and amend its license by July of this year to incorporate a corrective action program that reflects the results of this assessment. Next slide, please.

As for the staff's review of NFS's current performance, we conducted a licensee performance review in February of this year to assess NFS's performance during calendar year 2010. The results of the LPR showed

- 1 that NFS conducted its activities in a way that protected the health and safety of
- 2 the public and the environment. The LPR results noted progress in several
- 3 areas, however continued, sustained performance remains to be demonstrated.
- 4 There are several examples of that I'd like to share with you. First of all, NFS
- 5 has made improvements in the area of management, oversight, and decision-
- 6 making through the increased presence of managers and leadership, including in
- 7 the production areas. NFS has also created a conduct of operations procedure
- 8 to guide and institutionalize the restart decision-making processes following
- 9 process upsets.

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However, NFS has not yet demonstrated the ability to leverage the results of root cause analyses and implement corrective actions for human performance and organizational factors that have contributed to past performance efficiencies.

With regard to safety culture, NFS has demonstrated a greater questioning attitude when challenged by process and or equipment problems as well as a greater willingness to stop work in the face of uncertainty. However, based on our inspections, some employees continued to demonstrate lapses in safety, focus, and judgment.

The NFS has enhanced its corrective action program, procedural requirements for root cause evaluations, and given additional training to individuals who would be assigned to carry out root cause evaluations. However, while the corrective action program has been largely integrated into NFS's activities, some departments apply different thresholds for entering issues into the corrective action program, which they refer to as a "problem identification and resolution system control" program.

NFS has also instituted a new work control program to improve maintenance activity prioritization and the organization of work. However, based on our inspection, some plant employees expressed doubt that the work control process will relieve schedule pressures.

In addition, NFS modified its engineering and design control process to improve the guidance itself and to provide additional detail for establishing the technical basis for modifications. However, because this process was only recently changed and has not been used to implement the modification of any major system processes, it's insufficient -- it's too early for us to judge whether that change will be effective. Next slide, please.

Based on our current assessment of NFS's performance, additional regional initiative inspections are planned and some have already been conducted, beyond the core inspection program, to ensure that NFS continues to operate safely and to confirm that NFS's efforts to correct the underlying concerns demonstrated in the events of 2009. To this end, we've performed a problem identification resolution inspection, which we completed in February of this year. This inspection also included an assessment of NFS's implementation of its safety culture improvement plan and the quality of the safety conscious work environment on site.

The inspection concluded that NFS's corrective action program is actively being upgraded and employees and contractors consider the safety environment to be improved. However, the NFS still has work to do in this area to improve the consistency of the program's ability to resolve issues and to convince staff that the effectiveness of new initiatives, such as the work control group and the senior engineering watch are effective.

1	As part of our confirmatory order follow up, just last week, we
2	started an inspection to verify the adequacy of NFS's actions in response to the
3	remaining areas, specifically the use of root cause analyses and operational
4	decision making. This inspection is still ongoing and we'll close on that issue

soon.

As I mentioned, we conducted a restart readiness review of the
uranium hexafluoride process last week and I expect a decision on that soon as
well. Later this year, we will conduct a confirmatory order follow up inspection to
assess NFS's corrective actions for the fire damper falsification issue that I
mentioned earlier, as well as the corrective actions to achieve and sustain

progress in improving the facility's safety culture.

We also plan to conduct a design verification inspection to assess the effectiveness of NFS's process to evaluate proposed temporary and permanent changes in plant design. This inspection, which is planned to take place either later this year or early next year, will use a multidisciplinary team to evaluate the safety significant systems' fictional performance for one or more process lines.

Finally, we envision the need for additional problem identification and resolution, safety conscious work environment, as well as safety culture assessments and inspections of the amended corrective action program against the requirements of ASME NQA1.

This concludes my presentation. I will now turn it over to Mark Satorius.

MR. SATORIUS: Thanks, Vic and good morning Mr. Chairman and Commissioners. If we could have Slide 28.

1	This slide provides just an overview of what I intend to discuss with
2	regard to the Veterans Affairs and their performance during this last year. I
3	would like to take just a moment, as Vic had done, and provide a bit of a
4	historical perspective. At last year's briefing of the Commission on the results of
5	the AARM we the VA was discussed, primarily because of performance
6	issues associated with VA Philadelphia Medical Center and medical events that
7	went unreported at that facility. In March, before last year's AARM briefing, we
8	provided or we issued a significant enforcement action for the VA Philadelphia
9	problems that amounted to \$227,000 plus.

And then, at the AARM last year, we were also in the midst of performing continued increased oversight at VA facilities and conducted inspections of their other facilities that performed prostate cancer treatment programs. And additional performance-related issues were being revealed at those facilities as well, at that time.

Also, at the briefing of the Commission last year, we had conducted inspections of the National Health Physics program, which is the oversight organization that provides the licensing, enforcement allegations, and inspection oversight to VA permitees. Can I have slide 29?

As we finished those inspections of those facilities that performed those type of brachytherapy operations, we identified five violations at four facilities, not at the breadth and depth of problems that we had seen at the Philadelphia program, but certainly problems associated with procedures and the clarity of procedures, the consistency from location of those procedures and we took those into escalated enforcement and had an enforcement conference in June to deal with those issues. One of our concerns was that we had gotten

1 confirmation from the NHPP program that they would go out and we'd confirm

2 with the confirmatory action letter; they would go out and inspect all of their

3 programs and they did not find any problems. We did confirmatory inspections of

all those programs, as I had mentioned, and did identify a number of violations.

We had an enforcement conference with the Veterans Affairs June of last year. And in August we issued an enforcement action, which consisted of a civil penalty of \$39,000 and we escalated that penalty to reinforce our message that not only does -- did the VA need to ensure that their individual permitees were performing in a manner that was consistent with our requirements, but also their oversight organizations, such as the NHPP and the National Radiation Safety Committee was providing the governance and direction to their programs to be able to improve the overall performance. Can I have Slide 30?

As a result of our oversight, our inspections, and our enforcement actions, the VA has taken a broad range of corrective actions that began even before, to a certain extent, even before last year's AARM presentation. These included the implemented standard prostate brachytherapy procedures across all of their hospitals. They increased the oversight of prostate brachytherapy programs and instituted an annual focused inspection that they performed on the programs, program wide. They increased the member participation during their quarterly National Radiation Safety Committees and improved the quality of those meetings and their level of governance of the programs.

The Veterans Affairs established a management team to facilitate discussions with NRC regarding the VA Masters Materials License and Letter of Understanding. And introduced new staff, senior staff in that they made a change of the chairmanship of the National Radiation Safety Committee, who is

1 currently Dr. Gross, who will be a member of the Veterans Affairs that will brief

2 you later on this morning, as well as the Under Secretary provided a senior level

staff member, Mr. Frank Miles, who will be providing the VA's remarks later on

this morning to add additional focus to their oversight within the National

5 Radiation Safety Committee.

In addition to that, the Veterans Affairs inspection plans were revised to address current and emerging issues, such as executive management oversight, undue reliance on affiliates and contractors, safety conscious work environment, roles and responsibilities of the Radiation Safety Committees and the Radiation Safety Officer coverage. Veterans Affairs also instituted benchmarking initiatives and increased accompaniments during NRC inspections at VA hospitals. And this is a new concept that was developed in conjunction with our Region III program, is that as we perform our required independent inspections of the VA hospitals, they would assign their NHPP inspectors to accompany us. It's to provide them an opportunity to see what is -- what our expectations as a regulator is, as far as how they should be performing inspections. And we've seen good results as a result of that interaction.

And they've made rigorous improvements to their enforcement

I wanted to outline some of the concurrent activities that were taking place that the NRC was involved with. Last July, at the request of the Veterans Affairs, the Under Secretary of Health met with you, Chairman, and -- but was provided an opportunity to exchange views and I know that you had an opportunity to provide your expectations of their roles and responsibilities as far

process. And lastly, we believe that effective communications have been

enhanced. Could I have Slide 31, please?

as being a licensee of the NRC and the responsibility of the oversight to their permitees.

That set the stage for a meeting that was conducted in September, between Charlie Miller and myself, and the new senior members within the VA that were providing oversight and governance for their recovery. And that's Mr. Miles, who you'll talk with later, and also Dr. Gross.

At the end of September, we completed a biannual inspection of the VA. That's a requirement under the MML program, where we routinely -- every two years -- review their inspection program, their licensing program, their allegations program, and their enforcement to ensure that it aligns with our requirements. We had no violations during that inspection.

Region III put together a Veterans Affairs task group that was focused solely on interacting with the Veterans Affairs as they made improvements. It was chartered to enhance communications between the NRC and the Veterans Affairs, so we both would understand what their roles and responsibilities and we could provide guidance necessary for the VA to effectively implement their MML.

Also, it provided focus, oversight, and performance monitoring of NRC, of the Veterans Affairs, and their improvement activities; that proved to be quite effective. That task group has conducted independent in accompaniment inspections of VA facilities, to determine the effectiveness of the VA's corrective action and determine likely sustainability of those corrective actions. Since the task group was chartered last fall, 20 inspections have been completed by NRC, which includes follow up inspections of all but three hospitals that performed prostate brachytherapy implants. And those other three will be completed by

1 June of this year. No violations have been identified.

We've done six inspection accompaniments where we accompany
the NHPP organization and their inspectors as they inspect their permitees. Six
of those have been completed, which included an assessment of each of the
NHPP program managers. We've instituted biweekly conference calls with
NHPP and shared responsibility in alternating the leads in those calls so that
information can be passed back and forth. These are outreach activities that had
not previously been undertaken with an MML.

And lastly, the VA task group and myself have participated in the last three quarterly National Radiation Safety Committee meetings, where I've been able to provide my own perspectives on expectations, and roles, and responsibilities for that organization. Could I have Slide 32?

The frequency, and quality, and effectiveness of communications between the NRC and the VA have improved. Based on the current performance trend, projected oversight of the VA will be adjusted to maintain a graded approach of increased oversight communications with their performance. NRC will hold -- continue to hold periodic internal review meetings to evaluate the VA's performance and determine whether or not VA oversight adjustments are warranted. We see VA performance vector in the right direction, and that's a positive direction. We have the appropriate oversight in place to judge the sustainability of that performance and react if there would be problems. And that completes my remarks. Bill.

MR. BORCHARDT: Thanks, Mark. We continue to believe that the reactor and the materials oversight programs continue to be an effective approach to ensure the protection of public health and safety and the

1	environment.	These programs	allow the ap	opropriate re	egulatory	actions a	and all	low

- 2 us to make adjustments of resources when needed. And we also believe the
- 3 strength of this program that it allows us to continue to refine these programs
- 4 based upon lessons learned and feedback from our own staff and from
- 5 stakeholders.

We do acknowledge that we have before us two issues in the reactor world that will require significant attention, as was mentioned earlier, both the Browns Ferry and the Robinson issues. Browns Ferry was issued a red finding and was moved to Column IV in early May. They have until June 8th to appeal the significance of that finding. Absent any changes to that finding, we will, by our own processes, expect to have a Commission meeting within the six

That completes the staff's briefing.

months of the original placement into Column IV.

CHAIRMAN JACZKO: Well thank you Bill and everybody for a good briefing. We'll start with Commissioner Apostolakis.

COMMISSIONER APOSTOLAKIS: Thank you, Mr. Chairman. Let's go to Slide 9, Mr. Brown's slide.

There is something that is not too clear for me. If we have an event, a sequence consisting of a number of events, but the sequence itself may turn out to be significant. Let's say, we do an ASP and we find other conditional core damage probabilities, about 10 to the minus 3. But then that sequence, say, consists of four events, three events and here we have some like that.

Does the ROP process each one separately and would that give a misleading indication with regard to the severity of the event, if we do them separately? Because here, you say that there was one white finding for

- 1 SCRAMS and two white findings in the mitigating systems cornerstones. But if
- 2 you take them together, maybe it's a much more serious event. So now you do
- 3 say at the end though that there will be an ASP, and which is not part of the
- 4 ROP? Right, the ASP, and maybe there will be insights concerning what we
- 5 need to do to the ROP. So, can you comment on that?
- 6 MR. BROWN: Yes, sir. It's a really great question. It was
- 7 something that we on the staff spent a lot of time talking about at the AARM.
- 8 I'll attempt to provide the answer, and then the people that are
- 9 smarter than me at the table will correct everything I say wrong here. The ROP
- 10 fundamentally, when it was put together, was designed to assess licensee
- 11 performance focused on performance deficiencies within their programs. And so
- it accepts as a baseline that risk and those things that are allowed by license.
- 13 Out-of-service equipment is allowed by the technical specifications. That out-of-
- service equipment can affect the total risk when an event occurs, but within the
- 15 ROP, we break each performance deficiency out and look at it individually. We
- do, however, aggregate those individual performance deficiencies in the action
- 17 matrix. So two whites have the same effect as a yellow. We've implemented this
- 18 program for 10 years and we've seen that this approach works fairly well. I
- 19 guess, let me also say, the ASP looks at total risk, including the risk that was
- 20 inherent in the authorization basis for the facility. So we could find a risk-
- 21 significant condition that calls on the staff to look at regulatory changes, but really
- 22 doesn't reflect on the performance of an individual licensee at all. And so, it's
- 23 important to have the ASP and to look at integrated risk. But it's a separate focus
- and a potentially separate outcome.

The unique thing about the H.B. Robinson event is that most of the

1	input into the ASP calculation was actually associated with performance
2	deficiencies, but not all of it. And some of the performance deficiencies don't
3	reflect current performance under the rules of the ROP. And so, we end up with
4	results that appear to be different between integrating within the action matrix
5	and integrating within the calculation, but some of it is because it doesn't actually
6	reflect on licensee performance. So at the AARM, we had a very spirited
7	discussion and examined a lot of different options about whether we're at the
8	right place or whether there are changes that would be appropriate. And the
9	conclusion I would summarize that discussion as coming to the conclusion that
10	any fundamental change to the ROP SDP process would not be consistent with
11	the logical structure and policy decisions that were made in putting the ROP into
12	place, but that we could get to the right place, very similar to what we did this
13	year, by using the ASP insights to make sure that we and the licensee got to the
14	correct end result. And that's what we're formalizing. But there are different
15	programs with different objectives. I hope that helped.
16	COMMISSIONER APOSTOLAKIS: But you are saying that you
17	have identified an improvement opportunity within the ROP?
18	MR. BROWN: Yes sir, and that's formally documenting this
19	process of looking at the ASP results and making sure we will look at the
20	ASP results regardless and look for programmatic changes may be indicated.
21	But this change will make sure that we also look at those results to ensure that
22	the licensee has corrected all of the problems that need to be corrected to ensure
23	the level of performance going forward that are expected by the Commission
24	within the policy of the ROP.

1	individual evaluations, you come up with all whites, that the ASP and that takes
2	you to a particular column that the ASP will move you to another column?
3	MR. BROWN: Yes [inaudible] -
4	COMMISSIONER APOSTOLAKIS: As matter of judgment.
5	MR. BROWN: I would say that it is if you look at the numerical
6	results of the calculations, that you can run the SDP for the individual
7	performance deficiencies and get an outcome in the action matrix. And if SDP
8	were done the way ASP is done, the ASP results would look different. And that
9	is true. That's a feature and the nature of the program that was recognized. It's
10	been recognized over the history of the program and discussed. And so, the
11	purpose of this change is to make sure that we codify a requirement for us to go
12	back and assess whether that leads us to conclude that additional action is
13	required via deviation.
14	MR. BORCHARDT: The ASP does not feed into the action matrix.
15	The burden would fall to us do we want to assure deviation based upon what
16	we learned from the ASP or any other insight? And that's why we have those
17	flexibilities. But
18	COMMISSIONER APOSTOLAKIS: So, the action matrix then itself
19	it's not the the decision what to do is not based on strictly on the action
20	matrix. I mean, you look at other things too, like ASP. Is it action matrix
21	[inaudible]
22	MR. BORCHARDT: The action matrix is the default answer. We
23	retain, you know, the regulatory authority to have deviations to it. And you know,
24	we don't want to be tied exactly to it and have us not do the right thing because
25	the action matrix didn't predict that scenario. So, we have the flexibility but as we

talked about, for the vast majority of cases, the action matrix turns out to be the
 appropriate regulatory response.

3 MR. BROWN: We actually -- enforcement -- traditional

- 4 enforcement issues are utilized the same way within the structure of the ROP.
- 5 They don't drive the action matrix, but we consider them, as we will now, with the
- 6 ASP results, about whether there's a need for a different action.

COMMISSIONER APOSTOLAKIS: Okay. I'm very much interested in this, and you know, if you try to do something like concrete, I'd like to see it for my information because this is a perennial problem with sequences of events. I mean, you know, you can break up a sequence into many, many sub events and then each one will turn out to be insignificant. But put together, we have a problem.

Regarding human errors in materials and hospitals, I know that our Office of Research has done a lot of work on human error, but I think all of it or most of it is focused on reactor operators. Have we done any work on human error, tried to understand better, you know, what leads people to make mistakes and all that? That might be helpful in the non-reactor areas, so, have we taken advantage of this research or not?

MR. MOORE: We did a significant amount of human factors-type work during the 90s, in the medical area, and looked -- at that time, it was misadministrations versus medical events. And so, we have looked at that and ways to potentially prevent it. And at that time, it was certainly a newer field and was tied to the airline industry, in fact, and what they were doing within the airline industry. And we had staff on the -- we had staff within the agency. In the materials program, in fact, that were human factors experts. But specific

1 research projects, I'm not sure whether we have.

COMMISSIONER APOSTOLAKIS: Yeah. Sometimes human factors research is different from human error analysis. And it seems it was done in the 90s, maybe it would be a good idea to go back and look now, whether with the latest thinking in the reactor area, whether there any insights that could be transferred to the materials area. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: And -- I was talking about -- but we did, I thought, specifically, within the last five years, look at this particular issue. Didn't we come up with a tool box in the human factors, specifically looking at the medical events in the human factors aspect of it. But we can maybe get some information on that. Commissioner Magwood?

COMMISSIONER MAGWOOD: Thank you. First, let me thank

Mark and Vic for their work on these issues. It's sometimes it's easy to forget

from the remote location in Rockville, Maryland the important work that you folks

do on the front lines, so I appreciate what you and your staffs have been doing.

Let me start with you, Fred. The -- I'm looking forward to the staff paper on both the incorporation of the security into the larger ROP and also the affluence issue, that's something that, of course, we talked about quite a bit and looking forward to seeing staff's thoughts about that. But let me ask you a question about the security SDP. In having the discussion about reincorporating that into the ROP proper, was there much discussion with among the staff about the SDP itself and whether it's doing the job that we want it to do, in the security area?

MR. BROWN: Yes, sir. There is a lot of discussion about the security SDP, especially with respect to force-on-force right now. The Office of

1	NSIR is working with	industry in the	regions to atter	npt to modify t	that. There is a

- 2 paper, I believe, working its way to you, here in the near term, that looks at the
- 3 potential ramifications of different types of approach. I'm not directly involved
- 4 with that, but I am -- and we do coordinate, and I am familiar -- and the essential
- 5 answer is yes, it is under review.
- 6 COMMISSIONER MAGWOOD: I'm pleased to hear that and I look
- 7 forward to that. The -- I just -- you mentioned, Fred, just sort of in passing, the
- 8 NSPDP staff, that they're coming though -- and I've been to several plants so far
- 9 this year, and run into several of those people, and just sort of passed on, that
- 10 you know, I'm just really impressed with the young people. I spent some time
- 11 talking with all of them. The enthusiasm that they bring to the work is really quite
- impressive. And they do seem to be quickly inculcated into the NRC culture.
- And I appreciate the fact that we bring people into those opportunities. So I think
- 14 that's working out very well.
- Let me move on to Vic for a moment. I'm looking forward to
- hearing what NFS has to say to the Commission to this morning. But, one
- 17 aspect of NFS, of course, we've all observed is that it seems -- and I don't have --
- 18 I think that the Chairman said that this is the fourth time in a row that they've
- been here. This is my second time with them and it seems that every time they
- show up, they have a new person in charge.
- 21 CHAIRMAN JACZKO: And I think that's all true for all the four
- 22 times that they've been here --
- COMMISSIONER MAGWOOD: Four times, yeah. But that has to
- 24 have an impact on the work -- on the effort that they're pursuing, to try to improve
- 25 operations because -- and we'll discuss with NFS here at the table -- almost all

- 1 these issues come back to leadership. And if the leadership is eternally shifting it
- 2 has to be difficult to wrestle these things to the ground. Do you have any
- 3 observations about that, and how the leadership shifts, in the impact that their
- 4 efforts.
- 5 MR. MCCREE: Mr. Commissioner, thank you for the question.
- 6 And I would agree that it has to have some impact. Of course, our focus is less
- 7 so on the leadership changes themselves, but the impact that those changes
- 8 have on NFS's ability to drive improved performance. And of most importance,
- 9 as I shared, during 2010 we conducted some very intensive RESTART
- 10 Readiness inspections focused on those, the chronic issues, if you would, that
- surfaced in the fall of 2009, and were able to have reasonable assurance, if you
- would, that they had -- NFS had affected change to allow the restart of those
- 13 processes and were close on the remaining line as well.
- 14 I do suspect, however, that the leadership changes could affect the
- 15 pace of NFS's improvements in the area of safety culture. And I too am
- interested in what Mr. Henry and his leadership team are going to be able to do,
- 17 given the challenge that they have and the change that's occurred, to move that
- 18 forward. But we'll still focus on the results.
- 19 COMMISSIONER MAGWOOD: I appreciate that. Mark, the -- as
- 20 you've spent a lot of time with this issue with the VA and I appreciate some of the
- 21 insights you've provided in the previous discussions on this issue. But let me sort
- of look a little higher-level for the moment. When you look at this matter and you
- compare the performance of the VA hospitals to other hospitals who are direct
- 24 licensees of either NRC or the United States, do you perceive a difference in the
- 25 nature of the hospitals operating under the Masters Materials License versus the

direct licensees? And do you feel that the Master Materials License process is effective? Do you feel it's doing the right job or should we go back to having a

more direct relationship with these hospitals?

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MR. SATORIUS: I think -- I'm going to approach your question from the back end first. Do I think that the MML process is effective? Yes, I do. It necessitates a strong NHPP-like organization. In other words, the oversight aspect of the MML needs to be -- needs to have some strength to it. And it has to have the appropriate oversight and quidance. And that's where you may not get as much focus as what you needed. And that's what I think exactly happened with the VA hospital organizations in the past, was that the NHPP organization -- their oversight, their inspection, their enforcement, their allegations didn't have the strength or the governance at higher levels within the VA to be able to perform that NRC-like or regulator-type role. And I have to say that one thing that's interesting with the NHPP is that they have a difficult job because on the one hand, they need to remain at arm's length with their permitees, but at the same time, there's a certain level of coaching and describing what's right that they need to be able to do. And that's difficult. And it's taking some time. And I think that, in our work with the NHPP and with the National Radiation Safety Committee, we've been able to introduce those senses of what the appropriate roles and the responsibilities are. But they have to be able to perform those activities. So I hope that helps.

COMMISSIONER MAGWOOD: No, I appreciate that. And let me sort of ask the next obvious question. In hindsight, of course, hindsight is always a wonderful thing to have, would it have been impossible for us to detect those weaknesses before they ran into the problems in Philadelphia?

MR. SATORIUS: I think the word is "maybe." I think that there—as we look back at 2003, as they were first introduced into the Masters Materials program, there was some growing pains, let me just say. And the other thing—that I know that I talked about last year at a Commission briefing, not the AARM one, but it was before you were seated sir, on Masters and Materials program is we have three Masters Materials licenses within the agency. And two of them are the Air Force and the Navy. And they're different organizations than the Veterans Affairs. They are organizations that are military in nature and they have, what I would call, a compliance sort of mindset. And they're smaller programs as well. So there's a difference between the three, if you understand what I am saying, and I think that the larger challenges are, particularly with the Veterans Affairs, as opposed with the Navy and the Air Force.

COMMISSIONER MAGWOOD: And again, not trying to make a judgment here about this, but it seems to me that therein lies the issue, you know, the fact that the Veterans program is very different from other two. Yeah, because I suspect it might even be difficult to translate lessons learned from this to the other two MMLs.

MR. SATORIUS: And we have performed a lessons learned review focused pretty specifically about the Veterans Hospital in Philadelphia. And Scott's organization has performed that. And then I think we've gotten some -- the Inspector General has also performed an audit in that area as well. So we have a number of starting points that we -- that I know Scott's organization is planning on moving forward to examine MMLs, and do we need to make changes, you know, do we need to have certain hold points at various times that we need to do more closer assessments and realignments. So, I don't know if

- 1 you wanted to add anything to that, Scott.
- 2 MR. MOORE: Just that the VA MML task group came up with over
- 3 40 recommendations. We're in the process of implementing many of them.
- 4 Some of them will take time to implement. I think that one of the biggest lessons
- 5 from it is that the VA, I think, to answer your question was, I agree with Mark, in a
- 6 state of transition. And that made it different from the other two MMLs. And so,
- 7 some of the things we can learn from the VA experience in Philadelphia have to
- 8 do with transitioning any MMLs from the beginning, and we need to be very
- 9 careful as they move in. So -- but there are a number of recommendations that
- 10 we're moving on.
- 11 COMMISSIONER MAGWOOD: Thank you very much and thank
- 12 you, Chairman.
- 13 COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman.
- 14 Thank you all for your presentations. We'll start off on the reactor side here with
- 15 Fred and Bill, if you want to add to this quick, you know, response. Note that we
- 16 have the slides on -- that Commissioner Apostolakis discussed on Robinson.
- 17 We'll be hearing from Browns Ferry later this year.
- 18 I know we don't have a reactor licensee here today at the AARM.
- 19 Go back to, Fred, your Slide 8. And I know we don't cross those bars that you
- 20 have for the short-term prediction limit nor is there an assessed increase in trend
- 21 over time, but nevertheless, in 2010 we have a big spike. And just without
- targeting this question to any specific plant or utility, I'm just wondering, Fred, if
- 23 you and Bill have any comments or any thoughts on any concerns on the nuclear
- industry's ability to safely operate plants, based on what you're saying?
- MR. BROWN: So, one thing about this number that bears keeping

- 1 in mind of these events, there were two performance deficiencies, one each, at
- 2 Oconee and Browns Ferry that affected six units. So that as we do this on a per
- 3 unit basis, this is factual, but we did bear in mind that it was actually five,
- 4 essentially, performance problems that resulted in the spike. And we don't
- 5 believe that these five events reflect a broad industry issue. Each did give us
- 6 important insights about the individual licensees, but I think the unease that you
- 7 voiced was exactly the kind of discussion that we had at the AARM. We had
- 8 looked at this and had looked at each of these events and within the program
- 9 process, asked ourselves, "Is there a change to the ROP that's indicated?" And
- 10 we concluded there wasn't.
- But there is a need to go back and go -- and peel that onion a little
- 12 further and make sure we understand, at least at a root cause level,
- fundamentally, is there something here that could be broader that we need to be
- 14 aware of, and think about, and look more fully. And that was the result -- cause
- 15 for the additional action.
- 16 COMMISSIONER OSTENDORFF: Bill, do you --
- 17 MR. BORCHARDT: Yeah, Commissioner, as you know, INPO and
- then each individual plant has their own set of performance indicators that go into
- much more granularity than we use for ours. It's always a challenge every year.
- 20 We think about our -- is the regulatory threshold, which is these PIs are aimed at
- 21 -- getting an assessment offset at the right place? And so I think you need to
- look at all the information inspection findings, all our PIs from a regulator's
- perspective, and then recognize that there is that much more granular lower
- detailed set of performance indicators that the industry monitors on their own. So
- 25 I think right now, we're satisfied with the current thresholds of our Pls.

	COMMISSIONER	OSTENDORFF:	[unintelligible
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MR. SATORIUS: Yeah, if I could add a perspective, Commissioner -- and that is, both at the AARM, at the mid-cycle ROP sessions, at the end-of-cycle ROP sessions, on weekly calls that our Reactor Division directors have amongst themselves, and the discussions that we RAs have -- we are always looking at other aspects, and picking away, and questioning whether -- let's not allow ourselves to be convinced that there is more out there. And we talk about there's been a lot of special inspections in the last couple, three months. Is there anything to that?

You know, those kind of questioning attitudes, I think, are very, very healthy and we use those to attempt to flesh out any lower level issues that may cause us to have a circumspect look at what's actually out there.

COMISSIONER OSTENDORF: Okay. Vic?

MR. MCCREE: One example of that -- during the most recent endof-cycles that we had, at least in Region II, had seen a slight trend uptick in the
number of fire-related events. And we asked the question of ourselves and then
more broadly, at the Agency Action Review Meeting, whether an uptick in that
area was being witnessed in the other regions. And it turns out that that's not the
case. But there is that level discussion, at a lower level, if you would, that's
ongoing, to try to identify generic trends that would not only influence -- well, it
would influence what we would look at, how frequently, do we need to have
some reactive focus, if you would. Although it's a lifetime ago, I'd also mention
that this level of discussion also occurred at the Regulatory Information
Conference. During the regional breakout session, we of course discussed these
trends and the need to keep a close eye on any trends that may not be evident,

1 even in the data we're looking at.

2 COMMISSIONER OSTENDORFF: Okay. Mark, I'm shifting back 3 to you. I'm going to kind of fall on where Commissioner Magwood was -- his line 4 of questioning. Only about a year ago, after the first day -- or in the -- we had 5 attended here, the three of us – you and I chatted and then we had a subsequent 6 chat over the last year, a couple of chats about Region III's interface with the VA. 7 And I know that we saw the initial approach that had been undertaken by the 8 NRC was maybe not being as effective as it might be and I applaud you for this. 9 I think, through your leadership, took a course change in an innovative manner to 10 bring in the NRC through a partnership -- more of a mentoring, coaching, if I can 11 -- I think that's a fair assessment of what you've done. Is that correct? 12 MR. SATORIUS: Yeah, you know, I wanted to come here prepared 13 with the right word because -- but that's close. You know, and I'll let you finish 14 your question before I --15 COMMISSIONER OSTENDORFF: Yeah, exactly. And you talked 16 about bringing, you know, the -- having NRC inspections, inviting VA to 17 participate to kind of instill the same standards, at least in communicating to the 18 VA, "Here's what we're looking for." And just do it by looking at a facility. That 19 kind of thing, which I applaud that. And I'll give you a chance to maybe 20 characterize more accurately than I have, but I've been impressed what you have 21 done there. And I wanted to see, in your years of experience as a regulator – 22 let's go outside the VA piece here -- are there any lessons learned? Do you think 23 you have seen, potentially for the NRC as a regulator, to maybe capture those --24 that new approach in other areas outside of the VA or outside the MML? 25 MR. SATORIUS: The VA was a particularly special instance. And I

1	think we	've discussed	this before	, where to l	be a Masters	Materials	License, <u>y</u>	you
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2 have to be a member of the federal family. And we were the tough regulator that

we needed to be, and should continue to be, as we dealt with these enforcement

actions. But at one point in time last summer, we looked at the letter of

5 understanding. And as you'd said, the approach -- we have somewhat of a

paradigm shift in that, you know, this is a member of the federal family that we

want to succeed. And we have our regulatory responsibilities to remain at arm's

8 length.

But we need for the Veterans Affairs to be successful here. And looking at the letter of understanding, that allows us to maybe travel into some of these places we don't go normally with our own folks that we regulate, that the reverse accompaniments, you know, having their inspectors come with us as we perform inspections, having our inspectors go with -- we send our Allegations Coordinator down there to show them what good was.

So we thought we needed to do and we thought we had the responsibility to do that, as a member of the federal family with the very, very important job of seeing to the health of our veterans. Now, is that -- can we transfer that over to -- that would be a difficult step to make, to transfer. But there could be some lessons that might be learned. And I know that once that we sunset our task force -- which we intend to do in the June time frame -- we're going to take a look at some of the things that we've learned and certainly work with Scott's organization to see if there's --

COMMSSIONER OSTENDORFF: There's a good opportunity to learn something here.

MR. SATORIUS: Certainly.

1	COMMSSIONER OSTENDORFF: And I think it also but just not
2	in the context of this one piece, but a [unintelligible] and broader piece.
3	MR. SATORIUS: Agreed.
4	COMMISSIONER OSTENDORFF: And again, thank you for your
5	leadership in that area.
6	MR. SATORIUS: Thank you.
7	COMMSSIONER OSTENDORFF: Vic, I know we've had some I
8	want to turn real quickly, in the time I have left, to the NFS. We've had some
9	good discussions during trips we've had a chance to make here, just in the last
10	couple of months. I'm mindful the Chairman and Commissioner Magwood
11	discussed, you know, the four different, I think, leaders of NFS over a period of
12	time and challenges that brings to the equation. And certainly, I have the
13	privilege of working for Joe Henry. He was my boss for a period of time, back in
14	the 1990s. I have a tremendous respect for his leadership in nuclear
15	competence in the Navy. When I was in NNSA, he was brought in to help
16	improve nuclear safety at the Y-12 National Security Complex. Did a fantastic
17	job and I've got tremendous respect for Admiral Henry.
18	That said, whenever you have a dynamic where you've had a
19	number of leaders coming in always concerns. What is your assessment? And
20	I'm going to ask Admiral Henry the same question, of the willingness of the
21	organization that he's leading to respond to change and respond to leadership?
22	MR. MCCREE: We've seen positive observed positive response
23	from our inspections, most recently at the problem identification resolution
24	inspection that we completed in February that the people at NFS have
25	responded positively to the changes that have occurred over the last year or so.

1	There has beer	n significant	change in	nitiated at	NFS si	nce the	confirmatory	/ actior

- 2 letter was issued last January. And a number of those changes, which I'm sure
- 3 Admiral Henry is going to speak to are ongoing. There have been significant
- 4 process and procedural changes. There have been organizational changes that
- 5 have been made. When we talked about leadership, a number of the leaders
- 6 that were put in place and reorganized, if you would, more than a year ago,
- 7 remain in place. The organization is now structured in a manner that allows them
- 8 to drive change with a bit better span of control and organization -- organizational
- 9 effectiveness to what they're doing.

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But based on the insights from our inspections, the safety conscious work environment, types of looks we've gotten -- we've undertaken interviews with staff as well as managers. The organization has responded well to the changes that they put in place. We are -- what we need to see is continued, sustained, improved performance. And that's what we're waiting for and that's what -- that's the reason why NFS is here today, because we've not yet seen that type of performance.

COMMSSIONER OSTENDORFF: Thank you. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Svinicki.

COMMISSIONER SVINICKI: Thank you all for your presentations. I'm reminded that the AARM meeting that we have every year, there's a lot of assessment and work that the staff does in the lead-up to that, and so the Commissioners are provided with a lot of those annual assessments and background information prior to the meeting. I have some questions that have their basis in some of the assessments and evaluations that you do in the lead-

up to your AARM meeting.

One of them is the annual self-assessment of the ROP and that culminates in a SECY paper that we get, so I'll direct this to you, Fred. One of the areas that you're going to be looking at for potential improvements is the substantive cross-cutting issue process. Could you talk a little more about what the staff's planned evaluation is in that area?

MR. BROWN: Yes, definitely. The Commission policy statement on safety culture positions us now to have a dialogue with the industry about a common language of how to describe plant performance issues, so that they and we are talking about the same thing, where there are issues and aren't issues in the different data streams. They are broad data stream in our data stream of NRC identified in self-revealing issues.

And so we plan to meet with INPO along with NEI in the coming weeks and start the dialogue about filling in at the level below the policy statement with this common language. And then we can leverage that to revise the existing ROP processes to use a language that similar to what the industry will be using in their initiative. And then, once we're talking about the same things in the same way, hopefully that will eliminate some of what I believe has been talking past each other -- examples in the past. And it'll put us in a position as we see the fruits of the industry initiative to decide whether we want to make fundamental changes to the SCCI concept, based on performance and outcomes.

COMMISSIONER SVINICKI: So would it be accurate to say that you're looking for some definitional clarity there, maybe driven by the safety culture of policy statement and INPO's work, and that that might ultimately be

able to chip away at some of the concerns about maybe the subjectivity or the
iust opaqueness of substantive cross-cutting issues. Is that the intention?

3 MR. BROWN: I believe you said it very well -- yes.

COMMISSIONER SVINICKI: One of the other areas -- and you did make mention of this today is reintegrating or integrating safety or security back in the security cornerstone. But I think in one of the papers it said, it could be that a security issue would have the same root cause as a safety issue. Could you give me an example of what you're thinking about when you say that?

MR. BROWN: Yes. So, configuration management within the plant could manifest itself in a safety system that doesn't perform its intended function. And the same kind of configuration control processes could result in a security function not being performed. And that common inability to control modifications and operation of the plant would not be pulled together in an integrated way under the current structure would be two issues in -- excuse me -- separate action matrices. But that's the kind of thing we were talking about.

COMMISSIONER SVINICKI: And why -- explain to me how not being able, as you said, to pull those together affects our regulatory response. Is it because it would indicate that it's more pervasive and it requires a more severe regulatory response? Is that what you're not able to do, the way it's structured now?

MR. BROWN: Yes, essentially the difficulty is between Columns III and IV of the action matrix for the graded cornerstones. So the original construct of the action matrix was a yellow in mitigating systems, the example I just used, and a yellow in the safeguards security cornerstone would have resulted in multiple degraded cornerstones. And a 95-003 inspection and the associated

- 1 licensee actions to find that configuration management problem and address it,
- 2 and for us to assure it was addressed. And in the current construct, we don't
- 3 have that tool.

there, that with this reintegration, you would count the same condition multiple times? Meaning that it would be like if you found a safety issue in one electrical panel and you found it in the panel next to it, you're going to count every panel individually and then be able to have a greater cumulative weight there. Do you see what I'm saying? Configuration control, or whatever was the example you just used, if it's like in Room A and Room B, that doesn't make it twice as much a problem, necessarily.

MR. BROWN: We do have a provision in the ROP on double counting, not to take the same performance deficiency and apply it multiple times. However, a configuration problem that results in one set of safety-related equipment being inoperable and a separate application of the same problem, but in affecting different equipment through a different maintenance activity or different modification would be a separate input, both within the safety ROP currently, and as envisioned by the staff, within the security. But if it's a single occurrence, we don't double count it. If a single occurrence leads to multiple inputs, we only look at one input.

COMMISSIONER SVINICKI: Okay. Thank you, that's helpful. Fred, another item that I think you touched on. So I'll direct this to you, but I think Mr. Borchardt or actually our regional administrators might actually be closest to this issue. You do very careful assessments and evaluations, and I don't mean to do a disservice to that, you know, but I hear things as I move about, so I hear

1 anecdotes. And anecdotes are never a basis for decision-making but I think they 2 often merit looking at because sometimes we're looking for leading indicators of 3 things and maybe something isn't a systemic problem now, but if you begin to 4 hear anecdotes, you always want to think about it a little bit. So I want to 5 characterize this statement that I'm about to make, but, you talked about resident 6 inspector demographics. Maybe you spoke more broadly about inspectors, but 7 I'm interested in resident inspectors. And I have heard a couple of anecdotes 8 about, of course, senior resident inspectors often want to pursue promotions and 9 opportunities, and that's appropriate and we encourage them in that. But as we 10 go to fill senior resident inspector positions, obviously resident inspectors who 11 have some run time in the job want to be able to apply for those. And I've been 12 hearing about instances where, although, again, we encourage that resident 13 inspectors should want to move up to senior resident inspector jobs, that 14 sometimes the applicant pool is a bit thin and will include resident inspectors who 15 have, you know, little more than a year as a resident inspector. And I think that 16 we've had the luxury of having senior residents that have much more than maybe 17 one year experience as a resident inspector. 18

Do you look at those kind of indicators, going forward, that maybe we don't have a problem now, but if we were have to batch a senior residents moving on, either to other promotional opportunities or retiring, do we have a healthy pool of individuals that we would have good applicants for senior resident jobs?

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MR. BROWN: Yeah -- I'll address that at the metrics level on demographics and then let the Regions give you more specifics -- but one of the things that we see in the demographic report is that we do have residents who

have a good base of NRC experience and resident time experience and we've essentially maintained that for the last couple of years. That was the concern three years ago, that we had so much churn and turnover that we would have had a dire situation with staffing at the senior resident level and the resident level. But I think across the program right now, we're seeing more stability and more build in of NRC and resident inspector experience. I'll let the RAs talk about the selections.

MR. MCCREE: First of all, thank you for the question. And I feel very comfortable in saying that we have been able to hire, and train, and develop, and nurture a very strong group of resident inspectors that are poised to take on positions of greater leadership, both as senior residents or in positions in either headquarters or the region. It's something that we monitor continuously. There's a plan that each of their supervisors developed for them so that they're participating in the right activities vis-a-vis inspection at their site and or other sites, and again, through training, so that when these opportunities do become available, that they're positioned to be competitive for them. It's an ongoing process because there's a continuous change-out, if you would, in residents and senior resident inspectors, but I feel very comfortable about what we have in Region II.

MR. SATORIUS: Yeah, I share Vic's comfort in that, in that we've got a good pool. Do we think about it and worry about it? Every week we think about it. Who's unmasking my DRP director at least twice a month? Who's your next senior resident? Who's ready to go? Who's not ready to go? What do we need to do to get him ready to go? Vic made the point, too, or maybe Fred did, that we've had instances where we've had a resident that was a resident for a

- 1 year. And we moved him to a senior. But his background, the whole person you
- 2 know, was he or she licensed? You know, what's their background previous --
- 3 their nuclear experience previous to NRC? So, it's something that I think about
- 4 all the time.

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5 MR. BORCHARDT: I'd just like supplement with one idea. Even if

6 you took the worst case scenario, where we had to take somebody who didn't

7 have the level of experience today and put them into the senior resident position,

we have behind that -- or above that, a first line supervisor branch chief in the

region that -- this is another very highly qualified, capable set of supervisors that

can provide on-the-job training and direct oversight on a day-to-day activity for

11 those individuals and help them get up to speed quickly. So we're not -- you

know, we have a defense-in-depth into the quality of the inspection that we have,

that doesn't rely solely on the initial qualification and capabilities.

I -- without revealing too much, you'll be able to figure out where my anecdotes come from, but I am aware of that as a backstop. But then, what happens is I think that that branch chief in the region ends up spending a lot more time on that maybe than they had planned for when they were kind of resourcing themselves for the year. And so I'm not concerned about it from an ultimate backstop standpoint, but I think it does change the mix of resources. We've also had, as Mark said, kind of conversationally, a lot of special inspections and other things. So, the inspector, if you take regional inspectors and resident inspectors, you know, we've got a resource that's getting pretty much to the full commitment of their time and availability, so -- and then they don't have as much time, maybe, for training or, you know, rotational opportunities. And I know that that makes the

1	job less attractive then, so it all kind of slings back around. So thank you for
2	worrying about. That was my I think the most important thing is you definitely
3	have eyes on it. Thank you for that. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: I want to go back to the ASP and the STP difference. Part of [unintelligible], as Commissioner Apostolakis was saying, a significant difference, or one of the differences between the ASP and the STP has to do with how we're accumulating or adding different events to get a total number. And this is hypothetical, and hypotheticals are always probably difficult, but, I think part of what I heard, Fred, your comfort is that ultimately, the action matrix is adding back in or is doing that addition of events, or separate events, to get essentially the cumulative kind of risk number, which would be their placement in the action matrix.

If -- and I can see that that's true with white findings, and yellow findings. But if it's green findings, that's not necessarily the case. Now, maybe you can never get a significant precursor with events that wind up being all green findings, but is that a concern there? Because I mean, effectively, green findings don't add at all.

MR. BROWN: Yes, and the reason we had a spirited and energetic discussion at the agency action review meeting was pretty much exactly what you're describing. If you look at Robinson, there were latent challenges caused by things that were not reflective of current performance. And there were performance deficiencies that were individually green. And that led to the discussion that we had.

CHAIRMAN JACZKO: It was green -- there were green findings.

MR. BROWN: There were green findings associated with that

- 1 event. And at the end of the day, what we concluded was we have a tool that
- 2 seems to implement a policy effectively to ensure we get to the right place,
- 3 especially with the kind of closing the loop that we did. And every option that we
- 4 discussed as alternatives was going to create more problems, in our view. That's
- 5 not to say that this isn't a potential policy issue and that, you know, there are
- 6 other ways to do it. But we spent a lot of time really trying hard to see, is there a
- 7 clearly superior approach? And we did not come up with one in those
- 8 discussions.
- 9 CHAIRMAN JACZKO: I mean, in principle with -- I mean, in fact,
- 10 you could have an event that has an ASP that's even much higher that has
- absolutely no regulatory findings. I mean, I guess that's possible.
- MR. BROWN: Yes, absolutely. An initiating event, not associated
- with a performance deficiency that has a significant impact on plant safety profile,
- would show up in ASP and would lead us to look in at the regulatory structure
- across the industry, but would not be reflected on the individual licensee unless
- the individual licensee somehow had contributed to that vulnerability through not
- 17 meeting expected standards.
- 18 CHAIRMAN JACZKO: It is an area where there does not appear to
- 19 be a simple answer, but if I could look at it from a more generic perspective, I
- 20 think Commissioner Svinicki touched on this, I mean, there are a lot of other
- 21 inputs to how we look at performance that aren't necessarily factored into the
- 22 ROP. I think, Bill, you answered a question from Commissioner Apostolakis to
- that effect. But is this something that we're looking at? And again, I'm thinking of
- 24 things like special inspections. I mean, we may have a special inspection.
- 25 Special inspections aren't necessarily ROP related or reflected in licensee

- 1 performance in the action matrix.
- 2 Is there discussions about whether or not we should be, somehow,
- 3 looking at, I mean, is there a performance indicator that should track special
- 4 inspections, some other way to kind of bring that in, in a way that is consistent
- 5 with kind of the principles and objectives of the ROP?
- 6 MR. MCCREE: If I could, the reactive inspections that you're
- 7 speaking to under Management Directive 8.3 -- the specials, the AITs, and
- 8 incident investigations do evaluate the condition, if you would, do evaluate the
- 9 deterministic condition to see if it meets the threshold. And we then look at the
- 10 conditional core damage probability and or conditional [unintelligible] or early
- 11 release frequency and use that as a basis, if you would, for judging whether to
- 12 and what level of reactive inspection to send. So, it's more akin to the ASP
- 13 analysis in that it --
- 14 CHAIRMAN JACZKO: But, you know I understand that. What I'm
- 15 getting to more is our evaluation of licensee performance. If you've got a
- 16 licensee that's had 10 special inspections in an AIT and is in Column I of the
- 17 action matrix, is there a piece of information we're not missing that we should
- somehow be incorporating into that? That's more -- it's the same thing with the
- 19 ASP, but it's your significant information, but it's not tying into licensee
- 20 performance in the action matrix. Similarly with SI -- similarly you could go to the
- 21 point of escalating enforcement actions. That all of these are pieces of
- regulatory information, but as of now, they don't affect our assessment of
- 23 licensee performance in the action matrix.
- MR. SATORIUS: Actually, Chairman, it's pretty routine -- you
- 25 generally will get findings out of special inspections.

CHAIRMAN JACZKO:	Right.
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MR. SATORIUS: So then they do get plugged into the ROP and those performance issues that are identified have to be dealt with by the licensee, and it goes through our process. So, you know, for an example, we've had special inspections where we'll have white findings. And then that feeds the action matrix.

And another aspect is that if you've got five or six greens, typically you're going to have -- there are usually deeper-seated problems that result in substantive cross-cutting issues, so you have a lever there to use as a leverage with licensee management to push, because when licensees ask me, "Well, how do I not have any substantive cross-cutting issues?" And I said, "Well, don't have any findings. You don't have any findings, there are not going to be any substantive cross-cutting issues."

CHAIRMAN JACZKO: No, I appreciate that and I think that's a good point. And I think -- just one last comment on this and I'll move on to a couple of other things. But again, are we looking at the baseline inspection program when we see, you know. I think it certainly is a good thing if the supplemental-type inspections are identifying findings, but that's why we have a baseline inspection program. So, you know, again, is this telling us something about the program, where -- should we reevaluate our baseline inspection program in some way? I mean, these are things -- are these things you're looking at so, I mean, in theory, if there's an underlying issue, our baseline inspection should identify it. It shouldn't necessarily take a special inspection --

MR. BROWN: Absolutely, sir, and I'll give you two recent examples addressing the issues you raised. H.B. Robinson, led us to go back and look at

- 1 the way we do operator -- the licensed operator inspections and we're revising
- 2 our regualification inspection procedure at this time to address the lessons
- 3 learned from the AIT at Robinson. And the other thing I would say is we actually
- 4 do, and Vic said this, through the mid and end of cycle processes under our
- 5 management chapter -- inspection manual chapters -- look at inputs that are not
- 6 direct inputs into the action matrix, to identify additional actions. So, at San
- 7 Onofre, there was a deviation based on inputs that were not action matrix inputs.
- 8 It's not the norm and we police ourselves so that we're not pushing the limits, but
- 9 when it's appropriate, when those indicators are there, there's a lot of discussion,
- and it goes through Bill's level, to make sure that we're addressing performance
- in a way that's appropriate for that performance.

going to have its strengths and weaknesses.

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CHAIRMAN JACZKO: Vic, well thanks. I appreciate the comments and you're -- I know, it's obvious from your answers that these are not new issues to all of you that you're thinking about them and they're not simple issues to deal with. There's no perfect system and every system you make is always

The -- I did want to turn briefly to some other issues, in particular, related to our fuel cycle facilities. And one issue, I know -- I think we had discussed at an AARM several years ago was taking a look at, in particular, for the materials licensees, reexamining the criteria for how we would look at licensees that appeared in AARM and what they would do for a subsequent AARM. And I don't know if we've -- I think we've made progress on that. I don't know, Scott, if you would comment -- could comment on that. And do we come up with criteria? What those criteria are, and are we using them?

MR. MOORE: We published a federal register notice in the fall to

1 propose criteria be added to consideration. The criteria had to do with if

2 licensees had been considered in an AARM and had not made sufficient

3 progress against those criteria. And we got comments back. And we're in the

process of finalizing those criteria now. And so following this meeting, we should

5 move to finalize them.

CHAIRMAN JACZKO: Fine. Just one last comment -- I think it probably -- it tells me maybe I've been here too long, because I remember it was, I think 2006, where we were having a discussion about security and how to protect information in the action matrix. And what we wound up doing as a solution to fixing a security information problem was to separate out the security NEP cornerstones from the action matrix.

The goal wasn't to separate those things out of the action matrix.

The goal was to better be able to control and protect information. And so we've now come full circle, where we're back to looking at reintegrating those things and of course, at the time I had strong views about that. So I'm glad to see that after five years now, I think we're back to where I think we should have been to begin with. And I think, hopefully, you know, the Commission will support that. I think, as I said, I think it was an unfortunate side effect of an effort to ensure that we weren't providing information that could be of potential benefit to adversaries.

Unfortunately, what we did is we separated out two cornerstones.

And I think -- I mean, it's obvious now that there are plants that would be in, you know, the difference comes in, ultimately, in Column III or IV. I mean, effectively, if someone has a single white finding either in security or in the safety side, they get largely the same kind of effect from an inspection standpoint. But since we get beyond that into Columns III and IV, where those cumulative effects don't

- 1 really get addressed in the right way. And I bet right now, if we looked, there are
- 2 probably some plants that would probably be in a different column in the action
- 3 matrix if we combine those findings and -- but I'm not going to ask you that
- 4 because I don't necessarily need to get into that at this point, until we've
- 5 examined that. But I think it's principle. It's the right thing. The change was
- 6 never really intended for that purpose. The change was intended for another
- 7 purpose, so...
- 8 But anyway, I appreciate your presentations and all the hard work
- 9 that went into this meeting, so thanks very much. Any other comments or
- 10 questions from anyone? Great. Thanks. We'll flip the panels and hear from
- 11 stakeholders.
- We will now begin the second portion of our meeting with Nuclear
- 13 Fuel Services. So I'll turn over to Joe Henry. He'll be presenting the
- 14 presentation.
- MR. HENRY: Good morning, Mr. Chairman and Commissioners.
- 16 Before I make a brief statement, I'd like to introduce the people at the table with
- me. On my right is Ron Dailey, our Director of Engineering. And to his right is
- 18 Christa Reed, our Director of Operations. And to my left is our Director of
- 19 Quality, Safety, and Security, Mark Elliott. I also have some people in the
- 20 audience I'd like to introduce.
- 21 Our CEO and President of B&W Brandon C. Bethards is here.
- 22 The Chief Operating Officer, Mary Pat Salomone is here. We also have the
- 23 President of the Nuclear Operating Group for B&W, Sandy Baker. And we have
- 24 Dan Swaim, the Chairman of our Nuclear Safety Review Board, and one of his
- directors, Charlie Horne. And I'll talk a little bit more about that Board as I go on.

1	In January, I was asked if I would accept the role of President of
2	NFS. I eagerly jumped at the opportunity. I was very familiar with NFS and I
3	knew the vital nature that it plays in our national security. While I'm new to NFS,
4	I am not new to nuclear operations or safety. I had the privilege to serve in the
5	Navy, the nuclear Navy, for 33 years. And I also recently served, as Mr.
6	Ostendorff said, as the Chief of Nuclear Safety Operations at Y-12, our national
7	center of uranium excellence. Next slide, please.
8	As Mr. McCree said, we temporarily suspended operations in 2009.
9	During 2010, we made some significant changes in organization. We
10	established new processes and behavioral expectations. We demonstrated
11	significant improvement in our safety culture and conduct of operations. We
12	have institutionalized these changes and are demonstrating that they are
13	sustainable. We have started up all our systems with the exception of one. As
14	Mr. McCree stated, we hope to start that up in the near future.
15	In April of this year, at the license performance review, your staff
16	stated that we operated safely and securely, protecting the public and the
17	environment. They did indicate two areas we needed to improve in, and we're
18	working hard on those areas to continue to improve in them.
19	Commissioners, the training wheels are off. We're moving forward.
20	And we're moving forward deliberately and conservatively. That's not to say that
21	we won't hit a bump in the road. But we hope that the processes, the training,
22	and the behavioral expectations we put in place will help us respond to those
23	bumps correctly. And we know it'll take constant vigilance and reinforcement
24	every day. Next slide, please.
25	Safety is clearly our first priority. While we have production,

1 schedule, and cost goals, everyone in NFS now knows that safety comes first.

2 There are numerous examples observed by my managers, your site residents,

and visiting inspectors where our workers and management have exhibited a

willingness to stop, ask questions, and stop when they see something that's

5 unusual or unexpected. We continuously reinforce this and highlight it in all of

our communications to employees. Communications is really at the foundation of

any positive safety culture. And we're pursuing many paths of communications

within NFS. We have a daily plan of the day, which is the robust meeting of my

top 35 managers. We review the previous day's events, review what we expect

the next day, cover any issues, both safety and quality, and make sure that we're

all on the same page.

We have other meetings -- what I call "Lineman meetings" with our first line supervisors, who are at the point of the spear, supervising our hourlies and with our managerial staff, to make sure that we all have the same expectations, review what was to be done, what is to be done, and make sure we're proceeding forward.

On the deck plates we have put a number of tools into place to help us with communications. And we have a shift turnover checklist to make sure the right things are discussed during shift turnover. We have a Senior Engineering Watch, which I'll discuss at length in a minute, and they have shift turnover reports that are sent to our managers so we know what is going on. They're our eyes on the floor. And we have an operation plan of the day that tells everybody what we're doing to ensure that we're all going in the right direction. The goal is now to sustain these changes and to refine them as we move along. Next slide, please.

Conduct of operations. We've formalized our conduct of operations
in a procedure. And it covers the operational rhythm of the day. It sets how shift
turnover should be done those shift turnover checklists are contained in that
procedure. It has a notification protocol where if anything unexpected happens,
all my senior managers and your site representatives are notified within four
hours via e-mail. So there's a good, official communication process to make that
happen. Restart protocols are in there, and what is at the heart of all nuclear
operations procedural compliance is stressed at every area of that procedure.
Individual expectations and accountability are pointed out.

Our managers at all levels are now on the floor more than ever.

We have the Senior Management Observation Program, where weekly managers are required to be on the floor, conduct evaluations. They do spot corrections, but they also make a formal report that we then put in a database so that we can mine that for adverse trends and maybe head off issues before they actually occur.

The Senior Engineering Watch, which we told you about last year, and we said we would keep for six months after our first startup, I see that as very beneficial to our progress. It's a technical advisor immediately available on the floor. And it's eyes and ears of management all the time on the floor. So I made the decision to make that a permanent position in NFS and source it appropriately.

Our Configuration Control Program has been put in place to ensure that changes are well planned and appropriately reviewed before implementation. That program embeds a technical basis so that we make sure that any changes we make have a sound technical basis and are done safely.

- 1 We've implemented a work control management group. This is a group of now
- 2 10 dedicated individuals that plan our maintenance, write the procedures, ensure
- all the hazards are identified, and mitigate those hazards. There is some
- 4 resistance to that, because the workers think that it slows down their ability to fix
- 5 things and they know how to fix things. But what they're realizing is slowly, is
- 6 that the work's done more effectively. There is less rework. And it's a safer way
- 7 to do business. In the long run, it will get done more quickly because we won't
- 8 have to rework the issue. So we're making good progress in that, but it's still a
- 9 work in progress. Next slide, please.

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NFS has enhanced its problem identification resolution program, where we've included a safety culture implementation review, extent of cause review, and extent of condition. Our corrective action system has been embraced by all the workers and we are continually seeing that the workers are willing to make entries into our PERC system, where then we can screen it for priority and safety.

We have improved our root cause analysis program. We've increased the training of both our managers and our key investigators. We've implemented an operational experience program, which is basically a lessons learned program, so that we can gain immediate results from that on the floor and also have that for future works, and knowledge, and experience. We've implemented a tracking and trending system in our corrective action program, so that we can identify trends and take action before they can become issues and identify positive trends, so we know where we're having success. Next slide, please.

To ensure this continues, we've appointed an independent third-

1	party oversight group	 And we had talked 	about that last	vear too.	This group

- 2 was a group of nationally known experts in nuclear operations and safety culture.
- 3 They come to the plant every quarter and spend two to three days on site. They
- 4 interview our workers, our managers, and we review what we've done over the
- 5 last three months. That has proved to be very beneficial feedback as we
- 6 proceed forward. They report directly to the Board of Directors. Although they
- 7 talk to me, they report to the Board of Directors to ensure their independence and
- 8 objectivity.

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In summary, we've institutionalized the key processes that are important to a strong safety culture, and now we're internalizing them into the fabric of NFS. We've reinforced the appropriate behaviors and we'll continue to reinforce the appropriate behaviors. We are already seeing evidence that our organization understands and embraces the processes and behaviors that are necessary for a positive safety culture. Commissioners, we're on the right path. We will stay on the right path. But we know that that takes constant effort,

That completes my remarks and I'll be glad to answer any questions that you have.

constant reinforcement, and constant vigilance.

CHAIRMAN JACZKO: Well, thank you for that presentation. I'll start with Commissioner Apostolakis.

COMMISSIONER APOSTOLAKIS: Thank you. I have a couple of questions [inaudible] my information. When you mentioned "questioning attitude," I always wondered, how does one encourage that? How does one make people have a questioning attitude, besides telling them to be questioning? That's a tough one, isn't it?

1	MR. HENRY: It is a very tough one, but it's successful to any good
2	operation that involves a team because every leader has to have a team that's
3	willing to question what they're doing, but also willing to question what the
4	workers are doing themselves. And you do that by never criticizing anybody for
5	that questioning attitude. Whether it's right or wrong, no matter what reason they
6	stop work or they ask a question, you answer that question. You know, you
7	always hear that there's no such thing as a stupid question. And there are some
8	stupid questions. But you ought to stop. You ought to answer that question and
9	make them feel like they contributed, at every level, whether it's my assistant or
10	the lowest worker on the floor. And we're continually reinforcing that. In fact, our
11	Employee of the Month last year was recognized for stopping work because she
12	didn't understand something. And we put her picture on the front page of our
13	employee newsletter, and pointed what she did, and named her "Employee of the
14	Month" for her questioning attitude.
15	So, it's hard, but it's continual reinforcement. And reinforcement is
16	always a key of success.
17	COMMISSIONER APOSTOLAKIS: You also mentioned that you
18	have an improved root cause analysis.
19	MR. HENRY: Right.
20	COMMISSIONER APOSTOLAKIS: Now, as you know, root cause
21	analysis is really more of an art. I mean, it depends on how far down you want to
22	go. Are you encouraging people, when they do the root cause analysis, to go
23	down to the safety culture issues perhaps? That's not something that's done
24	routinely, as far as I know.

MR. HENRY: Yeah. We're now asking ourselves in every

1	investigation, "Are there safety culture implications of that?"
2	COMMISSIONER APOSTOLAKIS: Okay.
3	MR. HENRY: And looking at that across our site to make sure that
4	there aren't.
5	COMMISSIONER APOSTOLAKIS: And finally, does your facility
6	have an ISA integrated safety assessment?
7	MR. HENRY: Yes, we do.
8	COMMISSIONER APOSTOLAKIS: Does it play any role in all of
9	this, in trying to improve performance? I mean, are people are your people
10	aware of it?
11	MR. HENRY: Yes, yes.
12	COMMISSIONER APOSTOLAKIS: And they know
13	MR. HENRY: Now, they're aware at it at greater levels. Of course
14	the people who study it and execute it know it the most, but the people on the
15	floor know the end of result of that and what actions have to be taken, with
16	regard to what criticality safety issues we have before them, what the placards
17	say, and why they say that. So everybody's involved in that. But it's in a graded
18	manner.
19	COMMISSIONER APOSTOLAKIS: Thank you.
20	CHAIRMAN JACZKO: Commissioner Magwood?
21	COMMISSIONER MAGWOOD: Thank you. And welcome. At
22	some point, I'd like to speak with you about Commissioner Ostendorff's dark
23	past, and you can give me some insights into
24	[laughter]

how he makes decisions and that sort of thing. Very interesting
conversation. The, you know you heard that question that I asked the staff
earlier on about the changes in leadership that I asked the staff earlier on about
the changes in leadership that have observed over the years. I wanted to give
you a chance to sort of react to that. But more specifically, one good thing about
changes in leadership, it does bring a fresh set of eyes to every situation. And
I'm curious as to whether you had, as you entered this position, any observations
that or issues associated with the safety culture, with the safety conscious work
environment, that perhaps, were weaker than you expected when you got there
compared based on what you had heard. But just get a chance to respond to
the question.
MR. HENRY: Sure. First, while I don't intend to be back here next
year, I do intend to be in NFS. So I expect they'll be some [laughter] continuity.
I think the first thing that
CHAIRMAN JACZKO: We do transcribe these meetings, you

CHAIRMAN JACZKO: We do transcribe these meetings, you know, so. [laughter].

MR. HENRY: I think the first thing that struck me the most when I got to NFS was that we had made many changes over the last year, many significant changes. We had instituted many of the programs that are well-established in the industry through benchmarking. And they were very good programs, but we had to stop changing things. There was too much stuff in flux. We had to settle back and internalize those changes and have some sense of continuity. And that's what I think my major change was when I came. I stopped changing things. And we have continued going forward with the programs that are there, that are good and proven programs. I may change some things in the

- 1 future as we refine them. But right now there was too much activity in change. It
- 2 was time to say what are the basics, how do we use these programs and
- 3 continue them forward? And that's exactly what we're doing right now,
- 4 Commissioner.

appreciate your description of the kinds of communications you have internally and the meetings you have. We had a Commission meeting last year where we had representatives from the local community [inaudible] come and speak to the Commission about some of their concerns. And one of the concerns, I think, is fair to say, is that they felt they really weren't well-informed as to what was going on in some fashion. This, or have you been -- have you looked at the external communication with the local community, what sorts of steps have you taken in that direction?

MR. HENRY: We have. We've taken some significant steps. And we need to do more in that direction. We have a very, very supportive community. Every place I go into town, I get recognized and they thank me for what we're doing. And it helps that most of the community are also our employees. But they're very, very supportive. We have agreements with the fire department where we train together. So if we had a casualty on the site, they're cleared. They come on to the site. We fight side by side. So we have a very close relationship with the community.

I've met with all the senior leaders in the community. We're now setting up regular meetings to talk about what we're doing and to point out to them where we're going. We are making a significant investment in the infrastructure of NFS. They will see the landscape changing. We have a

- 1 warehouse going up right now, and we're going to put up a completely new entry
- 2 control point, state-of-the-art security. And so they'll see that going. So we're
- 3 having meetings, informing the community exactly what they're doing, so when
- 4 things start to change, they won't be surprised about it. So we talk frequently
- 5 with the community.
- 6 COMMISSIONER MAGWOOD: I appreciate that. Thank you,
- 7 Chairman. That's all I have.
- 8 CHAIRMAN JACZKO: Commissioner Ostendorff.
- 9 COMMISSIONER OSTENDORFF: Thank you, Chairman.
- 10 Commissioner Magwood, one of these days, I may consider showing you the
- 11 secret submarine force handshake. (Laughter). I'll think about that, though. I
- 12 appreciate the briefing today. I had a chance to visit NFS last July. It was a
- really good tour. Mindful, the discussions with the previous panel about the
- 14 continued change of leadership, and so forth, and I think, Joe, you've provided us
- 15 your briefing, a very helpful prospectus on where you see things and trying to
- tamp down your change across board. Let's focus on those things that are
- 17 important.
- 18 I'd asked Vic McCree, at the previous panel, what he sensed as to
- 19 the receptivity of your work force to accept change. I know you made a comment
- 20 during your presentation about, I think the work, management group, or
- 21 something like that, that there may be some resistance, and I know I think when
- 22 you were Y-12 we talked about this analogous issue with respect to the Y-12
- work force, I see Dan Swain back there. We talked about this at Pantex. I dealt
- 24 with it at Los Alamos, and Lawrence Livermore, and prior positions. And so
- 25 that's just a fact of life. People are people.

1	Do you feel like that your work force is pretty receptive to focusing			
2	on where you think the agency excuse me where your organization needs to			
3	head?			
4	MR. HENRY: I absolutely do. But like with any work force like that			
5	that they change slowly. And safety culture is an evolution. It's not a dictate.			
6	And we're on that path going through that right now. But they are receptive to			
7	change. We're seeing that across board. I think one of the best examples of it			
8	was on May 15th, we signed a new six-year contract with the union. Our last			
9	contract, as you know, was a very contentious strike. That was not the case.			
10	NFS has matured and has matured very well. And we now have a contract that			
11	is very acceptable to both the union and to the company, and we're moving			
12	forward as a team.			
13	Now, I do have a very experienced and a very localized work force.			
14	There's no doubt they are set in their ways, but they are clearly seeing the benefit			
15	of safety first and the benefit of thinking about what they're doing and being			
16	understanding operators and helping us run the business.			
17	Now, there's always going to be a bump and there's always going			
18	to be 10 percent that doesn't get the word. And we'll spend a lot of time on that			
19	10 percent. But my sense is that they come into work every day wanting to do a			
20	good job, and we just have to facilitate that they do that job correctly.			
21	COMMISSIONER OSTENDORFF: One final question. What do			
22	you see as the biggest challenge to sustained performance? And emphasizing			
23	the word "sustained" here.			
24	MR. HENRY: Yeah.			

COMMISSIONER OSTENDORFF: Going back to what the Region II administrator had commented about.

MR. HENRY: Sustain is clearly. And the answer is not to become complacent. This is not a program that you can succeed at. You don't invite me back here and I breathe these and I put it on the shelf and go back doing other things. This is a program, I think I've used the words, "has to be the fabric of NFS." We have the challenges to get it so internalized that it sustains itself and is contagious to the new people that come into our organization. You know, whenever anybody comes into an organization, you give them all the manuals and you have them go through all the training. But where they really gain their insight and their training is from the people they work side by side with. And until all those people have internalized it, we haven't completed. So they can pass that training on to the next generation. So it's going to be a continual, tough evolution, Commissioner, and we'll keep working on it.

COMMISSIONER OSTENDORFF: Thank you. Thank you, Mr. Chairman.

COMMISSIONER SVINICKI: Chairman Jaczko's comment about NFS's participation over multiple years caused me to reflect. So I believe I've been here -- this is the fourth time that NFS has been at the AARM. I've been here for all of these meetings, and I've never been at an AARM meeting that did not have NFS present. So the transcript that Chairman Jaczko referred to, I'm pretty confident that if we pulled last year's, we would see, Admiral Henry, that your predecessor sat in that exact same chair. And he said he would not be back, and he's not back. But I don't think for the reason -- [laughter] that he intended. So you were a bit more nuanced in your statement. You said you

1 wouldn't be back, you'd be at NFS. So he did not, I don't believe, make that 2 statement, although maybe he's sitting in his car in the parking lot there today so 3 he can make that statement true. But I would ask you in all seriousness, you 4 have a tremendous track record of achievement. What are you going to bring to 5 your leadership of NFS so that NFS would not be back here next year. And 6 again, very capable people before you have taken on this challenge. What are 7 you going to bring to it that you're going to have a different outcome here? 8 MR. HENRY: You know, in any organization, the leader casts a 9 strong shadow. But the successful leader is the one that the team really does all 10 the work and they solve the problems. And the first time I met with my team, I 11 told them, "Don't bring me a problem unless you bring me a solution with it." And 12 we're working on that. And I firmly believe, and I've seen many, many 13 organizations that many very smart people run. But when they reach a crisis, if 14 their team isn't well-developed and everything hasn't been delegated it all 15 depends on that one person, and often there's a failure. And so my goal, as I 16 move forward, is to develop the team at NFS, so they don't need me. Now, I 17 want them to need me because I need a job, but they're -- I want them to be able 18 to make the decision and carry us forward. And that's not just the senior 19 leadership team that's here with me. It's the team that's on the deck plates. The 20 first line supervisors, many of which used to be union workers who actually 21 control the unions, the hourlies. And they're the ones that have the most 22 influence. When I come into work every day, not one hourly worker looks at me 23 and says, I want to be him some day. But when the supervisors come in, there's 24 many hourly workers that say, I want to be him or her. And so I think the key is 25 to make sure that you're developing the leadership at all levels to handle

- 1 whatever comes up. And I think that's the challenge and that's the successful
- 2 team in the end because it doesn't need a new leader or a strong leader. It can
- 3 depend internally, it can discuss things, raise issues, there is a questioning
- 4 attitude, and that would -- that dictates success in the end.

COMMISSIONER SVINICKI: Thank you. And the other comment that you indicated, you have some of your corporate positions represented in the audience here. I think another key element is of course, any organization can try very hard but if it doesn't have the backing and the resources, if those become the determinate of success, is not going to be successful. Would you indicate to the Commission today that you're confident that if it became an issue that you needed something corporately or needed some support you would have access to it? Are you confident of that?

MR. HENRY: I'm absolutely confident. And I think the first indicator is that they're here with me today and they're making the commitments that I'm making and they're with me every day. I get a lot of help. And I'm getting good support. And B&W on a whole, is committed to the success of NFS. And it's not just saying that, they're walking the talk. They're sending people to help me. We've gained a lot of synergy. The only other license one activity is Lynchburg. And we're benchmarking back and forth. We're sending people up there. They're sending people down here. I've sent a benchmarking team to Y-12 where we're gaining lessons learned from them. And so there's a great synergy there as it exists now within the B&W group. And B&W is also making a significant capital investment in NFS because we're an aging plant and we need to replace some of our equipment and we're doing that on a regular plan right now. So Commissioner, I'm very confident of it.

1	COMMISSIONER SVINICKI: Thank you, and again, I thank you all
2	for what you're doing. I think sometimes the most frustrating thing to workers is
3	that they really want to succeed, but they're in a system that doesn't allow them
4	to succeed. So, thank you for, you know, your focus on that and your
5	commitment to that. I'm certain that you have a lot of very determined individuals
6	that don't want to have you sitting in that chair next year. So thank you. Thank

you, Mr. Chairman.

CHAIRMAN JACZKO: Well I appreciate your comments. One of the areas that the Commission has been focused on very heavily has been in the safety culture area. And when we initially came out with, I think, the first confirmatory order, a big piece of that, really, the whole piece of that order was this establishment of the Safety Culture Advisory Board. They came out with two reports. The second report, essentially, I think, as I would paraphrase it, said that they really hadn't been much change in that area. Given your comments, which I think are fair and appropriate about not wanting to have too much change at once that becomes unmanageable. Where do you see the changes that I think are still necessary or I still, I think committed to happen in the safety culture and where do you see those falling in your priority list and in terms of your list of things of change that you think should happen?

MR. HENRY: That report, as you know, came out in June 2010 and reflected what was there in June 2009. And we responded very aggressively to it but there was some substantive indicators there of things we needed to fix. We've just recently published our Safety Culture Improvement Plan, which is a very thorough plan, which where we went in and looked at every comment in that second report. And I think there was 140 observations or findings in there.

1	We've addressed each one of those separately, analyzed them, set out a plan of				
2	action and a due date on when we'll do that. I've appointed a champion for that,				
3	the head of our insurance program assurance group, which is independent				
4	from operations so they could champion that effort. And I've recently appointed a				
5	director, whose sole purpose is to progress how we're responding to that plan				
6	and how we're executing it. And will progress for the next two years every item				
7	that's in there. And 90 percent of that is safety culture to make sure we're going				
8	forward with that. But that's not a new change. I think it was taken on before I				
9	came. I've made it a little more granular by identifying exactly everything that				
10	plan said as we move forward. So it's still a large part of our evolution.				
11	CHAIRMAN JACZKO: Well, thank you, I appreciate that. And, as I				
12	said, for the agency, this has been an interesting opportunity for us to focus very				
13	heavily on the safety culture area, and in many ways that has been the				
14	fundamental regulatory focus for us in terms of putting up and you get back on a				
15	better sustainable path. So we'll certainly keep a close eye on that.				
16	I want to close just with a more of a hypothetical question. And				
17	we've had a lot of comments about how many times you've been here, NFS has				
18	been here. How many times consecutively do you think it's too much for a facility				
19	to come to appear in front of us before we should shut down a facility?				
20	MR. HENRY: That is a hypothetical question, but I think you				
21	certainly				
22	CHAIRMAN JACZKO: If it's less than four, it's probably not.				
23	(Laughter) But				
24	MR. HENRY: And I think it's a very good question. But I have to				

say that while we're here for some significant events, what you do, and I think is

- 1 the right answer, you look at the whole operation and you put it in perspective.
- 2 And while I was invited back this year, you had already decided that I was
- 3 operating safely and securely. You just wanted to see if I could sustain it. I think
- 4 when you get to the point where consecutively you've decided we're not
- 5 operating safely and securely, then you have to consider that. I think we could
- 6 come back, I'm not planning on it, but come back next year. And if you still
- 7 thought we we're unsafe or secure but you wanted to see more, you wanted to
- 8 see progression, you wouldn't think about that. But I think, Commissioner,
- 9 Chairman, that it's one of those things, you'll know it when you see it. And I think
- 10 coming before the Commission, it's a learning experience. And it's an
- 11 experience for us to understand exactly what the expectations are and move
- 12 forward. So I know when Mr. McCree called me, he said this wasn't a graded
- 13 thing. It's not a trial. And I appreciate that. And I appreciate the fact that I can --
- we can come forward. It forces us to put together our thoughts about exactly
- 15 how are we meeting your expectations and then we can hear them. So, I don't
- think there's a definitive answer to your question. You know, I know it's greater
- than four, thank you, but, you know, there isn't a definitive, and it never should
- 18 be. You should look at each individual that you may sense, sometime that after
- one event it's time to do it. And there may be a time when after eight visits, you
- see a continual evolution and you decide it's worthwhile. Because the work that
- 21 is being done is noble work and we both need to work at keeping it going in a
- 22 safe manner.

- CHAIRMAN JACZKO: Thank you, I appreciate that answer. And I
- think it [inaudible]. Those are the questions I had. I don't know if anybody has
- any other comments. Well, again, we appreciate you being here. The staff

1	obviously has done a	continued, thorough job with	their oversight and the
			· · · · · · · · · · · · · · · · · · ·

- 2 agency's oversight activities, and they'll continue to do that in the future. And we
- 3 look to see continued sustained progress. Thank you.
- 4 Yeah, we're on. And now hear from our last licensee, the -- well, I
- 5 guess, the big scope licensee, the veterans affairs -- Department of Veterans
- 6 Affairs. I'll turn it to Frank Miles, who's the Associate For Chief Patient Care
- 7 Services Officer.

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- 8 MR. MILES: Good morning, Chairman Jaczko and the NRC
- 9 Commissioners. I appreciate this opportunity to provide remarks on behalf of Dr.
- 10 Petzel, the VHA's Undersecretary for Health and about our ongoing efforts to
- 11 ensure the safety use of radioactive materials.

improve the effectiveness of our mission.

Today I want to discuss oversight initiatives implemented by VHA to ensure the safe uses of radioactive materials. I will be providing examples of changes and sustainment efforts that have resulted in immediate improvements and the establishment of a structure designed to sustain and continuously

I would like to state that the expanded and improved interaction and communications between VHA and the NRC at the senior leadership regional and staff levels has proven to be a catalyst in our efforts to accomplish the common goal of both organizations, which is the safe use of radioactive materials.

A meeting held on June 8, 2010, that included the Undersecretary for Health, the NRC chair, and the NRC Region III Administrator established that clear understanding of the desire for the VHA to achieve the highest levels of compliance with NRC regulations, standards and requirements. The outcome of

1 this meeting established the framework for follow up meetings to pursue a

2 collaborative effort to review, analyze and improve our relationship, including the

procedural and technical processes, which has formed the basis for a continuous

educational, consultative and open-communication forum that has, to date, been

5 highly effective.

I would like to commend the Chairman and his staff for the guidance, assistance, and transparency in achieving the over-arching goal to protect public health and safety and the delivery of quality care to our nation's veterans.

As the management representative to the VHA National Radiation Safety Committee, I've had the pleasure to interact with Mr. Satorius, NRC Region III Administrator, frequently in the past year to addressee emerging issues. Dr. Milton D. Gross, who is the chair of our National Radiation Safety Committee, has held a series of working group meetings with NRC and VHA representatives to identify opportunities for improvement, which may lead to revisions to the letter of understanding, that will enhance the task of implementing the requirements of the existing master materials license.

VHA feels strongly that the results of the working group meetings will not only have a positive impact on the execution of the master materials license, but the overall findings will assist NRC in the implementation of a master materials license with other federal agencies. Accompanying me today are Dr. Milton Gross and Mr. Gary E. Williams, director of the National Health Physics Program, which I will refer to as NHPP. They're available to discuss any questions from the Commissioners related to the overall performance of our National Radiation Safety Committee, the progress made by the working group,

1 the improved relationship between NHPP and NRC, and the status of actions

2 taken to improve VHA's overall performance, or any other pertinent issues.

I now want to outline briefly some key actions VHA has taken for sustainable oversight for the safe use of radioactive materials. These actions are discussed in depth at each meeting of the National Radiation Safety Committee.

One, VHA identified an executive committee of the national radiation safety committee that consists of the chair, executive secretary, management representative and two key physicians in addition to the alternate committee chair. The executive committee is in a position to evaluate time-urgent issues between former quarterly committee meetings, function as an information conduit to senior leadership, and help determine long-term and sustainable strategies for regulatory compliance. The result for this effort has been more involvement by senior leadership and a greater focus to programmatic oversight.

Two, VHA has continued to evaluate standard procedures and other criteria for prostate seed implant programs, including a revision to the standard procedure for medical event training, which was implemented effective April 1, 2011. A revision to the start and restart criteria for a prostate seed implant program that was approved by the committee in February 2011. This revision established a work load requirement for the number of patients to be treated if a program is to be started or restarted.

From a clinical perspective, VHA is developing a plan for physician peer review, an external accreditation for VHA facilities that complete prostate seed implants. The results is that the VHA has the most rigorous procedures for prostate seed implant treatments in the medical community today.

1	Three, VHA completed annual inspections for all prostate seed
2	implant programs with the most recent cycle of inspections being completed in
3	January 2011. These inspections have not identified any new medical events or
4	significant program deficiencies. The follow-up NRC inspections at the same
5	facilities have not identified medical events or significant program deficiencies.
6	Results of the revised procedures and annual inspections are continued
7	oversight for prostate seed implant programs currently approved within VHA.
8	Four, VHA expanded the inspection scope of our routine core
9	inspections to include new prescriptive requirements for facility-level radiation
10	safety committees. These new requirements establish more detailed review of
11	key issues at routine meetings, a time period for executive management review
12	of the meeting results, and tracking of any programmatic issues to their
13	completion.
14	Five, VHA successfully completed a routine biannual inspection by
15	NRC in September 2010. The inspection evaluated VHA inspections permitting
16	and investigations by VHA during the period since the last NRC routine
17	inspection in the spring 2007.
18	Six, VHA has provided continued detailed oversight for security of
19	radioactive materials with an emphasis on sealed sources under the NRC order
20	for increased controls. VHA has partnered with the Department of Energy to
21	complete security assessments at specific locations with the goal to enhance
22	security above and beyond the requirements in the NRC orders.
2	In the past year, the Department of Energy has completed four

In the past year, the Department of Energy has completed four assessments and disposed two dis-used sources for VHA. The VA Office of Operations Security and preparedness has provided oversight for VHA security

1	efforts. The result has been a decreased foot print for larger activity, sealed
2	sources through the disposals and ongoing security upgrades at the facilities with

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the remaining sealed sources.

prostate seed implant programs.

4 Seven, VHA has tracked NRC efforts for 10 CFR Part 35 5 rulemaking for the medical event definition for permanent brachytherapy and 6 other issues under the proposed expanded rulemaking. VHA has offered to pilot 7 test at a VHA facility new rulemaking proposals for the plain criteria for inspection 8 methods under the current medical event definition. VHA has offered to 9 participate in NRC rulemaking workshops. The results has been a pro-active 10 approach by VHA to offer input for NRC efforts in rulemaking and to use the most 11 current inspection methods available as VHA continues increased inspections at 12

Eight, VHA successfully completed all requirements under the NRC confirmatory action letter that was issued in October 2008 related to prostate seed implant programs.

Nine, VHA responded to the NRC inspection report related to the extent of conditions for prostate seed implant programs in a letter dated July 15, 2010. This letter outlined a list of future actions by VHA to ensure oversight for safe use of radioactive materials. The National Radiation Safety Committee's agenda for subsequent meeting has considered the future actions to ensure sustained and continued oversight. These include the tracking of the NRC rulemaking noted above, tracking issuing of the safety culture policy statement and rulemaking for security and a possible new 10 CFR Part 37.

Over the 12-month period of April 2010 through March 2011, NRC inspected 24 VHA facilities and cited two minor violations. No significant

1 violations were identified by NRC for escalated enforcement. NHPP in	spected
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- 2 72 facilities and cited 11 minor violations and one significant violation for
- 3 escalated enforcement related to radiation safety officer coverage. NRC
- 4 inspections included five of the seven active prostate seed implant programs.
- 5 N.H.P. inspections included all seven active programs, none of the violations
- 6 cited by either NHPP or NRC were related to prostate seed implant programs.

The current results provide validation of the effectiveness of VHA actions to date, ensuring safe use of radioactive materials and the delivery of quality care for our nation's veterans.

I now want to outline briefly some key actions by NRC and the results from our discussions with NRC that impact VHA's effort for sustainable oversight.

I have previously mentioned the increased interactions through all levels of our two agencies. I'm comfortable that NRC and VHA agree that master materials license is a unique type of license that requires continued refinement to implement successfully.

I know the NRC's understanding and support that VHA had a regulatory and a concurrent consultative role in ensuring safe practices in compliance with NRC regulations requirements.

There are many actions that have been identified that NRC has been involved in in assisting the VHA in making the improvements that we have talked about. These also include the facilitation of NHPP inspectors to actually accompany the NRC inspectors during their regular inspection activities and has been a great learning experience for both organizations.

1	in summary, the Undersecretary For Health is firmly committed to
2	sustain efforts to protect the public health and safety and achieve regulatory
3	compliance, which is consistent with this mission of VA health care, defining
4	excellence in the 21st Century. VHA looks forward to continuing this new
5	collaborative relationship with NRC as VHA implements a regulatory compliance
6	program consistent with NRC expectations. Dr. Gross, and Mr. Williams, and I
7	are available to respond to any questions or comments.
8	CHAIRMAN JACZKO: Well, thank you for your presentation. We'll
9	start with Commissioner Apostolakis, any questions or comments?
10	COMMISSIONER APOSTOLAKIS: Yeah, thank you, Mr.
11	Chairman. I think our regulatory activities in this area are unique in the sense
12	that we're dealing with medical doctors. And, of course, there's only so much we
13	should be doing. We are not experts in medicine. So we had several months
14	ago another meeting here discussing, you know, the definition of a medical
15	event, and so on. I'd like to know your perspective, especially, from Dr. Gross,
16	how do you view the NRC oversight, I mean, from your perspective? Are we too
17	intrusive? Should we be there at all? What is your perspective?
18	DR. GROSS: Well, I've been a practicing nuclear medicine
19	physician for over 30 years. And if you'd asked me that question before I took on
20	the chairmanship of the National Radiation Safety Committee, I would have said
21	to stay away, leave us alone. Looking at it from a systems perspective, we need
22	benchmarks. We need to be able to know that we're doing a good job. But we
23	need good definitions. We need good definitions of what constitutes a medical
24	event. And then we also have to make sure that when we call something a
25	medical event that we understand what that really means. Does that really mean

1	something that's bad or does it mean the patient was harmed by this or does it
2	mean that we just didn't meet a particular benchmark? So I would agree that,
3	yes, we need benchmarks. We need oversight, but we need oversight and
4	benchmarks that are appropriate for the given treatment that we're trying to
5	regulate.
6	COMMISSIONER GEORGE APOSTOLAKIS: And we don't have
7	those now?
8	DR. GROSS: Well, I would say we have, for the bulk of the use of
9	radioactive materials, I would say we do. I would say there are some differences
10	of opinion with respect to prostate C. Brachytherapy as to what would constitute
11	a medical event. That has been the topic of a lot of discussions amongst quite a
12	few people. I think that the NRC's involved in the appropriate way in those
13	discussions and hopefully, the groups, the practice groups, the NRC, the VA, all
14	have something to contribute. Frankly, if you look back on the last few years of
15	all of this, what has been a very difficult trial for the VA has actually been a very
16	useful place for discussion as to how as to what's appropriate for prostate C.
17	Brachytherapy and hopefully for perhaps new therapies that come along once we
18	develop the methods for dealing with those and their regulatory aspects.
19	COMMISSIONER APOSTOLAKIS: You said that before you got
20	involved with your current position, as a practicing physician, you would have
21	said, you know, leave us alone. You think that's a prevailing attitude among
22	physicians?
23	DR. GROSS: No. I think people recognize

24 COMMISSIONER APOSTOLAKIS: Just you?

1	DR. GROSS: No, I [laughter]. I've been known to say things I
2	shouldn't say, frequently. I would say that when one has a busy practice, one
3	tends to see paperwork as a problem, as a pain, all right? And that's the aspect
4	of it I'm considering. As opposed to decreasing the paperwork load, we've
5	increased the paperwork load. Now, again, it's verification. Trust with
6	verification. The only way that we know that people are doing a good job is for
7	them to fill out the appropriate paperwork. Again, I keep using that word,
8	"appropriate." Now that I'm actually overseeing a very large clinical enterprise,
9	hopefully, we'll work on what's appropriate. But I need to be able to go in with
10	these folks and Gary's folks and be able to say, yes, they what they said they
11	gave is what they gave and they did what they said they were going to do and
12	they met the patient's expectations of what's appropriate and the patient got the
13	appropriate treatment. The outcome who knows what the outcome's going to
14	be for any given patient, but at least we know that once we decide how we're
15	going to do something, that's the way people are going to do it. Thank you.
16	COMMISSIONER APOSTOLAKIS: Thank you, Mr. Chairman.
17	CHAIRMAN JACZKO: Okay. [inaudible].
18	DR. WILLIAMS: Can I add a statement to that? Dr. Hagan, who
19	presented to this group last year on behalf of the Veterans Health Administration,
20	you know, is our radiation oncology national program director. And he wanted us
21	to bring to your attention his very positive and favorable comments related to
22	your interactions with the ACMUI, which I think have been expanded and the
23	Commission has requested that there be a greater level of direct medical input to
24	the Commission that is viewed, I think, very positively in the medical community.

And we wanted to commend the Commission and NRC staff for moving that issue forward.

3 COMMISSIONER APOSTOLAKIS: Thank you Dr. Williams.

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COMMISSIONER MAGWOOD: Thank you. Let me pick up a little bit on your conversation with Commissioner Apostolakis. You know, I recognize the staff is holding, I think, two workshops this summer to sort of talk about some of these issues a bit. The medical events issue is one that we've talked about on the Commission on multiple occasions. It's a very interesting and complex issue. But one [inaudible] sort of think about the just leave us alone philosophy for a moment. You know, I suspect that one of the things that it would be correct to say is that there is a wide variance in experience and quality of programs as you go across the country, maybe within -- and it sits back within the VA system. And I'm certain that there are physicians that have certainly good experience and good records in using the brachytherapy process. But there are probably others who have, obviously less success and less experience. And I think that one of the things that, I'll be looking at as the staff comes back to us with the results of these workshops is to make sure that we're putting a safety net in the system as opposed to micromanaging, you know, everybody. And I think that that's really philosophically the direction that I'd like to see things moving on that.

MR. HENRY: Just a comment on that. Our national director for radiation Oncology, which is, Dr. Hagan, his implementation of peer review and his hands-on approach with the medical center directors across the nation, I feel, extremely confident that if we have a provider that is not providing up to standard, that we're taking the appropriate action in working with the medical

1 center directors to either look for proctorship to bring that individual up to looking

2 for either alternatives to provide that treatment.

COMMISSIONER MAGWOOD: And I appreciate that. I think that the point, I think Dr. Gross is making this point as well, that knowing that there's a problem is the first -- is the key. And especially in medical procedures.

Understanding that a problem has occurred is not always the easiest thing to

determine, which is why we have this debate about medical events. And it

seemed like you wanted to add something to that.

DR. GROSS: Well, peer review is critical in all of this. And that's a very difficult thing to get your arms around because each type of medical procedure needs a different peer review and it also needs a panel or colleagues as experts who can help you do this. I mean, the program that Gary and Frank are referring to that Mike Hagen put together is a review program, which is will actually do the kinds of things that we're talking about. You can set the number wherever you want to set it, but the real issue is, is, if you've decided upon a particular procedure, are you following that procedure? Sometimes it's simple in nuclear medicine, we're going to give 20 millicuries, you gave plus or minus 20 percent of 20 millicuries. With C. Brachytherapy, it's a little bit more nuanced than that. You have volumes and you have other issues which you have to deal. So that peer review and that quality management aspect is a very different one than looking at a piece of paper and a dose ticket, knowing that, yes, you gave what you said you were going to give.

COMMISSIONER MAGWOOD: Yeah, the incident with

Philadelphia Hospital got a lot of media coverage, obviously. And one of the
things I've heard from other practitioners of brachytherapy is that the coverage

- 1 led to sort of a sea change into thinking of people in that community. And I think
- 2 part of the sea change was that it is sort of what you said, yeah, we need to be
- 3 held responsible. We need to have standards. We need to have greater
- 4 specificity in the prescriptions upfront. And I'm curious. Do you feel that that's
- 5 penetrated into the VA system? Do you feel that the practitioners get it at this
- 6 stage? Do you feel like it's penetrated?

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8 understands the importance of documenting what they do and meeting

DR. GROSS: There isn't a doctor that I speak to that I don't believe

appropriate benchmarks. Everyone knows, at least in the VA, that Mr. Williams'

crew are going to come out and take a look. And frankly, given the VA's

transparency, there's no place to hide with these things. I mean, that's the

reason why we are what we are. We kind of see ourselves out there as kind of

the test bed for a lot of things and we're kind of the tip of that spear. But I don't

think anybody plans on hiding anything. That's not the intent. As a practicing

physician, some days get so crazy that you have trouble getting your arms

around things, so we've encouraged people to benchmark, you know, is to stop.

Call a time-out. If that's -- that's now an accepted medical approach to dealing

with things that are getting a little bit out of control. It's what our -- what's the

folks before us said they were going to do is stop work kind of activity. So these

things are in place. The culture in medicine, and it's not just the VA, is to work to

benchmarks. And I don't think that physicians who are involved at least in

organized medicine at the VA level are not unaware of that, let's put it that way.

MR. HENRY: Beyond the medical care, I think the VA has learned a great deal from the incident at Philadelphia. There were major systems issues outside of the medical care that contributed to the outcomes at the Philadelphia

1	facility. Dr. Hagan has worked closely with the facilities as well as with the
2	administrative side of the house. For example, contracts. We now have a
3	standardized contracts for scarce medical events with universities so we can
4	define what's expected of those individuals. There's been a renewed emphasize
5	on the medical staffs of each medical center to look at those contracts and look
6	at the quality assurance data that is moving forward from those activities. So I
7	think we've learned a great deal, not only from the outcomes of the physician
8	practice but the support systems that are there that should have caught some of
9	those issues before they became such an issue in Philadelphia.
10	COMMISSIONER MAGWOOD: All right. Thank you, thank you,
11	Chairman.
12	CHAIRMAN JACZKO: Commissioner Ostendorff.
13	COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman.
14	Thank you for being here today, and I appreciate your participation. I'll comment
15	first comment first that I've been pleased to see the progress that your
16	organization has made over the last year since the 2010 AARM meeting and
17	encouraged by what Mr. Satorius has said about the VA's willingness to really
18	listen and to acknowledge there is some improvements that could be made. And
19	I think that's a significant pause and reflection on the Veterans Administration.
20	I've also been pleased to see this partnership we talked about at
21	the prior panel, and I think and many communications understanding what the
22	NRC is looking at, the expectations and so forth. The same time as
23	Commissioner Apostolakis mentioned, we're not physicians and that's not our job
24	to practice medicine. But we do have a role of regulation safe use of materials
25	that the organization uses in its practice.

1	As result, the interface with NRC, are there any at a high level?
2	And I appreciate the discussion of the definition of medical events, but put that
3	aside for a minute, at a high level, are there any big philosophical differences that
4	your organization has or concerns with our nuclear safety policy statement or
5	how we, as an organization approach nuclear safety?

MR. HENRY: As you stated in the disagreement or continued discussion about the definition of a medical event will always be on the table.

And I think it's not just with the VA, but it's with the medical community in general. As far as the rest of the regulatory process by the NRC, I do not think there's any concerns at the senior level. I have direct access to Dr. Petzel as well as other senior leaders within the building. And there have never been any of those discussions come forward about concerns.

There's one issue that we'll continue to discuss as well is the timing factor of notifying NRC of a medical event. In some cases, we have a medical event and you meet the definition, but our concern initially is to take care of the patient. And we had one incident of that over the past year. And one of the staff was concentrating on taking care of the patient, trying to investigate the incident and find out what really happened, we missed the timeframe. And hence, we got sighted for not following the requirements of NRC. In those cases, while we respect the time frames and we expect timely reporting, our focus is always going to be on taking care of the patient first.

COMMISSIONER OSTENDORFF: Thank you.

COMMISSIONER SVINICKI: Well, it's an accident of timing. But as we sit here today on the threshold for many of us of our Memorial Day weekend plans, the freedom that we'll enjoy this weekend, of course, was

secured for us by the patient population that you serve. And so, I know that as a nation, we're all very committed in giving the quality of care to our veterans that they've earned, quite frankly. So, again, I'll join in complimenting you on the focus that you've put into having the best possible radiation health and health physics and safety so there's an occupational component here. There's also the patient component. And I think again, you're demonstrating the kind of improvement that we heard from Mark Satorius. So I think that's to your credit.

I would ask Mr. Williams one specific question of you, though. We heard from Mark Satorius about in a previous cycle of inspections the NHPP had not had findings from some inspections and then when the NRC had done a sampling of those same facilities, they had. Now, we heard about the most recent cycle of inspections, I think, in the testimony going back or ending in January of '11 where there was a better correlation between what you all had found. And I might ask, why do you think that that was? What changed between the previous cycle of inspections where NRC was finding things that the national health physics program had not found? Is it -- we've heard some discussion of the assistance of being able to go ahead and accompany NRC inspectors, so that obviously, I would think, would give your inspectors a sense of what is NRC looking for and how are they approaching it. Were there any other, though, things that were made the difference between the two cycle inspections?

MR. WILLIAMS: I think the difference is that immediately after the prostate seed implant situation in Philadelphia, we went out and looked at the facilities and we looked in a certain time frame of procedures that they had completed. After we completed our cycle of inspections, NRC went out and looked at a broader range, that is they took a larger sample. In that larger

sample, they found additional or issues that had occurred in past years. So I look at it more as a difference in the inspection approach, and in addition, at least one of the violations that they identified were -- was similar to what Mr. Miles said, a difference of opinion about how quickly something should be, you know, reported after an event might have been discovered. And we used our discretion not to cite that violation. So I think that you'll always see that there's differences in inspectors, there's differences in the scope of the inspection that they complete, and then there's differences when the inspection enforcement process occurs as to what might be the decision. So I looked at it more as a procedural and approach to what was done rather than as a deficiency in the sense that we were not cognizant of some of the issues or what the issues could have been if there had been inspection sampling for a much greater period of time. But we've been able to move forward, I think, in what I would stress as, you know, what we would do in the future. And that is by accompanying NRC inspectors and us having a, I think, a very strong ability to go back to NRC with our inspection results. There's a great deal of partnership or collaborative effort so that those types of issues are easy precluded for the future.

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COMMISSIONER SVINICKI: The broader motivation for my question was that I appreciated Mark Satorius's answer to, I think, Commissioner Magwood's questions about how -- what are the underpinnings of success in the master materials license kind of approach. And Mark had mentioned that having the NHPP be strong and adequately resourced and have available to it the right expertise was very important. And so, would it be your input to me today that you do feel that the NHPP has accessed in terms of resources and expertise and people, do you think that it's adequately equipped right now?

1	MR. WILLIAMS: Yes, we have adequate resources and we have, I
2	think, a very strengthened input from NRC in so far as helping us. One of the
3	things that was in the LOU that was issued in 2003 was a little paragraph that
4	said and at least I interpreted to mean that, you've just started with your master
5	materials license, you're probably going to have a lot of questions. And I think
6	our ability to ask those questions in the past and work with NRC wasn't what it
7	needed to be. I think that has been corrected with this paradigm shift that Mr.
8	Satorius mentioned. And so moving forward, I think that's the most significant
9	change.
10	COMMISSIONER SVINICKI: Thank you. Thank you, Mr.
11	Chairman.
12	CHAIRMAN JACZKO: Well, I don't have any specific questions for
13	you. Some very good questions from my colleagues. And certainly going
14	forward, I'm glad that we've seen some significant improvements. Obviously,
15	we'll want to see those sustained. And it's good to hear that we've established, I
16	think, I good level of dialogue and communication to make sure that we do that.
17	So, I encourage you to continue with your efforts to provide the kind of quality
18	care I know you want to and we'll continue in our efforts to assist you as you
19	oversee that program. So, I want to thank you for being here and all the work
20	that you do as a federal agency. Thank you, very much. We are adjourned.
21	[Whereupon, the proceedings were concluded]