UNITED STATES NUCLEAR REGULATORY COMMISSION

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

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THURSDAY,

MAY 27, 2010

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The Commission met at 9:30 a.m., the Honorable Gregory B. Jaczko, Chairman, presiding.

COMMISSIONERS PRESENT:

GREGORY B. JACZKO, Chairman

KRISTINE L. SVINICKI, Commissioner

GEORGE APOSTOLAKIS, Commissioner

WILLIAM D. MAGWOOD, IV, Commissioner

WILLIAM C. OSTENDORFF, Commissioner

PANEL ONE:

BILL BORCHARDT, Executive Director for operations

CHARLIE MILLER, Director, Office of Federal and State Materials and Environment

FREDRICK BROWN, Director, Division of Inspection and regional Support, NRR

VICTOR McCREE, Deputy Regional Administrator for Operations, Region II

MARK SATOURIS, Regional Administrator, Region I

PANEL TWO:

DAVID AMERINE, President, Nuclear Fuel Services

TIM LINDSTROM, VP Operations, NFS

MARK ELLIOTT, VP Quality, Safety, and Security, NFS

JOHN NAGY, VP Assurance, NFS

PANEL THREE:

MICHAEL HAGAN, M.D., PhD, National Director of the Radiation Oncology Program,

Department of Veteran Affairs

GARY WILLIAMS, Director of the National Health Physics Program, DVA

P-R-O-C-E-E-D-I-N-G-S

CHAIRMAN JACZKO: Good morning, everyone.

Today the Commission meets to receive a briefing on the results of the Agency Action Review Meeting.

As one of the final steps in the agency's annual evaluation of how our licensees are performing I believe that this is one of the most important meetings that the commission holds.

In 2009 both reactor and material licensees demonstrated good performance overall. At this year's AARM there were no reactor licensees that warranted discussion, and I think in the history of the ROP that is the first time that we've had that situation. And there were only two materials licensees that did. The commission is aware of safety culture challenges that Nuclear Fuel Services has experienced, one of the licensees we will hear from today, as well as the multiple medical events at the Veterans Affairs Medical Center in Philadelphia.

We will be very interested to hear from these licensees later this morning on how they plan to move forward in addressing these issues.

Although we have found that many licensees have performed very effectively, the agency always must be concerned with those that need to improve their performance in certain areas.

In addition to evaluating licensee performance, one of the key purposes of the AARM is also to assess the effectiveness of the reactor oversight process, and someday soon I hope to have a fuel cycle oversight process to assess the effectiveness of … that's something to say 10 times fast, assess the effectiveness of.

Over the last 10 years the ROP has proven to be a robust program, yet flexible and nimble enough to respond to new issues.

One example of that has been the agency's incorporation of safety culture into the ROP, and we need to continually reevaluate the ROP to ensure that its inspections and indicators are

providing us a sound understanding of actual planned performance.

We should also never lose sight of the fact that the linchpin of the ROP is the corrective action program.

So as we evaluate the ROP, it is important that we make sure that the corrective action program remains effective by maintaining a low threshold for identifying problems.

During today's meeting the commission first will hear presentations from the staff and then the two panels of representatives from Nuclear Fuel Services and the Department of Veterans Affairs, and I offer to my fellow commissioners if they would like to make any opening remarks.

Ms. Svinicki.

COMMISSIONER SVINICKI: Yes, just briefly, Mr. Chairman. This is my third AARM meeting and in that time I've come to share your view that is among the most important meetings that we have each year, so I look forward to the staff's presentation and also for the second panel, the panelists that we've invited.

Thank you.

CHAIRMAN JACZKO: Commissioner Magwood.

COMMISSIONER MAGWOOD: Mr. Chairman, Thank you. This is my first AARM meeting. At this point I don't have enough room at the table to pound sufficiently, so I'll have to make do.

I just wanted to observe that I do appreciate the notation that this is the first AARM that did not have a reactor present, but I just wanted to highlight that for those of us who are looking at the performance of the various licensees, that's not to say that there aren't still issues that we're following very closely. I know that the Chairman is very, very much focused on making sure we don't lose sight of that. So just for those who are listening, just because a reactor isn't here doesn't mean there aren't those who are watching very closely.

Thank you, Mr. Chairman. .

CHAIRMAN JACZKO: Very good point. Thanks.

CHAIRMAN JACZKO: Commissioner

Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman.

I add my comments to those of my colleagues here. I think that having a public meeting on this is extraordinarily important.

I think the fact that there are no reactor licensees here at this meeting is some note for us to think about. Certainly it's an indication that the industry has been paying attention and that our staff's been doing a very professional job.

That said, we all know that the nature of these operations day to day are significant and challenging and potentially hazardous and we can never take our eye off the ball and that complacency is the worst thing that can happen. And so I think that as we learn more about, you know, where we are in different areas, this is a good thing to have in a meeting.

Thank you.

CHAIRMAN JACZKO: Okay, Bill, I'll turn it over to you.

MR. BORCHARDT: Well, thank you. Good

morning. If we can go to the second slide, please. These are the objectives for today's commission meeting to review the appropriateness of our agency actions regarding reactors and materials licensees that have significant performance issues.

I'm sure that we have a coordinated course of action for moving forward over the next year, review the industry trends and not listed on the slide, but as you mentioned, as to review the reactor oversight program's annual assessment.

Next slide, please.

Fred Brown is going to be reviewing the industry trends program as well as the self-assessment program and Charlie Miller will be discussing the materials and waste program performance.

Slide four.

There's two facilities that warranted discussion at the agency action review meeting, Nuclear Fuel Services, which will be discussed by Victor McCree and then the Department of Veterans Affairs, the Philadelphia Medical

Center, which will be discussed by Mark Satorius.

Before I turn to Fred, he'll begin the actual presentation, I just wanted to make note of two individuals. One we've acknowledged before, Bruce Mallett. This will really be his last Commission meeting. We've been celebrating his retirement for months it seems like. So, I won't say anything more about Bruce.

But, also, this is very likely to be the last Commission meeting for Sam Collins. Sam's announced that he's going to be retiring very early in July, and Sam has a long and very distinguished career with the NRC, 30 years. He's worked in many different jobs in headquarters, including the director of Nuclear Reactor Regulation, and he was a deputy EDO for a time, started as a resident inspector in region one and also has held management positions in region four, so he's had a very strong and valuable influence on the staff and the NRC as a whole. So I'd like to recognize his contribution to the agency over those many

years.

And we will miss both those individuals very much, but I wish them the very best in their retirement.

With that, I'll turn to Fred.

MR. BROWN: Thank you, Bill. Good morning. May I have the first slide, please, on Industry Trends Program.

By way of background, I would start as the Chairman did by recognizing that the reactor oversight process, or ROP, was developed in recognition that the nuclear power industry was mature and that the corrective action programs were very effective in identifying and correcting low level problems before significant degradations in safety occur.

The staff implemented the industry trends program in 2001 for the purpose of assessing the continued accuracy of this founding principle.

The annual report on the industry trend program results is used by the NRC and the public to assess current performance of the

industry as a whole, and by extension, the continued appropriateness of the ROP.

Next slide, please.

As you can see on this slide, all the program's success measures were met and the staff has not identified any trends or indicators that would lead us to question the continued appropriateness of the ROP.

Also, the accident sequence precursor values for the most recent eight years of data reflect a statistically significant decreasing trend for all precursors. And there were no precursors with the highest conditional or increased core damage probability.

Next slide, please.

In addition to utilizing the industry trends data, the staff also performs an annual reactor oversight process self-assessment.

The staff concluded that the ROP continues to meet the goals of being objective, risk informed, understandable, and predictable based on the established assessment metrics, performance metrics.

Next slide, please.

Once again, the region's successfully completed the baseline inspection program at all reactor sites. There were no new ROP deviations in calendar year 2009, but I should note that we recently issued a deviation to allow follow-up on the demand for information on tritium issues at Vermont Yankee.

Total oversight related resources have been fairly constant for the last five years, and as I'll discuss in the next two slides, we continually check for potential improvements to the ROP, as Commissioner Ostendorff pointed out the need to avoid complacency is critical to us.

Changes continue to be evaluated and developed in close cooperation with the regions and in coordination with interested stakeholders.

Next slide, please.

I'll briefly mention three specific enhancements to the ROP last year.

The first focus area was the evaluation of existing plant performance indicators, or PIs, to ensure that they continue to provide meaningful inputs into the ROP plant assessment process.

Based upon the insights from these

evaluations we improved the effectiveness of the mitigating system performance index through technical changes. We also provided safety system functional failure training to the inspection staff to enhance awareness of reporting requirements and governing guidance associated with that performance indicator.

Secondly, we noted improvements in the resident inspector demographics in this year's self-assessment. We believe that this indicates that the Commission supported changes to resident inspector attraction and retention, which has been made over the last couple of years, are beginning to demonstrate effectiveness, although house price issues in some parts of the country continue to be a challenge to residents and to the regions.

The staff thanks the Commission for your strong support in this area and we will continue to closely monitor resident demographics and evaluate new tools as discussed at the regional program briefing earlier this year.

Finally, we enhanced internal and external communications of plant assessment results, including a revision to the action matrix

public website to provide a more current status of plant assessment.

The previous website provided a purely retrospective look at the previous quarter's data, and it could be confusing when a plant changed columns during the quarter.

Next slide, please.

Three items going forward, we've worked with stakeholders to develop a framework for evaluating potential new PIs for use in the ROP. We had a productive meeting in April, public meeting on framework, and we intend to continue to finalize, work to finalize the framework as described in our self-assessment paper.

The next step is likely to be an assessment of any gaps in the existing PI coverage so that we can better target and define near-term resource needs and success criteria as part of our continuous self-assessment process.

Secondly, we plan to continue to emphasize the availability and use of operating experience in the inspection program and plan to further integrate this emphasis into inspection procedures and guidance.

For example, we are revising the engineering inspection procedure to improve component sample selection based on operating experience.

Finally, the industry has proposed a safety culture oversight process for use by licensees. The staff is currently observing process pilots in order to understand the initiative, to provide feedback to the industry and to evaluate associated tools that could possibly be leveraged to gain efficiency in the ROP.

In addition, the staff will revise the ROP program guidance as necessary to align with the commission's safety culture policy statement once it has been finalized.

That concludes my remarks. I'll turn to Charlie.

MR. MILLER: Thank you. Good morning.

Before I begin, I want to quickly acknowledge Dwayne White who's sitting to Mike Weber's left. Dwayne is a member of my staff who is principal in keeping us focused on AARM activities in FSME.

What I'd like to start out with is putting the program in perspective.

One of the things in the materials area that is important to remember is that we're dealing with a very large number of licensees, over 22,000 nationwide, 3,400 of which are NRC licensees.

More importantly, we deal with a very wide variety of applications that range from industrial, medical, fuel cycle and research.

In some cases radiation is given to individuals intentionally for diagnostic or therapeutic purposes, and it's very important when that is done that it's done in a careful, controlled and safe manner.

When we discuss trends of reportable events, it's important to keep in mind the number of activities that are conducted every year.

For example, there are more than 20 million molecular imaging procedures performed every year. Over the last 10 years we've had about an average of 38 reportable medical events per year. So when you look at the ratios, it's very small.

This has very interesting implications when it comes to trending.

First, we're dealing with very small numbers in terms of statistics. Furthermore, the denominator is very large, but it's not exactly known. It's important to keep these in mind when we look at plots of data.

If I could get the next slide, please.

In conducting our performance evaluation program, industry data is collected and evaluated on an ongoing and periodic basis.

The process is intended to try to identify significant licensee performance issues, or NRC program gaps, that warrant management attention and awareness at the AARM. The AARM review is part of a broader oversight process that includes licensing, inspection and routine enforcement.

A defined process and criteria are used to identify those items and licensees that rise to the level of needing discussion at the AARM. It ranges from those where there are very serious events, those that trigger strategic measures, significant licensee performance or programmatic

issues, or NRC program gaps or failures that were identified.

Next slide, please.

The goals and criteria that we monitor against emphasize a graded approach ranging from higher level, higher consequence events to lower level precursor monitoring events and range from those that we're required to report to Congress to those that we evaluate internally. The process for doing this was articulated in the SECY papers shown on this slide.

Next slide, please.

For 2009 all strategic outcomes were realized and all our performance measures were within established goals, and in particular there were no unrecovered lost or stolen risks of significant sources in 2009.

Next slide, please.

However, there were nine abnormal occurrences that occurred in 2009. Three of these were in NRC licensee space and six were in Agreement State licensee space. Two of these events actually included dose to embryo fetus.

For the past 10 years, medical-related

events have dominated the total number of AOs very year.

What are possible reasons for this?

Well, it could be that's due to the large number of medical procedures that are performed.

Secondly, it is the only area that we regulate where intentional use of radioactive materials on individuals is applied.

However, the number of AO's is small compared to the total number of uses of the radioactive material, as I noted earlier. There were no discernible trends in the total number of AOs from year to year.

Next slide, please.

This part of our program tries to identify the significant licensee performance issues or gaps that warrant attention and awareness by the AARM process.

This year there were two, as Bill mentioned; Nuclear Fuel Services and Department of Veterans Affairs where Vic and Mark will talk about that when I'm finished.

After the review and the analysis of data, we did not identify any significant trending

issue with regard to the materials and waste programs. We also did not identify any major gaps or program gaps or failures that were identified on our part.

Next slide, please.

One of the things that we do every year is try to take a specific topic and evaluate it on a more in-depth basis. Every year we perform this special review of event data and try to look for performance trends. This year we looked at events involving portable gauge losses and thefts. The data was reviewed to determine if there were any trends in the area of losses and thefts in general. It was determined that there were not. Any measurable results that we could identify from 10 CFR 30.34(i), which is a rulemaking that was promulgated in 2005 to try to increase the security on portable gauges which required two barriers.

With regard to the example, I did say it did not give a trend, but it did give a statistically significant indication that the number of portable gauge lost and theft events over the last 10 years has decreased.

There's a significant decrease in the portable gauge events since 2005, which would indicate that the rulemaking appears to have the effect of what it was intended to do.

I'll now turn over the presentation to Vic McCree.

MR. McCREE: Good morning, Mr. Chairman and commissioners.

Next slide, please.

I would like to briefly give an overview of NFS's performance since issuance of the February 2007 confirmatory order, update you on NFS's recent performance in the second half of 2009 up to issuance of the confirmatory action letter in January of this year, as well as update you on NRC's response and oversight activities and our next steps.

Next slide, please.

NFS met the declining performance trend criteria established in SECY-08-135 for discussion at this year's agency action review meeting. NRC inspections and events at NFS prior to and during 2009 reveal significant performance issues that lasted for more than one inspection period. In

addition, there were unique aspects of NFS's performance that has required enhanced NRC oversight; namely, NRC's formation of a safety culture and configuration management oversight panel.

Next slide, please.

In late 2006 the NRC was deliberating on the appropriate agency response to a number of potential escalated enforcement actions. The issues under review included six apparent violations of safety and security requirements, some of which were willful. The NRC offered NFS the opportunity to participate in the alternate dispute resolution process and they agreed to that.

As a result of that, we agreed with NFS that a comprehensive third party review and assessment of its safety culture was warranted, that it represented the best approach to identify and develop, focus, relevant and lasting corrective actions.

NFS's response to the confirmatory order has included the formation of this independent third party review of its safety culture and the

implementation of actions in a long-term action plan to address the concerns identified by the review.

NRC's response, again, included the formation of this safety culture and configuration management oversight panel as well as implementation of a series of targeted inspections at NFS, including an inspection of the configuration management program and its effectiveness, as well as a targeted problem identification resolution inspection that we completed last spring.

Since 2007 there have been a continuation of mainly low-level safety and security significant violations. However, several escalated actions have also been taken for events and issues that occurred in 2007.

Next slide, please.

NFS has pursued various commercial endeavors to leverage their capabilities to process various forms of high enriched uranium. The commercial development line completed in the summer of 2009 is a facility that processes uranium hexafluoride material from the Department

of Energy complex and processes it for downblending or return to the Department of Energy.

During readiness inspections that we conducted last summer we identified one design issue that wherein appeared that NFS had not fully evaluated the potential accident scenarios. However, NFS completed corrective actions, adequate corrective actions for this issue prior to NRC authorizing start-up of that line.

During the start-up of that process, we did observe an enhanced management presence and generally a more methodical approach to resolving issues.

On October 13, 2009 NFS experienced an upset in the uranium aluminum processing operation which led to an excessive generation of nitrous oxide gasses. This caused a temporary evacuation of the process floor and led to the plastic deformation of some of the process off gas piping.

The upset resulted during NFS's initial attempt to process the aluminum material in the form of fines or very small particles.

As I mentioned, the start-up of the

commercial development line proceeded smoothly. But in November of 2009 NFS experienced a precursor event during the processing of a small cylinder of uranium hexafluoride material in that an unanticipated ember was observed. But due to their poor follow-up in that it wasn't communicated effectively or evaluated in disposition, NFS experienced a fire in a glove box processing UF6 shortly thereafter.

Next slide, please.

In response to the nitrous oxide gas generation event in the uranium aluminum process, Region II formed an augmented inspection team which was conducted from October through December of 2009. The AIT concluded that there was inadequate management oversight of the facility change procedures; that there was an inadequate questioning attitude on the part of NFS management and staff; that there was a production over safety approach; and that there was poor communication between NFS staff and management, as well as between various functional groups at the facility.

As the AIT was developing its preliminary findings in the November timeframe, we recognized

that a number of the findings, again, preliminary findings, appeared to relate to performance issues similar to those that we had recognized in the February of 2007 confirmatory order, as well as an inspections, the targeted inspections that we had conducted, including the problem identification resolution inspection that we conducted in the spring.

As a result of that interim review, we concluded that additional action was warranted at NFS to provide reasonable assurance that the facility could be operated safely.

Next slide, please.

We shared the results of this interim review with NFS management and detailed our concerns.

In response, NFS management agreed to keep all the process lines shut down until the specific actions or specific issues identified by the augmented inspection team were addressed, and there were some additional overarching safety management concerns that we identified that needed to be addressed as well.

NFS committed to these actions in

writing. We subsequently confirmed those actions in a confirmatory action letter that we issued on January 7, 2010. Included in that letter was our commitment to inspect NFS's implementation of those commitments prior to start-up and prior to our authorization to restart the process lines.

Next slide, please.

We've conducted several recent initiatives at NFS, including an AIT public exit meeting which was conducted in March.

Based on the restart readiness assessment team inspections of both the Navy product line and the uranium metal oxide product line, we authorized restart of the Navy product line on March 23rd. And just last week, on May 19, we authorized restart of the uranium metal oxide line.

In both cases we conducted enhanced oversight activities using resident inspectors as well as inspectors from Region II to oversee the start-up of those process lines.

Next slide, please.

We also conducted a public exit meeting for the restart readiness assessment team

inspection of the Navy product line on April 22nd, and I already mentioned the inspection of the uranium metal enhanced restart oversight.

Next slide, please.

Our next steps include restart readiness inspections of the uranium aluminum process line which we understand NFS may be positioned to receive the inspection team within the next three to four weeks.

NFS is also currently finalizing its second follow-up independent review of safety culture. Once we receive this document, which we anticipate receiving in late June or early July, we'll determine what follow-up actions are appropriate at NFS.

That completes my remarks.

MR. SATORIUS: Thanks, Vic.

Good morning, Mr. Chairman and commissioners.

If I could have the next slide, please.

I'm going to go through three areas and discuss briefly performance history, which is really the reason for the discussion today,

NRC actions, current VA performance and next steps.

If I could have the next slide.

The NRC determined that a significant performance issue existed at the VA hospital in Philadelphia that resulted in a programmatic breakdown of their prostate implant brachytherapy program that manifested itself into 17 abnormal occurrences being identified over a frame of about six years.

The problems identified as a result of the breakdown are of significant concerns to the NRC because of the sheer number of medical events involved, 97 events reported out of a total of 116 prostate brachytherapy treatments performed over six years; the period of time that passed before the problems were identified and then reported to the NRC; the potential consequences to the veterans who came to the VA for treatment; the lack of management oversight by VA Philadelphia's radiation safety officer and radiation safety committee that resulted in the programmatic breakdown of the program. And then lastly, a lack of safety culture at VA

Philadelphia resulted in safety concerns going unrecorded.

If I could have the next slide, please.

When the NRC became aware of these issues in June of 2008, we initiated a reactive inspection. That reactive inspection then was augmented to be a special inspection. We performed that and another special inspection over the course of the next year. We issued a confirmatory action letter in October of 2008 as we became aware of the scope and breadth of the issue.

We then more recently have taken enforcement actions in three phases. The first phase occurred with the issuance of a notice of violation and in a civil penalty in the amount of $227,500 as a result of the numerous medical events that occurred at the hospital.

We escalated the civil penalty for particularly poor performance that we had observed over the course of multiple years which led to an egregious number of medical events that occurred without being identified,

reported, or corrected.

As I said, 97 medical events out of a total of 116 treatments. The second phase is currently undergoing some work right now as the staff is considering the appropriate manner to resolve issues with the individuals involved with the large number of medical events.

And the third phase is the NRC conducted what I call an extent of condition inspection. We went out and looked at all the other hospitals that were performing these similar treatments to see if similar problems had manifested themselves in those hospitals. And we did identify violations of NRC requirements; however, they did not meet the same threshold of the substantial programmatic breakdowns and numerous medical events at VA Philadelphia.

And earlier this week we issued the extent of condition inspection report and have invited the licensee in for predecisional enforcement conference which we intend to hold in later June.

Can I have the next slide, please.

VA Philadelphia shut down their program in June of 2008 as soon as they had identified the scope and

the numbers of the medical events over the previous six years.

I've mentioned that we issued a confirmatory action letter, and in that letter we asked for a number of things, one of which was for the program that had been shut down, if it were to be restarted, that they would come to the NRC and inform us first so we would have an opportunity to perform an inspection.

We also in that confirmatory action letter confirmed that they would, that their oversight process would review the active prostate brachytherapy programs and provide results to the NRC.

This was their own extent of condition inspections which we then backed up with ours.

The Veterans Affairs inspections failed to identify the violations that the NRC identified during our own extent of condition inspections.

Initially all of our inspections were conducted after the VA conducted their inspections.

We identified a number of concerns with the National Health Physics Program, which is their oversight process, and the National Radiation

Safety Committee relative to their oversight and response to the events identified at the Philadelphia Veterans Affairs Medical Center.

We believe that the NHPP, their oversight process, is critical in improving VA's performance, and we would assess its performance now as adequate but needing improvement.

And I've mentioned that the NRC staff will conduct a predecisional enforcement conference towards the end of June to discuss the violations concerns with representatives from the Veterans Affairs.

Can I have the next slide, please.

The next steps from the staff's perspectives, as a result of the NRC escalated action, the VA will be subject to increased inspection effort. And this is a normal part of our enforcement process.

In addition to that, the program currently, the MML program currently has us inspecting 10 percent of the permittees over the course of a two-year period.

We're going to double that inspection effort to look at 20 percent of the permittees. So that will give us an opportunity to have additional

looks at licensee performance.

We're enhancing our oversight, which really amounts to NRC accompaniment of NHPP inspectors for event response over the next two-year period.

We're going to enhance our oversight, again, NRC accompaniment, of NHPP inspectors for reactive and routine inspections for the next two-year period.

And we will continue our management presence at the National Radiation Safety Committee meetings, which meet quarterly.

And then, lastly, from a previous SRM and a briefing to the commission, we are looking at, in general, at masters materials licenses and whether our current scope of oversight with those programs is appropriate or needs to be altered or revisited.

And then we'll also be looking, independent of that, more specifically at the Veterans Affair masters material license to determine if changes need to be made to that program.

And with that, that completes my presentation.

MR. BORCHARDT: Thanks, Mark.

I'd just like to make note of the very impressive

degree of cooperation that happens amongst the four regional offices, the program offices that are involved, Office of Enforcement, OI. The program gets accomplished and is able to react to many different events and circumstances because of that degree of cooperation, and there's a really strong sense of mutual support amongst those offices that happens to allow us and the program to be successful.

That completes the staff's presentation.

CHAIRMAN JACZKO: Thank you, Bill.

We will start our questions with Commissioner Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman.

My first question, Fred, is for you. Under slide 11 for the oversight process focus areas, you mentioned developing a framework to evaluate potential new performance indicators.

Could you comment on that and maybe give us some examples of particular factors you may be looking at.

MR. BROWN: Yes. We have a manual chapter that dates from the inception of the ROP

that lays out some of the criteria that were used at that time to develop the existing PIs, and have been used since then as we have introduced new PIs and worked on PIs. What we've done this year, and really focused on in April, was going back and looking at that criteria and making sure it was comprehensive.

So, some of the criteria, speaking from memory which is likely to get me in trouble, but the general concept's probably close - issues like how understandable and executable, how easily is the data available, do you have to construct data? The more you construct it, the further you get from actual performance.

So is there information available that we can objectively evaluate against a standard that has some meaning, to have a PI that really allows you to differentiate licensee performance, the norm and not the norm?

And so it's finishing up that update, that criteria. And then we actually started looking at general areas that might be gaps where new PIs would make sense, or change out of PIs or wherever that takes us. And that's really the focus, I

think, going forward.

COMMISSIONER OSTENDORFF: Do you envision any role that the cross-cutting issue indicators might play in this new framework, is somebody looking at that?

MR. BROWN: Actually, I think that was one of the areas that was brought up was are there objective indicators for cross-cutting?

We haven't narrowed a focus in on that. But it certainly will be subject to the gap review.

MR. BORCHARDT: One other thing I'd like to add, Commissioner, is that when we look at performance indicators, you can't ignore the inspection program, because it's a holistic approach and the two complement each other. So if we were to develop a new PI, that would, I think, influence us to at least consider modifying the inspection program as well. So it's not either/or, they're not look at in isolation.

COMMISSIONER OSTENDORFF: Charlie, a question for you, and this is on your slide 17.

You're looking at abnormal occurrences, and I appreciate your having put

it into perspective as to, I guess, 20 million medical imaging procedures were in the denominator year and I guess we've averaged about 38 instances per year. Looking at the explosion in medical technology and practices over the last few decades with IT with new imaging machines, CT scans, very complex technical developments, what are your thoughts or any observations you may care to share with the Commissioners on how do we -- you know, recognizing that technology typically leads policy and procedures.

How do we learn from that and try to have the procedures and policies in place to really safely use this new technology?

MR. MILLER: Thank you. Well, one of the things that's important to understand is that with this technology improvements, it gives tools to the medical profession that are ever increasingly valuable for them to do medical diagnosis, medical treatments.

That said, utilization of these tools is causing an increase in doses that not only the patients are getting, but the workers are getting.

Many of these technologies, however, in areas that the NRC doesn't regulate, like CT technology and things like that.

However, we can continue to stay informed about the things that we do regulate to make sure that they are used prudently.

One of the challenges that we have is that we don't, we don't regulate the practice of medicine. The doctors make the decisions on what should be the right amount of radiation a patient should receive for either diagnostic or therapeutic purposes. And therapeutic is really the biggest part.

That said, I think what we have to stay very diligent of constantly is that the techniques aren't overused. And then, post treatment, I think, you'll see in the case of the VA, for example, you want to make sure that the technology is also used to make sure that the procedure was completed as it was designed and that the patient did receive the radiation to the right areas as designed.

That's where we have to really come in, that you didn't get unintended uses of radiation.

So the cases -- it takes constant surveillance.

The one thing I will say is our medical regulations seem to be under constant, constant revision, because the technology moves so fast and we try, we try to stay up with it. But you're right, it does lag by the time we can make regulatory changes.

COMMISSIONER OSTENDORFF: Thank you. Vic, I'm going to turn to your briefing on nuclear fuel services for a question, please. I appreciated your kind of giving us the history of the last few years with the performance of that site and I thought that was very informative. And I guess this question -- let me try to bound it in time since January 2010 confirmatory order, how would you assess management's response to the deficiencies and problems that have occurred and to the problems identified by you and your team?

MR. McCREE: Thank you, Mr. Commissioner. We've been encouraged by Mr. Amerine and staff's response. Specifically they've responded very aggressively to the areas that were explicitly identified in the confirmatory action letter issued on January 7th, which enabled us to come in

and perform a very thorough inspection of both the Navy product line and the blended low enriched uranium process facility, uranium metal and oxide line. They were responsive in those cases.

We've also observed in the start-up, particularly of the Navy line more, I guess what I'd characterize as positive behavior among operators, which is very encouraging when they've reach points in the start-up where they, where it was unclear or they didn't, there was an unexpected or unanticipated response, they stopped and they got the procedure addressed or corrected.

So that's been very encouraging and we believe that's directly influenced by the new leadership team at NFS.

COMMISSIONER OSTENDORFF: Thank you.

Mark, I will ask you a similar question that I asked Vic.

My reactions to whenever an organization has problems is how seriously does the management take the problem? Is there any sense of denial? Is there acceptance that there's a problem and a commitment to get better?

And so in that vein I'll ask you a question with

respect to the VA.

I was looking in particular at your comments on the NHPP oversight and RSC oversight within the VA system. Recognizing those are bodies in place that had not fully recognized problems and performance issues, how do you characterize the response of VA senior management to these problems?

MR. SATORIUS: Thanks for that question.

I would call it somewhat defensive, not necessarily a full acceptance of our positions.

I'll give you an example, Commissioner. We had an enforcement conference in December where we brought the licensee in to discuss the problems that were specific to VA Philadelphia.

And during that conference of the seven proposed violations that we had interacted with them with, they denied six of those seven.

During the course of that conference we asked for their NHPP program leader to provide his perspective on what his insights

were, what his sense was on those violations, and he agreed with them. So there was just a lack of internal alignment there that, frankly, was a little bit startling. I did not expect to see that delta that appeared.

So there's been some push back. They have taken steps to improve procedures, improve QA programs so that oversight is better than it was. And as we did our extent of condition inspections at the 12 hospitals that had programs outside of VA Philadelphia, a number of which those programs had been shut down for a period of time, one restarted. And there was an indication there that there, there was the appropriate level of intrusiveness, but they did go ahead. They missed some of violations that we came behind them and found.

So, I see the alignment between their own internal assessment and performance organization and the VA itself.

COMMISSIONER OSTENDORFF: Thank you. Thank you, Chairman.

CHAIRMAN JACZKO: Ms. Svinicki?

COMMISSIONER SVINICKI: Thank you all for

the presentations.

I'd like to return to the question of performance indicators and the reactor oversight process and I'll build on what Commissioner Ostendorff questioned and also the responses you gave.

I'm going to attack at it from a slightly different angle here.

I'm looking at the ROP self assessment for this calendar year, which came out in early April. And on the PI specifically it says the external survey of stakeholders generally found that the PI program gave an objective indication of declining safety performance, contributed useful information to risk significant areas, was clearly defined and understandable and provided an appropriate overlap with the inspection program, which is what Bill mentioned.

But the paragraph concludes that the staff will continue to engage in discussion of potential new PIs for ROP implementation.

So I want to take those two statements and lay them next to each other and say, given

that the staff finds in its assessment of PIs all of the positive things that I outlined, how do you approach the development of different PIs given that you just acknowledged all the strengths that the current PIs are providing? And I guess I'd like an answer that goes to a level of detail more than just by saying you proceed cautiously.

And the other thing that I'll let you know is I think it's at least a year old now, but I did read the staff's white paper, I think that's the right term for potential PIs, new PIs. And while acknowledging that my understanding is that was a bit of a brainstorming exercise, I was struck, I'll be very candid with you, but a number of them, I thought, were really too subjective for regulatory use in the reactor oversight process and/or did not have significant or appropriate nexus with our regulatory reach. But again, acknowledging that that was a kind of, it was an impressive list of potential PIs, so I think it was a brainstorming exercise.

Could you just react to that

generally?

MR. BROWN: Yes, I will attempt.

It's a good question.

At the highest level, I think, that the Commission has directed the staff and the ROP to continuously challenge ourselves for blind spots on the part of licensees and blind spots on the part of staff and this, I believe, is part of that suite of responsibilities that we have.

At the same time, I don't think any of us think that we ought to break something in the process of trying to be challenging and ensure that we're doing the right thing.

And that becomes the gap analysis that I mentioned, really, is for us to ask ourselves -- we did brainstorming. We identified a lot of potential PIs, but how would we narrow that list down to a PI that gets meaningful regulatory information in an area either that we're not looking now or licensees aren't looking now, or an area that we're looking, and even though it may be working, there's agreement that there's a better way to look.

And this isn't just driven by the staff.

The industry brings things to us constantly that they believe that even though the system works, it could work at a higher, more efficient level.

And, so, I think you described well the challenge that we have: Don't do harm -- well, we're doing good -- but continue to challenge ourselves and look objectively for things, PIs that would meet the framework, that they do have to be verifiable, they've got to be indicative of performance in an area that is important to us.

And I would, I guess, end by saying that's part of why this has been an ongoing effort by the staff. It's not that there's a quick solution and we haven't rushed into making a change that we didn't take time to think through.

I hope that answers the question.

COMMISSIONER SVINICKI: Well, what you are expressing is your sensitivity to it, so I appreciate that.

I think that it needs to be interwoven in your engagement. And what you're describing in terms of approach is consistent with why you do the annual assessment of the ROP itself, so I think thematically that's broadly throughout your

assessment. And your conclusion in this assessment is that while the ROP, we didn't have a ten year anniversary party, but it's, you know, it's now more than 10 years old and this was the 2009 assessment. So again, there's a lot of positive findings that the staff has about what exists now.

So, maybe just making sure that we're sensitive to the baby in the bath water, you know, circumstance here.

You did mention the mitigating system, you said performance index. I'm not sure if it's index or indicator, but that you presented that as an accomplishment that the staff has specifically drilled down on that in 2009.

Would you assess -- the staff in the paper assesses their satisfaction now with additional training and other elements that you mentioned. But would you say generally stakeholders feel that there's been sufficient work on that or would you continue in future years to return to the MSPI and look at that particular indicator?

MR. BROWN: I'm not aware of any specific

thing that either the staff or the industry has requested further review on, on MSPI at my level. Certainly nothing that's gotten to me.

Every month when we do the ROP public interactions on the indicators, issues of implementation come up, things that hadn't been understood before or predicted or anticipated, and we've got an FAQ process to go through, how does it fit, what is the right answer?

I would never say never, but I'm not aware -- as best I can answer your question, I'm not assure of any current issues in that area.

I think if you go pack three years ago, the first ROP self-assessment paper that I signed out contained a concern on the part of the staff that we didn't think the performance indicator program was as effective as it should be. And I think in the last two years we've worked to improve through these kind of in-process changes, the confidence on the part of the staff, and I think as you indicate in this year's paper, the external survey was positive.

And I think, I hope, that we're working to close the gaps as we identify them and ensure

that there is confidence internally, externally, with all of our stakeholders. And we will continue to respond to questions about the indicators.

COMMISSIONER SVINICKI: And I appreciate that in the paper you indicate that out of 500 surveys sent out, you got five responses. And I know surveying is hard. And one way to look at that is that the five most motivated commenters returned the surveys. So in that way if you're blanketing the communities of interest, in theory the most motivated people will respond, so you will at least get passionate feedback. But I know that you are also going to look at the effectiveness of the survey as a tool because that's a rather low return rate.

But, again, your staff is already on top of that and it was acknowledged in the paper.

Just quickly with my time left I would ask, Commissioner Ostendorff asked substantive questions, Victor, of you and Mark. So I want to ask a more, maybe a do you have what you need question.

Bill Borchardt talked about the fact that

there's a bit of a mutual aid agreement between the regions when you have to augment inspection teams or you have emerging issues. But could you just tell me, raise my confidence, that when an issue arises in a region or on a subject area where you have the lead, like a master materials licenses, that you get not only the resources, not just the person that's available to augment, but the people you need are made available to you throughout the NRC; is that an accurate statement?

MR. McCREE: That is certainly an accurate statement for -- I like to think I'm speaking on behalf of all the regional administrators in saying that yes, we do have all the resources we need. When we are stressed, if you would, we share among the regions and particularly for nuclear fuel services, when we've needed additional resources we can always count on the Office of NMSS to provide resources in the areas that we need.

COMMISSIONER SVINICKI: And that's true of headquarters, like subject matter expertise, if you needed a criticality person or something, you can get access to them.

MR. McCREE: That's right. That's exactly right.

MR. SATORIUS: Vic's program is a little bit different because the regions aren't populated with a lot of fuel inspectors. They're pretty much right there in the support he gets from headquarters. Whereas for the standard materials license program, which is handled in Regions one, three, and four, we trade resources back and quite often. And we do it, also to benchmark each other, as well, to make sure we're all doing things pretty much the same way.

COMMISSIONER SVINICKI: Okay. Thank you for that. And I'll just close, Mark. In your response to Commissioner Ostendorff, you know, I think what -- I appreciate your fact-based answer, but I'm going to press you a little bit further.

In terms of the VA response to the things that the NRC has found, I think maybe what I'm hearing you say is that if they continue to approach these issues in the way they're approaching them now, from what you observe there is some likelihood that the Commission might be talking about these same

issues again next year; is that fair?

MR. SATORIUS: That's fair. That's fair.

COMMISSIONER SVINICKI: Thank you, Mr. Chairman.

MR. COLLINS: Good morning, Chairman, Commissioners.

Sam Collins, Region One.

Just to supplement Fred's responses, and I do appreciate the ROP and the program and the surveys, particularly.

I'd want to offer that we receive continual feedback on the reactor oversight process. Every time a manager or regional administrator goes to the site, we have a very scripted documentation of feedback from licensees. And those discussions at that level are very fruitful because they are very practical, usually site specific, but sometimes branch out to the fleet. And those insights are provided back to the program office. We also have the working group, of course. So there's a lot of dialogue around the reactor oversight process that goes around the surveys themselves.

Additionally, I would offer in addition to Fred's appropriate comments that as far as the performance indicators are concerned, we're always searching for what we call the Holy Grail, which is the leading performance indicator which will help us get ahead of the curve, so to speak.

That's all in the definition, of course, of when we want to define success.

And to my mind -- in the ROP. And this is somewhat subjective, we want to avoid plants getting into the last column where we have to make a safety decision and shut down a facility, not because we're concern about power production, but because that's a reflection back on our program and it being predictive to that sense.

And I think depending on where we are on that journey, the programs somewhat can be viewed as being successful to this point. Because we've had plants that have gone up to that point, but in some cases have been allowed to continue to operate under our very close oversight.

So that's an additional perspective. And I think to some extent that's based not only on performance and insights, but on technology, on our ability to gain information and digest that information and categorize it to be able to predict performance in the future. So that's just a supplement to Fred's response. Thank you.

COMMISSIONER SVINICKI: Thank you.

CHAIRMAN JACZKO: Mr. Apostolakis.

COMMISSIONER APOSTOLAKIS: Thank you, Mr. Chairman.

Well, let me pick up on the performance indicator issue.

I must say I'm a little surprised at all this emphasis on performance indicator.

I would expect the emphasis to be on the significance determination process and how to improve that. Because when you get inspection findings and you want to process them and see what happens to the core damage frequency, it seems to me there are major gaps there.

The performance indicators are a good

indicator, but not as big a deal as inspection findings in my view.

So why don't we hear that there is a lot of work trying to improve the SDP process as opposed to the PIs? Is it because the PIs is easier?

MR. BROWN: I say we're working both in trusting what gets focused on in the papers.

Two years ago in the annual ROP self-assessment we talked about ongoing improvements to the SDP process and those continue. It's not a new initiative. It started this year and probably did not get the attention it deserved in the paper.

But especially for operations that aren't covered -- you know, the PRAs are at-power based, and so we've had quite a few issues with non-at-power events and we're putting a lot of effort, as you suggest, into the very important work of refining and improving SDP for those shutdown, transition, radiation exposure kinds of risks.

COMMISSIONER APOSTOLAKIS: So there is work?

MR. BROWN: Yes, that's correct.

COMMISSIONER APOSTOLAKIS: It's just that you didn't choose to mention it.

MR. BROWN: That's correct.

COMMISSIONER APOSTOLAKIS: If I didn't know better, I would think from the way Mr. McCree and Mr. Satorius spoke, that this agency has resolved all the issues with safety culture and, you know, you mentioned it matter of factly that you recognized there was not a good safety culture and you made recommendations and all that. My problem is I do know better.

Do you know what the good safety culture is? Do you know what the good indications of a bad safety culture is?

And I mean if you do, why don't you tell the rest of us?

I am lost.

I thought we were still struggling to understand what a good safety culture is and, you know, what to do about it, how to make sure we have it.

Now, in all honesty I know a lot of experienced people, and I'm sure you are among them, who keep telling me that they walk into a

facility and within half an hour to two hours they can tell whether the culture is good, but they can't tell me why.

Is that the situation here, that you are so experienced, that when you go there you can say, well, this is pretty good, this is bad, but if I ask you to write a paper why, you might have a problem.

So what is your reaction to my -- to my innocent statement?

MR. SATORIUS: One of the reasons is I can tell you what a safety culture isn't.

And in particular, what we saw at VA Philadelphia Hospital, Commissioner, was we saw authorized users and medical technicians, medical physicists that were involved with brachytherapy treatment that knew that there were problems with seed placement, they knew there were problems with the procedure, they knew that there problems with where the doses were being given to parts of the body that were not intended to have doses given to them and they didn't bring those issues forward.

That's, that is not a safety culture,

that's a safety culture problem. That people, knowing that there's problems with various use of our materials, did not feel comfortable to bring forth those problems.

MR. McCREE: Similarly, let me first mention that there's always room for growth and for learning about what safety culture is and isn't.

It was apparent to us in 2006 and 2007 that there were a number of issues at NFS that were indicators of poor safety culture.

In the fall of 2006, I believe it's Regulatory Issue Summary 2006-13 issued in August, that laid out what we, the agency, view as 13 components of safety culture.

And as we evaluated the multiple apparent violations at NFS and looked at the causal factors, we were able to see evidence of safety culture issues that were clearly tied to what we felt were the components of safety culture.

One area to use as an example is the problem identification and resolution.

NFS has struggled with all elements,

if you would, of the corrective action program, with this identification, effective corrective actions to prevent recurrence, extent of condition reviews, extent of cause, et cetera, et cetera. So we recognize that as being a significant part of an effective safety culture and they've been challenged if that area.

MR. BORCHARDT: Well, I think what you're hearing is that when we see indicators, we can attribute it to safety culture. What we don't have a good definition for are a good program, and this is the reason we have a pilot program underway with the industry, is to be able to walk into a facility and do a safety culture assessment and walk out with a high degree of confidence that we completely understand it.

COMMISSIONER APOSTOLAKIS: So we can recognize a very bad safety culture.

But --

MR. BORCHARDT: Well, we can attribute events or conditions to the safety culture, but it's harder to do that upfront, independent assessment.

I think this is internationally an

area of great focus. They don't have the answer anywhere else in the world.

We have the pilots going on with the industry. We have a number of activities underway ourselves, and we hope to make progress.

I think this is going to be an illusive target though, much like the leading PI, but it's worthwhile pursuing.

COMMISSIONER APOSTOLAKIS: I suspected that was the answer.

Coming to precursors, I believe you made the statement that there were no significant precursors, right, and the metric for significance is delta core damage frequency I believe or LERF too, which tells me that you had on the lists who looked at these precursors and they went to the corresponding PRA, they processed them and they came up with a change in core damage frequency that was not significant. And that is conflicting with a statement that I saw in the original report on the precursors that said that 31 percent of the precursors identified were not in the PRA.

So I'm wondering now if they are not in the PRA, how does one develop a core damage frequency change?

Of course, I know the answer.

The thing, the reason why I bring it up is because --

CHAIRMAN JACZKO: And you are going to enlighten us, I suppose.

COMMISSIONER APOSTOLAKIS: Just a prelude, Mr. Chairman.

CHAIRMAN JACZKO: It's not a new technique for Commissioners.

COMMISSIONER APOSTOLAKIS: I think that statement did some damage, because I've heard people quoting it and the implementation is that the PRA model is no good, if 31 percent of the observations are not there.

There ought to have been another statement following that, that the PRA does not intend, or it is not the purpose of the PRA to show all the possible ways that something can fail. And the precursors usually identify causes of failure. And then the analyst takes that and goes to the PRA and says okay, this is

what failed, like the small LOCA for example, and then everything else is there.

So, I just wanted to be on the record that that statement may be misleading, that 31 percent of the precursors are not in the PRA, this is not -- I mean by itself it's a correct statement, but it should have been followed by the statement that it's not the job of the PRA to do that.

MR. BROWN: I would offer we've had some discussion on this topic and I think we understand the point and it is the plan of the staff to further clarify that in the future.

COMMISSIONER APOSTOLAKIS: Okay. Thank you.

Last question: As you know in the arena, in the reactor arena we have some incidents that are not threatening anybody's health or safety, and yet they are creating a lot of public complaints -- that's a mild word.

Now, in the FSME area where you're dealing with thousands and thousands of facilities, hospitals, and so on, do you have anything like that? Do you have situations

where you declare that something happened, but it didn't threaten the health and safety of anyone, and yet people are complaining that the NRC is not doing its job?

And, of course, I have the tritium thing and reactors in mind.

MR. MILLER: Every day, given the large volume, you've got a spectrum of stakeholders out there, okay? And we may have people that are complaining that we're doing our job too well and we're over regulating in the materials area, but there's others that think, you know, that we're not. Especially -- the medical area is very of like that, I think, if you look at the spectrum between physicians' perspective versus patients who may have concerns or patient advocates who may have concerns.

So we see the spectrum. We see the spectrum of things where those think we may be over regulating in some areas and we see a spectrum where they think we're very much under-regulating in some areas, that we should do more to prohibit certain things. And in many cases they're looking for something very

prescriptive.

We've tried to go to a more performance-based approach, but in some cases stakeholders are looking for something very prescriptive.

And, that's something that sometimes is hard to achieve, or when we do make overly prescriptive regulations in those areas, it ties the industry's hands sometimes in areas that really are not safety significant.

COMMISSIONER APOSTOLAKIS: I was wondering -- just a few more seconds. I was wondering, as you probably know, there is a widely held belief out there by people who work in risk that people's attitudes are very different toward voluntary risks versus involuntary risks.

MR. MILLER: Absolutely.

COMMISSIONER APOSTOLAKIS: So I would say that the tritium issue, you know, people look at it as an involuntary risk and they react in a certain way.

In your area, though, I would suspect that most of these risks are voluntary, right? So, do you see any difference in attitudes, I

mean ...

MR. MILLER: Oh, the risks are voluntary from the perspective of in the medical area, because if you're a patient, you're voluntarily, you know, agreeing for health reasons that you're willing to take that risk and get the treatments.

But the materials area regulates a wide variety of applications. In the industry area it's very much approached in the way that we approach reactors. Part of it is we want them to operate safely, but we're looking for avoidance of radiation. You want to make sure that people are not overexposed to radiation and are conducting a practice in a way where they don't. So ...

COMMISSIONER APOSTOLAKIS: So there is no difference you are saying?

MR. MILLER: I think that in many cases, yes.

Is it an involuntary risk? One can argue that everything is a voluntary risk if you agree to -- if you, if you, if you're a worker. Okay? But, I think the involuntary risk comes in where you want to make sure that members of the public are protected.

For example, I'll give you a quick example, well logging, okay? Radioactive materials used for well logging to try to find places where oil deposits may be.

Well, the well logging application is only one of a very small part of the industry where the majority of the workers are out there and they're going to run the rigs and they're going to drill for the oil and they're going to take the oil out of the ground.

Well, if there's poor radiation practices in the well logging tools, you could suppose members of the public who are not. And we've had a situation in the past where that has actually happened and we've taken enforcement against that.

So you have voluntary workers, you have members of the public who might be working in the vicinity who are not voluntarily exposing themself to that. So both sides come into the issue.

COMMISSIONER APOSTOLAKIS: Right. Thank you. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Magwood.

COMMISSIONER MAGWOOD: Thank you, Mr. Chairman.

I'm going to follow up a little be on Commissioner Apostolakis' line of thought and start with you, Fred.

This issue of safety culture is one that is kind of interesting because in some sense it may actually be the Holy Grail of performance indicators that we've been thinking about.

And I wonder, when you think about safety culture in the context of the ROP, that we have it right now as a cross-cutting issue. As you've talked and thought about this, and obviously this is something that has been, you know, chewed over by many people over a long period of time in different countries, is it -- do you have any observation you'd like to make about performance indicators that, perhaps, we currently are tracking that, that might have direct or indirect relationships to the safety culture, that might help us start to develop a more precise definition of safety culture that could be measured in an ROP context?

MR. BROWN: I'll leave time for Vic and Mark to help me if I miss a piece.

I think even the first question on the performance indicator for safety culture, I'm don't -- I'm not aware, sitting here now, of any of our current indicators that give us direct insights. As Bill said, we really look at the outcomes and we can see where something broke and attribute it back to safety cultural causal factors.

I think that part of what we're doing in watching the industry initiative is to see to see what comes out of that and what level of confidence we can have in it for application in either as an inspection target or as a performance indicator, if it's objective, if it's measurable, if it's transparent, and apply that kind of framework.

I guess I would end and turn down by saying that what we do today we think is a valuable tool. And there's clearly history for why we do it. But I believe that everyone in our process believes that there are refinements that can be made and there are better ways to do this. And as we explore the commission's work on the policy statement, that will, that will open doors.

As we've worked with INPO in the industry it's opened doors.

It's just the insight of the safety culture, establishing a safety culture, which is what a utility does, is as critical as the regulators' assessment of the outcomes associated with safety culture. And I'm not sure we thought that way four or five years ago.

But as we are thinking about it, it does open doors. I believe we're a long way from being at the point where we have confidence, a long way in terms of months or years for proposing a dramatic change.

MR. SATORIUS: Let me just add one thing, and that is the current ROP program does within the cross-cutting issue arena, that when you have repeat performers on cross-cutting issues, it does get to a point where we request licensees to perform a safety culture survey. And I will tell you that I get value from that. And more importantly, I think, we've seen indications where licensees have gotten value from that. They've seen things within their organization that maybe they hadn't seen before. So there's -- and they

take action.

So there's a little bit of a tie, Commissioner, there. But I think Fred is right, as far as the Holy Grail, you know we're, you're a couple days off, right?

COMMISSIONER MAGWOOD: I'll give you a couple of days then.

One observation that I'll make, and it is dangerous to generalize, but it's been my experience over the yours that the safety culture that you observe in reactor facilities is very, very different than the safety culture you generally, generalization, you observe in materials facilities.

And I wonder, in some sense I think that's because of the types of risk and the types of materials you're dealing with, there's a natural human inclination to maybe perhaps be more relaxed in the materials facility than you are in the reactor facility.

But -- and I'll ask the question generally, is there something on our side that promotes this thought? Is there some, is there some signals that we're sending through our

processes that safety culture isn't taken as seriously in material facilities as it is in the reactor facility?

MR. BORCHARDT: I don't think there's any intentional desire on our part to send that message.

I think we're careful to send, to make sure that we don't send it unintentionally, either.

I believe it has to do with the level of maturity of the licensees and the resources that these different entities have. I mean, the reactor community is a very mature industry with relatively plentiful resources to be able to dedicate to those activities. Many of the materials licensees are very small entities.

The risk, I would argue, is higher with the, in the activities that Charlie's organization oversees than it is, actually, to the standard worker at a reactor site.

So, I don't see it as being risk based, but I see it as a resource and organizational maturity issue.

COMMISSIONER MAGWOOD: Well, I guess I

would take little issue with that. I mean if you take, for example, the NFS, NFS is not exactly a poor organization. And I don't -- and they're also not an immature organization, it's an organization that has been around for quite a while. In that case, of course, and you've cited significant safety culture concerns.

While not following up too much on that point, it's an ongoing discussion, what happened with the safety culture at NFS? Is this -- did it take a turn at some point in the past where significant staff changes or some other change that led to a decline in safety culture? Can you characterize that for us?

MR. McCREE: I think broadly speaking -- and the record, the performance record at NFS will support this -- is that there had been a longstanding, decade or more, period of what I characterize as cyclic performance at NFS, wherein the attributes of safety culture that we spoke to in the 2007 order were evident even prior to that, but we had not reached a point in the maturation of the regulatory process in how we could ascribe safety culture to those issues.

We had not reached that point until, again, the fall of 2006, and we were able to take advantage of that, if you would, and the adventive use of the alternate dispute resolution process, and we were able to, to pinpoint what we believed, and NFS believed, the issues were, were being caused by.

There were a number of apparent violations and the corrective actions had not taken effect, and we were able to attribute the causes, if you would, to safety culture issues in that timeframe.

COMMISSIONER MAGWOOD: But what, what changed? What led to the decline? I mean the facility has been around for quite a while.

Is it your feeling that perhaps there were problems for even a longer period of time and we simply, they simply did not manifest themselves in the way that they did later or there was actually change in cultures? Can you ...

MR. McCREE: Again, I wouldn't indicate that there was a change in culture. Again, I believe that there had been a level of performance

that had not been pinpointed by the agency and characterized as, as evidence of poor safety culture prior to February of 2007.

COMMISSIONER MAGWOOD: Thank you.

Time is running a little bit short.

Let me ask you a question, Mark, about the safety culture in the context, in the context of the medical field.

I think in response to one of the earlier questions from the Commission, I believe it was Charlie Miller that sort of highlighted the fact that we don't regulate medical procedures.

However, there seems to be a very gray area in here somewhere where we are saying, well, you know, you put the seeds in the wrong place, there's a safety culture problem, and we're concerned about what you've done.

How do we talk about safety culture in the medical environment? I mean what, how, how do you look at a doctor and say this doctor is not practicing safety culture or doesn't have safety culture. How -- just sort of feel free to philosophize.

MR. SATORIUS: Well, you're, you're correct, there is a gray area in there that separates the use of, the safe use of our regulated material and medical practice. And we have to be cautious about not treading over onto the other side.

But in this case, in particular, there were just repeated times where oversight was not invoked, a questioning attitude by radiation safety committee in the RSO was not undertaken. Individuals were aware that there was not good communication, electronic communications to, to, to follow up on post procedure placement of the seeds, and they didn't say anything about it.

I will say this, as we did our extent of condition inspections at the other facilities, we didn't find an issue such as this. So I guess the good news/bad news here is that the good news is that it appears like this, this, this culture that existed within this relatively small program at the VA hospital in Philadelphia did not really manifest itself elsewhere. And when I say a

small program, 116 procedures over the course of five or six years is a relatively small program.

I'm not trying to lessen the impact on those that had been treated and resulted in medical events, but it is -- we didn't see it creeping its way, really, to other locations.

COMMISSIONER MAGWOOD: I appreciate that. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: It's been an interesting discussion on PIs and safety culture, and the -- I thought I might make a couple brief comments on the, on the PIs.

Fred, maybe you could just briefly comment, about how many PIs -- I mean the PIs have not been static. How many PIs -- if you were to look at the PIs that we added on to the ROP to the PIs we have today, approximately what percentage are the same?

MR. BROWN: Bill and Vic may be able to help.

MSPI clearly is a new PI. Scrams with complications were placed, scrams with loss of ultimate heat sync. We've eliminated two PIs

in the security cornerstone, and that's my window of experience. or LERF too,

CHAIRMAN JACZKO: It's not been a static set of PIs?

MR. BROWN: No. And the level below that in terms of definition and application of the PIs, multiple FAQs that have had substantive impact on the PIs that we have as well.

CHAIRMAN JACZKO: So this is kind of the effort to continue to look at these PIs, this is part of this ongoing process of reviewing them and looking at them.

MR. BROWN: Yes, sir.

CHAIRMAN JACZKO: Commissioner Svinicki raised a very good point and I think it's something that I've noticed around as well.

Part of the assessment we do is based on the survey. Five survey results is probably not a scientific sample, so it's probably something we should take a look at as we go forward. If that's going to be a measure for how we're judging the ROP, we need to find a better way, I think, than, you know, relying on a limited set of samples.

Because as I think Commission Svinicki said, you may have some folks who are motivated for a particular issue and that could then skew your results to give an impression that may, in fact, not necessarily be valid in terms of our assessment. So I think that's a good point to look at.

Commissioner Apostolakis made an interesting statement, and this is a question I'm going ask because I don't know the answer to. But he said that the SDP is more important than PIs.

Just out of curiosity, I mean, if we look at greater than green findings, do we tend to find more greater than green? I mean, I don't know, we probably know the numbers exactly. How many come from inspections, how many come from PIs as a percentage, do we, do we know?

Does it -- my anecdotal sense would be that a lot of white findings are PI-related, scrams, MSPI. The yellows I would say my sense is they tend to be inspection findings, and I don't know that we've had a PI that had gone to yellow.

If you have a sense, and if you don't have it, and you just want to provide it and send

it up in a note to the Commission just on how that breaks down and probably in general, findings of PIs versus, well, I guess really, no findings for green PIs necessarily, or there's no green, necessarily, because PIs only really kick in when they cross a threshold per se, and you can have green findings.

So, just if you can provide some information to the Commission on that. I think it's an interesting point, the relative importance of the two.

And just one last question on the PIs. OF course one of important aspects of the PIs is accurate reporting of information, and I get little bits and pieces of information from the staff about the safety system functional failure and whether or not the data that's going into that particular PI is being accurately reported.

Do you have a sense on that particular indicator and whether it's right now accurately -- that licensees are accurately reporting information in the PI?

MR. BROWN: Yes, and I'll be very careful around the word "accurately."

At the time the ROP was put in place, there were about three or four parallel changes that all occurred. That PI is tied to one of the reporting requirements in 50.72 or 50.73, and we changed the NUREG for guidance for implementing that reporting criteria.

In that change we brought in risk insights into a determination about some reporting criteria, but it wasn't meant to apply to safety system functional failures.

It was a -- there were licensees that applied the risk screen to their application of safety system functional failure reporting. That's what we got to in going back and looking at the data over the last two years and working with the industry, and that's what we've worked with the inspection staff to address, to inspect and to ensure compliance with the existing regulation.

CHAIRMAN JACZKO: Okay.

MR. BROWN: I don't believe we're aware of any inaccurate or incomplete information from a standpoint of willfulness.

CHAIRMAN JACZKO: I wasn't intending to insinuate that kind of inaccuracy.

MR. BROWN: But we are seeing an impact from that effort in that the number of safety system functional failures reported within the last year or so has increased, and it's based on a misunderstanding of the criteria.

CHAIRMAN JACZKO: From your perspective, now, it is clear though now what the criteria are?

MR. BROWN: Yes. And, actually, we've started a process to work with the industry on going back to the NUREG, to update it as necessary --

CHAIRMAN JACZKO: Okay.

MR. BROWN: -- so that there can be no confusion going forward, as well.

CHAIRMAN JACZKO: Okay.

The discussion on safety culture I think is a very interesting one and I appreciate the comments of several of my fellow Commissioners. I tend to think of safety culture as one of those things and I think, Bill, you captured it. We know a bad safety culture when we see it, but we don't necessarily know a declining safety culture, and we don't necessarily, can't always identify a good safety culture.

And I think that's the challenge we have in front of us, is, is to see if there is a way to do that, and moreover to -- that's why I think the policy statement is so important, is to define clearly what -- you know, that's the first place to begin is to make sure we all clearly understand what, what we mean by safety culture so we can start to figure out how to look for it.

I remember one of the first things I ever did as a Commissioner was go to the RIC back in 2005 and sit in on a panel discussion about safety culture, and there was somebody in the audience who asked -- I think the whole panel was dedicated to whether or not you can measure safety culture. And of course you had a spectrum of people on the panel. I think somebody -- there was somebody from the industry and then there was somebody, I think, from Synergy, which is a survey company contractor that does a lot of the safety culture work in the industry. And of course their answer was of course we can measure safety culture.

And so there are those who are out there who believe they can do it, and that there are ways to do it. I'm not sure that I'm convinced

yet. But I think the bottom line is, and I think as Commissioner Magwood said, that we find often with plants that have poor performance, that they have poor safety culture. So there may be something there. If we can identify the safety culture issues earlier, perhaps we can, we can work to identify earlier declining performance. And it's not an easy task by any means. But I think, Bill, as you said, it's one, I think, that's worth pursuing.

If I could just turn to a couple questions.

One of the issues that I think in the past we've look at are facilities that come in front of the Commission for the AARM and the Commission has made some changes over those criteria in the past. Perhaps a newer area that we're continuing to explore, without something like the ROP, we have a slightly less objective measure for performance, and that's in the area of materials and fuel cycle facilities that would be appearing in front of us.

What's the sense from the staff about the criteria we have now for when a facility would

appear before the Commission at the AARM, do those criteria need to be improved?

I know last year we, we suggested to the staff as part of the SRM that they take a look at those criteria and work on them, and I'm not sure we have a sense of where that stands.

MR. MILLER: Thank you, Chairman.

I neglected to say in my presentation that one of things that we do is we take an annual look of what have we learned over the past year and should the criteria be changed or not?

One of the things we identified this your was that the current criteria did not provide for, it did not provide for a formal item, I will say, within the criteria that would say if someone appeared before us last year, what would it take for them to appear before you the next year. And we felt that we needed to add that to the criteria, so that if someone's performance had not improved, based upon the reasons that got them there last year, what should we use as the criteria to say they should come back?

And it was felt that we needed to add that criteria at the AARM, we agreed that we would add that criteria. So FSME will be preparing a policy paper that will inform the Commission about that.

As part of that we have to put that out in the Federal Register and get public comments. And then once the public comments are put in place, to put a criteria in place, we have to give a performance period for licensees to be able to perform under that criteria before we evaluate them against it. So it usually takes another year after that before you can evaluate them. But we will be coming to you with a revised criteria issue.

CHAIRMAN JACZKO: One last question, and it's perhaps a more open ended, philosophical question.

We have, we have under the ROP and under the other mechanisms that we use for other types of facilities, fairly clearly established criteria for how we do the oversight, that’s in management directives and all these kinds of things.

One of the tools that seems to me to be ever more increasing in its usage is a confirmatory action letter.

I wondered if you can give me a sense of where you think we are? Have we properly formalized CALs as an enforcement tool or as a tool for encouraging or dealing with issues and dealing with concerns? And particularly, if you look at the ROP, is it well established within the ROP when would we turn to a CAL, what's the kind of effort that we'd use?

MR. BORCHARDT: Well, the confirmatory action letter, I think, is a longstanding practice. I believe I recall it being explicitly discussed in the enforcement policy, and that's where we derive the basic guidance.

I think there is an attractiveness to it because what it causes to happen is an interactive engagement to understand what the issues are, what the path forward is, and then ultimately what the criteria for closing that escalated amount of interaction or oversight is. And then, when, when that is done, then this confirmatory action letter is signed off

and issued rather than just having one party issue something which doesn't really satisfy the general purpose, which is always, from my perspective, to get adequate corrective action and allow for safe operation of the licensees' operations, whichever kind of licensee we're talking about.

So, I think that there is reasonable coverage. There have been some issued lately, it kind of goes in waves. So I don't really foresee a significant uptrend by policy that's being implemented.

MR. McCREE: The only thing I have to add to that is that -- and I agree with Bill, of course, but that using a confirmatory action letter does not preclude, in fact, it facilities, actually, additional action we take for reactor, vis-a-vis the significance termination process in the event there's a performance deficiency greater than green, a finding, or a traditional enforcement, or if a there's a need to engage the license itself and there's a need for an amendment because of something that's been identified.

That process can occur in parallel.

CHAIRMAN JACZKO: If you can be brief because we need to move on.

MR. SATORIUS: I think it's also an excellent tool for stakeholders. It's a very public way of putting a regulatory footprint out there that's formally tracked within the agency. So I think it's good for our stakeholders, Mr. Chairman.

CHAIRMAN JACZKO: Well, thank you. I appreciate the presentation from the staff. We'll take a quick, few minute break as we change the name tags and hear from the licensees. Thanks.

(A break was taken.)

CHAIRMAN JACZKO: I think we'll go ahead and get started unless Tim is going to begin. If Tim's not going to begin, then I think we'll go ahead and get started.

We're a little bit over our time. So if we can, if everyone can do a good job of keeping to the time we have laid out, we'll be able to get done in a reasonable period of time.

If you want to begin. We'll begin now our presentation from Nuclear Field Services and start with David Amerine.

MR. AMERINE: Good morning. Thank you.

My name is Dave Amerine and I've been the new president of Nuclear Fuel Services for a little over two months. This is my first time in approximately ten yours that I've appeared before the Commission. The last time was when I was vice president of Engineering Services for Millstone, during that recovery in the late '90s. At Millstone I had the collateral assignment to lead the establishment of a safety conscious work environment.

I also came to the Commission when I was site manage for Combustion Engineering at Palo Verde during that start-up and when I was the Assistant Vice President of Nuclear for the recovery of Davis-Besse in the mid '80s.

I've spent the last ten years in the DOE nuclear complex leading recoveries and turnarounds of several major nuclear projects.

As I told Luis Reyes, it's very good be back under the regulation of the Nuclear Regulatory Commission.

I have with me Tim Lindstrom, Vice President of the Operations Department at NFS;

Mark Elliot, Director of the Quality Safety and Security Department; and John Nagy, leader of the recently formed Assurance Department.

Among the staff behind us is Ron Daily, the head of the newly aligned Engineering Department. Also in attendance today are my boss, Winford Nash, President of Babcock and Wilcox Nuclear Operating Group, and Chairman of the NFS Board of Directors. And his boss, Mary Pat Salomone, B&W's Chief Operating Officer. They are here representing the ownership of NFS, by Babock and Wilcox, a corporation steeped if nuclear cooperation.

I will be talking about the slides, not reading them.

The second slide in my presentation lists our approach in returning the NFS facility to operation.

We have started a Navy fuel line and a BPF uranium metal, uranium oxide line. We're taking a slow, methodical approach to returning NFS to full operation.

The emphasis is on good conduct of operations supported by a safety conscious work

environment. I've told the expire organization that they cannot go too slow.

Additionally we have added several separate on-shift oversight entities each with its own purpose to support the initial operations.

To introduce a more disciplined coordination of activities, I have required the organization to build a fully integrated resource loaded schedule, which is managed by a plan of the day and plan of the week, and executed through a newly established work control center.

In the third slide I will discuss what is now different at NFS and how we plan to nurture the new approach and the revised attitude of the workforce.

We stress the following principles and descriptions in every venue possible, in all employee meetings and small group discussions, in the first line leadership meetings and on the production floor.

There is strong evidence that the workforce has intellectually embraced these

concepts, but now the challenge is to work toward a visceral adoption so that the allegiance to these principles is the fail-safe mode of our endeavor.

The workplace priorities are safety, quality, schedule, cost, in that order.

The safety priority is based on the principle of not putting anyone in harm's way. Even though our mission is vital to the national security and world stability, it is not worth anyone getting hurt in the execution of their daily tasks.

Quality is what we deliver as professionals, meeting and exceeding the codes and standards that govern our business and our industry.

Pragmatically, if we ever let these first two priorities suffer, schedule and cost will soon follow.

Our foster of a safety conscious work environment is built on the principle that any employee must feel free to bring up any issue without fear of retaliation. They must have the confidence that the issue will be addressed

expeditiously on its own merit without ascribing any motive for bringing up the concern in the first place. The safety conscious work environment is the foundation for a true safety culture.

The attributes of the conduct of operations or as I call it, conduct of business, since it applies to all disciplines, not just operations are personal accountability, procedure compliance, technical inquisitiveness and a willingness to stop and not proceed in the face of uncertainty.

I explained these attributes to the NFS employees in the following manner. The first attribute is not blame, but taking ownership of one's contribution to the effort as a professional.

Like a painter, one must be willing to sign his or her name to the end of the day or the end of the shift noting that they are proud of their contribution and that they did their very best.

Procedure compliance is how, when combined with our training and our experience,

we have the highest probability for success in whatever we're doing. It is essential in our very serious business.

Technical inquisitiveness or questioning attitude is fostering of a sense of wonderment at our surroundings and wanting to understand things in their full breadth and in their full depth. It is the motivation to make sure we understand the indications of our equipment, or the direction we have been given. It is engine that drives continuous improvement.

A willingness to stop and be sure that our actions will produce the desired results is perhaps the most important attribute. When combined with our first workplace priority, safety, it is another definition of a safety conscious work environment. Stopping to get help is honored as an act of integrity at NFS.

Our workforce is developing a sense of ownership of the schedule and its milestones. That accountability when combined with honoring the workplace priority and the conduct of ops attributes makes the most business sense.

Long-term production success, i.e., schedule and cost management, cannot be achieved without placing safety and quality first.

Like I tell our workforce, it is not coincidental that the best commercial nuclear power plants with respect to efficiency and cost metrics are also the best with respect to safety statistics.

We depend on our first line managers and are providing them the training and empowerment to do their job. We are improving -- removing, I should say, the administrative workload so they can focus on supervising their employees.

As I have been saying from my first day at NFS, the first line managers are the most important members of the management chain. We are teaching them practices and principles of participative management, the most important of which is listening to their employees and involving their employees in problem solving and decision making.

We are going to convert our metrics to

the information rich info key performance indicator format and then use algorithms for relating like indicators so that we can have a color roll-off scheme to four or six major topics as has been done in the commercial nuclear industry for years.

I first saw this approach on a visit to North Anna station and then brought it back to Millstone during that recovery. And again, I brought it to the DOE complex when I returned as Chief Operating Officer for Washington Group international government business unit.

It provides a quick way to determine where plant issues are and to drill down to the key performance indicator to understand what the problem is, why it exists, and what is being done about it. It supports our imperative of always working for continuous improvement.

At NFS we now believe that we must take the long view in our approach and that conservative decision-making will support us best.

Moving to the fourth slide, the basis

for the organization realignment is checks and balances.

However, an important alignment consideration was made before I arrived at NFS and that was to create the program management group to relieve the operations organization of project management responsibilities, allowing operations management to sharpen their focus on con ops, moving all quality assurance and quality control functions, which were dispersed and resided in organizations they were intended to monitor to an organization that not only reports to me and the board of directors best serves the checks and balance, as does creating the assurance organization which has that same dual reporting relationship.

Assurance has the responsibilities for such programs as assessment, corrective action, lessons learned and employee concerns.

However, the most important change is moving engineering to report to me.

While all organizations exist to serve operations or production, engineering must also be their alter ego. Engineering must provide

that check that keeps the rest of the organization in balance on a daily basis.

Engineering also has that sacred responsibility to maintain fidelity of the plant to configurate -- plant configuration to the design basis.

Their ability to do this demands independence from the operations organize.

Finally, moving to the fifth slide, our performance since starting Navy Fuel has continued to be positive. It is bolstered by management spending much more time in the workplace with employees, by tracking and meeting our commitments, and by a robust corrective action program.

We will continue to use both metrics in our assessment to prevent the program from backsliding.

The restart has not been without its challenges, both with equipment and with reinforcing the values and principles mentioned above.

The key is that we have taken the time to stop and address the expected vicissitudes

of starting a plant up after an extended outage and with requiring employees to adopt a new paradigm.

From the day I came to NFS, I set clear aspirations of fostering a safety conscious work environment. I have explained to our workforce how accountability for progress is absolutely compatible with our workplace priorities, good conduct of operations and a safety conscious work environmental.

However, we are truly a different facility than we have been over the last several years.

This difference is marked by a fundamental change in our conduct of operations, the implementation of a fully resource loaded schedule, an organization structured to ensure checks and balances, a stringent set of key performance indicators to measure performance and a theoretical and practical shift in understanding and implementation of our safety culture.

We have required our employees to view

things through a new prism and behave according to that revised view. We have looked for opportunities to reinforce the new paradigm by saying thanks when appropriate and by stopping to regroup when necessary.

We will continue to do so.

Our goal is to be a learning organization on a continuous improvement path with excellence in all endeavors as our target.

We understand and operate by the philosophy that the long view must trump all.

Thank you for your time and I'm glad to take your question.

CHAIRMAN JACZKO: Well, thank you for that presentation. We'll start with Mr. Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman.

David, I appreciate the fact that you've been there in your position for a very short period time, but also acknowledge that you've acknowledged that NFS has been at this meeting more than once.

And I guess I want to look at one

point. I was encouraged from your slide five where you note upper management presence in the field. And I'll go back to your slide three and note the third to last bullet about manager participating in employee inclusion. And I guess many years of operational experience in the submarine force and I share that with Mr. Lindstrom, we served in the Navy together years ago in my experience for years of operating plants on submarines and having submarines, some perform well, and some do not perform well. And in some situations you had an us versus them mentality, us being the leadership, the chief petty officers, the wardroom, the officers and the them being in some cases the operators, and sometimes there is muddled pictures. And I bring that background to frame the perspective of my question is with respect to what you're saying in your two months on the job, is everybody onboard kind of pulling the oar in the same direction? Is everyone onboard with where you're headed or is there any us versus them culture that you had to deal with with respect to director workforce?

MR. AMERINE: Well, I'm going to refer that question to Tim Lindstrom, our operations manager. But first, let me say a few things.

I've only been onboard for a little over two months, but the first two weeks I spent in training so I could have unescorted access to the protected area and to the material access area. That sent a tremendous message to the workforce, that the President was going to be out in the field. And I have been.

The second thing I did was on the very first day I met with the union leadership in an effort to establish a rapport, and I'm sure that I have done that.

I walk the plant about every two weeks with Debbie Green, who is the president of the union, and the stated purpose is to look at things through her eyes.

So I'm already forming that relationship and I'm asking and demanding that my staff do the same thing.

One of the main things that comes up repeatedly in the plan of the day is if we have

an issue that's being addressed by engineering or being addressed by integrated safety analysis, are you taking the time to go explain that to the operators?

When I was at Millstone and Vice President of Engineering, I had a rule: If you hadn't talked to an operator, a mechanic, a rad tech or a lab tech in the last three days, it had been too long.

I expected an honest answer whenever I asked an engineer that question, but that was the mode of operation and that is what I expect here at NFS, as well.

So I'll ask Tim to give you his perspective.

MR. LINDSTROM: Thank you.

And to elaborate on some of that, in the development of our, what we consider to be a prompt behavior change attendant with our shutdown in January, we developed a set of standards and behaviors that we wanted the expire workforce to understand and promote.

And rather than, you know, put that down in traditional line management format --

of course we did that, and we put out a document, but we also he a series of small group discussions that included, you know, groups of engineers, safety professionals, frontline supervisors and operators and discussed those in those settings to make sure that everybody would be on the same page; that the engineers would understand the frustrations of the frontline supervisors and vice-versa.

And so, you know, by developing that, those standards, and putting them out in that manner, we really fostered, you know, breaking down those barriers between the groups.

Additionally, when we put together some of the improvements relative to how could we get more management involved in the frontline and how could we get the frontline priorities better involved in production scheduling, we put together a team that included operators, frontline managers, engineers, safety professionals, as well as management, that developed those tools, and implemented them.

So there was a lot of buy in from the

very beginning across all of the different levels of the organization.

You know, we continued to monitor that through, through measuring behaviors. We have found the union to be very supportive. Where we note frustrations within our, particularly within our frontline organization, you know, we try to address those issues, as Dave said, by getting the engineer or the safety professional or the manager out to the front line and explaining why we made the decision we did or listening to understand the issue at hand.

You know, because we have some, you know, on-shift technical support that reports directly to me, we're able to identify early those issues when they come up and direct the right resources to answer that.

And then finally, I think, you know, through the implementation of a resource loaded schedule and a daily accountability meeting around that, we're able to assign an individual responsible, but the entire organization recognizes their part in supporting that objective.

It's not just an engineering issue, it's an engineering, safety and production issue relative to getting that action accomplished.

You know, are we still seeing elements of us versus them or one group not quite in continence? Well, certainly, we see examples of that every day. But the fact is we're looking for that and we're, we're taking positive steps to counter that where we see it.

MR. AMERINE: Just a quick note. Randy Shackleford, who's our Licensing Manager, he's also here today, for several weeks pointed out to me, hey, Dave, good job of embracing the hourly employees, but you're ignoring the white collar workforce. And he was right. And so I scheduled a series of meetings with our engineers and other white collar workers to explain to them the very same things that we were doing with the hourly employees. And that was a good call on his part, and I'm glad I did it, and I received positive feedback.

COMMISSIONER OSTENDORFF: Thank you Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Svinicki.

COMMISSIONER SVINICKI: I want to thank you for your presentation.

I mentioned at the opening of this meeting that this was my third AARM, and in that limited time period I've had the opportunity to see at least one reactor licensee that appeared at our AARM meeting and was then able to work themselves through a performance change so that they're not appearing at this year's AARM meeting.

And I think what that limited experience teaches me is that thematically there's some component elements of affecting organizational change when you find yourself at a performance level that's unacceptable to you. And I see in your presentation today a lot of those core elements that, you know, whether it's a materials licensee or a reactor facility.

So, it's a fancy way of saying that I'm seeing the right messages here and the right approaches.

But when I think about, really, the

challenges of affecting a performance change or an organizational change at a complex, engineering facility such as the one you operate, there's another element, which is really that it is a very sustained effort on the part of management, frontline supervisors and individual employees and those operating the facility.

And so one thing I'd communicate to you is that I hope that the fact that the Commission has an annual AARM meeting doesn't leave anyone with the impression that the committee itself somewhat parachutes in and out of these issues. I would express to you that this Commission operates under basically procedures with the NRC staff that when a facility such as yours is appearing at the AARM, the other, you know, consistently through the 12 months of year our offices are individually, we are kept informed of your path back to a higher performance level or other events that are occurring. And so that's what I'm getting to in the message is saying that consistency of focus and purpose on this.

And so the NRC operates in a way that appearing at the AARM is no, is no minor thing. And throughout the rest of the year, as a Commissioner, I will be kept updated of your progress moving forward.

So I know you're giving the right messages today about senior leadership's focus on this issue, but I would just reinforce and ask you to react to the fact that this is, it's really a 365 day a year kind of a thing. So it isn't a one day AARM event where you have the right elements, the Commission reacts positively and you go off.

And I know you don't view it that way, but if you'd care to react to that.

MR. AMERINE: Well, frankly, first of all, this is my eighth recovery or turnaround where I've been the leader or a member of the leadership team going all the way pack to Davis-Besse, as I mentioned.

No offense, but I don't like meeting you all under these circumstances. And I would much rather meet you when I don't have to. And I plan to develop that kind of relationship not

only with the Commission, but also with the Region, and go sit down with folks and develop that kind of relationship. I've done the same thing in previous venues.

The key across the board is establishing trust; trust with the workers, trust with the management team, trust with the regulators, and trust with all the other stakeholders.

And the key ingredient to trust is open communication.

My philosophy has always been all the cards on the table, face up, all the time.

Now, occasionally that's awkward. Once in awhile it's kind of painful. But in the long run it does serve the relationship best, in any relationship, in establishing that trust. And so that's going to be my path forward.

COMMISSIONER SVINICKI: I appreciate that.

Tim did you want to add anything to that?

MR. LINDSTROM: Well, I think it is

important to recognize that, you know, we had made some progress over the past couple of years and our performance this fall was, you know, totally unacceptable. You know, we recognize that and we've taken a hard look at what were the things that caused that lapse in performance.

I think some of things that Dave has brought, you know, the clear accountability, the production schedule that integrates safety and quality, you know, his top priorities, and the fact that management has been sending a clear message, and our behavior demonstrates, that it's the long view that matters will allow us to sustain the performance that we need to sustain to not be here next year.

COMMISSIONER SVINICKI: Okay. Thank you.

Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Apostolakis.

COMMISSIONER APOSTOLAKIS: Thank you, Mr. Chairman.

Mr. Amerine, you've described here a very ambitious organizational change, which if achieved, would really be a great achievement.

On the way there, I'm curious, what are the top two or three problems you are facing? Who is resisting it perhaps? Not because they are malicious people but, you know, there is people who do things in a certain way. So what are the two or three top challenges that you are facing?

MR. AMERINE: With respect to the organizational change?

COMMISSIONER APOSTOLAKIS: With respect to establishing this organization that you described.

MR. AMERINE: Well, I'm going to ask Mark Elliot to help me with that answer because Mark has not only taken over a new organization, but also had quality, assurance quality control moved under him recently. But he was also part of the transition when B&W acquired NFS. So I think he's got two different perspectives that can help answer your question.

The main challenge is articulating the reason why.

And I've found over my 45 years in this business now that anytime a manager,

regardless of what position you hold, if you're going to do anything, if you can take the time to say why, why you're giving this direction, why you're making this change, you build up a lot of credibility with the folks who have to then go execute that change or have to accommodate the change in the case of an organization change.

So we've slowly rolled out over a period of time, and I was looking for the right opportunity to make these changes. And finally, I decided we had alerted the workforce as to why, we had rolled it down through the management team and so we finally made the organization effective on the 17th.

Having done this seven times before, I knew that I need to, you know, get boots on the ground. That's why I went through that training to begin with, so that I could get a real feel going out and talking to operators, talking to mechanics, talking to engineers, and then making the adjustments.

The only one that I knew I needed to do from my study in Lynchburg before I came to

Irwin, Tennessee, was to move engineering out from under the operations organization and have it report to me. All the other changes are really, yeah, they're part of template I've used before, but that template has to be adjustable. And so I made those adjustments as I learned the organization and I learned the people.

With that, I'd like Mark to respond from his perspective.

MR. ELLIOTT: First of all, I think that one of the things we saw when we came in was we needed clearly to communicate the expectations to the organization of the behaviors that we expected.

We put in place some checks and balances.

As Dave said, the change in this organization wasn't taken very lightly. Any change, of course, brings on risk.

But from taking the long view, we felt that this was the right time to make those changes, and that if changes were made, are going to support the long view.

We -- in communicating the expectations to the workforce, we often find that the frequency of communication really supports the positive behaviors that we see. So when we do see those positive behaviors that are in line with those expectations, we act very swiftly to, to congratulate or celebrate those types of behaviors with, among the peers in the workforce, so that others can, can share in that.

Of course, when we do have backslides in, in performance or behaviors that aren't in accordance with our expectations, we certainly act swiftly with those too.

So I think that as we move forward and keep frequent accountability of the metrics that we have out there that are assessing these behaviors, I think that will offer us the opportunity to act swiftly when, when things start to deviate from, you know, from the goal.

COMMISSIONER APOSTOLAKIS: Well, you told me what you are doing and the implication, I guess, is that you are doing it and it works.

But my question was, what is it that

didn't work? That people, that you -- I mean, okay. You go and communicate to people and then automatically every time someone says, gee, this is great, let's all do it. I have a hard time believing that.

So, where were you challenged, that you said this is a good thing to do and then you go and try and implement it and then you realize there is resistance?

Is there something you can talk about?

MR. AMERINE: Well, you know, Tim's been here longer than I. I'll ask him to also help answer your question.

But let me just -- and this goes back to a question it was asked earlier. We're never going to be able to take our eye off this ball, you know. This is always going to be a work in progress. You don't get to spike the ball and do your touchdown dance.

But the important thing is to understand that and to continue to nurture those relationships.

And we've looked -- we have a number of different avenues for employees to express

their concerns and for us to respond to them.

Quite frankly, so far, the feedback has been very slight with regard to the new changes.

Tim, do you want to give your perspective?

MR. LINDSTROM: Right.

To give a good example of where we implemented something that we thought was a good idea, and we still think it's a good idea, but we've encountered some resistance. You know, Dave mentioned the work control group. In response to the frontline managers and frontline supervisors burdens associated with maintenance, supervision and, you know, maintenance oversight, we established a work control group that would take some of those responsibilities away from frontline supervision and put them in a centralized organization where we had the maintenance and the electronics and calibration groups all working within.

Well, no sooner had we done that when the frontline supervisors started to complain

about their lack of control now in that area. And of course you can't give up the, the responsibilities without giving up the control. So we really had found that we didn't market that well enough, that you know, we were putting this organization in place in response to frontline supervisor need, and yet, when we went to do it, they were resistant and we had to kind of pull back a little bit. You know, do our marketing, explain to them why we were doing what we were doing, how they're giving up some control was actually going to make their lives easier.

And you know, that has really come around now to the point where they are some of the biggest supporters in moving forward with that initiative.

But it was a real lesson for us and, you know, as Dave said, make sure you explain the why's and make sure that your communication is actually received.

Communication occurs in the ear of the receiver. And while we had said why we were doing this, I don't think we clearly explained

it and heard echoed back well enough to make sure it would be well received.

COMMISSIONER APOSTOLAKIS: Thank you.

CHAIRMAN JACZKO: Commissioner Magwood.

COMMISSIONER MAGWOOD: Thank you.

Let me start by welcoming our guests today.

You have been on the job for two months and I know how that feels exactly.

And I also note that we have a couple of things in common, including experience at the Fast Flux Test Facility, so anyone who has been through that certainly has earned some respect in my eyes.

One of the things that, I think, that clearly -- one message that I get from your prosecution is you clearly get that leadership counts in a facility like this, and any new facility. And I can certainly see that you are making an effort to try to take personal charge of what's happening in the facility in walk-arounds and things like that. You mentioned, I think, a part of that.

But -- and perhaps this is somewhat

where Commissioner Apostolakis was also trying to reach, too. When you're trying to put in place a safety conscious work environment in a facility that has had problems, there has to be, there has to be problems. If it were easy, they wouldn't need you. Right?

So to ask his question in a slightly different way, what, what, what -- how have you tried to push the safety conscious work environment philosophy beyond the posters and slogans? What have you tangibly done to try to push that into the organization?

MR. AMERINE: I'm going to ask John Nagy to talk about that, because a lot of the things that will be helping to sustain the safety conscious work environment are in that organization called assurance.

Let me just say that Millstone was an epiphany for me. And I had the very good fortune there of learning about a safety conscious work environment, so to speak, at the knee of Billie Garde. And we are very, very fortunate to have Billie, who has become a close friend of mine, now to be on the nuclear

safety review board that we're going to establish. We just got the Board of Directors to approve that and we're populating that now. But Billie has agreed to be on that. And I'm sure her reputation proceeds her here with the commission and with others. So she'll be there.

And I asked her one time to come out and look at the people team I assembled at the Hanford tank farm, and we had a meeting and I had a little energy around one subject, and when the meeting was over, she said, Amerine, your office, now.

And I found out that I wasn't exactly practicing what I had learned from her and she calibrated me. And I'm sure she'll calibrate, help calibrate the whole workforce here as we move forward with this.

It's not easy. It's counterintuitive in many respects, particularly to normal HR policies and practices. And the senior management behind me has recently approved my ability now to bring onboard the person who was my HR manager at Millstone, steeped in that

experience, also learning from Billie Garde, and he will be there with his, at least initial focus, just on the safety conscious work environment.

But some of those tools that we have to help foster that, really reside in John's organization.

MR. NAGY: Thank you.

Let me talk just briefly about some of the things we've done for promoting a safety conscious environment in particular. And that, of course, falls within a subset of thing just within safety culture that we have been trying to do at the plant.

But within a safety conscious work environment, first of all is making sure that our folks from the very first, you know, as they come to work at our plant, they start to understand that nuclear is different; they start to understand some of the fundamental aspects we want in a safety conscious work environment, that freedom to raise concerns of all kinds, not just safety concerns, but concerns about the plant itself in any respect.

And we start that from the very beginning with just basic training. But we also expand that to training of our supervisors and management corps, and giving them case studies to work through in small groups, as to how you would handle certain types of issues that might come up in the workplace and what we expect to have happen so it certainly starts with training.

But other aspects are tools, as well.

And an example of a tool is the employee concerns program. This is something that we didn't have until last year, and we got that put in place as one of the tools that we hope to help make our safety conscious work environment much stronger at Nuclear Field Services. And that has a very good manager, it's been put together with benchmarking within the nuclear reactor world where the employee concerns programs are very mature, and we've learned a lot from them and have modeled our programs after that.

Within the corrective action program we've recently added a different professional

opinions program. That is also another piece to a safety conscious work environment, we believe, that is important, is providing that mechanism for professionals, or anyone in our facility, to challenge the status quo, to provide that differing view and make sure that it gets heard by the right folks at our plant. And that mechanism is now formally in place. So there is another tool.

And we are in the process of putting together an ombudsman's program as well, to yet provide another aspect or place for people to go to perhaps get some advice or to vent on certain issues and understand better how they might actually use some of these very tools in our organization.

So those are just some examples.

MR. AMERINE: One thing I might add is I'm sure you know Glenn Podonski. I co-chaired with Glenn the safety culture task force for the Department of Energy for the whole complex. It took us a year to pull together things, and I was very interested in the safety culture conversation that took place before. But we actually came up

with a suite of tools to assess the safety culture, and another suite of tools based on those assessments to actually improve the safety culture.

And we piloted that with I think it was 11 different facilities throughout the DOE complex. And again, that took over a year to pull all that together, and I was very fortunate to have Glenn's complete support, and I plan to take a lot of that experience and bring that here as well.

COMMISSIONER MAGWOOD: Thank you very much. Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Following up on that, if you have not shared those with the staff, that would probably be something that would be of significant value, but we can have them reach out to DOE to get that information. We appreciate that.

The NRC's enforcement action with regard to NFS' performance has really been focused on really one issue, which is safety culture. And the confirmatory order we did by and large laid out a process to try and improve the safety

culture was a unique, I think, settlement in our alternate dispute resolution process, and perhaps this goes back to 2007. But I thought I would just ask a couple of questions about formally where we are with regard to addressing the issues in that order.

Fundamentally the order laid out that you would have an independent board, I guess the safety culture board of advisers would come in and do an assessment of safety culture and make recommendations. Maybe if you can give me a highlight of where you stand with all of those recommendations, John. I'm assuming some of the themes, like the employee concerns program, follow from those recommendations. Maybe if you can go through what's been done and what needs to be done still and when you see some of those things getting done.

Or David.

MR. AMERINE: Well, we have not received the report yet, although I've had a number of interfaces with John Gabere who heads up that team, and, as I believe, Victor McCree said earlier, we expect to get that report in the

second weekend in June.

CHAIRMAN JACZKO: That's the follow-up report, there was an initial report.

MR. AMERINE: I'm sorry, you're right, it is the follow-up report.

We -- John has committed to me, John Gabere has to committed to me to allow me to review the draft of that report. And quite frankly, I know that it's going to point out that we have a lot of work to do. But I already knew that. And so we're anxious to get the report. We will assess it, and then once I determine how we're going to address the things that the report points out, then I will be taking it to the Region.

CHAIRMAN JACZKO: I'm sorry, I wasn't clear. My question was on the first report of the recommendations in the first report, which I know predates your time with the organization.

MR. NAGY: And let me just provide perhaps some of the answer to that, and maybe Mr. Lindstrom will add more to it.

For instance, the human performance program at NFS. We went to places that had

been demonstrating better, stronger safety cultures and found that one of the things they pointed to was good human performance programs. And so we adopted that and began to build that program. And it is not easy to build. And we've spent a couple of years in earnest working hard on that and put a whole staff together to do that and have made a lot of progress.

We would, however, point out that one of the things I think we would go back and do differently, if we were to back today, is to focus on the white-collar workforce, on the knowledge workers of our plant.

We spent a lot of time on our, on our labor workforce and that was -- I think it's borne a lot of fruit. But if you look at the events of 2009, you'll find that the decision making issues were primarily within the management and the white-collar workforce. And that is not where our focus was in human performance base, so lesson learned there.

But human performance nevertheless being built. And the employee concern program

already mentioned.

Significant expanses of our corrective action program. It was mentioned earlier that that's an absolute fundamental requirement of a good safety culture is to have a good corrective action program, and we have been building that steadily over the past few years, adding more and better elements to it, strengthening it and adding staff to that.

So those are some examples of things that we've worked very hard on the last few years as a result of the safety culture improvement initiative that came out of the ADR.

CHAIRMAN JACZKO: What's not done? What are the recommendations that are there that you haven't yet tackled?

MR. NAGY: Well, certainly I mentioned the human performance, we're not where we want to be yet. that is one aspect. The corrective action program has some additional maturing to do to get it to where it really needs to be. I believe we know what that looks like, and we have a good vision for that and a plan to get there. And so

that is part of what's not there yet.

And I think Mr. Lindstrom might have a couple things to add.

MR. LINDSTROM: Right.

I would just add some other specifics.

You know, we don't have a comprehensive integrated operating experience program and we think one of the things we learned this fall was, you know, putting that on a, you know, delaying that in its implementation, which was a conscience decision, was probably a mistake, that we could have learned things through operating experience that might have impacted the events of this fall, you know, had we, had we done that.

One of the things that we did not have in place in the fall that we to now, and are continuing to enhance it, is the resource loaded schedule and integrated schedule that really helps take pressure off individuals relative to, you know, task performance. And it becomes very clear what, what things are on their plate and what can be accomplished within

the resources available and helps us, you know, put things in a proper chronological perspective.

In the area of work management, we still have yet to implement a software package which will help provide better work scheduling, work coordination. Although we do have the organization and really the people if place, as well as the procedures to implement that.

And then, you know, the things that John mentioned, you know, human performance, and we did very well in the blue collar workforce. We did not focus on the white collar workforce, and I think that was a mistake, and we have begun to rectify that.

And in the corrective action program, I know Victor mentioned that there were deficiencies in all areas of our corrective action program, and I think this was based on, you know, the 2007/2008 look. We think we've made great strides in the identification of issues, and we need to make equally great strides in, you know, positive, sustained, corrective action of those identified problems.

CHAIRMAN JACZKO: I appreciate that and I think, Mr. Amerine, as you said, the follow-up report will be coming in June, and I think that will provide a good benchmark for where you are in addressing the recommendations of that panel.

In past AARMs with NFS, one of the issues we have discussed is the permanency of that board of advisers. It sounds like with your interest in having a nuclear safety advisory board as part of the formal organizational structure, that that may to some extent encompass that. Because it, certainly in my mind, it's perhaps been one of the weakness of the Commission's order that this was very much, I guess, a two-time look at safety culture. There was the official report and then follow-up report 24 months later. But beyond that, there really wasn't any sustained action in this area from the Commission's perspective.

So it sounds like you've taken that on and I think that's certainly a positive development. But we'll certainly, as Commissioner Svinicki said, keep an eye out for

the new report and what it says and your response to those recommendations.

I appreciate everybody's appearance here and your insights and we look forward to seeing continued improvement in performance and seeing a point at which we no longer have you here discussing the safety challenges at NFS.

Thank you.

(A break was taken.)

Representing the Department of Veterans Affairs, we have Michael Hagan, and we have Gary Williams, Director of the National Health Physics program.

Dr. Hagan, I'll turn to you to start.

DR. HAGAN: Thank you, Mr. Chairman.

I'm going to present some introductory remarks and then the actions that have been completed by the Veterans Health Administration regarding the events in Philadelphia prior to our CAL, as a result of the CAL, and those that have been completed after the CAL issues have been resolved. And in addition, some ongoing efforts that are in the Veterans Health Administration to ensure that we don't return

to this meeting in the future.

I'd like to start off by first acknowledging that I absolutely agree with Mark, with Mr. Sartorius's comment earlier, that at the pre-enforcement there certainly was a push back from Philadelphia and I assure you, if you call the leadership in Philadelphia today, you won't find push back on any of the citations that were accepted by the VA, and fines have been paid.

My task today is a difficult one and I'm sure you'll tell me at the end whether I'm able to do this or not, but I need to separate two issues.

One is the handling of the inadequate implants at Philadelphia and then found at other centers in VHA during our extended condition evaluation with the description of the corrective actions that have been taken and those that are ongoing, and at the same time be able to present that in a chronological way so that I can separate another issue, and that issue is the difficulty in conducting the evaluation medical event determination that is

the regulatory compliance of these particular procedures.

Because it's with that difficulty that the evaluation in Philadelphia was troubled, at many places along the way, and in my opinion continues to be troubled.

I don't in any way, though, to have comments regarding the establishment of effective criteria for medical event determination to appear to mitigation inappropriate, inadequate implants, which certainly occurred in Philadelphia, and as you'll hear, in other centers, as well.

CHAIRMAN JACZKO: Doctor, if we could, this is an issue that the Commission will probably be addressing in the future and we have a meeting this afternoon to talk about kind of the next couple of months, and the issues that we will be dealing with as a Commission. And I suspect that this is one, particularly the medical events definition, that the Commission will have some interest in wanting to take a look at.

So I would certainly, from my perspective, encourage you to try and focus a

little bit more today on the events and what happened in that there's probably a broader policy issue in there, but that may be a topic for a different conversation.

DR. HAGAN: I understand. And as I can separate those, I certainly have separated those, and will keep remarks regarding medical events to a minimum. But you'll see that some of that has to bleed over into how the evaluation was done in Philadelphia.

The initial medical event discovery in May of, May 12, actually, of 2008, was reported by staff from the Philadelphia VA medical center to our NHPP program. That resulted in an initial site visit and determination by NHPP that a medical event had occurred on May 15, which was reported to the NRC operation center on May 16.

Following that, the physics, National Health Physics Program and inspectors conducted an on-site visit, and with that on-site visit identified that there were other medical events likely that had occurred and the program was rapidly brought to stand down. Began an extent

of condition evaluation and assembling the logistics to carry that out across the country. And that identified that implants that were inadequate had also occurred at the Jackson VA in Jackson, Mississippi. That program was suspended, as well.

These programs were immediately suspended and the veterans under follow-up care were verified by the leadership of both centers. The biochemical relapse free survivor in Philadelphia today is 90 percent for the 114 veterans treated there, and 93 percent in Jackson, which are well within industry standards. But that still doesn't mean that there weren't medical events or there weren't inadequate implants performed.

Root causes have been determined through a series of boards and corrective actions have been applied.

And the initial actions, those that occurred in the first six months, started initially with coordination with Region Three. And the slide above starts a list of seven actions that occurred in these first six

months.

The confirmatory action letter was received in October of 2008. The NHPP had already started its 100 percent evaluation of Philadelphia, which was ordered in June after the medical event in May was reported. NHPP cited Philadelphia for escalated enforcement and conducted a 10 case serial review of implants in the other 14 extant programs within the VA.

The regional network in which Philadelphia was located conducted administrative board for root cause analysis. Philadelphia, the deputy under secretary convened a risk assessment advisory board for prostate brachytherapy, and a separate administrative board chaired by Dr. Beijing reviewed collectivity issues between diagnostic and therapeutic planning system and diagnostic platforms across the VA.

Next we'll turn attention to those actions that occurred as a result of the seven point process delineated in the CAL.

First was to conduct reactive

expressions of brachytherapy programs which I have already enumerated. They were completed in January of 2009.

To develop and implement standard procedures for the VHA facilities. These procedures were developed, they were vetted, they were implemented and implementation verified by May of 2009.

Since that time each program has been inspected to ensure that the VHA standard procedures are, in fact, being applied and are active at each one of the active centers.

The incompatible data transmission issues found at Jackson and Philadelphia were actually corrected before the CAL was written, but the VA has committed to reconfirming that there are no connectivity problems in either one of those centers should they wish to restart brachytherapy. They are currently stood down and there is no anticipation of starting brachytherapy at either one of those centers again at present.

In terms of root cause analysis, the multiple boards that I've indicated earlier,

each came to the same conclusion, and that was there was a complete lack of quality assurance operations both at Philadelphia and at Jackson VA.

The VHA standard procedures include robust measures for quality assurance and they have been implemented through a national training program that took place in January of 2009 during which we brought to Crystal City everyone within the VA system, both authorized user, radiation safety officer, medical physicists who are involved in prostate brachytherapy and conducted training session using the national leaders in brachytherapy, in addition to representatives from Region Three who presented the regulatory environment associated with these implants at that time.

In terms of the medical event, let me just briefly introduce that at this point.

In 2005 the ACMUI recommended to NRC that the new regulatory language be constructed that prescribed the use of absorbed dose metrics for these particular implants, and in fact for all volume implants, but prostate in

particular.

There was new regulatory language on the street in the fall of 2008 for review.

It was in that timeframe that the NHPP Director was required to select criteria for evaluating each of the VA facilities.

And so, that criteria was chosen to be consistent with a technical assistance request that was on the public website from 2004. The Director at that time felt that that was the only available choice that was out there and documented and under an NRC letterhead, and went forward with that without realizing that actually it was the internal inconsistency in that TAR that led to the 2005 ACMUI meeting and that the letter from the ACMUI meeting had condemned absorbed dose metrics.

So it was actually with a metric that I would consider flawed that VA went forward with the evaluation.

In addition, that evaluation was compounded by a flawed implementation of that measure.

So the measure was done

retrospectively. And so when it was performed in at least three centers, three centers had done their prostate evaluations at a timeframe where the absorbed dose metric would have been inappropriate to be used.

So not all facilities did that. So most of the facilities had imaging that was available from day 30 after an implant and absorbed this metrics a little bit more robust, and it gives credit to the VA that in that process a total of 159 implants were looked at across the country, and out of those, 142 actually were satisfactory under that absorbed dose metric.

Of those that were not were in Philadelphia and Jackson, and largely represented, those implants that had been imaged at a different time frame during which the application of absorbed dose metric was questionable.

So, it was on the basis of using that metric that when I was appointed as the National Director in 2009, identified to the undersecretary that the metric being used by

the VA had actually been proscribed by the ACMUI and there were better metrics available. And that the way to go forward was to assemble a blue ribbon panel from the experts in the country to advise VHA on the correct set of, or a better set of criteria to be used for evaluation for regulatory compliance against the existing regulation.

And so that panel was put together in September of 2009. They issued their report to the VA in December of 2009. And by January we had reviewed all of the initial reviews of Philadelphia, Jackson, and throughout other centers as well as the medical event determination, according to our blue ribbon panel's set of criteria.

And it identified through it that indeed there were inadequate implants performed at Philadelphia; that evaluation for Jackson is continuing now by a third-party external review that's being carried out by the Image Therapy Guidance Center and Advanced Technology Consortium in St. Louis. It's being done against a database that didn't exist when this

process started, a database that the VA has stepped forward and paid to be assembled from the assets of the American College of Radiology.

Specifically what was absent when the VA started was any data whatsoever on the expected dose to other organs and tissues coming from a prostate implant other than scant data related to rectal exposures.

So there was no data that's available on the expected dose to bladder and periprostatic tissue. There was, however, a reasonable database that the American College of Radiology had through its radiation therapy oncology group, and we've contracted with the radiation therapy oncology group to determine expected doses from that database, and that has been done.

And now that determination is being verified against a second data set randomly selected from that database. Once those data are in place, we will complete the evaluation of Jackson.

So the evaluation of Philadelphia

certainly showed that there were medical events, but using the criteria supported by the blue ribbon panel to the VA, we determined that they had, those implants had been vastly over-reported, that the number was more likely to be approximately 13 to 20, depending on the eventual final determination of this database from RTOG, but nowhere near the 97 medical events that have been reported.

We requested to retract those with NRC Region 13, and it was the opinion of -- NRC Region Three, excuse me. It was the opinion of NRC Region Three that the, that the blue ribbon panel's medical event criteria were invalid.

CHAIRMAN JACZKO: If I could ask you to try and summarize fairly -- in the next couple minutes.

DR. HAGAN: We'll go next to the slides for recent actions that have taken place. And the last on this slide is the one that's up now.

This month, the Office of the Inspector General has issued its separate investigation of the events in Philadelphia. They also looked across the VA system and

inspected Jackson, as well.

Their report was the quality assessment at Philadelphia and Jackson were both seriously deficient, that absorbed dose metric -- values that had been used to do evaluations were unrelated to outcome at each center and unrelated to toxicity at each center. Further opining that the Veterans Health Administration and NRC should meet to agree on appropriate medical event criteria for evaluation of these implants.

So, current ongoing operations, I have already mentioned the work on the database to support medical event criteria.

In addition, my office has developed credentialing template for use by privileging credentially committees throughout the VA. And in addition, we have created a training module for instruction on medical event criteria should we be able to decide on medical event criteria that can be appropriately used.

And, in addition to the requirement that each VA center that practices brachytherapy submit for internal review and

annual audit to the NHPP, the results of their regulatory compliance for each procedure performed, each is now required to submit a ten case serial set for external review.

Recently, there has been an inter-agency publication on the state of radiation oncology in the country. One of the comments made by one of our national leaders in that publication was that there had been a decrease nationally in the performance of prostate brachytherapy, and cited as his understanding of a likely association with the events in Philadelphia as having introduced a chilling effect on the accomplishment of these procedures across the country.

So I encourage us both to work together on the difficult evaluation of these implants so that it is clear they are done safely and it is clear that the authorized user has done what he had attempted to do, and they are in compliance with 10 CFR Part 35.

And only would point out that although we have moved quickly, I think it's more important that we get the answer right, which

is why we have slowed down the evaluation of Jackson until we can put in place data that actually tell us what the expected dose to other organs and tissues should be with these implants.

So, with that, I'll take your questions.

CHAIRMAN JACZKO: Thank you.

We'll start with Mr. Ostendorff.

COMMISSIONER OSTENDORFF: Thank you, Mr. Chairman.

I appreciate that you've been in this job for maybe 15 or 16 months, something like that, and that the initial triggering events in Philadelphia preceded your current position tenure. I appreciate your response to the Region Three Administrator's comments in the first panel dealing with the defensive pushback issues associated with the initial response.

I wanted to ask some questions on the oversight area for either of you to address, if you care to.

Looking at the long-term corrective actions for what I understand, and correct me

if I have this wrong, but I understand there were problems in the existing VA oversight process at a couple of different levels. And I wanted to hear about any specific changes or improvements that might be made either for the National Health Physics Program or the Radiation Safety Committee process to move forward here.

DR. HAGAN: I'll start off and then let Mr. Williams carry on.

But if I understood your reference to be that the extent of condition evaluation found additional problems during that evaluation, what is true is that after the implementation of the standard procedures across the country, which include very detailed written procedure requirements for each of the programs, it is true that prior to the implementation of our standard procedures that there were programs that had poorly documented procedures and poorly described written procedures. That's no longer the case.

With the implementation we have also required that each of those who are performing,

that their medical physics and technical staff understand that if they find a problem with the process that is not addressed by the authorized user, that they will, without penalty, take that issue through the chain and up to, medical chain through chief in staff and to director through the medical physics chain as well, if the medical physicist is contracted through his own leadership, in addition to going through the VA leadership, so that we don't have a culture in place that created the problem that was specific to Philadelphia.

The problem in Jackson was similar but not quite the same. That is, it was not a matter of the physicists there recognizing there were inadequate implants and getting no voice, it was that contracted physicists had changed hands through a number of different contractors and the QA process was lost as we went from medical physics contractor to medical physics contractor. Without standard procedures in place, this was no requirement that the incumbent use any particular set of written procedures when he took over the

medical physics operation.

That is no longer the case.

Mr. Williams can respond, as well.

MR. WILLIAMS: From the regulatory oversight perspective, we initiated in August of 2008 on-site inspections, or we called them at that time site visits for all our facilities. Under the CAL we used the terminology reactive inspections. We completed that series. All the reports were provided to NRC.

And then in our CAL commitment, after I did the root cause analysis, we made a commitment to do annual inspections.

In August of 2009 we began a second series of inspections at all the facilities. These inspections allowed us to confirm that the VHA standard procedures had been implemented and that were based on use of an extensive audit checklist that we've developed -- I think it's seven or eight pages now -- where we can go through each and every issue that is pertinent to the, you know, correct and regulatory compliant to prostate seed implant procedures.

So we've gone through that cycle. We've also gone to Cincinnati and did a restart inspection, and they restarted patients and first patient was March the 30th of this year. And we'll start our next cycle of annual inspections August/September of this year again using our audit checklist.

It's my understanding that NRC is doing your own internal look at your inspection procedures and how in the past NRC has done inspections, and that report is due out I think later this summer. Of course we'd want to benchmark to that, because in our regulatory approach we are required to follow your procedures, insofar as we can, consistent within our resources.

So we're looking forward to whatever you decide, or your staff decides they need to correct, because some of these inspections that NRC might say that NHPP did not identify, medical events, the same facilities have been inspected by NRC staff and they did not identify any circumstances.

The National Radiation Safety

Committee did at the October 2004 meeting identify a generic issue about seed implant programs and tasked NHPP to do initial site visits for any program that was being initiated. And we also identified undue reliance on using the affiliate university, you know, which was the circumstance at Philadelphia, as one of the areas for us to look at.

Our focus was to explicit regulatory compliance to the requirements in 10 CFR 35, and that new focus that we had unfortunately, did not look at post-treatment dose analysis in the same perspective that we would do now since we've have learned a lot from the Philadelphia and the extent of condition inspections.

In addition, recently, we've developed prescriptive requirements for the local radiation safety committees, and these requirements have to be implemented for any meetings that are held on or after July the 15th of this year.

In these requirements, there's an additional level of prescriptive requirements

such as reviewing the written directives for all patients that had been treated. And the written directive is something that's required for a prostate therapy patient. And also to identify any possible issues that aren't resolved at an individual meeting and put them on a tracking matrix and make sure that they are then forwarded to executive management.

So it's a greatly increased level of oversight required at the local level in addition to our inspections.

For the National Radiation Safety Committee, of course I report to them quarterly. I give the results of core performance indicators, which include any medical events that might have occurred.

Also identify to them any significant enforcement actions either by NHPP or by NRC. And of course I'm required to look at possible trends or generic issues, look at things from the root cause perspective and then report to the committee about whatever would be appropriate as comprehensive corrective actions for any issues that we've identified.

We get information out to our facilities through a variety of means. Not only do we have user e-mail groups for the medical physics and RSOs and authorized users, we also issue frequently asked question, we have newsletters that we put out, and then we have individual one-on-one consultation with the facilities as appropriate based on their comments or questions.

So we have a whole series of efforts that we've taken for increased time, boots on the ground, if you would say, of us being there, but also by continuing to get information out to the facilities about expectations. And those are, from the regulatory perspective.

Dr. Hagan, of course, is the physician who would be giving the clinical oversight of that type issues and he speaks to that somewhat with the ten patient reviews each year.

And he's developing other initiatives, again, more for the clinical perspective, which is outside of my regulatory scope. And Dr. Hagan, of course, is a member of the National

Radiation Safety Committee, and he has input both as a committee member, but also in his role as a national program director to address the clinical issues.

COMMISSIONER OSTENDORFF: Thank you

CHAIRMAN JACZKO: Commissioner Svinicki.

COMMISSIONER SVINICKI: I want to thank you, Doctor Hagan, for your presentation and Mr. Williams for your presence here today.

I'm not, I won't cover any of the ground Commissioner Ostendorff covered quite a bit in terms of the events and the actions taken subsequent to that and I also feel like I've been well informed of the events as they were reported and the follow-up actions as they were occurring. So I'll just make a statement and I won't ask any questions today.

As Chairman Jaczko appropriately indicated, it may be that there will be issues on the margins of this event that will be more concretely before the Commission in the future in a different context. So, Dr. Hagan, I appreciate that you have tried to keep the issues succinct today. But one can certainly cast a shadow into

the other.

And it makes me reflect that I think as the NRC staff indicated in the first panel, we've got the practice of medicine occurring coincident with our use of NRC regulated materials or Agreement State regulated materials, so it's complex.

And obviously we do not interfere in the practice of medicine, but you've mentioned the existence of the Advisory Committee on the Medical Uses of Isotopes. The reason that NRC has that staff level advisory committee is so that our regulations will be medically informed.

And so although looking at the best medical information about patient impacts and outcomes is not something, it's not an expertise that resides in the Nuclear Regulatory Commission, we have that advisory committee, and opportunities for public comment by the medical community so that our regulations, which as the NRC staff said, regulate the use of nuclear materials in the practice of medicine are appropriately medically informed, as they should be.

So I appreciate again your presentation

here today, and the actions that VHA is taking. And again, for my part, I'll be following this closely and just commit it on a going forward basis to do what I can to make sure that our regulations have the appropriate medical impacts.

Thank you.

DR. HAGAN: Exactly, and that is that we recognize how thorny this issue is.

And that is, members of our Blue Ribbon Panel had come from the medical event subcommittee of the ACMUI in 2005, and here we are in 2010 and the new regulatory language is not complete. So we understand how difficult this issue has been all along the way.

CHAIRMAN JACZKO: Commissioner Apostolakis.

COMMISSIONER APOSTOLAKIS: No questions, Mr. Chairman.

CHAIRMAN JACZKO: Commissioner Magwood.

COMMISSIONER MAGWOOD: Just a brief, maybe more comment than question.

I appreciate your effort to try to separate the issue of the events that occurred from the concern about how the criteria is

established. And as Commissioner Svinicki and others have indicated, we'll be looking at that as time goes on.

But, however, I guess I would offer this: I do think that -- I think we all agree that significant problems did occur, particularly in Philadelphia, which were widely reported.

And I think that one message I would personally like to send is that it's so important to communicate to people the seriousness of these sorts of events, that I think that you run the risk of garbling the message when you talk so passionately about the criteria in this kind of a venue.

I would encourage you to take the opportunity in the future whenever these issues arise to worry less about the criteria. We will deal with that.

I think your job right now is to make sure that people understand how serious these events were, how they can’t be allowed to occur again, and how the staff has to incorporate into their everyday practice a respect for the

exposures that they're giving patients, the importance to make sure that people are asking questions, the importance to make sure that there's adequate training and oversight for everyone involved.

And I think that's the message that can only come from the top. It has to be sent from the top.

So, I don't want to sound too critical, but I just want to encourage you to send that message whenever you can and, you know, let the issue of the criteria play itself out. We will deal with that.

MR. WILLIAMS: I'd like to point out that Dr. Hagan is the clinician, I'm the regulator, and as a regulator we do enforce the current metric which we committed to NRC, the D-90, and we are doing those things that you mentioned with the facility so they do clearly understand what metric they have to use and what metric that I as the regulator would use to make reports of medical events. Dr. Hagan is keeping his clinical perspective, which is, of course, endorsed by VHA separately, and it's, to my understanding, it's

not impacting anything at the facility level.

COMMISSIONER MAGWOOD: Well, I appreciate that.

I simply indicate that, you know, it's clear that while your responsible for the regulatory aspects of this, I'm willing to bet that the physicians see Dr. Hagan as the person they are most worried about. So I just encourage you to send those messages whenever you can.

Thank you, Mr. Chairman.

CHAIRMAN JACZKO: Well thank you, I'm not sure that I have too much in the way of questions.

I would just comment, I think, as Commissioner Magwood indicated, the enforcement that the NRC took was not because of, I think, a misunderstanding about the concept of the criteria for medical events.

There were a series of actions that we documented through inspection, through your inspection, that led to the actions.

We had instances where I believe a Radiation Safety Officer and another individual did not come forward with concerns because they

did not feel comfortable coming forward with concerns about a particular physician's practices.

That was a significant finding.

We had a medical consultant who reviewed the cases, and I'll comment specifically from one of those inspection reports that accompanied our own inspection, as Commission Svinicki said, I think, you know, we are not medical professionals, so we go on and we get medical consultants. Now perhaps the consultant we used was not credible, but the consultant stated that it is clear that seed placement during these past events -- these are the words that are in this report, does not remotely meet current medical and physician standards.

So that's the basis for, I think, the enforcement action we've taken today, and I appreciate that there may be some confusion about the medical events definition, but with all due respect, that was an issue that came up, the staff fairly strongly, I think, indicated that they did not believe that that was a basis for changing the enforcement action that we took in the past.

This was clearly an activity that all the

issues, irrespective of the medical events, was not done appropriately.

There was not imaging capability following the procedures because there was some incompatibility with the computer systems, and that went on for a year. That was inconsistent with your own internal procedures. That had nothing to do with the medical events definition.

Those were all the kinds of actions that caused significant issues for us as an agency from a regulatory perspective.

So, you know, as we conclude this meeting, I think it's very important to recognize that while there may be some issues, and I think Dr. Hagan said that they are perhaps separate, I don't want to lose sight of the seriousness of the actions that we identified as part of our follow-up inspections that you identified as part of your follow-up inspections. That's the reason we're here today.

Even if we had had a separate medical events definition, it's not clear to me that that would have made a difference, because the definition simply was not being followed

regardless of what it was.

And moreover, there were practices in place that were not consistent with the appropriate focus on safety and the safety of the patient.

So, you know, I can't tell you as I looked at the inspector general, they have comments about the consistency of the errors in the procedure being within the norms of other procedures, I certainly can't comment on that beyond which to say that I'm not sure if that's a good thing or a bad thing. That may be that this procedure may have challenges.

And again, that may be something that, you know, was a broader question for the medical community, but does nexus with our involvement for the sources.

As we go forward, the agency will be looking at the whole concept of masters materials license to see whether that's really an appropriate mechanism to deal with these kinds of situations, all of which, I think, again, stem not from the confusion about the medical events definition, but about the practices of the VA.

So I appreciate your being here today and raising that issue. And I suspect as we go forward and look at the medical events, we would welcome your input because you do have some experience in this area and we'll make sure to give you an opportunity to provide that in that context.

But I do hope that going forward on the regulatory side that you have understanding of what the issues are and will work to make sure that from that radiation safety perspective that corrective actions are in place to ensure that those kinds of issues don't arise in the future.

Any comments? Please if you want to make any comments.

DR. HAGAN: And so my initial comment that I needed to be able to separate those two issues in your mind, clearly that's been a difficult task for us all here.

It is not trivial how the medical event definition played in the life of the physician involved.

Although we don't like to see one medical event, and certainly a program that has

double digit medical events by any set of criteria is a seriously flawed program and prompted VHA's response, which was aggressive and timely all the way throughout. But when that number is characterized as 97 out of 116, then it can lead to the public excoriation of the physician as opposed to a physician who committed some errors.

And so I think there are knock on effects that come from the, the criteria of being confused. And I'd like to point up for the panel that the medical event criteria and how they play out in these evaluation is not a trivial issue here.

CHAIRMAN JACZKO: I appreciate those comments. As I said, I think that will be an issue we'll be pursuing in the future.

Any other comments?

Well, thank you. We have about five minutes on the agenda for discussion and I'm not sure if Commissioners have any items they want to raise at this point, any items for the SRM consideration going forward?

COMMISSIONER MAGWOOD: Mr. Chairman, I

don't have an item for the SRM, but I just want to take this last final opportunity to salute Sam Collins and Bruce Mallett in their final appearance here with us today.

I've only had a short time to serve with them while joining the Commission, but I've known both of them over the years, and their presence obviously will be greatly missed.

So just one final time, thank you.

COMMISSIONER SVINICKI: I'll just say here, here.

CHAIRMAN JACZKO: Well, thank you. And again to Bruce and Sam, thank you.

(Whereupon, the proceedings were concluded)