NRC RESPONSE TO:
Post Hearing Questions for the Record for
Steven Reynolds
Director, Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
June 29, 2009
Senator Richard Burr

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 which authorize the possession and use of radioactive material. Approximately 583 NRC licensees are approved to use radioactive materials for brachytherapy. The NRC's database does not differentiate between prostate brachytherapy from other brachytherapy uses, so this number is all inclusive. The University of Pennsylvania possessed an NRC license until March 31, 2008, when the NRC transferred the authority for licensing to the Commonwealth of Pennsylvania.

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. The State of Pennsylvania became an Agreement State on March 31, 2008. Prior to becoming an Agreement State, the University of Pennsylvania Hospital was required to follow the NRC reporting requirements. Since March 31, 2008, they are required to follow the State of Pennsylvania 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 their regulations for the medical use of byproduct material are identical to NRC's.

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 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 prostate brachytherapy procedures that were administered to 208 patients. 43 of these reports were received from non-VA facilities and involved 95 patients. 10 reports were received from VA facilities and involved 113 patients.

Between 2002 and July 17, 2009, the NRC has conducted 806 inspections of licensees that perform brachytherapy procedures. The NRC does not tabulate enforcement data that is specific to just prostate implant brachytherapy programs. NRC inspections conducted during this time period identified 19 violations that the NRC considered cause for significant regulatory concern. Additional violations that the NRC considers less serious were also identified for brachytherapy programs. However, the NRC does not maintain this information in a readily retrievable format. 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 corrective actions and compliance with NRC requirements was achieved.

The NRC received one report of a medical event from the University of Pennsylvania involving a prostate implant. On May 5, 2001, the University 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 were identified during the special inspection. The NRC conducted inspections at the University of Pennsylvania, including the Hospital of the University of Pennsylvania. The most recent NRC inspection conducted on March 19 through 22, 2007, did not identify any violations associated with the prostate brachytherapy activities. Previous NRC inspections were conducted on 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.

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).

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 the Atomic Energy Act), the NRC enters into agreements with State governors. Those agreements authorize individual States to regulate the 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 using the same standards as the NRC are called Agreement States. Typically, Agreement States regulate additional sources of radiation that the NRC does not. This generally includes all naturally occurring radioactive materials (such as radium and radon) within their borders. In addition, the States regulate radiation-producing machines, such as X-ray machines (both medical and industrial) and particle accelerators. By contrast, Agreement States generally do not regulate nuclear power plants, large quantities of certain nuclear materials, and storage of high-level radioactive waste. Currently, 36 States have such agreements with the NRC.

   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. Normally, the Agreement States will adopt those identified regulations within a three year time frame. The regulations in 10 CFR Part 35, including regulations for reporting a medical event, have been identified as regulations that should 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.*

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 requirement to report "misadministrations" to the NRC became effective on May 14, 1980. From 1980 until 2002, the term "misadministration" was used in the regulations to describe these events. In 2002, the NRC replaced the term "misadministration" with "medical event" as this term more correctly and simply conveys that the radioactive material or the radiation there from, was not delivered as directed by the physician. The NRC's reporting requirements have been in place since 1980. Dr. Kao's statement that "the standard definition of a reportable medical event to the NRC was not in existence when the brachytherapy program started at the VA" is not accurate. The VA started their brachytherapy program in 2002 and the requirement to report medical events was in effect at that time.

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 purpose of reporting medical events 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 also have the potential to result in harm to the patient. However, 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.

   NRC 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. 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 arrived at its definition of a reportable medical event through the rulemaking process in 1980. Discussions for the need of a 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 death, harm, or large radiation doses to unanticipated tissues to patients. The definition of a medical event has had minor editorial changes since 1980. The most significant revision occurred on July 25, 1991, when the rule was revised to require that events where the calculated administered dose differed from the prescribed dose by more than 20% (instead of 10%).

The NRC's Advisory Committee on the Medical Uses of Isotopes 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. The NRC has an internal Medical Radiation Safety Team and Part 35 Working Group who discuss the issues that will be going through rulemaking. During the rulemaking process, the proposed rule is published in the *Federal Register* for stakeholder and public comment.

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 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 (i.e., stage, grade, and extent of the cancer, etc.) related aspects of the administration.

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 16, 2009, the NRC received 53 reports of medical events involving prostate brachytherapy procedures for 208 patient cases. Of these 53 reports, 32 involved seeds outside the prostate for 173 patients. The VA submitted 10 of these event reports where seeds were outside the prostate for 111 patients (92 of these patients were treated at the Philadelphia VA) and 43 reports were received from non-VA facilities where seeds were outside of the prostate for 62 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. The NRC strives for continuous improvements. We are enhancing our inspection process in an effort to minimize missed opportunities for early identification of precursors to medical events.

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: 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 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 routinely 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 nationwide since 2002 and has not seen anything to suggest such a high rate of occurrence. In this time frame, the NRC received 53 reports of medical events 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.

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

    Response: The Atomic Energy Act of 1954 and Energy Reorganization Act of 1974 gave the NRC the responsibility to regulate the safe use of byproduct, source and special nuclear material. In 1979, the NRC published a policy statement, "Regulation of the Medical Uses of Radioisotopes," (44 FR 8242 dated February 9, 1979) in which it informed NRC licensees, other Federal and State agencies, and the public of the

Commission's general intention in regulating the medical use of byproduct material. Specifically the policy states: 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; and 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. New regulations covering brachytherapy requirements were incorporated into 10 CFR Part 35 in 1980.

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

Response: The NRC is assessing whether any additional changes are needed to strengthen our regulatory oversight and are taking a critical look at enhancements to continually improve our 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 ensuring that 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 dose verification.

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 14, 1980:

FR 45 FR 31704, Final Rule On Misadministrations was issued which defined misadministration in 35.41, prompt reporting of therapy misadministrations in 35.42, the referring physician and patient or patient's responsible relative, and quarterly reporting of diagnostic misadministrations to NRC in 35.43, and required a record of all misadministrations in 35.44.

October 16, 1986:

FR 51 FR 36932, Final Rule On Medical Use of Byproduct Material. The diagnostic administration reporting requirement was changed to require reports for misadministrations when they resulted in a whole body dose greater than 500 millirem or an organ dose greater than 2 rem.

In this version of the regulations, the definition of misadministration in 10 CFR 35.2 meant the administration of (6) 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.

10 CFR 35.33 specifies the records and report of misadministrations.

July 25, 1991:

The term "misadministration" was revised in 35.2 to read that any dose of I-125 or I-131 greater than 30 microcuries, where the administered dosage differs from the prescribed dosage by more than 20 percent is reportable.

September 20, 1995:

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

April 24, 2002:

FR 67 FR 20340 is the current definition for medical events. This final rule deleted the name "misadministrations" and changed it to "medical events" and relocated the new definition from 10 CFR 35.41 to 10 CFR 35.2. Section 35.33 "Notifications, reports, and records of misadministrations" was deleted and reporting requirements were moved to Subparts L and M.

67 FR 20370, medical event means an event that meets the criteria in 35.3045 a.

March 27, 2006:

A minor edit to the definition of medical event, 71 FR 15008, medical event means an event that meets the criteria in 35.3045 (a) or (b).