

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

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ACTION OFFICE: EDO

AUTHOR: Roy Brown
AFFILIATION: CA
ADDRESSEE: Nils Diaz
SUBJECT: NRC's rulemaking on the expanded definition of byproduct material established by the Energy Policy Act of 2005

ACTION: Signature of Chairman
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Council on Radionuclides and Radiopharmaceuticals, Inc.

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Henry H. Kramer, Ph.D., FACNP
Executive Director

February 6, 2006

Nils J. Diaz, Ph.D.
Chairman
Nuclear Regulatory Commission
One White Flint North Building
11555 Rockville Pike
Rockville, MD 20852

RE: NRC's Rulemaking on the Expanded Definition of Byproduct Material Established by the Energy Policy Act of 2005

Dear Chairman Diaz,

The Council on Radionuclides and Radiopharmaceuticals (CORAR) is the North American Trade Association for the producers of medical radionuclides and radiopharmaceuticals. Our members are manufacturers and distributors of diagnostic and therapeutic radiopharmaceuticals, life science research radiochemicals and sealed sources used in therapy, diagnostic imaging and calibration of instruments used in medical applications. All of the major nuclear medicine and medical radionuclides suppliers in North America are members of CORAR. The Energy Policy Act of 2005 (The Act) granted NRC the authority over "any material that has been made radioactive by use of a particle accelerator...for a commercial, medical or research activity." NRC's new jurisdiction over accelerator-produced radioactive material (ARM) will have a dramatic impact on the practice of nuclear medicine.

CORAR has been supportive of NRC getting jurisdiction over ARM for many years. CORAR member companies have seen many inconsistencies in the way states handle the regulation of ARM. CORAR has viewed NRC's jurisdiction over ARM as a way to eliminate these inconsistencies. With the NRC gaining jurisdiction over ARM as a result of The Act, we now have the opportunity to reduce or eliminate these inconsistencies. CORAR has presented these concerns to the Organization of Agreement states at their annual meetings in 2004 and 2005. CORAR also made a presentation to the ACMUI in October, and participated in the NRC Workshop on "Rulemaking to Establish a Regulatory Framework for the Expanded Definition of

Byproduct Material Established by the Energy Policy Act”, which was conducted in November. The NRC staff has been very receptive to CORAR input and the concerns we have raised.

In spite of CORAR interaction with NRC staff and the states, we are concerned with the timetable for implementation of the final rule that is laid out in The Act. We realize the draft rule has been sent to the states for their review. With the accelerated timetable dictated by The Act, we are concerned that the regulated community will not get any more meaningful input to the rule before it is finalized. There are many very technical issues that need to be resolved before the rule should be finalized. The regulated community is in the best position to work with NRC staff to resolve these issues. We feel the NRC staff would be willing to work with us to resolve these issues, if they had sufficient time. Since this rulemaking is on an accelerated timetable because of The Act, we do not feel this time is available to us or the staff. For this reason we are asking the Commission to delay the implementation of this rule until these issues can be worked out with the regulated community. In order to get the most effective resolution of the technical issues in the rule at least one more workshop with the NRC staff and the regulated community will be necessary after the draft rulemaking is made available to the public. Before the rulemaking is finalized, one last workshop with the NRC staff and the regulated community should be conducted to resolve any confusion over the rule. These additional workshops will provide the regulated community the necessary input to the rule that will make the implementation of this rule effective for the NRC, the states and the regulated community.

Thank you for your consideration of extending the rulemaking and adding additional workshops with the regulated community. We believe this will greatly improve the effectiveness of the rule. I can be reached via email at roywbrown@sbcglobal.net or by phone at (314) 795-6166. We look forward to hearing from you.

Sincerely,



Roy W. Brown
Senior Director, Federal Affairs

cc:
Commissioner Merrifield
Commissioner Lyons
Commissioner Jaczko
Commissioner McGaffigan
Charlie Miller