

July 22, 2011

The Honorable John McCain  
United States Senate  
Washington, D.C. 20510

Dear Senator McCain:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter of June 30, 2011, forwarding correspondence from your constituent, (b)(6)

#6 (b)(6) describes the unfortunate difficulties he has experienced since (b)(6) (b)(6) We are well aware of (b)(6) situation and have worked with him in the past to address it. E. 6

#6 Let me first explain that Arizona is an Agreement State through an agreement that the State maintains with the NRC pursuant to Section 274b. of the Atomic Energy Act. Therefore, the State of Arizona, rather than the NRC, exercises regulatory jurisdiction over the activities described in (b)(6) The NRC does maintain an oversight role of Agreement State radioactive materials programs to ensure that they are adequate to protect public health and safety and compatible with the NRC's program. In this case, the relevant regulations of the State of Arizona have been found to be compatible with those of the NRC.

In accordance with the NRC's Medical Policy Statement regarding the use of byproduct material, the NRC and Agreement States minimize intrusion into medical judgments affecting patients and other areas traditionally considered to be the practice of medicine. NRC and Agreement State programs, therefore, do not review a decision by an authorized user physician as to what would constitute appropriate treatment. NRC and Agreement State programs do have jurisdiction to determine if the treatment prescribed by the authorized user physician is carried out according to the doctor's direction, which is a requirement in both NRC and Agreement State regulations.

#6 The NRC and State of Arizona have regulations that require the reporting of any event that meets certain criteria specified in the regulations as a "medical event." In 2010, the NRC, at the request of the State of Arizona, reviewed in detail (b)(6) and concluded that it was not a reportable "medical event" within the scope of NRC regulations and that the treatment was in accordance with the directions of the physician who signed the written directive for treatment. We informed (b)(6) of our conclusion in a letter dated June 23, 2010, and provided (b)(6) with a copy of our response to the State of Arizona that explained the reasons for our conclusion that this was not a reportable medical event. EX 6

#6 The fact that a treatment is not defined as a "medical event" and may not violate regulatory requirements does not indicate lack of patient harm, but it significantly limits the role of the NRC and the State of Arizona in efforts by (b)(6) to address any possible errors in (b)(6) treatment. Please be assured that the NRC takes its mission to protect public health and safety against the potential hazards associated with the use of radioactive materials very seriously. At this point, however, the NRC has nothing more to add to the information already provided to (b)(6) EX #6

(b)(6)

J. McCain

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If you need additional information or have any questions, please contact me or Ms. Rebecca Schmidt, Director of the Office of Congressional Affairs, at (301) 415-1776.

Sincerely,

*/RA Michael F. Weber for/*

R. W. Borchardt  
Executive Director  
for Operations