

EDO Principal Correspondence Control

FROM: DUE: 07/23/09 11:00am EDO CONTROL: G20090402
DOC DT: 07/13/09
FINAL REPLY:

Matt Lawrence
Senate Veterans' Affairs Committee

TO:

Powell, OCA

FOR SIGNATURE OF : ** GRN ** CRC NO:

DESC: ROUTING:

Post Hearing Qs from the June 29, 2009 Hearing with the Senate Veteran's Affairs Committee on Use of Nuclear Materials for Medical Treatment - VA Medical Center (EDATS: OEDO-2009-0435)

Borchardt
Virgilio
Mallett
Ash
Ordaz
Burns/Gray
Collins, RI
Satorius, RIII
Schmidt, OCA
Bagley, OEDO

DATE: 07/14/09

ASSIGNED TO: FSME CONTACT: Miller

SPECIAL INSTRUCTIONS OR REMARKS:

Please coordinate with Region I and Region III, as appropriate. Provide Q&As to Susan Bagley, OEDO by 11:00 a.m., July 23, 2009. Q&As are due to OCA by July 24, 2009.

Template: EDO-001

E-RIDS: EDO-01

EDATS

Electronic Document and Action Tracking System

EDATS Number: OEDO-2009-0435

Source: OEDO

General Information

Assigned To: FSME

OEDO Due Date: 7/23/2009 11:00 AM

Other Assignees:

SECY Due Date: NONE

Subject: Post Hearing Questions from the June 29, 2009 Hearing with the Senate Veterans' Affairs Committee on Use of Nuclear Materials for Medical Treatment - VA Medical Center

Description:

CC Routing: NONE

ADAMS Accession Numbers - Incoming: NONE

Response/Package: NONE

Other Information

Cross Reference Number: G20090402

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Recurring Item: NO

File Routing: EDATS

Agency Lesson Learned: NO

OEDO Monthly Report Item: NO

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Sensitivity: None

Signature Level: No Signature Required

Urgency: NO

OEDO Concurrence: NO

OCM Concurrence: NO

OCA Concurrence: NO

Special Instructions: Please coordinate with Region I and Region III, as appropriate. Please provide Q&As to Susan Bagley, OEDO by 11:00 a.m., July 23, 2009. Q&As are due to OCA by July 24, 2009.

Document Information

Originator Name: Matt Lawrence

Date of Incoming: 7/13/2009

Originating Organization: Congress

Document Received by OEDO Date: 7/14/2009

Addressee: Amy Powell, OCA

Date Response Requested by Originator: 8/3/2009

Incoming Task Received: E-mail

Jaegers, Cathy

From: Lawrence, Matt (Veterans Affairs) [Matt_Lawrence@vetaff.senate.gov]
Sent: Monday, July 13, 2009 1:23 PM
To: Powell, Amy
Subject: SVAC Post hearing Questions 6/29/09
Attachments: Brachytherapy QFR - Reynolds LW.doc

Hello,

Please answer these questions and return to the committee no later than August 3rd, 2009.
If you have any questions please feel free to direct them to me at this email address.

Thank you and have a good day.

Matt Lawrence

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(148.184.200.145) with Microsoft SMTP Server id 8.1.358.0; Mon, 13 Jul 2009
13:23:37 -0400

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X-SBRS: 4.5

X-MID: 4520514

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X-IronPort-Anti-Spam-Result:

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with ESMTP; 13 Jul 2009 13:23:36 -0400

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p-ess-sen4s.senate.gov (Switch-3.3.2mp/Switch-3.3.2mp) with ESMTP id
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13:23:36 -0400

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[156.33.248.20]) by p-ess-sen4s.senate.gov (Switch-3.3.2mp/Switch-3.3.2mp)
with ESMTP id n6DHNS1D032007 (version=TLSv1/SSLv3 cipher=RC4-MD5 bits=128
verify=FAIL) for <Amy.Powell@nrc.gov>; Mon, 13 Jul 2009 13:23:35 -0400

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SHARED-WSH-HT04.shared.usenate.us ([156.33.248.20]) with mapi; Mon, 13 Jul
2009 13:23:08 -0400

From: "Lawrence, Matt (Veterans Affairs)" <Matt_Lawrence@vetaff.senate.gov>

To: "Amy.Powell@nrc.gov" <Amy.Powell@nrc.gov>

Date: Mon, 13 Jul 2009 13:23:06 -0400

Subject: SVAC Post hearing Questions 6/29/09

Thread-Topic: SVAC Post hearing Questions 6/29/09

Thread-Index: AcoD3pWgULtPd08QaS+81kia/jt2Q==

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X-Attachments: ,Brachytherapy QFR - Reynolds LW.doc

Return-Path: Matt_Lawrence@vetaff.senate.gov

**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?
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?
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?
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?
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?
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.
 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?
 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.
 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?
 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?
 11. Please confirm when the NRC began to regulate brachytherapy procedures.
 12. What guidance has changed from the NRC over the past twelve months?
 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.

Example of Format

Questions and Answers

Q1. What results has the Commission to show for the funds we provided you for the scholarship and fellowship program under the Energy Policy Act of 2005?

A1. In 2007 we awarded \$385K in grants to 10 universities under the USNRC Scholarship and Fellowship program. To date 14 individuals have been chosen as recipients of these scholarships and fellowships. We have three of these students participating in a summer internship here at the NRC. One recipient has accepted a position with the NRC and is currently awaiting his security clearance.

Additionally, in 2007, as part of the Nuclear Education Grant Program, we awarded Curriculum Development grants to 27 universities in 17 states and the District of Columbia for a total of \$4.7M. The average award was \$200K.

In 2008, the Nuclear Education Grant Program received 168 letters of intent, and invited 108 universities to submit proposals. The panel recommended that 40 universities receive grants totaling \$4.7M in 25 states and the District of Columbia.

NRC used the authority from EPA2005 to award an additional \$15M grants comprised of the following: 22 scholarship and fellowship awards to universities located in 14 states; 21 Faculty Development grant awards to universities in 18 states, and 6 Trade School grants to junior and technical colleges in 6 states.

Q2. How is it that you are proceeding with reviews of COL applications when design certifications are not final from a rulemaking perspective?

A2. As allowed by our regulations, applicants can submit, at their risk, a COL application that does not reference a certified design. However, this poses challenges to the staff. The staff originally expected to first certify designs and then review COLs. Currently, the only complete certified design that has been referenced by a COL applicant is the Advanced Boiling Water Reactor design. The design-centered review approach allows parallel reviews as issues regarding the design are addressed during the DC review and site-specific issues are addressed during the COL review. The staff cannot issue the COL until the design has been certified. Our current schedules reflect the linkages between these reviews.

Q3. What impact will there be on the environmental reviews done by the Commission during the COL phase if an applicant comes in for a Limited Work Authorization prior to submittal of the COL?

A3. Pursuant to 10 CFR 51.76(b) and 2.101(a)(9) an applicant has the option to submit a phased LWA application. Phase one would probably include the information needed to support the LWA application, followed later by phase two - the full COL application. The rule allows the NRC to issue an EIS limited to the activities proposed under the LWA application in phase one. After the full COL application is submitted, the NRC will supplement the phase one EIS as necessary to address the environmental impact of the full application. NRC anticipates that fewer resources will be needed to complete the supplemental EIS assuming that there is no significant change in the description of those impacts in the full COL application. The amount of resources needed to prepare the supplemental EIS will