PUBLIC MEETING SUMMARY

Rulemaking to Establish a Regulatory Framework for the Expanded Definition of Byproduct Materials Established by the Energy Policy Act

November 9, 2005

NRC Headquarters, Room T2B3
Two White Flint North
11545 Rockville Pike
Rockville, MD

On November 9, 2005, the U.S. Nuclear Regulatory Commission (NRC) held a public meeting to discuss rulemaking activities to establish a regulatory framework for the expanded definition of byproduct material established by the Energy Policy Act of 2005. The format of the meeting was in a "roundtable" format to allow stakeholders an opportunity to discuss concerns and interact with other interested parties on the subject of NRC regulation of naturally occurring and accelerator produced material (NARM). Representatives from other Federal agencies, States', and a broad spectrum of interest groups who may be affected by the rulemaking were invited to participate in the "roundtable" discussion. A list of the roundtable participants is provided in Attachment 1. In addition to this meeting summary, a transcript of the proceedings of the meeting will also be posted on the NRC website at http://ruleforum.llnl.gov/.

Rulemaking Working Group and Energy Policy Act Task Force

NRC staff provided an overview of the Energy Policy Act of 2005, the rulemaking efforts, and the role of the task force that was established to address new programs and responsibilities. This includes developing a regulatory framework under which provisions of the Energy Policy Act applicable to the materials and waste arenas will be planned, managed, and implemented, and for providing technical support to the NARM rulemaking effort.

Overarching Issues

The next discussion was on overarching issues, such as the role of State regulations as the starting point for NRC regulations. The Rulemaking Working Group and the Task Force are evaluating current State regulations and how model Suggested State Regulations could be used in NRC's rulemaking.

The implications of radiopharmaceutical use and availability to patients and physicians for diagnostic and therapeutic applications were also discussed. The radiopharmaceuticals of particular interest are those related to Positron Emission Tomography (PET). Issues raised in the discussion include the need for consistency across States to minimize problems with access of these radiopharmaceuticals for medical procedures and the need to work with the U.S. Food and Drug Administration.

Definition of Discrete Source

The Energy Policy Act gave NRC authority to regulate discrete sources of radium-226; however, the term "discrete" was not defined in the Energy Policy Act. There was discussion as to what a discrete source is/is not, and the need to ensure that the definition truly encompasses only those sources that NRC intends to regulate.

NRC Jurisdiction of Accelerator-produced Material

The point at which accelerator-produced material should come under NRC jurisdiction was discussed. The Energy Policy Act gave NRC authority over accelerator-produced material, but not the accelerator, cyclotron, etc. that produced the material. There are some incidental materials that are radioactive as a result of the production of accelerator-produced material. Two primary questions were discussed: (1) At what point in production does the accelerator-produced material become byproduct material if it is being produced for a commercial, medical, or research use, and (2) Is the incidental material that is produced considered part of the accelerator-produced material and should these materials be regulated by NRC as well?

Waste Disposal and Transportation Issues

The provisions in the Energy Policy Act that specifically address waste disposal were discussed. Possible impacts on waste disposal depends on how NRC defines accelerator-produced radioactive material and where NRC's regulatory authority begins. The addition of radium-226 to the definition of byproduct material may have specific ramifications on waste disposal, in part depending on how NRC defines discrete sources.

It does not appear that there will be any impact on transportation requirements. There might be a minimal impact if there is a Type B quantity of material requiring a Type B package, but this should not be a common occurrence.

ATTACHMENT 1

LIST OF ROUNDTABLE PARTICIPANTS REPRESENTING CERTAIN FEDERAL AGENCIES, STATES, AND OTHER INTEREST GROUPS
AT
THE PUBLIC MEETING ON NOVEMBER 9, 2005
REGARDING
RULEMAKING TO ESTABLISH A REGULATORY FRAMEWORK FOR THE EXPANDED DEFINITION OF BYPRODUCT MATERIALS ESTABLISHED BY THE ENERGY POLICY ACT

ROUND TABLE PARTICIPANTS:	REPRESENTING:
BAILEY, Edgar	Conference of Radiation Control Program Directors
BEVEN, Terence	Society of Nuclear Medicine
BROWN, Roy	Council on Radionuclides and Radiopharmaceuticals
CASE, James	American Society of Nuclear Cardiologists
COX, Lee	State of North Carolina, Radioactive Material Branch
DILLEHAY, Gary	American College of Radiology
FAIROBENT, Lynne	American Association of Physicists in Medicine
FEJKA, Rich	Food and Drug Administration
GITLIN, Bonnie	Environmental Protection Agency
HAMRICK, Barbara	State of California, Organization of Agreement States
KELLY, Maria	American Society of Therapeutic Radiology and Oncology
KILLAR, Felix	Nuclear Energy Institute
LIETO, Ralph	Advisory Committee on the Medical Use of Isotopes
MCBURNEY, Ruth	Health Physics Society
MILLS, George	Food and Drug Administration
MOORE, Mary	American Association of Physicists in Medicine
MORONEY, Roger	PETNET Pharmaceuticals
PACKARD, Alan	Harvard Medical School-Research community