

April 1, 2006

Mr. Roy W. Brown  
Senior Director, Federal Affairs  
Council on Radionuclides and  
Radiopharmaceuticals, Inc.  
3911 Campolindo Drive  
Moraga, California 94556

Dear Mr. Brown:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter submitted by the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) on February 6, 2006. The purpose of your letter was to request that the Commission delay the implementation of NRC's Rulemaking on the Expanded Definition of Byproduct Material established by the Energy Policy Act of 2005 (the Act) and to request that NRC hold more workshops with the regulated community. The NRC appreciates your engagement thus far in developing the proposed rule and is carefully considering your comments and concerns. Early and meaningful public involvement is key to ensuring openness in our regulatory process.

As your letter noted, the Act dictates a schedule for implementation of the rule. Because the agency is directed by the Act to complete a final rule within 18 months, the NRC does not plan at this time on extending the schedule for publishing this proposed rule. However, the Act also directs the NRC to cooperate with States to the maximum extent practicable and to consider the impact of rulemaking on the availability of radiopharmaceuticals to physicians and patients. The Commission is aware of significant stakeholder concerns and recognizes that the need for substantial stakeholder involvement presents a challenge to meeting the deadline for issuance of a final rule.

The NRC will provide opportunities for stakeholder input while the rule is being developed. In particular, I am pleased that you and other stakeholders have agreed to participate in a Commission meeting on May 15, 2006, to discuss the proposed rule and other activities of the Commission in response to provisions of the Act. In addition, the NRC will post the draft proposed rule on our website while the Commission considers the document, in advance of issuing a proposed rule.

Furthermore, CORAR – and all interested members of the public – will have the opportunity to submit comments on the proposed rule during the upcoming public comment period. The NRC staff will also hold a public meeting to discuss the proposed rule and receive input during the public comment period. I would like to bring to your attention that opportunities to submit comments on the proposed rule will be made available on RuleForum, NRC's collaborative rulemaking online environment, at <http://ruleforum.llnl.gov>. Through RuleForum,

the user will find background information, news, contacts and rulemaking documents, as well as libraries containing comments. Regardless of the means by which your comments are submitted during the public comment period, the NRC will carefully consider all comments before the final rule is published.

Sincerely,

**/RA/**

Nils J. Diaz