COMMISSION BRIEFING SLIDES/EXHIBITS

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

MAY 27, 2010

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

Briefing on the Results of the Agency Action Review Meeting

Bill Borchardt, EDO

May 27, 2010

Objectives

- Review appropriateness of agency actions for reactor and material licensees
- Ensure coordinated courses of action
- Review industry trends

Agenda

- Industry Trends Program – Frederick Brown, NRR
- ROP Self-Assessment – Frederick Brown, NRR
- Materials and Waste Programs Performance – Charles Miller, FSME

Agenda (cont.)

- **Licensee Discussions**
  - **Nuclear Fuel Services, Inc. – Victor McCree, RII**
  - **Department of Veterans Affairs, Philadelphia Medical Center – Mark Satorius, RIII**

Reactor Assessments

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

Reactor Industry Trends Program

- Identifies Trends in Safety Performance
- Communicates Performance To Stakeholders
- Supports NRC Performance Goals and ROP Enhancements

FY 2009 Reactor Trend Results

- No Statistically Significant Adverse Trends in Safety Performance
- No Short term Prediction Limits were Exceeded
- No Significant Accident Sequence Precursors

ROP Self-Assessment

- Reviewed Against Program Goals
- Met Performance Goals and Achieved Intended Outcomes
- Focused Agency and Industry Resources Based on Performance

ROP Discussion Topics

- **Action Matrix Deviations**
- **Consistent ROP Resources**
- **ROP Enhancement Process**

2009 ROP Achievements

- Continued to Improve the PI Program
- Enhanced Relocation and Retention Processes for Resident Inspectors
- Improved Assessment Program Guidance and Communications

2010 ROP Focus Areas

- Develop Framework to Evaluate Potential New PIs
- Further Incorporate Operating Experience into Inspection Process
- Consider Additional Safety Culture Enhancements

Materials Assessments

Charles Miller, Director
FSME

Materials and Waste Programs Performance

Summary of the materials and waste program's performance

Performance Evaluation Program

- Systematic review to identify significant:
  - Operational performance trends
  - Licensee performance issues
  - NRC program issues/gaps

Performance Criteria

- Strategic Outcomes
- Performance Measures
- Abnormal Occurrences
- Significant Enforcement Actions
- Trending review of Event Data
- SECY-02-0216 and SECY-08-0135

Strategic Outcomes & Performance Measures

- **All Strategic Outcomes were realized**
- **Performance Measures were all within the established goals**

Abnormal Occurrences

- Nine abnormal occurrences (AOs) in FY 2009
- All AOs in FY 2009 were medical-related events
- No discernable trends on total number of AOs

Licensee Performance/ NRC Program Gaps

- Two nuclear materials licensees met the significant performance issues criteria for FY 2008
- No significant trending issues identified
- No NRC program gaps or failures identified

Review of Portable Gauge Losses and Thefts

- **Data Reviewed to determine:**
  - **Any trends in the area of portable gauge losses and thefts in general**
  - **Any measurable results from the 30.34(i) rulemaking that became effective in 2005**

Review of Portable Gauge Losses and Thefts

Conclusions:

- **Statistically significant decreasing trend in the number of events for the last 10 years**
- **Significant decrease in the number of portable gauge events since 2005**

Review of Nuclear Fuel Services Performance

Victor McCree, Deputy Regional Administrator for Operations, RII

Nuclear Fuel Services

- Basis for Discussion
- NFS Performance Overview
- Recent Performance
- NRC Response
- NRC Oversight
- Next Steps

Basis for Discussion

- **Significant Performance Issues for more than one Inspection Period**
- **Unique Performance Aspects Requiring Additional Oversight**

Performance History

- February 2007 Confirmatory Order
- NFS and NRC Response to Confirmatory Order
- NFS Performance Since February 2007
- November 2009 Confirmatory Order

Recent Performance

- **Startup Of UF6 Commercial Development – Summer 2009**
- **Operational upset in Uranium Aluminum Process Line – October 2009**
- **Fire in UF6 Commercial Development Line – November 2009**

NRC Response to Recent Performance

- Augmented Inspection Team (AIT) Inspection of October 2009 Upset
- Interim Performance Assessment

NRC Response to Recent Performance

- **NFS Commitment to Maintain All Process Lines Shutdown**
- **NRC Issued Confirmatory Action Letter – January 2010**

NRC Recent Oversight Initiatives

- AIT Public Exit Meeting – March 2010
- NRC Restart Readiness Assessment Team (RRAT) Inspection
- Navy Fuel Process Restart Authorized – March 2010
- Enhanced Oversight of Navy Fuel Process Line Restart Activities

NRC Recent Oversight Initiatives

- RRAT Inspection Public Exit Meeting – April 2010
- RRAT Inspection of Additional Process Line - Ongoing
- Enhanced Oversight of Process Line Restart Activities

Next Steps

- **Conduct Readiness Assessment Inspections for Additional Process Lines**
- **Assess Effectiveness of 2007 Confirmatory Order and Determine Appropriate Future Oversight**

Review of Department of Veterans Affairs Performance

Mark Satorius, Regional Administrator, RIII

Materials Licensee Briefing on the U.S. Department of Veterans Affairs

- Performance History
- NRC Actions
- Current Performance
- Next Steps

Performance History

- Substantial Programmatic Breakdown
- 97 Medical Events Reported
- 17 Medical Events Reported Were Also Abnormal Occurrences
- Lack of a Safety Culture

NRC Actions

- Two Special Inspections
- Confirmatory Action Letter
- Significant Enforcement Action with Substantial Civil Penalty
- Extent of Condition Inspection
- Predecisional Enforcement Conference

Current Performance

- Philadelphia VA Prostate Implant Program Shutdown June 2008
- Programmatic Actions Taken to Improve Performance
- VA Inspected All Other Active Prostate Implant Programs

Next Steps

- Increased NRC Inspection Effort
- Enhanced Oversight of VA Inspection Program
- Continued Management Presence
- Explore NRC Program Improvements

Conclusions

List of Acronyms

- AARM – Agency Action Review Meeting
- AIT – Augmented Inspection Team
- AO – Abnormal Occurrence
- ASP – Accident Sequence Precursor
- CY – Calendar Year

List of Acronyms (cont)

- EDO – Executive Director of Operations
- FMSE – Office of Federal and State Materials and Environmental Management Programs
- FY – Fiscal Year
- ITP – Industry Trends Program
- MD – Management Directive

List of Acronyms (cont)

- MSPI – Mitigating Systems Performance Index
- NEI – Nuclear Energy Institute
- NFS – Nuclear Fuel Services
- NMSS – Office of Nuclear Material Safety and Safeguards
- NRC – Nuclear Regulatory Commission

List of Acronyms (cont)

- NRR – Office of Nuclear Reactor Regulation
- PI – Performance Indicator
- RII – Region II
- RIII – Region III
- ROP – Reactor Oversight Process
- RRAT – Restart Readiness Assessment Team

List of Acronyms (cont)

- SECY – Office of the Secretary
- SSFF – Safety System Functional Failure
- UF6 – Uranium Hexafluoride
- VA – Department of Veterans Affairs

NUCLEAR FUEL SERVICES, INC.
a subsidiary of The Babcock & Wilcox Company

NEW PATH FORWARD FOR NUCLEAR FUEL SERVICES

May 27, 2010

David B. Amerine, President
Nuclear Fuel Services, Inc.

APPROACH TO RESTART

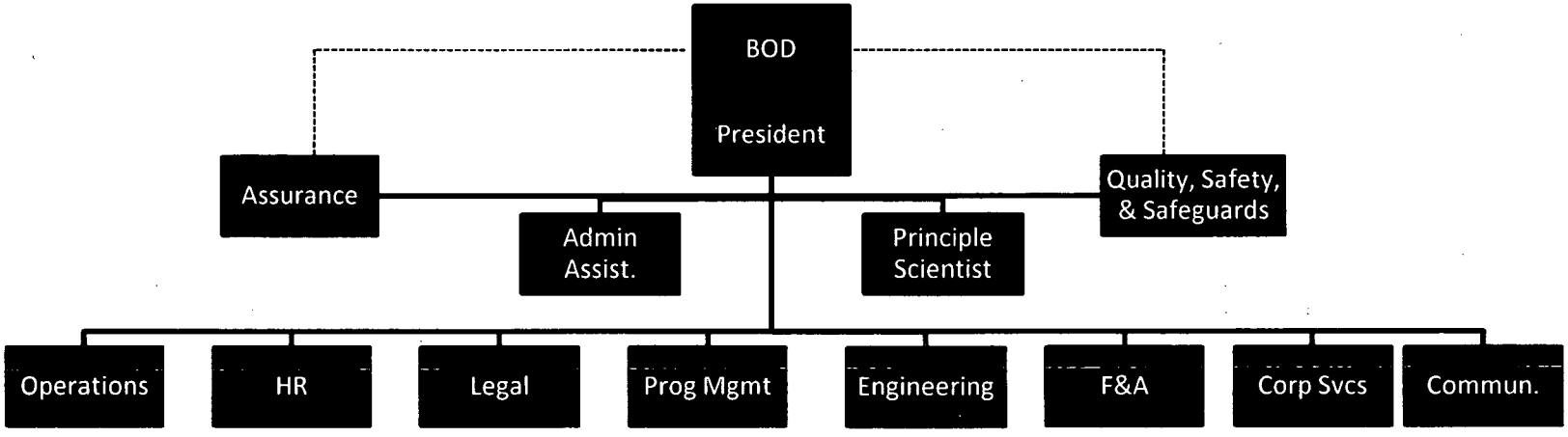
- Slow, Sequential Startup
  - Fuel Manufacturing Facility (FMF), then Blended Low Enriched Uranium Prep Facility (BPF) areas
  - Within each facility, one area at a time
  - Not production driven
- Restart Oversight and Additional Support
  - Senior Engineering Watch
  - Management on shift oversight
  - Engineering and Safety support
- Integrated, Resource-Loaded Schedule

What's Different?

- Workplace priorities: Safety, Quality, Schedule, Cost
- Safety conscious work environment
- Conduct of business attributes
- Schedule ownership and accountability
- First-line manager empowerment
- Work control focus
- Participative management / Employee inclusion
- Metrics using INPO format and color rollup
- Continuous improvement is our imperative

THE LONG VIEW MUST TRUMP ALL

Organizational Structure
Nuclear Fuel Services, Inc.
a subsidiary of the Babcock & Wilcox Company



PERFORMANCE

- Metrics/surveys show positive trend
- Upper management presence in field
- Commitments kept on track by use of metrics and assessments
- Corrective action program robust and improving
- NRC-observed force-on-force triennial exercise huge success
- FMF operation indicates intellectual acceptance of new paradigms are being reflected in actual operation
- Lessons learned from FMF being folded into Blended Low Enriched Uranium Preparation Facility (BPF) startup

LEARNING ORGANIZATION FOCUSED ON CONTINUOUS IMPROVEMENT

Veterans Health Administration response to the inadequate prostate implants performed at the Philadelphia VA Medical Center

Michael Hagan, M.D., Ph.D.
National Director, Radiation Oncology Program, VHA

Remarks prepared for the meeting of the NRC Commissioners, May 2010

Introduction

- Initial Medical Event (ME) discovery was by the Philadelphia VAMC (PVAMC) staff.
- National Health Physics Program (NHPP) verified the ME and initiated complete review of all VHA programs.
- Programs at PVAMC and the Jackson VAMC were found to have inadequate procedures.

Introduction

- These programs were immediately suspended and the Veterans' follow-up care verified.
- Root causes of the performance errors were identified.
- Corrective actions have been taken.

VHA Initial Actions

- Coordinated with Nuclear Regulatory Commission (NRC), Region III, for corrective actions
- 7-point process identified within a Confirmatory Action Letter (CAL)
- Conducted a 100% evaluation of the PVAMC program [NHPP cited PVAMC for escalated enforcement.]
- Performed serial 10-case reviews of the 14 other existent or former VHA prostate brachytherapy programs

VHA Initial Actions

- VHA's Veterans Integrated Service Network (VISN) 4 convened an administrative board to conduct a root cause analysis at Philadelphia.
- VHA Associate Deputy Under Secretary convened the Clinical Risk Assessment Advisory Board (CRAAB) for prostate brachytherapy.
- A specific administrative board reviewed connectivity between treatment platforms and diagnostic imaging within the VHA.

Actions related to the CAL

- Conduct reactive inspections at brachytherapy programs. ***Completed in January 2009.***
- Develop and implement standard procedures for all VHA facilities that are authorized to perform these treatments. ***These procedures were issued in January 2009 and the facilities confirmed implementation in May 2009. Each has been re-inspected.***
- Correct the incompatible data transmission. ***VHA verified the data transmission problems were corrected prior to the CAL.***

Actions related to the CAL

- Identify the root causes and corrective actions to prevent recurrence of these medical events.

  Multiple reviews concluded the lack of appropriate quality assessment (QA) led to the failure to recognize and correct faulty implants.

  QA, incorporated into the VHA standard procedures, is verified annually during on-site inspections.

Actions related to the CAL

- Immediately suspend programs where medical events are identified for 20% of cases. Develop enhanced criteria.

  The National Radiation Safety Committee approved "suspend criteria" on November 13, 2008.

  The programs suspended by VHA had ceased prostate brachytherapy before the formal criteria were approved.

Actions related to the CAL

- Confirm, prior to restart, the implementation of all corrective actions and notify the NRC.

  This process was completed for the recently restarted program at VA Medical Center Cincinnati. Restarts are not anticipated for the remaining three suspended programs.

- Confirm that any new program within the VHA has fully implemented the VHA standard procedures and that individuals have received the training indicated within the CAL.

  To date, no new programs have been initiated.

Recent Actions

- Appointment of a new National Director for Radiation Oncology
- Identification of the flawed ME reporting process at PVAMC
- USH convened panel to examine ME criteria used by the VHA
- All prostate implants at PVAMC and Jackson VAMC are reviewed under criteria offered by the panel and approved by the Under Secretary for Health (USH)

Recent Actions

- VHA contacted NRC Region III to retract inappropriately reported ME
- OIG reported after separate investigation:
  - Quality assessment at the PVAMC and the Jackson VAMC were seriously deficient.
  - Absorbed dose metric, D90-values, were unrelated to outcome
  - ME reports were unrelated to toxicity
  - VHA and NRC should meet to agree on appropriate ME criteria

On-going Actions

- Develop the first data ever presented to address NRC reporting requirement 10 CFR 35.3045(c).

  Develop with the ITC/ATC and RTOG, database and technical report to provide expected doses to other organs and tissues associated with prostate volume implant brachytherapy.

- Conclude the external review of all prostate brachytherapy procedures at the Jackson VAMC.

  The review is being completed by a national quality assurance center for radiation oncology.

- Develop and implement a training module for the new ME criteria. ***A training module has been created.***

On-going Actions

- Develop credentialing guidelines for prostate brachytherapy to be used by VHA.
- Support and work with similar efforts underway in the relevant professional organizations.
- Coordinate with the National Cancer Institute Program Manager, for periodic on-site reviews by the RPC of medical physics operations within the VHA.
- Require that, in addition to following the VHA Standard Procedures, each program providing these procedures have a minimum of 10 cases annually reviewed externally.

Summary

- Prostate brachytherapy procedures within the VHA are of the most rigorous in our industry.
- Problematic initial evaluation of the PVAMC program and sensationalization by the press may have produced an unintended chilling effect on prostate brachytherapy procedures nationwide.

Summary

- A recent inter-agency review of the state of radiation oncology in the United States noted that a recent reduction in these procedures likely reflected the confused circumstances at Philadelphia.
- It is incumbent of those of us who guide these clinical and regulatory processes to get the answers right. Truth, not time, is of the essence when inappropriate assessment may eliminate a very useful and safe therapy.

Veterans Health Admininstration response to the inadequate prostate implants performed at the Philadelphia VA Medical Center

Michael Hagan, M.D., Ph.D.

National Director, Radiation Oncology Program, VHA

Remarks prepared for the meeting of the NRC Commissioners, May 2010

Introduction

Self-initiated, internal investigations by the Veterans Health Administration (VHA) of our prostate brachytherapy programs identified a number of inadequate procedures that were performed at two medical centers: VA Medical Center, Philadelphia, Pennsylvania, and G. V. (Sonny) Montgomery VA Medical Center, Jackson, Mississippi. Senior healthcare managers at both medical centers promptly suspended these prostate brachytherapy programs (i.e., Philadelphia June 11, 2008 and Jackson, September 18, 2008), while verifying follow-up care of the involved Veterans. Cancer relapse-free survival is 90% at PVAMC and 93% at Jackson, results which are as expected for this form of treatment.

VHA completed detailed examinations of each of its prostate brachytherapy programs; identified root causes of performance errors; and implemented the comprehensive corrective actions, which I will detail. Close coordination with the NRC has occurred at every step.

Background

On May 12, 2008, staff at the Philadelphia VAMC contacted the VHA National Health Physics Program, (NHPP), our VHA internal regulators, about an error in seed activity for a prostate implant. After performing a follow-up dose assessment, a medical event was discovered on May 15 and on May 16 reported to the NRC Operations Center. NHPP verified the circumstances of the reported medical event via a prima facie site inspection. This regulatory inspection resulted in a promptly initiated, complete review of the entire prostate brachytherapy program at PVAMC.

The national regulatory setting under which this NHPP inspection was conducted is germane to this discussion and bears some mention. Responding to a 2005 report from its medical advisory committee (ACMUI), which identified substantial difficulties with the medical event reporting for these particular implants, NRC was at the time of the events in Philadelphia revising regulations to define methods for medical event reporting for volume implants of the prostate.

The NHPP Director, however, needed to employ a defined metric for the Philadelphia evaluation and for evaluations for other VHA facilities. The metric selected was an absorbed-dose metric offered by the NRC in a 2004 TAR posted on the NRC public Web site. The 2004 TAR advised the use of an absorbed-dose metric, the D90-value, for doses below the planned prescription dose, but cautioned the same metric was inappropriate for doses above the prescription dose.

Unfortunately, it was in part the inherent contradictions in the 2004 TAR, which had prompted the ACMUI meetings in 2005, which led to the eventual report mentioned earlier - a report which proscribed the use of absorbed dose metrics for a volume implant.

Thus, it was with a flawed metric, ultimately compounded with a faulty, retrospective application of that metric that the VHA facilities and NHPP proceeded. I will return to this issue.

VHA evaluation and actions re: volume implants of the prostate at VHA sites

Initial actions

Over the initial 6 months after the medical event was reported for Philadelphia, the VHA initiated or completed the following actions:

1. Coordinated with NRC, Region III, for corrective actions which resulted in an agreed upon 7-point process identified within a Confirmatory Action Letter (CAL).
2. Conducted a 100% evaluation of the Philadelphia prostate brachytherapy program including NHPP issuing an inspection report which cited escalated enforcement.
3. Performed serial 10-case reviews of each of the 14 other extant or former VHA prostate brachytherapy programs.
4. VHA's VISN 4 convened an administrative board for root cause analysis at Philadelphia.
5. VHA Associate Deputy Under Secretary for Health for Quality and Safety convened the Clinical Risk Assessment Advisory Board (CRAAB) for prostate brachytherapy.
6. A specific administrative board, chaired by Dr. J. Bagian, reviewed all issues related to connectivity between treatment platforms and diagnostic imaging within the VHA.

CAL related actions

The CAL process, which included NHPP evaluating the "extent of condition" within the VHA, established requirements for standardized brachytherapy and brachytherapy program procedures within the VHA. The process included the following actions:

1. VHA conducted reactive inspections at active prostate brachytherapy programs, which were completed in January 2009.
2. VHA developed and implemented standard procedures for conducting prostate brachytherapy treatments for all VHA facilities authorized to perform these treatments. These procedures were issued in January 2009. The facilities confirmed implementation in May 2009.
3. VHA corrected the incompatible data transmission problems identified at Philadelphia and Jackson. After verifying that the data transmission problems had been corrected by both facilities before the CAL was issued, VHA committed to re-confirm adequate connectivity prior to either facility restarting these treatments.
4. VHA identified the root causes and implemented corrective actions to prevent recurrence of these medical events. Multiple reviews and evaluations of both Philadelphia and Jackson have concluded that the lack of appropriate programs for quality assessment led to failures both to recognize and to correct faulty implants at each of these centers.

   Corrective actions, which establish a comprehensive program of quality assessment, have been incorporated into the VHA Standard Procedures for Prostate Brachytherapy. As I indicated earlier, implementation of the VHA standard procedures has been verified for each program. Compliance with these procedures, documented for each implant by the authorized user and the center's radiation safety committee, is also verified annually by on-site inspections.
5. VHA immediately suspends programs where medical events are identified for 20% or greater of treatments performed. VHA developed enhanced suspension criteria. The VHA National Radiation Safety Committee approved "suspend criteria" on November 13, 2008. These criteria have not had to be used. The four programs that were considered suspended by VHA ceased prostate brachytherapy before formal criteria were approved.
6. VHA will confirm by NHPP inspection prior to restart, the implementation of all corrective actions and notify the NRC. This restart process was completed for the recently restarted program at VA Medical Center, Cincinnati. Restarts are not anticipated for the remaining three suspended programs.
7. VHA will confirm by NHPP inspection prior to initiation, that any new program within the VHA has fully implemented the VHA standard procedures and that individuals performing these procedures have received the training indicated within the CAL.

   To date, no new programs have been initiated.

As a result of the external review efforts a total of 19 medical events were reported from the other VHA facilities. Ten of these from the Jackson VAMC may stand. A complete review of all Jackson cases is nearing completion. Nine of these MEs from two other programs are related to the ME definition and will not be upheld. In addition, three other medical events have been reported from facilities after the initial round of inspections. Each of these three is related to a confused ME definition and should ultimately be retracted.

Actions since Jan 2009

As a response, in part, to these efforts I was named in January 2009 as the National Director of Radiation Oncology for the VHA. At that time the final reporting from the medical center at Philadelphia was under internal review. I noted that reporting from this medical center was based on a flawed application of the D90 metric. This same flawed application had occurred for the evaluation of Cincinnati and was to be used for Jackson.

With the controversial use of the D90 metric, so-called, and the absence of published criteria for determining the expected dose to other organs and tissues, required by 10 CFR 35.3045(c), I asked the VHA Under Secretary for Health (USH) to convene a panel of nationally recognized brachtherapy scholars to advise the VHA regarding medical event criteria for these prostate brachytherapy procedures.

This panel, meeting initially on September 3, 2009, issued their recommendations to the USH on December 8, 2009. These recommendations were evaluated by the VHA National Radiation Safety Committee, which recommended their use. On January 14, 2010, the NRSC approved these ME criteria both for review of previously reported medical events and as criteria to evaluate any future prostate brachytherapy procedures.

The previously reported medical events at Philadelphia were immediately re-reviewed under these criteria verifying that medical events had occurred. This review indicated, however, that ME from Philadelphia had been vastly over-reported. On this basis, the NHPP sent a request to NRC, Region III, to retract those inappropriately reported medical events. In the inspection report issued for Philadelphia, NRC rejected the new metric. This month, the Office of the Inspector General reported on prostate brachytherapy at the PVAMC. The report confirming the absence of effective quality assurance at the PVAMC and the JVAMC, also noted that the D90 metric used for the evaluation of the Philadelphia program appeared to be without merit.

On-going actions

In coordination with the NRC, VHA will establish and verify workable ME criteria for prostate volume implants. Largely completed, this effort includes the following projects.

1. Develop the first data ever presented to address NRC reporting requirement 10 CFR 35.3045(c). Develop with the ITC and RTOG, the database and technical report to provide for national use "expected doses to other organs and tissues associated with prostate volume implant brachytherapy."

2. Conclude the external review of all prostate brachytherapy procedures at the Jackson VAMC. The review is being completed by a national quality assurance center for radiation oncology.

3. Develop and implement a training module for the new ME criteria. A training module has been created.

My office, which has developed credentialing guidelines for prostate brachytherapy to be used by the VAMC P&C Committees, is working with similar efforts underway in the relevant professional organizations.

In coordination with the NCI radiation oncology quality assurance Program Manager, my office will contract for periodic on-site reviews by the Radiologic Physics Center of medical physics operations within the VHA.

In an effort to reduce the likelihood of isolated practice patterns, VHA now requires that, in addition to the VHA standard procedures requirement for internal quality assessment, each program providing these procedures have a minimum of 10 cases annually reviewed externally.

Summary

As a result of these oversight and evaluation processes by VHA, prostate brachytherapy procedures within the VHA are the most rigorous in our industry. Unfortunately, this problematic initial evaluation of the Philadelphia treatments and its sensationalization by the press, may have produced an unintended chilling effect on prostate brachytherapy procedures nationwide.

It is incumbent of those of us who guide these clinical and regulatory processes to insure these therapies are well-designed and safely administered. Investigations by the VHA and OIG have noted that the Veterans at PVAMC and Jackson VAMC are doing well, yet the initial regulatory evaluations have been quite troubling. While the VA's response to Philadelphia has been both comprehensive and thoroughly coordinated with the NRC, I have described errors in this process - flaws VHA has addressed by reaching out to the country's radiation oncology leaders.

This is an important juncture with national implications. Truth, not time, is of the essence when an unwise or inappropriate assessment may eliminate a very useful and safe therapy.