PR 20,30,31,32,33,35,50,61,62,72,110,150,170 and 171
(71FR42952)

(27)

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Annette Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

September 11, 2006

Re: Comments proposed rule titled *Requirements for Expanded Definition of Byproduct Material* (71 *FR* 42952)

The American Association of Physicists in Medicine[1] (AAPM) is pleased to offer the following comments related to the draft proposed rule titled *Requirements for Expanded Definition of Byproduct Material* (71 *FR* 42952). These comments supplement or enhance the comments made during the August 22, 2006 public meeting.

Comments:

1. ***Therapy Accelerators.*** AAPM agrees with the Nuclear Regulatory Commission's (NRC) position that accelerators used to "only produce particle beams and not radioactive materials" (*i.e.*, those used in radiation therapy) should not be included in this regulation. AAPM agrees that the intent of Congress was that only the products produced from operating an accelerator be regulated by the NRC in accordance with the expanded definition in the Energy Policy Act of 2005. **AAPM recommends that a specific exemption for commercially available linear accelerators used only for medical purposes to treat patients (referred to as a "medical accelerator" hereafter) should be included in the final rule.**

[1] The 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 U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 6,000 medical physicists.

2. ***Definition of Particle Accelerator and Discrete Source.*** **AAPM recommends that the definition of "particle accelerator" be modified to state:** "Particle accelerator means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt and does not include machines that only produce particle beams and not radioactive materials. [Underline added by AAPM to the proposed definition in71 FR 42952.] For purposes of this definition, accelerator is an equivalent term."

   AAPM also recommends that the definition for "Particle Accelerator" and "Discrete Source" should be included in 10 CFR Part 35 in addition to 10 CFR Parts 20 and 30.

3. ***Derived Air Concentrations (DACs) for Radionuclides not previously contained in 10 CFR Part 20.*** In Section G of the proposed rulemaking, the NRC requested comments on a number of specific issues including (G.(4)) "The adequacy of the applicable default ALIs and DACs in Appendix B to 10 CFR 20 for oxygen-15 and nitrogen-13, and whether staff should develop larger specific values for these radionuclides." In the discussion of this issue, the NRC stated their reason for proposing to use default values is "[b]ecause the approach used [by the NRC staff] in calculating values for nitrogen-13 and oxygen-15 is different from that used for other radionuclides included in 10 CFR Part 20, Appendix B."

   The AAPM continues to believe it is appropriate for the NRC to use specific values for these radionuclides since unnecessarily restrictive default values can result in unjustified cost for unnecessary radiological monitoring and controls.

   During the August 22, 2006 public meeting, the Council on Radionuclides & Radiopharmaceuticals (CORAR) presented an approach by Dr. Michael G. Stabin, CHP, in the document attached to this enclosure. Dr. Stabin uses dose equivalent conversion factors for submersion in a semi-infinite cloud from Federal Guidance Report 12 (FGR-12), *External Exposure To Radionuclides In Air, Water, And Soil*, in conjunction with exposure limits and times used by the NRC in all other calculated values in 10 CFR Part 20, Appendix B. FGR-12 dose conversion values are currently endorsed and used by the NRC in 10 CFR Part 20, Appendix B for Hydrogen-3 and Argon-37. In addition, FGR-12 dose conversion values are endorsed and used by the NRC in other applications, such as dose modeling in support of the License Termination Rule. Therefore, Dr. Stabin's approach appears to be the same as that used for other radionuclides in the appendix.

   AAPM reviewed this methodology and endorses its use to calculate the DACs. AAPM agrees with the Health Physics Society that the values for the DAC's calculated by Dr. Stabin should be rounded to one significant number as is done with the other radionuclides in 10 CFR Part 20, Appendix B. This would result in specific DAC's for occupational exposure and effluent concentrations as follows:

Atomic No.	Radionuclide	Class	Table 1 Occupational Values			Table 2 Effluent Concentrations		Table 3 Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion ALI (μCi)	Inhalation		Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
				ALI (μCi/ml)	DAC (μCi/ml)			
7	Nitrogen-13	Submersion [1]	-	-	4E-6	2E-8	-	-
8	Oxygen-15	Submersion [1]	-	-	4E-6	2E-8	-	-

4. ***Need for a distribution license for PET facilities.*** Clarification is needed on the definition of "medical facilities in its consortium." AAPM agrees that a distribution license should not be necessary for PET facilities to distribute isotopes to medical facilities under contract with them. However it is unclear whether a cyclotron for producing PET isotopes located at Facility-A and operated under a separate license by Company-B, would need a commercial distribution license. **AAPM believes a distribution license is not necessary or intended by the proposed rule.** Additional clarification is needed if Company-B also supplies PET radiopharmaceuticals to other facilities in the geographical area under contract.

5. ***Decommissioning Issues.*** NRC needs to define "sufficient quantities" in the context of "only radionuclides with half-life of more than 120 days, that are present in 'sufficient quantities' to cause a public health and safety concern, need to be addressed for the purposes of establishing assurances for decommissioning leading to license termination." In defining these radionuclides, **AAPM recommends that the term "sufficient quantities" be defined in terms of 10 CFR Part 20 dose limits.**

   Second, 10 CFR Part 30 states "*Decommission* means to remove a facility or site safely from service and reduce residual radioactivity to a level that permits--

   (1) Release of the property for unrestricted use and termination of the license; or

   (2) Release of the property under restricted conditions and termination of the license."

   AAPM recommends that NRC include a specific exemption that states that "decommissioning" does not include:
   - **a) replacement of one medical accelerator for another;**
   - **b) upgrading of a medical accelerator;**
   - **c) replacement of one cyclotron for another within the same facility; or**
   - **d) upgrading of an existing cyclotron.**

AAPM recognizes that this exemption would not remove any requirements for transfer of radioactive materials between licensees should depleted uranium or activated components be present.

Third, NRC requests information regarding the decommissioning of accelerator facilities (71 FR 42957). Decommissioning requirements will vary greatly depending on the type of particle accelerated, beam current and other machine specific parameters. Clearly, electron accelerators of the type commonly used for external beam therapy for cancer do not require regulatory effort for safe decommissioning (based on long history and machine characteristics).

6. ***August 31, 2005 Waivers (71 FR 51581).*** **AAPM recommends that NRC clarify whether there is any additional action on the part of licensees that are currently covered by the waivers issued to the states.**

7. ***In Section F Termination of Waiver.*** NRC describes a phased-in approach for terminating the waivers issued in August 2005. The first to be terminated will be the waivers granted to Federal facilities and Indian Nations. **AAPM believes that clarification is needed on the potential impact to the medical community due to early termination of the waiver from the requirements of the Energy Policy Act granted to Federal facilities such as Veterans Hospitals;** *i.e.*, if waiver is terminated, could Federal facilities still accept radioactive drugs from companies that are still covered under the waiver.

8. ***Guidance Documents.*** **AAPM recommends the development of a comprehensive guidance document to be released upon implementation of the rule.**

9. ***Editorial Comment.*** 71 FR 42953 paragraph 2 under Section *Current Regulatory Structure for NARM*: please clarify the statement "Although the NRC has not regulated NARM in the past, all 33 Agreement ..." There are 34 Agreement States.

AAPM appreciates the opportunity to present these comments. If you have questions regarding these comments or those presented during the August 22nd public meeting, please contact Lynne Fairobent, AAPM's Manager of Legislative and Regulatory Affairs at 301-209-3364 or via email at lynne@aapm.org.

Sincerely,

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

From: Carol Gallagher
To: SECY
Date: Tue, Sep 12, 2006 10:01 AM
Subject: Comment letter on Requirements for Expanded Definition of Byproduct Material

Attached for docketing is a comment letter on the above noted proposed rule from Gerald A. White, Jr., AAPM, that I received via the rulemaking website on 9/11/06.

Thanks,
Carol

Mail Envelope Properties (4506BDC2.D21 : 5 : 35764)

Subject: Comment letter on Requirements for Expanded Definition of Byproduct Material
Creation Date Tue, Sep 12, 2006 10:01 AM
From: Carol Gallagher

Created By: CAG@nrc.gov

Recipients
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Post Office	Route
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Files	Size	Date & Time
MESSAGE	502	Tuesday, September 12, 2006 10:01 AM
TEXT.htm	467	
1646-0015.pdf	207954	Tuesday, September 12, 2006 9:57 AM

Options
Expiration Date: None
Priority: Standard
ReplyRequested: No
Return Notification: None

Concealed Subject: No
Security: Standard

Junk Mail Handling Evaluation Results
Message is not eligible for Junk Mail handling
Message is from an internal sender

Junk Mail settings when this message was delivered
Junk Mail handling disabled by User
Junk Mail handling disabled by Administrator
Junk List is not enabled
Junk Mail using personal address books is not enabled
Block List is not enabled