UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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NRC PREDECISIONAL ENFORCEMENT CONFERENCE-

VA PHILADELPHIA MEDICAL CENTER

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THURSDAY

DECEMBER 17, 2009

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The meeting convened at 1:00 p.m.

NUCLEAR REGULATORY COMMISSION STAFF

STEVE REYNOLDS, DIRECTOR OF THE DIVISION OF NUCLEAR MATERIAL SAFETY.

MARK SATORIUS, REGIONAL ADMINISTRATOR FOR REGION III.

CHARLES MILLER, DIRECTOR OF THE OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS.

ROY ZIMMERMAN, DIRECTOR OF THE OFFICE OF ENFORCEMENT.

JERROD HECK, REGIONAL ATTORNEY.

PATRICIA PELKE, BRANCH CHIEF FOR MITCHELL'S INSPECTION.

STEVE NORRIS, REGIONAL ENFORCEMENT OFFICER.

MR. ORTH, ENFORCEMENT OFFICER

DARREL WIEDEMAN, SENIOR HEALTH PHYSICIST.

CASSANDRA FRASER, SENIOR HEALTH FHYSICIST.

DEBORAH PERSCURE, HEALTH PHYSICIST.

VA PHILADELPHIA MEDICAL CENTER

RICHARD CITRON, DIRECTOR OF THE VA MEDICAL CENTER, PHILADELPHIA.

CHARLES ANDERSON, HEAD OF RADIATION SAFETY.

MICHAEL HAGAN, NATIONAL DIRECTOR FOR THE RADIATION ONCOLOGY PROGRAM OF THE VA.

STELLA DANIELS, DEPUTY CHIEF OFFICER FOR PATIENT CARE SERVICES IN VHA.

JOEL MASLOW, CHAIR OF THE RADIATION SAFETY COMMITTEE.

AMIT MAITY, CHIEF OF RADIATION ONCOLOGY AT PHILADELPHIA VA MEDICAL CENTER

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

MR. REYNOLDS: Good afternoon.

We are ready for this enforcement conference to begin.

I'm Steve Reynolds, I'm the Director of the Division of Nuclear Material Safety, the NRC's Region III Office in Lisle, Illinois, and I will be leading this conference today.

I will do introductions in just a moment. But first, just to be clear, this is a pre-decisional enforcement conference between the Nuclear Regulatory Commission, NRC, and the Department of Veterans Affairs to discuss issues associated with the multiple medical events involving the treatment of prostate cancer at the Department of Veterans Affairs Medical Center in Philadelphia, Pennsylvania, or VA Philadelphia.

These issues are documented and publicly available in special reports issued by the NRC dated March 30th of this year and November 17th of this year.

Some copies of these reports are available at both entrance doors for people interested.

Pre-decisional enforcement conferences such as this, are typically held in our regional offices.

However, due to the significance of these issues and to show the collective concern of the Agency, the decision was made to hold the pre-decisional conference here in NRC headquarters, here in the Commission Hearing room.

The Commission is open for public observation. Members of the public who are in attendance at this meeting and on the phone, you should be aware that this meeting is between the NRC and the Department of Veterans Affairs.

Following the conference, the NRC staff will be available to answer questions and receive comments from members of the public concerning the matters discussed at this conference.

We will take questions and comments from people here in the room and from people who are on the phone.

During that session, the NRC's Mr. Chip Cameron -- will you stand up -- will facilitate our

question and answer period.

Before we get started with that, let's start with introductions. There is a sign-up sheet going around, and again, my name is Steve Reynolds. I'm the Director of the Division of Nuclear Safety.

Next to me is my boss, Mr. Mark Satorius; he is a regional administrator for Region III.

Next to him is Dr. Charles Miller, he's the Director of Office of Federal and State Materials and Environment Management Programs.

Next to him is Mr. Roy Zimmerman, he's the Director of Office of Enforcement.

Next to him is Mr. Jerrod Heck. He is our regional attorney.

On my right here is Mrs. Patricia Pelke. She's the Branch Chief for Mitchell's Inspection Branch and she is the Manager with the direct oversight for the VA's Master Material License.

Next to her is Mr. Steve Norris. He is our regional Enforcement Officer.

I would also like to introduce the members of our inspection team, and we have them over here to

our far left.

Mr. Darrel Weideman, he is the Senior Health Physicist and NRC's Lead Inspector.

Next to him is Mrs. Cassandra Fraser, she is a Senior health physicist and she's the NRC's Project Manager for the VA's Mass Material License.

Next to her is Mrs. Deborah Perscure, a Health Physicist.

Not present, but also involved in our inspections was Dr. Donna Beth Howe.

At this time, would you introduce yourselves, please.

MR. CITRON: I'm Richard Citron. I'm the Director of the VA Medical Center, Philadelphia.

Accompanying me today -- well, let me defer to Dr. Anderson, head of Radiation Safety for the VA.

DR. ANDERSON: I'm Dr. Charles Anderson, I'm the Chair of the National Radiation Safety Committee.

MR. CITRON: Dr. Hagan, would you go next?

DR. HAGAN: Michael Hagan and I'm the National Director for the Radiation Oncology Program

of the VA.

MS. DANIELS: I'm Stella Daniels, I'm the Deputy Chief Officer for Patient Care Services in VHA.

DR. MASLOW: Joel Maslow, I am the Chair of the Radiation Safety Committee and also the Associate Chief of Staff for Research at the hospital and the Interim Chief of Medicine at the hospital.

MR. MAITY: Dr. Maiy, Chief of Radiation Oncology at the Philadelphia VA Medical Center.

MR. REYNOLDS: Thank you.

For our dinner this afternoon, Mr. Orth, our Enforcement Officer, will start with the purpose of this enforcement conference and then he will discuss aspects of enforcement policy as it relates to matters today.

Then Mr. Wiedeman will summarize our inspection findings, and then Mrs. Fraser will summarize our concerns that we documented in our special report.

After that time I will turn the meeting over to you, Mr. Citron, and then during your presentation we will be asking questions.

However, you should not take the questions, or their absence of questions, as indication of the Agency's final position.

After your presentation concludes, we will break for a caucus with the NRC staff to discuss any information that you provided and to formulate any final questions we want to ask before the end of the meeting.

Depending on how long this conference goes, we may take a short break around 3:00 p.m.

That is pretty much how we will run the agenda, and then after the meeting closes, we will do the public question and answer period.

Just to start off with some background: Prostate cancer patients at VA Philadelphia began receiving implants, brachytherapy, in 2002.

Records show that problems started immediately and continued unchecked until the Prostate Brachytherapy Program was suspended in the summer of 2008.

Based on reports to the NRC, the Department of Veterans Affairs has identified 97 medical events out

of the 114 patients treated.

Generally speaking, a medical event is a result of the actual treatment to the patient being different than what the physician prescribed.

The Prostate Brachytherapy Program at VA Philadelphia was run by physicians from the hospitals of the University of Pennsylvania, referred to as HUP.

Dr. Gary Kao performed the majority of the implants and Dr. Richard Whittington performed the rest.

Mr. Mike Bieda, Dr. George Lazurescu, and Mr. Greg Desobry were the medical physicists involved in these treatments.

Dr. Mary Moore was a radiation safety officer.

The Radiation Safety Officer is a person we expect to ensure the day-to-day safety in the use of radioactive material, and to ensure that the Medical Center follows her regulations.

VA Philadelphia also had a Radiation Safety Committee.

The Radiation Safety Committee is supposed to provide oversight to the entire medical program,

nuclear medical program, and ensure radioactive materials are used safely.

Lastly, the Department of Veterans Affairs National Health Physics program NHPP, conducted several inspections at the VA Philadelphia.

As we have heard over these several months, the last year and a half or so, the Department of Veterans Affairs -- as we have heard in the past, problems with these prostate treatments went unchecked and medical events went unreported from the beginning.

Through our inspections, we have identified eight apparent violations of NRC regulations, and we have identified several concerns involving inadequate management oversight including a lack of safety culture.

We are here today to hear from the Department of Veterans Affairs to hear what happened, why it happened, and what corrective actions have been and will be taken to prevent this from happening again throughout the Department of Veterans Affairs.

We also want to understand how the actions or inactions of the physicians, medical physicists,

Radiation Safety Officer, and the Radiation Safety Committee contributed to these problems and what actions have been taken to prevent problems in the future.

Before I turn things over to Mr. Orth, I believe Dr. Miller and Mr. Zimmerman and Mr. Satorius have opening remarks.

DR. MILLER: Thank you, Steve.

Good afternoon. As Steve mentioned, my name is Dr. Charles Miller and I'm the Director of the NRC's Office of Federal State Materials and Environmental Management Programs, which we refer to here at the NRC as FSME.

My office is responsible for developing, implementing and overseeing the regulatory framework for industrial, commercial, and medical uses of radioactive materials in the United States. The Region III office of the NRC has oversight of the U.S. Department of Veterans Affairs and FSME has programmatic oversight of all NRC materials and licensees.

Based on the findings of this case, my office will evaluate what changes are necessary to reduce the likelihood

of this type of situation happening again at the VA or elsewhere.

Thank you.

MR. ZIMMERMAN: [NO AUDIO]

MR. SATORIUS: Quickly, I am Mark Satorius, and I am the Regional Administrator in Region III.

My region is responsible for a good deal of the oversight on the Veterans Affairs Hospitals.

I have been looking forward to this conference for months before it's been scheduled.

I wanted to hear directly from the Veteran Affairs how you dealt with this issue, how you've checked to see that the corrective actions that you take are going to preclude any further type of problems, and to hear directly from you how you've internalized some of the safety culture issues that our inspections have uncovered.

Thanks.

MR. ORTH: Good afternoon.

The NRC -- I want to take a few minutes here to describe the NRC Enforcement Program Policy and how we arrived here today.

The NRC's Enforcement Program is governed by the Commission's Enforcement Policy.

The purposes of the policy are to encourage compliance with our requirements and encourage licensees to identify and to take prompt and comprehensive corrective actions.

After we identify a potentially safety significant issue, we determine whether or not it involves a violation of NRC requirements.

When an apparent violation is identified, the NRC evaluates its actual or potential safety significance in accordance with our enforcement policy, which is publicly available on our website and we have additional copies here in the room at both entrances today.

The apparent violation is a sign of preliminary severity level one through four, with one being the highest.

Severity levels one, two, and three violations are considered escalated enforcement.

If the violation appears to warrant an escalated enforcement, the NRC holds an internal meeting first, called an Enforcement Panel.

One of the purposes of this meeting is to ensure that the NRC is consistently applying the Enforcement Policy.

At this meeting, the NRC will make a preliminary determination about the appropriate outcome for the issues.

We will also discuss whether a civil penalty appears warranted.

As one outcome of the meeting, the NRC can decide whether we have sufficient information to go forward to make a final decision, or whether additional information is necessary.

In cases where we determined that additional information is needed, we will request that a licensee participate in a pre-decisional enforcement conference. It is important to note that the decision to hold a pre-decisional enforcement conference does not mean that the Agency has made a final enforcement decision.

The apparent violations that we will discuss today are subject to further review and may change prior to any resulting final enforcement action based

in part, by the information we discuss today.

If the NRC determines that a violation did occur, there are a number of available enforcement sanctions available to us.

They include notice of the violations, civil penalties and orders.

Normal civil penalty amounts are contained in our enforcement policy. However, the NRC can either escalate or mitigate the amount of the civil penalties or the severity levels of the violations based on factors such as identification, corrective actions, prior enforcement history, and whether the violations willful.

The nature and extent of the enforcement action is intended to reflect the seriousness of the violations.

The NRC has requested this enforcement conference prior to making the enforcement decision on the eight apparent violations surrounding the medical events at the Philadelphia VA Medical Center.

As mentioned in our letter dated November 17, 2009, pre-decisional enforcement conference provides

the Department of Veterans Affairs with an opportunity to assist the NRC in making our enforcement decision by providing us your understanding of the facts and circumstances surrounding the apparent violations, and whether you agree or disagree with the NRC's understanding as provided in our inspection reports.

We would also like you to provide your understanding of the cause or causes for the issues, your views on the safety significance, and a description of the immediate and long-term corrective actions that you have taken or planned to take.

During this discussion, we would also ask that you address the additional concerns documented in our inspection reports which will be discussed by Mrs. Fraser, which include, in particular, the safety culture at your facilities.

Finally, this conference provides you an opportunity to present any additional information that you believe is important to us to consider before we make our final enforcement decision.

This meeting is not intended to be a debate.

Each apparent violation discussed at this conference is subject to further review and may change prior to any resulting enforcement action.

It is important to understand that decision to conduct this conference means that the NRC has not yet made a final enforcement decision.

The purpose of the NRC's questions here at this conference are to gain information to aid us in the evaluation of the issues.

Before we continue with the discussion of the apparent violations I'd like to ask if you have any questions concerning the NRC's enforcement policy.

MR. REYNOLDS: Mr. Weiderman will now summarize the inspection findings.

MR. WEIDERMAN: Copies of our slides are available at the doorway if you are interested.

Regarding the first apparent violation, the licensee failed to develop adequate written procedures to provide high competence that each prostate seed implanted administration was in accordance with the written directive as required by Title X of the Code of Federal Regulations, 10 CFR

35.41 (a) (2).

As a result, this led to 97 reported medical events.

Regarding the Apparent Violation No. 2, the licensee failed to develop procedures that address methods for verifying that the administration is in accordance with a treatment plan and the written directive as required by 10 CFR 35.41 (b) (2).

Specifically, the procedures did not include alternate methods to verify that the treatment was in accordance with the written directive when the normal verification method was unavailable.

As a result, the licensee did not perform post-treatment dose verifications for 16 patients from November 2006 to December 2007.

Regarding Apparent Violation No. 3 , the licensee failed to develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and the written directive as required by 10 CFR 35.41 (b) (2).

Specifically, the licensee's procedures did not address reviewing both the applicable treatment plan and the

written directive.

As a result, for a treatment on May 5,2008, the wrong seed activity was implanted.

Regarding Apparent Violation No. 4, the licensee failed to instruct supervised individuals regarding identification and reporting requirements for medical events as required by 10 CFR 35.27 (a (1).

Two medical physicists, who were supervised individuals, did not receive training on the identification and reporting requirements for a medical event.

Regarding Apparent Violation No. 5, the licensee failed to instruct an authorized physician user regarding his responsibility to promptly report to the licensee any condition which may lead or cause a violation of the Commission's regulations as required by 10 CFR 19.12 (a)(4).

Specifically, the licensee failed to provide the physician instructions for identifying and reporting medical events.

Regarding Apparent Violation No. 6, the licensee failed to notify the NRC operations center by telephone no later than the next calendar day after discovery of a

medical event as required by 10 CFR 35.3045 (c).

The licensee had sufficient information available at the completion of the prostate treatments to make a determination that numerous medical events occurred.

Regarding Apparent Violation No. 7, the licensee failed to record the total dose, the number of sources implanted, and the total source strength on a written directive as required by 10 CFR 30.40 (b) (6 (ii).

Regarding Apparent Violation No. 8, the licensee failed to provide complete and accurate information in accordance with 10 CFR 30.9 (a), and several 15 day written reports to the NRC as required by 10 CFR 35.3045 (d).

MR. REYNOLDS: Thank you Mr. Wiedeman.

Now Mrs. Fraser will summarize our concerns.

MRS. FASER: Area of Concern No. 1:

Inadequate quarterly audits of the Brachytherapy Program by the radiation safety staff.

As an example, the audits indicated that written directives were in full compliance. However, the administered dose was not in accordance with the written directive and the pre-treatment plan.

Area of Concern No. 2: Failure of the Radiation Safety Committee to take action regarding computer interface problems that prevented post-treatment dose verifications from being performed from November 2006 to December 2007. The licensee continues to treat patients during this time period.

Area of Concern No. 3: The annual audits of the Radiation Safety Program conducted by the radiation safety officer for 2006 and 2007 were not finalized and provided to the Radiation Safety Committee for review and approval.

Area of Concern No. 4: The licensee lacked a safety culture for reporting radiation safety concerns associated with the Brachytherapy Program to appropriate individuals. For example, two medical physicists failed to express their concern to licensee management and the Radiation Safety Officer regarding the quality of the implants performed.

Area of Concern No. 5: The licensee did not complete the final dose assessments until October 2009, approximately one year after the last medical events were reported. The dose assessment lacked the rigor and formality required to demonstrate its commitment to

performance improvements.

There was no criteria established for assessing doses in a consistent manner, nor apparent leadership or senior management direction to establish milestones for completing the assessments.

MR. REYNOLDS: Thank you.

At this time, I will turn the meeting over to you Mr. Citron.

MR. CITRON: Thank you.

I would like to ask Dr. Anderson to be the first speaker for the VA.

Dr. Anderson?

DR. ANDERSON: Good morning.

Mr. Satorius and other NRC attendees, thank you for this opportunity to discuss the prostate brachytherapy medical event circumstances at the Philadelphia VA Medical Center.

In my opening remarks I would like to make several points that will be presented in greater detail by the other speakers.

As you know, prostate brachytherapy is an appropriate treatment for low-risk patients with prostate

cancer, and as a local booster patients with more advanced disease.

Although risk to healthy tissues in the body is minimal, side effects do occur.

Implant quality must be monitored closely at each case and facilities performing the seven space therapeutic procedure must be regularly reviewed both for regulatory compliance and best clinical practices.

In 2008, VHA performed prostate brachytherapy at 13 VA medical centers.

In some medical centers the procedures were carried out by VHA employees, in other centers the procedures were carried out by contractors.

Procedures at Philadelphia VA were performed by contract staff of the Hospital of the University of Pennsylvania.

Should be noted that University of Pennsylvania has one of the leading radiation oncology programs in the nation.

In June of 2008, Philadelphia reported a brachytherapy procedure in which the delivered dose

was less than the prescribed dose.

This report set in motion a series of VA investigations that ultimately discovered 97 treatments that were reported as possible medical events on the basis that the dose delivered to the prostate was lower than intended, or radiation to adjacent tissues was higher than intended.

We have apologized to our patients for this error.

The Philadelphia VA has notified patients by mail and by telephone and is covering all costs associated with additional tests, while continuing to monitor the care for patients whether the patients are seen at VHA or at private facilities.

A dose error that must be reported to NRC is called a medical event. The term, "medical event" does not necessarily mean a patient was injured, nor does it mean that the patient will have a poor treatment outcome.

The fact that patient injury may or may not have occurred does not mitigate our deepest regret that the episode exists and does not alter our sincere commitment to our patients.

Doctors Maity and Hagan will present outcome

data later that will show that relatively few patients required additional treatment and that the number of treatment failures was not very different than would be expected if there were no medical events.

The fact that there is such a wide discrepancy between the large number of recordable events and the small number of patients who required additional treatment has caused VHA to question our definition of a medical event.

I would note that the issue of how to define a medical event has been a source of ongoing debate among brachytherapy experts.

It would be useful if a nationally standardized definition could be arrived at.

An important consideration in choosing a definition is that the calculation of a medical event will have implications for how implants are performed in the future.

Dr. Hagan will speak to this issue in more detail during his testimony.

When the National Health Physics Program, which we abbreviate as NHPP, inspected Philadelphia VA in 2008, they

cited the medical center for failing to have adequate written procedures and for failing to report medical events for patient treatments from 2002 to 2008.

These medical events occurred due to inadequate seed distributions achieved by the physician authorized user. Of particular significance was the lack of adequate post-implant reviews, which resulted in the failure to identify and correct poor prostate seed distributions.

In addition, there was a lack of peer reviews that would've identified poor technique.

Peer reviews, as you know, are an examination of the treatment methodology made either during or after the course of treatment by a second practitioner.

Peer reviews are the standard of care in radiation oncology practice.

The failure to review prostate implants allowed inadequate patient procedures to continue for several years and to be performed on many patients.

NHPP agreed with the identification of root cause findings made by the Medical Center Review Team.

The more significant root causes included a lack

of peer reviews, a lack of oversight by the Radiation Safety Committee, and failure of subordinate staff to report treatment errors to the medical center safety officials.

A permanent implant prostate brachytherapy program at Philadelphia was suspended in June of 2008.

At this time, VHA does not anticipate that the program will restart in the near future.

If restart is considered, VHA will follow specific criteria for training, mentoring, inspections, dose verification, and peer reviews that we have developed with approval of the NRC.

In addition, the Undersecretary for Health must approve the plan to resume services.

I serve as Chair of the National Radiation Safety Committee. This committee is established under a charter and delegation of authority issued by the Undersecretary for Health who is the named license official.

The committee provides oversight for NHPP.

NHPP is assigned to implement the license on a day-to-day basis.

NHPP's task include reviewing permit amendment

requests, completing routine inspections, and responding to incidents or reports of radiation safety concerns.

The committee requires NHPP to follow NRC inspection methods to evaluate compliance by our VHA facilities during inspections and other interactions with those facilities.

Enforcing program safety standards is essential to ensure that patients receive the care they require.

VHA, as do other health systems, relies on a complementary system of accountability to identify quality programs both within the system and at individual levels.

VHA uses multiple internal and external survey and inspection processes; for example, the Joint Commission, American College of Radiation Oncology, the American College of Radiology, the Nuclear Regulatory Commission, and others, as well as individual peer review.

The deficiencies in the brachytherapy program at Philadelphia went undetected by many of these systems for almost six years. Only the recognition of the potential

problems by medical center staff and an NHPP inspection eventually led to the more in-depth investigations, reviews, and subsequent disclosure to patients.

In November 2008, VHA established national criteria for suspending a prostate program.

Programs are suspended if medical events are discovered for 20 percent or more of patient treatments reviewed or evaluated for regulatory compliance.

Moreover, VHA also requires NHPP to inspect any facility that reports a medical event to confirm regulatory compliance and implementation of standard procedures.

VHA will suspend any prostate brachytherapy program if the results of the inspection indicate significant program deficiencies and program suspension is deemed warranted by the National Radiation Safety Committee in consultation with the Director of the National Radiation Oncology Program and the principal deputy Undersecretary for Health.

In response to issues raised by NRC and to ensure other VHA facilities where performing permanent implant

prostate brachytherapy procedures correctly, NHPP inspected all VHA permanent implant prostate brachytherapy during the period from August 2008 through January 2009.

Seven facilities including Albany, Boston, Brooklyn, Minneapolis, Richmond, Virginia, San Francisco, and Seattle are currently active and offering brachytherapy treatments.

Two facilities that have used contract physicians, that would be Durham and Los Angeles, have stopped providing procedures within their facilities although we did not find treatments to be deficient at those centers.

We suspended four programs in 2008 as initial assessments of possible medical events were completed.

In addition to Philadelphia, the suspended programs are Cincinnati, Washington and Jackson, Mississippi.

Although the program at Cincinnati was suspended as an initial precautionary measure, further reviews indicate the facility was performing clinically adequate implants.

Cincinnati has recently completed the restart

requirements and has requested authorization from the Undersecretary to resume permanent implant prostate brachytherapy procedures.

Likewise, the three previously reported medical events for Washington were ultimately retracted.

That facility plans to undergo the restart procedure in the near future. A review of Jackson is ongoing.

Standard procedures for permanent implant prostate brachytherapy have now been established at all VHA programs.

The procedures were reviewed with VHA practitioners at a face-to-face conference in January of 2009.

System-wide implementation was confirmed in May of 2009.

These standard procedures include the following.

Initial and periodic training for physicians, medical physicists, dissymmetrists, and radiation safety officers and staff.

Training in the definition and criteria of medical events, how to identify a medical event, and reporting requirements for medical events.

Methods and procedures for verifying correct seed placement, and determining proper needle placement during prostate brachytherapy procedures; preparation and completion of written directives, and methods and procedures for pre-implant treatment planning, post-implant treatment planning, and post-treatment dose analysis.

VHA clinical standards and procedures are now among the most rigorous in the healthcare industry.

As a further action to prevent similar situations, VHA has asked the American College of Radiology to conduct site surveys at each facility, performing permanent implant prostate brachytherapy.

Our goal is 100% accreditation of our facilities.

I note that only 15% of practices in the private sector are accredited.

Furthermore, each VHA facility performing permanent implant prostate brachytherapy must develop, maintain, and implement written procedures based on the American College of Radiology's practice guideline for transparent permanent brachytherapy of

prostate cancer, and based on publications by American Association of Physicists in Medicine.

NHPP has initiated annual inspections for the seven facilities with current approval for permanent implant prostate brachytherapy. One-year inspections for Albany, Boston, San Francisco, Seattle and Richmond have been completed and the inspection results confirm the facilities have successfully implemented VHA standard procedures.

In addition, NHPP requires these facilities to complete periodic audits using a detailed checklist to evaluate their permanent implant prostate program.

Let me summarize some key points.

The role of VHA NHPP program is to assure compliance with NRC regulations. NHPP and VHA take that role very seriously. While it is true that VA was unaware of the implant problems for several years, once errors were uncovered, VHA acted swiftly and comprehensively to investigate and correct treatment practices.

During this time NHPP kept NRC informed of all of our actions.

NHPP has shown itself to be a responsible and

effective program.

The failure to detect treatment errors resulted from an undue reliance of contractors to perform their own peer reviews, which we understood were conducted as part of the Radiation Oncology Program at the University.

As a result of this failure, we have extended our standard procedures to all contractors who perform brachytherapy procedures in our hospitals.

The investigation and reporting errors was complicated by the lack of a national standardized definition of a medical event. The definition we chose resulted in reporting numerous events. Selection of a different definition, as other hospitals have done, would've resulted in reporting a smaller number of events.

Thank you once again for the opportunity to make an opening statement.

MR. CITRON: At this time I would like to proceed with my statement.

Good afternoon, Mr. Satorius and other attendees from the Nuclear Regulatory Commission. Thank you for the opportunity to testify today as we approach

closure on this very difficult situation. As I noted, I am accompanied by Dr. Joel Maslow, the Philadelphia Chief of Research and Chair of our Radiation Safety Committee, Dr. Amit Maity, the Philadelphia Chief of Radiation Therapy.

Dr. Maity is going to discuss the current status of Philadelphia's brachytherapy patients, including their follow-up care and prognosis.

Then, Dr. Hagan will outline his own findings and the recommendations of a blue ribbon panel concerning the definition of a medical event in brachytherapy.

Finally, Dr. Maslow will provide the Philadelphia VA's perspective on alleged violations and concerns in the NRC inspection report of November 17, 2009. We have other staff members with us from the Radiation Safety Program and who have worked closely with our veterans throughout this difficult period.

They will be available for questions and answers.

I am going to focus my remarks on the actions taken by our Philadelphia VA staff since we discovered possible dosing issues in May of 2008.

The first point I want to make is that the men and

women of the Philadelphia VA are dedicated to providing the highest level of quality health care to our veterans.

We treated more than 50000 veterans this year, including at our medical center, nursing home, and five community-based clinics in Pennsylvania and New Jersey.

We served a very diverse veteran population, including a new generation of combat veterans from Afghanistan and Iraq.

I am very proud of the work done at the Philadelphia VA, I am also deeply troubled and even angry anytime my fellow veterans may not receive the level of health care they deserve.

I am a Vietnam veteran myself and have almost 40 years of VA healthcare experience.

I can state from experience that the brachytherapy situation does not reflect the excellent health care offered by the VA.

However, this incident did indeed occur at the Philadelphia VA, and I want to again state that I apologize for any harm we may have caused any patient.

Our staff at the Philadelphia VA medical Center discovered the problem of possible under-dosing and incorrect dosage in May of 2008, and I did not hesitate to immediately suspended the program.

Our first priority was on our veterans, so we took proactive steps to notify all 114 who underwent brachytherapy in Philadelphia.

Whether we suspected dosing issues in their case or not, we called them on the phone, sent certified letters, established a toll-free number, issued a press release, and notified all area congressional offices and veterans service officers.

All follow-up care came at no cost to the veteran whether it was at the Philadelphia VA, another VA hospital, or a non-VA facility.

We also advised every veteran or his family of their right to file a tort claim or seek additional VA benefits.

Most importantly, our staff has worked diligently with each veteran to provide information about their treatment and to provide advice and care.

Notably, they have been steadfast in their

concerns for the patients in the program.

Again, our first priority is the well-being of our veterans and we have taken every step to do the right thing by them and their families.

Along with caring for our veterans, our other top priority was to find out what happened and to take the necessary steps to prevent it from happening again.

To that end, there have been multiple internal and external reviews, including an investigation still underway by the VA office of the Inspector General.

When our staff discovered and reported the situation, the NHPP conducted a reactive inspection on May 28th and 29th, 2008.

An external review team looked at every case in June 2008, NHPP along with the NRC visited the Philadelphia VA Medical Center in June 2008, the first of many visits over the ensuing 18 months.

On July 2, 2008, I convened an administrative board of investigation to provide another look at the facts and to provide me with recommendations, they concluded their work in September 2008.

The VA's National Director of Patient Safety conducted his own review.

Finally, there have been two congressional hearings at the Philadelphia brachytherapy program, including a field hearing held at our Medical Center on June 29 of this year.

We have national leaders with us here today, Dr. Anderson and Dr. Hagan, who will discuss how the lessons learned in Philadelphia have been implemented across the VA.

Both in terms of patient safety and concerning the definition of a medical event.

In the case of Philadelphia, we have strengthened the contracting process to ensure VA has quality assurance oversight of any treatments provided to our veterans.

The culture of safety at the Philadelphia VA has been strengthened and stressed as paramount.

Finally, people have been held accountable and there have been multiple administrative actions taken.

No one can change history or reverse what happened

from 2002 to 2008.

Clearly there were missed opportunities and I regret that it took so long to uncover the problems.

Also, we may have been the subject, we have been the subject of intense media interest some of it inflammatory and much of it using words such as botched, rogue, or flawed. This attention, whether warranted or not, has shaken the trust and confidence that many of our veterans have in their VA healthcare system.

However, I am proud of our staff's actions since we discovered this problem, and I pledge that we will continue to rebuild that trust.

Again, Dr. Maity will discuss brachytherapy and follow-up care for the 114 patients.

Dr. Maity received his medical degree from the Boston University School of Medicine and his PhD from the University of Pennsylvania.

Dr. Maity has an impressive background and has earned specialty certification from the American Board of Internal Medicine and American Board of Radiology.

He is an associate professor of radiation oncology at the University of Pennsylvania, and has been our Philadelphia VA Chief of Radiation Therapy for just over two years.

Dr. Maslow is going to address the specifics in the NRC report of November 17, 2009.

Dr. Maslow earned his PhD in Theoretical Nuclear Physics from the University of Virginia, his medical degree from Jefferson Medical College and a Masters in Business Administration from Drexel University.

He is our Associate Chief of Staff of Research and became Chair of the Philadelphia Radiation Safety Committee in August 2006, nearly five years into the brachytherapy program.

Dr. Maslow has also served as our acting Chief of Medicine for just over a year, and headed our review into the details surrounding the brachytherapy program.

I became the Director of the Philadelphia VA in August 2007, never expecting that we would soon discover such a terrible situation.

This is easily among the most difficult

situations I have faced.

However, I am proud of the work done on behalf of our veterans in a very complex Medical Center.

There were clearly missed opportunities along the way, but I stand by our efforts on behalf of our veterans over the past 19 months.

Again, I am sorry for any harm which may have been caused to any of our veterans.

Thank you again for this opportunity.

MR. MAITY: Good afternoon, thank you for the opportunity to discuss follow-up of patient care for those 114 veterans who underwent brachytherapy at the Philadelphia VA Medical Center.

Throughout my career I've trained or practiced in a range of institutions, including Mount Sinai Hospital in New York City, the hospital at the University of Pennsylvania, known as HUP, Fox Chase Cancer Center, John Hopkins Medical Center, Children's Hospital of Philadelphia, and the VA Medical Center in Philadelphia.

I consider it an honor and a privilege to care for veterans and I'm proud of the excellent work done

by the team in Philadelphia.

Prior to coming to the VA, I worked as an Attending Physician at HUP and at Children's Hospital of Philadelphia, mostly treating adults with brain tumors and children with cancer.

I became Chief of Radiation Oncology in November 2007.

After several months as acting Chief, and six months before our staff discovered possible dosing issues in May of 2008.

My priority since the summer of 2008, in regards to the patients who received brachytherapy, has been to make sure that they are being properly followed so that we can determine if they have had a recurrence of their prostate cancer or a complication from treatment.

For those patients who appear to have recurrence or complications, I have referred them to appropriate specialists, often outside the Philadelphia VA, to discuss further therapy for their prostate cancer or procedures to help their complications.

We have made every effort to either see patients

in follow-up ourselves, or to make sure that they are being followed by other health care providers.

Of the 114 patients, 69 are being followed on a regular basis in our department at the Philadelphia VA. The remaining patients who live more than 2 to 3 hours away are being followed at their home facilities.

We have contacted the referring health care providers for these patients to stress the importance of regular PSA surveillance and physical examinations.

We track these outside follow-ups via our electronic medical record system.

Finally, four patients have died, each from causes other than prostate cancer.

None of these four deaths was related to recurrence of prostate cancer or complication of therapy.

I would like to spend a few moments discussing particulars regarding our patients.

First, control of prostate cancer.

Prostate-Specific Antigen, or PSA, is a standard test for assessing control of prostate cancer.

Typically, the PSA falls after brachytherapy over a period of several years reaching a minimum value termed the Nader.

After the PSA has reached this Nader, we watch to see any evidence of a rising PSA with a possible relapse occurring when there is a rise in PSA to 2 nanograms per milliliter above the Nader value, this is known as the Phoenix Definition.

Many prostate cancer specialists will accept this as a sufficient indication to institute further therapy for presumed recurrent cancer, others may insist on a prostate biopsy before starting therapy.

Our definition of a relapse is a patient who met the Phoenix Definition and/or had a positive biopsy.

In addition to this, one patient was classified as having a relapse because he was placed on hormones by his Urologist for a rising PSA that did not meet the Phoenix definition.

Based on these criteria, we have had 11 relapses out of 114 patients, for 90.4% biochemical relapse free survival with a medium length of follow-up of 3.8 years in temporary prostate brachytherapy series

to long-term biochemical relapse; free survival rates for low risk prostate cancer ranging from the mid-80% to the mid- 90% range treatment for patients with low doses or rising PSA's.

During our brachytherapy review in the summer of 2008, we discussed management of cases with Dr. Kent Wallner at the Seattle VA.

For patients who have been treated approximately in the one year period prior to this time, the possibility of a second implant was discussed.

Of the patients who met the criteria, 17 patients had such discussions with Dr. Wallner and eight of them went to the Seattle VA to undergo a second implant.

For patients who have relapsed, multiple salvage treatment options are available.

Treatment options as relevant are discussed on an individual basis with each patient.

Rectal complications.

MR. REYNOLDS: Excuse me.

You talk about the 11 relapses and then the 17 patients that were considered for Dr. Wallner, are

those overlapped there or we have 11 and 17.

MR. MAITY: No, for those 17 patients had not relapsed.

Those 17 patients were identified as not having received the dose that we wanted to give them, and preemptively it was discussed to undergo a second implant.

MR. SATORIUS: And of those 17, 8 actually did receive a second.

MR. MAITY: Rectal complications.

Patients who undergo brachytherapy may experience rectal complications ranging from increased frequency of bowel movements, to rectal bleeding, rectal ulcers, or fistula formation.

The definition of adverse events is detailed and the common terminology criteria for adverse events, CTCAE Version 4.0.

Grade 2 toxicities can be managed with conservative therapy, whereas Grade 3 and 4 toxicities require more aggressive surgical or procedural interventions.

A recent review of contemporary brachytherapy

series Fan et al Cancer 2009.

The incidents of Grade 2 rectal toxicity range from 3.7 to 8 percent, and the rate of Grade 3 or 4 toxicity ranged from less than 1 percent to 8 percent.

Of the 114 patients reported here, six patients, or 5 percent, had Grade 2 rectal bleeding thought to be due to radiation proctitis.

None of these six patients has required blood transfusions.

For five of the six patients, the rectal bleeding was self-limited and has resolved.

The one exception is a patient taking both Plavix and Coumadin who continues to have intermittent rectal bleeding, which is being managed conservatively.

Three patients, 2.6percent, have developed a Grade 3 rectal toxicity. One of these three developed a rectal ulcer requiring surgery.

A second patient developed an anorectal stricture requiring dilitation, and a third developed chronic proctitis and bleeding that has responded to Hyperbaric

Oxygen therapy.

No patient developed a Grade 4 rectal toxicity.

Genitourinary, or GU, complications.

Brachytherapy can also lead to GU complications.

These range from lower urinary tract symptoms such as painful urination, known as Dysuria, urinary frequency, incomplete bladder emptying, to scarring of the urethra, radiation bladder damage, or incontinence.

As the NRC Medical Consultant, Dr. Goans, states in his report dated December 12th, 2008, the occurrence of urinary symptoms is "a fairly routine event after brachytherapy and is not thought to be specifically related to seed placement."

His most recent report dated October 12, 2009, Dr. Goans states, based on his review of 39 cases, that "most patients appear to be doing well clinically, most have symptoms of Dysuria and urinary frequency to be expected for this type of procedure."

Based on my review of all 114 patients, I agree with the statement.

However, three patients --

MR. REYNOLDS: Do you agree with the rest of his statements in the report?

MR. MAITY: Please be specific.

MR. REYNOLDS: All of his statements. I can pull them out and read them for you.

MR. MAITY: I'm not sure --

MR. REYNOLDS: Did you read his report? 2.6 percent developed a Grade 3 GU toxicity.

MR. MAITY: Yes, I did. I can't read your mind; you have to give me some specifics. Give me a specific comment that he made.

MR. REYNOLDS: I'll pull it out for you. You can go on, and I'll pull it out for you.

MR. MAITY: Three patients, 2.6%, developed a Grade 3 GU toxicity. Two of these patients had urethral strictures requiring intervention, and one patient developed radiation cystitis that has responded to Hyperbaric Oxygen therapy.

No patient developed a Grade 4 GU toxicity.

In the literature of the incidence of Grade 3 or 4 GU toxicity has been reported to be in the 3 to 4% range.

On the other hand, erectile dysfunction is a common problem following brachytherapy affecting 40 to 50% of patients in many reports.

Out of our 114 patients, 36, or 32 percent had erectile dysfunction prior to brachytherapy.

While an additional 30 patients have developed ED following their implants, or 38.5 percent of patients who did not have ED at baseline.

Patients meeting the NRC internal abnormal occurance criteria.

The NRC inspection report number 030-34325 2009 001 identified 17 patients who met the NRC's internal abnormal occurance criteria.

There have been no relapses in this group of patients. Out of these 17 patients, only one has developed a Grade 3 rectal or GU toxicity and has already been discussed.

As I stated in my introduction, I consider it an honor to work with the Philadelphia VA, and I believe our team has done the right thing for our veterans since discovering the problem 19 months ago.

While we have provided extensive data on

patients so the NRC could complete its review, we have also protected the patient's privacy and dignity by referring to them by such terms as patient XRT 045 or XRT 071. But these are our patients, they are not merely numbers.

Part of the Philadelphia team today is Pam Devine, sitting behind me, a registered nurse in Radiation Oncology.

Ms. Devine, or I, have personally followed every veteran who has undergone brachytherapy at Philadelphia explaining the process to them and their families and working to allay their fears.

We see many of these patients involved and we know them by name and face. Our focus has been to make sure they get the necessary follow-up that they need.

While this is an unfortunate situation and the dosing issues are very troubling, I believe that the clinical outcomes are promising in the vast majority of these 114 patients.

Where there have been complications, we have ensured each patient is informed of the range of treatment options and receives the best treatment for

his personal situation. Thank you very much.

MR. REYNOLDS: I of four statements.

This is on page 17 of his most recent report.

He says a number of deficiencies have been noted, so I would like your opinion on this one, lack of proper quality control and management of the brachytherapy program.

MR. MAITY: I think Mr. Citron has already addressed that.

MR. REYNOLDS: The consensus is that there was insufficient quality assurance. So, you agree?

MR. MAITY: Yes.

MR. REYNOLDS: Then a lack of policies to address post-implant management of patients and patient dose.

MR. MAITY: Could you repeat that?

MR. REYNOLDS: Lack of policies to address post-implant management of patients and patient dose.

MR. CITRON: That question is going to be addressed by Dr. Maslow, is one of the areas of a violation.

My preference, if you don't mind, is to come

back and wait until Dr. Maslow presents his.

MR. REYNOLDS: That will be fine. Dr. Maity was quoting certain sections of the report I just wanted to know what his view was on the entire report. I will ask two more, maybe Dr. Maslow will answer them at that time. Lack of program oversight and with inadequate reviews surrounding past trigger events; now or later?

MR. CITRON: I think in the past there was lack of oversight. We recognize that, I believe Dr. Anderson already spoke to that that was one of the root causes.

MR. REYNOLDS: I understand, I was try to get Dr. Maity's view on that. I appreciate you answering that that is fine. Then he says in his professional medical opinion is that the prior brachytherapy program did not remotely meet current medical standards.

MR. MAITY: I think that will be addressed by Dr. Hagan as well, but I think there were some glaring deficiencies in the program.

MR. REYNOLDS: Thank you.

MR. MAITY: Next, we would like to go to Dr. Hagan.

DR. HAGAN: Largely involving the regulatory evaluation of the implant at Philadelphia, or the application of criteria used for application of the regulatory evaluation of Philadelphia.

I joined the VA in January of 2009, this year, to find that the Philadelphia staff had been asked, they had been required to apply multiple sets of criteria, some with overlap, some with justifications, some with poor justification leading to confusing set of applications and reporting of medical events through the year.

From Dr. Maity's presentation, you should note that the 90 percent level for relapse free survival and urinary complication rates were consistent with the expected results from the best centers nationally.

As follow-up is extended into the first decade, however, these results may change.

For now, the results are absolutely consistent with our expectations of the clinical results of these procedures.

That is not to say the procedures performed at the Philadelphia VA Medical Center met our expectations for them. While the clinical evaluation of brachytherapy at Philadelphia shows excellent results thus far, the regulatory evaluation serves a very different purpose.

The regulatory assessment of the implant established criteria 10 CFR 35, throughout 2008 and to date.

Philadelphia has reported, as we've heard, 97 medical events from 114 patients there; 36, I believe, for dose to other organs and tissue and 61 for an erroneous dose to the prostate.

Turning attention to those reported erroneous dose to the prostate, the criterion that was added to the evaluation in Philadelphia to the Philadelphia staff after the investigation had begun, was the D-90 or the absorbed dose to a minimum of 90% of the target volume for which these patients plus the prostate.

Beginning in 2005, we have seen conflicting recommendations, multiple panels in the country, leading experts in Radiation Oncology, brachytherapy, and medical physicists have concluded that no

absorbed dose metric is appropriate for medical event criteria for volume implants of prostate.

Although I will touch on that briefly, I'm certainly willing to provide much more information in-depth then that charge.

On that background, in September of 2009, VHA convened a blue ribbon panel of national experts to provide guidance regarding criteria to be used for evaluation of volume implants of the prostate for regulatory compliance.

There is group slides here, somewhere, that I hope to be able to show.

The first slide --

MR. REYNOLDS: Doctor, is this what it looks like?

DR. HAGAN: Yes.

MR. REYNOLDS: We will get it figured out here in a second.

DR. HAGAN: This is the panel makeup Chaired by Dr. Michael Zelefsky from Memorial Sloan-Kettering, expert names of which many of us recognize from, not only the literature, but from their standing radiation oncology community.

They were asked to provide guidance regarding criteria to use evaluate volume implants.

After reviewing the 10 CFR 35 and their own experience with prostate brachytherapy, the panel members advised the VA to adopt a treatment total activity standard as the standard for evaluation of dose to the prostate. That is for the evaluation of the treatment site, an image-based verification of source localization after the implant should be used and not absorbed dose standard, such as D-90 or B-100.

D-90, B-100 recommended for clinical evaluations of these implants in the literature are dose estimates, not dose measures.

While important for clinical reporting, they are too imprecise, too subjective, the panel thought to be useful as dose measures.

In addition, the D-90 estimated at one point along a several week volume trajectory of the prostate following implant, poorly reflects the absorbed dose over the integrated totality of the time at which the prostate volume is changing.

Also, it may not reflect well the intentions of the provider.

For example, a desired purposefully undertreat the medium load that some providers may choose in their seed distribution, or to add additional treatment to the apex of the prostate, may be poorly reflected in a retrospective application of a standard that was not employed at the time the implant was conducted.

The panel's criteria, shown in the next three slides, starts with the treatment site accuracy pathway with a recommendation of considering a medical event when 20 percent of the source activity has not been placed in a designated treatment site. The panel went on to further define the treatment site for prostate implants allowing an expansion outside the prostate upon the attention of the practitioner to include additional volume outside the prostate.

But also, an expansion to include the area where the practitioner intends to place seeds.

We will see that in specific example of Philadelphia implant later. Designated treatment site is not limited to the prostate.

It is a definition of the area that the practitioner decides to place seeds in order to treat the prostate.

The next slide, a little more straightforward, it is just an application of the pertinent paragraph so that wrong isotope, wrong patient use of leaking seals is an application that is straight out of the regulatory language.

The next slide shows an area that is problematic. That is the application of the wrong site pathway according to the current regulation, which requires a report for dose to scan organ or tissue that exceeds 5.5 seabirds, dose to organ or tissue and 50 percent more than the dose expected and that is the difficulty.

What tissues constitute other organs and tissue for the prostate and what's the expected dose.

There are no published standards for these criteria.

There are no published cohorts of accepted prostate implants from which to develop these data.

So the panel believe that you could characterize

it a mutually exclusive way, the bladder, rectum, and all periprostatic tissue which would include all of the tissue surrounding the prostate and assign individual criteria for that, 1cc of the rectum, 1cc of the bladder, and 2 of periprostatic tissue.

Evaluating for dose by dose volume histogram, doses to those structures looking at the highest dose, the very high bar, the highest dose to those small volumes and comparing it to 150 percent of the highest expected dose, which the Philadelphia has supplied by use of the prescription dose.

The next slide shows the application of the standards. The first thing that has to happen to be able to apply the treatment site algorithm is identification of the prostate, which by itself is a difficult endeavor.

We use CT evaluations in identifying the process, and the CT evaluation is not easy.

Prostate contours has been identified here shown in cartoon in red with the seeds shown in green.

Then the expansion criteria to designate the treatment site based on the intent of the program, or in this case, the authorized user, to give the blue

volume all the way over on the right.

Then the total activity standard is applied by determining the seed count outside of that volume to the total seed count, and when it is 20 percent or more, then the implant has not been conducted in a way that was consistent with the intention of the authorized user.

In terms of dose to other organs and tissues, similar expansion occurs, but after that a dose volume histogram looks at these small volumes for periprostatic tissue, dose to bladder, or dose to the rectum.

And in this case, seeds that are inferior to the prostate, shown in its expanded form over on the right, delivers more than the prescription dose, in fact more than 150 percent of the prescription dose, to a very small volume of periprostatic tissue rendering this particular example a medical event secondary to other organ and tissue dose.

The next slide: What I will do is take you through a particular case from Philadelphia.

The seeds are shown, once again, in green and the prostate contours in red all the way in the upper

left-hand corner and on the next image, the prostate is rendered opaque.

So the only seeds you can see are seeds that were intended to be placed outside of the prostate.

This is typical of the Philadelphia plans. Many seeds were intended to be placed outside of the prostate in order to dose the prostate volume.

The expansion allowed applying the rubrics from the Blue Ribbon Panel is shown again in blue.

You can see there are actually seeds that are inferior, seeds to the left, in this case is inferior to that blue volume.

Using the maximum expansion allowed or recommended by our Blue Ribbon Panel, the Zelefsky panel, we can see that the practitioner here had intended to put seeds an additional 2 to 5 millimeters inferior to that expansion.

Down below, we look at the post-implant evaluation. This is CT that has been done after the implant has occurred; the same expansion on the CT contours has been accomplished.

You can see that there are six seeds that are

inferior lateral to the prostate, or to the designated treatment site, shown in blue. Here are three, but very closely the volume that was intended; the three are distant.

The three don't rise to 20 percent level so this is not a medical event from the total activity standard.

This implant was, however, reported as a medical event based on D-90 criteria.

The prescription dose was 160 gray, so 128 gray for a D-90 would qualify for a report, and this patient was reported. This implant was reported as a medical event.

I want to draw attention to the coverage shown in the lower right-hand corner.

The D-90 is 123 gray. Currently there is one Phase III randomized prostate brachytherapy implant trial being conducted by the oncology group, this is the Radiation Therapy Oncology group specifically sponsored by the ACR.

There are detailed quality assessments that go with that protocol.

That protocol for D-90 assigns the goal of treatment as a D-90 of 90 percent to the CT volume, which is what we are looking at here.

So, a thoroughly protocol compatible implant would involve a D-90 that goes from 115 gray to an upper limit that's substantially more, 189 gray.

That's the current definition and quality assessment of implants under this Phase III protocol.

This implant, had it been submitted for inclusion in the Archie Oji study, would've met all of the QA criteria. This very reasonably done, very adequate implant is reported still as a medical event.

If we look at the next slide, you will see here two cases which are also reported as medical events that by any lay person's eye, seeds are not placed anywhere near the prostate. I can expand that prostate to a very large volume and still not include those seeds.

There were, in fact, implants that were done very poorly at Philadelphia in Tier two these reported as D-90 failures. The next slide showed two implants also reported as D-90 failures.

Under the same rubric reported from the Philadelphia cohort of 114, these two implants also meet all of the QA criteria for the current Archie Oji protocol.

I only mention that because there are no other agreed-upon standards that we could apply.

These implants are actually very adequate from a clinical standpoint.

Next slide shows that application of this expanded volume to create a designated treatment site does not take the authorized user off the hook.

These poorly done implants continue to meet medical event criteria by this standard as well.

In fact, if we look at the 114 implants done out of Philadelphia, there is a clearly definable group by applying this standard that stand alone, and on the next slide you will see them.

MR. REYNOLDS: Doctor, could I ask real quickly; the numbers here I presume are reference numbers to specific cases that took place at VA Philly, is that right?

DR. HAGAN: We identified reference numbers associated with the case through the Philly staff, or by the Philly staff.

MR. REYNOLDS: So, the 114 are scattered through this like one is 27, one is number 28, one is

number 35.

DR. HAGAN: Right.

MR. REYNOLDS: Ok, thanks.

DR. HAGAN: If you look at this slide, this slide shows 19 cases, which with my review of using the CT contouring done by Philadelphia and using the expansions of -- recommended by the Zelefsky Panel, identify all of these as medical events.

Of these, 11 are medical events because of too many seeds outside the treatment volume, greater than 20 percent. There are another 8 that are medical events because of additional dose beyond 150% level, mostly periprostatic tissue, because you can see the miss here was almost always inferior, sometimes posterior, but almost always inferior.

Now, many of those overlap. Many of these cases, in fact every case but one that was a medical event are having too many seeds outside the prostate also delivered too much dose to periprostatic tissue. But independently, there are 19.

What I want to do now is quickly go through the other implants bringing us to the total of 114.

So you will have seen at least the sizable view of each one of these implants from Philadelphia.

I think as we go through those, starting with the next slide, you can see that these are very different.

If we look at seeds that are abutting the expansion volume, you will see that there are, in fact, seed trains occasionally that are outside clearly poorly placed, but the majority of seeds, in fact, the overwhelming majority of seeds, are in the designated treatment sites.

We go to the next slide. I will take you through each one of those, but you can see the same sort of thing.

There is a single slide that is up on 38. Anytime the seeds were inferior, I have also asked for the rectum to be shown so you could see whether the seed actually is within the rectal wall or not.

Case number 47, you can see that there are six seeds. Those six seeds abut the treatment site and there is no posterior expansion allowed, so are in the prostate, not in the rectum.

The next group, and the next, and the next.

Here on this one, 65 and 79 come close, not for

dose to periprostatic tissue, but for total number of seeds outside the prostate.

Both were greater than 15, but under 20 percent of seeds outside the prostate.

None of the others were close. Next.

And one last. The purpose for this characterization is not to mitigate implants at Philadelphia in any way, but to present a more balanced presentation of which implants not only failed regulatory application for compliance, but clinically failed as well.

An erroneous implant should be corrected, as was discussed earlier with the 17 patients who were given the opportunity to get a supplemental implant.

A technical explanation of the defects of the erroneous implants needs to be examined so that QA can be more effective in preventing a second occurrence of the same seed.

And these implants used as a tool for the quality improvement program within the facility.

What this analysis that I've shown you does do, however, is bring into alignment the clinical expectation for these patients and the regulatory

application of a reasonable set of criteria.

We have heard mentioned by several colleagues that the medical event definition was not clear.

The medical event is defined. It is defined in the current regulation. The question is the criteria used to apply that evaluation of that definition by the medical center.

The initial use of a clinical tool as a regulatory metric identified a number of implants as medical events which were clinically fully acceptable. Subjective nature of this assessment, which was well known at the time of this investigation, was reflected with a multiplicity of cases ruled in or out as another expert would come and do contours.

The original contours would identify one set of patients as not meeting D-90 criteria. Another expert would come in and contour, and an additional set would be identified. A third application of new contours from the use of a VA expert generated yet another set.

The use of CT scanning well beyond the period associated with post radiation atrophy for the evaluation resulted in medical events reported from grossly inaccurate

imaging.

To summarize, the application of guidelines that have been recommended by the Zelefsky Panel identifies 11 cases as wrong dose criteria and another eight as wrong site criteria. And I will be certainly willing to take questions on the application and the significance of the use of the Zelefsky Panel recommendations.

MR. REYNOLDS: I have a few questions.

I am also aware that AAPM just came out with their e recommendations on reporting methods. How does that mesh with your Blue Ribbon Panel?

DR. HAGAN: You're talking about the TG-137 that came out in November.

MR. REYNOLDS: Yes, sir.

DR. HAGAN: Which is a recommendation for clinical reporting, not regulatory reporting. In fact, that prompted a telephone call between myself and Dr. Nath who is the Chair of TG-137. Dr. Nath has authored a letter to verify that TG-137 was to apply only to clinical reporting, and that letter is now making its way through the AAPM internal regulatory apparatus.

It will come out of the government relations

committee.

MR. REYNOLDS: You said earlier on the clinical target volume, that area is designated by the physician. So the ones that you showed today --

DR. HAGAN: There is no clinical target volume. The clinical target volume was the gross target volume of the prostate. So, there was no additional expansion to include a clinical target volume.

MR. REYNOLDS: Okay, so what the physician had intended was just the prostate?

DR. HAGAN: That was the assumption made with this retrospective application of new contouring and new contouring assessments to implants that occurred in 2002.

There was no indication from the medical record that the practitioner had intended to treat a volume beyond the prostate. However, it was clear that in many and most, in fact almost all of the implants, the intention was to put seeds outside of the prostate in order to ensure that dose to the prostate. That was the common style, it is not the style in every program. There are many programs that limit

all seeds being placed internally within the prostate, not outside of the prostate. In Philadelphia, the intention was to place seeds both within and without the prostate.

MR. REYNOLDS: You just confused me because I thought you said there was no record of what the Doctor intended.

DR. HAGAN: No, no, there is a record of what the doctor intended. I did not mean to imply that there was no record. There was no evidence that the Doctor intended to treat a volume beyond the prostate volume.

MR. REYNOLDS: The records show he intended to treat just the prostate volume. In fact he did not do that. Is that correct?

DR. HAGAN: The second part of that is not correct. The first part of that -- and for many of his prostate implants he did treat the prostate volume very nicely. What he didn't do was intend to place all of his seeds within the prostate.

MR. REYNOLDS: He did not do what he intended by putting them all in the prostate.

DR. HAGAN: That's not true.

MR. REYNOLDS: I was trying to repeat back what you are telling me.

DR. HAGAN: But you're getting it wrong.

He intended to treat the prostate. He intended to dose the prostate to be the target of his treatment.

In order to ensure dose to the prostate, it was his intention to place seeds both inside the prostate and outside of the prostate, which was the reason for showing that case 32 there where you could see.

You get a feel for how many seeds he would intend to put outside the prostate. That is not unusual.

MR. ORTH: Can I ask a follow-up question? When you look at the treatment cases and the documented treatment, documented on that, it would indicate that there is a certain amount that is supposed to be or intended to be outside of the prostate when you look at your records.

DR. HAGAN: For every implant there is a pre-implant plan. I showed you one for case 32 just to show you so you could get a feel for how many

seeds he intended to put outside the prostate.

For each implant there is a preplan that shows the intention in terms of the placement of seeds. One of the difficulties is that preplanned its based on ultrasound imaging. Ultrasound imaging shows very nicely or much better than CT, the Tesla border of the prostate.

CT is notoriously inaccurate at showing that.

Yet, it is the CT volume that we have to rely on in order to do the evaluation of seeds in or seeds outside of the target volume.

It is, in fact, the inaccuracy that is associated with that contouring that has given panels in the past difficulty in concluding that you could apply an absorbed dose metric because the contouring from one practitioner to another is so different.

In fact, the current guidelines, the current ACR guidelines for conduct of these implants cautions against using D-90 to compared between observers specifically, for that reason. That contouring is so subjective that using a similar D-90 or other absorbed dose criteria between two practitioners is a difficult thing to accomplish.

In fact, RTOG that is currently conducting RTOG

protocol 232 had a precursor protocol just to demonstrate that you could get enough congruency and contours to be able to conduct a protocol. It's not easy.

MR. ZIMMERMAN: Dr. Hagan, can I follow-up on that question to make sure I understand what you said?

If I understood what you said, you're saying ultrasound will give you a better image. Is that the right word for the contour of the prostate? It gives you a better picture, a better representation for what the contour of the prostate is than CT?

DR. HAGAN: And if you could see the seeds on ultrasound, we would probably be using ultrasound instead of CT.

DR. MILLER: That was my follow-up question; why would ultrasound not be used in place of CT or why would you use CT from a clinical perspective?

DR. HAGAN: This specific question gets debated from time to time in the literature. And I can say that probably at bottom-line looked at one of the ABS meetings several years ago is that MRI is the

best imaging modality because it gives you the prostate volume very accurately, even zonal anatomy within the prostate, and you can see the seeds well enough to get a fairly accurate seed count off of MRI. But it is very expensive.

So, when we look at the ability of post-implant imaging to be able to demonstrate in a reasonable way the achievement of the clinical goal, CT accomplishes that.

It does not accomplish that as accurately as we would like and for doing something like trying to parse out a 20 percent absorbed dose metric, that CT subjectivity is paralyzing to that effort. A small change in the contours of the base of the prostate can make a 15 to 20 percent difference in the D-90, the apparent D-90.

So, to try to expect to get 20 percent accuracy based on CT imaging is very difficult. To be able to look at a large cohort of patients to evaluate a treatment program, CT is a very reasonable tool for looking at the clinical success of your program, and it is much more cost effective than doing MRI.

But each of us these days will use an MRI when the

CT image is on the borderline of indicating a medical event.

So, if we are doing a CT evaluation in a post-implant setting and it appears that the base is underpopulated, that is the part of the prostate that is closest to the bladder which is frequently an area that is problematic is underpopulated, before we conclude that it is in fact underpopulated, we will have an MRI to be the decision-maker there.

If we had an infinite amount of bucks to spend in the prostate evaluation, we would all be doing MRIs for these implants.

DR. MILLER: Following that logic, there is a certain amount of uncertainty on the part of the clinician in placement of the seeds as to what the actual boundary of the contour that they are trying to achieve is, and based upon the information you have available by which technique they use, they attempt to do their best to try to keep it within that contour, whatever it be. Although there is some uncertainty as to what the actual boundary of that is.

DR. HAGAN: Right.

DR. MILLER: Thank you.

MR. SATORIUS: I understand what you were saying that the plan may include placing some seeds outside of the prostate in addition to those in, but isn't it important that the outside placements be conducted with a level of precision to reduce the amount of unintended dose to other tissues; isn't that just as important that they are placed correctly?

DR. HAGAN: Oh, certainly. Every seed, it is important that every seed be placed as accurately as possible. Evaluating where that seed is placed in terms of inside or outside the prostate, how far it is away from the prostate is a much easier job than determining the absorbed dose that is occurring within the prostate volume at any particular date along the way.

So, the ACR currently will recommend that patients be evaluated either 4-6 weeks out after an implant so that most of the swelling of the implant has resolved, or at day zero, so perhaps most of the swelling has not occurred yet.

In between becomes an area that is fraught with

difficulty. Comparing one patient to the next becomes a very difficult undertaking which is the other reason.

Contour subjectivity and volume change of prostate are identified over and over again by those who say the application of absorbed dose metric for prostate just cannot be done with the precision to be able to deliver on a 20 percent requirement.

MR. REYNOLDS: This Blue Ribbon Panel came up with this new criteria and that's all well and good. Do you know what the criteria was used at VA Philadelphia from 2002 to 2008 for a medical event?

DR. HAGAN: I will let Dr. Maslow respond to that, but I know they had criteria in place, and I know the VA through the application of their internal review across the country imposed on them the use of the D-90 standard.

We required the use of the D-90 standard. But I will let Dr. Maslow describe what they were using prior to the imposition of the standard.

MR. REYNOLDS: One of the main reasons of the inspection reports is we struggle with getting consistent information from you on what's a medical

event and what's not, and now you come here again with a new criteria with a new panel.

I'm not sure, next week, are you going to come with another criteria and say no, we don't have 11 or 8, we only have 5? It's been troubling since last summer.

DR. HAGAN: I understand the trouble and I would like to remove perhaps the inflammatory part of that comment. Our goal in VHA was to have one set of criteria that we could use across the system.

So in September, we realized that the problem you're describing was occurring. And we were getting different sets of criteria dependent on the inspection that was undergoing and the inspector who was on site, and the interpretation of the staff of what they heard from the inspector. So the application of criteria was changing on a monthly basis.

It needed to bring clarity to this. And so our interest was to bring in those scholars who had a track record in brachytherapy that was undeniable, represented some of the leadership in radiation oncology in the country, and who had been involved in this process before, either

through association with HACKMEWE as panel members or perhaps ad hoc members in the past and could bring coherence to provide exactly -- so I have no interest in having a second panel and a second set of criteria.

These have been now raised to the Undersecretary level and we will apply these only if the Undersecretary signs that these are the VHA's criteria.

DR. MILLER: If I could follow-up on that to make sure I understand what you said.

In that respect, the criteria that the Blue Ribbon Panel came up with would be a forward-looking criteria if the Undersecretary endorses it, so that you have a consistent methodology across the VA.

DR. HAGAN: Right.

DR. MILLER: That said, if I understood what you presented in your slides, you were saying if that criteria had been utilized in the case of the medical events that got reported, it would be a much smaller number of medical events that would've been reported; is that a correct statement?

DR. HAGAN: I think is an accurate statement. Those that we can easily see were

clinically well done, but yet called -- that didn't meet D-90 criteria, one of these separate investigation would not have fallen out.

More to the point, I think people here in Philadelphia wanted to apply these criteria, that these were the Philadelphia criteria until D-90 was applied and they were required to use it.

When Philadelphia was required to develop one consistent set of criteria for other organs and tissues, they came up with very similar criteria the Blue Ribbon Panel used, not precisely the same a little different volumes that they chose, but Philadelphia's criteria, the medical center's criteria were very close to the Blue Ribbon Panel's criteria. I think you will hear Dr. Maslow speak to that.

MS. PELKE: If I could just ask a question, Dr. Hagan.

DR. HAGAN: Sure.

MS. PELKE: As I understand the methodology that you outlined from the Blue Ribbon Panel, it appears to me that this is activity based as opposed to dose based, is that correct?

DR. HAGAN: Correct.

MS. PELKE: And Philadelphia, when they were doing their implants, the written directive actually prescribed a dose, not an activity to the prostate; is that correct? It was not an activity necessarily to the prostate. The physician, the clinician was prescribing a dose of 160 Gray to the prostate consistently. That is how we understand the procedures were being conducted?

DR. HAGAN: The written directives, the prescriptions list both the dose but the written directive is listed as the number of the seeds to be placed.

MS. PELKE: And where was the verification on placement of the seeds to indicate that the dose would've been delivered as intended?

DR. HAGAN: Well, the quality control is the issue that has come up repeatedly. I will direct your attention to the definition of dose from the same regulatory language that exists today, that defines dose for these manual brachytherapy procedures as either total activity or dose with the

implications that that's absorbed dose.

That is the current definition. But I think the use of total activity fulfills the criteria of a dose specification.

MR. SATORIUS: As long as it is placed properly. You have to put it in the right place.

DR. HAGAN: Certainly the case, but within the criteria of the current regulation that more than 80 percent of the total activity is placed within the designated treatment site.

That then removes the regulatory evaluation from a clinical evaluation.

So, when you quickly move to, well, the dose has to be right. What is right for the dose? Is it right for the dose that D-90 is 90 percent of the prescription dose, or is the goal 90 percent of the CT estimate of the prostate, which is currently what is used by most practitioners.

There is a 10 percent difference in the evaluation of an absorbed dose criteria just based on that interpretation. And so the need to separate the clinician's decision on whether he will accept under population of an

area of the prostate as an intention of his coverage, and an increased coverage in other areas as his intention, is a clinical decision.

MR. SATORIUS: I appreciate that, I do.

I think that my issue is more going to be dealt with here in this last presentation, because my issue was you have to know where you are putting the seeds and you didn't know where you were putting the seeds a lot of times.

DR. HAGAN: I have no disagreement.

MR. CITRON: Our next speaker would be Dr. Joel Maslow.

DR. MASLOW: Thank you, Mr. Citron.

Good afternoon Mr. Satorius, NRC staff, visitors. I'm going to provide an overview of how possible dosing issues were discovered by our own Philadelphia VA staff in May 2008 followed by the staff's taken to mitigate the problem as well as corrective actions taken.

Please let me first say that this is a terrible situation which everybody at the Philadelphia VA takes very seriously. It will take time to rebuild the trust of our

veterans and their families. I want them to know that their health and well-being is our top priority.

Please let me first stress that the Philadelphia VA reported these cases as possible medical events, regardless of the probability that any one case represented a true medical event. Our intent was to be as inclusive as possible with a goal to retract cases at a later date to those deemed not true represent medical events.

The Philadelphia VA currently is in the process of retracting multiple cases originally reported as medical events.

The hospital's implemented a number of corrective actions to prevent future occurrences, and to address systems issues to improve patient care.

Many corrective actions were implemented in the fall of 2008 and are cited in both the March 30, 2009 and also the November 17, 2009 NRC special inspection reports. The corrective actions will be addressed in detail below.

However, it is to be noted that the hospital voluntarily and proactively suspended the Brachytherapy Program in June 2008, and it has not been restarted.

I will first address the eight alleged violations cited by the NRC and the response of the Philadelphia VA medical center to correct and address them.

I will subsequently address the areas of concern listed in the reports.

The NRC has detailed many of the corrective actions and changes implemented in the hospital in the reports that were just cited.

I wish to stress the fact that regardless of whether we concur or disagree with any alleged violations, we are very troubled by the events that have unfolded over the past year and a half, and consider that the problems that have been reported to represent a lapse in our commitment to patients to provide the very best clinical care.

The medical center has taken significant strides to ensure that such an event never occurs again, and that our patients' safety is our primary goal. The Philadelphia VA has continued to review all cases to ensure that dose irregularities of present are completely understood, and has comprehensively reviewed documents to provide an accurate

response to the alleged violations and its concerns.

My testimony includes all information from documents reviewed and/or discovered to date.

The first three alleged violations address a single issue that VA policies and procedures did not meet 10 CFR 35.41. We will discuss in detail four collective sets of documents.

First, the NRC special inspection report dated June 30, 2003, and the reactive inspection report of the NHPP dated November 8th, 2005. The PBA MCMs, the medical center memoranda 1117 and 0076, which is our Seal Source Policy. I'll also discuss the brachytherapy algorithm that was developed for the program, as well as the radiation oncology contract with the affiliate University.

In 2003, the NRC conducted a special inspection of the PBAMC Brachytherapy Program and issued its report dated June 30 of that year.

The inspection scope included, and I quote, "Inspection of the procedures developed in accordance with 10 CFR 35.41, and concluded that no violations of 10 CFR 35.41 requirements were identified." In particular, the inspection addressed whether, and I

quote again "an authorized user or the medical physicist" -- I'm sorry -- "an authorized user or the medical physicist will review the treatment plan to assure the final plans of treatment and related calculations are in accordance with the written directive."

The policies and procedures of the Philadelphia VA were again reviewed in 2005 by the NHPP under the offices of NRC Region III.

As before, no violations of 10 CFR 35.41 were identified. The policies and procedures of the PBAMC Brachytherapy Program have remained consistent over the period from 2002 through 2008 with only minimal changes.

It is important to note that both of the events that were cited that prompted investigations by the NRC and the NHPP were evaluated by an activity metric, and they were recorded and reported similarly. Thus, while the policies and procedures of the PBAMC concerning this brachytherapy program have some limitations will be detailed, the NRC and NHPP have determined that the medical center's policies and procedures were adequate.

In their assessment they previously concluded on two occasions that no violations of 10 CFR 35.41 exist.

The Philadelphia VA Seal Source Policy medical center memorandum 0076 and its precursor MCM 1117 that were in place at the time of the Brachytherapy Program states in section 3A subsection 1 of the 2005 revision, "That radiation oncology authorized users prepare written directives and treatment plans that ensure compliance with the written directive and provide the written directive to the radiation safety officer" as per section 3A subsection 3.

The Seal Source Policy further sites in section 3(b) subsection (h) the need to, and I quote, "Evaluate deviations from the written directive to determine the need for reporting to the NHPP, and that deviations of 10 percent are required to be reported."

The policy then states in section 4.8 subsection (14) that, and I quote again, "Radiation therapy shall use appropriate imaging modalities and list a few ultrasound CT fluoroscopy during implantation and proposed treatment source position verification."

In contrast to the alleged violations, the policy requires the brachytherapy implants follow necessary rules and regulations to adhere to the written directive and provides direction for post-implantation monitoring.

The policy, however, does have the following limitations.

It does not provide explicit citation of 10 CFR 35.40 as the basis for the adherence to the written directive violation.

There is no timeframe listed when post-implantation imaging should occur.

The definition of a medical event and its relation to the implantation are not explicitly mentioned, and mention of post-implantation dose calculation is not included.

The PBAMC prostate brachytherapy algorithm was authored by the lead physician for the program and codeveloped with the program's medical physicists.

The algorithm was conceived in 2001 and revised multiple times to include times in November 2005 and 2007, as well as other instances.

The algorithm provides a detailed operational

approach to prostate brachytherapy to include the requirement that pelvic CT scans be performed the day following the procedure, and verification of the number of seeds that have been implanted.

The policy is limited in that there is no specific requirement to compare dose delivered to the prostate with planned dose, but does require that the day when CT scan be evaluated for seed placement.

The policies requirement of a post-implant CT scan on the day following the procedure does comply with accepted standards, but it is not considered as optimal by many in radiation oncology.

A swelling of the prostate gland may, at this point, falsely lower absorbed dose measurements.

Finally, the radiation oncology contract between the Philadelphia VA and the affiliate University included specific reference to brachytherapy, and alleviated the need for and I quote, "verification of implantation in dose symmetry with calculation from actual implantation."

Thus, the policy requiring that implantation procedures include verification. The contract further states that, and I quote, "each nonresident physician will

abide by the bylaws, rules, and regulations of the PBMC."

The contract was revised during the 2003 event to require that dose deviations be reported to the radiation safety officer, and states that to assure patient and staff safety, medical physicists and radiation safety activities, be reviewed routinely with the RSO.

It later states, however, that while the government may evaluate the quality of professional administrative services provided, it retains no control over professional aspects of the services rendered, including by examples specific medical treatments. The latter clearly is a weakness of the contract that removes quality assurance oversight from the purview of the VA, but should not have been expected to adversely affect care if oversight by either party was being adequately performed. I think this addresses one of your comments from before.

Together, the three documents clearly delineate the need for post implant dose verification in compliance with 10 CFR 35.41. However, specific reference to 35.40 is lacking and there is no mention of a medical event.

In summary, the NRC and NHPP have already

concluded that the policies of the medical center are in compliance with 10 CFR 35.41. The Philadelphia VA also concludes that these policies and procedures are in compliance.

However, while the VA concludes that no regulatory violation exists relevant to its policies and procedures, this does not condone the fact that such policies were not followed. It also concedes that the policies could have been strengthened.

The VA failed in its responsibility to ensure that all brachytherapy cases met the best standard of care, for which even one core case would've been too many.

The medical center has concluded that there were three key points in time when the policies and contracts could have been amended and strengthened. First was when the documents were written. The second was at the time of revision of the Seal Source Policy and brachytherapy algorithm were at the renewal of the radiation oncology contract.

I did mention one change that went into the contract requiring 10 percent deviation reporting.

Finally, the third and perhaps most relevant time point which these policies and contracts could have been revised was following or in conjunction with the 2003 NRC special inspection or following the NHPP and NRC's 2005 reactive inspection of the Brachytherapy Program.

However, recommendations for significant revision of the policies are not deemed necessary at those points in time.

The Philadelphia VA has undertaken numerous corrective actions. It is noted from the November 17 NRC special inspection report and cited again in the 30th March 2009 report, the Philadelphia VA had already completed the following items.

Number one: Revising its procedures for the prostate brachytherapy treatments to ensure evaluation and verification that the administered dose was in accordance with the written directive. Two: Directions that require the radiation oncology staff to stop the procedure if there was any uncertainty associated with the treatment.

Three: Amending the PBAMC Seal Source Radiotherapy Policy to include A: The comparison and

evaluation of treatment plans and associated calculations with the written directive:

B: Direction to allow prostate brachytherapy treatments; to proceed only when the treatment planning computer is able to produce pre and post treatment plans.

And C: Immediately reporting all deviations that exceed 10 percent of the prescribed dose or dose fraction to the radiation safety officer and quality management staff.

As I noted, this requirement had already been implemented in 2003. Instituting a medical center peer review system for radiation oncology services and post treatment evaluations.

Five: Providing radiation safety training to radiation oncology staff, nuclear medicine staff, new employees, trainees, and contractors regarding NRC regulations for written directives and medical events.

Six: Revising the contract for radiation oncology services to realign these services under the RSO, the Radiation Safety Officer, the Radiation Safety Office.

Seven: Instituting an internal quality assurance program to ensure communications between radiation oncology team members regarding safety and treatment

concerns.

Eight: Suspending prostate brachytherapy treatments until all the corrective actions have been completed and that they are approved to restart by the NHPP.

Additionally, the medical center has revised the radiation oncology contract to include post-implant dose verification, specific requirements to follow not only regulatory and also local policy, and also quality assurance.

The Seal Source Policy continues to undergo review and revision to enhance its effectiveness as a working policy in that a policy that continues to accomplice new medical knowledge, changes in regulatory policy, and addresses clinical concerns as they come up.

The radiation oncology quality management program continues as a vibrant patient safety initiative.

The Philadelphia VA has taken steps to ensure that quality oversights in radiation oncology is our paramount consideration, and that no similar occurrences are experienced in the future.

We wish to repeat that while we do not consider

that the hospital is in violation of 10 CFR 35.41, there were inexcusable lapses in clinical care and quality oversight. Alleged Violation No. 4 deals with the training of supervised individuals regarding identification and reporting requirements for medical events under 10 CFR 35.27.

Regarding training and policies for the Philadelphia VA medical Center, the medical center has documentation of training in brachytherapy policy and procedure that immediately predates the start of the program. Moreover, the contract physicist codeveloped the brachytherapy algorithm as it has been stated previously.

Finally, the contract affiliate lead medical physicist who started in January 2008 and took over the Brachytherapy Program, confirmed that he was trained in procedures of Philadelphia VA by the former contract physicist demonstrating knowledge of local procedure by both individuals.

MR. REYNOLDS: Can you state that again, please?

DR. MASLOW: Let me just repeat what I said. Finally, the contract affiliate lead medical

physicist who started in January 2008, confirmed that he was trained in procedures of the Philadelphia VA by the former contractor physicist, demonstrating knowledge of local procedure by both individuals.

MR. REYNOLDS: Okay.

DR. MASLOW: Regarding the question of knowledge of NRC regulation, documents faxed to the NRC on March 17th, 2009 provide clear evidence that the medical physicists were knowledgeable as to the definition of a medical event and reporting requirements with evidence of acknowledgment.

Also, the contract physicist was the primary author for the affiliate training manual that includes the definition of a medical event.

The 15 day report for both the 2003 and 2005 possible medical events, notes that post-implantation dissymmetry in relation to medical event reporting for the case was reviewed with the medical physicists.

I have copies of these documents today. As part of the corrective actions, the Philadelphia VA has included all contract physicists and other contract personnel of facility mandated training regarding NRC

regulation and reporting requirements as it pertains to radiation oncology.

The Philadelphia VA has also initiated a schedule of regular training sessions of all radiation oncology staff and relevant regulatory and local policy.

Radiation oncology has reviewed and amended local policy and practice to incorporate chart review and peer review to address medical issues and safety concerns.

The definition of a medical event occurred at multiple radiation safety committee meetings and has been reviewed, and these committee meetings were through the end of 2008 and 2009, as being reviewed with all radiation oncology and is continuing education function.

The Radiation Oncology Department has included medical physicists as part of the departmental QA functions. As above, while the Philadelphia VA does not consider that a violation of 10 CFR 35.27 exists, it is apparent that the medical physicists did not report concerns or procedures.

Whether this was related to unwillingness to inform the VA of concerns because they were employed by the

affiliate university, whether they were unwilling to report events to superiors at the affiliate due to some unwritten code of conduct, or whether there was a lapse in knowledge is not known but is not relevant.

The fact that such lapses occurred raises significant concerns that while there have been significant information disseminated about a culture of safety at the VA, a culture of excellence was not in place in the Brachytherapy Program.

MR. REYNOLDS: Dr. Maslow, I am sorry. You made a statement about something not being relevant. And could you repeat what it was that you consider not being relevant. If you need to drop back into your testimony.

DR. MASLOW: The reason that any events may not have been reported. That events were not reported is the key issue. Other issues are speculative and I do not wish to speculate.

MR. REYNOLDS: You talked about safety culture being an issue and there was some reluctance for some of the medical physicists or whatever to report out of standard issues or issues that they did

not think were right.

DR. MASLOW: That I do not know why things were reported.

MR. REYNOLDS: Could you then explain to me what safety culture type issues you were talking about?

DR. MASLOW: I was reporting that there were cases that have been presented by Dr. Hagan that clearly did not -- that seemed inferior and those cases were not reported.

MR. REYNOLDS: Is that part of the relevant statement? You believe that to be relevant or not relevant?

DR. MASLOW: I'm sorry, I am missing the question.

MR. REYNOLDS: Let me try again.

I heard something about you did not consider it relevant. Is safety culture relevant to your operation?

DR. MASLOW: Of theoretical reasons why things may not have been reported. Upon why the theoretics are, to me, not the relevant issue.

The fact is that they weren't reported is the relevant issue, and trying to figure that out certainly is, looking behind, to me is not trying to correct the past but to ensure that in the future that we do not have these kinds of events, that regardless of why things are, we can make up reasons today for things that occurred years passed.

The issue is to bring them all on board, to make sure that the does not occur great.

MR. REYNOLDS: I would disagree with you there.

I'll ask the question another way that will be simpler.

What I'm trying to say is, is it important to VA Philadelphia that your employees feel free and comfortable in coming forward with these issues?

DR. MASLOW: Absolutely.

MR. REYNOLDS: Thank you.

DR. MASLOW: That was a point that I was trying to make.

MR. REYNOLDS: I would like to follow this up too; isn't it important to know why these weren't

reported in order to correct going forward in the future, that problem so it will be reported in the future?

DR. MASLOW: It is. That's not -- the overarching issue is that there may be multiple reasons and one can go back and try to parse those out at a date well into the future.

MR. REYNOLDS: If you don't do that, you don't know why they happen so you can't preclude them in the future.

DR. MASLOW: Thank you very much, and we have been doing that for a year and a half. But the issue is to bring everybody into the fold and basically make sure that reporting is a free and open process that not only is not punished, but is rewarded is the function.

MR. REYNOLDS: You've drilled down far enough to satisfy yourself. You understand the reasons why there were weaknesses in the safety culture such that you can take actions that will not preclude recurrence?

DR. MASLOW: Well, we have taken actions

that I think will preclude recurrence.

MR. REYNOLDS: We will be interested in finding out what some of those are.

MR. CITRON: We have taken a number of steps to try to improve the culture of safety.

To begin with we have a new Chief of radiation oncology who is not only technically very sound and well respected by the entire staff, but he is very approachable.

He is on site every day. We have a radiation safety officer that goes through the department everyday and is very approachable by all the staff.

We instruct the staff much better than we ever have before on coming forward if they have any concerns or issues. I know in talking to Dr. Maity recently, he indicated to me that there was a recent example of somebody being a little uncomfortable and let me ask Dr. Maity to speak to that.

MR. MAITY: I just want to talk about this whole issue of culture safety. It is one that I personally take very seriously. I have on numerous occasions by my actions and words try to convey to

the staff that work under me, that any issue that is of patient concern, needs to be brought to my attention and that I will act upon it.

Recently there was an issue where we were about to deploy new technology, one person in the department expressed some concern. And I said, stop it until you've actually satisfied yourself and satisfied everyone else that this is safe. So we delayed deployment by a week.

I personally am very committed to this.

I hired our chief technologist who is extremely compulsive and takes quality assurance as seriously as I do. I have made every effort to make sure that our staff understand this. In addition to this, if I am not available or if the staff for some reason want to go to someone else, we have someone from radiation safety who comes down almost every day.

So, this person is known to the staff. If there were ever a reason for the staff to go to them it would be very easy, they don't even have to walk out of the department. They just have to wait for this person to come and say I'm not comfortable with something.

My immediate superior, Dr Gyner (phn) who is

the ACOS for clinical support services, we are on very good terms with him. He is actually very interested in the running of the department.

He comes down on a regular basis, at least once a week, just to talk to people and I'm not necessarily around when he comes. He has been identified as somebody who is interested in the welfare of the patients and in how our department is running, and people know that he is someone very approachable. They can go up to him and say this isn't right. And in fact we have been having discussions in terms of instituting new technologies.

We have weekly meetings where we actually try to work out how to institute these in the most efficient manner and he is very much involved, and people work under him.

So there are many layers. We have two safety officers at the VA who are identified as people who that's their job is to make sure that patient safety is of paramount concern.

We have a list of people who can be contacted posted in our conference room where we have lunch.

It is very visible and it is very clear. They certainly should come to me and I would expect that

they would, but if I'm not around there are many people that they can go to. And I try to reinforce it over and over and I know that Mary Moore and her staff have had personal conversations with all of our staff to try to make sure that they understand that patient safety is very important and they should not be doing things if they have any concerns about them or they should be notifying somebody higher up. I'm very confident that we have improved the culture of safety in our department.

MR. REYNOLDS: Thank you for that.

DR. MASLOW: Also, the staff knows that they come to me as the Chair of Radiation Safety.

If something needs to be immediately brought to the attention of Mr. Citron, that door is open.

If I need to get access to he or any of the top management, those paths are open and immediate if there are concerns.

We have if need be, we will institute stop work immediately if there are concerns. So that is very apparent. The past is problematic, we agree. The future will not be.

MR. REYNOLDS: I trust that you understand why I think Mr. Heck and I were probing that because you got to look into the past and know what the problems are so they don't happen again.

DR. MASLOW: Right. But -- well, I'll go on. Alleged violation No. 5 --

MR. REYNOLDS: Let me stop before you go to the next one. So if I understand you correctly to violation No 4, 35.27(a)(1), you're telling us that the VA did train the medical physicists?

DR. MASLOW: What I'm saying is that they were trained in policy. They had knowledge of NRC regulation, yes.

MR. REYNOLDS: They were trained by the VA?

DR. MASLOW: Trained by the VA in --

MR. REYNOLDS: In identification and reporting requirements of medical events like the violations cited?

DR. MASLOW: The medical physicists received significant training during the events of 2003, 2005 in what was NRC regulation reporting requirements, medical events determination.

MR. REYNOLDS: I don't think you provided that information to us when we asked repeatedly for the last year and a half.

In fact, it's contrary to what we've heard from your staff and from the individuals themselves.

It concerns me that somebody doesn't have their story quite right.

DR. MASLOW: If you look at the correspondence that, I believe was forwarded in March, the contract physician -- the contract physicist, I'm sorry, were very intimately involved in medical event determination in 2003 and 2005.

I guess it was 2005 is what you have. And if you look at the reports of the medical center, the physicists were a part of the medical event determination and discussions were held. So, yes.

MR. REYNOLDS: So, the VA's position is that the medical physicist did know what a medical event is and they should've known to report that?

DR. MASLOW: Our contention is that they should've know, yes. They didn't.

MR. REYNOLDS: Okay. Let's go back to the

first violation. I wasn't clear if your assessment, whether your procedures provided -- a high level of confidence was based on inspection reports or on your own assessment?

DR. MASLOW: I'm sorry, could you provide a little bit more detail?

MR. REYNOLDS: I'm having a little bit of trouble following you when you said that you didn't think that was a violation and you cited the NRC's Inspection Report 2003 and NHPP's Inspection Report 2005. I wasn't sure if that was your two reasons for saying it was not a violation, or you did look at it yourself and say your procedure is adequate, because besides those two inspection reports, we have the inspection report that NHPP just recently issued and I believe you responded back and you didn't disagree at that time.

Then we have two inspection reports out today that says those violations, I was trying to figure out what you relied on to say your procedures were adequate.

DR. MASLOW: I reviewed the various documents that exist at the medical center. Those

included the two MCMs, the Seal Source Policy, the various iterations of the Seal Source Policy, reviewed the brachytherapy algorithm, and also reviewed the contract.

So, as a group, each one has indication to check dose. Whether policy was followed, is another issue.

MR. REYNOLDS: You say your policies are adequate?

DR. MASLOW: What I said was the policies were in compliance. The policies certainly could be improved. I actually listed the areas of improvements and where I thought that they were deficient.

MR. REYNOLDS: So, procedures weren't implemented correctly, then that resulted in these medical events? You had inadequate procedures or procedures weren't followed. It's one or the other, or you didn't have procedures at all.

DR. MASLOW: Procedures weren't followed.

MR. REYNOLDS: Okay, so the doctors, the medical physicists, and the staff involved did not follow procedures, or did not follow them well enough

to prevent medical events?

DR. MASLOW: Things were not reported up to the Radiation Safety Office as potential problems.

MR. REYNOLDS: I understand that very well.

DR. MASLOW: And so by definition the policies were not followed as they should have been.

MR. ORTH: I think I might've heard you say, and you can correct me if I'm wrong, that some deficiencies you did identify something as significant as medical event criteria and a time frame for performing those verifications which, to me, seem like pretty significant aspects of what we are talking about.

DR. MASLOW: Am I supposed to comment on that?

MR. ORTH: If I am mistaken that those are some of those deficiencies that you had identified.

DR. MASLOW: I went and looked at each of the policies, basically drilling down to be the most prescriptive. Those are the areas where I feel the policies certainly could be strengthened.

MR. ORTH: Did the policies, though,

contain the criteria for declaring a medical event? I am just trying to reaffirm because I thought that's what I heard you indicate earlier.

DR. MASLOW: The policies didn't list the words "medical event" by name.

MS. PELKE: Mr. Citron, I have one clarification: Did the policies indicate that dose discrepancies beyond the ten percent should be evaluated?

MR. MASLOW: I'm not sure. The policies indicated that the dose discrepancies beyond ten percent should be recorded to the RSL.

MS. PELKE: They did say that?

MR. MASLOW: Yes. Alleged violation No. 5 deals with instructing a non-supervised individual that may lead to a violation under 10 CFR 19.12.

The Philadelphia VA notes that the alleged individual has received training at the Philadelphia VA in 2002 and 2006 as part of the hospital's mandatory review that requires employees to be cognizant of the NRC rules and regulations relevant to their position requirement. And additionally important, both of these annual trainings include

training that addresses worker radiation exposures.

These documents were provided to the NRC by fax on 17 March, 2009.

Additionally, the NRC requirements for reporting are posted prominently in the radiation Oncology Department.

The non-supervised individual involved in the decisionmaking of whether the 2003, the 2005 events, reported to the NRC constituted medical events and provided the criteria to the radiation safety officer to enable medical events reporting.

As part of the documents faxed to the NRC on March 17, there was clear documentation that the physician was knowledgeable about the definition of the medical event and its reporting requirement. And finally, documents provided to the RSL in response to inquiries regarding prior training and knowledge, indicates that the non-supervised individual had received formal regulatory training with regard to brachytherapy.

I'm not sure if this last one has been forwarded as of yet to the NRC.

I have copies of these documents today.

MR. SATORIOUS: So you trained him and he didn't follow your expectations or your procedures; is that what you're saying?

MR. MASLOW: I said that a couple of times, yes.

MR. SATORIOUS: I just want to be sure.

MR. MASLOW: Therefore the Philadelphia VA does not concur with the alleged violation. The Philadelphia VA continues to assure that all authorized users are fully trained for reporting requirements for medical events as noted by the NRC on pages 3 and 15 of the special report dated March 30, and again cited in the November 17 report; the Radiation Safety Office has conducted training sessions with the staff and radiation oncology to review the definitions of a medical event and the reporting requirements thereof.

As part of these training sessions, and in training sessions going forward, there will be greater attention to ensure the working knowledge of reporting requirements.

As we have stated, regardless of whether we

consider the regulatory violation has occurred, it is apparent that the physicians and the physicists associated with the program had a duty to ensure that all cases met the best standard of care in the medical center, had a duty to ensure that all such standards were reached. We failed in that duty. We have ensured that no similar event will occur again as we've not only provided greater oversight but more importantly, reaffirmed with all personnel, the need to report any concerns and have included all radiation oncology staff and QA functions to own the process.

While radiation therapy is by definition a team effort, team building has become a clear priority to ensure that all members are clearly communicated to ensure that patient safety is paramount.

Alleged Violation No.6 deals with the recording of total dose on written directive under 10, CFR 35.40; Philadelphia VA acknowledges this violation as a one time event, as confirmed by comprehensive review of all of the cases at the medical center. The event was acknowledged by the provider as an

oversight and corrective action has been taken that the provider in question received training and proper procedure and no further occurrences have been documented.

Alleged Violation No. 7 deals with completeness and accuracy of VA information provided to the NRC under 10 CFR 35.3045 part(d).

The Philadelphia VA does not concur with this alleged violation and contends that it had provided both timely and accurate information as available in the 15 day reports.

The NRC has published in the Federal Register, Volume 67, number 79 on April 24, 2002, statements and consideration on reporting medical event under 10 CFR 35.3045 as quoted, we reworded these paragraphs to read the effects on the individual and what actions if any have been taken or planned to prevent recurrence. The words if any were planned were added because there might not be any effect or any actions taken at the time the event is reported. End quote.

Philadelphia VA does not concur with this violation. As communicated to the NRC as early as

their first reactive inspection in June, 2008, the Philadelphia VA commenced the comprehensive evaluation with the brachytherapy program.

This response entailed a thorough review of all patients to include clinical status and prostate brachytherapy studies, internal reviews and external reviews of the program. The requisite portions of the QA reports are addressed below.

The information was critical to this determination of why the event occurred.

That fact-finding was ongoing. It was dutifully communicated to the NRC in relevant 15 day reports and also communicated during visits and other communications.

Recording casualty prior to the completion of these reviews would be considered as improper and any reported information would therefore be speculative rather than based on fact.

This could potentially represent a violation for reporting false information. Information was reported when known.

The effect to individuals was also an ongoing

process that required individual assessment of each patient and critical evaluation of studies and reports.

Clinical information on individual patients known at the time of each 15 day report was communicated to the NRC as required.

The immediate and most definitive action to prevent recurrence was closure of the program until a thorough evaluation had been completed and processes and procedures revised as needed.

The final alleged violation, deals with delay and reporting medical event on under 10 CFR 35.3045(d).

There was no detail in the report as to the nature of this alleged violation or its basis. The Philadelphia VA does not agree that medical events were reported in delayed manner. All medical events were reported within 24 hours of discovery as required by the statute nor was discovery delayed. Therefore the medical center does not agree that a violation had occurred.

MR. REYNOLDS: So you're saying when you had the

cartoon as Dr. Hagan referred to back 2002, 2003, 4, 5 and you saw there was a prostate and here are the seeds. And you trained all those people, that you recorded at that point in time because that's when it was reported that it was a medical event?

MR. MASLOW: The reporting and discovery by the medical center was made in 2008.

MR. REYNOLDS: That's my understanding, yes.

MR. MASLOW: Right. So those were reported as they were discovered in realtime.

MR. REYNOLDS: Well, realtime would have been back when you -- that would have been ideal. You had the information right then and there to know that it was medical events and you didn't report it.

MR. MASLOW: There were no concerns raised to the center and with that when it was discovered by the RSO and those events were looked at, they were reported.

MR. REYNOLDS: So nobody from the medical center looked at those medical records as this time just your contractors? Is that what you're telling me?

Mr. Citron: As soon as we knew there was a

medical event, we reported it and we learned of the medical event in 2008.

Did we know that there was a medical event back in 2002, 3, 5 and so forth? We did not.

MR. REYNOLDS: Well, our contention is that the information was there and your staff including contractors had knowledge of it and in fact, I think in your administrative order of investigation report, you say that Dr. Wedington was aware of these treatments and failed to report them at that time.

I would say you knew it back then and you didn't report it, that is a violation.

I understand that once you identified them in 2008, you eventually reported them but you had the information back during the treatment to report them.

MR. ZIMMERMAN: I'm kind of curious on the scorecard that you went over.

Where did you consider to be a valid NRC violations.

MR. MASLOW: The one that we had concurred with is the violation -- the numbering is a little different depending on where you read it but it's the

one listed 10 CFR 35.3540. I don't know if that is six or five under your numbering system.

MR. SATORIOUS: Five is -- based on our slide.

MS. PELKE: Violation No. 7.

DR. MASLOW: Violation No. 7 on our slide which correspondence do not having total on a written directive.

MR. CITRON: I think it would be good if Dr. Maslow could continue and address some of the other concerns and alleged violations.

MR. MASLOW: Beyond the alleged violations, the NRC cited five areas of concern.

The first two concerns address the lack of interface between radiology and the variance planning computers in radiation oncology. Philadelphia VA self discovered and self reported the fact that during the time period from November 2006 through November, 2007 that connectivity between the CT scanner and radiology and the planning computer had been disrupted.

This interruption appeared to affect a total of 18 scans for 18 patients. However, one scan that was

performed in February 2007 was retrieved and post planned dissymmetry completed in March 2007.

The statement that post treatment plans were not performed for patients with brachytherapy procedures was completed during this time interval is an untrue statement. As noted, one patient's post plan was completed in March, 2007.

An additional nine patients had post planning performed between 11 -- on November 19, 2007 and November, 30, 2007.

And one patient's scan was retrieved in June, 2008 after significant effort.

For the remaining 7 patients, multiple attempts to retrieve CT scans were made, however, digital archives could not be converted into a dye com format and were therefore not accessible for calculation.

The interruption and connectivity was the subject of a VA sponsored review and a hospital internal investigation with root cause found to be several factors. First, after the computer was temporarily disconnected from the VA computer system to test a second planning computer, reconnection was

disallowed due to security concerns raised by a stand alone computer having access to the VA network.

Resolution was complicated by the fact that the VA had just revised its security guidelines and that information technology no longer reported to the medical center leadership but through a separate product line within the VA.

Further complicating this problem is the fact that IT realignment resulted in no VA department having oversight for the variance planning computer although biomedical engineering committee did assume oversight but unfamiliar with the computer.

Also, active work in the planning system radiation oncology was confused with work on the variance planning computer and adding to the confusion was the knowledge that dissymmetry had been completed on a scan performed in February 2007 suggesting that the problem had been resolved.

And finally, audit reports which I believe speaks to one of the points that you were making previously, provided to the radiation safety committee provided important information with the

treatment listed as being completed as planned.

That this was not included as an action item in the minutes of the Radiation Safety Committee. It's true, however, it belies the fact that significant effort was in process to address the connectivity issue, an effort that involved significant involvement by the radiation safety officer.

A coordinated approach to IT and biomedical interface problems was now in place and in radiation oncology to prevent problems in the external program.

Audit reports reflect better actual dosing information.

The VA should have done better to ensure back-up systems were in place should ordinary systems fail.

To ensure that similar events do not occur in the future, the medical center has assured that clinical care trumps all matters and that care must be provided in the environment to ensure maximal safety.

The third area of concern states that annual audits of the Radiation Safety Program for 2006 and

2007 were not finalized and provided to the Radiation Safety Committee for review.

Both reports were disseminated to the Radiation Safety Committee in October, 2008. While there are two reports related to distribution, the reports had been completed even at the time of the first inspection.

And the findings of the audits and the necessary corrective action instituted in the timely manner as documented in the minutes of the Radiation Safety Committee.

The Radiation Safety Office is scheduled to complete future reports in a more timely manner such that similar delays in distribution does not occur.

MR. ZIMMERMAN: So you agree that getting 2006 audit in 2008 is unacceptable?

MR. MASLOW: We do.

MR. ZIMMERMAN: Thank you.

We did address the concerns in a very timely manner. They were not formerly disseminated to the committee though.

The fourth area of concern deals with a

perceived lack of safety culture for reporting radiation concerns.

Philadelphia VA shares the NRC's concern of allegations and implications that were stated in the report.

The fact that patients may have had poor implants and that any patient was under dosed as part of the prostate cancer treatment program is not excusable and indicates that no matter what level of cooperation existed between physicians, physicists and the Radiation Safety Office, that the systems in place were not sufficient to provide adequate safety net to patients.

The VA has made numerous changes to ensure that this does not occur again since the care of our patients is absolutely paramount.

The fact that the NRC and others have stated that during interviews conducted in 2008, that the medical physicists voice reservations about clinical care is also of great concern. However, this is in contrast to the correspondence between the medical physicists and physicians involved in the

brachytherapy program following the 2003 incident that appears to indicate that open lines of communication regarding safety issues existed and that decision making was the result of input from all parties.

Importantly, the primary concerns in these communications that were raised was that patient safety was paramount which appears to belie both the allegation that safety culture did not exist, and that the medical physicists were not able to voice concern. As stated before, additionally during the investigation of 2003 and 2005 events, all involved staff were extensively interviewed and no concerns were voiced. Therefore, although concerns were raised by staff from May 2008 and onward, no concerns were brought forward to senior staff at the VA or the affiliate university. And no concerns were raised during in-depth discussions by NRC and NHPP in 2003 and 2005. And yet, while clear lines of communication appear to have existed between physician physicists and the Radiation Safety Program and the fact that the medical center in

particular and the VA in general has stressed a safety culture for all aspects of care for over two decades, the reality for the brachytherapy program would appear to be different.

That reality is now in place. The medical center has gone to great lengths to ensure meaningful interaction in all areas of oncology. Dr. Maity has worked extensively with staff to empower all concerns, no matter how minimal and without regard to rank or position so that there is honest discourse and discussion to resolve problems before they develop and to foster and enhance the team approach to patient treatments within radiation oncology.

The final area of concern --

MR. ZIMMERMAN: So let me make sure I understand. So what you're saying there is you agree with the area of concern but the problem has been resolved?

MR. MASLOW: Yes. The problem as you know is always an ongoing process.

MR. ZIMMERMAN: Sure. Thank you.

Dr. MASLOW: The final area of concern deals with

the rigor and formality of our dose assessments which were completed in October of 2009. In response, I stress again that we have had two areas of focus during the various reviews and investigations.

First, was to ensure the highest level of follow-up clinical care for a veteran patient. And second, to ensure that the dosing information was absolutely correct in order to better delineate appropriate clinical and regulatory decision making. Regarding the first, you have heard from Dr. Maity that we are confident that we are doing the right thing for our veterans. And second, Philadelphia VA continues to work through numerous internal and external reviews of the Brachytherapy Program.

Nobody wants closure on these issues more than the staff at Philadelphia. However, it was important to get these measurements done correctly. The medical center leadership dedicated significant resources to complete this review.

We hired a contract physicist who worked overtime to perform additional dose assessments. Our own staff worked nights and weekends to get these

assessments correct.

I personally was taking calls from vacation in Boston. We hosted teams from NHPP and NRC on multiple occasions, accordingly, we were deliberative in our reviews and are confident in our assessment as our primary concern was for accuracy and patient safety rather than speed. And the fact remains the program remains closed without plans to reopen.

In summary, the Philadelphia VA immediately stopped the Brachytherapy Program and initiated a comprehensive and thorough investigation once our own staff discovered the problem.

The medical center has shared all findings and possible shortcomings in a open manner with regulatory agencies, investigative bodies, the public and our patients.

The Philadelphia VA rather than restricting its evaluation of brachytherapy to the 10 or 20 cases as requested by the NHPP for a retrospective review in May and early June of 2008, we quickly opened the investigation to include the entire program to its inception.

In 2002, based on a few irregularities that I had discovered and regardless of the political and public relations impact, the Philadelphia over reported rather than under reported possible medical events, reporting cases regardless of the probability that these represented true problems from a regulatory perspective.

We were the first to point out cases that we considered deficient to all those that came to visit Philadelphia and we were very self critical during the various investigations.

This was done to ensure that all deficiencies were known to enable both complete disclosure but more importantly to be able to address any area of concern so that no similar events would occur in the future.

It is to be noted that the retraction process for some declared medical events has only just begun. It is important going back to Dr. Hagan's comments in 2003, 2005 events that occurred in Philadelphia were both reported on the basis of an activity metric and they were both evaluated by NHPP and NRC under an

activity metric.

However, as this investigation unfolded, we were instructed by NHPP to alter that and to utilize a D-90 metric. However, documentation by NHPP, the formal documentation to require using a D-90 metric for evaluation of medical events was not made public until January of 2009, months after the closure of our program.

The VHA Blue Ribbon panel has developed criteria for a medical event in line with their 2005 ACMUI, Advisory Committee on the medical use of isotopes recommendations that were provided under a activity metric that would be consistent with the community at-large. It is noted that those recommendations that the Blue Ribbon Panel are very consistent with the documents we forwarded in August of 2009 delineating all the summary of all our medical events. I'm not sure that that document made it through to the NRC since NHPP was still using a D-90 metric.

Importantly, both the activity metric and reasons for using an activity metric were delineated

in detail. And also, the doses to the non-prostatic organs were detailed and again, comply very closely with what the Blue Ribbon Panel subsequently evolved.

Moreover, Philadelphia VA used reporting criteria for medical events that we used was actually more stringent than the Blue Ribbon Panel. Yet, regardless of whether 20 or 97 medical events were determined to have occurred, the fact that even one may have occurred is of concern.

Thus, the Philadelphia VA has been a harsh self critic during this process. In conclusion: The Philadelphia V has a long standing history of excellence marred by this highly regrettable incident.

While we do not concur with most of the alleged regulatory violations cited by the NRC, we do consider the level of clinical care and quality oversight provided in the Brachytherapy Program did not meet our high standard and have taken significant measures to ensure that there is never a similar recurrence.

The trust placed in us by our patients has been

shaken. That needs to be rebuilt, a process that is slow and painstaking.

While no amount of apology will reverse the wrongs of the past, we remain committed to ensuring the best environment for care going forward for our veterans.

I thank you and I welcome your questions.

MR. REYNOLDS: I think at this point in time, we will take a bit of a break or do you have more.

MR. CITRON: That concludes our presentation.

MR. REYNOLDS: I think we will talk a break for a caucus. We'll be gone about usually takes about 30 minutes. I believe we have staff here that can take you to another room if you would like to get together yourself.

MR. CITRON: Yes, thank you.

MR. REYNOLDS: So and there will be access to facilities because we been at it for two and a half hours now.

(Break taken)

(SESSION RESUMES)

MR. REYNOLDS: All right, we will go ahead and

get started again. We have a few clarifying questions. Mr. Orth and myself will ask some before we have closing remarks.

First, you presented a lot of information today on information that was different that we heard in the past 18 months.

So we are going to ask you to document that and the basis for your position and we would appreciate if we could have that by January 15th.

MR. SATORIOUS: Just to clarify, we will go through what that is that we will need from you.

I think what you just said as we go through our questions, we make it clear what additional things we will want from you in writing because they differ from what we heard earlier.

MR. REYNOLDS: That is -- we want -- Dr. Maslow went through quite a lot of issues.

And it is different from what we heard the last 18 months. We would like your full response for each violation written down, your complete response and the basis for that and any supporting document.

MR. CITRON: We will be pleased to provide that.

MR. REYNOLDS: We will go through each of the 8 violations and ask some clarifying questions and Mr. Orth will be leading off with that.

MR. ORTH: thank you Mr. Reynolds.

I would like to target with the first three violations that we identified the apparent violations having to do with the inadequacy of procedures. There were two questions we had relative to that and I start off by saying if you can indicate whether the National Health Physicists Program and NHPP agree with the assessments that the procedures were adequate? And I don't know who would be best to answer that.

MR. CITRON: Let me ask Gary Williams to come up and speak with us.

MR. WILLIAMS: Gary Williams, National Health Physicists Program. Mr. Williams.

MR. ORTH: The question we would like you to answer, sir, is the VA stated earlier that with regard to apparent violations 1 through 3 that goes to the adequacy of procedures as they exist to implement 10 CF 35.41(b(2) and 10 CFR 35.41 (b)(2).

They indicated that their review shows that the procedures were adequate or in place and adequate. And our question was to you, did you have similar findings? Do you concur?

MR. WILLIAMS: As issued in our inspection report more than a year ago, we cited them for violations similar to that and we stand on that violation.

Mr. Orth: Thank you, sir.

With that, I would ask Dr. Maslow if you could, to repeat your bases for your consideration that your procedures were adequate?

MR. MASLOW: Sure. As I stated in the testimony, the procedures -- went through each of the various documents that were there.

One of the key issues is that our procedures as we reported cases in '03 and '05 were based on an activity metric.

The documents that I cited, Seal Source Policy, the brachytherapy algorithm, again, required that seed placement be checked 10 percent deviations after '03 to be reported.

So, those are consistent with how people were being told as far as an activity metric.

The issue which we discussed is that we were then instructed in '08 to change to D-90 metric for this assessment which we have decided that is improper and we -- the

MR. CITRON: -- Well, let me try to help out here. I think when we were trying do these assessments, we found that we were in uncharted territory.

As Dr. Hagan has pointed out, the criteria on a medical event were not exactly clear. And we were looking at two different ways of determining whether we had a medical event, one based on seed activity, another based on the D-90 level.

And we started out using activity level but we were directed to go to the D-90.

Now, after the Blue Ribbon Panel has reviewed things and come up with more clear definition of what the criteria should be, we want to go back to the activity level. And that seems to be the best standard to use.

MR. MASLOW: Although we put that forward in August as I mentioned.

MR. CITRON: I would add, I'm sorry it has taken so long but when the criteria at the outset weren't very clear, we struggled with this and we went to the best experts that we could find to help us find the right path to choose. And it has taken a long time. We are truly sorry about that.

But it was more important for us to get it right and be accurate and fully account for how this occurred rather than to rush through and try to get this behind us.

MR. SATORIOUS: Let me ask maybe a simpler question and I'm not familiar with the specific case numbers but select a case number out of 2004.

Just pick one that determined that there has been a medical event as a result of that.

Did you have adequate procedures at that point in time? That's what we are talking about, at that point in time. I'm not talking about today or last month or six months ago. I'm talking about in 2004, because we claim you don't.

MR. CITRON: We didn't have an adequate quality assurance program at the outset in 2002 and 2008.

That was the key failing. And your NRC inspectors were correct in identifying an area of concern being with quality assurance and we agree with that, that was a key failing.

MR. SATORIOUS: Did that spill over into the quality of your procedures?

Mr. Citron: The fact -- yes, the fact there was no peer review and quality assurance program; yes, it spilled over.

MR. SATORIOUS: So in my interpretation just what you told me in 2004, because of quality assurance issues and other issues, you didn't have good enough procedures?

MR. CITRON: Well, we had policies and procedures in place and external reviews had no issues with the policies and procedures in place.

But the quality assurance aspect was not there.

MR. SATORIOUS: So you're convinced that you had adequate procedures in 2004?

MR. CITRON: I'm saying that the policies and

procedures that we had in 2004 were deemed adequate and we stand by that.

Did we had adequate quality assurance? No.

MR. SATORIUS: Okay, I think I got enough. Thank you.

MR. REYNOLDS: I'm going to go on to the question, Violation 4 and 5 but go ahead and read them to make sure we're clear on what you mean by fail to instruct, fail to train, supervise individuals regarding identification and reporting requirements for medical events as required in 10 CFR 35.27. And fail to instruct a non-supervised individual regarding identification and requiring a medical event as required by 10 CFR 19.12(a(4).

Tell me again, you contend that the Philadelphia VA trained physicians and the medical physicists?

MR. MASLOW: Again, what I said was that one of the physicians was sent out to a course by the VA. There was discussion of misadministration during the course. When the physician was brought in with the required documentation of knowledge of regulatory knowledge and we have that documentation --

MR. HECK: Could you give us a rough time frame when the physician was sent to the course you're referring?

MR. MASLOW: The course was 1999.

MR. HECK: So in 1999 a physician had received some training in administration as you put it.

MR. MASLOW: And in 2000, we have documentation from the affiliate.

MR. HECK: Anything after that?

MR. MASLOW: Again, there is the -- there is the -- what do you call -- the mandatory reviews that occurred in 2002, 2006. And there is also in 2003 and 2005, medical events determination.

MR. HECK: The '03 and '05 medical event determinations, you considered that training?

MR. MASLOW: When I am asked to do procedures sitting in our classroom and going through procedures as opposed to actually getting out there and doing them, I will consider going out and doing the procedures training.

MR. HECK: Sort of on-the-job training, if you will.

MR. MASLOW: But in addition, it's on the job training with definitions discussed, applied et cetera.

MR. REYNOLDS: With both physicians and all three medical physicists? I know you're talked about Dr. Hagan. I just what to know about Dr. Wedington and your 3 medical physicists. And you referred to earlier some records provided us in March. And unless we missed it, those records had nothing in them about training on medical events.

So I'm confused by what we have seen and heard that your staff has told us and what you're telling me today. That's why I keep going back over it. I'm just surprised.

MR. MASLOW: I'm sorry about your surprise. I interrupted you, I'm sorry.

MR. REYNOLDS: Both doctors and physicists have been trained by the VA on definition of medical events; yes or no?

MR. MASLOW: Both physicians have been to annual review.

MR. REYNOLDS: Have they been trained? I'm

asking for a yes or no answer?

MR. MASLOW: Both were required as part of their requirements to be cognizant of the requirements of the regulatory requirements for their jobs.

MR. REYNOLDS: Including a medical event? So your answer is yes?

MR. MASLOW: Yes.

MR. REYNOLDS: Thank you.

MR. ORTH: Dr. Maslow, we had a question regarding your view on apparent Violation No 6.

That was -- I'll read the apparent violation. "The licensee failed to notify the NRC Operations Center by telephone no later than the next calendar day after discovering a medical event, 10 CFR 35.2045(c) licensee had sufficient information available at the completion of prostate treatments to make the determination that numerous medical events occurred."

The question that I would like to ask is: At the time the events occurred, contract, staff, individuals performing the procedures had information that would have indicated a medical event. My

understanding is that it's not known to you until it gets to the Radiation Safety Officer or Radiation Safety Committee. Is that the differentiation that you indicated?

MR. MASLOW: Right. The annual audits, the annual report, again, the information was coming to the medical center was that when there was discovery, they were reported.

Mr. Orth: I would kind of add to that, when we look at the licensee and the activity of all of their employees as that licensee body and hence, that is the reason why we cited this apparent violation, was that when licensee know it's not -- when the CE0 knows or the Radiation Safety Officer knows, it's when the licensee a member of the licensee staff essentially has that knowledge whether they transmit to the highest level of the organization or not, doesn't fully play into whether we look at the apparent violation.

So I would indicate that.

MR. MASLOW: Whether he had knowledge or should have had knowledge, again is a nuance that...

MR. ORTH: Just to reconfirm apparent Violation Number 7, the licensee failed to record the total dose, the number of source implants and the total source strength written directive as required by 10 CFR 35.40(b(6(2).

My understanding is that you did agree with that apparent violation?

MR. MASLOW: That was a single event, yes.

MR. ORTH: And then finally the two seconds on that one and move on. I just wanted to reconfirm where we were on that. And on Violation No. 8, the licensee failed to provide complete and accurate information in accordance to 10 CFR 30.9 (a) in several 15 day written reports, the NRC is required by 10 CFR 35.3045(d), Delta. Your position on that was that you did not agree?

MR. MASLOW: Correct. We reported what we knew as we knew it. We reported all we knew, as we knew it.

MR. MILLER: If you don't mind, Steve, I had a couple of more questions. The NRC is looking at two physicians and a few medical physicists to try to

understand what the training program for medical events and understanding reporting requirements was.

I heard you say that in '99 one physician was sent outside to a course for training.

Can you describe that training?

MR. MASLOW: Since I'm not familiar with, that I need to defer to --

MR. MILLER: Well, let me hold that then. In '99, this physician was sent to a course. Was a second physician also sent to that course?

MR, MASLOW: No, the second physician was an expert that came over from the affiliate.

MR. MILLER: And that was a medical physicist?

MR. MASLOW: Medical physicist again, coming from the affiliate.

MR. HECK: So in '99, one physician was sent to this training course. You mentioned 2000 who and 2006 mandatory reviews.

Were those for the physicians?

MR. MASLOW: Those were for the physicians, correct, not the medical physicists.

MR. HECK: And was there some element of the

mandatory review that you considered? If so, could you describe it?

Is it more than I certify that I am knowledgeable. Is there teaching that goes with this?

MR. MASLOW: There is review, would that be deferred?

MR. CITRON: I would like to see if Mary Moore, our Radiation Safety Officer could try to speak to that question.

MR. REYNOLDS: Ma'am for the record, if you could identify yourself, that would be good.

MS. MOORE: I'm Mary Moore, the Radiation Safety Officer at the Philadelphia VA. The mandatory review training that was required for all employees covers over two days and employees are given several hours or however much time they need to be able to go through.

Each safety office including radiation safety has a table and we have a handout of information and a test that the employees have to take. And there is one section not only on our -- about our open door

policy, but also the requirements for them to know the regulations and reporting requirements and that they have to inform the Radiation Safety Officer and one of those reporting requirements identified is misadministration because of the '02 when we did the mandatory review, the changes in Part 35 really had not come about. And quite honestly in '02 and '03, we were still calling medical events, misadministration. So we had that training.

We also had -- one thing that needs to be known about the medical physicists prior to them coming to us particularly the one physicist who was there in '98 and '99, was the medical physicist who was actively busy in our Uranium Implant Program and was experienced. And the Brachytherapy Program, the medical physicist was on -- was practicing brachytherapy medical physicists at two other NRC licensed sites, that he had come it with a lot of credentials and experience.

So in the dialogues and emails that Dr. Maslow referred to was the dialogue among these two physicists and the physicians and myself about

criteria, how we could end up having medical events by using seeds and having a leaking seed.

So there was a lot of dialogue and discussion and review of the regulations in developing the algorithm and the entire program.

MR. HECK: I think we understand there were conversations and one of the fundamental questions in looking at, is there a training program where training instruction, not conversations that occur when things go wrong but a program that exist that instructs these users?

MS. MOORE: We have an example of that as well that we just recently found was an email from the physician to the two medical physicists to assist me with training of the operating staff for the Brachytherapy Program. And during that training that they assisted with an attendant, we discussed the need for tracking of the seeds, collecting the seeds and the dissymmetry aspect and we particularly talked about because the OR staff wanted to know -- had some specific questions.

And complication reg came up in the idea of a

seed could be implanted or migrated into a blood vessel going to the lung and that would be considered treating an external site and the misadministration and we would have to report that. So --

MR. CITRON: For the sake of time, I think we can provide you with some documentation.

MS. MOORE: We have sign in sheets and the agenda and it was January, 2002.

It was a few days before our first implant where we conducted training not only for the OR staff, but the nursing staff, recovery room floor, EMS and dietary.

MR. HECK: And after that? I appreciate that. '02 -- I heard some training in '99 and '02.

MS. MOORE: For the physician, for the lead physician. The medical physicists and that lead physician also attended the -- we did the first one in February of '02 so it was January of '02 for that training program. And then that was supplemented by multiple discussions and reviews and particularly during the '03 and the '05 events where detailed review of the regulations occurred.

MR. CITRON: Let me cut in so we can move on to other issues if that's all right with Mr. Heck and Mr. Satorius.

MR. HECK: Certainly.

MR. SATORIOUS: I think in fairness, one of the reasons why we are looking very closely and asking a number of questions on thee two violations associated with training is that we have sworn statements from the five individuals that indicate that claim they have not gotten any training. So only in fairness, that's why it is important that we receive documentation from you if you have it that will get the straight answer.

So, that's why we need that. Thanks.

MR. REYNOLDS: Any other questions before we close?

MR. ZIMMERMAN: I just wanted to follow up on two things quickly. In getting that information, I think it is important for us to not only get the record and training was attended but to understand what that training included, okay for clarity.

The other point: Mr. Citron, you had made a

comment that one of the things you had been struggling with was what the medical event criteria was, that it was unclear.

Could you just explain a little by what the source of the uncertainty or unclearness was if you will, where is it unclear to help us?

MR. CITRON: I'm probably the least qualified person in the room to discuss that but I will try.

If you permit me,I will defer to Dr. Hagan.

MR. ZIMMERMAN: I'm not pointing that question at you. Any one on your team that you feel comfortable answering that question.

MR. HAGAN: As I understand it from a straightforward point of view, Philadelphia, the permittee, NHPP as their intervenor regulatory authority between NRC and the permitee and NRC all have authority or charges to apply the regulations and assert criteria for the evaluation of a particular procedure.

And Philadelphia as I understand from Dr. Maslow, Philadelphia's criteria for evaluating their implant had been to evaluate imaging of the implant

and determine that the seeds determined by the authorized user, that the seeds were placed with respect to the treatment site in the manner that he had intended and that this was done by a seed counting method.

This was done by identifying the seeds by imaging and then, tracking the seeds counting inside and outside of the treatment site.

This was the Philadelphia mechanism. This was a Philadelphia criteria in that the procedures reflected that and the actual performance reflected that. And so when connectivity was lost, there was no hit taken by their procedure because you could see the images in the pack system.

You could see that the seeds were placed vis-a-vis the prostate but you couldn't do a post dose reassessment because you could not share that information with the treatment planning computer. But that was not what Philadelphia was doing for those years.

They were not doing post evaluation dose reconstructions as a method of identifying their

compliance with 10 CFR 35. They were -- they switched to that metric when NHPP during the evaluation said you must evaluate all 114 patients under this metric.

At that point, they had a number of patients for whom their CTs were not helpful.

CTs were performed at a time when the volume of the prostate was so excessive that they believed their dose estimates to be unreliable.

So they set about trying to acquire and use the best images available and this caused a significant delay as they went back through cases and tried to apply this new metric. This is my understanding of Philadelphia.

And then, after several iterations of attempt to identify criteria for other organs and tissues in paragraph three, finally, decided to put together a set of cogent well described clear medical event criteria for other organs and tissue and so that did not exist to that point.

That is not something that they had included in their medical event determination to that point, that

point being summer of 2009.

So crafted that in order to be able to evaluate for other organs and tissues, and evaluated all 114 cases under those criteria and then, reported based on that.

So the report based on their total activity standard, reported based on their DPA criteria for dose to periprostatic activity rectum bladder but also along the way, had reported because at one point, a few seeds in the bladder may be a medical event or a few seeds in the rectum wall may be a medical event and so reported based on that. And my understanding was that was in addition, an effort to avoid under reporting.

No criteria existed. Let's look at something that we can at least measure.

And so there are patients reported for other organs and tissues based on 3 seeds in the bladder or 3 seeds in the rectum or 5 seeds in the peri-prostatic tissue.

No justification, no data, no literature to support that, just this sort of seemed like a

reasonable application. And so during the course from 2008 to date they reported on multiple criteria and they reported both total activity and D-90 and their use of D-90 was because NHPP internal regulators said you must report based on D-90 because that's our choice because you must report based on D-90.

MR. CITRON: It wasn't the medical center's choice based on activity but that was not us to decide.

As you can see, there are a couple of different methods of reporting. And it was difficult to determine what was the right way to do this and it's taken a long time.

I'm very thankful Dr. Hagan has stepped into this position and called for a Blue Ribbon Panel to deliberate this and I think going forward, the whole nation will benefit from the work of the Blue Ribbon Panel and a better clarity on what a medical event is.

MR. ZIMMERMAN: Just about four hours we've been at this and I'm curious if you are comfortable

and if here is a way after all the dialogue the two federal agencies have had, if you can try to craft a message to those veterans that went through this process in terms of what they should take away from this four hour dialogue.

MR. CITRON: We have a -- let me offer a message that comes -- that I would like to convey to the veterans: That we have a wonderful VA healthcare system with a lot of talented personnel.

And I'm truly sorry that the VA care, the quality assurance of our care has lapsed and if we have harmed any veteran, we apologize for that.

We have a great troupe of personnel at the VA medical center in Philadelphia. I been to over 13 VAs around the country in my career and worked in many and nowhere have I seen more talented doctors and nurses, compassionate caregivers than at the Philadelphia VA.

We want our veterans to have confidence in us, to return to get their care at the VA. And we want to assure them that we will ever be more vigilant in trying to identify problems and quality of care

issues because we did fail a number of our veterans over the period that we had our Brachytherapy Program. Thank you.

MR. REYNOLDS: All right, any other questions anybody? A couple of thoughts and I will turn it over to Dr. Miller and Mr. Satorius to close. But first, I appreciate your coming in.

Our staff has spent thousands of hours doing inspections and I'm sure your staff have spent equally if not more and Dr. Anderson has spent a lot of time on this.

That said, you could have violation on written procedures and training and I'm still confused by your position. And I'll even go back and in response to the NHPP report November 21, 2008 and you state Mr. Citron, the medical center concurs that authorized user physicians for prostate brachytherapy and authorized medical physicists did not receive formal training from staff about the regulatory requirements to identify and report medical events.

And then, your December 29th response says violations had a lack of adequate written procedures

and accepts the violation as cited and described the root and basic causes in the inspection report: Notes basic causes related to inadequate and ineffective policy and routine procedures, the lack of program reviews and lack of training.

There is another violation, another lack of lack of inadequate written procedures and accept the violation as cited. You note that basic cause relate to ineffective policy and lack of program reviews. The NHPP sites you again for failure to complete a written directive and you accept those violations.

So I hope you appreciate where I'm coming from. We've been through this for 18 months hearing from your staff one thing and you have written responses to your own internal NHPP but sworn testimony from staff and you come today and what Dr. Maslow says is different.

So, again, that's why I'm surprised and I guess I'll stop here and say, we hope when you provide your written response, you can either address and agree with what you told NHPP or provide us with the basis where you told them was wrong and what our staff has

told you over 18 months incorrect.

MR. CITRON: As this process has unfolded, we asked ourselves questions about how could we have missed this or that and how could some of these errors have occurred and we dug deeper and deeper into our pile and uncovered some new information and we appreciate your willingness to take a look at it.

MR. REYNOLDS: We will, thank you.

MR. ORTH: If I could just wrap up policy type issues. Just to kind of reconfirm, we are then expecting a written response from you, addressing each of the apparent violations that you disagree with and providing a basis and in particular with the training one, we are looking forward to documentation that indicates the training that was taken and the substance of that training. Okay.

And we will be looking for that response on or before January 15, 2010. Now, I'll just go over some procedural type elements of our program to wrap up. As we discussed earlier this afternoon, this is a pretty simple enforcement conference, statements and opinions made by the NRC staff during the conference

or silence should not be taken as NRC position or acceptance of your view. We take into consideration all the information developed about the issues including the information presented at today's conference, information presented in your formal written response to us.

And following the receipt of that information, Region III staff in coordination with our headquarters staff, our Office of General Counsel, our Office of Enforcement, our Office of Federal State Materials and Environmental Management programs will review that information and reach a formal enforcement decision.

And you should expect that about 4 to 6 weeks probably after you provide to us your written response. We will notify you by telephone prior to issuing a decision and via letter.

As I mentioned earlier, we have basically three options. We can impose no enforcement action, a notice of violation only, or notice of violation of civil penalty.

If a civil penalty is imposed, there will be a

press release with that and you will have the opportunity to either pay the civil penalty or protest the imposition of the civil penalty in whole or in part.

If you protest it, we review your case and may agree with your response or if we disagree, we can issue a order imposing in whole or in part.

At that point, you can face civil penalty or request a hearing. With that, I will ask if you have any questions regarding the process as we go forward?

MR. CITRON: No questions.

MR. ORTH: Thank you.

MR. MILLER: Thank you. I just wanted to make a brief statement in closing. The medical area is extremely important to me because it is the only area of NRC regulation where individuals are given radiation intentionally. We spend the rest of our time trying to avoid people getting too much radiation. So it is extremely important to myself and my staff that we as regulators do all we can to make sure that it's done in a safe manner.

I'm very sure that you spend every hour of every day trying to assure that the veterans get the top

quality care. Veterans are a very important subset of the public that we serve and we certainly want to make sure that all the public gets quality care.

In that light, we try to make sure that from everything that we learn constantly that we are constantly looking at our requirements to make sure that adequate protection is always provided in a safe manner.

So, it's our duty as regulators to make sure that happens. Thank you for coming in today.

MR. SATORIUS: Thanks Charlie. Those are good words. I truly think that we all benefited. I know I benefited from the exchange that we had today and we filled the whole afternoon all four hours with that exchange. But, it's always good to hear and talk across the table clearly at each other on issues such as this.

I sense a certain level of contriteness by the VA over this. I don't think that is a bad thing.

I think that makes one look retrospectively at and you always got to look at what happened in the past. You always have to do that. You can't figure

out to not make it happen again unless it's done right. I think there's been a little bit of confusion here at the end on some of your positions on the issues that Steve just pointed out.

I hear that you been digging deeper. We will look forward to getting that information because we intend to do the right thing in this matter and make sure that you understand our level of focus on nuclear safety and the safety of nuclear materials.

And you're in a better place today I think than you were in some years past but it was a place you needed to go to.

Lastly, I would just like to say that going to that place is a journey and if you want to continue that is not a journey you are ever going to get to the end of. It is always a journey.

So Steve?

MR. REYNOLDS: That takes us to the end. Right, thank you. With that, we will conclude this portion of the meeting and we will be opening up for questions for the public.

Mr. Citron, you and staff are welcome to stay if

you like or welcome to leave and if you're interested to take any questions you can do that too but it is your pleasure.

MR. SATORIOUS: This is our portion of the meeting, our outreach to the public. So you're under no obligation to stay. It's up to you.

MR. WIEDEMAN: This is an opportunity for people in the audience --

MR. CITRON: Will you entertain questions on the phone? The representatives of the Philadelphia VA will stay.

MR. WIEDEMAN: And are you going to answer any questions? Okay, thank you very much. We have people in the audience, we have people on the phones. And what I would like to do is just go to anybody in the audience who has a question or a comment. And if you could just introduce yourself to us and then, we will go to the phones. Anybody in the audience have a question for either the NRC staff or the VA staff? Okay, let me check in with people on the phone.

Do we still have people on the phone? Did we ever have anybody on the phone?

MR. REYNOLDS: Chip, we are not going to the phone.

MR WIEDEMAN: Oh, okay.

MR. REYNOLDS: My fault for telling you that, so it is just the people here.

MR. WIEDEMAN: I just would ask one more time whether anybody has anything that they would like to say on this matter? And I would just thank the VA for staying with us. There does not appear to be any comments or questions Steve so I will turn it back over to you.

MR. REYNOLDS: With that, this meeting has come to an initial close. Thank you. For those of you traveling, safe travel.

(Whereupon, the proceedings were concluded)

CERTIFICATE OF REPORTER

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission in the matter of NRC Predecisional Enforcement Conference on December 17, 2009, Rockville, Maryland was held as herein appears and that this is the Original Transcript thereof for the file at the U.S. Nuclear Regulatory Commission taken by Caption Reporters Inc., and that the transcript is a true and accurate record of the foregoing proceedings.

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