October 5, 2007

William Stein, III, M.D.
Oncology and Oncology Specialists, LLC
4228 Houma Boulevard, Suite 130
Metairie, LA 70006

Dear Dr. Stein:

I am responding to the petition for rulemaking, dated March 20, 2006, that you submitted to the U.S. Nuclear Regulatory Commission (NRC). Your petition requested that the NRC amend its regulations at 10 CFR Part 35 to codify 80 hours of classroom and laboratory training, together with appropriate work experience and written attestation as appropriate and sufficient for physicians desiring to attain authorized user status for the parenteral administration of therapeutic doses of samarium-153 lexidronam (Quadramet), iodine-131 tositumomab (Bexxar), and yttrium-90 ibritumomab tiuxetan (Zevalin).

The NRC docketed your petition as PRM-35-19 and published a notice of receipt of your petition in the *Federal Register* on June 14, 2006 (71 FR 34285). The comment period closed on August 28, 2006. We received 25 comment letters in response to the notice published in the *Federal Register*.

The NRC has considered the petition, your supporting rationale, and the comments submitted to the NRC. For the reasons provided in the enclosed *Federal Register* notice, your petition is denied. In summary, your petition is being denied because we have determined that current requirements in the NRC regulations of 10 CFR Part 35 are necessary for the NRC to have reasonable assurance that public health and safety are adequately protected. The NRC established the current training and experience requirements in Part 35 through two rulemakings which involved extensive input from the medical community, Agreement States, and the public, and afforded substantial opportunity for public comment. In this connection, while increasing the number of hours for training and experience for use of unsealed byproduct material requiring a written directive, the NRC specifically determined not to increase the training and experience required for oral administration of sodium iodide I-131. The NRC has determined that you have not provided sufficient information in your petition to warrant revising the current regulations.

The Federal Register notice denying the petition is being transmitted to the Office of the Federal Register for publication.

Sincerely,

/RA/

William F. Kane
Acting Executive Director
for Operations

Enclosure: *Federal Register* Notice
Denying Petition

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Acting Executive Director
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Enclosure: *Federal Register* Notice
Denying Petition

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