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FIELD HEARING: PHILADELPHIA VA TERMINATED CANCER TREATMENT PROGRAM

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

JUNE 29, 2009

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FIELD HEARING: PHILADELPHIA VA TERMINATED CANCER TREATMENT PROGRAM

MONDAY, JUNE 29, 2008

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Philadelphia, PA.

The Committee met, pursuant to notice, at 10 a.m., in multipurpose room 1, Philadelphia VA Medical Center, Hon. Arlen Specter, presiding.

Present: Senator Specter, House Representatives Adler and Fattah.

OPENING STATEMENT OF HON. ARLEN SPECTER, U.S. SENATOR FROM PENNSYLVANIA

Senator SPECTER. Good morning, ladies and gentlemen. The hour of 10 having arrived, we will proceed with this hearing of the Veterans' Affairs Committee of the U.S. Senate.

One of the constitutional responsibilities of the Senate is to conduct oversight on activities of the Federal Government. We all know the tremendous debt which is owed by our society to the veterans of America who have fought in wars to establish and maintain our liberty, and one of the responses by a grateful government has been to provide medical care for the veterans. This is a subject which is very near and dear to my heart, because the first veteran I knew was my own father, Harry Specter.

My story is a typical American story, both parents were immigrants. My father came to this country from Russia in 1911 at the age of 18 and spoke about the privilege of being an American and serving with the American expeditionary force in France in 1918 to make the world safe for democracy. He was wounded in action. The government promised World War I veterans a $500 bonus—you could say they made him a $500 promise, too—and that promise was broken, as so many promises are broken by the Federal Government.

After being elected in 1980, I immediately joined the Veterans' Affairs Committee in the U.S. Senate because of my concern for fair and equitable treatment for veterans, and had the honor to serve for 6 years as Chairman of the Veterans' Affairs Committee.

This hearing has been convened as a result of widespread publicity about problems in the Veterans Administration here in the city of Philadelphia. A week ago yesterday, there were extensive Sunday stories by both the *Philadelphia Inquirer* and *The New York Times*. Those stories reported that there was a systematic problem on the treatment of prostate cancer at the Philadelphia VA

Medical Center, causing 82 veterans to receive incorrect doses of radiation. There was a procedure undertaken where there were seeds implanted to kill the cancer cells, but the seeds were planted, in some cases, in the bladder or elsewhere. *The New York Times* characterized the procedures here as a "rogue cancer unit."

One factor which we will inquire about today is why these errors were not detected for a period of some 6 years; and why the oversight was done by the operative physicians themselves, as opposed to some independent agency; and a major question exists as to what can be done to correct whatever problem existed; and what assurances can be given to the veterans and the public that the procedures will be maintained and corrected so that appropriate service will be given to the veterans who are served here.

We now turn to our first witness, who is Reverend Ricardo Flippin, a patient who was mentioned in the articles that I referred to. Reverend Flippin is a 21-year veteran of the U.S. Air Force who received his treatment here. He is a native of Philadelphia, but currently resides in Charleston, West Virginia.

In accordance with the standard procedures, we will have testimony limited to 5 minutes, and then there will be questioning.

I expect to be joined by Congressman John Adler from New Jersey of the House of Representatives Veterans' Committee, and we will ask all witnesses to observe the time limit. There is a clock in front of each witness.

Reverend Flippin, we thank you for coming from West Virginia. We understand that you are a native of Philadelphia, Pennsylvania and we look forward to your testimony. You may proceed.

STATEMENT OF REVEREND RICARDO FLIPPIN, UNITED STATES AIR FORCE VETERAN

Rev. FLIPPIN. Thank you. Senator Specter, I would like to thank you for your interest in this situation at the Philadelphia VA, and for inviting me here today.

Although I was born and raised in Philadelphia, I had been absent from the Philadelphia area from the time that I left to join the Air Force. I returned to Philadelphia in 2004 to take care of my mother, whose health was failing. As I did not have a private physician in this area, I decided that I would try to take advantage of my benefits as a veteran and I sought medical care from the Philadelphia VA. This was my first contact with the VA health care system.

On April 15, 2004, I made my first trip to the Philadelphia VAMC, because my family doctor in Charleston told me that my PSA was increasing and that I should make a point of following up with the doctor when I got to Philadelphia. A PSA test was performed on my first visit, which showed a level of 7.04. It took the VA until May 9, 2005, to actually treat my prostate.

On June 3, 2004, I returned to the Philadelphia VA and was given a referral for a urology consult. This consult took place on June 29, 2004. I was scheduled for a biopsy which took place on August 26, 2004.

On September 23, 2004, I was advised that I had cancer. In December 2004, I met with a physician to discuss my opinions.

In January 2005, I believe that I met with the radiation oncologist. He was quite convincing that brachytherapy was the best option for my situation and that he had received good results from this procedure in the past; and he had performed hundreds of them. Let me say at this point that that is what impressed me, that this physician had told me—looking me eyeball to eyeball—that he had actually performed over 600 brachytherapy procedures. My procedure was not scheduled until May 9, 2005. By then, my mother had passed away and I had returned to Charleston, West Virginia to be with my wife, my granddaughter, and my niece.

During the time after my procedure, I had medical problems that required me to return to the VA on several occasions for additional medical care. Eventually, the VA sent me to the Ohio State University for an additional procedure with a specialist. Until I received notification from the VA in Philadelphia that they were investigating my medical care as well as the medical care of other veterans, no one had ever told me that there had been any problem with the procedure that was performed at the Philadelphia VA. To date, no one from the Philadelphia VA has specifically told me what went wrong with my procedure, nor have I been advised to what the effects of this procedure has been and will be on me.

On July 2, 2008, they sent me a letter saying, "Our review of your treatment program has indicated that there is a possibility that you received the radiation to your prostate gland that was less than your physician intended," which led me to believe that there was something wrong with the seeds or perhaps the equipment. The letter never mentioned that other parts of my body apparently got a radiation dose greater than my physician intended.

On August 15, 2008, they sent me a letter saying that the treatment did not meet the VA standard of care. The results of a CT scan indicate that the treatment that you received did not meet the VA's high standard of care. "You recently were notified by telephone of this result, and this letter is being sent to confirm that conversation. We have also advised your VA primary care physician of this fact, and we will send him/her a copy of this letter."

They sent me some forms for filing a claim, which was nice of them, but not one person in the VA told me what the effects of the surgery that I received were. No one from the Philadelphia VA and no one from the West Virginia VA has written me or called me and said that I am more likely to get a reoccurrence. No one has said——

Senator SPECTER. Reverend Flippin, before your time expires, would you tell us what injuries, if any, you sustained.

Rev. FLIPPIN. I sustained a radiation burn to my rectum which caused me to be laid up for 5 months; 24 hours a day, bedridden.

Senator SPECTER. You may proceed.

Rev. FLIPPIN. For the last several years, I have worked with a program designed to help veterans deal with the issues that they face. My biggest concern is that there may be veterans out there who have had this happen to them and they have not gotten the message from the VA. As someone who has spent 20 years active duty in the Air Force and as someone who regularly works with veterans to see that they get the services they need, I know that there are probably some veterans out there who received letters

but did not open them because they were from the VA. They also may have received phone calls they did not return because they were from the VA. And my hope is that the attention that this is creating will make those guys or, more likely, their spouses or family members, go back and open those letters and get the follow-up treatment that they need.

Finally, I really cannot add anything to the discussion about Dr. Kao. I have never met the gentleman. He was not the doctor who I met with to decide the type of therapy to select. I was surprised to learn this week that he was a contractor. No one told me that my surgery was going to be done by someone who did not work for the VA.

Thank you for your concern about the medical care that veterans are receiving from the Department of Veterans' Affairs.

[The prepared statement of Rev. Flippin follows:]

PREPARED STATEMENT OF REV. RICARDO C. FLIPPIN, U.S. AIR FORCE VETERAN, CHARLESTON, WEST VIRGINIA

I would like to thank you for your interest in the situation at the Philadelphia VA, and for inviting the here today.

Although I was born and raised in Philadelphia, I had been absent from the Philadelphia area from the time that I left to join the Air Force. I returned to Philadelphia and 2004 to take care of my mother, whose health was failing. As I did not have a private physician in this area, I decided that I would try to take advantage of my benefits as a veteran and I sought medical care from the Philadelphia VA. This was my first contact the VA health care system.

On April 15, 2004, I made my first trip to the Philadelphia VA, because my family doctor in Charleston had told me that my PSA was increasing and that I should make a point of following up with the doctor, when I got Philadelphia. A PSA test was performed on my first visit, which showed a level of 7.04. It took the VA until May 9, 2005, to actually treat my prostate.

On June 3, 2004, I returned to the Philadelphia VA and was given a referral for an urology consult. This consult took place on June 29, 2004. I was scheduled for a biopsy, which took place on August 26, 2004. On September 23, 2004, I was advised that I had cancer. In December 2004, I met with the physician to discuss my options. In January 2005, I believe that I met with a radiation oncologist. He was quite convincing that brachytherapy was the best option for my situation and that he had received good results from this procedure in the past and had performed hundreds of them. My procedure was not scheduled until May 9, 2005. By then, my mother had passed away and I had returned to Charleston, West Virginia, to be with my wife, my granddaughter and niece.

During the time after my procedure, I had medical problems that required me to return to the VA on several occasions for additional medical care. Eventually, the VA sent me to Ohio State University for an additional procedure with a specialist. Until I received notification from the VA, in Philadelphia, that they were investigating my medical care, as well as the medical care of other veterans, no one ever told me that there had been any problem with the procedure that was performed at the Philadelphia VA. To date, no one from the Philadelphia VA has specifically told me what went wrong with my procedure, nor have I been advised as to what the effects of this procedure have and will be on me.

On July 2, 2008, they sent me a letter saying ". . . Our review of your treatment program has indicated that there is a possibility that you received a radiation dose to your prostate gland that was less than your physician intended. . . ."

Which led me to believe, that there was something wrong with the seeds, or perhaps the equipment? The letter never mentions that other parts of my body, apparently, got a radiation dose greater than my doctor intended.

[The July 2, 2008, letter follows:]

Dear Mr. Flippin,

Recently, the Philadelphia VA Medical Center has begun a review of our brachytherapy program, including the treatment of patients who, like you, received care through that program. Our review of your treatment program has indicated that there is a possibility that you received a radiation dose to your prostate gland that was less than your physician intended. Because of this, we ask that you visit the medical center at your earliest convenience to have your condition examined and to undergo a new computed tomographic exam (CT scan) so that we can determine whether the treatment you received was adequate for your needs.

If you have not already been contacted, I'd appreciate it if you would call Pamela Devine, RN, in the Radiation Oncology Department at (215) 823-5855 or toll free at (800) 949-1001 extension [redacted] to set up a time for your visit. There will be no co-payment associated with this appointment. We have also established a special toll free number for you to call if you have any questions about your care. That number is (866) 709-4598. A VA employee will be available to help you between the hours of 7:00 a.m. and 5:00 p.m.

Additionally, we can provide you with information regarding administrative claims and claims for benefits that are available to you if you believe you were harmed by your radiation therapy. For more information, please contact Sue Kirlin, RN at 800-949-1001 extension 6338.

Please accept my sincere apology for the situation that prompted this letter. I understand the responsibility and trust you place in us, and my staff and I will do all we can to promptly and effectively address this issue.

On August 15, 2008, they sent me a letter saying that the treatment did not meet the VA's standard of care.

> ". . . The results of the CT scan indicate that the treatment you received did not meet VA's high standard of care. You recently were notified by telephone of this result and this letter is being sent to confirm that conversation. We have also advised your VA primary care physician of this fact, and we will send him/her a copy of this letter."

[The August 15, 2008, letter follows:]

Dear Mr. Flippin,

Recently a letter was sent to notify you that the care you received for prostate cancer at the Philadelphia VA Medical Center was being reviewed. As part of the follow up to assess your treatment, a follow-up CT scan was performed. The results of the CT scan indicate that the treatment you received did not meet VA's high standard of care. You recently were notified by telephone of this result and this letter is being sent to confirm that conversation. We have also advised your VA primary care physician of this fact, and we will send him/her a copy of this letter.

If you have any further questions, please call Pamela Devine, RN, in the Radiation Oncology Department at (215) 823-5855 to set up a time for your visit.

Included in this packet is information regarding the filing of administrative claims and benefits for which you may be eligible. If you have questions about the benefits or claims, please call Sue Kirlin, RN, Risk Manager, at (215) 823-6338 or toll free at (800) 949-1001, extension 6338 or 6022.

I apologize for any inconvenience, or concerns this may cause regarding the care that you received at the Philadelphia VA Medical Center.

Sincerely,

Richard S. Citron

RICHARD S. CITRON, FACHE
Medical Center Director

They sent me some forms for filing a claim, which was nice of them, but not one person in the VA told me what the effects of the surgery that I received were. No one from the Philadelphia VA, no one from the Charleston VA, has written me, or called me, and said that I'm more likely to get a reoccurrence, no one has said that I should come in more regularly for monitoring, no one from the VA has said that you're going to be fine. I learned from the newspaper that they had 6 veterans go out to the Seattle VA to have their procedures redone, so I hope that I'm not that bad. It is particularly upsetting that they have not told me anything about my future because some of the NRC materials make it seem as if a very thorough investigation has been commissioned by the VA and that an expert has reviewed each of the cases. As a matter of fairness, one would think that they would have told each veteran what the results of the outside study were, or that they would have provided this information to my primary care doctor, to help them with my future medical care.

For the last several years I have worked with a program designed to help veterans deal with the issues that they face. My biggest concern is that there may be veterans out there who have had this happen to them, and they have not gotten the message from the VA. As someone who spent twenty years on active duty in the Air Force, and as someone who regularly works with veterans, to see that they get the services that they need, I know that are probably some veterans out there who didn't open the letters that they got from the VA, because they were from the VA, they didn't return the phone calls they got from the VA, because they were from the VA, and my hope is that the attention that this hearing is creating will make those guys, or more likely their spouses or family members, go back and open those letters and get the follow up treatment that they may need.

Finally, I really can't add anything to the discussion about Dr. Kao. I have never met the gentleman. He was not the doctor who I met with to decide which type of therapy to select. I was surprised to learn this week that he was a contractor; no one told me that my surgery was going to be done by someone who did not work for the VA.

Thank you for your concern about the medical care that veterans are receiving from the Department of Veterans Affairs.

Senator SPECTER. Thank you, Reverend Flippin.

Without objection, I will put into the record a statement from U.S. Representative Allyson Y. Schwartz of Pennsylvania's District 13.

[The prepared statement of Ms. Schwartz is found in the Appendix.]

Senator SPECTER. I would like to turn now to Congressman John Adler, House of Representatives, who is a member of the Veterans' Affairs Committee and who, early on, spoke out about this issue.

Welcome, Congressman Adler. Would you care to make an opening statement?

STATEMENT OF HON. JOHN ADLER, REPRESENTATIVE FROM NEW JERSEY

Mr. ADLER. Senator, thank you very much, and thank you as well on behalf of the veterans of America and the people of America for your calling this field hearing here today. You acted promptly when you learned about the troubles we have had with the brachytherapy program here at this VA hospital. Your concern for veterans has been noted for a number of years, but the fact that you would have such a prompt hearing, I think the country thanks you for that.

Our first President, George Washington, once said, "The willingness with which our young people are likely to serve in any war, no matter how justified, shall be directly proportional as to how they perceive the veterans of earlier wars were treated and appreciated by their country."

The veterans like Reverend Flippin who sought treatment for their 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 care in brachytherapy let our veterans down and sent the wrong message to young men and women thinking about joining our all-volunteer Armed Forces. We must do better for them.

So, it is my sense that this hearing today and the hearing we will have in Washington next week are about evaluating what happened, not to cast blame, although there is certainly some blame to go around, but to reassure our veterans and those considering volunteering for our Armed Forces in the future, that we will keep faith with the commitment we have made to them as they have kept faith with us by keeping us safe, keeping us free, and keeping us the strongest country in the world.

Reverend Flippin, I thank you for your 20 years of active duty service; that would have been enough. But I thank you as well for coming forward to share with us in this room, the newspapers, and America, the substandard care you received. It would have been enough if you had just soldiered on as you had while on active duty and suffered quietly, but the fact that you would share your experience, share your physical pain and your emotional trauma so that we can learn from it, so that we can set in place a new standard of care to meet the needs of our veterans, like yourself, going forward, is greatly to your credit. It is part of your ongoing service to your country, and I appreciate it. I am sure Senator Specter appreciates it, Representative Schwartz appreciates it, all the people from our region and from the whole country should join us in thanking you for testifying.

I wonder at what point you first decided we were letting you down as a country. At what point did you think—during your process, during your treatment—that the VA Hospital was not giving you the standard of care you deserved.

Senator SPECTER. Congressman Adler, we are going to hold the questions for the first round of questioning.

Mr. ADLER. I am sorry. Fine. I apologize.

Senator SPECTER. It is OK.

We will turn now to Congressman Chaka Fattah for an opening statement.

Thank you for joining us, Congressman Fattah.

OPENING STATEMENT HON. CHAKA FATTAH, REPRESENTATIVE FROM PENNSYLVANIA

Mr. FATTAH. Well, Senator, I rearranged my schedule so that I could be here. I want to thank you for holding this hearing. It is very timely. This is a great facility that has provided a lot of care for our veterans over many years, but this incident raises an extraordinary level of concern, and I want to thank you for convening us today. I am here to get some answers.

So, rather than giving a major opening statement, I want to thank the Reverend for his service to the country. My brother also served in the Air Force, and I think it also says a great deal about you that you returned to Philadelphia to care for your ailing moth-

er, and that you are leading a faith community. You are of service to our country in every respect, and we want to get to the bottom of what happened. In incidents where mistakes happened, we are all human beings—but the question becomes, what was done once the mistake was realized, and whether or not, in this instance, all of our veterans were best served.

I thank the Senator for using the weight of his office to convene us so that we could begin to get to the answers to this question. Senator Specter, for your leadership on this subject, I thank you.

Senator SPECTER. Thank you, Congressman Fattah.

Before turning to questions, we are going to hear from other witnesses.

I would like to call now Dr. Gary Kao to the witness stand, if Dr. Kao would step forward.

Dr. Kao has a bachelor's degree from John Hopkins University, an M.D. from John Hopkins School of Medicine, and a Ph.D. from the University of Pennsylvania. He was board certified in 1994 by the American Board of Radiology, and was contracted by the VA in 2002.

We are calling on Dr. Kao early because he has been identified in the news accounts as having performed a number of the operative procedures in question.

I note that you are accompanied Dr. Kao, and if those who have accompanied you would identify themselves, I would appreciate it.

Mr. VAIRA. Good morning, Senator Specter, Congressmen. I am Peter Vaira of the Law Firm of Vaira & Riley, and my associate is William Murray, from my law firm.

Senator SPECTER. Thank you very much, Mr. Vaira.

Dr. Kao, the floor is yours and you may proceed.

STATEMENT OF GARY KAO, M.D., PH.D., ASSOCIATE PROFESSOR, RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA; ACCOMPANIED BY PETER F. VAIRA, ATTORNEY, SHAREHOLDER, VAIRA & RILEY, P.C.; AND WILLIAM J. MURRAY JR., ASSOCIATE, VAIRA & RILEY, P.C.

Dr. KAO. Thank you, Senator Specter and Congressmen, for the opportunity to voluntarily appear before you so that I may be heard on this very important subject matter and correct some very serious false allegations contained in recent publications about me, 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 bachelor's degree and a medical doctorate degree from Johns Hopkins University and its School of Medicine, followed by medical internship and residency and radiation oncology residency. This culminated in board certification in radiation oncology.

I am especially proud that, in 15 years of continuous medical practice, there has not been a single malpractice claim against me. My impeccable background and commitment to the care of my patients make the false accusations against me particularly devastating and misguided.

Let me first express my sincere sadness to the plight of Reverend Flippin. I would have welcomed the opportunity to do anything I

could to help him, but I have never been contacted by Reverend Flippin or anyone on his behalf after the procedure; and therefore, do not know about his complaints and symptoms which arose about a year after his procedure.

I was first notified about Reverend Flippin from *The New York Times* article published the previous Sunday, and because I have not had access to any of his records since leaving the VA, I am unable to further comment on his medical treatment or condition.

What I can truthfully report is that I, along with others at the Philadelphia VA, implemented the program for brachytherapy to serve the best interest of veterans. Contrary to allegations that I was a "rogue physician," there were precise standard operating procedures formulated and followed and a system of monitoring and oversight. We formulated the first algorithm of any radiation oncology procedure at the VA to define those standard operating procedures. As with any program, it is not without incidents or challenges; however, I have always acted in the best interests of the patients in delivering this important treatment. I have never, nor would I ever, falsify documents, cover up results, or act in a manner detrimental to the interest of any patient.

What has become clear is that a misunderstanding of elementary principles or concepts have led some to inappropriately and incorrectly conclude that deficient care was routinely rendered; it was not the case. It is important that these issues be clearly understood. A fundamental issue which I want to directly address and which has been misunderstood is the subject of what the NRC defines as a reportable medical event and its applicability to our work at the VA.

Here are the facts:

Fact one, the standard definition of a reportable medical event to the NRC was not in existence when the brachytherapy program started at the VA. The definition was specifically never mentioned 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 on site at the Philadelphia VA. This definition was not the subject of any training provided to us by the NRC or the VA.

Fact two, the definition of a reportable medical event to the NRC does not define a standard of effectiveness of medical treatment either scientifically or medically.

A patient whose treatment results in a reportable medical event may still have received effective treatment and be within the appropriate standard of medical care.

Fact three, the appropriate standard of medical care for brachytherapy should not be determined by the NRC definition of a reportable medical event. There are many more significant factors that determine appropriate treatment, such as the number of seeds, the location of seeds in the prostate, location of seeds outside the prostate, the concentration of seeds in the affected area of the prostate, the size, shape of the prostate, the stage, grade, extent, and location of the cancer, and the clinical follow-up of the PSA test results, all of which are not addressed in the NRC defined standards.

The field of brachytherapy during the period of 2002 to 2008 was, and still is, an 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—that during my tenure the patients received appropriate medical care, which was effective in addressing their cancer.

In considering my experience at the VA and experience in the brachytherapy program, however, there are certainly issues which need to be addressed and implemented regarding the care provided to our veterans. These include the following:

One, a system should be established so that a treating VA physician is notified when 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.

For complex medical procedures such as brachytherapy, two, 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 treatment.

Three, there should be a method of categorizing systemic 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 to be quickly resolved.

Four, there should be a formal system by which the NRC and other national regulatory bodies would be required to continually train doctors and other personnel in the latest defined standards.

Five, 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.

Six, 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.

Thank you, Senator and Congressmen.

[The prepared statement of Dr. Kao follows:]

PREPARED STATEMENT OF GARY KAO, M.D., PH.D., ASSOCIATE PROFESSOR, RADIATION ONCOLOGY, UNIVERSITY OF PENNSYLVANIA

INTRODUCTION

I became a doctor because of my desire to help people. I am and always have considered myself to be a compassionate dedicated physician who prides himself in taking care of his patients. I have never knowingly hurt any of my patients and my record shows that to be true—I am proud that I have not had a single malpractice claim filed against me in fifteen years of continuous clinical practice. In 1984 I graduated from Johns Hopkins University with a Bachelor of Arts in Philosophy and graduated in 1988 as a Medical Doctor from the Johns Hopkins School of Medicine. I completed two years of Internal Medicine Residency followed by completion of a Residency in Radiation Oncology, all at the University of Pennsylvania School of

Medicine ("Penn"). I have been Board Certified in Radiation Oncology since 1994, and an Attending Physician at Penn since that time. I am also a member of American Society for Therapeutic Radiation Oncology.

In order to gain additional expertise in anticancer treatment, I completed a doctoral dissertation at Penn in Molecular Biology, which I successfully defended in 1998 and was awarded a Ph.D. from Penn in Molecular Biology. While still on staff at Penn, I completed a Postdoctoral Fellowship at the Fox Chase Cancer Center in 2002. Shortly after completing my Fellowship, I was assigned to the Philadelphia Veterans Affairs Medical Center ("PVAMC") and then became a full-time staff member of the PVAMC. I was asked by the PVAMC to start a brachytherapy program at the PVAMC and was proud to have earned this honor. I accepted the responsibility and worked hard with others at the PVAMC to develop a top notch program in this evolving area of medicine. I remained a PVAMC staff physician in Radiation Oncology continuously until the beginning of 2008.

Given all that I have worked so hard to achieve and my commitment to patient care, I was devastated, personally and professionally, by the false allegations published in *The New York Times* on Father's Day, branding me as a "rogue doctor" who had covered up mistakes and operated in isolation and without supervision. Never in my career have I ever falsified any medical records and never have I participated in a cover-up.

On the contrary, what happened at the PVAMC in connection with the brachytherapy program is in no way what has been depicted by the *New York Times* article. The truth is that the Prostate Brachytherapy team at the PVAMC was a collaborative interdisciplinary effort that I led, but which was minutely supervised every step of the way by the Radiation Oncology Department, the Radiation Safety Office and ultimately by the Administration of the PVAMC. Under sometimes challenging circumstances, the Team tried to deliver quality care to veterans, who would otherwise not have access to treatment.

That is why the malicious allegations against me and the Program are so deeply hurtful. So too is the claim that I operated on my own, without supervision and without guidance. The falsity of that allegation is easily demonstrated because there was a standard operating procedure for the administration of brachytherapy. The procedure was codified in a Prostate Brachytherapy Algorithm that was jointly created by Radiation Oncology, Medical Physics, Urology, Radiation Safety and Nursing and disseminated to and approved by all levels of the PVAMC Administration. This Algorithm was constantly reviewed and revised as our Team gained more expertise in delivering care to our patients. The Algorithm established a consensus, providing structure for a procedure that had no precedence or guiding standards at the PVAMC when I was asked to help start this Program. Each brachytherapy patient treated by me or any other physician at the PVAMC was cared for according to the SOP established by Algorithm.

The following points address specific aspects in greater detail:

1. The PVAMC Prostate Brachytherapy Program was a multidisciplinary collaboration.

The members of the Brachytherapy Team consisted of:

i. Radiation Oncology
ii. Urology
iii. Radiation Safety
iv. Medical Physics
v. Nursing/Program Coordinator
vi. Administration

The program was supervised by Radiation Safety. I was not a member of the Radiation Safety Committee and was not invited to attend meetings of the Committee.

2. The PVAMC Brachytherapy Program team members received the necessary training for Prostate Brachytherapy.

a. As a resident physician, I was taught prostate brachytherapy at Penn by senior attending physicians.

b. I completed the same Prostate Brachytherapy course in Seattle, WA at the Northwest Hospital that others from the PVAMC also attended.

c. We observed the Prostate Brachytherapy Program at the Mercer Hospital affiliate of the Department of Radiation Oncology in Trenton, NJ, a program that also utilized the preloaded method of brachytherapy.

d. I was proctored in the performing of my first ten Brachytherapy cases at the PVAMC by experienced physicians.

e. Other physicians were available for immediate consultation and additional mentoring.

f. The allegations in the NY Times of a lack of brachytherapy training or supervision are therefore untrue.

3. I created the protocol for providing brachytherapy treatment ("Algorithm") with collective multidisciplinary input, vetted through the PVAMC Administration.

a. The absence of standard policy regarding Brachytherapy in the PVAMC prompted the need for written consensus when the Program was first created in February 2002:

b. The first version was completed before the first patient was treated in February 2002, and continuously updated through the years of the Program.

c. The Algorithm was collaboratively written by all members of the Brachytherapy Team, and represented our collaborative expertise regarding the Standard Operating Procedure for providing brachytherapy.

d. The Algorithm describes those patients for whom brachytherapy was most suited as well as those for whom the procedure would not be effective. It also details the steps each patient undergoes through the Brachytherapy process beginning with the pre- procedure planning and following through with the actual procedure and the post-procedure follow up.

e. The Algorithm does not include any reference to reportable Medical Events as defined by the Nuclear Regulatory Commission ("NRC") because no such definitions existed at the start of the program.

f. Because the PVAMC served a wide geographical patient population, the Algorithm recognized that those patients living far from Philadelphia may have to receive post procedure care at their local hospitals.

g. The NRC, in its investigation, and the NY Times failed to mention the existence and purpose of the VA Prostate Brachytherapy Algorithm.

4. The Initial and Revised Written Directives serve different purposes.

a. The New York Times article falsely accuses me of altering the Written Directive.

b. The Written Directive is mandated by the NRC and VA's Office of Radiation Safety. The forms were designed by Radiation Safety, completed by both Medical Physics and Radiation Oncology, signed by the physicians, and processed by Radiation Safety.

c. The Initial Written Directive (WD) specifies the number of seeds to be ordered by Radiation Safety, i.e. the prescription for number of seeds. It is completed by the Medical Physicist together with the Radiation Oncologist physician, who then signs the WD.

d. A copy of the Initial WD is submitted to Radiation Safety, which places the order of the number of seeds, and then receives and secures the seeds. The original WD remains in the patient's medical chart.

e. On the day of the Brachytherapy procedure, Radiation Safety brings the seeds to the procedure room (adjacent to the OR suite), remains in the room to supervise the procedure, and to store and safeguard any seeds that are retrieved by Urology from the bladder or found outside the patient.

f. Integral to the procedure is the Urologist. Immediately after the implanting of the seeds, the Urologist, using a cystoscope, will retrieve any seeds that have either migrated to or been implanted in the bladder. This action by the Urologist is done in connection with every procedure since a recognized risk of the procedure is that seeds will come to rest in the bladder.

g. After the seeds are retrieved by the Urologist, that physician and Radiation Safety inform the Radiation Oncologist of the number of seeds that do not remain in the patient. Through this collaborative process, the Team determines the actual number of seeds that remain in the patient.

h. Under supervision by Radiation Safety, the Radiation Oncologist completes the Revised WD that states the actual number of seeds retained within the patient. The Revised WD is submitted to Radiation Safety, and a copy is again placed in the patient's medical chart. Radiation Safety staff and Urology are present throughout the brachytherapy procedure.

i. The WD can be revised yet again prior to the discharge of the patient on the day following the procedure. This revision would reflect any seeds passed by the patient in his urine while recovering from the procedure. If there is a second revision, it too is submitted to Radiation Safety and a copy is retained in the patient's chart.

j. The procedure described above assures that there is an accurate count of the disposition of all of the seeds originally ordered by Radiation Safety for a particular procedure.

k. Given the appropriateness and the different purposes of the Initial and Revised Written Directives, my handling of the Written Directives was entirely appropriate and legal. I did not falsify or erase any Written Directive at any time, contrary to the allegations of the New York Times, nor was it likely that any other member of the Team did so. It is for this reason that these allegations are not only false but scurrilously so.

5. How the Brachytherapy Procedure is performed.

a. The prostate is an organ the size of a walnut and is immediately adjacent to the bladder and rectum.

b. The procedure performed at the PVAMC was via the Preplanned, Preloaded Method. This entailed a transrectal ultrasound sizing of the prostate completed at least two weeks prior to the actual implant of the seeds. This ultrasound serves as the basis for the treatment planning which includes determining the number of seeds and needles required to be ordered by Radiation Safety via the Initial Written Directive.

c. Informed consent is obtained from the patient, who is counseled that seeds can migrate away from the prostate, and that up to 5% of patients may develop complications that include an inflammatory condition of the rectum known as radiation proctitis.

d. The patient is taken into the procedure room and anesthesia is induced.

e. Stabilizing needles are inserted.

f. The Urologist places the ultrasound probe, and inserts the first needle containing seeds into the prostate, and deposits the seeds contained within the first needle. This establishes the base of the prostate, and the deepest extent that all subsequent needles will reach.

g. The Radiation Oncologist then inserts the remaining needles following the lead of the Urologist and deposits the remainder of the seeds.

h. The Urologist then performs the previously mentioned cystoscopy to scan for and remove any blood clots or seeds from the bladder.

i. Radiation Safety uses a Geiger counter to scan the entire room and every person leaving the room, to retrieve and store any seeds not in the patient.

j. Anesthesia is reversed, and patient is moved to recovery.

6. The brachytherapy incident of 2003 was reported to the NRC and resulted in a thorough investigation.

a. A patient who was implanted on February 3, 2003, had a significant number of seeds in his bladder. All such seeds were retrieved by the Urologist

b. As per standard operating procedure and under the direction of Radiation Safety, the patient had an Initial WD that specified the numbers of seeds ordered, and then a revised WD to reflect the actual number of seeds that were retained within the patient A copy of both the Initial and Revised directive was retained by Radiation Safety, and the original put in the patient's medical chart.

c. This event was promptly reported to the NRC, who then came to PVAMC to conduct a full multiday investigation. The NRC ultimately cleared the Program to resume treating patients.

d. Because the dose of radiation delivered to the prostate was considered inadequate, a repeat brachytherapy was performed on March 31, 2003. This was successful in increasing the radiation dose received by the prostate. There were subsequently no unusual or unexpected complications or toxicity reported.

e. Contrary to what was alleged by the New York Times, at no time did I or anyone cover-up the patient's treatment by altering the Written Directive.

7. The brachytherapy incident of 2005 was reported to the NRC and resulted in a thorough investigation.

a. A patient was initially seen and accepted for Brachytherapy by another Radiation Oncologist I performed the Brachytherapy on 5/19/05. Because of poor imaging quality (due to the patient's inability to complete the necessary bowel preparation), many seeds were inserted into the bladder.

b. As per the standard operating procedure and under the direction of Radiation Safety, the patient had an Initial WD that specified the numbers of seeds ordered, and then a revised WD to reflect the actual number of seeds that were retained within the patient. A copy of both the Initial and Revised directive was retained by Radiation Safety, and the original put in the patient's medical chart.

c. During the course of the cystoscopy that is performed after every brachytherapy, a large number of seeds were retrieved from the bladder. This fulfilled the definition of a reportable Medical Event as I understood that defini-

tion at that time, and the case was promptly reported to the NRC. The NRC then came to PVAMC to conduct a full multiday investigation, and ultimately cleared the Program to resume treating patients.

d. On re-evaluation of the patient, the consensus among the Prostate Brachytherapy Team was not to reimplant this patient, as the patient's limited expected life span rendered the risks greater than the expected benefit

e. Contrary to what was alleged by the New York Times, the NRC performed a thorough investigation of this case.

8. The NRC definition of a reportable Medical Event has evolved over time and continues to be a subject of debate.

a. There was no NRC definition of a reportable Medical Event when the Brachytherapy Program was first started at the PVAMC in 2002.

b. The physicians and physicists never received NRC training on this issue throughout the years the Program was operational.

c. The instruction following the investigation by NRC of the 2003 prostate brachytherapy incident was that "if greater than 20% of the seeds prescribed were retrieved from the bladder;" this would constitute a reportable Medical Event and would trigger a repeat NRC investigation.

d. The brachytherapy incident of 2005 was clearly therefore a reportable Medical Event and appropriately reported.

e. The Prostate Brachytherapy Team was never instructed regarding 090 (the % of the prescribed dose that 90% of the prostate receives) as a metric that constitutes a reportable Medical Event. This means that no one on the Team was advised that if the dose received by the prostate was 20% greater or 20% less than the optimal dose it would constitute a Medical Event and would have to be reported to the NRC.

f. The definition of a medically reportable Medical Event that consists of a 090 that is either 20% above or below the prescribed dose was not in existence when the Prostate Brachytherapy Program was first started, nor was that ever an instruction provided to the Team.

g. While achieving a 090 that is not over and below 20% of the prescribed radiation dose rule is an optimal standard to strive for under NRC guidelines, it does not constitute a clinical standard of care for brachytherapy treatment. Indeed, recent articles published in the medical literature suggest treatment may be appropriate even when the 090 is less than 80%. I am happy to provide copies of those articles to the Committee should it wish to review them.

9. I have never ordered the wrong seed strength.

a. My cases have been standardized on the 0.509 mCi seed strength.

b. The discrepancy between 0.380 mCi and 0.509 mCi seed strengths that are mentioned in the NRC Inspection Report of March 30, 2009, involved prostate brachytherapy cases at the PVAMC that did not involve my patients.

c. The discrepancy between the seed strengths calculated and actually ordered was discovered by Radiation Safety and reported to the NRC.

10. The dose to the rectum has not been defined as a reportable Medical Event by the NRC.

a. As already stated, and as counseled in every consent form, radiation proctitis is a known and recognized risk of brachytherapy.

b. Given the close proximity of the rectum to the prostate, brachytherapy cannot be performed in a way that avoids dose to the rectum. In fact, every seed implanted in the prostate delivers radiation dose to the rectum, since the prostate is immediately adjacent to the rectum.

c. The dose to the rectum was not a metric that either PVAMC Radiation Safety or the NRC requested that we measure.

11. Despite the lack of computer interface between the CT scanner and the Variseed treatment planning workstation during 2006–2007. I provided effective treatment to my patients.

a. At the conclusion of a procedure, a CT scan is done to determine the location of the seeds.

b. The images of the CT scan are then transferred to a workstation that contains the software program called Variseed and which calculates the dose actually received.

c. In or around November 2006 a computer interface problem between the CT scanner and the workstation containing the Variseed software occurred that prevented the precise calculation of doses of radiation.

d. I reported this issue on several occasions to the appropriate persons overseeing the Program, but the problem persisted.

e. I offered to take the CT scans on disk or flash drive to Penn to perform the Variseed calculations. However this was refused by the PVAMC due to confidentiality/privacy/security concerns.

f. CT images however were still viewable and showed the location of the seeds, all of which were concentrated in areas of the prostate that contained cancer.

g. I had only two choices: to stop the Brachytherapy Program, or to continue to deliver medical care which the patients needed. Most of the patients treated for Brachytherapy did not have the option of alternative treatments such as surgery or external beam radiation. External beam radiation would have required the patients to be treated on a daily basis, five days a week, for eight weeks. Surgery also had serious drawbacks including incontinence and impotence. Without brachytherapy, the patients' cancers would have gone untreated.

h. I elected to continue treatment based on Concern for the patients' welfare.

i. The treatment was effective and well within the standard of care and was effective. The proof of the effectiveness was demonstrated in follow up visits with the patients and evaluation of their PSA levels.

12. There were a number of systematic failures at the PVAMC that affected the Brachytherapy Program.

a. Prior to the development of the PVAMC Prostate Brachytherapy Program, there were no guidelines or policies for the design and operation of a VA brachytherapy program. Consequently, the Brachytherapy Team had to design its own set of procedures and policies, which led to the creation of the Prostate Brachytherapy Algorithm.

b. When the Brachytherapy Program was first started, there was no standard definition of what is a reportable Medical Event.

c. There was no system to train key members of the Brachytherapy Program on what later became a definition of a reportable Medical Event.

d. There was no full time medical physicist dedicated to the brachytherapy program. This impacted on the ability to timely calculate the dose received by the patients.

e. The lack of a computer interface between the CT scanner and the Variseed dose calculation workstation prevented the precise calculation of the doses of radiation received by the patient.

f. There was no mechanism by which concerns regarding key steps of the procedure could bypass the chain of command to solve problems, such as the computer interface problem.

g. Understandable concerns about patient confidentiality prevented the alternative transport of data from the CT scanner via memory storage media and devices.

13. To address some of these concerns, the Brachytherapy Program was in the process of moving from Preloaded to Real-time Treatment Systems.

a. The members of the Brachytherapy Program recognized the drawbacks of the Preloaded Brachytherapy System, such as the inability to customize the placement of the seeds to match the patient's actual anatomy.

b. Consequently, members of the Team were in the process of receiving training in the Real-time Treatment System, which does account for changes in the patient's anatomy and which includes continuous fluoroscopic verification of the location of the deposited seeds.

c. Real-time treatment would allow for the seeds to be customized to the prostate on the day of the procedure.

d. The Brachytherapy Program was halted before the change in Treatment approach could be implemented.

14. During a meeting of the Advisory Committee on the Medical Uses of Isotopes of the NRC, held in Rockville, MD, on May 7, 2009, it was falsely alleged that a key physician of the Brachytherapy Program had made certain statements and actions ("Committee Meeting Transcript"). Inflammatory statements and actions were falsely attributed to this member of the Prostate Brachytherapy Program, including:

i. "The physician that did this particular implant, once again, he felt that the 24 Gray was clinically acceptable." Committee Meeting Transcript at page 192.

ii. "And if he felt that 24 Gray was satisfactory, that is the way it was." Committee Meeting Transcript at page 192.

iii. "Well, one of the things that we noticed was that the physician that was primarily involved in the brachytherapy program, he consistently did this. They didn't use fluoroscopy during seed placement. He refused to use

fluoroscopy, said he didn't need it." Committee Meeting Transcript at page 204.

iv. "—yes, 2002, and—but from the time the physician had received training to the time they started the implant program, there was some delay. And there was no—there was no effort on the part of the physician to maybe proctor or observe or be involved with some implants before they decided to go and proceed and treat their first patient . . . that was a decision that was made by the Authorized User." Committee Meeting Transcript at page 221.

v. "No. According to him, it was clinically acceptable. As a matter of fact, his exact words are, '43 Gray is better than zero Gray.'" Committee Meeting Transcript at page 241.

vi. "But it is mindboggling to me that a physician could say that a dose of 40 Gray, 24 Gray, is acceptable, and then look at these implants and not realize that this is gross incompetence." Committee Meeting Transcript at page 243.

a. These inflammatory actions and statements that are being attributed to a key physician are being attributed to me, but are not accurate. I neither said these statements nor took the actions described.

b. These false attributions are appropriately alarming and inflamed the subsequent discussions of the Committee.

CONCLUSION

I have come to the hearing today to answer questions and to submit this written statement in order to correct the record and salvage my reputation. I hope that, through the hearing process, the investigations and through media reports, the truth will emerge. I am not the physician who has been portrayed in the media. I am not willing to be the scapegoat for the complex, systematic problems that affected the Brachytherapy Program at the PVAMC. I hope that the information I have provided today will help the Committee understand my role and responsibilities in developing and directing the Brachytherapy' Program. More importantly, it is also my hope that this information will help improve future medical care for veterans.

RESPONSE TO POST-HEARING QUESTIONS SUBMITTED BY HON. RICHARD BURR TO DR. GARY D. KAO, M.D., PH.D.

Question 1. In your written testimony, you stated that, "Shortly after completing my Fellowship, I was assigned to the Philadelphia Veterans Affairs Medical Center ("PVAMC") and then became a full-time staff member of the PVAMC." The VA maintains that you were not a VA physician but that you were on contract from the University of Pennsylvania. Can you please clarify your current and past employers and employment status?

Response. In 2003, I was awarded an Advanced Research Career Development Award (ARCD) by the Office of Research and Development Medical Research Service, Department of Veterans Affairs. This provided support not only for laboratory research but also for my clinical activities at the PVAMC. My understanding of the ARCD Award is that it mandated that I became a full-time employee of the Research Service of the PVAMC. In fact, from that point forward I was compensated by the PVAMC and received W–2 tax forms each year. When the ARCD ended in or around March 2007, I was switched to the Medical Service of the PVAMC as a "5/8's" staff physician and I continued to be compensated by the PVAMC and continued to receive W–2's for my work at the PVAMC. Near the end of 2007 or beginning of 2008, I became a "contract physician" of the University of Pennsylvania, assigned to the VA. At that point, I no longer received compensation from the PVAMC, but instead was paid directly by Penn.

Question 2. At the hearing, you testified that, ". . . at the time that the program was implemented, the definition of what is reportable to the NRC was not in existence and only came later on."

When asked about this statement, the NRC's Mr. Reynolds testified that, ". . . Dr Kao is mistaken. The requirements to report to NRC when there is adverse care to patients went into effect in 1979."

Can you please clarify, if necessary, your statement, or explain why Mr. Reynolds is mistaken?

Response. Mr. Reynolds is mistaken on two accounts. First, the NRC has never clarified the definition of a reportable medical event as it pertains to brachytherapy.

The NRC's current regulation to report variations in delivered dose does not directly address brachytherapy or the determination of a medical event related to that therapy. [See relevant portions of the current regulation, attached as Exhibit 4].[1] In the current regulation, "total dose delivered" is not defined. In contrast to external beam radiation, for example, where the target does not change in size or shape and would be expected to receive all the dose of radiation delivered, for brachytherapy the dose delivered to the target depends on numerous factors and hence is subjective. The subjectivity is inherent in the procedure due to multiple factors including how one contours the prostate, when the prostate is contoured after brachytherapy (when the prostate can be swollen), the recognized risk of seed migration away from the prostate and the implantation of seeds in tissues or other organs adjacent to the prostate, and the contribution of radiation dose from all the seeds, whether or not actually implanted into the prostate. Without clarification of these parameters, the definition of what constitutes a reportable medical event remains quite subjective. Even after the NRC investigations of 2003 and 2005 were conducted on-site at the PVAMC, the NRC provided no clear definition of a reportable event other than the number of seeds located outside the prostate, as was communicated to the Brachytherapy Team by officials of the PVAMC Radiation Safety Office. [See note from PVAMC Radiation Safety, Exhibit 5].

The NRC's definition of a reportable Medical Event for brachytherapy continues to be unsettled. On August 6, 2008, the NRC published a proposed rule aimed, in part, at how properly to determine a medical event in the context of brachytherapy. As was stated by the NRC in the proposed rule, it was reconsidering "the appropriateness and adequacy of the regulations for ME's (Medical Events) and WD's (Written Directives) with regard to the use of byproduct material that required completion of a WD" (like brachytherapy). The proposed rule, if adopted, will change the definition of what constitutes a ME from one based on dose received by the prostate to one based on "activity" (i.e. radioactivity, or the number of seeds implanted in the prostate).

In proposing the adoption of this rule (which, in my view, is akin to an effort to account for the location and disposition of nuclear byproducts, a function uniquely suited to the NRC, different from evaluating the clinical efficacy of a procedure, clearly not within the expertise of the NRC), the agency stated that under current guidelines based on dose (related to brachytherapy), "there is no basis for determining whether an ME has occurred." [See Proposed Rule, I. Background, page 4, recognizing the necessary distinctions between brachytherapy treatment and other treatments utilizing byproduct material, and Sections 35.40(b) and 35.3045(a)(2), attached as Exhibit 7].

In addition to the proposed rule, the NRC's own Advisory Committee on the Medical Uses of Isotopes (ACMUI) has repeatedly urged that the definition of a Medical Event be changed from a definition that is strictly dose-based to a definition that is radiation activity-based, i.e. that relies on the counting of the number of seeds inside versus outside the prostate [See memo from ACMUI to the NRC Director, Exhibit 8, and transcript of May 7, 2009 ACMUI meeting, Exhibit 9, pages 193–197]. The NRC has acknowledged that this proposed definition, if adopted, would likely decrease the number of cases that the NRC regards as reportable Medical Events, including the cases performed at the PVAMC [See Proposed Rule, I. Background, Exhibit 7]. Members of the ACMUI have asked the NRC to analyze the PVAMC's brachytherapy cases using this new definition but, to our knowledge, the NRC has not yet done so.

In evaluating the brachytherapy cases at the PVAMC, the NRC has utilized an unpublished (and inappropriate) interpretation of the current regulation to determine the existence of reportable medical events at the PVAMC in the 2002–2008 period. Under this unpublished interpretation of a reportable Medical Event, the NRC based it calculations on the use of the D90 metric. This calculation, which measures the dose that 90% of the prostate receives, while not part of the current reportable Medical Event regulation, was applied retroactively to determine that the bulk of the brachytherapy procedures done at the PVAMC were performed in a manner contrary to the regulation. D90 is a metric that has never appeared in any regulations or notices issued by the NRC. Nevertheless, the NRC in its recent investigation determined that a reportable Medical Event existed where the dose received by the prostate was less than 80% of the D90 dose. It is for all these reasons that I can state that the NRC's current definition of a reportable medical event that is

[1] These Exhibits were attached to the Written Testimony recently submitted to the House Veterans' Affairs Committee (HVAC). We have elected to retain the same numbering system for each Exhibit as employed in the submission to the HVAC in order to avoid confusion for readers who may read this document as well as the documents submitted to the HVAC.

now based on D90 was not in existence in 2002, remains unpublished and may soon change due to a proposed rule change.

Second, Mr Reynolds is mistaken in his claim that "requirements to report to NRC when there is adverse care to patients went into effect in 1979." He appears to be referring to the Medical Policy Statement published by the NRC in 1979. This document (attached) in fact is a broad statement of the intent of the NRC to regulate the medical use of radioisotopes. It did not contain details regarding the reporting of Medical Events to the NRC and states that the NRC "will (not intrude) into medical judgments affecting patients and other areas . . . of the practice of medicine." More recently, the NRC again acknowledged that it "does not prescribe dose (as it is) a medical decision" [See page 192 line 16–19 of the NRC transcript of May 2009, Exhibit 9].

I continue to believe that appropriate care was provided to veterans by the PVAMC Prostate Brachytherapy Program. The treatment has been effective, and any adverse effects have been within the known risks of the procedure. The effectiveness of the treatment can be seen, in part, based upon the recent admission of Mr. Reynolds during his testimony of July 22, 2009 before the House Veterans' Affairs Committee, Subcommittee on Oversight and Investigations. When directly asked about the results of the treatment rendered at the PVAMC, Mr. Reynolds conceded that of the 114 total cases, the NRC was aware of only six cases where the PSA has risen on consecutive testing and another eight cases where a rise in PSA has been noted. However, none of these patients have undergone rebiopsy to confirm whether or not the cancer has returned. A rebiopsy is crucial because temporary PSA increases are common after prostate brachytherapy even in the absence of tumor recurrence, a phenomenon that is well-recognized among prostate cancer experts and often referred as "PSA bounce."[2]

The importance of Mr. Reynolds' concession is his recognition that at least 100 out of the 114 cases did not result in ineffective treatments. This represents an effective treatment rate that is at least 88%. Nonetheless, the NRC, in applying an unpublished standard during its reanalysis of the procedures performed at the PVAMC, inappropriately judged that the Program had caused harm to the patients. The cumulative effect of the NRC's action in casting the reporting of a Medical Event as a medical judgment on the efficacy of the treatment provided has unduly alarmed veterans and the public, and adversely affected the perception of brachytherapy by them and by physicians. In all these ways, the NRC has interfered with the delivery of medical care.

[2] Crook J, Gillan C, Yeung I, Austen L, McLean M, Lockwood G. PSA kinetics and PSA bounce following permanent seed prostate brachytherapy. Int J Radiat Oncol Biol Phys. 2007 Oct 1;69(2):426–33.

EXHIBITS TO DR. GARY D. KAO'S RESPONSE TO POST-HEARING QUESTIONS SUBMITTED BY HON. RICHARD BURR

Exhibit 4

Subpart M--Reports

§ 35.3045 Report and notification of a medical event.

(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(i) The total dose delivered differs from the prescribed dose by 20 percent or more;

(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--

(i) An administration of a wrong radioactive drug containing byproduct material;

(ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

(c) The licensee shall notify by telephone the NRC Operations Center[3] no later than the next calendar day after discovery of the medical event.

(d) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.

(1) The written report must include--

(i) The licensee's name;

(ii) The name of the prescribing physician;

(iii) A brief description of the event;

(iv) Why the event occurred;

(v) The effect, if any, on the individual(s) who received the administration;

(vi) What actions, if any, have been taken or are planned to prevent recurrence; and

(vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.

(e) The licensee shall provide notification of the event to the referring physician and also notify the individual who is the subject of the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this paragraph, the notification of the individual who is the subject of the medical event may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

(f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians.

(g) A licensee shall:

(1) Annotate a copy of the report provided to the NRC with the:

(i) Name of the individual who is the subject of the event; and

(ii) Social security number or other identification number, if one has been assigned, of the individual who is the subject of the event; and

(2) Provide a copy of the annotated report to the referring physician, if other than the licensee, no later than 15 days after the discovery of the event.

[68 FR 58805, Oct. 10, 2003]

[3] The commercial telephone number of the NRC Operations Center is (301) 951-0550.

Exhibit 5

Adobe Acrobat - [Exhibit 5 - Oct 3, 2005 email.pdf]

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Page 1 of 1

From: Moore, Mary E. (MaryE.Moore@va.gov)
To: Kao, Gary; Malkowicz, Stanley B.
Date: Monday, October 3, 2005 7:58:15 PM
Cc: Whittington, Richard; Devine, Pamela; [redacted]; Gregory Desobry; Lazarescu, George; Shimko, Richard; Session, Ethel; Aumiller, Linda; Fox, Catherine; Scanlon, Mary; Scott, William S.; Gary Kao; McNeal, Rosalyn
Subject: RE: Burns brachytherapy

Gary and Bruce,

I share Gary's hope that this patient does not need a second implant.

This case appears to be similar to the previous one which captured the attention of the NRC and NHPP, and for which we did an RCA. To ensure that this message reaches you, I've sent it to your VA and HUP addresses.

Since the number of seeds retrieved exceeded 20% of the original prescription, we have to determine if a reportable "Medical Event" occurred. We have 24 hours to report a Medical Event after it's been discovered. Our goal is to make that determination by tomorrow (10/4) afternoon, as early as possible, to ensure we comply with the strictest interpretation of the regulations.

We need to know the number and location of implanted seeds, the dose to the bladder and any other involved tissue or organ, and to review a copy of the Written Directive.
Dr Smith confirmed she ordered the CT. Radiology will do the CT early tomorrow morning to allow George time to do the post-treatment plan and locate the seeds. The CT results will then be compared to the Written Directive. This should allow us to determine if we have to notify the NHPP. They are the ones who report it to the NRC.

Whether it's a reportable issue or not, we still have to reconstruct events and review cause for 50% of the implanted seeds being in the bladder.
To help us do that, I've asked Greg, Marteena, Rich, Drs. Dutta and Smith to provide timelines, or notes for what they remember.
We need you both to provide this information as well. Your input is essential for identifying the sequence of events and evaluating options for preventing this in the future.

If you are not here tomorrow, please provide a phone, or beeper, number where you can be reached.
My phone and beeper numbers are below.

Thank you for your assistance and cooperation.

Mary

Mary E. Moore
PVAMC Radiation Safety Officer
(215) 823-6009
Fax (215) 823-4113
Beeper: 877-591-7592
MaryE.Moore@med.va.gov

-----Original Message-----
From: Kao, Gary
Sent: Monday, October 03, 2005 1:14 PM
To: Malkowicz, Stanley B.
Cc: Moore, Mary E.; Whittington, Richard; Devine, Pamela; [redacted]
Subject: Burns brachytherapy

Bruce:
Just a note on the brachytherapy case this morning. Although Ariana retrieved 45 seeds today, that still leaves

Exhibit 8

ADVISORY COMMITTEE
ON THE MEDICAL
USES OF ISOTOPES

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 19, 2005

MEMORANDUM TO: Charles L. Miller, Director
Division of Industrial and Medical
Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

FROM: Leon S. Malmud, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

SUBJECT: SUBMISSION OF GUIDING PRINCIPLES FOR NUCLEAR REGULATORY COMMISSION STAFF USE IN FORMULATING MEDICAL EVENT CRITERIA FOR PERMANENT IMPLANT BRACHYTHERAPY PROCEDURES

On June 28, 2005, the Medical Event Subcommittee (MESC) of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a public teleconference meeting to discuss a set of guiding principles for staff use while the staff writes a rule that will define medical events resulting from permanent implant brachytherapy procedures.

During the discussion, the MESC refined the principles and submitted them to the full ACMUI for a vote. All principles were unanimously passed by the full ACMUI.

Please see the attached to review the principles. Request that you submit these principles to your staff, as guidance to assist staff in defining a rule to capture medical events resulting from permanent implant brachytherapy procedures.

Primary contact for any questions is Jeffrey F. Williamson, PhD, Chair, MESC, at (804) 628-1047. Alternate contact is Leon S. Malmud, Chair, ACMUI, at (215) 707-7078.

Attachment: Recommendations of the ACMUI on the Definition of Medical Event for Permanent Interstitial Brachytherapy

Revised 7 July 2005

Recommendations of the ACMUI on the Definition of Medical Event for Permanent Interstitial Brachytherapy

This document outlines the recommendations of the Advisory Committee on Medical Use of Isotopes (ACMUI) regarding the need to revise the Medical Event (ME) reporting requirement and associated definitions for permanent brachytherapy. These recommendations are based upon a report formulated by ACMUI's Medical Event Subcommittee (MESC), which was chaired by Jeffrey Williamson, Ph.D. and consisting of ACMUI members Subir Nag, M.D., Ralph Lieto, M.S., and David Diamond, M.D.; invited consultant Louis Potters, M.D.; and NRC Staff Liaison Ronald Zelac, Ph.D. MESC unanimously approved forwarding these recommendations to ACMUI for further consideration during a closed teleconference held on 13 June 2005.

Because of the technical difficulty in formulating its recommendations in proposed rule language, ACMUI's recommendations are presented in the form of ordinary-language descriptions, principles, and examples. However, in the opinion of ACMUI, the approach outlined below does constitute a consistent and complete alternative to the current permanent implant ME regulation that the NRC staff can use as the basis for drafting an alternative ME rule and associated definitions.

A Status of current ME rule and associated definitions

1) ACMUI understands that the NRC Office of General Counsel (OGC) has ruled that an authorized user (AU) may revise a permanent implant Written Directive (WD) (In Part 35 language "complete the WD") at any time during the interval between completion of seed insertion (called "implantation" in 10CFR35) and availability of the post-implant dose distribution. Availability of the post-implant dose distribution has been accepted by OGC to be the "completion of the procedure" for permanent implants; other interpretations are possible since "completion of the procedure" is not defined by 10CFR35. Moreover, this interpretation of "completion of the procedure" is necessary if (a) the WD is specified in terms of absorbed dose and (b) the ME definition is based upon the discrepancy between prescribed absorbed dose and delivered absorbed dose.
2) For permanent implant WDs, the current rule states that AUs must specify the total absorbed dose prior to implantation, but may specify either the total source strength actually implanted or the absorbed dose by the end of the procedure. The practical impact of OGCs recent interpretation is that "dose," "total dose," and "total source strength" maybe used interchangeably in permanent implant WD's both prior to implantation and prior to completion of the procedure.
3) ACMUI does not believe that a 20% ME criterion is reasonable for absorbed dose WDs that are compared to absorbed dose distributions based upon any form of post-implant imaging.

   Rationale: The 20% dose threshold is comparable to the variation encountered in normal medical practice, due mainly to the limited control the authorized user has over the positioning of seeds and hence the dose delivered by permanent implants. Raising the relative absorbed dose threshold, e.g., to 50%, would reduce the number of clinically acceptable implants deemed Medical Events but at the expense of not capturing implants that do exhibit technical errors of quality assurance (QA) significance. The variations in post-implant absorbed dose distributions relative to the originally prescribed dose are due to

- Limited AU control over seed positioning
- Legitimate intraoperative adaptations of the preplanned source distribution
- Discrepancies between imaging modalities used for seed placement (ultrasound) and post-implant evaluation (x-ray CT) as well as physician organ contouring variations
- Postoperative changes such as prostate edema and seed migration
- Variable interval between seed implantation and post-implant imaging

4) The wrong site criterion (50% dose discrepancy of at least 50 Rem) is workable only for wrong site implantations far from the intended site. For identifying implants with excessive seed placement in organs adjacent to the treatment site, this dose-based wrong site criterion has all of the problems described in 3). Moreover, for many implantation sites and procedures, the current criterion cannot be evaluated explicitly, since what constitutes the intended adjacent organ dose is not clear or may not be specified in advance of the implantation procedure. Intended adjacent organ doses are not documented in the WD and not all implant procedures involve preoperative planning.

B Consensus principles for guiding NRC staff in reformulating the ME reporting rule and associated definitions

1) For all permanent implants, ME should be defined in terms of the total source strength implanted in the treatment site, not in terms of absorbed dose

   Rationale: This proposed criterion focuses on what the AU can control, namely into which organ or treatment site the sources are implanted, instead of the absorbed dose distribution, over which AU control is limited. In addition, for the most commonly practiced forms of image-guided source implantation, definitive dose distributions may not be available until several weeks after completion of the procedure. On the other hand, the number of sources implanted in the treatment site (and hence total source strength) can be assessed, e.g., via intraoperative imaging for prostate implants, before releasing the patient from licensee control, will capture the majority of technical errors of interest to NRC, and is relatively insensitive to small, clinically acceptable, errors in positioning radioactive seeds relative to their planned locations.

2) Treatment-site accuracy ME pathway: Specifically ACMUI recommends that any implant in which the total source strength implanted in the treatment site deviates from the written directive by more than 20% (in either direction) should be classified as a ME. Several comments on this "treatment site accuracy" ME pathway are in order.
   a) The intent of this proposal is to provide the AU option of positioning up to 20% of the prescribed number of seeds into tissue or organs adjacent to the treatment volume (treatment site). Often, a small number radioactive seeds need to be placed 2-10 mm outside the prostate in order to provide adequate dosimetric coverage. In addition, the 20% latitude also accounts for variations in treatment-site definition, difficulties in visualizing the target organ by intraoperative imaging, and other phenomena that contribute to uncertainty in estimating the fraction of seeds implanted in the treatment site.
   b) As in the current ME rule, ACMUI intends that seed migration be specifically excluded as grounds for a treatment-site accuracy ME.

c) The technology for image-guided seed positioning and verification is most developed and mature for prostate brachytherapy. However, even in this clinical setting, the precision with which the fraction of seeds implanted in the prostate can be determined from post-implant CT or intraoperative ultrasound imaging may be limited, due either to image artifacts or operator variability in defining the treatment site. For some treatment sites, e.g., postoperative brachytherapy of a tumor bed, there is no well-encapsulated or radiographically visible target volume that can be used to precisely determine whether the implant is a treatment-site accuracy ME. In such cases, only grossly erroneous MEs can be determined with certainty. NRC enforcement policy must be based upon realistic expectations of the precision that can be achieved in ME determination in different clinical settings.

3) Wrong-site ME pathway: The ACMUI recommends that the revised "wrong site" ME criterion distinguish between two scenarios: tissue or organs immediately adjacent to the treatment site and organs that are distant from the treatment site. For permanent implants, tissues that are more than 3 cm from the treatment site boundary can be considered distant, as the dose has fallen to subtherapeutic levels (1-5% of the prescribed dose).

a) Adjacent tissue wrong site ME: Implants in which more than 20% of the total source strength documented in the preimplantation WD is implanted in tissue or organs adjacent to the treatment site should be classified as MEs.

In this setting, a 20% threshold strikes a reasonable balance between permitting seed implantation outside of the target to boost peripheral doses [a medically legitimate objective] and detecting gross mispositioning of seeds into an adjacent organ rather than the intended treatment site.

b) Distant organ/tissue wrong site ME: For erroneous implantation of radioactive seeds in an organ distant from the intended treatment site, ACMUI recommends that such implants be classified as MEs if (i) seeds are actually implanted in a distant organ, (ii) the excess dose to the distant organ exceeds 50 Rem, and (iii) the excess dose to the organ is at least 50% greater than the dose that would have been delivered had the seeds been implanted in the correct tissue volume.
This definition is very similar to the wrong site pathway in the current ME definition except that it is invoked only when seeds are placed in the distant organ. An example of a distant organ ME is implanting the seeds in the left kidney when the right kidney was intended. Such an error could arise if the wrong medical record is used to confirm the treatment site or if the surgeon mistakenly exposed the kidney on the wrong side of the patient.

c) For both adjacent and distant wrong-site MEs, it is important to exclude seeds that were correctly implanted but subsequently migrated as grounds for an ME. Because a seed may occasionally migrate a large distance from the correctly implanted treatment site, it may be difficult to distinguish between true distant site MEs and seed migration by means of post-implant imaging alone.

4) Given a source-strength-based ME criterion of 20% in either direction (described in section B.3)), it is reasonable to require that the AU complete any revisions to the WD for permanent implants before the patient is released from licensee control.

Rationale: Using intraoperative imaging, a competent brachytherapist will be able to determine whether the fraction of seeds implanted in the treatment site agrees with the written directive within 20%. Hence the preimplantation WD can be revised at the time of the procedure to account for any medically necessary plan adaptations. This revision would effectively limit the AUs authority to revise the WD to the implantation procedure or the immediate post-operative period.

5) Dose-based ME pathway for permanent implants: In addition to incorporating the activity-based ME pathway (described above) into Part 35, ACMUI recommends retaining a limited dose-based ME criterion. **An implant is a ME if the dose calculations used to determine the total source strength documented in the WD are in error by more than 20% in either direction.**

For example, suppose that an AU intended to deliver a dose of 145 Gy to the prostate using ^{125}I seeds. Based upon pretreatment ultrasound imaging of the prostate, treatment-planning software is used estimate the source strength/seed (e.g., 0.44 mCi) and number of seeds (e.g., 100) needed to deliver 145 Gy to the contoured treatment volume. Suppose the dose-calculation algorithm erroneously used a ^{103}Pd seed dose rate constant (0.68), rather than the value (0.94) appropriate to iodine seed model to be implanted. This would overestimate the activity per seed by 38% (e.g., assuming that the correct ^{125}I monotherapy activity/seed is 0.32 mCi, the planning system would predict that 100 seeds of 0.44 mCi are needed to deliver 145 Gy to the target. Suppose that this dose-calculation error went undetected and that the AU recorded 100 seeds of 0.44 mCi/seed in the WD and actually implanted these seeds into the treatment site. This byproduct material administration would be a ME under the proposed dose-based criterion.

Rationale:

- In mainstream prostate brachytherapy practice, the AU describes his or her treatment intention in units of absorbed dose to a target volume. Through treatment planning, the source strength, number of seeds and seed arrangement are identified that realize this prescription. Preplanning can be a complex activity with the potential for mistakes that could result in large dose-delivery errors. Even nomogram-based systems seek to deliver a certain dose to a specified target volume. Defining ME solely in terms of correctly implanting the source strength specified in the WD would make all treatment-planning errors, many of which could adversely affect the patient's clinical outcome, exempt from regulatory oversight.
- In the current ME rule (and the previous misadministration rule), dose calculations that mediate between the AUs goal to deliver a certain dose and treatment device settings (treatment time, number of sources, etc), are currently subject to regulatory oversight for all modalities including permanent brachytherapy. Eliminating this oversight would be viewed as NRC backing away from patient safety. A single well-

publicized error or series of errors due to dose-calculation errors would be very embarrassing if NRC had no regulatory authority in this area.

- The "limited" ME dose pathway proposed here would focus only on preplanning or intraoperative planning, not post-implant evaluation. Hence, it avoids the difficulties of the current ME definition.

5

C Risk Communication

1) Problem definition: From the regulated community's point of view, ME reporting stigmatizes the licensee and all but assures increased regulatory scrutiny, which is viewed as punitive. Even though many ME reports do not result in license violations, licensees view the process as punitive because (a) regulatory intrusion into the patient-physician relationship; (b) placing the event reporting process in the public record; and (c) reactive inspections following ME reports appear to equate even minor MEs with nuclear reactor events having much greater potential public safety consequences. A perceived punitive regulatory response, along with the ambiguity of some ME criteria and their lack of medical relevance, results in potential under-reporting and almost certainly discourages reporting of borderline or ambiguous cases that might be helpful to NRC in constructing a more complete picture of error pathways. ACMUI affirms that there is no scientific basis for treating medical events (MEs) as a surrogate or harbinger of patient harm, or even of increased probability of patient harm. The SC believes that efforts to revise ME definitions to improve its correlation with potential or actual harmful effects is misguided and undercuts its value as QA performance index. Provided that ME incidence is decoupled from the concept of patient harm, the current 20% is a reasonable if arbitrary threshold for identifying events indicative technical or QA problems in accurately realizing the AUs clinical intentions.
2) The role of the 10CFR35.3045 ME reporting rule as a technical quality performance indicator should be decoupled from its use as a potential patient harm index. To this end, the patient reporting requirement 35.3045(e) should be amended to require informing the patient and/or friends and relatives only if the licensee determines that the ME may have harmed the patient, could potentially harm the patient, or is materially relevant to the patient's future medical treatment decisions.
3) The SC recommended that NRC staff strive to make the ME reporting and subsequent enforcement processes more like the regulated community's own QA practice of followup and QA process review that occurs following detection of a delivery error or potential error.

   Rationale: Comprehensive institutional QA programs are based upon three broad principles:

   a) Avoid making the occurrence of a medical error grounds for actual or perceived disciplinary action. Medical health professionals should be encouraged to report errors, not discouraged from doing so.
   b) Avoid increasing an institution's legal liability associated with its QA deliberations and process improvements made in response to a medical error. Regulatory actions that make quality improvement activities a source of institutional liability discourage adherence to comprehensive quality assurance standards and undermine the quality of patient care.
   c) Encourage use of medical error reports as input to systematic efforts to improve planning, delivery, safety, QA, and documentation processes.
4) ACMUI recommendations for making ME reports more like industry standard error reporting

   a) To the extent possible, NRC's ME reporting and followup procedures should be designed to not increase Licensee liability. Keeping ME reports, or at least the

Licensee's identity out of the public record, is probably the single most useful improvement NRC could make in this regard.

b) NRC is encouraged to develop a more graded and risk-informed process for responding to ME reports that ties the intensity and immediacy of its inspection response to individual patient risk and public health implications of the event. For example, for relatively minor MEs, where public health and safety is not in question, NRC could minimize reactive inspections of Licensee pending a satisfactory investigation and quality-improvement response on the part of the Licensee. Thus, ACMUI recommends that NRC manage minor MEs much like recordable events in Old Part 35.

c) Change the 24 hour Operations Center reporting procedure. The current process which requires verbally reporting MEs to the Operations Center within 24 hours and appears to equate Medical Events, most of which do not cause actual harm to the patient, with serious nuclear reactor events, which the potential to affect large numbers of people. Reports to the Operations Center are immediately available to the World Wide Web. This results in adverse publicity and adds to the liability concerns raised above. Thus for all but the most serious MEs, an alternative and more appropriate reporting mechanism should be devised. Specifically, the ACMUI recommends that MEs that have not harmed the patient; have little potential for harming the patient, and are not materially relevant to the patient's future medical treatment decisions, as evaluated by the Licensee, be reported to NRC by means of written notification within 7 days of their discovery.

Exhibit 9

1 administered was actually 43 Gray.

2 Now, an interesting thing about this was

3 that for about a one-year time period they were unable

4 to do post implants, because the CTs would not talk to

5 the VariSeed program. There was an interface problem.

6 But that didn't stop them from doing the implants.

7 So, basically, for about a year, a lot of

8 their patients they didn't even know what the actual

9 dose was. And as you can see, there are quite a few

10 seeds on the outside of the prostate. Here is one

11 where they just about missed the prostate completely.

12 In this case, 160 Gray was prescribed.

13 However, only 24 Gray was administered. The physician

14 that did this particular implant, once again, he felt

15 that the 24 Gray was clinically acceptable.

16 And, once again, we don't prescribe what

17 the dose is for the patient. That is a medical

18 decision. And if he felt that 24 Gray was

19 satisfactory, that is the way it was.

20 Okay. Anything else, Sandy?

21 (No response.)

22 Any questions? Yes, sir.

23 MEMBER NAG: Yes. There will be plenty of

24 questions, and I will just go one by one. What was

25 the numerator? You have said there are 92 medical

DRAFT

1 implants. Out of how many total that were examined?
2 And how many total implants were there at the VA?
3 MR. WIEDEMAN: One hundred fourteen
4 treatments.
5 MEMBER NAG: Okay. So out of 114, 92 were
6 medical events. That is about 80 percent or so. Now,
7 out of these 92, how many were medical events because
8 of something like this, where half the seeds are
9 outside the prostate?
10 MR. WIEDEMAN: 57.
11 MEMBER NAG: Versus how many were medical
12 events, because they just met the criteria of medical
13 event as it was defined in 2005/2006? Because I am
14 sure you realize that the ACMUI -- and we have
15 documentation that many of the criteria for medical
16 events that were there are not really appropriate to
17 define medical event for permanent brachytherapy.
18 So that separation is very, very
19 important. Otherwise, you create fear in the public.
20 MR. WIEDEMAN: There are -- 57 of those
21 implants were considered underdoses. One of them was
22 considered 20 percent above the prescribed dose. The
23 other --
24 MEMBER NAG: My question is different.
25 How many were underdosed because of something like

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1 this, where most, if not all, of the seeds were
2 outside the prostate versus how many of those 57 were
3 underdosed? Because when you implant the prostate,
4 the prostate can expand. It depends on how you -- on
5 the contour, and you may get 72 percent, and that is
6 still an underdosing but not necessarily an underdose
7 based on the current definition that we are
8 recommending.
9 So there are two different -- one is
10 something like you show it here, which is an obvious
11 underdose. And the other would be all or most of the
12 seeds are put -- or have been placed within the
13 prostate volume, but because the prostate has expanded
14 in between, the final dose after one month -- a CT
15 done after one month, and during that time the
16 prostate has either grown bigger or smaller.
17 And, therefore, when you finally do the
18 dosimetry, you find the number is now 72 percent of
19 what you expect. And that difference is something
20 that is very, very important, at least to me, because
21 I am going to make a comment about the two
22 differences.
23 MS. FRAZIER: Dr. Nag, let me make sure I
24 understand. Are you saying that maybe if they were
25 recontoured that a number would have been different?

1 MEMBER NAG: No. What I am saying is that
2 even if you do a proper medical implant of a prostate,
3 and an implant -- you had thought you needed 30
4 millicuries, you give 145 Gray. Even if you execute
5 it properly, there will be certain cases where it will
6 not meet the dose criteria.
7 We recognized that in 2003 we had -- the
8 ACMUI had said that it is not appropriate. There was
9 a subcommittee meeting to come up with new ways to
10 examine prostate -- oh, not prostate, permanent
11 brachytherapy. We came up with those recommendations.
12 We know very well that the prostate,
13 especially prostate, for any permanent brachytherapy,
14 you cannot really examine it those ways. You have to
15 examine it based on the activity that has been
16 prescribed. Was it the activity that had ended up in
17 the treatment area? And that is all the discussion
18 that has been going on in the last two or three years.
19 I know you have been reacting by going --
20 by what is on the criteria in the books, but I want to
21 make that differentiation, because what is happening
22 is that you may have five cases where the seed is
23 completely outside the prostate. That is a bad
24 medical practice.
25 And another 20 or 30 where the seed

1 already implanted itself, but it also, for various
2 reasons, like prostate shrinking or prostate
3 expanding, and so forth, it became a medical implant
4 based on the criteria that are in the books.
5 So that differentiation is very important
6 to make the differentiation for the public. I mean,
7 from a purely medical -- based on what we have in the
8 book, you may be correct. But then, if you go and
9 examine the entire county based on the method that you
10 have done on this book, you are going to find about
11 maybe 20 percent or so that will not meet the
12 criteria.
13 And so of the 100,000 of them that have
14 been done in the country that became a permanent
15 implant, you are going to have 20,000 cases which will
16 meet the current definition of "medical implant." And
17 that is the reason why we changed the definition of
18 "medical implant" from being a dose-based to being
19 activity-based or source-based.
20 MR. WIEDEMAN: Dr. Nag, I think I
21 understand your question. It is a good question. I
22 will say this is not the only view that looks like
23 this. There are several that I have seen. I can't
24 tell you there was 45 out of the 57. Maybe the region
25 knows that.

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1 What we are asking the regional inspection
2 team to do is verify compliance with the current
3 regulation, though.
4 MEMBER NAG: Sure. I understand.
5 MR. WIEDEMAN: We have an action from the
6 results of this study, which we have actually delayed
7 the "medical events" definition rule to make sure that
8 the things that we learn from this inspection are
9 factored into that rule and how we ultimately redefine
10 "medical events."
11 MEMBER NAG: Right. Are you going to see
12 -- you are going to have 20,000 medical events at
13 least in the country, if you examine everyone.
14 MR. WIEDEMAN: We have --
15 MEMBER NAG: If you use the same rule that
16 you are applying now.
17 MR. WIEDEMAN: We have done a lot of
18 inspections of brachytherapy, and we don't see a lot
19 of inspections that have results like we saw at the
20 VA.
21 MS. PELKE: If I can just carry on to
22 Rob's comment, and also, Dr. Nag, your comments. We
23 are assessing these treatments in accordance with
24 current rules and current requirements. So we were
25 looking at the plus or minus 80 percent of the D-90.

1 We did determine that we could go with D-90, and there
2 was a consensus, and we have documentation that that
3 was an appropriate measure for prescribed dose.
4 What we had here -- and we had to make an
5 assessment based on what we saw at this particular VA
6 facility in Philadelphia, and assess, well, could this
7 possibly -- could we have the situation at other VA
8 permittees that were doing prostate brachytherapy?
9 And so we went out and did an extended
10 condition inspection. That inspection activity is
11 still open, but what we have found at the other
12 facilities conducting permanent prostate brachytherapy
13 is dramatically different than what was going on at VA
14 Philadelphia.
15 There were some situations or some
16 scenarios that aren't necessarily unique to a
17 Veterans' Affairs hospital. They employ contractors
18 they -- going on good faith that the contractors that
19 they had retained were experts in the field, they
20 believe.
21 And we have not only seen this at the VA,
22 but we have seen this at other medical institutions
23 that have actually had medical events identified with
24 the modalities that were practiced by that contracted
25 group, is that when a contractor comes on board, and

1 they are experts in the field, that there is some
2 assumption that they are experts, they should be
3 running the shop, and that we should be getting, you
4 know, a high standard of care. And that is not
5 necessarily so.
6 So we do believe, once we have wrapped up
7 all of our inspection activities, and we have
8 completed the extent of condition, that we will
9 hopefully be coming out with some type of generic
10 communication, just on the contracted services, and
11 reminding licensees of their responsibility going
12 forward.
13 And I will say that the events and the
14 treatments that were done at Philadelphia, there are
15 -- you know, there were two precursor events, in 2002
16 and 2005. And as a result of those precursor events,
17 there was a concern by the physician about putting
18 seeds into the bladder. And as a result of that, the
19 physician, in their technique, tended to back off, but
20 without any quantitative measurement of how far they
21 were backing off. And as a result of that, you see an
22 example of the quality of the implants.
23 And then, they also had an extenuating
24 circumstance in that the treatment planning system
25 they were using, the VariSeed, they had done some

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1 upgrades on security. And as a result of some of the
2 upgrades that they did, they had experienced problems
3 with transmission of the images they were using of the
4 prostate into the VariSeed treatment planning system.
5 They had been working on resolving those
6 issues, but in the meantime approximately one year
7 went by where they continued to treat patients. That
8 kind of never crossed their mind, that maybe we should
9 suspend the program until we get this treatment
10 planning system up and running, and our images or
11 input, so we are getting accurate results. They
12 didn't do that.
13 So, you know, there is a number of issues
14 relative to some of the decisionmaking. And we did
15 have a team there. We didn't have necessarily an
16 Authorized Medical Physicist, because that is not
17 required, as you know, for permanent prostate
18 brachytherapy. But we certainly had medical
19 physicists involved, as well as qualified Authorized
20 Users.
21 So, really, I think that there is a
22 benefit coming out of this in that, you know, the
23 timing is right. We have proposed rulemaking on the
24 table. We are going to be able to better inform that
25 process, so that we will get a rule moving forward

1 that includes all of the parameters that we may want
2 to consider moving forward. But right now we are
3 still with a dose-based requirement.
4 MEMBER NAG: May I -- I agree with all of
5 the points you made. What I am trying to say is that
6 you will probably make this a better report if you did
7 write those two kinds of medical implants separately,
8 one where there was a definite case where the seeds
9 are either well below or well above the prostate
10 versus what you have done at -- you have two different
11 kinds of problems, one a problem with a definite seed
12 outside the prostate, and that is called a medical
13 event, and I agree wholeheartedly with that.
14 But, at the same time, you have quite a
15 few -- I don't know how many -- that have opened up a
16 full medical event, just because it meets the
17 definition of "medical event," although from a -- if
18 you are using activity-based it would not be called a
19 medical event. And if you lump the two together, you
20 are going to create a fear throughout the community,
21 because people are going to say, "I am doing the right
22 thing. I have put all my seeds into the prostate,"
23 but it is still called a medical implant, because you
24 are going by dose-based.
25 If you separate the two issues, you will

1 realized back in 2002 that there was a problem, and
2 then just recently, in 2007, another physicist said
3 the same thing, that he felt that the seeds were
4 improperly implanted. And he was concerned about
5 it, but unfortunately he didn't take it to the
6 licensee and discuss it with them. He discussed it
7 with people across the street, the university
8 hospital.
9 And the one thing -- we found that there
10 was poor management oversight, or there was none, of
11 the contractors. The training, when we interviewed
12 various different people, they indicated they have
13 never been trained on the definition of a medical
14 event, who to report a medical event to if they did
15 discover one, and the typical things that you would
16 expect a medical physicist to know. But in this case
17 they claimed that they were not very knowledgeable
18 about that.
19 And then, we found that the contractors,
20 both the physicist and the physician contractors, no
21 one was looking over their work. The radiation safety
22 staff, they did quarterly audits, but their audits
23 didn't pick up any of these problems. So we also have
24 another problem.
25 CHAIRMAN MALMUD: Mr. Lieto, you had a

Exhibit 10

UNITED STATES NUCLEAR REGULATORY COMMISSION

RULES and REGULATIONS

TITLE 10, CHAPTER 1, CODE OF FEDERAL REGULATIONS—ENERGY

COMMISSION NOTICES
POLICY STATEMENTS

MEDICAL USES

44 FR 8242
Published 2/9/79
Effective 2/9/79

Regulation of the Medical Uses of Radioisotopes; Statement of General Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Policy Statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) has the following policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

EFFECTIVE DATE: February 9, 1979.

FOR FURTHER INFORMATION CONTACT

Mr. Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5860).

SUPPLEMENTAL INFORMATION: The NRC has developed the following three part policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. On March 17, 1978, the three part policy statement was published in the FEDERAL REGISTER (43 FR 11208) for public comment. Copies of the policy statement were sent to all NRC medical licensees, the States and 25 professional societies, Federal agencies, and individuals. The comment period expired May 16, 1978. Twenty-two comments were received. Nine commenters favored all three parts of the policy statement, four commenters opposed one part of the policy statement and nine commenters addressed specific issues discussed in the March 17, 1978 FEDERAL REGISTER notice. The comments are discussed in Section II. Copies of the comments may be examined in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C.

I. STATEMENT OF GENERAL POLICY

This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes.

It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

Based on past experience and the comments and advice of the public, other Federal agencies, the States, and NRC's Advisory Committee on the Medical Uses of Isotopes, the Commission has developed the following statement of general policy to guide its regulation of the medical uses of radioisotopes:[1]

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

[1] NRC licenses radioisotopes in three categories: byproduct, source and special nuclear material. The NRC does not regulate naturally occurring or accelerator produced radioisotopes. The term *byproduct material* means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term *source material* means (1) uranium, thorium or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of (1) uranium, (II) thorium or (III) any combination thereof. Source material does not include special nuclear material. *Special nuclear material* means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any of the foregoing, but does not include source material.

II. RATIONALE

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Uses of Isotopes. This regulation has been generally oriented toward assisting qualified physicians in discharging their responsibilities to patients. However, regulation by AEC/NRC has at one time or another encompassed nearly every aspect of the delivery of radioisotope medical services to patients. The broadest regulation occurred between 1962 and 1975, when the Food and Drug Administration (FDA) exempted from its requirements for new drugs all radiopharmaceuticals regulated by AEC. During this period AEC regulated the radiation safety of workers and the general public and the safety and efficacy of radioactive drugs and devices with respect to patients. AEC regulation included production of the radioisotope, manufacture of the final radioactive drug product or device, distribution, use and disposal of the products. In 1975, the FDA terminated the exemption for radiopharmaceuticals, stating that it would now regulate the safety and efficacy of radioactive drugs with respect to patients. (As noted later in this statement, FDA does not regulate the physician's routine use of radiopharmaceuticals.) At the same time, NRC withdrew from regulating radioactive drug safety and efficacy, stating that it would regulate the radiation safety of the workers and the public. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act extended FDA's authority over medical devices (including devices containing radioactive materials) in a way similar to its authority over drugs.

NRC's authority to regulate domestically the medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. For example, section 81 of that Act authorizes NRC "to issue general or specific licenses to applicants seeking to use byproduct material for * * * medical therapy * * *." Section 81 directs NRC

to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import and export of byproduct material. Finally, Section 81 also directs that:

> The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Commission regulations, for the most part set forth in 10 CFR Parts 30 through 35, were promulgated to carry out the broad regulatory scheme envisaged by section 81. For example, Part 35 establishes regulations specific to human uses of byproduct material. FDA's statutory authority (Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*) does not diminish NRC's authority. Where NRC's and FDA's authorities overlap, the respective authorities can be harmonized by interagency agreement.

The central question is a question of *policy* not *authority*, namely:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of *authority*, it is clear that NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material, for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion. From the standpoint of *policy*, these limits depend upon how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

The first part of NRC's policy statement indicates that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.[5] This is the traditional regulatory function of NRC for all uses of byproduct, source and special nuclear material. It is a regulatory role that was not questioned by any of the commenters but, rather, it was consistently recognized as a necessary role in the medical uses of radioisotopes.

NRC's regulation of the radiation safety of workers and the general public in the medical uses of radioisotopes is relinquished by NRC to Agreement States; does not overlap with FDA's activities; is in harmony with regulation by the Department of Transportation, Social Security Administration and the Joint Commission on Accreditation of Hospitals; and dovetails with Occupational Safety and Health Administration regulation of the work-place for the use of naturally-occurring and accelerator-produced radioactive materials.

The second part of NRC's policy statement indicates that NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. As noted before, NRC has the authority to regulate the radiation safety of patients.

The NAS-BEIR[6] report discusses limiting the exposure of the population to medical applications of ionizing radiation. That report, which includes all medical uses of ionizing radiation, shows an average dose rate from radiopharmaceuticals of 1 mrem/year and an average dose rate from diagnostic radiology of 72 mrem/year in 1970.

The following quotation is from the NAS-BEIR report:

> In the foreseeable future, the major contributors to radiation exposure of the population will continue to be natural background with an average whole body dose of about 100 mrem/year, and medical applications which now contribute comparable exposures to various tissues of the body. Medical exposures are not under control or guidance by regulation or law at present. The use of ionizing radiation in medicine is of tremendous value but it is essential to reduce exposures since this can be accomplished without loss of benefit and at relatively low cost. The aim is not only to reduce the radiation exposure to the individual but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum radiation exposure.

NRC will act to help ensure that radiation exposure to patients is as low as is reasonably achievable, consistent with competent medical care and with minimal intrusion into medical judgments. NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Wherever possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners to limit unnecessary patient radiation exposure.

The third part of NRC's policy statement indicates that NRC will minimize its intrusion into medical judgments affecting the patient and into other areas traditionally considered to be a part of the practice of medicine. The Commission recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be a part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

The regulations try to find a balance between adequate controls and avoidance of undue interference in medical judgments. A consequence of too much regulation could be poorer health care delivery to patients. A consequence of leaving to physicians the majority of the decisions concerning their patients is that the physicians will make mistakes. The tightest regulation of physicians' decisions by Federal, State and professional groups will not be able to prevent future incidents in the medical uses of radioisotopes.

The Commission recognizes that FDA regulates the manufacture and interstate distribution of drugs, including those that are radioactive. FDA also regulates the investigational and research uses of drugs as well as the specific guidance on doses and procedures found in the product labeling. However, FDA does not have the authority to restrict the routine use of drugs to procedures (described in the product labeling) FDA has approved as safe and effective. Indeed, NRC is the only Federal Agency that is currently authorized to regulate the routine use of radioactive drugs from the standpoint of reducing unnecessary radiation exposure to patients.

The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection and dose level for most diagnostic uses of radioisotopes. For all therapeutic uses of radioactive drugs, and in certain diagnostic uses—for example, the use of phosphorus-32 for localization of eye tumors—the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs. NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures, because these procedures are so specialized and patient specific.

Congress recently gave FDA authority to regulate medical devices, similar to FDA's authority to regulate drugs, but with additional authority to restrict the routine use of medical de-

[5] The term general public in this statement specifically excludes patients.

[6] National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR) report, *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. National Academy of Sciences—National Research Council*, Washington, D.C. (1972).

POLICY STATEMENTS

vices as may be necessary to provide reasonable assurance of their safety and effectiveness. FDA has not yet had sufficient time to implement its full authority to regulate medical devices containing byproduct, source or special nuclear material. Therefore, NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

The Commission does not consider equipment calibration, qualifications of paramedical personnel or reporting to NRC misadministrations of radioactive material to be exclusively the practice of medicine or a part of physician-patient relationships. The Commission intends to regulate these areas of patient radiation safety where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

III. DISCUSSION OF PUBLIC COMMENTS

A. COMMENTS ON THE POLICY STATEMENT

One commenter opposed the use of the general term "radioisotopes" in the first part of the policy statement. This commenter was concerned that, if taken out of the context of the footnote, it could be interpreted to include naturally occurring and accelerator produced radioisotopes.

The Commission believes that the general term "radioisotopes" is plain English and easily recognized by the public. It was properly footnoted in the policy statement to include the more cumbersome but specific terms: byproduct, source and special nuclear material and to exclude naturally occurring and accelerator produced radioactive material.

One commenter, in opposition to NRC's regulation of patient radiation safety, suggested that NRC limit its role to the radiation safety of the hospital staff and the general patient population. He believes that patient dosimetry is a responsibility of the individual institution and not NRC. This commenter feels that NRC should first require adequate staffing, including a board certified physician or radiopharmacist and a radiation safety officer, and then essentially leave the institution alone regarding dosimetry, instrumentation, calibration, drug procurement or any other function considered to be the practice of medicine.

NRC does require the licensee to staff its operation with a radiation safety officer and a physician (not necessarily board certified) trained to administer radioactive material or radiation to patients. However, the Commission cannot limit its regulatory role to protecting the hospital staff and the general patient population and at the same time fulfill its congressional mandate to protect the health and safety of the public as regards source, byproduct and special nuclear material. The patient being treated or diagnosed with radioactive material, as well as the general public who may be exposed to radiation as a result of that treatment, are all members of the public to be protected by NRC.

Two commenters objected to NRC's regulation of patient radiation safety because they believe that NRC does not have the authority to regulate patient safety. They note that NRC's enabling legislation does not specifically mention the radiation safety of patients. They believe that patient safety is the responsibility of the physician, a responsibility that cannot be shared. They believe that the Commission is in error to equate patients with the public and to consider patients as users rather than recipients of radioactive material.

As noted in the analysis of the similar comment above, the NRC's overriding congressional mandate is to protect the health and safety of the public. The patient is a member of the public, notwithstanding the Commission's recognition of physicians' primary responsibility for protection of their patients. The policy statement and, indeed, all of the Commission's actions in regulating the medical uses of radioisotopes, acknowledge the secondary but necessary role of NRC in regulating the radiation safety of patients. The Commission also considers patients to be both users and recipients of radioactive material. However, the distinction between receipt and use of radioactive materials is not meaningful in this case because NRC regulates, among other things, receipt, possession, use and transfer of byproduct, source and special nuclear material in protecting the health and safety of the public.

B. COMMENTS ON SPECIFIC ISSUES

There were six comments on the question of reporting misadministrations of radioactive material. Three commenters opposed any misadministration reporting and three commenters offered suggestions on how they should be reported. All of the comments will be considered in dealing with NRC's newly proposed misadministration reporting requirement that was published in the FEDERAL REGISTER for public comment on July 7, 1978 (43 FR 29297).

There were six comments on the specific issue of paramedical training. Three commenters believe that it is unnecessary for NRC to become involved in paramedical training because several organizations are already providing or developing minimum standards, guidelines or certification. One commenter believed that NRC should be involved in this area because the technologist, not the physician, does most of the work with radioisotopes. Two commenters believe that radiological physicists should be separated out from other paramedical personnel and one of these commenters offered a definition of radiological physicist.

As noted in the proposed policy statement, NRC is studying the various allied health certification programs currently in effect or being drafted by other Federal, State and professional groups. If the coverage provided by these programs is not adequate to protect the patient from unnecessary radiation exposure, NRC will work with these groups to develop a new NRC proposed rule for the training of allied health personnel.

There were five comments on the specific subject of nuclear pharmacies (radiopharmacies).

One commenter urged NRC to distinguish between radiopharmacists working in a hospital setting and those working in a retail environment (commercial nuclear pharmacy). This commenter also noted the complexity of the problem of definition when the hospital based radiopharmacy provides radiopharmaceuticals to other hospitals and practitioners in its area.

As noted in the proposed policy statement, the NRC will defer to the Food and Drug Administration (FDA) regarding a determination of those activities of nuclear pharmacies that will be considered manufacture and those activities that will be considered the ordinary practice of pharmacy (compounding and dispensing).

Four commenters objected to NRC's licensing nuclear pharmacies to distribute only those products that they have prepared from FDA-approved radiopharmaceuticals or reagent kits. One commenter cited the practice of nuclear pharmacies supplying radiochemicals to researchers who use them on humans under their own FDA "Notice of Claimed Investigational Exemption for a New Drug" (IND). One commenter noted that FDA permits nuclear pharmacies to operate in the absence of a final determination of their status, providing they meet all State and local pharmaceutical regulations. The two other commenters characterized the NRC's restrictions on the distribution of radiopharmaceuticals by nuclear pharmacies as an unwarranted intrusion into the practice of pharmacy which is regulated by the States.

NRC licenses nuclear pharmacies to distribute radioactive drugs that have been approved by FDA. This includes radioactive drugs subject to an FDA-approved "New Drug Application" (NDA), or "Notice of Claimed Investigational Exemption for a New Drug" (IND). NRC relies on FDA approval of radioactive drugs because NRC has not regulated the safety and effectiveness of radioactive drugs since 1975. Also, there are not many States that are equipped to regulate radioactive drug safety and effectiveness.

Dated at Washington, D.C. this 1st day of February 1979.

Senator SPECTER. Thank you, Dr. Kao.

We are now going to turn to Panel 3 before any of the questioning so we can have a factual basis for the questioning beyond what has appeared in the press.

So, I would like to call at this time Dr. Gerald Cross, Dr. Richard Whittington, Director Michael Moreland, Director Richard Citron, Dr. Michael Hagan, and Director Steve Reynolds.

Our first witness on this panel will be Dr. Gerald Cross, who has an M.D. from Loma Linda University. He is the Veteran Administration's top doctor, and is the Principal Deputy Under Secretary for Health. Dr. Cross appeared at a hearing of the Senate Veterans' Affairs Committee last week and graciously consented to come to this hearing, although it caused a change to his plans. So, we appreciate your becoming available, as we did want to proceed at the earliest practical date.

Dr. Cross, the floor is yours for 5 minutes.

STATEMENT OF GERALD M. CROSS, MD, FAAFP, ACTING UNDER SECRETARY FOR HEALTH, U.S. DEPARTMENT OF VETERANS' AFFAIRS; ACCOMPANIED BY MICHAEL E. MORELAND, FACHE, DIRECTOR, VISN 4; RICHARD CITRON, FACHE, DIRECTOR, PHILADELPHIA VA MEDICAL CENTER; MICHAEL HAGAN, MD, PHD, NATIONAL DIRECTOR, RADIATION ONCOLOGY PROGRAM, RICHMOND VA MEDICAL CENTER; MARY MOORE, RADIATION SAFETY OFFICER, PHILADELPHIA VA MEDICAL CENTER; AND JOEL MASLOW, MD, CHAIRMAN, PHILADELPHIA VA MEDICAL CENTER RADIATION SAFETY COMMITTEE

Dr. CROSS. Good morning, Senator and Congressmen. Thank you for the opportunity to discuss the treatment of veterans with prostate cancer through brachytherapy.

VA has a well-documented record of quality care, but when there are exceptions, whatever the cause may be, we apologize and express our deep regret to the patient, as I do now.

Indeed, we go beyond that. We work with the individual patient to provide them the care that they need. We further analyze what went wrong, we take corrective actions, and we look at the 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 to make as few mistakes as possible.

The staff at the Philadelphia VAMC discovered the problem, a possible underdosing and incorrect dosage of patients in May 2008, and the VA Medical Center Director immediately suspended the program and convened the Administrative Board of Investigation to uncover the facts.

We informed and treated all affected veterans. The VA National Director of Radiation Oncology continues to investigate the reasons why these problems were not detected earlier.

My testimony today will briefly describe brachytherapy, explain what happened as we currently understand the facts, and describe VA's response.

In brachytherapy for prostate cancer, small radioactive seeds are implanted in the prostate to destroy cancerous cells. Although the risk to healthy tissues to the body is minimal, side effects may occur.

So, what has been learned? A lot. We value our relationships with universities, but the responsibilities for care and oversight must be well defined at the outset, even when, as in this case, there is a contract with a university. Despite those facts, at the end of the day, VA must oversee the quality of care for veterans.

External oversight is also important, but not sufficient. Noteworthy is the fact that the VA program is accredited while about 85 percent of the programs outside the VA are not.

We will continue to ensure that all stakeholders are made aware of all-important developments, positive and negative, concerning veterans' health care.

Now, I will describe the details. On May 5, 2008, a radiation oncologist performed a brachytherapy procedure using seeds of a lower apparent activity than intended. A physicist discovered this underdosing 10 days after the initial procedure. The physicist notified the facility's radiation safety officer, who immediately reported the problem to VA's National Health Physics Program.

On May 16, 2008, VA's National Health Physics Program also notified the Nuclear Regulatory Commission. VA convened a clinical risk assessment advisory board, which recommended that all prior treatments be reviewed and notification of all patients who received inadequate radiation dosages.

External physicians and physicists with no involvement with the Philadelphia VAMC brachytherapy program conducted these examinations of patient scans, dosages, and medical records. During this review, we found up to 92 potential events involving underdosing or imprecise placement.

It is important to highlight for these additional cases that the definition of "medical event" does not necessarily mean veterans were harmed, and experts still debate the long-term impact of the treatment. Nonetheless, VA took the conservative approach of notifying these veterans.

On July 2, 2008, the Philadelphia VAMC issued a press release and notified local Members of Congress and veteran service organizations; that was in 2008. The facility also took the proactive steps to contact each of the 114 veterans who underwent brachytherapy at VAMC from 2002, when the program started, to 2008, whether they experienced a medical event or not.

VA sent each veteran a certified letter and called each veteran or the veteran's family directly. We also established a toll-free telephone number to answer questions. VA is covering all costs associated with additional tests and continuing to monitor their care at other VA and private facilities.

We regret this problem went undetected. VA, as with other health systems, relies on complimentary systems of accountability to identify quality problems. Many of these systems failed to detect the less-than-optimal care in this case, and in fact, it was only the recognition of potential problems by VA staff that eventually led to more in-depth investigation, review, and subsequent disclosure to patients and to the public.

The Philadelphia VAMC brachytherapy program has been suspended since June 2008, and will not reopen until the NRC's concerns have been satisfied and until requirements of the VA radiation oncology program are met.

Senator SPECTER. Did you say suspended in June 2008?

Dr. CROSS. Yes, sir. This notice was sent out in June 2008.

VA currently offers brachytherapy at nine other facilities, and we are working to ensure the highest quality of care for prostate

brachytherapy. Currently, the NRC is refining the definition of medical event as it pertains to these procedures.

VA has developed criteria for suspending and restarting prostate brachytherapy program. VA's National Health Physics Program will continue to conduct the site inspections at all facilities where prostate brachytherapy is conducted.

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

Secretary Shinseki in VA——

Senator SPECTER. Dr. Cross, how much more time will you need?

Dr. CROSS. Thirty seconds.

Senator SPECTER. Thank you.

Dr. CROSS. Thank you, sir.

VA Secretary Shinseki and VA senior leadership are conducting a top-to-bottom review of the Department and are implementing aggressive actions to ensure the right procedures are in place to protect our veterans in providing them the highest quality of care possible.

Let me again emphasize our regret that this incident occurred and how proud I am of the work our staff at the Philadelphia VAMC does on behalf of America's veterans. While we recognize the seriousness of this situation, it is important that our veterans and their loved ones have faith and confidence in our medical system.

Thank you once again for the opportunity to testify, Senator.

[The prepared statement of Dr. Cross follows:]

PREPARED STATEMENT OF GERALD M. CROSS, MD, ACTING UNDER SECRETARY FOR HEALTH, U.S. DEPARTMENT OF VETERANS AFFAIRS

Good morning, Senator Specter and Congressman Adler. Thank you for the opportunity to discuss the Philadelphia Veterans Affairs Medical Center's (VAMC) treatment of Veterans with prostate cancer through brachytherapy. I am accompanied today by Mr. Michael E. Moreland, Director, VISN 4; Mr. Richard Citron, Director, Philadelphia VA Medical Center; Dr. Michael Hagan, National Director for Radiation Oncology in the Veterans Health Administration; and Dr. Richard Whittington, Physician in Radiation Therapy at the Philadelphia VAMC. The staff at the Philadelphia VAMC discovered the problem of possible under-dosing and incorrect dosage of patients in May 2008, and the VA medical center director did not hesitate to immediately suspend the program and convene an Administrative Board of Investigation to uncover the facts. We informed and treated all affected Veterans and promptly suspended the program. The VA National Director of Radiation Oncology is continuing to investigate the reasons why these problems were not detected earlier. My testimony today will briefly describe brachytherapy, explain what happened as we currently understand the facts, and describe VA's response. Please let me begin by saying I am disappointed my fellow Veterans did not always receive the quality health care they deserve.

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.

On May 5, 2008, a radiation oncologist performed a permanent implant prostate brachytherapy procedure using seeds of a lower apparent activity than intended. A physicist discovered this under-dosage ten days after the initial procedure. The physicist notified the facility's Radiation Safety Officer, who immediately reported the problem to VA's National Health Physics Program. On May 16, 2008, VA's National Health Physics Program also notified the Nuclear Regulatory Commission (NRC). VA convened a Clinical Risk Assessment Advisory Board, which recommended that all prior treatments be reviewed and that all patients who received inadequate radiation dosages be notified. Independent, external physicians and physicists with no involvement with the Philadelphia VAMC's brachytherapy program conducted these examinations of patient scans, dosages, and medical records. During this review, it was discovered that 92 events involving under-dosing or doses to

organs or tissues other than the treatment site were found that met the definition of a medical event according to the NRC. VA has regularly informed the NRC of any updates. It is important to highlight for these additional cases that the definition of "medical event" does not necessarily mean Veterans were harmed, and experts still debate the long-term impact of this treatment. Nonetheless, VA took the conservative approach of notifying these Veterans because we did not deliver a treatment as promised.

On July 2, 2008, the Philadelphia VAMC issued a press release and notified local Members of Congress and Veterans Service Organizations. The facility also took proactive steps to contact each of the 114 Veterans who underwent brachytherapy at the VAMC from 2002 (when the program started) to 2008, whether they experienced a medical event or not. VA sent each Veteran a certified letter and called each Veteran or the Veteran's family directly. We also established a toll-free telephone number to answer questions. VA is covering all costs associated with additional tests and continuing to monitor their care at other VA and private facilities.

We regret this problem went undetected for nearly six years. VA, as 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); review of public databases such as the National Practitioner Data bank; patient satisfaction and complaints; and individual peer review. Many of these systems failed to detect the aberrant care at Philadelphia, and, in fact, it was only the recognition of potential problems by VA staff that eventually led to more in-depth investigation, review, and subsequent disclosure to patients and the public.

The Philadelphia VAMC's brachytherapy program has been suspended since June 2008 and will not be reopened until the NRC's concerns have been satisfied and until requirements of the VA Radiation Oncology Program are met. VA also temporarily suspended programs at facilities in Washington, DC, Cincinnati, Ohio, and Jackson, Mississippi. Based upon these reviews, the Cincinnati program was found satisfactory and is in the process of fulfilling national VA requirements for resuming prostate brachytherapy. Complete reviews of the Jackson and Washington programs continue. VA will also notify any additional Veterans if we determine they experienced a medical event.

VA currently offers brachytherapy at nine other facilities, and we are working with the NRC on regulatory issues related to prostate brachytherapy. Currently, the NRC is refining the definition of "medical event" as it pertains to these procedures. VA has developed criteria for suspending and restarting prostate brachytherapy programs. VA's National Health Physics Program will be conducting periodic site inspections at all facilities where prostate brachytherapy is performed and whenever a possible medical event is reported. VA clinical standards and procedures are now among the most rigorous in the health care industry.

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.

Let me again emphasize our regret that this incident occurred, and add how proud I am of the work our staff at the Philadelphia VAMC does on behalf of America's Veterans. Nearly 60,000 Veterans receive world-class health care at this facility every year and these events are uncharacteristic of the level of care we provide. While we recognize the seriousness of the situation, 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.

RESPONSE TO POST-HEARING QUESTIONS SUBMITTED BY HON. RICHARD BURR TO U.S. DEPARTMENT OF VETERANS AFFAIRS

Question 1a: I am trying to better understand the number of VA facilities affected by the issues surrounding the brachytherapy program.

On Monday, June 22, SVAC staff met with Dr. Cross and other staff at VACO. VA informed the staff that there were 13 facilities nationwide where this procedure was performed, and 3 facilities had reported problems (Philadelphia, PA, Jackson, MS, and Washington, DC). When asked to clarify whether the other ten facilities were foud to not have issues and continued to operate, VA answered in the affirmative.

In a follow up briefing on Friday, June 26 given to SVAC and HVAC staff, VA detailed that there actually were four hospitals where problems were discovered, informing the staff about issues at the Cincinnati hospital.

At the Monday, June 29 hearing on this issue in Philadelphia, VA reaffirmed this number four and testified that, "The Philadelphia VAMC's brachytherapy program has been suspended since June 2008 . . . VA also temporarily suspended programs at facilities in Washington, DC, Cincinnati, OH, and Jackson, MS."

Yet, in written testimony, Mr. Reynolds of the NRC stated that, "The VA has agreed to not restart the prostate brachytherapy treatment programs at five sites, including the VA Philadelphia, until all commitments have been met."

According to the NRC, procedures at the Los Angeles VAMC were also "suspended." When SVAC staff went back to VA to confirm the number of facilities still open, they learned that the Durham VAMC had voluntarily halted these procedures. In addition, two other hospitals, in Reno and Birmingham, maintain inactive programs. Therefore, I am now under the impression that only seven of the 15 hospitals that offered this procedure since 2005 are still performing brachytherapy.

To clarify for the record, how many of these 15 hospitals are considered to have "active" brachytherapy programs? How many have been "suspended" by the NRC? How many have voluntarily ceased operations?

Response. Beginning in June 2008, the Department of Veterans Affairs (VA) used the situation in Philadelphia to proactively conduct a comprehensive review of its prostate brachytherapy programs. Fifteen VA facilities have provided prostate implants since 2005. Of those 15 sites, 2 had already voluntarily deactivated its programs prior to the comprehensive 2008 review for reasons other than regulatory violations. Of those two inactive programs (Birmingham, AL and Reno, NV), Birmingham does not plan to restart and Reno plans to consider resumption of its program upon hiring of appropriate urology staff.

Of the 13 remaining programs, 4 (Cincinnati, OH; Philadelphia, PA; Washington, DC; and Jackson, MS) have been suspended by VA's National Health Physics Program (NHPP).

There are currently nine programs that meet the standard to provide brachytherapy. Seven facilities, including Albany, NY; Boston, MA; Brooklyn, NY; Minneapolis, MN; Richmond, VA; San Francisco, CA; and Seattle, WA are active and offering brachytherapy treatments. In our comprehensive review, we found these facilities have provided treatments within approved standards.

Two programs meet the standard to provide brachytherapy but are currently not active. These include the Durham, NC, VA Medical Center (VAMC), which 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, and the Greater Los Angeles Healthcare System (GLA). After internally deciding to pause to review its procedures, GLA had planned to resume its program in July 2009, but the Nuclear Regulatory Commission (NRC) reported during the field hearing June 29, 2009 that the prostate brachytherapy program at the facility was suspended. The Veterans Health Administration (VHA) has requested clarification from NRC and we are awaiting a response.

The following provides a summary for the 15 facilities mentioned above:

Albany	Active
Birmingham	Inactive, with no current plans to restart this service
Boston	Active
Brooklyn	Active
Cincinnati	Suspended by VA's NHPP, completing the process to restart the program
Durham	Non-active; service chief elected to no longer provide this procedure in-house
Greater LA	Non-active; chief of staff and service chief elected to pause the program to review procedures. NRC concluded the pause represented suspension requiring the facility to have a restart inspection. Upon completion of this review the facility will begin the restart process.
Jackson	Suspended by NHPP (100 percent look-back to 2005 ordered)
Minneapolis	Active
Philadelphia	Suspended by NHPP (100 percent look-back); will not be reopened until all NRC concerns have been satisfied and until the requirements of VA's radiation oncology program are met
Reno	Inactive, but will consider restarting the program upon hiring of appropriate urology staff

Richmond	Active
San Francisco	Active
Seattle	Active
Washington, DC	Suspended by NHPP (100 percent look-back to 2005 ordered)

Question 1b: How many of the facilities that offer brachytherapy treatment do so on an in-house basis, contract basis with an outside provider or contract basis but within the VA facility?

Response. Of the 13 programs cited in our response to Question 1a, Albany, NY; Boston, MA; Brooklyn, NY; Cincinnati, OH; Richmond, VA; Seattle, WA; and Washington, DC, exclusively conducted operations in house during 2008. Greater Los Angeles, Philadelphia, and San Francisco exclusively used fee-basis or contract authority to provide these services in 2008. Durham, Jackson and Minneapolis conducted these operations in-house and through fee-basis or contract authority in 2008.

Question 1c: For those eight hospitals that are no longer performing these procedures, please state the individual reasons for each becoming inactive. Have they been mandated for shutdown by an outside entity or has VA central office or local VA officials elected to stop the procedures independently?

Response. VA's NHPP has temporarily suspended four programs, including Cincinnati, Washington, DC, Jackson and Philadelphia because problems were found involving under-dosing. Based upon a comprehensive review, the Cincinnati program was found to be in compliance with VA clinical standards and is completing the process to fulfill national VA requirements for resuming prostate brachytherapy. Cincinnati underwent a restart inspection during June 30 to July 1, 2009, with one pending action to obtain a new treatment planning system. A restart might be possible in August 2009 from the VHA perspective; however, NRC informed VHA that restart must be approved by NRC. Philadelphia was suspended by the Veterans Integrated Service Network (VISN) and VAMC after a comprehensive review found that 91 possible events involving under-dosing or doses to organs or tissues other than the treatment site were found that met the definition of a medical event according to NRC. Philadelphia's program will not be reopened until all NRC concerns have been satisfied and until the requirements of VA's radiation oncology program are met. Complete reviews of the Jackson and Washington, DC, programs continue.

Two facilities (Birmingham and Reno) voluntarily deactivated its programs prior to a comprehensive internal review for reasons other than regulatory violations. Reno intends to re-open its program when they have re-established a urology support program, but Birmingham does not intend to resume operations. No medical events were found with past patients at these two sites. Durham voluntarily chose to no longer provide these services and GLA has temporarily paused its program.

Question 1d: Is there a reason for VA's oversight to mention the Los Angeles and Durham facilities at the various briefings and hearing on this topic?

Response. The Durham VAMC is still authorized to perform this procedure; however, the service chief 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. In mid 2008, VHA, through NHPP, made a commitment to the NRC to use D90, which is the dose to 90 percent of the volume of the prostate, to determine if a medical event had occurred. The physician who was on contract to provide these services in-house at Durham believed that using this parameter for regulatory purposes is unacceptable. He decided to stop offering the procedure because he was concerned regarding the risk of liability for medical events as defined by the D90 parameter. His concern was triggered by the intense regulatory scrutiny of the brachytherapy program, with numerous inspections over the last year involving multiple definitions of the term, medical event. Patients requiring this procedure are currently being provided it on a fee-basis at the Durham Regional Hospital.

There is a proposed revision to the NRC regulations pertaining to the definition of medical event as regards these procedures, which, if adopted, would allow reconsideration of the decision.

The prostate implant program at Durham has been inspected numerous times within the last year, and no regulatory violations have been cited.

The VA GLA has elected on its own to pause its program to conduct a review of procedures; upon completion of this review the facility will begin the restart process. NRC has made an interpretation that the local decision requires the facility to have a restart inspection. This is the basis for NRC to have listed a fifth seed implant program as being suspended. Confusion might have resulted from use of the "suspended" terminology by facility staff during the on-site NRC inspection. VHA does not agree with this interpretation and has requested clarification on this issue from NRC.

Question 1e: In VA's written statement, after describing problems found in Philadelphia, Jackson, Washington, DC, and Cincinnati, you testified that, "VA currently offers brachytherapy at nine other facilities . . ." In light of the information about Los Angeles and Durham, does VA stand by this testimony?

Response. The information provided to the Committee in our testimony should have been more precise: VA offers brachytherapy at seven other facilities. There are nine programs that meet the standard to provide brachytherapy, but as indicated earlier, Los Angeles and Durham are not currently offering such procedures. Los Angeles is working to restart brachytherapy, while Durham has chosen not to offer the procedure in-house.

Question 2a: With respect to Dr. Kao, Reverend Flippin testified that, "I have never met the gentleman. He was not the doctor who I met with to decide the type of therapy to select." VA has informed SVAC staff that, "the veteran who testified at the Philadelphia field hearing concerning prostate brachytherapy received treatment from Dr. Kao, not another provider." Please clarify for the record if Dr. Kao was in fact the doctor who performed the brachytherapy procedure on Reverend Flippin.

Response. Dr. Kao performed the brachytherapy implant; a note written by Dr. Kao in the patient's medical record states that he performed the implant.

Question 2b: More broadly, what is VA's policy with respect to informing veterans of the doctor performing a medical procedure on them? Is it protocol that a VA doctor meet with a patient before performing a procedure on them? Does VA allow a doctor to perform a procedure on a patient without the specific consent of that patient regarding the identity of the doctor performing the procedure?

Response. VHA Handbook 1004.1, *VHA Informed Consent for Clinical Treatments and Procedures*, requires that informed consent be obtained and documented by a practitioner who is clinically privileged to perform the treatment or procedure in question. Clinicians in training (e.g., medical or dental residents) are also authorized by the policy to obtain informed consent. Clinicians in training must identify their supervising attending on the consent form and the patient must be informed of that supervising attending's name and the names of any other individuals responsible for authorizing or performing the treatment or procedure. The policy does not require that the individual obtaining consent be the practitioner who ends up performing the procedure although practitioners are obligated to identify, on the consent form, the clinicians on the treatment team who will perform the procedure.

Due to the requirements of medical training programs, VA attendings and residents rotate services regularly. It is common for practitioners to cover a medical service at the time of obtaining the informed consent and then to rotate off service before the procedure is scheduled or performed. For this reason, the performing and supervising practitioners identified on the consent form may not always be the practitioners ultimately assigned to the case. In such instances, policy requires that the patient be notified of the change, and that the discussion and the patient's assent be documented in the record. This documentation clarifies that the patient was made aware of the change and agreed to the change of providers. The policy does not require that a new signature consent form be completed in such instances. Please note that Handbook 1004.1 is currently in revision and is expected to be published by the fall of 2009. However, requirements for informing patients of who will be performing the treatment or procedure will remain unchanged in the revised version.

Senator SPECTER. Thank you very much, Dr. Cross.

Our next witness is Dr. Richard Whittington. Dr. Whittington is the physician on radiation therapy at the Philadelphia VA Medical Center, former head of radiation oncology here; his doctorate degree and M.D. are from Rice University.

Thank you for joining us, Dr. Whittington, and we look forward to your testimony.

STATEMENT OF RICHARD WHITTINGTON, M.D., CHIEF OF RADIATION ONCOLOGY, PHILADELPHIA VA MEDICAL CENTER

Dr. WHITTINGTON. I do not have a formal opening statement, Senator. I am sorry.

All I would like to say is that I have been around the Veterans' Administration for most of my life. My father recently retired from the Veteran's Administration after working with the VA for 52

years. My sister has worked for the VA for 33 years. My brother worked for the Veterans' Administration until the day he died. I am a veteran myself, and I have to say that these incidents that are described are the low point in my professional career, because it happened on my watch.

Senator SPECTER. Thank you. We will turn next to Steve Reynolds, a Director of the Division of Nuclear Materials Safety from the Nuclear Regulatory Commission, bachelor of science in engineering from Florida Institute of Technology, and the Director of the Nuclear Materials Safety Center since 2005.

Thank you for joining us, Director Reynolds, and the floor is yours for 5 minutes.

STATEMENT OF STEVE A. REYNOLDS, DIRECTOR, DIVISION OF NUCLEAR MATERIALS SAFETY, REGION III, U.S. NUCLEAR REGULATORY COMMISSION

Mr. REYNOLDS. Thank you. Senator Specter, Congressman Adler, and Congressman Fattah, I am honored to represent the U.S. Nuclear Regulatory Commission at today's hearing.

The NRC is very concerned about this issue. An important part of our mission as the regulator for the civilian use of nuclear material is to protect public health and safety, including medical uses. Therefore, we are concerned about all patients receiving medical care, including our veterans.

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 a holder of the NRC license, it is the responsibility of the VA to identify problems in medical treatments and report those problems to the NRC.

The NRC, once notified of the apparent problems, began increasingly intensive inspections of the brachytherapy program at VA Philadelphia and at 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, including Philadelphia, and they will not restart until we, the NRC, are satisfied they have addressed all the problems. Our inspections are continuing, and once we complete these later this summer, the Agency will determine if enforcement action is necessary.

We are also looking at NRC procedures to see if there are improvements we can make in our oversight system. We will continue to look critically at our inspection and licensing programs, as well as to consider proposed regulatory changes.

In closing, the NRC takes these medical events very seriously, and continues to be actively engaged on these issues. Thank you.

[The prepared statement of Mr. Reynolds follows:]

PREPARED STATEMENT OF STEVEN REYNOLDS DIRECTOR, DIVISION OF NUCLEAR MATERIALS SAFETY REGION III, U.S. NUCLEAR REGULATORY COMMISSION

INTRODUCTION

Senator Specter, Members of the Committee, and Representative Adler, 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 Af-

fairs 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 ensure the adequate protection of those working with radioactive material, the public, the environment and that the patient receives the doctor's intended radiation dose.

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 organizations 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 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 inspection and enforcement policies, procedures, and guidance. In 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 underdose 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 implementing 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 startup 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 to not 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 also apply the findings of our evaluations to our own regulatory practices. In this case, two areas that we have identified 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.

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.

RESPONSE TO POST-HEARING QUESTIONS SUBMITTED BY HON. RICHARD BURR TO STEVEN REYNOLDS, DIRECTOR, DIVISION OF NUCLEAR MATERIALS SAFETY, UNITED STATES NUCLEAR REGULATORY COMMISSION

Question 1. How many non-VA facilities has the NRC issued licenses to for the possession and use of radioactive material? How many facilities use that material for prostate brachytherapy treatment? Is the University of Pennsylvania Hospital one of the facilities which possesses a license?

Response. There are currently approximately 3400 active NRC licenses in the 13 States regulated by NRC which authorize the possession and use of radioactive material. Over 500 NRC licensees are approved to use radioactive materials for brachytherapy. The NRC's database does not differentiate between prostate brachytherapy and other brachytherapy uses, so this number is all-inclusive. The University of Pennsylvania possessed an NRC license until March 31, 2008, when the NRC relinquished the authority for licensing to the Commonwealth of Pennsylvania. On that date, Pennsylvania became an Agreement State. Under certain conditions (as allowed by Section 274 of the Atomic Energy Act), the NRC enters into agreements with State Governors. Those agreements authorize individual States to regulate the safe use of specific radioactive materials within their borders. This includes radioisotopes used in medicine and industry.

Question 2. Are the NRC guidelines that VA follows for reporting a potential medical event the same guidelines that non-VA facilities are required to follow? Are they the same guidelines that the University of Pennsylvania Hospital is required to follow?

Response. Yes, the NRC reporting requirements for both VA and non-VA facilities are the same. The NRC reporting requirements are found in Title 10 of the Code of Federal Regulations (CFR), Part 35, Section 35.3045. Prior to the Commonwealth of Pennsylvania becoming an Agreement State on March 31, 2008, the University of Pennsylvania Hospital was required to follow the NRC reporting requirements. Since March 31, 2008, the University of Pennsylvania Hospital is required to follow Pennsylvania's reporting requirements, which are identical to the NRC's. Pennsylvania's Code Title 25, Chapter 224.10 (a) incorporates 10 CFR Part 35 by reference, meaning that Pennsylvania's regulations for the medical use of byproduct material are identical to NRC's.

Question 3. How many brachytherapy treatment procedures were conducted nationwide since 2002? How many reports of potential medical events with respect to brachytherapy treatment have you received from non-VA facility licensees since that time? How many on-site inspections has the NRC performed since that time on non-VA facilities authorized to perform brachytherapy treatments? How many actual violations have you found? How many facilities have had to suspend their brachytherapy treatment programs until compliance with NRC guidelines was achieved? Did the NRC ever receive reports of potential medical events from the University of Pennsylvania Hospital? Did the NRC ever investigate the University of Pennsylvania Hospital's brachytherapy treatment program? If so, what was the conclusion?

Response. The NRC understands that the question pertains to manual prostate seed implant brachytherapy procedures. The NRC does not maintain statistics regarding the number of brachytherapy treatment procedures conducted annually. However, based on information gathered from professional organizations involved in brachytherapy, an estimated annual average of 40,000 brachytherapy procedures (all-inclusive, not limited to prostate brachytherapy) have been conducted nationwide since 2002. Between 2002 and July 17, 2009, the NRC received 53 reports of medical events involving manual prostate seed implant brachytherapy procedures that were administered to 208 patients. Forty-three of these reports were received from non-VA facilities and involved 95 patients. Ten reports were received from VA facilities and involved 113 patients.

Between 2002 and July 17, 2009, the NRC conducted 806 inspections at non-VA facilities that perform all types of brachytherapy, including prostate brachytherapy. The NRC does not maintain separate inspection statistics limited to only prostate brachytherapy. The NRC issued a total of seven violations specific to prostate brachytherapy. In addition to the five suspended VA brachytherapy programs, two non-VA facilities suspended their brachytherapy programs as a result of medical events. These two programs resumed after implementing corrective actions to achieve compliance with NRC requirements.

The NRC received one report of a medical event from the University of Pennsylvania Hospital involving a prostate implant. On May 5, 2001, that hospital reported a misadministration (now referred to as a "medical event") involving a leaking seed

which was implanted into the prostate of a patient. The NRC conducted a special inspection on May 7, 2001. No violations of regulatory requirements were identified during the special inspection. It should be noted that having a medical event in itself is not a violation.

The NRC conducted other inspections at the University of Pennsylvania, including its hospital. The most recent NRC inspection conducted March 19 through 22, 2007, did not identify any violations associated with the prostate brachytherapy activities. Previous NRC inspections were conducted November 29 through December 3, 2004 and December 9 through 12, 2002; no violations were identified regarding the prostate brachytherapy program during these previous inspections.

Question 4. Your testimony states that "VA has agreed to not restart prostate brachytherapy treatment programs at five sites . . . ." However, VA testimony states that only four sites, including Philadelphia, were temporarily suspended. What is the 5th site you are referring to that VA is not? Why would that site not be included in VA's testimony?

Response. The fifth site NRC referred to was the VA Greater Los Angeles (GLA) Medical Center. The NRC included this as a suspended site based on information provided in a report dated February 24, 2009 from the VA National Health Physics Program (NHPP), which states "the prostate implant program at GLA was suspended by the GLA Chief of Staff on February 13, 2009." The other four VA sites were suspended by the NHPP (in consultation with each VA Medical Center's senior management) and include: VA Philadelphia, Pennsylvania (June 11, 2008); VA Jackson, Mississippi (September 2008); VA Washington, D.C (September 26, 2008); VA Cincinnati, Ohio (October 2008). Each of these VA prostate brachytherapy programs remain suspended. The NRC does not have an explanation or any additional information regarding why the VA's testimony did not include the fifth site (GLA).

Question 5. I have learned that the Durham VA medical center voluntarily ceased its brachytherapy program, in large part due to a provider's discomfort with adhering to NRC's guidelines. I understand that this same provider will perform brachytherapy treatments at Duke University Hospital which is subject to North Carolina guidelines on what is a reportable medical event. Does the NRC delegate licensing authority to States? What is the difference between the state guidelines and NRC's guidelines? Are States free to use their own guidelines on reportable medical events or must they follow the NRC's? If they may use their own guidelines, does it make sense to have two different standards?

Response. Under certain conditions (as allowed by Section 274 of the Atomic Energy Act), the NRC enters into agreements with State Governors. Those agreements authorize individual States to regulate the safe use of specific radioactive materials within their borders. This includes radioisotopes used in medicine and industry.

States that meet these conditions and agree to regulate materials must meet specific criteria for compatability with NRC requirements. Typically, Agreement States regulate additional sources of radiation that the NRC does not. This generally includes naturally occurring radioactive materials within their borders. In addition, the States regulate radiation-producing machines, such as X-ray machines (both medical and industrial) and particle accelerators.

When an agreement is signed, the NRC discontinues its authority and the State asserts State authority under its laws and regulations for the material under the Agreement. However, under the Agreement, certain regulations and program elements are adopted by an Agreement State to maintain a compatible program with NRC requirements in accordance with criteria for compatibility. These criteria sometimes must require identical regulations and sometimes allow limited flexibility to the state in implementing its program. With respect to guidelines for reporting medical events, the Agreement State requirements must be identical to the NRC requirements. Normally, the Agreement States will adopt those identified regulations within a three year timeframe. The regulations in 10 CFR Part 35, including regulations for reporting a medical event, have been identified as regulations that must be adopted by Agreement States to maintain a compatible program. North Carolina's regulations for the Records and Reports of Misadministration, found in North Carolina Administrative Code Title 15A, Chapter 11, Section .0350 are identical to NRC 10 CFR 35.3045, Report and Notification of a Medical Event.

Question 6. You stated at the hearing that the requirements to report to NRC when there is adverse care to patients went into effect in 1979. Dr. Kao's testimony states that the standard definition of a reportable medical event to the NRC "was not in existence when the Brachytherapy Program started at the VA." Were you and he talking about two different things? Please resolve the apparent contradiction.

Response. The VA started its brachytherapy program in February 2002. The requirement to report "misadministrations" to the NRC was incorporated into the reg-

ulations in 1980 (45 FR 31701; May 14, 1980). Events were then classified as misadministrations when the calculated administered dose differed from the prescribed dose by more than 20%. In 2002 (April, 24), the NRC replaced the term "misadministration" with "medical event" and revised the reporting requirements. The term "medical event" more correctly and simply conveys that the radioactive material, or the radiation from there, was not delivered as directed by the physician. NRC has therefore had reporting requirements in place since 1980 that require reporting of events such as those that took place at the VA hospitals.

Question 7. Dr. Kao's testimony also states that "The definition of a reportable medical event to the NRC does not define a standard of effectiveness of medical treatment either scientifically or medically. A patient whose treatment results in a reportable medical event may still have received effective treatment and be within the appropriate standard of medical care." Is he correct? How did NRC arrive at its definition of what is a reportable medical event? Does the NRC collaborate with the medical and scientific community when arriving at a definition?

Response. The reason for medical event reporting requirements is to identify incidents where the end result of a medical use of radioactive material is significantly different from what was planned. The medical event could be a result of an error in calculating or delivering a radiation dose, administering the wrong radionuclide or the wrong amount of the correct radionuclide or other factors that are described in 10 CFR 35.3045.

The occurrence of medical events may reflect quality assurance problems with the licensees' programs and the reporting of medical events in accordance with the criteria established in section 35.3045 is intended to capture those events that result in actual harm to the patient. However, the threshold for reporting medical events is set at a level so as to also capture precursor events that may lead to harm to a patient, if not reported and investigated. Therefore, it is possible that patients, whose treatment results in a reportable medical event, may still have received effective treatment and be within the appropriate standard of medical care. However, the NRC has determined that the reporting requirements are necessary to protect public health and safety.

NRC's Medical Use Policy for radioactive materials is not to intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public. Under this policy, NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure that the use of radionuclides is in accordance with the physician's directions.

The NRC developed the first definition of reportable misadministrations through a rulemaking process that culminated in the final rule published in 1980. Discussions of the need for this definition began in 1972, based on an incident that occurred where the use of radiopharmaceuticals on a patient resulted in death. Discussions on the definition and incident data collection continued through the 1970s, focusing on patient death, harm, or large radiation doses to unanticipated tissues. The definition of a misadministration has been substantially changed since its inception in 1980. One revision occurred on July 25, 1991, when the rule was revised to require that events be classified as misadministrations when the calculated administered dose differed from the prescribed dose by more than 20% (instead of 10%). Another revision occurred in April 2002, when the term "misadministration" was changed to "medical event."

All of the revisions described above were implemented through the NRC's rulemaking process, which requires that proposed rules are published in the Federal Register and that the public is given time to provide written comments for consideration by the NRC staff. Once the public comment period has closed, the public comments are addressed and the final rule is published in the Federal Register. The NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), which provided input in all of the above rule changes, advises NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive materials in diagnosis and therapy. Members of this Committee include health care professionals from various disciplines who provide comments and recommendations on changes to NRC regulations and guidance and bring key issues to the attention of the Commission.

Question 8. Dr. Kao's testimony suggests other significant factors that the NRC should include in its defined standards (see "Fact 3" in his testimony). Please comment on his suggestions.

Response. The significant factors identified by Dr. Kao as standards that should be addressed in the NRC definition of a reportable medical event include: number of seeds; location of the seeds in the prostate; location of seeds outside the prostate; concentration of seeds to the affected areas of the prostate; stage, grade and extent

of the cancer; and the clinical follow up of the PSA test results. These significant factors pertain to the practice of medicine and the medical judgment of the physician. In accordance with NRC's Medical Use Policy Statement (65 FR 47654 dated August 3, 2000), NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public. It is not the policy of NRC to regulate the practice of medicine. The practice of medicine is regulated by the States' boards of medicine. The NRC Medical Use Policy Statement also states that the NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards or compliance with these standards are inadequate. This is why the NRC requires identification of the treatment site, radionuclide, and dose in the written directive. The purpose of NRC regulations of the medical use of byproduct material is to reduce unnecessary radiation exposure to patients, workers, and the public. The focus of NRC regulation to protect the patient's health and safety is primarily to ensure that the authorized user physician's directions are followed as they pertain to the administration of the radiation or radionuclide, rather than to other, non-radiation (e.g., stage, grade, and extent of the cancer) related aspects of the administration.

Question 9. In response to questions for Representative Fattah, Dr. Kao stated that "it is almost unavoidable" that some implanted seeds end up outside the prostate because it is an "inherently subjective procedure." You stated, however, that based on what is reported to you and based on NRC's own independent inspections that "medical events dealing with seeds outside the prostate happen very, very infrequently." Is it possible that Dr. Kao is right and that these events simply aren't being reported to NRC, or that you are not catching them during your inspections?

Response. Based on a search of NRC's events database, between 2002 and July 17, 2009, the NRC received 53 reports of medical events involving manual prostate seed implant brachytherapy procedures that were administered to 208 patients. Forty-three of these reports were received from non-VA facilities and involved 95 patients. Ten reports were received from VA facilities and involved 113 patients. These statistics demonstrate that events are being identified and reported to the NRC and that a percentage of the events include seeds that were implanted outside of the prostate. Additionally, the NRC periodically performs inspections of licensees with brachytherapy programs. One part of the inspections is to review a sample of records and determine if the licensees are correctly evaluating their procedures for medical events, and reporting the medical events when, and if, they occur.

Question 10. During the hearing Dr. Kao referenced transcripts in which a physician advisor to the NRC commented that if NRC "were to audit all the programs that do brachytherapy in this country, there would be 20,000 reportable medical events." You, in response to a question from Representative Fattah, stated that NRC receives "very few" medically reportable events. Is the physician advisor in error with his statement? Or, could it be that he's correct, and that lax oversight has resulted in very few events being reported?

Response. NRC understands the question to pertain to manual prostate seed implant brachytherapy procedures. Dr. Kao referenced a section of transcript made by a physician advisor from NRC's Advisory Committee on the Medical Uses of Isotopes meeting in May 2009. The physician advisor was speaking to a hypothetical situation and was not implying that 20,000 medical events go undetected by NRC.

NRC regulations in 10 CFR 35.3045(c) require medical licensees to report medical events the next calendar day after they are discovered. NRC requires licensees to be familiar with the regulations, identify a medical event, and report it to the agency.

Licensees performing permanent implant brachytherapy are inspected every 2–3 years, depending on the size of the medical use program. NRC has performed over 800 inspections of licensees with brachytherapy programs since 2002 and has not seen anything to suggest such a high rate of occurrence. One part of the inspections is to review a sample of records and determine if the licensees are correctly evaluating their procedures for medical events, and reporting the medical events when, and if, they occur. In this timeframe, the NRC received 53 reports of medical events nationwide from NRC licensees and Agreement State regulators, involving prostate brachytherapy procedures that were administered to 208 patients. Of these reports, 43 were received from non-VA facilities and involved 95 patients. The remaining 10 reports were received from VA facilities and involved 113 patients.

Question 11. Please confirm when the NRC began to regulate brachytherapy procedures.

Response. The Atomic Energy Act of 1954 and Energy Reorganization Act of 1974 give the NRC the responsibility to regulate the safe use of byproduct, source and special nuclear material. In 1954, NRC's precursor, the Atomic Energy Commission, implemented its authority to regulate the use of sealed sources for "human use" by

physicians in 10 CFR 30.24(c). In 1975, NRC specifically amended its regulations to include the regulation of brachytherapy sources in 10 CFR 35.14 and 10 CFR 35.100, Schedule A, group VI. Additional regulations covering brachytherapy requirements were incorporated into 10 CFR Part 35 in 1980.

Question 12. What guidance has changed from the NRC over the past twelve months?

Response. The NRC is currently assessing whether any additional changes are needed to its regulations or guidance, and is taking a critical look at potential enhancements to continually improve its processes. These enhancements include an increased focus on the safety culture at medical facilities, increased focus on medical facilities' oversight of contracted medical professionals, increased focus on whether the involved medical professionals and radiation safety staff understand the definition of a medical event and reporting requirements, increased focus on extent of condition reviews, and increased focus on post treatment results, to verify that the results are in accordance with the physicians' written directives.

Question 13. Please outline any changes throughout the years that have been made to the guidelines issued by the NRC as to what is considered a medical event.

Response. The following is an outline of changes that have been made to guidelines issued by the NRC as to what is considered a medical event:

May 1980: 45 FR 31704, Final Rule On Misadministrations was issued, which established misadministration criteria in 10 CFR 35.41, reporting of therapy misadministrations in 10 CFR 35.42, reporting of diagnostic misadministrations to NRC in 10 CFR 35.43, and requiring a record of all misadministrations in 10 CFR 35.44.

October 1986: 51 FR 36932, Final Rule On Medical Use of Byproduct Material. The diagnostic administration reporting requirement in 10 CFR 35.33 was changed to require reports of misadministrations that resulted in a whole body dose greater than 500 millirem, or an organ dose greater than 2 rem.

Misadministration was defined in part in 10 CFR 35.2 as an administration of a therapy radiation dose from a sealed source such that errors in the treatment geometry in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

July 1991: The definition of "misadministration" was revised in 10 CFR 35.2 to add as reportable events any dosage of I–125 or I–131 greater than 30 microcuries, where the administered dosage differs from the prescribed dosage by more than 20 percent. Also, a dose threshold of 5 rem dose equivalent or 50 rem dose equivalent to any individual organ was added to the definition of a diagnostic radiopharmaceutical misadministration.

September 1995: The definition of misadministration in 10 CFR 35.2 was amended by removing the term "patient or human research subject" and inserting the word "individual."

April 2002: Final rule was promulgated, which provides the current definition for medical events, 67 FR 20370. The term "misadministrations" was changed to "medical events." Section 35.33 "Notifications, reports, and records of misadministrations" was deleted and reporting requirements were moved to section 35.3045.

The dose threshold of 5 rem dose equivalent or 50 rem dose equivalent to any individual organ is added to the criteria for reporting an incident as a medical event.

Changes to the requirements made the reporting threshold dose-based where possible and addressed two problem areas, patient intervention and wrong treatment site.

March 2006: A minor edit to the definition of medical event, 71 FR 15008. Medical event is defined as an event that meets the criteria in 10 CFR 35.3045(a) or (b).

Senator SPECTER. Thank you very much, Director Reynolds.

The other individuals who are here are for the purpose of answering questions. So, at this time, I would like Reverend Flippin and Dr. Kao to return to the witness table, and Dr. Cross and Director Reynolds to stay, and the other prospective witnesses to step back and we may call on you as the occasion presents itself.

We will now turn to the opening rounds of questions of the witnesses, and they will also be 5 minutes in duration.

Dr. Cross, according to the media accounts, there were 92 veterans at the Philadelphia VA Medical Center who received incorrect doses of radiation. They received substantially less than the radioactive seeds and other patients received excessive radiation to

nearby tissue, including bladder and other organs. The incorrect doses were performed, according to media reports, at the University of Pennsylvania by a doctor under contract to the VA, and that doctor has been identified as Dr. Gary Kao.

According to the press reports: it took more than 6 years to catch the mistakes; and the checks were made by those who were in the program; that the quality assurance aspects of the program were conducted by the contracted doctors themselves and were not independent enough to assure getting an unbiased report.

What has your investigation disclosed with respect to those allegations?

Dr. CROSS. We have indeed found on our own investigation after we discovered this problem ourselves that up to 92 individuals could have been underdosed—and that is potentially underdosed. Some investigation still continues into that area.

It is important to understand—and I am a family physician, so this is not my area of specialty, but as I have learned more about this in the recent days, I have been impressed—this is both an art and a science. The art is in how the patient is addressed; how the seeds are actually lined up and planted.

We did not rely just on internal review, Senator, and that is important for you to know. And I want to read one 10-second statement.

We also had external review. We were accredited whereas most programs are non-accredited, and we received a statement in 2007 from the American College of Radiation Oncology that specifically mentions brachytherapy. In summary it states the following of the review: "In summary, your PVMC practice, as noted above, is a well organized and operated radiation oncology practice that not only meets but in many aspects exceeds the ACRO standards for practice accreditation, and we are pleased to inform you that the PVAMC has been awarded a 3-year accreditation."

They go on to complement the quality assurance program and so forth. Now, this is an external review organization that came in to review our program.

Senator SPECTER. Dr. Cross, you have stated in your opening statement that it is up to the Veterans Administration to do the oversight.

Dr. CROSS. Yes, sir.

Senator SPECTER. What is your response to the allegation that the quality assurance aspects of the program were conducted by the contracted doctors themselves and were not independent enough to assure that there was an unbiased report?

Dr. CROSS. I think that is a valid statement.

Senator SPECTER. Why, Dr. Cross, did it take 6 years to find out what was going on?

Dr. CROSS. For two reasons.

The first is that any complication or underdosing is not immediately apparent unless specifically measured.

Number 2, the measures that were put in place to check on the quality, like the one that I just read to you, suggested that things were not only good, but better than the national average.

Senator SPECTER. Dr. Cross, with respect to the VA procedure generally, is this aberrational what went on here at the veterans'

hospital? Or is this, with respect to two items, something that could be occurring other places, and that is, number 1, the failure of having objective observers to make a determination; and, second, a failure to find a problem for such a long period of time?

We are obviously concerned about what happened here, but we are also very concerned about what the practices are by the VA nationally.

My time is up and the red light is on. I am going to shift and have 10-minute questioning rounds by each of the panelists to give you a chance to respond, Dr. Cross.

Dr. CROSS. There is, in fact, something unique in this situation at Philadelphia that I think is more so than we would find at other locations, and that is the nature of the contract and the nature of the relationship with the University.

In my review of this program, it is almost indistinguishable as to where the University ends and the VA begins. In fact, the radiation oncology reviewer——

Senator SPECTER. Well, that may be indistinguishable, but you are saying that the Veterans' Administration has the responsibility for oversight.

Dr. CROSS. That is exactly my point. That arrangement, I think, was part of the problem. We value tremendously our relationship with our university affiliates, but in this case there was a contract, and the contract had some rather, in my experience, unusual language to the point that when the reviewers reviewed the program from the American College of Radiation Oncology, they made the following statement: "This VA radiation oncology department is under the control of the University of Pennsylvania."

I think that we, regardless of any such relationships, regardless of any such contracts, we, the VA, must prevail in having our oversight of this program and other programs.

Senator SPECTER. Well, what are you doing to correct this kind of problem here and nationally?

Dr. CROSS. It is quite a long list of things, Senator, but let me highlight just a couple of them.

Number 1, we hired a highly regarded radiation oncologist to review our programs.

Number 2, we invested in training—mandatory training. In fact, in January of this year, we brought all of the key individuals involved in these programs to Washington, DC, for additional review and training of current procedures and policies.

Number 3, when we found the problem here at Philadelphia, we did not stop there. We mandated that we review all of our other programs, as well, and we did that ourselves.

Senator SPECTER. When you suspended the program in June 2008, as you testified, did you know about these failures at that time?

Dr. CROSS. When we curtailed the program here at Philadelphia in 2008, we notified the VSOs, we notified the Congressional Offices, we notified the media, then we took further action——

Senator SPECTER. The answer to my question is, yes, you did know about the problem?

Dr. CROSS. No, sir. We decided to start an investigation at that time of all of our other sites, as well.

Senator SPECTER. And did you later find out about the problems?

Dr. CROSS. We did find some other problems, as well.

Senator SPECTER. And what action did you take at that time to notify congressional oversight?

Dr. CROSS. We notified the Committee Members.

Senator SPECTER. Notified?

Dr. CROSS. Committee staffers.

Senator SPECTER. I did not hear you.

Dr. CROSS. We notified Committee staffers.

Senator SPECTER. Let me turn to you, Dr. Kao. You have counsel with you; but let me say that, as you have noted, you are appearing here voluntarily and you are under no obligation to respond to questions. But we do appreciate your being here.

The allegations, as you have already heard, are very serious. You have been identified as the individual who performed these procedures on most of the 92 veterans. The allegation has been made that the seeds were not planted in the prostate where they should have been, but they were instead lodged in the bladder and other organs that there were insufficient seeds planted. Did you plant seeds that went into the bladder and other organs?

Dr. KAO. Senator, let me first correct something that has been incorrectly stated——

Senator SPECTER. Why don't you do that, but answer my question first.

Dr. KAO. Sir, yes, there have been occasions where seeds have been implanted in the bladder or outside the prostate.

Senator SPECTER. What action did you take on that to notify the patients?

Dr. KAO. The chance of seeds in the bladder or outside of the prostate is a recognized risk of the procedure and——

Senator SPECTER. Well, it is a recognized risk, but did you notify the patients?

Dr. KAO. No, sir.

Senator SPECTER. Why not?

Dr. KAO. Even when seeds are outside the prostate, they still contribute a radiation dose to the cancer, so——

Senator SPECTER. The allegations are that you also had excessive radiation. Is that true?

Dr. KAO. I believe some of our cases had seeds and radiation outside the prostate which would constitute a medically reportable event.

Senator SPECTER. But did you have excessive radiation?

Dr. KAO. By that definition, sir, it would be yes.

Senator SPECTER. And did you notify those patients about the excessive radiation?

Dr. KAO. I did not.

Senator SPECTER. I am 35 seconds over.

Congressman Adler——

Mr. VAIRA. Can he explain that?

Senator SPECTER. Oh, yes. Pardon me. You may proceed with explanation.

Mr. VAIRA. He would just like to explain that. Yes or no sometimes gives a bad definition.

Dr. Kao, would you please, in about a minute, explain that.

Senator SPECTER. Take whatever time you need, Dr. Kao. I wanted you to answer my questions, but you are privileged to say whatever you care to on that.

Dr. KAO. So, every step of the brachytherapy procedure was defined in the algorithm that we collaboratively wrote; and at the time that the program was implemented, the definition of what is reportable to the NRC was not in existence and only came later on. If we had been aware of this definition, we would have acted to notify the NRC and the patient.

We were working very closely and continually supervised by the radiation safety of the VA and we trusted their advice as to what should be reported. In retrospect, I should have known that the definition of what is reportable has changed through the years.

Senator SPECTER. Thank you, Dr. Kao.

I will turn now to Congressman Adler.

Mr. ADLER. Thank you, Senator.

Doctor, you seem to be the only person in this room except perhaps counsel that fails to recognize the statistics we have been dealing with. Colleagues at your table here have been acknowledging that we have, out of 116 procedures, 92 botched procedures.

You quarrel with the *New York Times*, you quarrel with the *Philadelphia Inquirer*, it seems you are quarreling with the panelists here who are acknowledging the VA has responsibility to 92 for inadequate medical care.

Do you care in any way to refine your testimony to talk about whether there was any substandard care on your part.

Dr. KAO. No, Congressman, I do not believe that our procedures were botched.

I do recognize there were occasions where we could have done better. I still maintain that we rendered effective treatment, Senator.

Through the years of the program, we were continually improving our results, and yet, we recognize that we can still do better and we were in the process of transitioning to the real-time brachytherapy system, which would have also helped in improving the quality of our treatment, Congressman.

Mr. ADLER. Doctor, I heard you earlier, I think, sort of blame a lack of training for the problems that this program encountered. I heard you sort of blame the Radiation Oncology Department and its lack of supervision of you and your coworkers. I heard you blame the Radiation Safety Office and the VA hospital administration, it is in your written testimony.

I am sort of baffled. We have these 92 people who got, by any fair measure, substandard care. I understand there are legal concerns you face right now. I am concerned about the medical concerns and the America-obligation concerns these 92 people—this is a good chance for you to say I am sorry—not to take all the blame. There may be other people that deserve blame. This would be your chance to say to Reverend Flippin, I am sorry for what you went through.

This would be a good chance. Why don't you do that right now, say, I am sorry for the pain you suffered, sir.

Dr. KAO. Congressman, I agree with you. I do accept a share of the blame. I do believe that we could have and should be doing bet-

ter. I am saddened by the plight of the Reverend and wish that I had the chance to do anything, anything at all to help him.

Mr. ADLER. Gosh, it seems to me you had a chance when you were performing the radiation procedure on him; that was the chance.

Dr. Cross, you told us a moment ago that after the revelation of this problem in June 2008, you reviewed all programs. Can you go into a little bit more detail, because I guess what we need to hear, not just for patients coming to this VA hospital which, by and large, as Congressman Fattah suggests, has provided very good care in so many different fields for so many different veterans over the years,—but why don't you reassure us that you, in fact, reviewed all of the programs so that this problem—which was not isolated to one doctor, but this program occurred massively here at Philadelphia and, to a lesser extent, I guess, in Jackson, in Cincinnati, and in Washington, DC—that this problem is unique and that, by and large, the VA program is delivering the quality of care that America owes its veterans.

Dr. CROSS. Thank you, Congressman. Of course, VA does deliver good quality of care, but we are also a trusted organization. And the point here is, when we find something wrong, our policy, our ethics is to acknowledge it, accept it, and do something about it. And that is what we did.

We found the problem. It was not the external reviewers, it was not all those accrediting groups that found it, it was our own staff who found it. And when they found it, they brought it forward, bravely, appropriately; and our leadership then said, let's disclose it, let's notify Congress, let's notify the media, let's notify the VSOs, and let's take action.

One of the things that we discuss when we find a problem is, well, that is one place. Could this problem be occurring elsewhere? And so, we mandated that all of our other facilities undergo a special review which our staff put together and conducted to see how they were doing.

We did find some problems, not to the level of concern that I had in Philadelphia, but when we find those problems, we work with the NRC—who have been very collaborative and helpful with us as a partner in this—to make sure that the corrective actions are taken. We are still working on that.

Mr. ADLER. Doctor, I thank you for that answer.

I guess I am still stumped as to how this could have gone on for 6 years before it reached your level to be addressed for this facility and nationally.

How could it have gone on for that long? It seems like a long time for the folks at the top not to know what the folks in the field are doing to rather than for our veterans.

Dr. CROSS. I think the lesson learned here is we have to find a better way to monitor this kind of very highly, highly specialized, relatively unusual procedure that we deal with in hospitals nationwide. I do not think this is just an issue for the VA, I think this is an issue for the entire national health system, that we have to address this and do a better job of it.

As a result of that, that is why we are working with the NRC and the Joint Commission and others to make sure that we have

the lessons learned from this and are better able to detect it more quickly.

Mr. ADLER. I guess I am still not getting the answer I need to hear for my satisfaction and for the satisfaction of the people of America about why it took so long to catch it in the sense that this was 6 years from the first botched procedure to the closure of the program. Why 6 years? Why not, we caught it after 20 patients got substandard treatment? Why do we wait for 92 patients to get less than what they deserved, having served in uniform our country? Why did it take that long for us to catch a problem and really stop it?

Dr. CROSS. My impression, based on the reviews I have done, is there was not adequate follow-up on the measurement done afterwards, number 1.

Number 2, all of the people that we brought in to do the external review said we were doing a great job.

Mr. ADLER. Maybe I could turn to Mr. Reynolds.

We treat nuclear products, whether very small, like a radiation seed, or very large, like a nuclear power plant, very seriously. That is why we have a Federal agency to keep America safe, the Nuclear Regulatory Commission. So, whether it is power plants around the country or whether it is a nuclear materials program, I have to think that it cannot be a good thing to put nuclear material in the wrong parts of somebody's body. Am I wrong on that?

Mr. REYNOLDS. We expect that when the medical professionals use radioactive material they put it in the right spot in the body; absolutely, sir.

Mr. ADLER. Is it in any way problematic to you—to me, it is outrageous—but maybe just problematic, a lower threshold, that we are taking these seeds of nuclear radioactive material and putting them not where they are designed to fight a cancer, but in other body parts in that general region, but not actually the spot that has the cancer. Is that not at least problematic to you?

Mr. REYNOLDS. Right. We expect—in fact, the VA's license requires them to identify problems like this and report them to us.

Mr. ADLER. Well, given the seriousness of putting nuclear material in somebody's body, how did it break down so badly here where—apparently just one doctor doing the procedures, but lots of people floating around in the hospital in the VA system, with the NRC—how do so many people not catch this and say, this is a pattern of substandard care? How did it take so long before the NRC or the VA system shut this outrage down?

Mr. REYNOLDS. Let me try to answer that for you.

Again, I will go back. The VA is responsible for identifying their medical problems and reporting them to us. This means that the doctors involved—Dr. Kao and the other doctor, the medical physicist—when they perform the procedures, when they identify a problem, they are supposed to report that. They are required to identify the problem and report it. This also includes the VA Philadelphia's Radiation Safety Officer. She is responsible for the day-to-day oversight of the doctors and the medical physicists and the rest of the medical staff in their use of radioactive material. This also includes the VA Philadelphia's Radiation Safety Committee, who is responsible here in Philadelphia for reviewing medical treatments and re-

viewing them critically, then assessing if anything needs to happen and reporting them. Also responsible is the VA National Health Physics Program. The National Health Physics Program is responsible for performing inspections at the VA hospitals where they use radioactive material. All those people did not identify the problems and did not report them.

What we have seen and what we have documented in our inspection report is a lack of a strong safety culture here at the VA Philadelphia; and safety culture is one where people are expected and are free to raise safety issues. Based on interviews we have had with some of the medical physicists and others, they were aware of substandard treatments, and for whatever reason that I do not understand, they did not raise that to their management or to the NRC.

Mr. ADLER. Do other VA hospitals around the country that have brachytherapy programs have a different reporting standard, or did this VA hospital just fail to meet the standard that is nationwide?

Mr. REYNOLDS. The reporting standard is the same for all hospitals, VA or otherwise, that do this treatment.

Mr. ADLER. My time is expired.

Senator SPECTER. Thank you Congressman Adler, Congressman Fattah.

Mr. FATTAH. Thank you.

Mr. Reynolds, is it not true that these reporting standards for a medically reportable event were not in place at the time that these procedures were taking place?

Mr. REYNOLDS. No, sir. I believe Dr. Kao is mistaken. The requirements to report to NRC when there is adverse care to patients went into effect in 1979.

Mr. FATTAH. Was this part of that doctrine in 1979, because we were not doing seeds in 1979, were we? We were implanting seeds in 1979?

Mr. REYNOLDS. I am not sure exactly when prostate brachytherapy started.

Mr. FATTAH. OK. I will come back to that.

Doctor—how do you pronounce your name?

Dr. KAO. Kao.

Mr. FATTAH. Kao. Let me thank you. You are one of the most educated people in the country when it comes to cancer and radiation therapy, is that correct?

Dr. KAO. Thank you, Congressman, yes.

Mr. FATTAH. A journalist wrote a story claiming that you did certain things, so I would like to give you a chance to get some things cleared up here.

When the allegation in the *New York Times* story said that seeds or overdoses of radiation in these seeds that were implanted in patients, did that relate to any of the patients that you treated?

Dr. KAO. I believe, yes, Congressman.

Mr. FATTAH. So, didn't you use a standardized seed strength?

Dr. KAO. Yes, Congressman.

Mr. FATTAH. So, when there are references made to more strength than might have been desired, or weakened, what does that refer to?

Dr. KAO. I believe the allegation was that there was an incorrect number of seeds outside or inside the prostate, Congressman.

Mr. FATTAH. Now, the prostate is a walnut-sized organ, right?

Dr. KAO. Yes, Congressman. I am sorry, it is difficult to see from your angle, but it is this little thing that sits below the prostate—I am sorry, below the bladder, in front of the rectum, and above the testicles.

Mr. FATTAH. Is it a normal occurrence when you are implanting seeds that some seeds end up outside the prostate, across the breadth and width of this type of medical treatment?

Dr. KAO. It is almost unavoidable, Congressman. Brachytherapy is an inherently subjective procedure where seeds are put in by hand, and so that is a recognized risk and in every consent form, Congressman.

Mr. FATTAH. So, if we looked at all these cases across the country, it would be an abnormality for seeds not to end up outside the prostate.

Dr. KAO. It would be very frequent.

Mr. FATTAH. OK. It would be very frequent for them to end up in the rectum or in the bladder.

Dr. KAO. Bladder or outside—and sometimes it migrates into other organs, such as the lung.

Mr. FATTAH. Now, Dr. Reynolds, is it a reportable medical event if a seed ends up in the rectum, under the rules of the NRC?

Mr. REYNOLDS. Well, the requirements have not changed since Dr. Kao has been practicing and——

Mr. FATTAH. No, no. I am asking—is it a reportable event if a seed ends up in the rectum?

Mr. REYNOLDS. It depends on the placement of the seed and the strength of that seed, but most likely, yes.

Mr. FATTAH. It is not always reportable, but in some cases, it is.

Mr. REYNOLDS. Right. It depends on what the doctor has prescribed for the patient.

Mr. FATTAH. Now, there is a Safety Committee at the NRC. And there was a meeting on May 7, 2009, where there were various quotes that were ascribed to the doctor from that meeting. He says in his testimony, his voluntary testimony before the Committee today, in his written testimony, that none of these quotes were made by him.

Dr. Cross, is there any way for us to figure out how that can be the case, that there are quotes in a report ascribed to the doctor, that he asserts before this Committee that he did not make?

Dr. CROSS. Sir, did you say that is the NRC Committee or——

Mr. FATTAH. Yes, it is an NRC Committee, not a VA committee, but I am asking you——

Dr. CROSS. I would not be able to comment.

Mr. FATTAH. OK. So, well, it was a VA procedure, so I just figured you may have had some input in this process.

Can you help us, Director Reynolds.

Mr. REYNOLDS. I am sorry. I am confused about what, specifically, you are talking about.

Mr. FATTAH. Well on number 14 of page 8, the doctor says that there are a number of quotes—and he goes through them, in de-

tail—from this safety report, which he says he did not make and the report says that he did.

Mr. REYNOLDS. Could you mention the doctor's name for me?

Mr. FATTAH. Dr. Kao.

Mr. REYNOLDS. Oh, OK. I am sorry. I was thinking you were saying somebody else.

Mr. FATTAH. Is there anyone accompanying you who can help us with this mystery?

Mr. REYNOLDS. I thought you were talking about somebody else. Please ask your question, again. I think I can answer it.

Mr. FATTAH. There are some quotes in the report from May 7, 2009, from the Safety Committee, and it ascribes specific quotes, extensive quotes to the doctor that he asserts in his written testimony to the Committee today that he did not make.

I am trying to figure out how we can determine how that could have happened.

Mr. VAIRA. There are two statements that we handed out. One is a lengthy one, and I think that is the one you are quoting from. It is about 14 or 15 pages.

Mr. FATTAH. Yes.

Mr. VAIRA. I do not know if the Director—your examiner there—has that in front of him.

Mr. FATTAH. OK. Well, it is probably too much of a time constraint for us to try to get to it at this point, but it is of interest that you can have these extensive quotes—yes?

Mr. REYNOLDS. I am sorry. They handed me his statements right now. This is information that, when our inspectors talked to Dr. Kao, this is what he told our inspectors.

It may not be verbatim what Dr. Kao told our inspectors, but this is our inspectors' words of what Dr. Kao said to our inspectors during our inspection.

Mr. FATTAH. So, these are quotes that are not quotes.

Mr. REYNOLDS. No, these are quotes of what was said at the Advisory Committee for the Medical Use of Isotopes (ACMUI) meeting.

Mr. FATTAH. OK. Well, thank you.

Dr. Cross, you said in your response to Senator Specter, there are a number of VA programs in terms of prostate cancer that have been put on hold. How many are there that have been put on hold?

Dr. CROSS. At the moment, I believe we have two that are still under investigation and several more that——

Mr. FATTAH. Well, originally that were put on hold, based on this review.

Dr. CROSS. I would have to—I do not have my experts at the table with me, so——

Mr. FATTAH. The gentleman that is behind you is trying to tell you.

Dr. CROSS. Four.

Mr. FATTAH. Four, OK. So, this is not a Philadelphia VA issue, this is something that you were looking at across the board.

Dr. CROSS. Exactly, and that is the routine procedure for us. When we find a problem in one place we look——

Mr. FATTAH. Did you say that this problem exists in non-VA medical facilities, and perhaps even more so?

Dr. CROSS. I think the issue of compliance with the standards, the oversight, and the accreditation are all issues that apply not only to the VA but to the broader system, as well.

Mr. FATTAH. OK. Senator Specter, I also want to acknowledge the presence of Congressman Brady, who has a staffer here and Councilwoman Jannie Blackwell, who represents this area. I want to thank you again for holding this hearing.

Senator SPECTER. Thank you very much, Congressman Fattah.

We will proceed now with a second round of questioning—5 minutes.

Reverend Flippin, what injuries did you sustain as a result of this procedure?

Rev. FLIPPIN. I was informed by a doctor at Ohio State University that I had a radiation burn to my rectum.

Senator SPECTER. And what is the consequence of that?

Rev. FLIPPIN. The consequence of that was loss of a job, approximately 4½ months of 24/7 bedrest——

Senator SPECTER. You earlier told me that there was bleeding involved.

Rev. FLIPPIN. Oh, yes, when I went to the bathroom.

Senator SPECTER. Indelicate as it is, it is important for the record. What specifically happened to you in that respect.

Rev. FLIPPIN. OK. What sent me back to the West Virginia VA hospital was that I started experiencing bleeding in my stool and——

Senator SPECTER. Reverend Flippin, you had testified earlier that no one from the VA ever informed you about what had happened. Is that so?

Rev. FLIPPIN. Right. I did not know anything about this until I receive the first letter.

Senator SPECTER. First letter from whom?

Rev. FLIPPIN. From the VA.

Senator SPECTER. When did you get that?

Rev. FLIPPIN. Last year. It was July 2, 2008, when I received the letter about the brachytherapy and the care that I had received.

Senator SPECTER. Dr. Cross, the information is that there were similar problems in Jackson, Cincinnati, the District of Columbia, where Philadelphia had 97, Jackson 8, Cincinnati 6, and DC 3. What action has the Veterans' Administration taken with respect to those other sites.

Dr. CROSS. The one definitive action, I believe, in Cincinnati, is that they have been cleared. It turned out that they got a good review, and when we get a go from the NRC, they can proceed to continue on.

The only two that are still being reviewed further are Washington, DC, and Jackson, as I recall.

Senator SPECTER. Dr. Cross, you testified that there needs to be some attention to this kind of issue, as you put it, by a national health system. Would you amplify what you think could be done? We are now considering comprehensive health reform. This could well be an issue to be included. What specifically would you like to see be done by the national health system?

Dr. CROSS. Sir, I was not referring to health reform, I was referring to the oversight organizations that we work with every day. We work with a number of them.

Senator SPECTER. Well, what could be done better on the oversight, then?

Dr. CROSS. I think that we have to put in place some better, clearer, more easily understood standards, perhaps. There is still debate on some of the issues as to whether or not these specific standards that are in place right now, which we are trying vigorously to enforce, are really relevant clinically in the long term, over time. That has to be clarified, and I think we would like to work with the organizations that do that, to be useful in that regard.

Senator SPECTER. Director Reynolds, Dr. Kao has stated that there was not a sufficient definition of a reportable medical standard.

Do you think there is any substance to that position?

Mr. REYNOLDS. The entire medical community across the Nation has been subject to that standard for many years and has used it successfully.

Senator SPECTER. You think there is a sufficient definition of a reportable incident?

Mr. REYNOLDS. Yes, sir.

Senator SPECTER. So, you think that if there was excessive radiation or seeds went into the bladder that would clearly be something that ought to be reported, at least to the patient.

Mr. REYNOLDS. Yes, sir. In fact——

Senator SPECTER. What corrective action do you anticipate from your Nuclear Regulatory Commission?

Mr. REYNOLDS. Well, first, we expect the VA to address all their problems to ensure these problems will not happen again; and that includes developing nationwide standards and procedures, and it includes training of all the staff that Dr. Cross already talked about. And then, we are also looking at our inspection procedures to see if we can enhance them, and would we want the VA's National Health Physics Program to do inspections more often. Then, do we need to do more inspections on the VA and the VA's National Health Physics Program?

Senator SPECTER. Congressman Adler, would you like a second round of 5 minutes?

Mr. ADLER. Reverend Flippin, Let us just imagine that over the course of 6 years you performed 116 sermons, and out of those 116 sermons, 92 of them were lousy, don't you think you would get booed out of your church?

Rev. FLIPPIN. Yes, sir.

Mr. ADLER. Aren't you, as I am, surprised that Dr. Kao still has a medical license after botching 92 of 116 procedures?

Rev. FLIPPIN. I do not know anything about Dr. Kao. The only thing I would say is that when you mentioned, wouldn't it be nice to say something to Reverend Flippin, I was moved, and I thought he might look at me and say something. Now, I have an impression of Dr. Kao that I had not before coming in here.

Mr. ADLER. I thought we both got the same impression, sir.

Dr. Cross, you heard Dr. Kao say that there might be grossly inadequate training for the physicians who perform brachytherapy

procedures. Do you have any comment about the adequacy of training the doctors receive or standards that the VA uses to evaluate doctors before allowing them to perform this procedure in Philadelphia or anywhere around the country over the last number of years.

Dr. CROSS. I am not sure I heard the statement as you quoted it; however, training is always important, and when we find an issue like this, my natural inclination is to look at training and see if it was adequate. That is always the first place to look.

We have good people, and if they are well trained and ready to go, we can usually avoid problems. So, I think, naturally, that is the first place to look; and then the accreditation and the oversight and all those kind of things that go along with it.

Mr. ADLER. I kind of heard Dr. Kao pointing at you and the VA system and that is why he did not do such a good job.

I also heard Mr. Reynolds say the reason the NRC did not hear about problems is because people in the VA system failed to report to the NRC some of these problems.

Is that generally accurate, Mr. Reynolds?

Mr. REYNOLDS. Correct.

Mr. ADLER. So, I guess I am asking you what you—not you, personally, but the system—would have done differently over the years to report to the NRC this inadequate use of radioactive materials in the bodies of veterans who are coming for good care, and lots of cases—80 percent of the time—did not get that good care.

Dr. CROSS. First, I think it is important to note that we did report to the NRC at the time that this was uncovered in June 2008, and in fact, I have the exact date right here and who was contacted.

We consider them to be important allies in this effort. The point that you are making is we should have done that sooner and that should have been discovered sooner. And that is where we have to put the mechanisms in place within the VA and outside the VA which will ensure that this is more easily detected, and more quickly detected.

Mr. ADLER. Do you have a sense why peer review did not catch this problem here, right in the hospital, before it ever got to 20 patients and 40 patients and 60 patients—before it got to 92 patients.

Dr. CROSS. I think I do, actually. There was a quality assurance program, but perhaps not as effective as it should have been.

Peer review really focuses more on finding things where there are complications that have occurred, grading them, and taking action as a result. In none of these situations would such an event have occurred—where there was a clear complication happening.

Mr. ADLER. I guess you are sitting next to a clear complication. Poor Reverend Flippin had a——

Dr. CROSS. I am pointing out that that was over a year later, and I think that is the point right there—that time lag and the lack of identifiable complications right then.

Mr. ADLER. I guess I am hoping that you and Mr. Reynolds—the NRC and the VA system—can coordinate better. I am hearing some sort of blame, at least from the NRC toward the VA system. I think you have been much more respectful about owning up to responsibility in a shared way. But I guess I am hoping to leave this hear-

ing, and maybe a subsequent hearing in Washington, with greater confidence than I had coming in here since you have owned the problems, shared the responsibility with the NRC, and are defining a reporting schedule, a peer review system, a level of checks and balances throughout the system so we do not have to hear from the next Reverend Flippin, the next Air Force or Army, Marine, or Navy person who came to get good care—maybe not on prostate but on something else—and it somehow slipped through in a different way, different than this one, but just as troubling as this one.

Can you give you me and this Committee the reassurance we need for America?

Dr. CROSS. Absolutely. I can do that because I view our colleagues who do oversight—whether it be the Joint Commission, the ACRO, or the Nuclear Regulatory Commission—as colleagues. I believe they are allies. I see them as very important to this effort, and I engage them, pull them into our discussions, invite them to our meetings, and invite them to our offices to work closely with us. That is the kind of relationship we are going to have, and that relationship is going to make this a success.

Mr. ADLER. Well, Doctor, we certainly need that process and we certainly need better results.

Thank you.

Senator SPECTER. Congressman Fattah.

Mr. FATTAH. Thank you, Senator.

Dr. Reynolds, I want to try to delve into this on a more general basis here.

Do you have a sense of how many of these procedures have been done, say, over the last 5 years, in our country.

Mr. REYNOLDS. At VA hospitals or across the board?

Mr. FATTAH. No, across the board.

Mr. REYNOLDS. Thousands.

Mr. FATTAH. Thousands. Can you tell us or give us a general understanding of how many medically reported events have occurred that have been reported to you?

Mr. REYNOLDS. Very few.

Mr. FATTAH. Very few. That is what I want to delve into. I want to try to reconcile a couple of things.

The doctor who is one of the experts in this whole field says that it is a very frequent occurrence that, in planting these seeds, that this happens. And my colleague says that anyone who does this, has botched a procedure; and he is surprised that the doctor still has a medical license. But if this is going on in thousands of cases and nobody is reporting it to you, then I am trying to figure out—and this gets to Senator Specter's earlier point—is if we are trying to fix health care nationwide we need to figure out how we deal with this on a systematic basis. If this is happening, it is not an event that can be avoided because of the proximity of the prostate to the rectum and the bladder; and, therefore, it is going to be visited upon almost anyone who gets this treatment, or it is a botched procedure in which nobody who is performing them are reporting them to you anywhere across the country. Now, which one is it?

Mr. REYNOLDS. In addition to licensees, including the VA being required to report problems to us, we go out and do independent

inspections. Based on our independent inspections of the other hospitals that do brachytherapy treatment, we have not seen this problem. The prostate is properly treated with seeds. We do not see medical events nowhere near the extent you see at VA Philadelphia.

Mr. FATTAH. So, you are saying this is an aberration, and that it is not the case that seeds end up outside the prostate on a normal occurrence.

Mr. REYNOLDS. You may have an occasional——

Mr. FATTAH. I am going to give you a chance to review that before you comment.

Mr. REYNOLDS. Could you ask your question again, I lost my train of thought.

Mr. FATTAH. Is this occurring in a great many of these procedures?

Mr. REYNOLDS. No. Medical events——

Mr. FATTAH. No, not just the generality of medical events, but a reportable medical event having to do with seeds ending up outside the prostate.

Mr. REYNOLDS. Right. Medical events dealing with seeds outside the prostate happen very, very infrequently based on reports to us and based on our direct inspections.

Mr. FATTAH. So, you get almost no reports.

Mr. REYNOLDS. That is correct.

Mr. FATTAH. And therefore, you believe it almost never happens.

Mr. REYNOLDS. Based on the reporting to us and our inspections, that is correct—outside of VA Philadelphia.

Mr. FATTAH. So, then the doctor is completely wrong that this is a frequent occurrence.

Doctor, go right ahead.

Dr. KAO. In the same transcript that, Congressman, you had referenced earlier, a physician advisor to the NRC has commented that if they were to audit all the programs that do brachytherapy in this country, there would be 20,000 reportable medical events. No program has undergone the level of scrutiny that this program has undergone, Congressman.

Mr. FATTAH. So, there could be cases where the Reverend who got this treatment ended up with a situation and nobody told him about it. There could be a lot of people who are facing symptoms from seeds outside the prostate which may not be avoidable, but nonetheless, could—because, at the end of the procedure, the urologist is supposed to go in and get the seeds, right?

Dr. KAO. That is correct.

Mr. FATTAH. And there are seeds that are unaccounted for. That is how this works, right?

Dr. KAO. That is correct.

Mr. FATTAH. And those seeds are somewhere.

Dr. KAO. That is correct, Congressman.

Mr. FATTAH. And they are probably somewhere close to the prostate, either in the rectum or the bladder.

Dr. KAO. Or in the tissue surrounding the prostate, Congressman.

Mr. FATTAH. So, there is a great deal of interest in this matter based on the way the *New York Times* wrote this story. I think that

the bigger story here is that this is not about this hospital or this doctor. This is about a procedure designed to help men with a very serious health problem in which, part and parcel to that procedure, is the real danger that these seeds can end up outside the prostate, and which almost no doctors are reporting—to doctors to anybody, including you.

You are the person that it should be reported to, both inside the VA and outside the VA. I think that Senator Specter has brought this to our attention in a way that will impact national policy and that will be meaningful; and it is not part of any kind of witch hunt about a particular program or doctor here in Philadelphia.

Senator SPECTER. Thank you, Congressman Fattah.

Congressman Adler, do you care to make a final statement.

Mr. ADLER. Let me first, again, thank Senator Specter for organizing this field hearing, and thank all the panelists for coming before us. I particularly thank Dr. Cross and folks from the VA hospital who have owned up to the seriousness of the problem that occurred here. For some of these procedures to have half the seeds planted wrongly outside the prostate, that is not a near miss; that is clearly a mistake. I thank Dr. Cross and Dr. Whittington and other folks from the hospital and from the VA system who want to solve a problem, who acknowledge the seriousness of the problem, who know that we let down patients who came here to get high-quality care and did not get it. I thank the VA system for shutting down this program until they get it right, and shutting down programs around the country until they get it right.

I understand a couple programs have been reopened. I hope this program is restored properly here. But until it is gotten right, we should not do it. This is not just an art; there is a science to it, and the science is to put these seeds in the right body part, not kind of close, but right where they are needed to destroy the cancer rather than cause harm to patients who came here for good medical care.

Mr. Reynolds, I thank you for sharing your concerns about the reporting up to the NRC. I am hoping you will be more active in redefining what is a medical event so that you get more of the reporting that Congressman Fattah was talking about, because I think we need to have better communication and a better understanding of what is going right and what is going wrong. My sense is that this hospital does a lot of things right, but in this one program was doing a lot of things wrong, and it is the aberration for this very good facility. But it is an aberration that lasted for too long.

I hope we get to the bottom of this situation here. I hope it does not recur in this program, in this facility, or anywhere in the country. I think our veterans deserve better care than they got in this particular situation here.

Thank you, Senator.

Senator SPECTER. Thank you, Congressman Adler.

Congressman Fattah, closing statement?

Mr. FATTAH. No, I think I agree with my colleague when he says that our veterans deserve the very best care and that this is a great hospital. I definitely agree with that, since it is headquartered in my District.

I just think that, again, the real issue here and the benefit of this hearing is in our opportunity to impact national policy; and I want to thank Senator Specter for convening us.

Senator SPECTER. Thank you, Congressman Fattah.

One final point, Dr. Kao. Reverend Flippin raised the issue about your looking at him directly and saying something to him personally. You were not the doctor who attended Reverend Flippin, but you represent the whole process.

Would you care to look at him and say something to him?

Dr. KAO. Reverend Flippin, we should have, we can do better. I hope we will have the chance to do better by you and your colleagues in the future.

Senator SPECTER. Well, that is great symbolism to conclude our hearing.

Mr. VAIRA. Senator Specter.

Senator SPECTER. Sure.

Mr. VAIRA. Congressman Fattah quoted from a not lengthy but about a 15-page statement that my client made. It is damn good. It has got a lot of medical definitions and explanations in it.

If you want a copy, I know the staff has a copy. If anybody here wants a copy—we do not have enough with us—call my law firm and we will make it available to everybody. It is a good learning experience.

Thank you very much, Senator.

Senator SPECTER. Thank you, Mr. Vaira. Now that you have testified, I think you have to understand that you are subject to cross-examination.

Mr. VAIRA. You and I go a long way back, Senator, a long, long, way.

Senator SPECTER. Peter Vaira is used to cross-examination, and customarily, he is doing it, but thank you.

Thank you, Dr. Kao, for being as candid as you have been, and thank you, Dr. Cross, for similarly giving up your vacation plans and coming here today. Director Reynolds and Reverend Flippin, the most important thing that needs to come out of this hearing is that this is not the final chapter. The House Veterans' Affairs Committee will be having a hearing in Washington. I will be talking to the Chairman of the Senate Veterans' Affairs Committee, Senator Akaka, and we will be looking further. But we have identified some very, very serious problems, and we need to learn from our mistakes. When Dr. Kao candidly said he planted seeds in the wrong organs and should have told people; he candidly said there was excessive radiation and he should have told people. That should be a lesson for other doctors similarly situated.

The business of not having review and oversight by somebody who is outside the system is obvious, but that has to be done. And we have identified it as a national problem in Cincinnati, DC, and across the country. So, this is something which has to be attended to.

I want to thank my staff, Will Wagner and Trevor Benitone and others who have worked here on short order. I thought it was very important to have this initial oversight done very promptly because I hear a lot of street talk about what is going on and what the care is for veterans. When great institutions like the Hospital of the

University of Pennsylvania and the Philadelphia VA Center has a problem like this it causes a lot of skepticism and doubt. But I think we have taken a significant step forward and very symbolic to have Dr. Kao and Reverend Flippin embrace, which is a great sign for America.

That concludes our hearing.

[Whereupon, at 11:35 a.m., the hearing was concluded.]

A P P E N D I X

PREPARED STATEMENT OF HON. ALLYSON Y. SCHWARTZ, REPRESENTATIVE IN CONGRESS FROM THE STATE OF PENNSYLVANIA

Mr. Chairman, today's hearing is an important step toward restoring confidence in the Philadelphia VA Medical Center. I commend Senator Arlen Specter for working quickly to convene this field hearing to shine light on the reports of an ongoing and serious pattern of error in prostate cancer care at the Philadelphia VA.

According to the Nuclear Regulatory Commission (NRC), serious, health-jeopardizing errors were committed in 92 out of 116 prostate brachytherapy treatments performed at the Philadelphia VA between February 2002 and May 2008. In 57 of those cases, patients received less than 80 percent of the prescribed radiation dose, and in 35 cases, patients received excessive doses to other organs.

When this disturbing pattern came to light in June 2008, the leadership of the Philadelphia VA acted appropriately to terminate the prostate brachytherapy program and to contact the affected veterans. However, two questions remain: Why did it take so long for this disturbing pattern of substandard care to come to light? And are there other areas of the veterans' healthcare system that also lack necessary quality safeguards?

Our Nation's veterans deserve to know that they are receiving the highest quality of care from the VA health system. It is my hope that the scrutiny of Congress will help to ensure that the Department of Veterans Affairs offers an honest accounting of what happened in prostate cancer care in Philadelphia, and even more importantly, to take steps to make sure that no similar pattern of error is allowed to take place again.

Thank you.

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