ENFORCEMENT OF THE U.S. DEPARTMENT OF VETERANS AFFAIRS' BRACHYTHERAPY PROGRAM SAFETY STANDARDS

HEARING

BEFORE THE

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

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CONTENTS

July 22, 2009

ENFORCEMENT OF THE U.S. DEPARTMENT OF VETERANS AFFAIRS' BRACHYTHERAPY PROGRAM SAFETY STANDARDS

WEDNESDAY, JULY 22, 2009

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON OVERSIGHT
AND INVESTIGATIONS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:00 a.m., in Room 334, Cannon House Office Building, Hon. Harry E. Mitchell [Chairman of the Subcommittee] presiding.

Present: Representatives Mitchell, Walz, Adler, Hall, and Roe.

Also Present: Representative Fattah.

OPENING STATEMENT OF CHAIRMAN MITCHELL

Mr. MITCHELL. Good morning, and welcome to the Subcommittee on Oversight Investigations Hearing on Enforcement of U.S. Department of Veterans Affairs' (VA's) Brachytherapy Program Safety Standards. This is July 22, 2009, and this hearing will come to order.

I ask unanimous consent that Mr. Fattah of Pennsylvania be invited to sit at the dais for the Subcommittee hearing today. Hearing no objection so ordered. Mr. Fattah, you are invited when you do come in, to come up to the dais.

I would like to thank everyone for attending today's Oversight and Investigations Subcommittee Hearing entitled, Enforcement of U.S. Department of Veterans Affairs' Brachytherapy Safety Standards. Thank you especially to our witnesses for testifying today.

All Members of this Subcommittee take particular interest in this issue, as well as the care of our Nation's veterans; however, I would like to especially thank Congressman John Adler of New Jersey for being such a passionate advocate for this issue.

Reports of botched prostate cancer procedures, a lack of quality and standard controls in the VA health care system, and egregious errors in the brachytherapy treatment at the Philadelphia VA Medical Center are unacceptable and wrong.

Brachytherapy is a form of radiotherapy often used to treat prostate cancer in which radioactive seeds are placed inside or next to a patient's malignancy. Failure to accurately place the radioactive seeds can cause serious damage. To say that it is disturbing to learn that veterans received bungled procedures and that safety protocols failed to safeguard against such mistreatment would be

an understatement. As a result, we are here today to examine the system-wide safety standards for these procedures to ensure that our veterans are receiving the best and safest care possible.

In 2003 and 2005, the Nuclear Regulatory Commission (NRC) received reports of botched placement of radioactive seeds and inconsistent dosages at the Philadelphia VA Medical Center. After careful review, it was determined that no NRC protocols were violated.

In May of last year, the NRC received a notification of potential under dosing at the Philadelphia VA Center. This led to a VA Hospital Health Physics Program inspection evaluating all the 116 brachytherapy treatments that took place since the creation of the program in 2002.

The New York Times reported last month that investigators for the Nuclear Regulatory Commission and VA officials found that 92 of the 116 men treated at the VA Medical Center in Philadelphia's brachytherapy program received incorrect doses of radiation seeds, often because they landed in nearby organs or surrounding tissue rather than the prostate.

Dr. Gary Kao, who is here today at this hearing, performed the majority of the procedures under a VA contract with the University of Pennsylvania where he was on staff. Out of the four suspended brachytherapy programs, we know that Philadelphia was by the far the worst.

On top of this, in March of this year the NRC issued a detailed inspection report citing the Philadelphia VA Medical Center with six violations of NRC regulations. This is downright unacceptable.

While we are disturbed that perhaps there was a lack of proper local quality controls and management of these brachytherapy programs, our main concern is that the problem marring the program in Philadelphia could be happening at the other nine facilities still doing these procedures. As such, we have asked the VA Office of Inspector General (OIG) to review and assess the VA's brachytherapy programs, and although the complete NRC inspection report on the Philadelphia program, along with the other VA facilities using brachytherapy treatments, as well as the National Health Physics Program (NHPP) performance is not complete, we look forward to reading that report when it becomes available.

Though it is commendable that VA's leadership took swift action once these issues were reported, it is still troubling that it took almost 6 years for these events to actually be reported. Even more troubling is just last month we were here discussing quality control and lack of proper procedures and oversight of endoscopy procedures being conducted by the VA, yet we are here again questioning the quality of care our veterans receive.

The VA health system relies upon a complementary system of accountability to identify quality control problems throughout the entire system and at individual levels. Failure to ensure consistent oversight and safe treatment is unacceptable and wrong.

I am anxious to hear VA assurances not only to this Subcommittee, but to all the veterans they serve, that the issues identified once a thorough review has been conducted is not occurring at any of the remaining brachytherapy programs across the country, and that the four suspended programs may continue to deliver this important treatment to our veterans.

Last, I am equally interested in hearing from one of one our witnesses, Dr. Kao, regarding all allegations of erratic seed placements, as well as experts we have invited to provide their thoughts on the safety and effectiveness of the treatment.

Thank you again to all of our witnesses who are testifying today and we look forward to your testimony.

And before I recognize the Ranking Republican Member for his remarks I would like to swear in our witnesses. I ask that all witnesses from all three panels to please stand. Please raise your right hand.

[Witnesses sworn.]

Thank you. I now recognize Dr. Roe for opening remarks.

[The prepared statement of Chairman Mitchell appears on p. 47.]

OPENING STATEMENT OF HON. DAVID P. ROE

Mr. ROE. Thank you, Mr. Chairman, other Committee Members for being here today, I appreciate you holding this hearing.

The issue we should really be addressing today is not only the instance of alleged medical malfeasance by one particular medical practitioner, but whether or not this is a symptom of an overreaching patient safety issue across the entire VA.

Just last month, as the Chairman mentioned we held a hearing on the problems relating to cleaning and reprocessing of endoscopic equipment at the VA. Now we are hearing testimony today to discuss problems with brachytherapy treatments at the VA Medical Center in Philadelphia.

Prostate cancer is a major problem for adults over 50 in the United States, and brachytherapy is an important tool used by oncologists to treat prostate and other cancers. The VA treats about 575 veterans annually with low dose brachytherapy at 13 centers nationwide.

We need to tread cautiously today. We are here to hear testimony from the VA and other officials. We need to keep in mind the good quality care most veterans seem to be receiving in VA medical facilities and not seek to undermine the confidence veterans have in going to the VA for their health care needs.

That being said, I am gravely concerned that these issues continue to crop up in the news media. VA needs to do a better job at policing itself before they let the New York Times sensationalize an issue in order to break the public's trust.

Mr. Chairman, protection of our Nation's veterans who look at the VA for their care of a primary importance. To hear continual reports of various health issues such as an endoscopic cleaning issue last month and now the problem with brachytherapy at select facilities is worrisome to me and others on this Committee. We must continue to ensure that our veterans receive the best possible care available.

I look forward to hearing the testimony from today's witnesses. And once again, Mr. Chairman, thank you for holding this hearing. I yield back my time.

[The prepared statement of Congressman Roe appears on p. 48.]

Mr. MITCHELL. Thank you, Dr. Roe. At this time I would like to recognize Mr. Adler.

OPENING STATEMENT OF HON. JOHN H. ADLER

Mr. ADLER. I would like to thank Chairman Filner, Chairman Mitchell, the House Veterans Affairs' Committee, and the Subcommittee on Oversight and Investigation for holding today's hearing on the VA's brachytherapy program safety standards. I would also like to thank our witnesses for agreeing to testify.

The veterans who sought treatment for prostate cancer at the Philadelphia VA Hospital did not receive the quality health care their selfless service to our country earned them. The people responsible for administering the substandard medical care in the brachytherapy program let our veterans down and sent the wrong message to young men and women thinking about joining our all-volunteer armed forces.

We are here today to evaluate the suspended brachytherapy program at the Philadelphia VA Hospital who have treated prostate cancer patients from 2002 until the program was forced to close in June 2008, and also to evaluate the VA's broader brachytherapy program safety standards.

News reports have depicted a rogue cancer unit and a rogue physician who botched nearly 80 percent of the procedures he was contracted to perform on our veterans. These multiple failures which went undetected year after year highlight significant problems in the VA's oversight system.

Recent newspaper articles highlighted a prostate cancer treatment program that operated for 6 years with a glaring lack of oversight that should have been in place to protect our veterans.

I am outraged. The brave men who so selflessly served our country have been subjected to such poor treatment and neglect by a hospital and a system that was created to protect them.

I am further appalled that the routine safeguards that could have been in place to protect our veterans were either woefully inadequate or blatantly absent. Exposing our veterans to this type of mistreatment is not only unacceptable, it violates the bond our country made with them when they agreed to fight for the safety and security of this Nation.

We must find and analyze the specific gaps in our system so these failures never happen again in this program, in this hospital, in any program in any VA hospital.

What occurred at the Philadelphia's VA brachytherapy program is more than just one doctor's incompetence, the Federal Government failed on many levels to protect our veterans.

The multiple-pronged system currently in place to oversee radiation procedures across the country is not working. It certainly was not working in Philadelphia. That is why the VA temporarily or permanently suspended other brachytherapy programs in Cincinnati, Washington, and Jackson, Mississippi.

This hearing is an opportunity to continue our investigation into the failures that resulted in the forced closings of 4 out of 13 brachytherapy programs throughout our country. We must avoid a recurrence of this problem at all VA medical facilities.

This hearing is also an opportunity to begin examining the entire VA health care system. This is a start of an ongoing process to ensure that our veterans are receiving the highest standard of medical care they deserve everywhere in the country.

I am looking forward to getting some answers from the VA today about what steps they are taking to ensure that the problems of the brachytherapy program in Philadelphia are not repeated elsewhere in the VA health care system. My hope is that the VA can give our veterans some confidence that the VA system is working to provide the highest level of care.

I yield back the balance of my time.

Mr. MITCHELL. Thank you. Mr. Hall.

OPENING STATEMENT OF HON. JOHN J. HALL

Mr. HALL. Thank you, Mr. Chairman, and thank you for holding this hearing. Also, thank you Ranking Member Roe.

I agree with the comments of Mr. Adler and yourself and the Ranking Member, all of which are complimentary. Our veterans need to have obviously the best care available to them—and the VA I believe is in the process of trying to correct these problems where they are been identified.

I am interested in not only answers to what went on and how it can be avoided, these cases of mistreatment or inadequate treatment, possibly harmful treatment to the patients can be avoided, but also your reaction to a New York Times article that came out recently that said that a prostate cancer diagnosis usually offers the patient the choice of five different routes, seed implantation being one of them, and that the most radical and expensive is proton acceleration, the least expensive is watchful waiting, and in between you have the removal of the prostate, radiation therapy, seed implantation, et cetera, and that no statistical difference has been shown yet in any of the studies in terms of lengthening the patient's life, especially if they are diagnosed at 65 years or older.

So are we in the VA medical system looking at the cost benefit analysis of these various choices of treatment and telling the veteran, the patient, what the choices are and the true statistical fact—it appears to be a fact—that one is not guaranteed a longer life by having one treatment over another?

So if I may, Mr. Chairman, I will submit a longer statement for the record, but thank you again for holding the hearing and thank our witnesses for their testimony and I yield back.

[No statement was submitted.]

Mr. MITCHELL. Thank you. Mr. Walz.

Mr. WALZ. Well thank you Chairman and Ranking Member for once again holding an important hearing. I am going to yield back my time so we can get right to our witnesses.

Mr. MITCHELL. Thank you. Mr. Fattah.

OPENING STATEMENT OF HON. CHAKA FATTAH

Mr. FATTAH. Thank you, Mr. Chairman, and let me be brief. Let me thank the Committee and the Subcommittee for holding this hearing, and I think that it is important that we hear from the witnesses. When I first heard about this, I was obviously like others, outraged. Nevertheless, the more you dig into it there is more nuance to it and subtleties to this procedure, and I want us to make sure that we don't do anything to discourage people from seeking treatment.

I think it would be very helpful to hear from the experts so that we can better understand what happened and where we can go from here. Specifically, to what degree were there difficulties in what is one of the best VA hospitals in this system, which is in Philadelphia, what was done about it, and where we can go from here. So thank you, Mr. Chairman.

Mr. MITCHELL. Thank you. I ask unanimous consent that all Members have 5 legislative days to submit a statement for the record. Hearing no objection so ordered.

At this time I would like to welcome Panel One to the witness table. Joining us on our first panel is Dr. Gary Kao, Associate Professor in the Department of Radiation Oncology at the University of Pennsylvania. Also joining us is Dr. Steven Hahn, Professor and Chair of the Department of Radiation Oncology, University of Pennsylvania; Michael Bieda, Clinical Chief in the Division of Medical Physics, Department of Radiation Oncology, University of Pennsylvania. Mr. Bieda is accompanied by Dr. Greg Desobry, Medical Physicist, Division of Medical Physics, Department of Radiation Oncology, University of Pennsylvania; and Dr. George Lazarescu, Medical Physicist, Division of Medical Physics, Department of Radiation Oncology, University of Pennsylvania.

I ask that all witnesses please stay within 5 minutes for their opening remarks. Your complete statements will be made part of the hearing record.

At this time I would like to recognize Dr. Kao, then Dr. Hahn, and Mr. Bieda for up to 5 minutes each.

Dr. Kao.

STATEMENTS GARY D. KAO, M.D., PH.D., ASSOCIATE PROFESSOR OF RADIATION ONCOLOGY, DEPARTMENT OF RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA, SCHOOL OF MEDICINE, PHILADELPHIA, PA; STEPHEN M. HAHN, M.D., HENRY K. PANCOAST PROFESSOR AND CHAIR, DEPARTMENT OF RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA, SCHOOL OF MEDICINE, PHILADELPHIA, PA; MICHAEL R. BIEDA, M.S., CLINICAL CHIEF, DIVISION OF MEDICAL PHYSICS, DEPARTMENT OF RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA, SCHOOL OF MEDICINE, PHILADELPHIA, PA; ACCOMPANIED BY GREGORY E. DESOBRY, PH.D., MEDICAL PHYSICIST, DIVISION OF MEDICAL PHYSICS, DEPARTMENT OF RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA, SCHOOL OF MEDICINE, PHILADELPHIA, PA; AND GEORGE LAZARESCU, PH.D., MEDICAL PHYSICIST, DIVISION OF MEDICAL PHYSICS, DEPARTMENT OF RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA, SCHOOL OF MEDICINE, PHILADELPHIA, PA

STATEMENT OF GARY D. KAO, M.D., PH.D.

Dr. KAO. Thank you, Congressman Mitchell and other Members of the Subcommittee for the opportunity to appear before you so that we may be heard on this important subject matter and correct some very serious false allegations that have appeared in the media recently about me and the Philadelphia VA brachytherapy program.

I have always worked very hard to best serve the field of radiation oncology and my patients in over 15 years of clinical practice. My dedication to my work is reflected in my educational achievements earning a bachelors degree in philosophy and a medical doctor degree from the John Hopkins University and its School of Medicine, followed by medical internship and residency, and completion of residency in radiation oncology at the University of Pennsylvania School of Medicine. This culminated in board certification in Radiation Oncology. I further earned a second doctorate, a Ph.D., in researching better ways of treating cancer.

I am especially proud that during continuous clinical practice of medicine for over 15 years I have not had a single malpractice claim filed against me. My record and my commitment to the care of my patients make the false allegations against me and the brachytherapy program particularly devastating and misguided.

I, along with others at the VA, implemented the program for brachytherapy in 2002 to best serve the interests of veterans. Contrary to the allegations that I was unsupervised and we were a rogue unit, we developed precise standard operating procedures and a system of oversight and monitoring of what was then a state of the art treatment for prostate cancer. We formulated the first algorithm of any radiation oncology procedure at the VA to define the standard operating procedure.

As would be expected in any new program the brachytherapy program was not without its challenges. However, what has become clear over the last month is that a fundamental misunderstanding of elementary principles and concepts has led some to arrive at an inappropriate and incorrect conclusion that deficient care was routinely rendered to veterans who received brachytherapy in Philadelphia. This was not the case.

To understand why it is important to understand certain critical issues related to the NRC's definition of a reportable medical event and its applicability to our work. Here are the facts.

Fact 1: A standard definition of a reportable medical event as it applies to brachytherapy was not in existence when the program started at the VA. This definition was not referenced in my training in brachytherapy at the Northwest Hospital in Seattle, nor was it clarified by NRC personnel in their investigations in 2003 and 2005 when they were onsite in Philadelphia.

The definition that the NRC has now chosen to retroactively apply to all cases of the Philadelphia program is predicated on a deviation from D90, the dose received by 90 percent of the prostate, but this is a definition that does not appear anywhere in the regulations published by the NRC.

It should also be noted that there is disagreement within the medical community regarding the appropriateness of D90 as a defining metric for overall efficacy of the treatment.

Fact 2: The definition of a reportable medical event as it applies to brachytherapy is not only unclear, but it is evolving. The Medical Advisory Committee of the NRC has repeatedly recommended that the definition be changed from one that is dose-based to one that is activity-based, in other words, in the number of seeds. Last summer, the NRC proposed a rule to change the definition, but the

NRC is still using the old unpublished definition to judge the Philadelphia VA's brachytherapy cases.

Fact 3: Even if a reportable medical event using the D90 based metric occurred, this does not mean the treatment failed the standard of care.

For example, the treatment of an unusually large prostate may result in a D90 that is under-dosed or a treatment of a small prostate may result in a D90 overdose, but in both cases the treatment could still be appropriate and effective in eradicating the cancer.

Fact 4: Whether treatment delivered has been consistent with the standard of care should not be determined by whether the treatment resulted in a reportable medical event to the NRC.

There are many more significant factors that determine appropriate treatment such as number of seeds; location of the seeds in a prostate; location of seeds outside the prostate; concentration of seeds to the affected area of the prostate; stage, grade, extent and location of the cancer; and the clinical follow up of prostrate-specific antigen (PSA) test results. None of these factors are addressed by the NRC.

I also wish to address the now oft-repeated reference to 92 botched cases. This characterization is simply wrong. It is unfair and extremely misleading. A case that meets the NRC definition of a reportable medical event does not mean the patient received ineffective or botched care. The efficacy of the treatments is evidenced by the fact that there had been no confirmed cases of tumor recurrence by the time the program was terminated, with many patients doing well up to 5 years after their treatment.

Furthermore, the NRC review, which allegedly resulted in 92 reportable cases, was determined through a re-analysis of our data without our participation. This participation would have been essential, since it is well recognized among radiation oncologists that prostate contouring is very subjective and volumes can vary substantially depending on who does the contouring. Because of this variability, the D90 dose calculated by different reviewers can vary by as much as 60 percent. The calculations that we performed indicated that the number of patients with D90 lower or higher than 20 percent were far fewer than 92 cases. I do not believe that even with the use of a D90 base metric there are close to 92 reported cases.

Brachytherapy is a relatively new and evolving field. While I recognize that certain conditions and circumstances at the Philadelphia VA could have been improved, but I remain confident based on my knowledge of the field and the nature of the patients that we treated that the patients received appropriate medical care and which was effective.

I hope that through my statements and testimony I am able to contribute to a fuller understanding of brachytherapy treatment, but also bring a degree of reassurance to our veterans regarding the treatment that was provided, and ultimately improve the care for our veterans. Thank you.

[The prepared statement of Dr. Kao appears on p. 48.]

Mr. MITCHELL. Thank you. Dr. Hahn.

STATEMENT OF STEPHEN M. HAHN, M.D.

Dr. HAHN. Yes, sir.

Mr. Chairman and Members of the Subcommittee, I am grateful for the opportunity to appear before you here today.

I am a professor of radiation oncology at the University of Pennsylvania, and since 2005 have been chair of the University's Department of Radiation Oncology.

Before going any further I want to express my deepest regret that prostate cancer patients receiving brachytherapy at the Philadelphia VA Medical Center did not in every instance receive the best possible care. My highest priority as a physician and as chair of the Department of Radiation Oncology is to make sure that patients do indeed receive the best possible care.

I want to personally apologize to the patients and their families for the distress that this has caused. I also know that the entire experience has been very difficult for the VA health care system, particularly in Philadelphia, as it has been for my department.

Penn Medicine's relationship with the VA is long standing and we value it greatly. It is very important to our mission as an academic medical center dedicated to patient care, teaching, and research. We value this work and we believe that both of our organizations have learned a great deal from this painful experience.

I will focus most of my testimony today on the steps we have taken in the last year in response to this situation and the process improvements we have implemented at Penn that we believe will improve the quality of care.

The University's Department of Radiation Oncology, through a contract with the VA, provides radiation services, including brachytherapy. Radiation oncologists working at the VA are either directly employed by the VA or Department faculty provided under the contract.

When the Department first learned in May of 2008 of potential concerns about the prostate brachytherapy program at the VA we took immediate action. The Department provided several faculty Members and staff to the VA to assist in its quality review of all prostate brachytherapy cases.

In June 2008, when concerns arose regarding Dr. Kao's cases in particular, Dr. Kao agreed, at my request, to suspend his clinical practice, and he has not treated any patients since that time at the VA or at our hospitals.

Since last summer, Departmental faculty, as part of their responsibilities at the VA, have been coordinating patients' follow-up.

In addition, since the VA and the NRC began investigations into this matter in June 2008, we have cooperated fully, and we will certainly continue to do so.

In June 2008, we also reviewed quality control and improvement measures to enhance them and to prevent a situation like this from ever happening again.

We have adopted an additional review process that provides for patients who did not take part in the original brachytherapy procedure to assess its quality by reviewing the Computerized Axial Tomography (CT) scan and recalculating the delivered dose.

We also have established a multi-level internal reporting system so that even a slight anomaly will be reported to our quality assurance (QA) Committee.

Another notable development for us is that at Penn we recently completed the transition to a new treatment approach called "real-time dosimetry," a technology that provides for instantaneous feedback about dose to the attending physician. We believe this approach should enhance our program.

I do not know if the VA intends to restart its permanent prostate brachytherapy program, but if and when it does, we would of course be very happy to assist the VA in any way possible.

Our Department's response has also been reviewed by Penn medicine quality reviewers and senior physicians. Further, to assure ourselves that we have considered every safety and quality option, we will be requesting an additional review by outside experts.

Before closing, I want to briefly address NRC regulations, because the NRC, the VA, and the University all share a goal of seeing patients receive the best possible care. My hope is that we can work with the NRC to clarify the relevant regulations which should make early detection even more likely.

Mr. Chairman and Members of the Subcommittee, I want to reiterate that I am sorry for the distress this has caused patients and their families. Let me again stress that Penn is committed to providing the highest standard of care to our Nation's veterans and to work closely with the VA moving forward. Thank you.

[The prepared statement of Dr. Hahn appears on p. 51.]

Mr. MITCHELL. Thank you. Dr. Bieda.

STATEMENT OF MICHAEL R. BIEDA, M.S.

Mr. BIEDA. Mr. Chairman and Members of the Subcommittee, thank you for the invitation to appear here today.

I would like to use my time to provide you with some information about my background, as well as a description of the medical physicist's role in prostate brachytherapy. I am giving this statement on my behalf, as well as that of my two colleagues, Mr. Desobry and Lazarescu.

In 1996, I was awarded a master's degree in physics from the University of Tennessee, and in 1999 was graduated from the master's program in medical physics at the MD Anderson Cancer Center at the University of Texas at Houston. Since that time, I have worked as a medical physicist at the Johns Hopkins University Oncology Center; at Christiana Care Health Systems in Newark, Delaware; and at Bryn Mawr Hospital in Bryn Mawr, Pennsylvania, in addition to the University of Pennsylvania's Department of Radiation Oncology. I worked at Penn from 2002 to 2005, and then returned in August 2006 to take the position of Clinical Chief of Medical Physics for the Department. I am certified by the American Board of Radiology in therapeutic radiological physics and I have had several publications in the *Journal of Medical Physics*.

I will describe three things that a medical physicist does to assist in prostate brachytherapy.

First, based on the physician's prescription, which specifies the amount of radioactivity implanted into the patient, a physicist prepares what is called a "preplan." To do this the physicist will re-

view a series of ultrasound images of the prostate that is taken by the doctor in which the physician has identified the prostate. With this information from the doctor, the physicist will plan the places where the radioactive seeds will be implanted into and around the prostate and estimates the radioactive dose to be delivered to the prostate. This plan is always confirmed or potentially revised by the doctor.

Second, not long after the doctor is to perform the implant, the physicist will check the activity level of a sample of seeds to be implanted and deliver those seeds to the doctor in the operating room (OR).

The third thing a physicist does takes place after the implant. At the Pennsylvania VA Medical Center the doctor would order a CT scan of the patient's prostate the day after the implant. On this CT scan the physicist would identify the location of the implanted seeds, using a dedicated computer program for this purpose. Once this was done, the doctor would locate the prostate on the CT scan and draw it in. This would allow the computer program to generate what we call a "dose volume histogram," which is essentially a graph showing how much of the prostate received how much of the prescription dose, as well as different dose parameters. This information is often referred to as "post-implant dosimetry."

Post-implant dosimetry is performed so that the doctor might evaluate the implant as part of his overall assessment of his ongoing treatment plan for the patient.

I recognize that the Subcommittee may have questions and I will do my best to answer them. Again, thank you for your consideration of my testimony.

[The prepared statement of Mr. Bieda appears on p. 53.]

Mr. MITCHELL. Thank you very much. I have a couple questions. First of all I want to start with Dr. Kao.

First, can you please explain the quality of care provided at the VA compared to the quality of care at other facilities you have worked at.

Dr. KAO. The brachytherapy procedure that we adopted at the VA was identical to the system that was used at the University of Pennsylvania and also one of its satellites. And in my training, in fact, I went to observe brachytherapy procedures performed in art satellite in Trenton, New Jersey, and as a resident I was trained in brachytherapy by senior physicians at the University of Pennsylvania.

Mr. MITCHELL. What quality of care metrics do other facilities follow?

Dr. KAO. My understanding is that the quality control—the quality assurance procedures are similar in that a CT is performed after the procedure and the dosimetry calculated from that CT.

Mr. MITCHELL. And the last one I have. What markers or red flags when conducting the brachytherapy procedures indicated a problem?

Dr. KAO. I now understand that—one of my regrets is that I could have been much more assertive in engaging the NRC in what it defines as a reportable medical event.

As a result of their investigation in 2003 and 2005, we were under the understanding that the definition of a reportable medical

event was based on the number of seeds laying outside the prostate. Subsequently, I found out that that was not the case, that the NRC apparently is now relying on a D90 metric, and that is something that to my regret I could have been much more focused on using that metric.

Mr. MITCHELL. Mr. Bieda.

Mr. BIEDA. Yes.

Mr. MITCHELL. What do you think could have been done differently by the VA that would have prevented us having this hearing today?

Mr. BIEDA. Differently compared to Penn, differently compared to other hospitals?

Mr. MITCHELL. Differently so we wouldn't have had to have this hearing.

Mr. BIEDA. Right. My only, you know, potential thought on what could be done differently is to have a stricter peer review process by, you know, external physicians not involved directly in the cases, that probably could have, you know, helped the situation.

Mr. MITCHELL. And this is to either three of you. My understanding was that what caused this to become a red flag was the under dosage that the patients received. As a result of the under dosage what has happened with these patients in terms of prostate cancer? Has it come back? Has it been taken care of?

Dr. HAHN. Mr. Chairman, the VA's own internal QA system picked up the sort of index situation that led to this discovery. And we personally, although we supplied physicians for the review of the patients' cases at the VA, this has been an internal VA investigation. We would not personally have a lot of information with respect to that clinical outcome, sir.

Mr. MITCHELL. One last question. You were called in I guess as a radiation oncology to perform this procedure. Who does that? Is it a urologist? There are other ways to handle prostate cancer. How is it determined that brachytherapy was the process to use here? Or do you know that?

Dr. HAHN. Are you asking me, sir?

Mr. MITCHELL. Anybody there on the panel.

Dr. KAO. You are correct, Mr. Chairman, patients with prostate cancer have different treatments available to them. The patient population that we served at the Philadelphia VA however was very special in that many of the patients came from very far away, from West Virginia, Ohio, upstate Pennsylvania for brachytherapy because they could not undergo surgery or external beam radiation, you know, due to the lack of these treatments back home or because of their individual personal situations.

Mr. MITCHELL. Okay.

Dr. KAO. External beam radiation for instance would require 8 weeks of daily Monday through Friday treatments, and I had a number of patients who for instance were farmers who could not afford the 2 months being away from their farm. It would have been economically devastating for them.

Mr. MITCHELL. Thank you. Dr. Roe.

Mr. ROE. I am going to try to put a little English translation on all this for the non-medical people in here.

What happens when you have—let us say you have a PSA that is elevated, you do a biopsy and you find a cancer, that cancer has a score called a "Gleason score," which goes from zero to ten, and they also evaluate the size of your prostate gland, it is how big it is, how many cc's of volume does it have. So a very large volume prostate gland would not be one you would choose to treat with brachytherapy.

And brachytherapy has really been developed since probably the 1970s, and one of my closest friends has been doing this actively since 1997, so it is not really new.

When that diagnosis is made and you have a patient that meets the criteria they go to the operating room, they have an anesthetic, they have a rectal ultrasound placed in, and they have a device placed on the perineum.

The calculations, and I would like to commend you on your choice of undergraduate schools too by the way, UT, the physicist has made a pretreatment plan. These seeds then under direct ultrasound guidance are placed. And the way—and I will let the physicist explain this a little closer in a minute—the way these calculations are made there is a thing called the "inverse square law" and I won't go through all of that, but basically on where the seeds are, you can calculate how many grays or how many reds of therapy are given to a specific spot, and then the patient has a CT scan at some point after the procedure is over and they are able to look and he would make this calculation that yes, the dosimetry is right and he would know how many grays are required to kill a cancer cell that is fairly slow growing, let us say of a Gleason score of five.

The problem that came up with the placement of these seeds, and I was looking here, and this may come up later in the testimony, but in one particular instance here there were 45 seeds out of the 70 something that were placed that were not in the prostate gland but were in the bladder. So what had happened was, and I reviewed some of these diagrams here, that the seed placement was not appropriate and it didn't seem to be in the prostate. It was not in the prostate gland. And, therefore, when that happened, when the calculation was made afterward the dosimetry was not correct for the treatment of the disease. Am I right on that, Dr. Hahn?

Dr. HAHN. Yes, correct.

Mr. ROE. And would you either Dr. Kao or Dr. Hahn, one of you, discuss on placement of the seeds, because that is absolutely critical. And what the Chairman brought up is sometimes a radiation oncologist does that, sometimes a urologist does that in consultation with the oncologist, and sometimes they do it together. So it is not standard. Could you comment on placement of the seeds, and is that where the problem was?

Dr. HAHN. So at our institution, Congressman Roe, the procedure is typically mostly done by the radiation oncologist with some participation by the urologist both in terms of identifying the base of the prostate using an ultrasound in the OR as you described, as well as perhaps the placement of some seeds. The predominant amount of seeds—number of seeds—is performed by the radiation oncologist in the operating room.

Mr. ROE. And to just again further clarify for those, when you place this needle in as you bring it out you drop these seeds along, but if that needle is not in the prostate gland it obviously isn't getting it treated if it is near the rectum or if it is in the bladder. And I asked my colleague, my good friend that I have operated with hundreds, if not a thousands times, how many seeds that he dropped in the bladder over the years in the hundreds of cases that he had done, and he said now it almost never happens because of the ability—and it has happened in obstetrics ultrasound how refined the ultrasound is.

So I guess I am asking the question, why did that happen? Why there were so many seeds placed outside the prostate or the dosimetry seemed to be? I think that is why when the calculations were made that the dose didn't seem to be proper.

Dr. KAO. If I could address your question. As Dr. Hahn mentioned, the way we do brachytherapy in Philadelphia is in conjunction with the urologist. The urologist places the very first needle, and needle determines the depth by which all subsequent needles fall. So if that very first needle is off, as you pointed out, then the subsequent needles may also be off.

The placement of the seeds also depends on the image quality. And early in the learning curve in our first few cases we did not prep the patients as thoroughly as needed, so if there is some stool in the rectum that would degrade the image quality of the ultrasound.

The case that you are referring to, sir, I believe is one of the cases that resulted in an NRC investigation. We implemented several measures after that first case to help ensure that this situation did not arise again.

Mr. ROE. Thank you, Mr. Chairman, I will have further questions later.

Mr. MITCHELL. Thank you. Mr. Adler.

Mr. ADLER. Thank you, Mr. Chairman. I guess my first question is for Dr. Kao. We have heard about the closure of this program in June of 2008. We have heard about possibly 92 cases out of 116 with some concern. Some of us use the word "botched," you don't like that word. We have heard that the National Health Physics Program reported to NRC at least 35 medical events later in 2008. We heard Dr. Hahn just now acknowledge on behalf of UPenn that not in every instance did every patient get the best possible care. This program is still closed. You were running this program. You were the principal operator of this program at the VA in Philadelphia.

How do you reconcile your view in your own testimony here today that patients received appropriate medical care with the VA's view that it made mistakes during this period of years with UPenn's recognition that not every patient got the best possible care, with NHPP and NRC saying there are medical events even in a context where we probably don't define medical event sufficiently to trigger reporting to the extent probably we would want reporting? So let us assume there is some under-reporting going on. Even with under-reporting we have at least 35 instances from 2008 reported about over a period of time a program you ran.

I am thinking you are in a dream world right now. I am thinking everybody else, all the other experts are looking at this and saying it didn't go well enough, that whether the number is 92 or some less than 92 we want the number to be zero botched cases.

How do you reconcile your view that every patient received appropriate medical care with a view of every other expert, every potential supervisor, every contracting body, every regulatory body? I kind of want to hear you acknowledge you did things less well than you would have wanted to have done.

Dr. KAO. Sir, I don't disagree with many of the other comments that were made. Medicine is both an art and a science, and the art of is it that even though the treatment may be effective it may be made to be even more optimal.

A central theme here is what is defined as a reportable medical event. And a case that is a reportable medical event does not mean that the patient was harmed or did not receive effective treatment.

When the program was closed in 2008, we did not have any confirmed cases of tumor recurrence. The NRC itself recognizes that a reportable medical event does not mean that it does not address the efficacy of the treatment.

So in summary, I recognize there are many things—several things that I could have done better, but I still believe that the patients received the standard of care that was in place at the time.

Mr. ADLER. I am just seeing it differently than you are I guess.

I understand from some news reports that it was at least a period of a year where you were not getting post-implant dosimetry information to gauge whether the patients had had the seeds placed properly and the seeds had stayed where you wanted them to be. Is it true that there was a year when you did not have that sort of post-implant dosimetry information?

Dr. KAO. It is true that for a period of about 14 months there was a computer interface problem at the VA, that although the CTs that could be performed after the brachytherapy, but that data could not be transmitted to the workstation used to calculate the doses.

During that time I followed the chain of command. I complained to radiation safety, to the Chief of the VA Radiology Oncology Department, and other Members of the program did the same, but this problem was never fixed.

I was then faced with the very difficult choice of either stopping the program, but if I had done so then the patients would not have received any care. As I mentioned earlier, many of the patients who came to us did not have surgery or other forms of radiation as a choice. So given the choice between delivering no care and having their cancers progress or to go ahead and perform the procedure I made that decision.

I could still see from the CT that the seeds were in the prostate and I could judge that the seeds were concentrated around the part of the prostate where the cancer was located. So these gave me a measure of confidence that the patients were being appropriately treated. But it is, you are correct, sir, that is one of my regrets that I should have broken the chain of command, I should have been more assertive, I should have stopped the program at that point.

Mr. ADLER. Well what number would you say is the number of patients who didn't get adequate care? The total you did was 116, of that number what would you say? I have heard numbers, 57, 35, and 92. What number would you say was the number?

Dr. KAO. Sir, since 2008, I have not had access to the patient records, but I believe based on the calculations that our team performed before it was shut down that the cases were far fewer and probably closer to 20 cases that were reported—that were defined as medical events. But again, a case that is defined as a medical event does not mean that the treatment was not effective, sir.

Mr. ADLER. Dr. Hahn, let me ask you. What lessons can UPenn take away from the situation and what sort of failures of oversight would you say were present from a UPenn perspective?

Dr. HAHN. I think that we and our partners at the VA both would agree that there are many lessons that we have learned and will continue to learn from this very painful episode. And let me just say even if it were just one human being who did not receive the best possible care, Congressman Adler, that would be unacceptable.

When we became aware of the allegations in June of 2008, we did a review of quality assurance and peer review, and we determined that they certainly could be improved. And as I mentioned in my statement, but not in great detail, we did institute a number of measures to allow for that improvement, including the oversight of each brachytherapy case that is performed by outside health care team Members within the Department but who didn't perform the procedure who will review the CT as well as the dosimetry to give another level of review.

We have also instituted a system whereby the reportable events to the Department's leadership are such a low threshold such that even a slight anomaly would be reported giving us the opportunity to capture everything.

We have also, in partnership with the VA, instituted a Department-wide system for reporting levels of toxicity. This uses clinical outcomes. If we detect severe or unexpected toxicities, it triggers presentation of what we call our morbidity and mortality conference where people inside and outside of the Department review those toxicities.

And then this other issue of real-time dosimetry, which allows us to see the needle go in and see the dose in real-time with instantaneous feedback.

We feel that these measures are prudent certainly, and that they will and should prevent similar occurrences from occurring in the future.

Mr. ADLER. Thank you, my time has expired. Mr. Chairman.

Mr. MITCHELL. Thank you, Mr. Walz.

Mr. WALZ. Well thank you again, Mr. Chairman, and I want to thank all of our witnesses for being here, and as I always say there is no doubt that everyone in this room wants the best care for our veterans, that is an absolute given. And I also say that it is a zero sum game, so I agree with you, Dr. Hahn. And I think talking about this there is a human face on this. There is Pastor Flippin and his story that was told. We keep that in mind.

I also want to though note, and my colleague from Pennsylvania I think started hitting on this, that your willingness to come here today and answer questions openly is truly appreciated, and it is very obvious that your sense of concern on this is very real, and I am very appreciative of that. Because all too often we get caught up in the legal barriers that people are unwilling to try and fix this, and it is imperative that we get this right.

So with that being said, I also want to thank Dr. Roe, he is always very helpful for me to understand the medical side of this. My postgraduate work was in systems analysis, so that is the part that I am most concerned about, and it seems that many times we keep coming back to that of looking at these things to see if they are not just isolated incidents, but if there are things—and building on what Mr. Adler was talking about—a couple of questions I have had.

We have recently had the questions that come up here, improperly sterilized equipment, and we are asking where best practices fall. And something as simple as a checklist for who last cleaned the equipment, none of that was available.

So one of the red flags I think in this whole thing that came up for me was listening to people talk about the lack of peer review involved in this. And many, and I think it was Dr. Welch who commented, in all of his medical practice he has never seen such a lack of peer review in the process that was happening.

Can one of you comment on that of do you think that is true in the radial—the oncology here at VA as it stood in Philadelphia? Was there a severe break down in peer review, which is meant to be there as a safeguard? Can anyone comment on that?

Dr. HAHN. Congressman Walz, there was peer review in place. Brachytherapy represents about 5 percent of the treatments that we give, and there is peer review for both external beam as well as all the treatments that are given. I think Congressman Walz, there is no question in our mind that when we looked back at the peer review processes, and I think it was the first process that we implemented—process change—that being dependent upon the local treatment team in and of itself to report quality issues without having a secondary look by external physicians and physicists was something that needed to be improved, sir.

Mr. WALZ. Would it be your experience, Dr. Hahn, that this same lack of peer review in the beginning or not strong enough is happening at other VA Medical Centers? The reason I ask this is, is the one nearest to me in Minneapolis that also practices this technique has not had—they are reporting zero medical events in this.

And I want to be very clear on this, one of the things that gets highlighted on this is we don't know at private practices if this is happening because there is no reporting, so I think that needs to be kept in mind. Because I am wondering across our entire health care system outside the VA it is hard to make those comparisons. But inside the VA are there different peer review standards at different institutions as far as you know?

Dr. HAHN. Congressman Walz, I wouldn't know the answer to that question at other VA institutions. I can tell you that at Penn across our own institution our processes were the same for all the patients that we delivered care to both at the satellites outside fa-

cilities and at Penn, and again, this provided us with an opportunity to look at our processes because we do uniformly apply them and to make sure that they get better constantly.

Mr. WALZ. Should this be something in your opinion, Dr. Hahn, on these things, and it comes up again, it is very similar to the question on the unsterilized equipment in the last hearing, should there be stronger standards set across the VA system, or do you still need to allow the Veterans Integrated Services Networks (VISNs), do you need flexibility on this for best practices, or is there a uniform best practice in this process that could have been set, followed, and that is it?

Dr. HAHN. Well I think my esteemed colleague Dr. Lee will speak to some of these issues in the next panel, but I think that if you look at practice guidelines for brachytherapy, the consistency and application of those sort of guidelines would be very helpful, and I think we have learned a lot of this across medicine. You probably know better than I in terms of processes that standardization is often a very helpful thing with respect to ensuring quality.

Mr. WALZ. Very good. My last question, and this is to all of you as again a charge that was made, and I again want to make sure and I think it has been pointed out, that this is about improving the process not about finding fault.

But the one thing was there was a comment made by Darrell Wideman I believe it is, senior health physicist for the Nuclear Commission that said, "There was far too much trust put in contractors, that the VA said we hired the best, we went to a well-regarded team and we just turned over and capitulated our responsibility."

Can you comment on that? I know it is a little bit—I am going to ask each panel this or try and get that out. Being the contractors involved in this do you think there was a sense of that, that it is you guys do it and that is where it sets?

Dr. HAHN. Congressman, I think one of the things, and I agree with you sort of what we learned about this and we sensed this—and I don't want to speak for the VA—but we sensed this as a joint responsibility of oversight, and sometimes when there is joint responsibility there is lack clarity and definition, and so I think there is plenty food for thought for us for all on this. And I really welcome the opportunity to work with the Philadelphia VA to provide clarity surrounding that.

Mr. WALZ. Well I appreciate your candidness and I yield back. Thank you, Mr. Chairman.

Mr. MITCHELL. Thank you. Mr. Fattah.

Mr. FATTAH. Thank you, Mr. Chairman. Let me just try to clarify one thing before I ask the question. I know that Senator Specter tried to do this at the last hearing, so I want to make sure we clarify this on the record. Reverend Flippin was not your patient; is that correct, Mr. Kao?

Dr. KAO. He was initially seen by another radiation oncologist.

Mr. FATTAH. Right.

Dr. KAO. But then I did the brachytherapy.

Mr. FATTAH. Okay. So he was in this program, brachytherapy. I looked at Google, and it says that one of the normal problems that

comes up for brachytherapy is seeds outside the prostate in the rectum or in other areas.

My point is that if this is a normal occurrence and this happens generally, why are there so few reports by the NRC that this is a medical reportable event? And I am speaking in generality, across both private and VA, you know, if it is happening regularly and nobody is reporting it then there seems to be a more system-wide problem that we may want to attend to that is well beyond the VA.

Dr. KAO. Yes. As I testified last month at the panel, sir, that you were on, the definition of a reportable medical event is evolving, and it is likely that many practitioners are not aware of it or apply it. The Medical Advisory Committee to the NRC one Member, Dr. Nag, estimated that applying the current definition of a reportable medical event there should be 20,000 reported cases, and this definition is, therefore, changing. So it is still not quite settled what constitutes a reportable medical event I think for most practitioners.

Mr. FATTAH. And how many were reported? If the NRC's medical advisor felt there should be 20,000, how many were reported across the country?

Dr. KAO. Sir, I do not know.

Mr. FATTAH. Okay, all right. Now the program at a number of the VA centers, four of them have been closed down, including Philadelphia. So patients who were being treated, and I think you said that none of these tumors have re-emerged, where are they now being treated if they need this service?

Dr. KAO. Our program made the decision early on that after the brachytherapy the patients could return back to their doctor that took care of them from where they were located. And that is one of my regrets is that we should have—we could have mandated that they come back to Philadelphia for follow up.

In the case of Reverend Flippin, as I testified last month, I wasn't notified that he had developed problems. I wish I was, I could have done something about it.

And so that is one of the recommendations that I had proposed in my written detailed testimony to the Committee that the VA could institute a system by which any patient that develops a problem that the original treating physician could be notified, and perhaps that would have prevented something like what happened to Reverend Flippin.

Mr. FATTAH. Well is it, and let me ask the Chair of the Department since, Penn has been treating people both in the VA and outside of the VA, you know, privately, right? Now again, when you research this on the Web it says that seeds going into the rectum or you know going outside the prostate is one of the problems that arises with this type of procedure, right? When patients have these challenges, is someone notified at the NRC? Are we reporting this as a medical noteworthy event or where are we at in this process now? I assume even though the VA program is shut down, Penn is continuing to provide this service to the patient.

Dr. HAHN. Once we put our process improvements in place in the real-time dosimetry program yes, we recently did restart our prostate brachytherapy program, Congressman.

Mr. FATTAH. All right.

Dr. HAHN. And I think Dr. Lee in his written testimony has written about many of the standards that the NRC, particularly with respect to dose, that the NRC has in its regulation.

I can't speak per se to the VA and its reporting mechanism since it is a separate hospital and has a separate regulatory reporting. I will say in light of that, that the standard that has been applied to these cases is one that is in our belief complex and controversial, and is not——

Mr. FATTAH. Is that because the 90D fluctuates up to 60 percent either way? So you are saying 90 percent of the dose should have been inside the prostate and it could fluctuate by a wide variance?

Dr. HAHN. There can be some variation, yes, Congressman. And that standard or that criteria that has been recently applied isn't universally accepted by all the experts in the field.

I think this goes back to the original comment that I had made, Congressman, about the fact that we would all very much welcome further clarification with respect to that. And the other part is that sort of distinction between a medical reportable event and clinical significance and outcome.

Mr. FATTAH. Right. Well, the main thing about prostate cancer is you don't want to get it, but if you want to get it you want to get treated, and we have a great difficulty getting men to get treated, to get checked out. So I want to make sure that we are careful here as we proceed when we have a treatment that—in this instance tumors didn't reemerge, and yes there was some discomfort. I read on Google that discomfort in the rectum or seeds in the rectum it is a very common occurrence in this procedure, right? So I want to make sure that we are not sending the wrong message to men in that we create a situation where they don't proceed with getting effective treatment that could save their lives.

Dr. HAHN. Congressman, I think that is a really important point, and sir, I would like to sort of emphasize the fact that radiation therapy, despite the issues here, is a highly effective therapy for prostate cancer, and in the appropriate patients that is indeed the case.

Mr. MITCHELL. Thank you. I would hope that since University of Pennsylvania is a teaching hospital and research that what you have learned from this gets put into the appropriate journals, gets distributed to every urologist and everyone. I would think this would be a great source of information for other people doing the same thing.

If the panel would indulge me I would like to call on Dr. Roe, he had a couple more questions.

Mr. ROE. Just a couple things quickly. When you do this procedure you know, and I may be talking to the physicist, but we know what adequate dosimetry is, I mean that is a calculation, if you go below that level you know that you haven't received what we would consider adequate. That is fairly well determined, correct?

Mr. BIEDA. It is determined to the extent that the prostate can be defined on the imaging modality, in the case, CT. So it is well defined mathematically and algorithmatically, but there is some subjectivity because of the ability to clearly image the prostate, particularly in post-implant dosimetry.

Mr. ROE. I know there is an art to it too, I certainly understand that.

Mr. BIEDA. Yeah.

Mr. ROE. When you would see a pattern like this though, I was looking at these images last night, this being the prostate gland, these little green things here are the seeds, when you look at that the next day when you do the CT, some do it a month later, I think Duke does it a month later and looks at the dosimetry, I mean that would be a cause of concern when you would have a pattern that looked like that wouldn't it?

Mr. BIEDA. Yes, that would be a cause of concern, but what you have to understand is what you are visualizing there is a 3–D rendering, that red object is the physician's, I would almost say best guess, at the contour of the prostate. You know, it is a dramatic diagram for sure, but it doesn't necessarily tell the whole story just because of the subjectivity of imaging the prostate.

Mr. ROE. I mean, you would be like me——

Mr. BIEDA. Yeah.

Mr. ROE [continuing]. You would be a whole lot happier if it looked like that.

Mr. BIEDA. Yes.

Mr. ROE. I mean, I know I would be if that were my prostate and you had put seeds in it or radioactive iodine or palladium or whatever you used, I would be happier with that one.

Mr. BIEDA. I would.

Mr. ROE. I guess the other question I had was why was it—Dr. Kao's issue is that what was the problem with getting the dosimetry results back? And I guess I have confusion with that. Why was that so hard?

Mr. BIEDA. That was so hard simply because there was a roadblock in terms of an information technology (IT) issue at the—you know—at the VA. And to get these images into our system to do that full analysis was deemed to be nearly, you know, pretty much impossible, and we knew that the physician was reviewing the CTs, they just weren't able to get it into the system where the full analysis could be done.

Mr. ROE. I would think that would be a system breakdown, I believe, and I think Dr. Kao is right about that, to be able to get that information.

I know Congressman Walz is gone, but where we are at our university and in our tumor registry, we register every tumor patient and they are followed so you will know. I don't know what kind of follow up we had on these veterans or not, but in most places there is a tumor registry, there is a follow up, there is a follow up form. Has that been done for the veterans that have received this treatment? Dr. Hahn or Kao or whoever can answer that.

Dr. KAO. I don't know the answer, sir.

Mr. ROE. Not to interrupt, my time is about out, but that is critical, because you don't know what you are doing if you don't know what your patients are doing, so we register all ours on a tumor registry and follow those folks, have a method to do that. Congressman Fattah was right on the money, are these folks—how are they doing, what is the outcomes? And you can't say they are doing all right if you don't follow them, so that is a system break down.

And I think that just to follow up, brachytherapy is an effective treatment for prostate cancer. My friend that I work with a lot said he had patients that could go out and golf in 2 or 3 days after this so men won't be afraid to get that therapy. It is a good effective therapy when done appropriately.

Thank you, Mr. Chairman, I yield back.

Mr. MITCHELL. Thank you. Does anyone else want to follow up before we go to the next panel?

Mr. ADLER. Maybe just one. I heard the colloquy between Dr. Kao and Congressman Fattah about sort of the art of brachytherapy that maybe not all the radiation seeds get to the prostate, that some of them may drift out to other parts around the prostate. What percentage of the seeds should end up in the prostate? If you have 100 percent of the seeds going in what is the percentage that should be ending up in the prostate for the art to be effective science? Because I guess what I am hearing is maybe a third sometimes drift around, half of them may get here or there. I would think that most of them should be ending up in the prostate if in fact the tumor you are addressing is in the prostate.

Dr. KAO. That is correct. Most of the seeds should be in the prostate. However there are situations where it may be advantageous to have seeds actually outside the prostate. The prostate is a pear-shaped gland with a pointy end pointing down. If you have a cancer that is located in this apex of the prostate the seeds in the prostate alone may not be sufficient, so in that case you may intentionally want to place some seeds outside the prostate, which can then contribute radiation to treat that special location. So it depends on the location of the cancer and the extent.

We are very careful to restrict brachytherapy to patients that only had a very early stage non-aggressive form of prostate cancer, sir.

Mr. ADLER. Thank you, I yield back.

Mr. MITCHELL. Mr. Fattah, do you have any other questions of this panel?

Mr. FATTAH. No, let me just thank the panel for their lifetime of study of this issue of cancer, it is a major challenge to our health in our country today, and prostate cancer is something that for veterans is a major issue, and in the African American community, particularly among African American males prostate cancer is a tremendously devastating disease. So I want to thank them for their studies and their work, and I think that as we go forward we want to see that we can make this an even more perfect process at the VA and outside the VA. Thank you.

Mr. MITCHELL. Thank you. And I would like to excuse the panel and thank you for your service and thank you as Mr. Fattah said for the research that you are doing.

At this time I would like to welcome Panel Two to the witness table. From our second panel we will hear from Dr. Robert Lee, Professor in the Department of Radiation Oncology at Duke University testifying on behalf of the American Society for Radiation Oncology (ASTRO); Dr. Paul Schyve, Senior Vice President for Health Care Improvement at The Joint Commission; and Steven Reynolds, Director of Division of Nuclear Materials Safety Region III, U.S. Nuclear Regulatory Commission. Mr. Reynolds is accom-

panied by Dr. Charles Miller, Director of the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission.

Dr. Lee, before you begin your testimony I believe there are some slides that we are going to view and I would like for you to comment on the slides you find acceptable and the slides that are unacceptable in your professional medication.

Before I begin I just want to say to Dr. Lee, Dr. Schyve and Mr. Reynolds, you have up to 5 minutes for your testimony and all of what you would like to say will be entered in the record. Dr. Lee.

Dr. LEE. So a quick question, my comments on the slides and images——

Mr. MITCHELL. Will not be part of your other testimony.

Dr. LEE. Thank you.

Mr. MITCHELL. Yeah.

Dr. LEE. You want me to comment on the image in front of me?

Mr. MITCHELL. We don't have any.

Dr. LEE. I think I see it but no one else does.

Mr. MITCHELL. Okay, we have just an IT problem, maybe we will move onto the next witnesses and come back to it. Okay. Dr. Schyve.

STATEMENTS OF PAUL M. SCHYVE, M.D., SENIOR VICE PRESIDENT, THE JOINT COMMISSION; STEVEN A. REYNOLDS, DIRECTOR, DIVISION OF NUCLEAR MATERIALS SAFETY REGION III, UNITED STATES NUCLEAR REGULATORY COMMISSION; ACCOMPANIED BY CHARLES L. MILLER, PH.D., DIRECTOR, OFFICE OF FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS, UNITED STATES NUCLEAR REGULATORY COMMISSION; AND W. ROBERT LEE, M.D., M.S., M.ED., PROFESSOR, DEPARTMENT OF RADIATION ONCOLOGY, DUKE UNIVERSITY, SCHOOL OF MEDICINE, DURHAM, NC, ON BEHALF OF THE AMERICAN SOCIETY FOR RADIATION ONCOLOGY

STATEMENT OF PAUL M. SCHYVE, M.D.

Dr. SCHYVE. On behalf of The Joint Commission, thank you for the opportunity to testify at this important hearing. The Joint Commission's accreditation of Department of Veterans Affairs' hospitals strives to assure that our Nation's veterans are receiving high quality and safe care. The accreditation process reduces risks to patients through periodic unannounced on-site surveys of each hospital and feedback to the hospital of required improvements. However, no oversight process can entirely eliminate risk in health care, which has all the characteristics identified in other high risk endeavors, including complexity and heavy dependence on human intervention. By studying high risk endeavors that have developed enviable safety records, health care is learning how to become a high reliability endeavor.

The first step is the development of evidence-based standardized policies and procedures, educating personnel in their implementation, making them available as memory aids to facilitate their use, and monitoring whether they are followed. However, in health care

unexpected adverse events will still occur despite the best policies and procedures.

To create high reliability requires three additional components. First, constant attention to things that go wrong in order to learn how to prevent them. But people will only report adverse events in an atmosphere of trust in which they are encouraged to report and their reports are acted upon.

Second, prospective risk identification and prevention whenever new processes are planned or existing processes changed. Patients can be protected from harm by redesigning the proposed processes to eliminate the risk or building in protections for patients when the risk cannot be eliminated.

And third, a culture of safety. In a "culture of safety," safety is always on everyone's mind. There is preoccupation with the possibility of failure, a sensitivity to the detail of operations, and constant vigilance for unexpected events. Because, in complex processes such as those in health care, even small events can led to big, sometimes disastrous outcomes.

Unfortunately, no oversight body can identify all the risks or breakdowns in a hospital, nor create the cultures of trust and safety needed for high reliability. Only the hospital itself can. The oversight bodies can set expectations, provide guidance, educate, and evaluate in order to enable and incentivize the hospital to make this change.

To that end, The Joint Commission has established standards that require the hospital to create a culture in which adverse events are reported and evaluated for underlying causes and preventative actions are taken; to identify high-risk processes and prospectively determine their possible modes of failure, the effects of those failures, and the actions that will prevent the failures or mitigate their effects; and to establish a culture of safety throughout the hospital. This last accreditation requirement became effective January 1st, 2009.

With respect to brachytherapy, when the Joint Commission surveys a hospital the surveyors examine the radiology imaging services and, if the hospital provides it, its oncology service. However, a hospital may provide a brachytherapy service that, because it is usually a low volume, specialized service within the radiation oncology or other department, may not be reported to the surveyor and therefore may be unknown to the surveyor.

In addition, brachytherapy is highly specialized and technical, utilizing the expertise of urologists, radiation oncologists, and radiation physicists. Even when its presence is known, it is not possible for the surveyor to have the specialized technical knowledge to review the effectiveness of the dosing schedule for a patient.

Based on this case, the Joint Commission will instruct its surveyors to specifically ask if brachytherapy is provided, and, if so, to examine whether the hospital is providing the monitoring and peer review oversight that brachytherapy requires. And beginning this year, the surveyors are evaluating what the hospital's leaders are doing to create a culture of safety in their hospital.

The Veterans Health Administration (VHA) central office has been a leader in learning from adverse events in its hospitals, in disseminating that knowledge to other hospitals in its system, and

in openly discussing with the Joint Commission the events and what they have learned. They have also focused on creating a culture of safety in their hospitals.

The Joint Commission's goal is to assist both the Veterans Health Administration and its individual hospitals to make this transition. Only by transforming our Nation's hospitals into high reliability organizations will health care fulfill its obligation to all our Nation's citizens, including its veterans, to "first do no harm."

On behalf of The Joint Commission, I would like to thank you again for this opportunity to testify.

[The prepared statement of Dr. Schyve appears on p. 53.]

Mr. MITCHELL. Thank you. Mr. Reynolds.

STATEMENT OF STEVEN A. REYNOLDS

Mr. REYNOLDS. Chairman Mitchell, Ranking Member Roe, Members of the Subcommittee and Congressman Fattah, I am honored to represent the U.S. Nuclear Regulatory Commission staff at today's hearing.

The NRC is very concerned about what happened at the VA hospital in Philadelphia.

Our mission as the regulator for the civilian use of nuclear material is to protect public health and safety, including medical uses of radioactive material. We take our mission very seriously and strive to make sure all patients, including our veterans, receive safe and effective medical care. We recognize that is not what happened at VA Philadelphia.

The NRC does not regulate the practice of medicine. We do, however, set the rules under which licensees such as the VA use radioactive material. As the holder of an NRC license, it is the responsibility of the VA to identify problems in medical treatments using radioactive material and report those problems to the NRC.

The NRC, once notified of the apparent problems at VA Philadelphia, began increasingly intensive inspections of the brachytherapy program at VA Philadelphia and the 12 other VA facilities that conduct this medical procedure. We are concerned about what we have found to date.

The VA has suspended this procedure at five sites, includes VA Philadelphia, and they will not restart until we, the NRC, are satisfied they have addressed the problems. Our inspections are continuing, and once we complete our inspections later this summer, the agency will determine what, if any, enforcement actions are appropriate.

As a regulatory agency we are accountable for ensuring the safe use of radioactive material in medical treatments; we have an obligation to aggressively oversee radioactive material use and make sure patients are properly treated. The VA's license issued by the NRC requires the VA to establish an internal, independent framework of oversight consistent with NRC regulations, and with inspection and enforcement policies, procedures, and guidance. The NRC relies on the integrity of this framework. Based on what we have identified to date, we, the NRC, are making changes. Had these changes been in effect in the past, we are confident that these issues would have been identified and resolved earlier.

We have already initiated steps to enhance our oversight. These include an increased focus on safety culture at medical facilities, an increased focus on medical facilities oversight of contracted medical professionals, increased focus on ensuring that involved medical professionals and radiation safety staff understand the definition of a medical event and reportable requirements, an increased focus on extent of condition reviews, and increased focus on post-treatment dose verification. The NRC is also increasing our oversight of, and reducing our reliance on, the VA's National Health Physics Program.

Going forward, we will continue to look critically at improving our inspection and licensing programs, as well as to consider proposed regulatory changes. The NRC is also assessing whether any additional changes are needed to strengthen our regulatory oversight of the VA with respect to the VA's internal regulatory framework.

In closing, the NRC takes these medical events very seriously. We will do what it takes to ensure the use of radioactive material in medical treatments is as safe as possible. Thank you and I would be pleased to answer any questions.

[The prepared statement of Mr. Reynolds appears on p. 55.]

Mr. MITCHELL. Thank you. Dr. Lee, I think we are ready.

STATEMENT OF W. ROBERT LEE, M.D., M.S., M.ED.

Dr. LEE. I would first like to thank the Committee for the opportunity to testify.

I want to begin by pointing out that images are frequently deceptive, and I am going to hypothesize that—I am using the cursor here—that the green is the bladder, the red is the prostate, and the blue is the rectum. Recognize that there is a certain amount of disagreement among experts about what the red may look like, therefore any dosimetric quantifiers that are related to this volume may be different according to different reviewers.

Now to Dr. Roe's point, would I rather have my seeds in my prostate here than down here? Absolutely. And I think one can look at that image, and if one assumes that the contours are done correctly, one can conclude that the seeds are in the prostate, but it does not follow necessarily that this is a good implant. It could be that there are too many seeds of too high activity, in which case there is an overdose, it could be that there are too few seeds of lower activity, hence too low of a dose.

So I want to emphasize to the panel that images can be deceptive, and frequently you need more information.

Additional information I would like to know is when was this image obtained? If it is obtained 2 hours after the implant then my standards for what is an acceptable implant are different than if it is done 30 days after an implant, and we really have no idea what the implications are of CT scans done a year or two after implants.

I assume you have another image of—anything further there? I can't advance the images. Okay. I am going to take this opportunity to use this image as an example as was pointed out by Congressman Fattah.

Frequently the radiation oncologist calls for and intends to place seeds outside of the prostate. There are many different techniques that are used. Some people like to keep the seeds inside, some people like to put a lot of extra prostatic seeds to lower the dose centrally. That is sort of the stylistic technique. And these seeds, which may be technically outside of the prostate, are in fact having a purpose in that it is physically not possible to bring your dose out far enough, especially at the edge of the prostate, unless you put seeds at the edge of or in fact outside of the prostate.

Posteriorly, which is where most of the toxicity is, you need to be much more careful. And so a seed outside of the prostate here I am less concerned about than a seed outside of the prostate or multiple seeds out of the prostate posteriorly.

Want me to scroll through? Okay. Given the uncertainty about when this was obtained relative to the prostate implant and the uncertainty with which the volumes are created this doesn't look good. There are no two ways about it. And if I saw this in one of my cases then this is a medical event. The question then becomes what do you do? Can you fix it? Do you put in more seeds up here? Do you add external beam? And that is where I don't think we have any confidence.

Shall I proceed with testimony? Thank you.

Chairman Mitchell, Ranking Member Roe, and Members of this distinguished Subcommittee, good morning and thank you for the opportunity to testify today on the use of brachytherapy to treat prostate cancer. I have personally witnessed the benefits of brachytherapy, and look forward to telling you about this treatment, focusing on its safety and its effectiveness.

I am currently Professor of Radiation Oncology at Duke University School of Medicine and have performed prostate brachytherapy since 1997. I evaluate over 300 new prostate cancer patients each year. I have authored 100 or more original articles and reviews on reproductive and urinary system cancer, and I am considered an expert in the field of prostate cancer. I believe my testimony is critical to help Congress and the public understand that brachytherapy is a safe and effective procedure.

On a more personal level, I am the son of a retired air force navigator who presently depends on the VA system for his health care.

While I am not personally involved in the investigation into the Philadelphia VA, based on the information that is publicly available, I agree that there is cause for concern.

ASTRO, whom I represent, is deeply troubled by the problems identified, but we are heartened that the NRC has found no evidence of widespread medical events involving brachytherapy. In fact, there are approximately 50,000 brachytherapy treatments performed in the U.S., and according to the most recent advisory Committee, only about 0.22 percentage of the procedures nationwide resulted in a medical event. Clearly brachytherapy is a very safe procedure.

My hope is that patients, including our Nation's veterans, will recognize that the situation at the Philadelphia VA is an isolated incident, it should not dissuade patients from choosing brachytherapy if appropriate as a treatment for their cancer. At the same time, ASTRO is committed to working with Federal regu-

lators to learn all of the facts from these serious events and use this information to ensure that this episode is not repeated.

Radiation therapy is the use of radiation to safely and effectively treat cancer and other diseases. Patients receive radiation therapy externally or internally. During external beam radiation, a beam of radiation is directed at the tumor from the outside of the patient. Internal radiation or brachytherapy, is the placement of radioactive sources into or next a tumor. For more than 100 years brachytherapy has been an effective method of delivering radiation to the tumor while sparing surrounding tissues.

I would be remiss if I didn't take this opportunity to briefly call your attention to the centers for Medicare and Medicaid Services' recent proposals to cut Medicare payments for community radiation oncology by 19 percent. ASTRO urges Congress to help prevent these draconian cuts that are certain to limit patient access to these life saving cancer services.

ASTRO is also very concerned that had perverse financial incentives and rampant self-referral of radiation therapy services in the Medicare Program is resulting in prostate cancer patients not being fully informed of the full range of options, particularly brachytherapy, and we hope that the appropriate concerns over the brachytherapy program at the Philadelphia VA will not exacerbate the under use of this very effective treatment option.

Prostate brachytherapy is a safe, effective, minimally invasive outpatient procedure that is associated with a quick recovery and return to normal activity and work. The benefits of prostate brachytherapy include equivalent cure rates with a lower incidence of impotence and incontinence than other treatments.

Prostate brachytherapy is performed by inserting small metal seeds of radioactive iodine and palladium directly into the prostate gland and the periprostatic tissue.

My written testimony includes clinical practice guidelines that have been published in the peer reviewed literature for at least a decade, and in particular, I want to highlight the importance of performing post-implant dosimetric assessment of some type of. Post-implant dosimetric assessment documents the actual dose that the prostate has received and the nearby normal tissues to identify any over dosage or under dosage.

As you know, the NRC has jurisdiction over the use of radioactive materials, including medical isotopes and safety measures to protect the public and patients. Almost all radiation oncologists meet NRC's requirement by completing 4 years of training within a residency program accredited by the Accreditation Council for Graduate Medical Education. Such training requires 700 years of work and study, including radiation physics, radiation biology, as well as safe handling, and use of radioactive materials. This is in addition to the extensive clinical training in oncology. Duke Medical Center has considerable safety protocols and procedures for prostate brachytherapy, the details of which can be found in my written testimony.

Finally, I would like to illustrate the benefits of brachytherapy by telling you about the story of one of my patients. He is a university professor and an ardent long-distance runner. I met him 8 years ago. He had early stage prostate cancer, and after discussion

of all treatments, he chose brachytherapy. He told me he chose brachytherapy so he could continue to teach his students, coach his daughter's soccer team, and train for an upcoming marathon. He was treated with brachytherapy in the spring and later that year he ran in the Marine Corps marathon. Seven years after his treatment, his PSA is undetectable and he is very likely cured. He has run in a marathon every year since his treatment.

ASTRO shares the Committee's concerns about the health and safety of veterans and recognizes the importance of maintaining veterans access to high quality cancer treatment. We look forward to having all of the facts from the VA investigation made public by making these issues transparent. Necessary steps can be taken to implement any corrective actions and enhance quality.

ASTRO is committed to ensures that radiation oncologists and Members of the treatment team adhere to strict safety standards and clinical guidelines for all radiation therapy, including brachytherapy.

Thank you for the opportunity to testify.

[The prepared statement of Dr. Lee appears on p. 58.]

Mr. MITCHELL. Thank you very much. I just got a couple questions here, and this is for Dr. Lee.

In your opinion, the situation in Philadelphia at the Medical Center there, is it an isolated event, or does the VA have a much larger problem? And I want to extend that, I don't want to just pick on the VA, because I have a feeling since what happened in Philadelphia was done with a contract with the University of Pennsylvania, that if this same procedure would have happened at the University of Pennsylvania hospital the same results would have occurred, it wouldn't have occurred just because it is in the VA hospital. I don't know if that is right or not. But is there a problem period, maybe in the VA system or in the system throughout this country with this—with the follow up and the therapy that was given which brought this to light to begin with?

Dr. LEE. So I am speaking as an informed sort of professional here. Based on what I know publicly the NRC has been very proactive and is presenting a very high bar for the VAs to meet. In fact, perhaps some of the best and most important work in this field of prostate brachytherapy comes from the VA in Seattle. So that there is precedent and documented evidence that this can be done well within the VA system. I don't think it has anything to do with the VA.

Mr. MITCHELL. Well what about what happened in Philadelphia happening in private hospitals or happening other places?

Dr. LEE. So the concern that this is a more widespread phenomenon?

Mr. MITCHELL. Right.

Dr. LEE. I would say the NRC data suggests that that is not true, and there are two additional pieces of information that make me feel confident that good high quality brachytherapy is being done across the country.

One piece of information relates to something called the "Radiation Therapy Oncology Group," which is an National Cancer Institute (NCI) supported oncology cooperative group in which institutions across North America treat patients according to protocols,

and they had two, and have a third ongoing study at a deals specifically with prostate brachytherapy in which all of the information, including the post-implant CT scans, are sent centrally and reviewed by a reviewer. And I was the principal investigator of one of those reports, and based on my assessment of those institutions, good quality brachytherapy is available across the country.

The second piece of information that I use to feel good that good brachytherapy is accomplished across the country is we do have some large Medicare claims-based data looking at prostate brachytherapy and looking for significant severe complications. And we have several publications in the literature that demonstrate that from 1991 all the way up to about 2000 that the complication rate associated with this procedure across the country in Medicare beneficiaries is very low, which is another piece of information that makes me feel confident that it is being done well.

Mr. MITCHELL. You mentioned one of your patients as a marathon runner and so on. When a person comes to you, you said you do about 300 or over 300—you see 300 prostate patients a year?

Dr. LEE. I don't do 300 prostate brachytherapy, I see 300 new prostate cancer patients.

Mr. MITCHELL. Right.

Dr. LEE. Yeah.

Mr. MITCHELL. Does a person come to you after they have seen a urologist, or do they just come to you straight saying I want to look at brachytherapy? When does a patient get the pros and cons of all the treatments?

Dr. LEE. So typically most of the patients I see have been biopsied by a urologist, and then frequently will ask for a quote, "second opinion."

So at Duke where I work and like many other places we have something called a "multi-disciplinary clinic" in which patients with newly diagnosed prostate cancer come in, they see me as a radiation oncologist, they see a urologist, and they see a medical oncologist simultaneously in which the pros and cons of each treatment are discussed. And the vast majority of the time the treatment decision comes down to patients, and that it is very clear to pick a winner amongst the many treatments out there, and frequently the patient will decide based on his or his family's own concern.

So in the best of all worlds all prostate cancer patients would be seen by a urologist and a radiation oncologist. I don't know how frequently that happens. At Duke it happens a lot, which is good.

Mr. MITCHELL. Are you aware when the brachytherapy is done, are there urologists in the room at the time?

Dr. LEE. So this is a procedure that I continue to be amazed can be done in a number of different ways, and you still seem to come up with reasonably good results.

So in my practice from the very beginning I have involved a urologist and we do it together. We train each other such that I can do it by myself and he can do it by himself, but we are there together, and I think it is sometimes better to have two heads. He brings his urologic or she brings her urologic expertise, I bring my understanding of three dimensional anatomy in physics, and together I think you get a better product.

That said, there are multiple examples of radiation oncologists doing it themselves. Okay? And I have seen cases where urologists essentially do everything, and the radiation oncologist stands in the corner. Urologists can't do this because by themselves they need an authorized user, but it can be done any number of different ways.

At Duke I do it with a urologist that has been doing it for 10 years or 15 years, as much as I have, and he does a needle, I do a needle, he does a needle, I do a needle.

Mr. MITCHELL. Thank you.

Dr. LEE. You are welcome.

Mr. MITCHELL. Dr. Roe.

Mr. ROE. Dr. Lee, thank you, I am going to say hello to a mutual friend of ours, Dr. David Alballa. I spoke to him yesterday and I knew you were coming up here.

So I guess a couple of things, and I won't take too long because we have to go with some votes here in a minute, but at the VA when they were doing this and they couldn't get the dosimetry, would that have waved a red flag for you to say wait a minute, if you can't get the dosimetry why are you continuing to do these cases?

Dr. LEE. Yes, I think to be fair. And this is where I don't know the specifics so I don't want to be too critical. But from the very beginning of my practice, and I have been preaching this from the very beginning, is that post-implant dosimetric assessment is part of the treatment. It is a perfect example of how you can use safety measures. It is a feedback loop. You put the seeds in and then a period of time later you see well how well did we do? And if you are consistently low or consistently high or something like that then you can tweak your practice.

So if I were in that situation then I would either stop the program or I would come up with a work around, where if they could get the images it is possible to do it by hand—do it the old fashion way and circle the prostate. It is a little bit more tedious and it takes more time and it is not as easy to bring the data into the treatment planning system digitally, but it is so vital that if it were me and someone told me tomorrow we can't do post-implant dosimetry for whatever reason, then I would say the program is shut down.

Mr. ROE. And we should be able to, I know that I have worked with Duke and had patients treated there over the years, there is a tumor registry that we follow these patients and you know—and I will bet the VA does this. I know there is not anyone up there and you can't answer this, but I would almost bet that they do have a tumor registry and follow them and be able to tell what the outcomes are.

The other thing I guess, and I would like to know, is what is a definition of a medical event? And it seems to be a moving target.

Dr. LEE. Right.

Mr. ROE. And could you elaborate a little bit on that?

Dr. LEE. So I can tell you what a medical event is at Duke. Medical event is wrong patient, wrong organ, wrong isotope, wrong dose in this context. So if you are supposed to put in iodine and

you put in palladium, medical event. If you put Mr. Jones' seeds in Mr. Miller's prostate, medical event.

Mr. ROE. Pretty common sense stuff. But is that standardized across the country? Because what happened with this I think when we saw this 112 or 114 patients and there were 92 medical events, I started asking myself what is a medical event?

Dr. LEE. Uh-huh.

Mr. ROE. And is the definition the same at Duke as it is at the VA in Philadelphia, and maybe the NRC, Mr. Reynolds can answer that.

Dr. LEE. This is where the NRC I think should comment. In 2002, this misadministration changed to a medical event. So a little bit of it is semantics. Okay? But the wrong patient, wrong isotope, wrong organ, wrong dose have been there for at least ever since I have been in the business.

I think it is fair to say though that there has been some inhomogeneity in how in particular the dose question has been asked. From what I have seen of the VA rules, they for the first time have incorporated this specific dosimetric quantifier D90, which does not appear in any of the NRC's statutes. Okay? And I think that is one possible explanation. That said, I think anyone if they see this that is a medical event.

Mr. ROE. What would be the wrong dose at Duke University? How would you define wrong dose?

Dr. LEE. So for a medical event if I were using—this is the problem, is there is some inconsistency. Do you use D90 or do you do D100? Okay. I fortunately haven't had any medical events. And if I were pressed to say what is your medical event for dose it would be—I would actually go lower, I would say D80 of 80 percent, so I wouldn't put it as high. And the reason I do that is because I am concerned if you put the bar too high then community practitioners that attempt to get over that bar will end up putting in too much activity and increase toxicity.

Mr. ROE. But if you weren't doing the dosimetry you wouldn't know you had a medical event.

Dr. LEE. Correct, absolutely.

Mr. ROE. Which is what was happening.

Dr. LEE. Right.

Mr. ROE. So you wouldn't even know. And I think that is critical to know that so you can change. I mean, not anybody in this room has not wanted to do the job right. There is no question in my mind about that. The problem is you don't know you are doing it right if you don't get the right data.

So Mr. Reynolds, do you have any comment on that?

Mr. REYNOLDS. I was just going to read to you what our regulations say a medical event is.

Mr. ROE. Okay, thank you.

Mr. REYNOLDS. I will read two versions. One is the one that was published January 1st, 2009. "The total dose delivered differs from the prescribed dose by 20 percent or more."

Mr. ROE. Okay.

Mr. REYNOLDS. It also talks about the other things that Dr. Lee talked about.

Now I will read from the January 1st, 2001, version of Title 10 Code of Federal Regulation, Part 35. "When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose." Twenty percent.

Mr. ROE. Twenty percent, so it is pretty well defined. And to let folks know that these seeds when they go in, I want to make it clear, they have a half-life between 17 and 60 days, so that radiation is not there forever.

Dr. LEE. If I can just comment. Twenty percent sounds like a well it is 20 percent or not? The problem that I see is that frequently that dose in the brachytherapy world has been translated to mean activity, and so that if you order 100 seeds of.4 millicuries and you have 40 millicuries, if you put in 20 percent more than that or 20 percent less than that then that is a medical event. I am not saying that is right, I am not saying that is wise, what I am saying is that in my conversations with many people across the country that that is their interpretation of the NRC statute.

Mr. ROE. Thank you, Mr. Chairman.

Mr. MITCHELL. Thank you. Mr. Adler.

Mr. ADLER. Thank you, Mr. Chairman.

Dr. Schyve, as I heard your testimony and read your written testimony my sense was you were explaining how the Joint Commission accredited the Philadelphia VA just 2 days after the prostate cancer program—the brachytherapy program was shut down in Philadelphia. My sense was you were saying it is such a small program, such a low volume program, 20, 30, 40 patients a year, that it sort of flew under the radar of the surveyor, wasn't reported by Philadelphia to the surveyor, so Joint Commission sort of couldn't find it unless it knew to ask for that particular program. Is that really the essence of your testimony?

Dr. SCHYVE. That is basically correct. The surveyor is looking throughout the organization at all kinds of things, always visits the imaging service and always asks if there is radiation oncology, and if so looks at that. But if, as it may be common, the radiation oncology department doesn't say, "Oh, and we are also doing brachytherapy over here," the surveyor may be unaware that brachytherapy is there. And so consequently doesn't look at whether or not there is adequate peer review and so on for brachytherapy, as the surveyor does for radiation oncology in general.

Mr. ADLER. I would respectfully suggest to you that maybe the Joint Commission should pay particular attention to those programs that are more likely to fly under the radar because of the low volume, because those are the programs that probably don't have quality assurance, don't have peer review, don't because of the low volume have the proficiency that comes with doing a program over and over and over again. You get better as you do it more.

Dr. SCHYVE. Yes.

Mr. ADLER. I am hoping one of your take aways for the Joint Commission is to ask those questions. Not about brachytherapy, I think we are now a little bit more cognizant of that program which is going well in most parts of the country, wasn't going so well in Philadelphia, but there might be 3 or 33 other programs like that

in the world that we have to ask about so we don't accredit too quickly. Is that a fair take away for you?

Dr. SCHYVE. Yes. As I indicated in my testimony we will clearly be asking about brachytherapy, but we have had exactly the same thought that that you just described. In fact, we may make that part of the application form that organizations complete before the survey—to tell us and check off that they do we have this service, do have this service and so on. So we would know before the surveyor goes in.

Mr. ADLER. I would really respectfully urge you to do that so that Congress doesn't mandate you to do that, because I think our big concern here is that we don't have failures in other programs somewhere else in the country. We have identified an isolated situation, one small program in Philadelphia which is unique, in Philadelphia it is otherwise a very good history of providing very high medical care as Congressman Fattah said. We want to make sure it doesn't happen in some other similar small volume program elsewhere, whether it is Philadelphia or elsewhere in the country geographically.

Dr. Lee, let me come back to you. You mentioned the situation in Philadelphia that it was an isolated incident. Would you overall agree that it didn't go that well?

Dr. LEE. Absolutely.

Mr. ADLER. Okay. Because I guess I kept hearing from Dr. Kao in Philadelphia when we spoke with him in a hearing there and then again today that it was adequate medical care. My sense was the program wasn't good enough, and I think everyone else acknowledges it, UPenn, VA Philadelphia, VA nationally, NHPP, NRC. You would concur that it wasn't really the best level program.

Dr. LEE. Yes.

Mr. ADLER. Okay. I just wanted to sort of establish that so there is no confusion factually other than from Dr. Kao's own testimony.

Mr. Reynolds, are you satisfied now that you and the VA are sort of on a common track toward having a definition of medical event that is in the patient's best interest?

Mr. REYNOLDS. Yes, sir.

Mr. ADLER. Do we already have it, or we are on the way toward getting it? I guess that is part of my confusion. Because I heard from our previous conversations in Philadelphia, my sense was NRC sort of thought it was the VA's fault that they didn't report well enough and so the program didn't come to light as a problem until the fall of 2008, and that seems to me at least is too late, and maybe your standards have to be different to make them report more clearly so that we catch it sooner.

Mr. REYNOLDS. Well we always look at how we can enhance our regulations and make them clearer. What I read to you seems fairly clear to me. But as I said in my opening statement, we are making changes, trying to get better, and we are looking for the VA to make changes to get better.

Mr. ADLER. I thank you, sir. Dr. Miller.

Dr. MILLER. Congressman Adler if I can amplify that.

Mr. ADLER. You have to amplify with the button on.

Dr. MILLER. There we go. My office is responsible for setting the programmatic standards for the NRC, and we consider ourselves a learning organization. We would like to take what we have learned from VA, what we have heard here today, and information we get from the medical community to always try to make sure that our standards and the guidance that goes along with those standards are clear. Where we find that it hasn't been clear or if we find that people are having trouble interpreting it, we strive to make it clear so that it does set a standard across the industry, and we will continue to strive to do so.

Mr. ADLER. Thank you, doctor.

Mr. MITCHELL. Mr. Adler, votes have just been called so very quickly if you don't mind I would like to see if Mr. Fattah has any quick questions of this panel.

Mr. FATTAH. Yes, I do, and thank you, Mr. Chairman.

So Dr. Lee, first of all, thank you for your work that you are doing at Duke and with ASTRO.

There were 50,000 of procedures last year, and based on your testimony there were 111 medical events in which 102 of them were related to the VA. So that in all of the other private hospitals, private facilities where this is done there were literally almost none. When you play golf, you self-report when you do something wrong, right? And what is amazing to me is that basically if you close down the program at Philadelphia, right, nobody else has made a mistake anywhere in the country in 50,000 different surgeries. Does that seem plausible?

Dr. LEE. Well I think there is an event rate, it is very small. Let me state emphatically that I completely disagree with Dr. Nag's statement about 20,000 medical events out of 50,000 implants.

Mr. FATTAH. He is the medical advisor to the NRC.

Dr. LEE. I know Dr. Nag very well. I have no idea where he comes up with that number.

Mr. FATTAH. Okay.

Dr. LEE. I base my statements on the NRC data, my own individual experience with looking at many post-implant CTs from institutions all across the country within the context of an NCI supported cancer oncology group, and it strikes me that——

Mr. FATTAH. Let us assume that the VA got out of this business, there would be no medical events in this surgery anywhere in the country this year given if you pushed these statistics forward, right? This notion of self-reporting challenges people at times in all different professions, with the exception of surgeons who perform this surgery.

Dr. LEE. I am not sure I understand your question.

Mr. FATTAH. What I am saying is how reliable should the NRC or anyone else be that since there were almost no reportable medical events outside the VA at these four institutions that were cited, should we just assume that there aren't any other instances or that people are not reporting them? Which side of this should we come down on given your expertise?

Dr. LEE. You know, I guess I find no objective data to suggest that it is as widespread as you seem to intimate.

Mr. FATTAH. No, I am not trying to intimate, I am going off your testimony. You said 50,000 surgeries——

Dr. LEE. Fifty thousand, and I am using the NRC data.

Mr. FATTAH. There are 111 medical events.

Dr. LEE. And for the last decade——

Mr. FATTAH. And 102 of them were from the VA.

Dr. LEE [continuing]. And for the last decade roughly a handful of prostate brachytherapy have been medical events each year.

Mr. FATTAH. No problem.

Dr. LEE. So I think wrong dose, wrong isotope, wrong patient, those should be rare events.

Mr. FATTAH. Okay. And I just have one last question, Dr. Lee.

Dr. LEE. And when you look at it in context to wrong site surgery our number is probably much less. And forgive me for tooting the radiation oncology's own horn, but from day one in training programs there is a safety culture. Residents learn that this is radiation. It is the gift that keeps on giving. You cannot take it back.

Mr. FATTAH. I think it is a very safe procedure from what I have read.

One last question. Is a medical event, which in this instance we are talking about low dosage, right?

Dr. LEE. Low dose rate, yes.

Mr. FATTAH. Okay. What does that really mean? Is it as ominous as it sounds or in your view is it something that when reported—in this instance in Philadelphia this was reported by the institution, this wasn't discovered by someone else—and when it is reported what should we take from that in terms of what it means to the—in terms of this program in Philadelphia?

Dr. LEE. So that is an excellent question. I think the panel should be careful not to equate medical event with malpractice, negligence, patient harm, et cetera. A medical event is a specific definition that the NRC has come up with, and it does not necessarily mean that the patient is harmed. I suspect that——

Mr. FATTAH. So when Dr. Kao said the same thing, my colleague who from New Jersey, Congressman Adler was puzzled by it, and that is why I think it is important to hear you comment on it.

And I thank the Chairman for his time.

Mr. MITCHELL. Thank you very much. And I want to thank you for appearing here today. We are going to excuse this panel. We are going take a recess because we have only about 7 minutes left to vote. We have five votes. And we will come back and continue this. Thank you very much. Let us plan on a 30 minute recess.

[Recess.]

Mr. MITCHELL. And I would like to welcome Panel Three to the witness table. Joining us on the third panel is Joseph Williams, Assistant Deputy Under Secretary for Health for Operations and Management, the Veterans Health Administration, U.S. Department of Veterans Affairs. Can you put that all on a name tag? Assistant Deputy Under Secretary for Health for Operations and Management, Veterans Health Administration, U.S. Department of Veterans Affairs. That's a pretty good title. Mr. Williams is accompanied by Dr. Madhulika Agarwal, Chief Officer for Patient Care Services; Dr. Michael Hagan, National Director of Radiation Oncology Services, E. Lynn McGuire, National Health Physics Program Director; Michael Moreland, Network Director for VISN 4; Dr. Richard Whittington, a Staff Physician at the Philadelphia VA

Medical Center; Dr. Kent Wallner, Chief of Radiation Oncology, Puget Sound Health Care System and Associate Professor of Medicine at the University of Washington.

We will recognize Mr. Williams for 7 minutes, and then anything that goes over, of course, your testimony will be in the record and then we will have questions. Thank you for appearing.

STATEMENT OF JOSEPH A. WILLIAMS, JR., RN, BSN, MPM, ASSISTANT DEPUTY UNDER SECRETARY FOR HEALTH FOR OPERATIONS AND MANAGEMENT, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY MADHULIKA AGARWAL, M.D., MPH, CHIEF OFFICER, PATIENT CARE SERVICES, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; MICHAEL HAGAN, M.D., PH.D., NATIONAL DIRECTOR OF RADIATION ONCOLOGY SERVICES, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; E. LYNN McGUIRE, MS, DABMP, NATIONAL HEALTH PHYSICS PROGRAM DIRECTOR, OFFICE OF PATIENT CARE SERVICES, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; MICHAEL E. MORELAND, FACHE, NETWORK DIRECTOR, VA HEALTH CARE–VISN 4, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; RICHARD WHITTINGTON, M.D., STAFF PHYSICIAN, PHILADELPHIA VETERANS AFFAIRS MEDICAL CENTER, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS; AND KENT E. WALLNER, M.D., CHIEF RADIATION ONCOLOGY, PUGET SOUND HEALTH CARE SYSTEM, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS, AND ASSOCIATE PROFESSOR OF MEDICINE, UNIVERSITY OF WASHINGTON, SCHOOL OF MEDICINE, SEATTLE, WA

Mr. WILLIAMS. Thank you, Mr. Chairman and Members of the Subcommittee. Thanks for the opportunity to discuss VA's enforcement of brachytherapy program safety standards.

First before I proceed I would like to take the opportunity to reach out and give my apologies to the veterans and the families that have been affected by this event.

In addition, I would like to acknowledge the Subcommittee and the Members that you represent, as well as the Nation that we have committed to taking care of those who have served in this country.

VA has a well-documented record of quality care, but when there are exceptions, whatever the cause may be, we accept the responsibility and we work with individuals at every level to ensure that we address the needs. We further analyze what went wrong. We take corrective actions. And we look for lessons learned that can be applied throughout our National health care system. VA is not afraid to admit when we make a mistake, and we strive for as few mistakes as possible. We also understand that with transparency comes great responsibility.

My testimony today will briefly describe brachytherapy, review what happened at the Philadelphia VA Medical Center, will ex-

plain the VA's enforcement of safety standards for brachytherapy, and discuss the current status of those programs throughout VA.

Brachytherapy, as you know, is a therapy for prostate cancer. This is a form of nuclear radiotherapy where small radioactive seeds are implanted in the prostate to destroy cancerous cells. Although risk to healthy tissues in the body is minimal, side effects are known to occur.

Brachytherapy is an appropriate treatment and it is an appropriate approach for low-risk patients with prostate cancer, but implant quality must be monitored closely, and in each case performed, and with each procedure it must be reviewed regularly.

And I am thankful that a VA employee identified this and brought it forward, but I regret that it took so long for this to be recognized.

We accept responsibility for the care of your veterans, and we acknowledge that some of the brachytherapy treatments provided at the Philadelphia VA Medical Center did not deliver the intended dose, and we regret that, but we have reached out to the patients. We have notified them by mail and by telephone. We are covering all costs associated with the additional tests while continuing to monitor the care of our patients.

A review was conducted by independent, external physicians and physicists with no involvement with the Philadelphia program. Ninety-two events involving possible under-dosing or doses to organs other than to treatment site were found that met the definition of medical event according to the NRC. It is important to highlight that the definition of medical event does not necessarily mean that a veteran was harmed, and experts still debate the long-term impact of this treatment.

We are working with NRC on regulatory issues related to prostate brachytherapy, and NRC is refining the definition of a medical event as this pertains to these procedures.

The Philadelphia Medical Center brachytherapy program has been suspended since June 2008 and will not be reopened until NRC's concerns have been satisfied and until requirements for the VA's Radiation Oncology Program are met.

Enforcing program safety standards is essential to ensuring patients receive the care that they require. VA, as do other health systems, relies on complementary systems of accountability to identify issues. These are both important to us as it relates to system issues and opportunities, as well as individual issues.

We use multiple internal and external surveys and inspection processes; we use patient satisfaction reports; complaints; individual peer review in our oversight process. The deficits in this program at the Philadelphia Medical Center went undetected by many of these systems for almost 6 years, and it was the recognition of the potential problems by an employee, as I noted earlier, that brought this forward and eventually lead to an in-depth investigation, review, and subsequent disclosure to patients.

We have made much progress since May 2008 and we continue to strengthen our partnership with the people who were on the panels earlier; the University, NRC, Joint Commission, et cetera, and we do this in an effort to strengthen our standards and improve our outcomes.

In November 2008, VA amended the criteria for suspending prostate brachytherapy programs, and we required immediate suspension for any such program where medical events were discovered for 20 percent or more of the patient treatment that were reviewed or evaluated by regulatory compliance.

Moreover, VA also requires the National Health Physics Program to inspect any report of medical events to confirm regulatory compliance and implementation of VHA standards. VA will suspend any prostate brachytherapy program if the results of this inspection indicates 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 Under Secretary for Health.

In response to the concerns raised by the NRC and to ensure other VAMCs were performing prostate brachytherapy procedures correctly, VA completed inspections by January of 2009 of all VA facilities that had active programs. VA also developed and implemented standard procedures to prostate brachytherapy programs addressing quality issues and assurance measures for the safety program.

Regarding future actions to prevent similar situations, VA has asked the American College of Radiology (ACR) to conduct site surveys for each facility, that is each facility performing brachytherapy for prostate cancer. Our goal is 100 percent accreditation. And it is important to note that nationally in the private sector in the VA, only 15 percent of their practices are accredited now.

Furthermore, each facility performing permanent implant prostate brachytherapy must develop, maintain, and implement written procedures based on the American College of Radiology's Practice Guidelines for Transperineal Permanent Brachytherapy of Prostate Cancer and publications by the American Association of Physicists in Medicine.

We embrace change and we are ready to learn from it. VA has used the situation in Philadelphia to conduct a comprehensive review of brachytherapy programs and has developed criteria for suspending and restarting these programs. The VHA clinical standards and procedures are now among the most rigorous standards in the health care industry. There are currently nine programs that meet the standard for brachytherapy, and at this time seven of those nine are active programs. Durham has voluntarily elected to contract their patients in the greater Los Angeles facility as positive program.

Senior leadership in VA is committed to a top down, bottom up review, and we are going to hold the facilities, the networks to the highest quality of standards for our organization.

We regret that these incidents occurred and we are prepared this afternoon to answer any questions that you may have regarding the situation.

Thank you very much for the opportunity.

[The prepared statement of Mr. Williams appears on p. 65.]

Mr. MITCHELL. Thank you very much. I have just got a couple questions, Mr. Williams.

In the brachytherapy procedures conducted at the VA, what is the measure of success?

Mr. WILLIAMS. Well could I defer that to Dr. Hagan?

Dr. HAGAN. Well ultimately the measure of success is a low and stable PSA for the remainder of the patient's lifetime. So the goal of treatment is to remove all vestige of disease. And so patients are diagnosed on the basis of generally having a PSA, prostrate-specific antigen, that is either rising too fast or is above abnormal limits, and so that is the metric that we use to follow patients for the success of their treatment.

Mr. MITCHELL. As a follow up to that, how do you know it has been successful? Do you bring the patient back in?

Dr. HAGAN. Oh, yes.

Mr. MITCHELL. How often is that done? I mean, I would have thought that that would have been caught in Philadelphia. So how often do you bring them in?

I happen to have had prostate cancer, and every year I get a letter from my hospital with a questionnaire, and I also see my urologist every year. It didn't seem like that is what happened in Philadelphia. Or did it?

Dr. HAGAN. Well, I believe it did actually, Mr. Chairman. And the last report I have from the chief at Philadelphia is that out of the 116 cases that we have heard discussed that Dr. Kao treated, there are 6 patients who have met criteria for biochemical failure, that is a rising PSA, that has met our current guidelines of PSA of two above the nadir value, which I can explain if you are interested in the specifics. And there are a further eight who have rising PSAs. The rest are low and stable. But I hasten to add that this is a procedure that the success of which, as you well know, we find out in the long term. And so the fact that there are many of these that are low and stable at present doesn't mean that they will continue to be low and stable through the next decade.

Mr. MITCHELL. This is a question for Dr. Wallner.

Dr. Wallner, what lessons can other VA facilities learn from the implants that happened in Philadelphia? What are we going to do different?

Dr. WALLNER. Well, I think we do need oversight for these sort of low volume procedures that are done in a limited number of places. And I think what the NRC is doing and the VA is doing is a step in the right direction. I mean, there are going to be other procedures where this is going to come up and hopefully we can keep on top of it better than this. I mean, it is a moving target.

Mr. MITCHELL. One of the things I gathered from the earlier testimony is that there was a failure in some of the IT equipment and that they would have noticed this earlier and quicker if the equipment would have been up and operating.

Dr. WALLNER. Yeah, I mean, it is difficult. I have worked in VA for 11 years, I love it, but it is difficult sometimes to get things done in a timely fashion.

I mean, there is no question that the head of the program should have stopped it right then. I mean, you cannot do an implant if you do not have the feedback to know if you did a good job. I mean, to me that was probably the biggest fault in the whole thing.

Mr. MITCHELL. And that was a fault of the equipment or the facility in Philadelphia?

Dr. WALLNER. Well, I mean, the people running the program should have stopped it.

Mr. MITCHELL. You know, the contract between Philadelphia and the VA Medical Center and the University of Pennsylvania was on an interim contract with extensions for 4 years. What was the contracting authority that led the VA to extend this? Did you have authority to extend this?

Mr. MORELAND. Yes, sir, we did have authority to extend it. We issue contracts, and then we at different times we extend the contract or we don't extend the contract or we go out and find a new vendor. But in this case we had a contract and we extended it.

Mr. MITCHELL. I understand that the VA and the OIG Office of Contract Review did a pre-award audit for a new award contract in 2005. And can you tell us why that contract was awarded?

Mr. MORELAND. I don't have that information at my hand.

Mr. MITCHELL. All right, thank you. Dr. Roe.

Mr. ROE. Thank you, Mr. Chairman.

I think one of the things that we have learned and the Chairman and I have been on a number of these in the last 7 months is that we need to have systems. We saw it in our endoscopy oversight and investigation meeting where systems broke down within the hospitals. And it is very complex. This is not a simple procedure that you are doing, where the endoscopy systems broke down. And when we did our last medical malpractice review—the last two we have done in Tennessee—we do it with airline pilots to go through checklists, and they have—something medicine really ought to look at. The more I hear of this the more I am convinced we ought to be doing that. And Dr. Wallner, I know at the VA where you are, at least what I have heard, is you have some of the best results that there are in the country in the VA system. Anything you can share that you are doing with other VAs, I think you have to look at sites of excellence and see what are you doing. Have you done that?

Dr. WALLNER. Yeah, I mean, that is a really tough one to answer. I mean, we happen to do a huge number of these procedures, and we have it done to a science, we specialize in it, we get scans on patients before we let them out the door. I mean, my feeling is I can't sleep well at night unless we check these before the patient walks out the door. Not every place can do that. They are doing a lot of other things. They don't do a lot of this particular procedure. I don't have an easy answer. I still would go back to the NRC and an oversight of the programs would probably be the most practical.

Mr. ROE. Well it would seem like—I guess what I would say, there is no reason to reinvent the wheel. You have already got systems in place, and to share those experiences that you have with the other ten or so VAs that are doing that across the country, since there are not that many sites. This is a lot easier to get a handle on I think.

Dr. WALLNER. Yeah, I mean, it is tough. You know it was in the newspaper today about some of the lawsuits I have been through over the years. I mean, I think if anything unfortunately this is

scaring some of the practitioners away from this, because it is difficult to do it right, and I don't know what the answer is to that.

Mr. ROE. You are talking to an obstetrician here.

Dr. WALLNER. Yeah, that is even worse.

Mr. ROE. I understand.

Mr. WILLIAMS. Sir, if I may comment.

Mr. ROE. Mr. Williams.

Mr. WILLIAMS. We are an organization that is committed to continuous learning. We have learned from this situation and we have made a number of—taken a number of actions to address that. Things that range from training. NRC has spoke about the standards that they were putting in place. I would offer to you, sir, that we have worked very closely with the NRC in establishing those standards and implements those standards in our facilities. Two include pre-implant assessments, assessments during and after treatment for implants. So we have learned from this.

When we talk about how we convey information and training and education and lessons learned to other parts of an organization, you know, we have a vast network of systems and we are using the lessons learned from this, the hard lessons learned from this.

Mr. ROE. I guess one of the things that concern me was that you have your patient there, you have a vital piece of information which is dosimetry, very critical piece of information, and nobody had that information, and yet we kept on doing the procedure, and that was a time I think to take a deep breath, a step back and call a time out and stop.

Mr. WILLIAMS. Yes, sir.

Mr. ROE. The other thing, and I know I feel like I know Dr. Agarwal now by her first name, I have seen her so many times up here. But I know the VA has a tumor registry, at least ours at Mountain Home does, and our hospital does. Very, very vital to have that information. You may think you are doing a pretty good job until you look back over a few years and find out maybe I need to change here. That piece of information is something that you get long term. Five, 10, 15, 20 year data is critical to therapy that you are doing now and you may want to change it. Would you comment on that?

Dr. AGARWAL. Sir, you're absolutely correct. We do have a very robust tumor registry, and we have a tracking system right now that also helps us in going back and looking longitudinally on the interventions that have been administered to our patients and some of the outcomes. So we certainly have been part of the larger system in having that in place. And in fact at Philadelphia itself all the patients who had this procedure have been tracked and have been followed up.

Mr. ROE. So everyone has been.

I guess the last question before we finish, and this will be again to Dr. Wallner. In absence of a national standard, would the VA in Seattle be the gold standard, should that be?

Dr. WALLNER. I think we are looked at as doing an extremely good job at this, and you know, we want to be involved with helping set a standard.

Mr. ROE. Okay. Thank you, Mr. Chairman.

Mr. MITCHELL. Thank you. Mr. Adler.

Mr. ADLER. Mr. Chairman, thank you.

First I would like to thank the panelists. I have met with most of you, not all of you, but most of you some days ago, and it helped my thinking, made me appreciate the professionalism that you have undertaken over a number of years and also your seriousness of purpose to make sure that what happened in Philadelphia isn't a recurring problem, not just in this particular program, but in any program for any veteran anywhere in the country, and so I really appreciate your commitment and your recommitment to provide the level of care that our veterans have earned by their service to our country.

I would like to speak for a couple minutes about the notion of using independent contractors, because my sense is that in Philadelphia at least there was inadequate oversight by VA professionals of the UPenn professional who was running the program and whatever sort of folks that UPenn had working with that professional. So could you comment on your sense of whether or not there was adequate, or as I believe, inadequate VA supervision of the brachytherapy program in Philadelphia?

Mr. MORELAND. Yes, Congressman, I have mentioned to you before, I believe that there was an absence of good oversight at the front end level of this from both our staff and by the provider as well. And had we had that kind of quality data to be looking at this more closely we would have identified this much earlier.

Again, I am proud of the staff at the VA in Philadelphia because they did find out, all be it late, but they did find it. There was courage to bring it forward and point it out, and we have taken significant action since then.

But I do believe that the issue was the frontline oversight to make sure that we were getting the quality data that we needed to get, and that was missed, and we have learned a lot from that. It has allowed us to go back and look at other areas where we have a very low volume technical procedure where we have limited people who know what the procedure is and how it works, that we can bring in other experts to help us. Mr. Williams mentioned some of the external experts we have hired to come in and do that system wide. I think that will benefit all of us.

So sir, I think you are right, I think that is in fact the root cause of the issue at our facility any way, and we have identified that and we are moving forward.

Mr. ADLER. Maybe Mr. Moreland, you can help some of the other panelists as well address this concern about the low-volume procedures. Because my conversation with Dr. Schyve about the problem in Philadelphia from an accreditation point of view is a problem I feel may arise somewhere else in the system for veterans somewhere in the country. So maybe all of you could discuss for a moment what you have undertaken to review low-volume programs to make sure those programs that might not get as much attention are the ones that right now are getting the attention they need so that we have the supervision that guarantees the quality of care the veterans deserve.

And just to be clear, I am not just asking in a brachytherapy context, in a prostate cancer context, in a cancer context, I am asking in a veterans medical care context across the spectrum.

Dr. HAGAN. Well Congressman, I can answer in terms of what we have done VHA wide for brachytherapy, but in the wider context I won't have the information that you are looking for. But for brachytherapy we have implemented standard procedures at each one of the sites that are currently performing. So conducting implants under ACR guidelines is a requirement. A checklist was developed and used based on those centers that were performing excellently, and that checklist is a requirement for each program. It is part of a seven point response to Philadelphia that was crafted by the NRC and our NHPP that identified criteria for evaluating programs, that conducted a nationwide evaluation of those programs, recognized those that didn't meet the standard and suspended them, developed criteria for restarting programs, criteria for initiating programs in centers that are not currently providing radiation oncology brachytherapy for prostate. And each one of the programs as of the 1st of May had implemented the standard procedures across the country.

Mr. ADLER. Doctor, I thank you. I am sorry to interrupt you. I wonder if Dr. Agarwal can describe more generally for other programs across the country where the VA is now trying to identify those low-volume programs and procedures and target them for medical effectiveness.

Dr. AGARWAL. Congressman, thank you for that question. You are absolutely correct. You know, we are committed to providing quality health care all across the board. We have a rigorous performance measurement system with about 250 or so indicators that are currently in place that are used to track at the individual level, the facility level, the network level, and at the national level. But I think it has been eluded to, at least I think by the individual from Joint Commission, that no matter how many measurements or measures you have in place it is somewhat of a challenge to do it very comprehensively for every nuance where we deliver health care.

So we have learned a lot from some of the instances that have happened in our recent past, or even more distant past, and every time when an issue arises, be it a surgical issue in a certain place or the use of endoscopy or reprocessing issues, or right now with brachytherapy, we take that as something to improve our entire system.

There is a very rigorous effort to look at it internally with internal oversights with our System-wide Ongoing Assessment and Review Strategy (SOARS) program and our Clinician Administered PTSD Scale (CAPS), and of course we have external accrediting bodies that come into play.

There are a couple recent directives that have been in place and—a relatively new office—Office of Associate Deputy Under Secretary for Quality and Safety has been stood up with the explicit purpose of ensuring that we continue to maintain and sustain high quality care and have a higher degree of accountability in quality and safety for all health care delivery across the Nation.

Mr. ADLER. Doctor, I thank you, I am sure you don't want to have to come testify before us again and again. I can assure you on behalf of the Members of the Subcommittee we don't want to have to bring panels before us to explain why veterans didn't get

the quality of care they deserve, and most importantly I am sure veterans don't want to be missing the care they have earned.

Dr. AGARWAL. Congressman, you are right.

Mr. ADLER. I thank you. I yield back, thank you.

Mr. MITCHELL. Thank you. Just two quick questions.

First, I understand that the VA OIG report found that none of the clinical staff in Philadelphia had received the Nuclear Regulatory Commission recommended training. Is that correct?

Mr. MORELAND. I don't have that information with me. I can certainly get that information and provide it to you, sir.

[The report was received on August 5, 2009, and will be retained in the Committee files.]

Mr. MITCHELL. Yeah, this was just a report that, it was the Administrative Board of Investigation. Any way, if that is true I am sure that we need to make sure that all of those procedures are followed and that everybody involved with this has the recommended training.

Dr. HAGAN. Mr. Chairman, I can add that they have certainly received that training now. That was part of the response to NRC. As one of the seven points ways that training would be conducted. This was fully implemented as of the 1st of May. So all centers have had that training now.

Mr. MITCHELL. One other quick question.

Dr. Agarwal, you mentioned that everyone has been contacted, everyone who received the brachytherapy. And you also said, Dr. Hagan, that success is based on if the PSA goes up or whatever. Those that had low dosages because the seeds were not properly implanted, do you know if any of those were the ones that the PSA has gone up?

Because what is horrible about this is that there is not too many options once you have the radiation therapy, and the options aren't really the nicest. And so I just wonder if anybody who had undergone the treatment at Philadelphia who had low doses, if any of those people are one that is are having an elevated PSA.

Dr. HAGAN. Mr. Chairman, I can't specifically——

Mr. MITCHELL. Yeah, and it could happen in spite of that any way. They could have had the right ones and it still could have gone up.

Dr. HAGAN. And I would not be surprised to find that that is the case.

However, one piece of information I can add is that it is very unusual to see recurrent disease within the prostate in an area that has been adequately treated with brachytherapy. The corollary to that statement is that it is possible then with a supplemental implant or a salvage implant as we term it in the literature, to recapture PSA control in disease that has not escaped the prostate. And so that is a procedure that though not done commonly has been done. We have done it in Richmond. And Dr. Wallner has addressed some of the patients from Philadelphia in that regard.

Mr. MITCHELL. Thank you. Dr. Roe.

Mr. ROE. Just very quickly. I guess one of the things that I would bring up and you all probably looked at it, there is a certain volume of patients you need to do to get good at something, and if you are doing 14, 15, 1 a month, it is a lot harder to get really

good at it unless you are doing 1 a day or 1 every 3 days or something like that like probably you are in Washington. So I would look at my volumes. If you look at volumes in cardiac surgery and any other surgery, cancer, chemotherapy, whatever, you are doing a lot of you are just good at it. And I would certainly look at it. And maybe it is more inconvenient for the veteran, but it is better to get it done right than to get it done not right, so I would do that. And I think very simply it would be easy to get a set of standards for nine hospitals. I say easy, relatively easy, and follow those procedures. That is exactly what we found in our endoscopy, and then expect people to do it. Train them.

One of the things, Mr. Chairman, we insisted on during that, if you remember, is the training that all are to have, and it sounds like we need to document everybody that has been trained, are we doing the same procedure, and if you vary in that procedure you better halt what you are doing until you're back doing the correct thing. And I think that could easily be done in this therapy.

And I also want to thank whoever stepped up. This happened in Murfreesboro, the endoscopy issue, and whoever the person that stepped up and said we want to do what is right for patients, even though they knew it was going to bring them a lot of grief, which it did I am sure, was the right thing to do, and I applaud someone who will step up and look after the benefit of patients.

So I appreciate you all being here today and I yield back, Mr. Chairman.

Mr. MITCHELL. Thank you. Any other questions?

Well again, I would just as Dr. Roe said, thank you so much for doing this, and we understand this was self-reported, and you taking corrective actions, and that is the important thing, that these things don't happen again and we can learn from all these mistakes and hopefully get better at it.

So again thank you very, very much. And with that this hearing is adjourned.

[Whereupon, at 1:21 p.m., the Subcommittee was adjourned.]

A P P E N D I X

Prepared Statement of Hon. Harry E. Mitchell, Chairman, Subcommittee on Oversight and Investigations

I would like to thank everyone for attending today's Oversight and Investigations Subcommittee hearing entitled, *Enforcement of U.S. Department of Veterans Affairs Brachytherapy Safety Standards*. Thank you especially to our witnesses for testifying today.

All the Members of this Subcommittee take particular interest in this issue as well as the care of our Nation's veterans; however, I would like to especially thank Congressman John Adler of New Jersey for being such a passionate advocate of this issue. Reports of botched prostate cancer procedures, a lack of quality and standard controls in the VA health care system and egregious errors in the brachytherapy treatment at the Philadelphia VA Medical Center are unacceptable and wrong.

Brachytherapy is a form of radiotherapy, often used to treat prostate cancer, in which radioactive seeds are placed inside or next to a patient's malignancy. Failure to accurately place the radioactive seeds can cause serious harm. To say that it is disturbing to learn that veterans received bungled procedures and that safety protocols failed to safeguard against such mistreatment would be an understatement. As a result, we are here today to examine the system-wide safety standards for these procedures to ensure that our veterans are receiving the best and safest care available.

In 2003 and 2005, the Nuclear Regulatory Commission (NRC) received reports of botched placement of radioactive seeds and inconsistent dosage at the Philadelphia VA Medical Center. After careful review, it was determined that no NRC protocols were violated. In May of last year, the NRC received a notification of potential under dosing at the Philadelphia VA Medical Center. This led to a VA National Health Physics Program Inspection (NHPP), evaluating all 116 brachytherapy treatments that took place since the creation of the program in 2002.

The *New York Times* reported last month that investigators for the Nuclear Regulatory Commission and VA officials found that 92 of the 116 men treated at the VA Medical Center in Philadelphia's brachytherapy program received incorrect doses of the radiation seeds, often because they landed in nearby organs or surrounding tissue, rather than the prostate. Dr. Gary Kao, who is here today at this hearing, performed the majority of the procedures under a VA contract with the University of Pennsylvania, where he was on staff. Out of the four suspended brachytherapy programs, we know that Philadelphia was by far the worst.

On top of this, in March of this year, the NRC issued a detailed inspection report citing the Philadelphia VA Medical Center with six violations of NRC regulations. This is downright unacceptable. While we are disturbed that, perhaps, there was a lack of proper local quality controls and management of these brachytherapy programs, our main concern is that the problems marring the program in Philadelphia could be happening at the other nine facilities still doing these procedures.

As such, we have asked the VA Office of Inspector General to review and assess the VA's brachytherapy programs and, although the complete NRC inspection report on the Philadelphia program, along with the other VA facilities using brachytherapy treatments, as well as the NHPP performance is not complete, we look forward to reading that report when it becomes available.

Though it is commendable that VA's leadership took swift action once these issues were reported, it is still troubling that it took almost 6 years for these events to actually be reported. Even more troubling is just last month we were here discussing quality control and lack of proper procedures and oversight of endoscopy procedures being conducted by the VA, yet we are here again, questioning the quality of care our veterans receive.

The VA health care system relies upon a complementary system of accountability to identify quality control problems throughout the entire system and at individual levels. Failure to ensure consistent oversight and safe treatment is unacceptable

and wrong. I am anxious to hear VA assurances not only to this Subcommittee, but to all the veterans they serve, that the issues identified, once a thorough review has been conducted, is not occurring at any of the remaining brachytherapy programs across the country, and that the four suspended programs may continue to deliver this important treatment to our veterans. Last, I am equally interested in hearing from one of one our witnesses, Dr. Kao, regarding allegations of erratic seed placements, as well as experts we have invited to provide their thoughts on the safety and effectiveness of the treatment.

Thank you again to all of our witnesses for testifying today and we look forward to your testimony.

Prepared Statement of Hon. David P. Roe, Ranking Republican Member, Subcommittee on Oversight and Investigations

Mr. Chairman, I appreciate you holding this hearing today.

The issue we should really be addressing today is not only the instance of alleged medical malfeasance by one particular medical practitioner, but whether or not this is a symptom of an overreaching patient safety issue across the VA. Just last month, we held a hearing on the problems relating to the cleaning and reprocessing of endoscopy equipment at the VA. Now we are hearing testimony today to discuss problems with brachytherapy treatments at the VA Medical Center in Philadelphia.

Prostate cancer is a major problem for adults over age 50 in the United States, and brachytherapy is a treatment tool used by oncologists to treat prostate and other cancers. The VA treats around 575 veterans annually with low dose-rate brachytherapy at 13 centers nationwide.

We need to tread cautiously here today. As we hear testimony from the VA and other officials, we need to keep in mind the good quality care most veterans seem to be receiving at VA medical facilities, and not seek to undermine the confidence veterans have in going to the VA for their health care needs. That being said, I am gravely concerned that these issues continue to crop up in the news media. VA needs to do a better job at policing itself, before they let the New York Times sensationalize an issue in order to break the public's trust.

Mr. Chairman, the protection of our Nation's veterans who look to the VA for their care is of primary importance. To hear continual reports of various health issues, such as the endoscopy cleaning issue last month, and now the problem with brachytherapy at select facilities is worrisome to me. We must continue to ensure that our veterans receive the best possible care available. I look forward to hearing the testimony from today's witnesses and yield back my time.

Prepared Statement of Gary D. Kao, M.D., Ph.D., Associate Professor of Radiation Oncology, Department of Radiation Oncology, University of Pennsylvania, School of Medicine, Philadelphia, PA

Thank you, Congressman Mitchell and other Members of the Committee, for the opportunity to voluntarily appear before you so that I may be heard on this important subject matter and correct some very serious false allegations about me contained in recent publications, most notably the *New York Times*.

I have worked very hard in my life to best serve the field of radiation oncology and my patients in over 15 years of clinical practice. My dedication to my work is reflected in my educational achievements—earning a Bachelors degree in Philosophy and a Medical Doctor degree from John Hopkins University and its School of Medicine, followed by medical internship and residency, and completion of residency in Radiation Oncology at the University of Pennsylvania School of Medicine. This culminated in Board Certification in Radiation Oncology. I am especially proud that during continuous clinical practice of medicine for over 15 years, I have not had a single malpractice claim filed against me. My record and my commitment to the care of my patients make the false accusations against me particularly devastating and misguided.

I, along with others at the VA, implemented the Program for Brachytherapy in 2002 within the Philadelphia VA to serve the best interests of veterans. Contrary to the allegations that I was a "rogue" physician, we developed precise standard operating procedures and a system of oversight and monitoring of what was then a state-of-art treatment. We formulated the first algorithm of any radiation oncology procedure at the VA, to define the standard operating procedure. As would be ex-

pected in any new program, the brachytherapy program was not without its challenges.

However, what has become clear over the last month is that a fundamental misunderstanding of elementary principles and concepts has led some to arrive at an inappropriate and incorrect conclusion—that deficient care was routinely rendered to veterans who received brachytherapy at the Philadelphia VA. This was not the case and to understand why it is important to understand certain critical issues related to the NRC's definition of a reportable medical event and its applicability to our work at the VA.

Here are the facts:

Fact 1: A standard definition of a reportable medical event as it applies to Brachytherapy was not in existence when the Program started at the VA. The definition was not referenced in my training in Brachytherapy at the Northwest Hospital in Seattle, nor was it clarified by NRC personnel in their investigations in 2003 or 2005 when they were onsite at the Philadelphia VA. The definition that the NRC has now chosen to retroactively apply to all cases of the Philadelphia VA Program is predicated on a deviation from D90, the dose received by 90 percent of the prostate, but it is a definition that does not appear anywhere in the regulations published by the NRC. It should also be noted that there is significant disagreement within the medical community regarding the appropriateness of D90 as a defining metric for a reportable Medical Event. Studies analyzing large numbers of patients appropriately selected for brachytherapy suggest that there are very few relapses even in patients who had a D90 < 80 percent.

Fact 2: The definition of a reportable medical event as it applies to brachytherapy is not only unclear, but it is evolving. The Medical Advisory Committee of the NRC has repeatedly recommended that the definition be changed from one that is dose-based to a definition that is activity-based, i.e. the number of seeds. Last summer, the NRC proposed a rule to change the definition, but the NRC is still using the old definition—unpublished—to evaluate the Philadelphia VA's brachytherapy cases.

Fact 3: The fact that a reportable medical event to the NRC occurred does not mean that the treatment did not meet the standard of care. A patient whose treatment results in a reportable medical event may still have received effective treatment that is within the appropriate standard of medical care. A patient's prostate may temporarily swell after the procedure, or the size and shape of the prostate or the patient's medical condition may dictate that a higher or lower dose of radiation is prudent.

Fact 4: Whether brachytherapy treatment has been delivered consistent with the standard of care should not be determined by whether the treatment resulted in a reportable medical event to the NRC. There are many more significant factors that determine appropriate treatment such as: the number of seeds; the location of the seeds in the prostate; the location of seeds outside the prostate; the concentration of seeds to the affected area of the prostate; the size and shape of the prostate; the stage, grade, extent and location of the cancer; and the clinical follow up of PSA test results. None of these factors are addressed by the NRC.

I also wish to address the now oft-repeated reference to "92 botched cases." This characterization is simply wrong—it is unfair and extremely misleading. A case that meets the NRC definition of a reportable Medical Event does not mean that a patient received ineffective or "botched" care or that the treatment did not meet the standard of care that existed at the time the treatment was given. The Preplanned Method that we used was "state of the art" in 2002, and was used effectively to treat the patients that we carefully screened for the procedure. The efficacy of the treatments is evidenced by the fact that there were no confirmed cases of tumor recurrence at the time the Program was terminated in 2008, with many patients doing well up to 5 years after their brachytherapy treatment.

Furthermore, the NRC review which allegedly resulted in "92 reportable cases," was determined by the NRC through a reanalysis of our data without the participation of the personnel who administered the Brachytherapy Program. Such participation would have been essential to an understanding by the NRC investigators of how each of the prostates was contoured prior to the treatment. It is well recognized in the radiation oncology community that the prostate contouring process is very subjective and that prostate volumes can vary substantially depending on who performs the contouring. The D90 dose calculated by different reviewers may vary by as much as 60 percent. The calculations performed by our Team indicated that the number of patients with D90 below or higher by 20 percent than prescribed was far fewer than 92 cases. Although I do not have access to the patients' data and files, I do not believe that there are close to the 92 reportable cases identified by the

NRC, even by applying the NRC's unpublished D90 standard. While I acknowledge that there would likely have been a higher number of reportable Medical Events at the PVAMC if we had been informed of the current NRC definition, the number would be substantially below 92 cases.

The field of Brachytherapy is a relatively new and rapidly evolving field. While certain conditions and circumstances at the Philadelphia VA could have been improved, I am confident, based on my knowledge of the field and the nature of the patients treated at the VA during my tenure, that the patients received appropriate medical care that was effective in addressing their prostate cancer.

It is my hope that, through my statements and my testimony, I am able to contribute to a fuller understanding of brachytherapy treatment, bring a degree of reassurance to our veterans regarding the treatment that was provided, and ultimately help to improve care for our veterans.

ADDENDUM

As the physician that led the PVAMC Prostate Brachytherapy Program ("Program"), I must accept a portion of the responsibility for some of the breakdowns in performance of the Program. However, as explained in the statements provided to the U.S. Senate Committee on Veterans' Affairs Field Hearing on June 29, 2009, many of the allegations and conclusions concerning the Program are simply not accurate and convey inappropriate conclusions about the care provided to the veterans and the import of the NRC regulations concerning "reportable Medical Events". My efforts in supplying the statements, in voluntarily appearing at the Senate Field Hearing and in providing this Addendum are not designed to affix blame to others, but rather to provide better insight to the appropriate context of the fundamental precepts of brachytherapy at the VA. In so doing, I expect that the false statements made about the Program will be re-addressed and that some measure of comfort will be rendered to the veterans who received care at the VA. Additionally, I recognize that improvements to the Program and the VA can be made and therefore, have made certain recommendations based on my experience with the Brachytherapy Program at the VA in Philadelphia. For purposes of convenience, I reiterate those recommendations here as follows:

1. A system should be established so that a treating VA physician is notified whenever his or her patient presents for treatment at any other VA medical center. This should be accomplished with appropriate confidentiality and privacy safeguards, but which would enable a VA physician to have access to the patient's electronic medical records at any other VA medical center.
2. For complex medical procedures such as brachytherapy, there should be a uniform set of standard operating procedures established through a collaboration of the involved health care professionals and administrative personnel. Once defined, these standard operating procedures should be applied throughout the entire VA system, with appropriate training.
3. There should be a method of categorizing systematic problems by level of urgency so that serious problems, such as those involving failures of medical equipment or transfer of patient-related data, will receive immediate attention from the proper personnel and be quickly resolved.
4. There should be a formal system which would require the NRC and other national regulatory bodies to continually train doctors and other personnel in the latest defined standards.
5. The respective medical disciplines of separate VA hospitals should have a formal system of continuous dialog together about difficulties encountered during practice, and possible suggested solutions. This could be accomplished with the aid of a videoconferencing system to which all VA physicians have access.
6. For every complex medical procedure, there should be sufficient funds for the VA to provide timely and complete care to veterans. Relating to my own experience, having a full-time medical physicist dedicated to brachytherapy would have enabled us to transition earlier to a real-time system of brachytherapy.

As a final note, I wish to draw attention to two issues discussed at the June 29 Hearing which should be clarified.

First, regarding the number of reportable Medical Events, it should be noted that the Philadelphia VA hospital was not the only VA facility which was found to have unreported Medical Events. In at least three other VA hospitals the NRC found unreported events. It is significant to note that the reviews of these other hospitals consisted only of a small sampling of their cases, a fact that has not been revealed to date. In contrast, the Philadelphia VA was subjected to a full audit. A full audit at those other institutions would have disclosed more than a few instances of reportable Medical Events. Supporting the probability of a higher number of Medical

Events that currently remain unreported, a Member of the advisory Committee to the NRC (Advisory Committee on Medical Uses of Isotopes), Subir Nag, M.D., said that of the 100,000 cases of the Prostate Brachytherapy Program across the country (including those outside the VA) applying the current NRC definition of reportable Medical Event, "you are going to have 20,000 cases which will meet the current definition of [reportable Medical Event]." It is highly unlikely that the Philadelphia VA would be an isolated aberration, if a similar degree of audit was to be performed.

Second, at the hearing, there were several references to "92 botched cases". This was very misleading as I explained in my original submitted statements. For the many reasons articulated, a case that fits the NRC definition of a reportable Medical Event does not imply that ineffective or "botched" care was given, and which did not meet the medical standard of care. Furthermore, the NRC review which allegedly resulted in 92 reportable cases, was a reanalysis of our data performed without the participation of the personnel who administered the Brachytherapy Program. We dispute that there were 92 reportable Medical Events, but we do not have access to the patients' data and files. It is well recognized in the radiation oncology community that the prostate contouring process is very subjective, and prostate volumes can vary substantially depending on who performs the contouring. The D90 dose calculated by different reviewers can therefore vary by as much as 60 percent. While we acknowledge that there would have been a substantial number of reportable Medical Events at Philadelphia VA had we been informed of the current NRC definition; the number would be substantially below the now oft-quoted allegation of 92 cases.

Prepared Statement of Stephen M. Hahn, M.D., Henry K. Pancoast Professor and Chair, Department of Radiation Oncology, University of Pennsylvania, School of Medicine, Philadelphia, PA

Mr. Chairman and Members of the Committee, I am grateful for the opportunity to appear here today. I am a professor of radiation oncology at the University of Pennsylvania and since 2005 have been the chair of the University's Department of Radiation Oncology.

Before going any further, I want to express my deepest regret that prostate cancer patients receiving brachytherapy at the Philadelphia Veterans Affairs Medical Center (PVAMC) did not in every instance receive the best possible care. My highest priority as a physician and as chair of our Department is to make sure patients receive the best possible care. I want to personally apologize to the patients and their families for the distress this has caused. I also know that this entire experience has been very difficult for the VA health care system, particularly in Philadelphia, as it has been for my Department. Penn Medicine's relationship with the PVAMC is long standing and very important to our mission as an academic medical center dedicated to patient care, teaching and research. We value our work with the PVAMC highly and believe that both our organizations have learned a great deal from this painful experience that will serve to improve patient care in the future.

I will focus most of my testimony today on the steps we have taken in the last year in response to this situation and the process improvements we have implemented at Penn that we believe will enhance the quality of care for patients undergoing brachytherapy. First, however, I want to provide some background information which I think should be useful regarding prostate brachytherapy as well as a description of our Department's role at the PVAMC.

Prostate brachytherapy refers to the permanent implantation of small radioactive seeds into or around the prostate gland to treat prostate cancer. Along with prostate removal surgery and external beam radiotherapy, prostate brachytherapy represents a well-established option for the treatment of prostate cancer. During the procedure, the physician implants the seeds using loaded needles. The placement of the needles and seeds is determined by a "pre-plan," in which the dose to the prostate and desired location are estimated by a medical physicist and confirmed by the physician (based on an ultrasound image of the patient's prostate), as well as ultrasonic image guidance at the time of the implant.

The implanted seeds' location determines the radioactive dose delivered to the prostate and surrounding tissue. It is important to note, however, that even among experienced and skilled physicians there is variation in the results afforded by prostate implant brachytherapy, not only with respect to patient outcome and possible complications, but also with respect to dose delivered to the prostate volume and surrounding tissue. This can be due to patient anatomy (the texture of the prostate, and normal anatomical variation); prostate swelling after implantation; and the way

that the dose to the prostate is measured after the implant—often by identifying the prostate and seeds on a CT scan—which itself can allow for considerable variation in the measured dose. I offer these facts not as an excuse, but only to make the point that this is a complicated therapy.

The University's Department of Radiation Oncology, through a contract with the PVAMC, provides radiation oncology services, including brachytherapy. Radiation oncologists working at the PVAMC are either employed directly by the PVAMC or Department faculty provided under the contract.

When the Department first learned in May 2008 of potential concerns about the prostate brachytherapy program at the PVAMC, we took immediate action. The Department provided several faculty members and staff to the PVAMC to assist with a quality review of all prostate brachytherapy cases. In June 2008, when concerns arose regarding Dr. Gary Kao's cases in particular, Dr. Kao agreed, at my request, to suspend his clinical practice, and he has not treated any patients since that time at the PVAMC or at our hospitals. Since last summer, Department faculty, as part of their responsibilities at the PVAMC, have been coordinating patients' follow-up care and closely following PVAMC patients with symptoms of concern. In addition, since the VA and the Nuclear Regulatory Commission (NRC) began investigations into this matter in June 2008, we have cooperated fully, and we will continue to do so.

At the same time as the VA and NRC undertook their investigations, in June 2008 we also reviewed quality control and improvement measures to determine whether we could enhance them to prevent a situation like this from ever happening again. Although our Department's brachytherapy programs have been in compliance with the American College of Radiology and the American Society of Therapeutic Radiology and Oncology's Practice Guideline, we have adopted an additional review process that provides for persons who did not take part in the procedure to assess the quality of each prostate brachytherapy implant. This quality review process includes a re-review of the CT scan and a recalculation of the delivered dose. We also have established a multi-level internal reporting system so that even slight anomalies will be reported to our quality assurance Committee and reviewed, regardless of whether they rise to the level of an NRC-reportable event.

Another very significant development is that we recently completed the transition to a new brachytherapy implant protocol. At the Hospital of the University of Pennsylvania, in early 2008, as part of ongoing quality improvement, we began transitioning to what is called "real-time dosimetry," which incorporates new equipment and programming and allows for calculation and recalculation of the dose delivered to the prostate after each radioactive seed is implanted during the procedure. This provides the attending physician with instantaneous feedback and an opportunity to modify his or her plan if necessary to achieve the desired radioactive dose to the prostate. We believe this approach should lead to greater consistency with respect to seed location and the delivered dose.

I do not know if the PVAMC intends to restart its permanent prostate brachytherapy program, but if and when it does, we would of course assist the PVAMC in modernizing its program along these lines.

The steps my Department has taken in response to this issue also have been reviewed by Penn Medicine quality reviewers and senior physicians. Further, to assure ourselves that we have considered every safety and quality option, we will be requesting an additional review by outside experts.

Before closing, I want to address briefly the NRC regulations applicable to prostate brachytherapy. I am confident that the NRC, the PVAMC, and the University all share the desire to see clear and consistent prostate brachytherapy regulations instituted so that we can all be confident that uniformly high quality care is delivered to all patients who undergo this procedure. In August 2008, the NRC, based on recommendations from its Advisory Committee for the Medical Uses of Isotopes, published proposed amendments to its regulation that establishes what constitutes a reportable "medical event." That proposed rule would have gone some way toward removing the ambiguity that exists in the current rule as applied to prostate brachytherapy, inasmuch as the current rule does not specify how a deviation from desired dose is to be measured, or at what point in the treatment process. It is my understanding, however, that the NRC is reconsidering the proposed rule in light of this case. In my view, the criteria the NRC applied to these cases are overbroad, and they are not generally accepted by experts in the field or, I believe, experts on the NRC's own Advisory Committee. The criteria could result in reporting to the NRC when there was neither a poor implant nor suboptimal patient care. My point here is not to contest the importance of the issue we are dealing with today—were it simply one instance in which a veteran received less than the best possible health care, I would find that just as unacceptable. I share a desire with my colleagues

at the VA and the NRC to create clear rules and regulations leading to the delivery of quality care, and I believe it would be of great use to the medical community at large for the NRC to clarify its regulations as they apply to prostate brachytherapy, which will make it more likely that any developing problem elsewhere will be discovered at the earliest possible time.

Mr. Chairman, and Members of the Committee, let me again stress that Penn is committed to providing the highest standard of care to our Nation's veterans and to working closely with the VA moving forward.

Prepared Statement of Michael R. Bieda, M.S., Clinical Chief, Division of Medical Physics, Department of Radiation Oncology, University of Pennsylvania, School of Medicine, Philadelphia, PA

Mr. Chairman and Members of the Committee, thank you for the invitation to appear here today. I would like to use my time to provide you with some information about my background, as well as a description of the medical physicist's role in prostate brachytherapy.

In 1996, I was awarded a master's degree in physics from University of Tennessee, and in 1999, was graduated from the master's program in medical physics at the MD Anderson Cancer Center at the University of Texas Health Science Center at Houston. Since that time, I have worked as a medical physicist at the Johns Hopkins University Oncology Center in Baltimore; at Christiana Care Health Systems in Newark, Delaware; and at Bryn Mawr Hospital In Bryn Mawr, Pennsylvania, in addition to the University of Pennsylvania's Department of Radiation Oncology. I first worked at Penn from 2002 to 2005, and then returned in August 2006 to take the position of clinical chief of medical physics for the Department.

I am certified by the American Board of Radiology, in therapeutic radiological physics, and I have had several publications in the journal *Medical Physics*.

A medical physicist does three things to assist in prostate brachytherapy.

First, based on the doctor's prescription, which specifies the amount of radioactivity to be implanted into the patient, the physicist prepares what is called a preplan. To do this, the physicist will review a series of ultrasound images of the prostate that is taken by a doctor and in which the doctor has identified the prostate. With this information from the doctor, the physicist will plan the places where the radioactive seeds should be implanted into and around the prostate and estimates the radioactive dose to be delivered to the prostate. This plan always is confirmed (or revised) by the doctor.

Second, not long before the doctor is to perform the implant, the physicist will check the activity level of a sample of the seeds to be implanted and deliver those seeds to the doctor in the operating room.

The third thing a physicist does takes place after the implant. At the PVAMC, the doctor would order a CT scan of the patient's prostate the day after the implant. On this CT scan, the physicist would identify the location of the implanted seeds, using a dedicated computer program for this purpose. Once this was done, the doctor would locate the prostate on the CT scan and draw it in. This would allow the computer program to generate a "dose volume histogram," essentially a graph showing how much of the prostate received how much of a dose, as well as different dose parameters. This information is often referred to as "post-implant dosimetry."

Post-implant dosimetry is performed so that the doctor might evaluate the implant as part of his overall assessment of his ongoing treatment plan for the patient.

I recognize that the Committee may have questions, and I will do my best to answer them.

Again, thank you for your consideration of my testimony.

Prepared Statement of Paul M. Schyve, M.D., Senior Vice President, The Joint Commission

Mr. Chairman, Ranking Member, and Members of the Committee, on behalf of The Joint Commission, thank you for the opportunity to testify at this important hearing.

The Joint Commission accredits approximately 146 Department of Veterans Affairs organizations, including all of its hospitals. We strive to assure that our Nation's veterans are receiving high quality and safe care.

Joint Commission accreditation is a risk-reduction process, based on:

- First, establishing evidence-based Standards, National Patient Safety Goals, and Performance Measures
- Second, collection of data about a hospital in the form of performance measures (including patient outcomes), complaints, and past survey results
- Third, periodic unannounced onsite surveys of the hospital, focused on the care provided to a selected cohort of patients whose care is "traced" throughout their hospitalization
- Fourth, feedback to the hospital of the results of its survey and required improvements, including a timeline for their implementation
- Fifth, public reporting of the results of the survey on the Internet and to the Veterans' Health Administration
- Sixth, an annual self-assessment by the hospital of its ongoing compliance with Joint Commission standards

I described accreditation as a risk-reduction process. No process can entirely eliminate risk in health care. Hospital-level health care is inherently risky. It has all the characteristics identified in other high-risk endeavors:

- Complexity
- Variable input—that is, patients
- Time constraint
- Tight coupling
- Heavy dependence on human intervention—since "to err is human."

So in health care, adverse events will happen. The Joint Commission, the Veterans' Administration, and this Committee all share the goal of reducing adverse events and protecting patients from their harmful effects.

By studying other high risk endeavors that have developed enviable safety records—such as the commercial air passenger system, nuclear power, and aircraft carrier flight decks—health care is learning how to become a "high reliability" endeavor also.

The first step is the development of evidence-based, standardized policies and procedures, educating personnel in their implementation, making them available as memory-aids (such as in check lists) to facilitate their use, and monitoring whether they are followed. This may be all that is necessary to assure high reliability in a production line to manufacture widgets. But it is only the beginning in a high risk endeavor like health care.

In health care, unexpected adverse events and unpredicted outcomes—often called "unintended consequences"—occur regularly, despite the best designed and monitored policies and procedures. To create high reliability in health care, therefore, requires three additional components:

- The first component is constant attention to things that are unexpected or go wrong in order to learn from them so as to prevent their recurrence. However, personnel will only report errors and other adverse events in an atmosphere of trust in which they will be rewarded, not punished, for reporting, and their reports will be taken seriously and acted upon.
- The second component is prospective risk identification and prevention whenever new processes are to be implemented or existing processes changed. By prospectively redesigning the proposed processes to eliminate the risk or building in protections for patients when the risk cannot be eliminated, patients can be protected from harm. While the first component is to learn *from* adverse events to prevent their *recurrence*, this second component is to learn *before* the adverse events to prevent their *occurrence*.
- The third component of high reliability—and perhaps the hardest to achieve and maintain—is a "culture of safety." A culture of safety means that safety is consistently on everyone's mind, there is preoccupation with the possibility of failure, a sensitivity to the detail of operations, and constant vigilance for the small unexpected events—because small events can lead to big, sometimes disastrous outcomes in complex processes such as those in health care.

Unfortunately, no oversight body, whether the Veterans' Health Administration, the Nuclear Regulatory Commission, or The Joint Commission, is able to identify all the risks and even all the actual breakdowns in a hospital. Nor can the oversight bodies create the cultures of trust and safety in the hospital needed for high reliability. Only the hospital itself can. The oversight bodies can set expectations, provide guidance, educate, and evaluate in order to enable and incentivize the hospital to make this change.

To that end, The Joint Commission has established standards that require the hospital to:

- Create a culture in which adverse events are reported and evaluated for underlying ("root") causes, and preventative actions are taken.
- Identify high-risk processes and prospectively determine their possible modes of failure, the effects of those failures, and the actions that will prevent the failures or mitigate their effects.
- Establish a culture of safety throughout the hospital. This accreditation standard became effective January 1, 2009, although its purpose and expectations were publicized for over a year in advance.

When The Joint Commission surveys a hospital, the surveyors always physically examine the radiology imaging services and, if the hospital provides it, its external beam radiation oncology services. From this case, The Joint Commission has learned that a hospital may provide brachytherapy services that, because they are usually a low-volume, highly specialized service within the radiation oncology department, may not be reported by the department as part of the services it provides—and, therefore, may be unknown to the surveyor. Brachytherapy is especially highly specialized and technical—utilizing the expertise of a urologist, a radiation oncologist, and a radiation physicist. Even when its presence is known to the surveyor, it is not possible for the surveyor to have the specialized technical knowledge to review the effectiveness of the dosing schedule for the patient. However, based on this case, The Joint Commission will instruct its surveyors to ask if brachytherapy is provided, and, if so, to examine whether the hospital is providing the monitoring and peer review oversight that brachytherapy requires. And, beginning this year, the surveyors are evaluating what the hospital's leaders are doing to create a culture of safety in their hospital.

The Veterans' Health Administration has been a leader in learning from adverse events in its hospitals, in disseminating that knowledge to other hospitals in its system, and in openly discussing with The Joint Commission the events and their investigations and responses. They have also started down the long road of creating a culture of safety in their hospitals. The Joint Commission's goal is to assist both the Veterans' Health Administration and its individual hospitals to make this transition. Only by transforming our Nation's hospitals into high reliability organizations will health care fulfill its obligation to all our Nation's citizens—including its veterans—to "first, do no harm."

On behalf of The Joint Commission, I would like to thank you again for this opportunity to testify.

Prepared Statement of Steven A. Reynolds, Director, Division of Nuclear Materials Safety Region III, United States Nuclear Regulatory Commission

INTRODUCTION

Chairman Mitchell, Ranking Member Roe, and Members of the Committee, I am honored to appear before you today to discuss the U.S. Nuclear Regulatory Commission's (NRC) regulatory role, actions, and findings to date regarding medical events at the U.S. Department of Veterans Affairs hospitals, particularly the Veterans Affairs Medical Center in Philadelphia, Pennsylvania (VA Philadelphia). I hope that my testimony will be helpful to the Committee's work.

NRC'S REGULATORY ROLE

The NRC is an independent agency created by Congress to license and regulate the civilian use of radioactive materials. The NRC issues licenses to facilities that authorize the safe and secure possession and use of radioactive material. In the nuclear medicine area, the NRC does not regulate the practice of medicine. NRC's regulations seek to ensure the adequate protection of those working with radioactive material, as well as the public and the environment, and that the patient receives the radiation dose intended and prescribed by the medical practitioner.

The NRC has a specific set of regulatory requirements for the medical use of radioactive materials. These regulations include the definition, criteria, and reporting requirements for medical events. Prior to 2002, the term "misadministration" was used in the regulations to describe these events. The NRC replaced the term "misadministration" with "medical event" as this term more correctly and simply conveys that the radioactive material or the radiation from the material, was not delivered as directed by the physician.

The NRC requires licensees to report a medical event because such an event indicates that the licensee had technical or quality assurance problems in administering the physician's prescription. A dose error of 20 percent or more may indicate treatment delivery problems in the medical facility's operations that need correcting. Actual harm to a patient, whether it is an injury from overexposure or inadequate treatment due to underexposure, must be determined through a separate analysis by a physician. In severe events, when the dose error is well over 20 percent too high or too low, such as the events that occurred at the VA Philadelphia, NRC inspection teams are supplemented with a medical consultant, who is a licensed physician. The medical consultant assesses the patient's risk of harm.

The agency's Region III office, based in Lisle, Illinois, provides regulatory oversight of the Department of Veterans Affairs' license. The VA was issued a master materials license (MML) in March 2003. An MML is issued only to Federal Government agencies or departments and authorizes the use of radioactive material at multiple sites. The holder of the MML is responsible for ensuring that NRC requirements are met. Prior to issuance of the MML, the NRC issued a separate license to each VA site throughout the United States. The VA's license requires the VA to establish an internal, independent framework of oversight consistent with NRC regulations, and with inspection and enforcement policies, procedures, and guidance. Within this framework, the responsibility for patient safety and day-to-day oversight of VA medical procedures using radioactive materials lies with the VA's National Radiation Safety Committee. The VA's National Health Physics Program (NHPP) acts as the VA's regulatory organization and is responsible for issuing permits, conducting inspections and event follow-up, investigating incidents, allegations, and enforcement.

BACKGROUND OF THE VA MEDICAL CENTER IN PHILADELPHIA

VA Philadelphia began performing permanent implant prostate brachytherapy in 2002, using contracted doctors from the University of Pennsylvania Hospital. The NRC received a report of a potential medical event in 2003. The NRC conducted an inspection and examined the record of the event, as well as the procedures for prostate implants, and interviewed the physician involved but did not identify any violations of NRC regulations. In 2005, a similar potential medical event was reported to the VA's NHPP. The NRC was informed of the event and evaluated the performance of the NHPP inspectors by observing the NHPP inspection of the event. NHPP did not identify any violations at VA Philadelphia.

On May 18, 2008, the NRC received notification of a potential medical event from the VA that a patient undergoing treatment for prostate cancer at the VA Philadelphia received a dose that was over 20 percent lower than what was prescribed.

In response to this prostate under dose at VA Philadelphia, the NHPP conducted an inspection at the facility in May 2008. Based on the preliminary inspection findings, the NHPP requested VA Philadelphia to review more prostate brachytherapy treatments. Ultimately, all 116 prostate brachytherapy treatments performed since the inception of the program were reviewed by the VA.

NRC'S RESPONSE TO DATE

NRC closely followed the initial actions of the VA Philadelphia and the NHPP and, based on additional potential events, determined that it was necessary to accelerate our direct involvement.

First, the NRC conducted an independent inspection at VA Philadelphia in July 2008. Second, based on the NRC's preliminary inspection findings and the growing number of potential medical events, the NRC launched a Special Inspection in September 2008. The NRC's ongoing Special Inspection was tasked to:

- conduct further on-site inspections at the VA Philadelphia;
- conduct on-site inspections at all of the VA hospitals authorized to perform prostate brachytherapy treatments;
- review the circumstances surrounding the multiple medical events at the VA Philadelphia;
- assess prostate brachytherapy programs at the other VA facilities;
- assess the performance of the NHPP;
- determine whether the problems at the VA Philadelphia could be affecting other medical facilities; and
- conduct, with the assistance of a medical consultant, an independent assessment of possible health effects on patients who had received the wrong doses.

Third, in October 2008, the NRC issued a Confirmatory Action Letter to the VA, which confirms commitments made to the NRC by the VA to identify, address, and

prevent the problems that have led to these medical events, including the following actions:

- conduct NHPP inspections at all 13 VA hospitals authorized to perform prostate brachytherapy treatments;
- develop and implement standardized procedures for prostate brachytherapy treatments at all VA hospitals;
- identify causes of the medical events and implement corrective actions;
- suspend any prostate brachytherapy treatment program where 20 percent or more of the treatments have been identified as medical events;
- conduct an inspection to confirm that all necessary corrective actions have been taken prior to restarting any suspended brachytherapy treatment program; and
- conduct an inspection of new prostate brachytherapy treatment programs prior to start up to confirm they meet the enhanced standards.

Because the physician conducting many of the prostrate brachytherapy treatments also worked at a local hospital, the Commonwealth of Pennsylvania and the local hospital were notified.

The NRC will verify through inspections that the commitments in the Confirmatory Action Letter have been successfully completed. The VA has agreed not to restart prostate brachytherapy treatment programs at five sites, including the VA Philadelphia, until all commitments have been met.

Fourth, on March 30, 2009, the NRC issued a Special Inspection Report on the medical events at the Philadelphia VA that identified six apparent violations of NRC regulations: (1) the failure to develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive; (2) the failure to develop procedures that address methods for verifying that administration is in accordance with the treatment plan and written directive; (3) the failure to train supervised individuals regarding identification and reporting requirements for medical events; (4) the failure to instruct a non-supervised individual regarding identification and reporting of medical events; (5) the failure to record total dose received by a patient on a written directive; and, (6) the failure to provide required information in several 15-day reports to the NRC. In addition to these apparent violations, the NRC identified concerns involving inadequate management oversight by the Radiation Safety Officer and the Radiation Safety Committee at VA Philadelphia, and a pattern of unreported safety concerns.

Finally, in response to a Demand For Information issued to him by the NRC, the physician who performed the majority of the brachytherapy treatments at the VA Philadelphia, confirmed that he is currently not performing these treatments at any facility—VA or otherwise. He has also confirmed that he would give prior notification to the NRC if and when he resumes these treatments.

FUTURE NRC ACTIONS

The NRC is continuing to review the events at VA Philadelphia. We plan to issue separate Special Inspection reports that will address the findings of the inspections conducted at VA Philadelphia and at the other VA facilities authorized to perform prostate brachytherapy treatments, and the NHPP's performance at the conclusion of these inspection activities. As part of our response, the agency will consider what enforcement actions are warranted in these cases. The NRC will also notify all facilities administering this type of treatment about findings from these inspections that may inform their practice and where there may be common implications for the medical community and other stakeholders. These actions will be publicly available.

The NRC will apply the findings of our evaluations to our own regulatory practices. In this case, two areas that we have identified so far as needing increased NRC attention are licensee oversight of contract doctors and the safety culture at materials licensees. We will continue to look critically at our licensing and inspection program to determine what enhancements are needed. The NRC is also assessing whether any specific changes may be needed to strengthen our regulatory oversight of the VA's MML with respect to both the VA's internal regulatory framework and the NRC's regulatory practices.

Prior to the current events at the VA, the NRC had been evaluating, with input from the nuclear medicine community and other stakeholders, a proposed change to our regulations that may prohibit physicians from changing written treatment orders after the procedure begins. The issue of changing these orders during procedures was identified as a concern in the practice at the VA Philadelphia.

CONCLUSION

The NRC takes these medical events very seriously and continues our in-depth inspection. Once we have completed this work, we will evaluate the VA's response

to our findings and determine what enforcement actions are warranted. Thank you for the opportunity to testify here today. I would be pleased to respond to your questions.

Prepared Statement of W. Robert Lee, M.D., M.S., M.Ed., Professor, Department of Radiation Oncology, Duke University, School of Medicine, Durham, NC, on Behalf of the American Society for Radiation Oncology

Chairman Mitchell, Ranking Member Roe, and Members of this distinguished Committee, good morning and thank you for the opportunity to testify today on the use of brachytherapy in the treatment of prostate cancer. I have personally witnessed the great benefits of brachytherapy for cancer patients and look forward to telling you the history of this treatment, how it works, as well as the required training and safety requirements and clinical practice guidelines.

I received my undergraduate training at the College of William and Mary studying Chemistry and Classical Antiquities. I matriculated at the University of Virginia School of Medicine and received my medical degree in 1989. I completed a residency in radiation oncology at the University of Florida in 1993. I have held faculty positions at Fox Chase Cancer Center in Philadelphia, Wake Forest University School of Medicine in Winston-Salem, NC, and at present I am a Professor of Radiation Oncology at the Duke University School of Medicine. I have authored over 100 original articles and reviews on many aspects of genitourinary cancer. My clinical practice is limited to men with prostate cancer. Together with my colleagues at Duke, I see more than 300 new patients per year. I have used prostate brachytherapy and external beam radiation therapy for more than a decade. My particular research interests are exploring innovation with external beam radiation treatment of prostate cancer and the measurement of quality following prostate brachytherapy. In addition, I am the incoming Chairman of the Residency Review Committee that oversees all radiation oncology training programs, and I have served as an oral examiner for individuals that take the radiation oncology board exam. I am also a Past-president of the American Brachytherapy Society (ABS) and the Director of the Duke Radiation Oncology Training Program.

I am considered an expert in the field of prostate cancer and believe my testimony is critical to help Congress and the public understand that brachytherapy is a very safe procedure with a long track record of effectively curing cancer with minimal side effects compared to other treatments. I am not personally involved in the investigation into the Philadelphia VA and my knowledge of the specific circumstances in the case consists of a number of reports from the Nuclear Regulatory Commission (NRC), Department of Veterans Affairs (VA) and news publications. It is also important to note that neither I, nor ASTRO, were involved in the accreditation of any health care facilities, including the Veterans Affairs Medical Centers. Based on information that 92 medical events were identified out of 116 cases, including 35 involving unintended doses to an organ or tissue other than the prostate and 57 events where the dose delivered to the prostate was less than prescribed, I agree that there is clearly cause for concern that inadequate care was delivered to veterans treated at this facility.

While ASTRO is deeply troubled by the problems identified at brachytherapy programs at the Philadelphia and other VA centers, we are heartened that NRC investigators have found no evidence of widespread medical events involving brachytherapy. Based on my clinical training and my experience with brachytherapy, I would have been very surprised if investigators found problems with this important radiation therapy procedure. In fact, there have been only an infinitesimally small number of reported medical events nationwide.

Each year, there are approximately 50,000 brachytherapy treatments performed in the United States. According to the Advisory Commission on the Medical Uses of Isotopes' report to the NRC at a May 2009 meeting, there were a total of 9 reported medical events involving 111 patients nationwide in 2008. Of the 111 patients involved, 102 were from 2 medical events that occurred within the VA system. Ninety-two of these patients were treated at the Philadelphia VA. The other 7 medical events involved 9 patients—with the most common error being misidentification of the prostate in transrectal ultrasound (3 medical events; 3 patients). While the VA investigation spans several years, these medical events were all reported in 2008. Even with the consolidation of these medical events into 1 year, only about 0.22 percent of the procedures nationwide resulted in a reportable event. Brachytherapy is an extremely safe and effective procedure.

My hope is that patients, particularly our Nation's veterans, will recognize that the situation at the Philadelphia VAMC is an isolated incident and should not dissuade patients from choosing brachytherapy, if appropriate, as a treatment for their cancer. At the same time, the radiation oncology community is committed to working with Federal regulators to learn from these serious events and apply the lessons to help ensure that such mistakes don't happen again.

ASTRO and Radiation Oncology

Founded in 1958, ASTRO's mission is to advance the practice of radiation oncology by promoting excellence in patient care, providing opportunities for educational and professional development, promoting research and disseminating research results and representing radiation oncology in the rapidly evolving health care environment. Radiation oncologists, radiation oncology nurses, medical physicists, radiation technologists, dosimetrists and biologists comprise ASTRO's more than 10,000 members, making it the largest radiation oncology organization in the world. These medical professionals, found at hospitals and cancer treatment centers around the globe, make up the radiation therapy treatment teams that are critical in the fight against cancer.

Radiation therapy is the use of various forms of radiation to safely and effectively treat cancer and other diseases. Doctors use radiation therapy to eradicate cancer, to control the growth of the cancer or to relieve symptoms, such as pain. It can be used to treat cancer in almost any part of the body, although breast cancer, lung cancer and prostate cancer typically make up more than half of all patients receiving radiation therapy. Radiation may also be used to treat several benign diseases, such as non-cancerous tumors, heart disorders and thyroid problems.

Patients receive radiation therapy in one of two ways: externally or internally. During external beam radiation, a beam of radiation is directed to the tumor and immediate surrounding area in order to destroy the tumor and any nearby cancer cells. Internal radiation, or brachytherapy, from the Greek word *brachy* meaning close by, is the placement of radioactive sources in or next to a tumor. To position the sources accurately, special catheters or applicators are used. Because the radiation sources are placed so close to the tumor, doctors can deliver a large dose of radiation directly to the cancer cells with minimal exposure to normal tissue.

Radiation therapy works by damaging the DNA in cancer cells so that they cannot repair or reproduce. New technology and improved techniques allow radiation oncologists to better target radiation to eliminate cancer cells while protecting healthy cells. Radiation therapy is less invasive than other cancer treatments, making it an attractive option for men and women who want to maintain their lifestyles and jobs while receiving treatments. When a physician determines that radiation therapy may be a treatment option for his or her patient, a referral is made to a radiation oncologist. As highly trained specialists, radiation oncologists know the various forms of radiation therapy—brachytherapy or external beam radiation—their efficacy in specific cases, and the potential side effects and risks.

Radiation oncology practices, including caring treatment teams of clinical nurses, physicists and technologists, use sophisticated equipment to provide patients with safe, effective care. Radiation oncologists discuss and agree upon treatment options with their patients and their families and plan and deliver that care in conjunction with the patient's other physicians, as well as non-physician members of the patient's care team. This team approach assures that the radiation therapy component of a patient's clinical care fits appropriately in the overall patient treatment plan.

ASTRO supports Congressional efforts to promote quality measurement and improvement, particularly through the adoption and effective use of health information technology (HIT). ASTRO has devoted significant time and resources to developing clinical guidelines and quality measures for radiation oncology, including the treatment of prostate cancer. ASTRO also is proud of the high rates of HIT adoption among radiation oncology practices. ASTRO is leading efforts to develop interoperability standards to allow vital clinical information to be passed seamlessly from one radiation oncology system to another system, within and across practices, and made readily available at the point of care. In sum, ASTRO wants patients to have peace of mind when it comes to safety, quality and efficacy of radiation therapy.

History of Brachytherapy

In the early 1900s, Marie and Pierre Curie laboriously extracted the element Polonium from tons of Uranium ore and, shortly after, extracted Radium. In 1901, Pierre Curie, after observing a burn on his skin from a sample of radium left in his coat pocket, suggested to doctors at St. Louis Hospital in Paris that a small radium tube be inserted into a tumor to produce the same effect. This was the birth of brachytherapy. Independently that same year, Alexander Graham Bell made a

similar suggestion. It was found in these early experiences that inserting radioactive materials into tumors caused cancers to shrink.

Brachytherapy is a highly effective way of delivering radiation tailored to the shape of the tumor while sparing surrounding normal tissues. Estimates are that approximately 40,000 Medicare beneficiaries chose brachytherapy as part of their cancer treatment plan each year. Over the last 15 years, sophisticated computerized treatment planning and advances in medical imaging have helped to achieve increased accuracy and superior, optimized dose distribution for cancer patients.

Prostate Cancer and Brachytherapy

Much has been made about the difficulty prostate cancer patients face in determining a treatment option for their disease. Indeed, the Agency for Health Care Research and Quality issued a February 2008 comparative effectiveness report on therapies for clinically localized prostate cancer that found that no one therapy—watchful waiting (active surveillance), surgery to remove the prostate gland (radical prostatectomy), external beam radiotherapy (EBRT) and interstitial radiotherapy (brachytherapy), freezing the prostate (cryotherapy) or androgen deprivation therapy (ADT)—could be considered the preferred treatment for localized prostate cancer due to limitations in the body of evidence as well as the likely tradeoffs an individual patient must make between estimated treatment effectiveness, necessity, and adverse effects. In 2008, the Institute for Clinical Effectiveness Research in the United Kingdom suggested that when brachytherapy is clinically indicated, its high efficacy and low cost make it a particularly cost-effective option in prostate cancer.

As a prostate cancer expert, I work to analyze the path of my patient's prostate cancer and discuss with him the benefits and risks of each treatment option. Some men can safely postpone treatment for prostate cancer and watch it closely to see if treatment is needed. This is called watchful waiting or active surveillance. For others, surgery or external beam radiation therapy may, for a number of particular clinical reasons, be preferred. If the cancer is relatively small and not too aggressive and the man has a small prostate and good urinary function then brachytherapy becomes a reasonable option. Brachytherapy may be used alone or in conjunction with external radiation treatments to treat prostate cancer. A combination of treatments, such as external beam radiation followed by brachytherapy, is often preferred for men with more advanced cancer. I will advise patients of the management option that is most appropriate to their specific case. (For additional information, see Attachment A, "Radiation Therapy for Prostate Cancer.")

The benefits of brachytherapy vary depending on the patient, their priorities, their age and diagnosis stage and preferences. Brachytherapy is a relatively simple, minimally invasive outpatient procedure that avoids hospitalization and allows the patient an early recovery and rapid return to normal activity. It produces good 10-year outcomes with relatively low morbidity. The benefits of using brachytherapy in the treatment of early stage prostate cancer are quite pronounced and include a lower incidence of impotence and incontinence than is commonly reported with a radical prostatectomy. The high degree of accuracy achievable in prostate implants nowadays is partly due to technological improvements, but quality implants still require skill, adequate training, and attention to detail.

ASTRO has expressed concerns to Congress and the Administration that financial incentives and rampant self-referral of radiation therapy services in the Medicare program are leading to patients not being fully informed on the full range of treatment options, particularly brachytherapy. Instead, business arrangements have flourished that involve frequently steering patients to more expensive and profitable prostate cancer treatments. We hope that the appropriate concerns over the prostate cancer brachytherapy program at the Philadelphia VAMC will not exacerbate underuse of this important treatment option.

Brachytherapy Clinical Practice Guidelines

Prostate brachytherapy, or seed implants, are given by inserting small metal seeds of radioactive iodine or palladium directly into the prostate gland. These radioactive sources have relatively low energy levels and half-lives of between 17 and 60 days. Patients are under anesthesia during this brief outpatient surgery procedure. The seeds are temporarily radioactive and deliver the radiation to the prostate over several weeks. After losing their radioactivity, the seeds remain in the prostate. The seeds are then harmless and should not bother the patient. For the short time that the seeds are giving off radiation, men are asked not to be in close proximity to children or pregnant women because of the very small chance that the radiation may harm their rapidly growing bodies.

It is essential that postimplant dosimetry be performed on all patients undergoing permanent prostate brachytherapy. Dosimetry is the calculation of the absorbed

dose in tissue resulting from the exposure to ionizing radiation. The dose distributions following implantation are never exactly the same for each man as those planned prior to the implant. Because the dose distributions may differ ever so slightly, it is important to document the actual dose that the prostate and normal adjacent tissues will receive over the life of the implant. This can only be determined if a postimplant dosimetric assessment is performed. It is my understanding that this key step may have been missed in the cases that were reviewed for the NRC report.

The information obtained from postimplant dosimetry is essential for optimal patient care. Significant over-dosing of the prostate may increase the risk of side-effects. Significant under-dosing of the prostate can lead to treatment failure. The latter can potentially be rectified using supplemental external beam radiation therapy or additional seed implants. While the timing may vary in part due to the half-life of the isotope, the most reproducible dosimetric results will be obtained if the scan is performed 1 month post-implant.

According to clinical practice guidelines, brachytherapy is indicated for treatment where the target volume or tumor can be well defined and is accessible to source placement. The goal of treatment (curative, palliative, or to establish local tumor control) should be documented as clearly as possible. Treatment options and their relative merits and risks should be discussed with the patient. A summary of the consultation should be communicated to the referring physician.

Guidelines also recommend that brachytherapy involve the interaction of multiple specialists. The choice and placement of radioactive sources are the responsibility of the radiation oncologist. Each type of brachytherapy procedure has its own set of unique characteristics. The brachytherapy team should operate according to an established system of procedural steps that have been developed by the radiation oncologist and brachytherapy team members. This systematic approach to applicator or source insertion should include a description of pre-implantation steps, sedation or anesthesia procedures, the specific applicators used, and the insertion techniques. Standard orders or care guidelines may enhance the systematic approach to the insertion process.

At the conclusion of the course of treatment, a written summary of the treatment delivery parameters is generated, including the total dose of brachytherapy and the total dose of external beam therapy if given, treatment technique, treatment volume, acute side effects, clinical course, and patient disposition. Patients treated with brachytherapy should be evaluated after treatment at regular intervals by the radiation oncologist for response and early and late effects on normal tissues.

NRC Training Requirements

As you know, the NRC has jurisdiction over the use of radioactive materials—including medical isotopes—and safety measures to protect the public and patients. Unlike other medical procedures where physicians must simply have a State license to practice medicine, the NRC requires certain training requirements for physicians who use radioactive materials. While the NRC recognized an alternative pathway to achieve permission to perform permanent seed implants with similar requirements, most radiation oncologists meet or exceed NRC's requirement that physicians complete a 3-year radiation oncology residency training (The Accreditation Council for Graduate Medical Education (ACGME) requires 4 years of training).

This training must include a structured educational program in basic radionuclide handling techniques applicable to the use of brachytherapy sources that includes 500 hours of work experience in preparing, implanting, and removing brachytherapy sources; using administrative controls to prevent a medical event involving the use of radioactive material; ordering, receiving and unpacking radioactive materials safely and performing the related radiation surveys; checking survey meters for proper operation; maintaining running inventories of material on hand; and using emergency procedures to control radioactive material. Further, the NRC requires these radiation oncology residency programs to include 200 hours of classroom and laboratory training in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, and radiation biology.

These combined 700 hours are in addition to the extensive clinical training in oncology, such as taking histories and conducting physical exams, understanding behavior and spread of cancers, interpreting pathology reports and laboratory tests, and evaluating scans and X-rays. Finally, those physicians who have successfully completed a radiation oncology residency program must then pass an oral exam related to these topics. As an examiner for the Board, I find students who have completed the training to be quite thorough in their knowledge of radiation biology and

safety and the appropriate clinical applications for radiation to treat cancer. Those who are not thorough in their knowledge do not pass this rigorous exam.

The brachytherapy team also includes a medical physicist. Per NRC requirements, medical physicists who are authorized to participate in brachytherapy must have a master's or doctoral degree in physics, medical physics or other physical science (such as engineering or applied mathematics from an accredited college or university) and have 2 years of full-time practical training and/or supervised experience in medical physics under the supervision of a medical physicist who is board certified or working with a physician who performs brachytherapy.

A variety of applicators are used in brachytherapy. These applicators, as well as treatment-planning computers and software, and treatment aids should be appropriately selected for the clinical application. Regular inspection, maintenance, and repair of this equipment are mandatory. In general, the physicist supervising the quality improvement program is responsible for documenting the maintenance and repair of manual equipment and applicators. The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of continuing quality improvement (CQI). It is the responsibility of the director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions.

The NRC also requires that brachytherapy is administered according to a written directive that must be signed and dated by the radiation oncologist. Before loading, the written directive must designate the treatment site, the type of radiation (isotope) to be used, the number of sources, the planned dose, and the dose rate to designated points. Applicator geometry and isotope positions are defined with simulation radiographs. The specific isotope positions are designated by the radiation oncologist. Computerized dosimetry is performed by the medical physicist or designee and approved by the radiation oncologist. Independent verification of brachytherapy dose calculations (by another person or another method) is done pretreatment.

Prostate Brachytherapy at Duke

As an example, I would like to share with the Committee the safety protocols and procedures for brachytherapy at my institution. I believe these protocols are representative of those across radiation oncology departments nationwide as they rely on published guidelines and best practices. Our own procedure at Duke is as follows:

Initial consultation with patient

a. History, physical exam, and review of all pertinent lab and scan data.
b. Determine whether or not treatment for the prostate cancer is necessary and, if so, whether or not brachytherapy is an appropriate option.
c. Determine whether the patient fully understands all their options together with the advantages and disadvantages of each approach.

Volume study

The patient returns to have a complete assessment of their prostate made by the radiation oncologist and a urologist. This involves a transrectal ultrasound (TRUS) study in which a series of images are taken through the entire length of the prostate. On each of these, the radiation oncologist outlines the "target volume". This is usually the prostate plus, in some cases, a small margin if there is concern that the cancer may have leaked through the prostate capsule. In some cases, where there are case-specific concerns about the risk of side effects the target volume may be less than the entire prostate. The images are then downloaded to a computer containing the radiation planning software. A record is made of the exact position of the patient during the volume study so that the position may be reproduced at the implantation procedure in the operating room on a subsequent date. If, for anatomic reasons the prostate is poorly visualized or if, on scan, it is determined that the prostate has a large median lobe or the bladder empties incompletely, then the patient will not proceed to brachytherapy. We will choose a different option as the risk of a complication is increased by any of these factors.

At the end of the procedure, the radiation oncologist writes clearly the preferred choice of radioactive isotope (iodine or palladium) and the prescription radiation dose in grays (Gy). The radiation oncologist will also state constraints for specific normal tissues (e.g., the urethra is not to receive more than 130 percent of the prescribed dose or, say, reduce dose to the anterior base of the prostate to 90 percent). These constraints are tailored to patients individually and help to minimize morbidity. The radiation oncologist will specify whether seeds are to be "free" or "stranded".

Plan development

The physicist will then reconstruct a 3-dimensional image of the prostate on a computer and then determine the best number and "activity" of the seeds and their best placement within or around the prostate in order to match the radiation oncologists prescription. The radiation oncologist will then choose between several of these plans picking the best for the individual patient. Each needle is planned to deliver one or more seeds at the pre-determined insertion point in the prostate and a check list of these needle locations is then drawn up. The plan is then verified by a second physicist. This plan which includes the dose prescription and number and activity of seeds is the written directive. A date is made for the brachytherapy procedure and the seeds ordered.

Pre-operative testing

A physical exam and relevant blood work, EKG and chest X-ray are taken 1 week before the procedure to determine the patients suitability for general anesthesia. The patient is given a prescription for antibiotics to reduce the risk of infection, an alpha-blocker to improve the urine flow in the first post-implant month, and occasionally a steroid medication. The latter is given to those with larger prostate glands to reduce the risk that, as a result of acute swelling, they will be unable to urinate after the procedure.

Radioactive source intake

Upon arrival at Duke, the physicist will determine the position of the seeds within the pre-loaded brachytherapy needles and verify by X-ray film. The film exposes the exact location of each seed and this allows a check on the number and position of each seed within each needle.

Brachytherapy procedure

a. "Time out" in which all Members of the team (radiation oncologist, urologist, anesthesiologist, operating room nurse and physicists) agree on the patient using two different identifiers and the procedure.
b. The plan is once again checked by radiation oncologist and physicist.
c. General anesthesia is used to ensure an immobile patient.
d. The patient is placed in a position that mirrors the one used in the volume study.
e. Aerated gel is placed into the urethra to visualize, and thus avoid, the urethra.
f. Transrectal ultrasound is placed into rectum and manipulated until the image exactly mirrors the image obtained at volume study. The probe is then locked into place. If visualization is poor the procedure is canceled.
g. Needles containing seeds are numbered according to the plan and called sequentially by the physicist. A double check on the correct number of seeds is made by observing the length of protrusion of the trocar from each needle. The protrusion length correlates exactly with seed number. Each needle is then placed into the correct position within the prostate as called by the radiation physicist working from the plan and the checklist. The correct placement is ensured by visualizing each numbered needle as it passes through a perineal template and into the prostate gland. The needle location is verified using transverse images which show its side-to-side and up-and-down location and a sagittal image which shows whether or not the needle has reached the correct depth within the prostate. Image verification is made for each needle and a double check comes from measuring the degree of protrusion of the needle from the template. When needles are correctly placed, and agreement reached between physicist and radiation oncologist, the seeds may be unloaded into the prostate.
h. At repeated intervals during the procedure, an assessment is made of the position of the prostate base as this can become deeper if the prostate swells.
i. A final check is made with ultrasound and/or fluoroscopy to determine whether any regions of the prostate appear under-implanted and whether or not there are any seeds in the bladder.
j. If any visible area of under-implantation is identified, additional seeds, which are always pre-ordered, may be inserted at this point and a notation is made of their number.
k. The bladder may be irrigated or a cystoscopy performed in the unlikely event that a seed has passed into that organ. If so, the seed is retrieved safely and either a substitute seed is inserted or its absence noted.
l. The patient is awakened and brought to the recovery room.

m. The patient goes home one to 4 hours later once he has urinated spontaneously.
n. Prior to departure from the hospital, measurements are taken of radiation activity at the patient's skin surface and at one meter. These are to ensure safe levels for family members. Measurements are taken within the operating room, recovery room, and from the patients urine and linen to ensure no seeds have been unknowingly lost.
o. The patient goes home with procedure safety instructions, a lead container and a urinary sieve. They are instructed to pass their urine through this sieve and, if any seeds are retrieved, to place them into a lead container with tweezers and bring them back to the Duke Radiation Oncology Department during their next visit.

Post-implant dosimetry

Approximately 1 month after the procedure, patients return for a history and physical evaluation to determine whether or not the side effects are in line with expectations and to determine that they are successfully emptying their bladders. Any passed seeds may be returned to the radiation oncologist at this time and these must be accounted for in the post-implant dosimetry.

A CT scan is performed of the prostate area and the images analyzed using seed identification software. The prostate is then outlined and a computer calculation then made by the physicist of the radiation distribution. The volume drawing and measurements are performed by the trained physicist independent of the radiation oncologist to ensure veracity and consistency. Certain measurable parameters are collected including the urethral dose and the dose to the rectum to confirm that it is not greater than the dose prescribed. These may be used for internal quality control and for comparison with national measures. These parameters are peer-reviewed by the multidisciplinary genitourinary radiation oncology group within our department.

Medical events

At Duke, we adhere to the following protocols that conform to NRC regulations. Per those protocols, we determine that a medical event has occurred if any of the following situations apply:

1. Wrong patient treated.
2. Wrong area/side implanted (for a partial prostate implant).
3. Wrong isotope used.
4. Wrong dose used in patient (±20 percent).

If it is determined that a medical event has occurred, a report is immediately made to the Duke Radiation Safety Officer, who evaluates and reports to the NRC. The patient and referring physician would also be alerted immediately. ASTRO and ABS are participating in the NRC's rulemaking process to ensure that the revised definition of a medical event for permanent implant brachytherapy protects the safety of patients.

Subsequent follow-up

Visits to the radiation oncologist in the clinic occur every 3 to 6 months. History, physical exam, and PSA measurement are performed at each visit. Parameters are recorded in the institutional prospective quality assurance database.

Finally, I would like to illustrate the benefits of brachytherapy by telling you the story of one of my patients. He is a 50-year-old university professor and ardent long-distance runner whom I first met about 8 years ago. He had early stage prostate cancer and after discussion of all treatment options, he elected prostate brachytherapy. He told me that he chose brachytherapy so that he could continue to teach his students, coach his daughter's soccer team and train for an upcoming marathon. I, along with my colleagues at Wake Forest, performed prostate brachytherapy in the spring and he ran in the Marine Corps marathon later that year. His postimplant dosimetry was good and 7 years after his treatment, his PSA is undetectable and he has excellent urinary function. He has run in a marathon every year since his treatment.

ASTRO shares the Committee's concerns about the health and safety of veterans and recognizes the importance of maintaining veterans' access to high quality cancer treatment. We support the NRC's investigation into the causes of the medical events at the Philadelphia VAMC. By bringing these issues to the forefront, necessary steps can be taken to implement corrective actions and enhance quality of care standards for prostate cancer treatments at all VA hospitals. ASTRO appreciates

the opportunity to work closely with the Committee and NRC to ensure the safety of radioactive materials for medical use.

ASTRO is committed to ensuring that radiation oncologists and members of the treatment team adhere to strict safety standards and clinical guidelines for all radiation therapy, including brachytherapy. Thank you again for the opportunity to testify.

Online References:

- Agency for Health Care Research and Quality (http://www.effectivehealthcare.ahrq.gov/repFiles/2008_0204ProstateCancerExecSum.pdf)
- American Brachytherapy Society (www.americanbrachytherapy.org)
- American College of Radiology (http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/ro/low_dose_rate_brachytherapy.aspx; http://www.acr.org/SecondaryMainMenuCategories/quality_safety/app_criteria/pdf/ExpertPanelonRadiationOncologyProstateWorkGroup/PermanentSourceBrachytherapyforProstateCancerDoc5.aspx)
- American Urologic Association (http://www.auanet.org/content/guidelines-and-qualitycare/clinical-guidelines/main-reports/proscan07/content.pdf)
- Nuclear Regulatory Commission (http://www.nrc.gov/reading-rm/doccollections/cfr/part035/)
- RT Answers (www.rtanswers.org)

Bibliography:

- Nag, S et al. *American Brachytherapy Society (ABS) Recommendations for Transperineal Permanent Brachytherapy of Prostate Cancer*, Int. J. Radiation Oncology Biol. Phys., Vol. 44, No. 4, pp. 789–799, 1999.
- Nag, S et al. *American Brachytherapy Society (ABS) Recommendations for Permanent Prostate Brachytherapy Postimplant Dosimetric Analysis*, Int. J. Radiation Oncology Biol. Phys., Vol. 46, No. 1, pp. 221–230, 2000.

Prepared Statement of Joseph A. Williams, Jr., RN, BSN, MPM, Assistant Deputy Under Secretary for Health for Operations and Management, Veterans Health Administration, U.S. Department of Veterans Affairs

Good morning, Mr. Chairman and Members of the Subcommittee. Thank you for the opportunity to discuss the Department of Veterans Affairs' (VA) enforcement of VA's brachytherapy program safety standards. I am accompanied today by Dr. Madhulika Agarwal, Chief Officer, Patient Care Services, Veterans Health Administration (VHA); Dr. Michael Hagan, National Director for Radiation Oncology in VHA; E. Lynn McGuire, MS, DABMP, National Health Physics Program Director in the Office of Patient Care Services, VHA, Michael E. Moreland, FACHE, Network Director, VA Health care—VISN 4, and Dr. Richard Whittington, a physician at the Philadelphia VA Medical Center (VAMC).

My testimony today will briefly describe brachytherapy, review what happened at the Philadelphia VAMC, explain VA's enforcement of safety standards for brachytherapy, and discuss the current status of these programs throughout VA. Brachytherapy for prostate cancer is a form of nuclear radiotherapy where small radioactive seeds are implanted in the prostate to destroy cancerous cells. Although risk to healthy tissues in the body is minimal, side effects may occur. Brachytherapy is an appropriate treatment approach for low-risk patients with prostate cancer, but implant quality must be monitored closely in each case and programs performing this procedure must be regularly reviewed.

VA acknowledges that some of the brachytherapy treatments provided at the Philadelphia VAMC did not deliver the intended dose; we regret this occurred. We have notified patients by mail and by telephone and are covering all costs associated with additional tests while continuing to monitor the care of our patients, whether they are seen at VA or private facilities. A review by independent, external physicians and physicists with no involvement in the Philadelphia VAMC's brachytherapy program examined patient scans, dosages and medical records and discovered that 92 events involving under-dosing or doses to organs other than the treatment site were found that met the definition of a medical event according to the Nuclear Regulatory Commission (NRC). It is important to highlight that the definition of "medical event" does not necessarily mean Veterans were harmed, and experts still debate the long-term impact of this treatment. We are working with NRC on regulatory issues related to prostate brachytherapy, and NRC is refining the definition of "medical event" as it pertains to these procedures. The Philadelphia

VAMC's brachytherapy program has been suspended since June 2008 and will not be reopened until NRC's concerns have been satisfied and until requirements of the VA's Radiation Oncology program are met. VA's National Health Physics Program (NHPP) is responsible for radiation safety oversight through a license issued by NRC and reports to VA's National Radiation Safety Committee. NHPP has conducted site inspections at all facilities where prostate brachytherapy is performed and when a possible medical event is reported.

Enforcing program safety standards is essential to ensuring patients receive the care they require. VA, as do other health systems, relies on complementary systems of accountability to identify quality problems like these on the system and individual levels. We use multiple internal and external survey and inspection processes (e.g., Joint Commission, American College of Radiology Oncology, American College of Radiology, Nuclear Regulatory Commission, and others); patient satisfaction and complaints; and individual peer review. The deficits in this program at the Philadelphia VAMC went undetected by many of these systems for almost 6 years, and it was only the recognition of potential problems by the staff at the Philadelphia VAMC that eventually led to more in-depth investigation, review and subsequent disclosure to patients and the public.

In November 2008, VA amended the criteria for suspending a prostate brachytherapy program to require immediate suspension of any such program where medical events are discovered for 20 percent or more of patient treatments reviewed or evaluated for regulatory compliance. VA is requiring these reviews use a minimum sample size of 10 recent patient treatments or the total number of patient treatments in the last 3 years, whichever is less, for initial evaluation. If 20 percent or more patient treatments are discovered as medical events, VA requires increasing the sample size to at least 30 or all patient treatments within the last 3 years, whichever is less. If 20 percent or more of the final sample size is confirmed to be medical events, the program must be immediately suspended. Moreover, VA also requires its NHPP to inspect any report of medical events to confirm regulatory compliance and implementation of VHA standard procedures. VA will suspend any prostate brachytherapy program if the results of this 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 Under Secretary for Health.

In response to concerns raised by NRC and to ensure other VAMCs were performing prostate brachytherapy procedures correctly, VA completed inspections by January 2009 of all VA facilities with active programs. VA also developed and implemented standard procedures for prostate brachytherapy programs, addressing quality assurance measures and patient safety. These include the following:

- Initial and periodic training for physicians, medical physicists, dosimetrists, and Radiation Safety Officers and staff;
- Training in the definition and criteria of medical events, how to identity 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.

VA clinical standards and procedures are now among the most rigorous in the health care industry.

Regarding future actions to prevent similar situations, VA has asked the American College of Radiology (ACR) to conduct site surveys at each facility performing brachytherapy for prostate cancer. Our goal is 100 percent accreditation of our facilities; nationally in the private sector and VA, only 15 percent of practices are accredited now. Furthermore, each facility performing permanent implant prostate brachytherapy must develop, maintain and implement written procedures based on the American College of Radiology's "Practice Guidelines for Transperineal Permanent Brachytherapy of Prostate Cancer" and publications by the American Association of Physicists in Medicine. We are also drafting a VHA handbook for radiation oncology.

VA has used the situation in Philadelphia to conduct a comprehensive review of its prostate brachytherapy programs. Fifteen VA facilities have provided prostate implants since 2005, although two, Reno, NV and Birmingham, AL, are currently inactive without plans for resumption. Seven facilities, including Albany, NY, Boston, MA, Brooklyn, NY, Minneapolis, MN, Richmond, VA, San Francisco, CA, and Seattle, WA, are currently active and offering brachytherapy treatments. In our comprehensive review, we found these facilities have provided appropriate treat-

ments. VA's NHPP has temporarily suspended four programs, including Cincinnati, OH; Washington, DC; Jackson, MS; and Philadelphia because problems were found involving under-dosing. Based upon these reviews, the Cincinnati program was found to be in compliance with VA standards and is in the process of fulfilling national VA requirements for resuming prostate brachytherapy. Complete reviews of the Jackson and Washington programs continue. Problems with the treatments offered at the Philadelphia VAMC were discussed previously. The Durham, NC, VAMC has voluntarily chosen to no longer provide this procedure in-house and is providing this service through a fee-basis agreement with Durham Regional Hospital. The VA Greater Los Angeles Health Care System in California has elected to pause its program to conduct a review of procedures, with new patients scheduled for July 2009.

Secretary Shinseki and VA's senior leadership are conducting a top-to-bottom review of the Department and are implementing aggressive actions to ensure the right policies and procedures are in place to protect our Veterans while providing them the highest quality health care possible. It is important that our Veterans and their loved ones have faith and confidence in our medical system and in our system of care. Thank you once again for the opportunity to testify. My colleagues and I are prepared to answer your questions at this time.

Statement of Gregory E. Desobry, Ph.D., Medical Physicist, Division of Medical Physics, Department of Radiation Oncology, University of Pennsylvania, School of Medicine, Philadelphia, PA

Mr. Chairman and Members of the Committee, thank you for the invitation to appear here today. I would like to use my time to provide you with some information about my background, as well as a description of the medical physicist's role in prostate brachytherapy.

Before undertaking my graduate studies in physics, I studied for about 10 years in the Jesuit order of the Catholic church. During that time, among other things I did missionary work in Zambia, teaching junior high school students science, math, and English. Afterward, I returned to school, and in 1976 I was awarded a Ph.D. in physics from the University of Virginia. My early career as a physicist included work for the McDonnell Douglas Corp. in Houston, Texas, designing and testing NASA's space shuttle software.

I began studying to become a medical physicist in 1986, and in 1989, I was certified by the American Board of Radiology in therapeutic radiological physics. Thereafter, I was an assistant physicist at the MD Anderson Cancer Center in Houston and a clinical physicist for Fox Chase Cancer Center in Philadelphia. In 1999, I joined the Department of Radiation Oncology at the University of Pennsylvania.

I first assisted with prostate brachytherapy implants a few years thereafter, received some training from Dr. Richard Whittington, and worked part-time at the Philadelphia Veterans Affairs Medical Center from the start of the prostate brachytherapy program there in 2002 until 2007.

A medical physicist does three things to assist In prostate brachytherapy.

First, based on the doctor's prescription, which specifies the amount of radioactivity to be implanted into the patient, the physicist prepares what is called a preplan. To do this, the physicist will review a series of ultrasound images of the prostate that is taken by a doctor and in which the doctor has identified the prostate. With this information from the doctor, the physicist will plan the places where the radioactive seeds should be implanted into and around the prostate and estimates the radioactive dose to be delivered to the prostate. This plan always is confirmed (or revised) by the doctor.

Second, not long before the doctor is to perform the implant, the physicist will verify that the activity level and the loading of the seeds is correct. The physicist also delivers the seeds to the doctor in the operating room.

The third thing a physicist does takes place after the implant. At the PVAMC, the doctor would order a CT scan of the patient's prostate the day after the implant. On this CT scan, the physicist would identify the location of the implanted seeds, using a dedicated computer program for this purpose.

Once this was done, the doctor would locate the prostate on the CT scan and draw it in. This would allow the computer program to generate a "dose volume histogram," essentially a graph showing how much of the prostate received how much of a dose, as well as different dose parameters. This information is often referred to as "post-implant dosimetry."

Post-implant dosimetry is performed so that the doctor might evaluate the implant as part of his overall assessment of his ongoing treatment plan for the patient.

I recognize that the Committee may have questions, and I will do my best to answer them.

Again, thank you for your consideration of my testimony.

Statement of George Lazarescu, Ph.D., Medical Physicist, Division of Medical Physics, Department of Radiation Oncology, University of Pennsylvania, School of Medicine, Philadelphia, PA

Mr. Chairman and Members of the Committee, thank you for the invitation to appear here today. I will offer in these prepared remarks a brief description of my background.

I received a Ph.D. in physics in 1974 from the Institute for Atomic Physics in Bucharest, Romania, and in 1991 was graduated with a master of science in medical physics from the Medical Physics Graduate Program of the Wayne State University School of Medicine in Detroit, Michigan. In 1996, I was certified in radiation oncology physics by the American Board of Medical Physics, which is a certification recognized by the American Board of Radiology.

From 1996 to 2003, I was an associate professor at the State University of New York Health Science Center in Brooklyn, New York, and in 2003 I joined the Hospital of the University of Pennsylvania's Department of Radiation Oncology as a medical physicist. My clinical work since that time has primarily been at the Philadelphia Veterans Affairs Medical Center, working with external beam radiotherapy.

I recognize that the Committee may have questions, and I will do my best to answer them. Again, thank you for your consideration of my testimony.

Statement of Hon. Cliff Stearns, a Representative in Congress from the State of Florida

Thank you, Mr. Chairman.

I am pleased to be here for this important hearing, although I do wish we were here under better circumstances.

For almost 6 years, serious problems with the brachytherapy program at the Philadelphia VA Medical Center (VAMC) went undetected. That's 6 years in which potential harm could have been caused to some of our Nation's veterans seeking treatment for prostate cancer. Presently, 4 of the VA's brachytherapy programs have been suspended—this is a worrisome number given there are only a total of 7 active programs at the moment—so more than half of the VA's active brachytherapy programs are suspended. That's a dismal statistic.

From May through October 2008, a series of "medical events" were finally detected and reported, with the stand-out case being the Philly VAMC in which 92 events involving either under dosing, or dosing to organs other than the intended treatment site, were reported. Seventeen other medical events were also reported at VA Medical Centers in Jackson, MS, Cincinnati, OH, and Washington, DC.

I am dismayed that prior to this issue coming to light, the VA did not have standard procedures for prostate brachytherapy programs, including methods and procedures to verify seed placement and for determining proper dosage of post treatment dose analysis. It seems like the VA is often more reactive than proactive, and this shouldn't be the case given the fact that the VA is a national leader in quality health care.

To the VA's credit, they have taken proper action since the discovery of these problems, and they appear to be working toward a comprehensive makeover of its brachytherapy programs. However, VA ultimately holds responsibility for the safety and health of our veterans treated at VA facilities.

It is my hope that today's hearing will afford us the opportunity to address the issues surrounding the evolving definition of a reportable "medical event," and to clear up the discrepancy over why there was no peer review or Quality Assurance of the brachytherapy program at the Philly VA.

Thank you, and I look forward to the hearing.

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