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FINAL REPLY:

Gerald A. White
American Association of Physicists
in Medicine

TO:

Chairman Diaz

FOR SIGNATURE OF : ** GRN ** CRC NO: 06-0083

DESC: ROUTING:
NRC's Rulemaking on the Expanded Definition of Reyes
Byproduct Material Established by the Energy Virgilio
Policy Act of 2005 Kane
Silber
Dean
Cyr/Burns
Strosnider, NMSS

DATE: 02/17/06

ASSIGNED TO: CONTACT:
ADM Hagan

SPECIAL INSTRUCTIONS OR REMARKS:

For Appropriate Action.

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AUTHOR: Gerald White
AFFILIATION: AAPM
ADDRESSEE: CHRM Nils Diaz
SUBJECT: NRC's Rulemaking on the Expanded Definition of Byproduct Material Established by the Energy Policy of 2005

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CHAIRMAN REC'D
06 FEB 14 AM 7:48

The Honorable Nils J. Diaz
Chairman
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

February 9, 2006

Dear Chairman Diaz:

The American Association of Physicists in Medicine (AAPM)¹ is pleased to have participated in the November 9, 2005 roundtable to discuss the Energy Policy Act of 2005 (the Act) and specifically the implications of the expanded definition of byproduct material on the practice of medicine. With the accelerated timetable dictated by the Act, AAPM is concerned that the regulated community will not have the opportunity for meaningful input to the rule before it is finalized.

There are a number of technical and practical issues that need to be vetted during the promulgation of the rule and in particular before finalization. AAPM is willing to work with the NRC staff to develop a rule that meets the intent of Congress but will not unduly impact the practice of medicine and patient access to the valuable diagnostic and therapeutic services covered by the use of accelerators and accelerator-produced isotopes in medicine. This rulemaking is on an accelerated timetable at the request of Congress, but the schedule does not offer sufficient time for analysis and review by either the NRC staff or the regulated community. The time constraints (if left unmodified) may well result in a final regulatory product that does not meet the intent of Congress to adequately protect the public while maintaining the highest quality of medical practice.

¹ AAPM's mission is to advance the practice of physics in medicine and biology by encouraging innovative research and development, disseminating scientific and technical information, fostering the education and professional development of medical physicists, and promoting the highest quality medical services for patients. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the Nuclear Regulatory Commission and various State Health Departments. AAPM represents over 5,000 medical physicists.

Although we applaud the Commission's desire to meet the timetable mandated by Congress in the Act, AAPM believes that it is in the best interest of the NRC, the regulated community and patients that adequate discussion of these issues occur before final promulgation of the rules to comply with the Act. We recommend that the NRC extend the timetable now to ensure that issues are brought forward, discussed, understood and resolved rather than promulgating rules without appropriate staff and community reflection and discussion that would adversely impact patient access and the practice of medicine upon issuance.

For this reason we are asking the Commission to assure a 60 -75 day comment period, and, if needed, delay the implementation of these rules until these issues can be worked out with the regulated community. For effective resolution of the technical issues in the rule, AAPM urges the Commission to make the proposed rules available for public review as soon as possible, *i.e.*, the AAPM requests that the staff SECY paper be made public while the Commission is reviewing it. In addition, AAPM urges the Commission to hold two additional roundtables once the rules are published to allow for sufficient vetting of the issues and to resolve any potential misunderstanding of the intent of the regulations. The added roundtables could be done during the comment period.

AAPM is aware that the draft SECY paper and the proposed rule have been distributed to the Agreement States and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) for their preliminary review. The timetable extension would allow the States and the ACMUI time to thoroughly analyze the proposed rule and provide the Commission with valuable insight that their collective expertise brings to the regulation of accelerator-produced materials.

Thank you for your consideration of extending the rulemaking and adding workshops with the regulated community. We believe these measures will greatly improve the effectiveness of the rule. Please contact Lynne Fairbent, AAPM's Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email at lynne@aapm.org. We look forward to hearing from you.

Sincerely,



Gerald A. White, Jr., M.S.
Chair, AAPM Professional Council

cc: Commissioner McGaffigan, Jr.
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons