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

(7)

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
ATTN: Rulemaking and Adjudications Staff

Subject: RIN 3150-AH84 Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 "*Requirements for Expanded Definition of Byproduct Material*"

Dear Madam Secretary:

The Arkansas Department of Health and Human Services, Radiation Control Section, Radioactive Materials Program (RAM Program), provides the enclosed comments regarding the proposed rule that would amend the NRC regulations to include certain Naturally Occurring and Accelerator Produced Radioactive Materials (NARM). The rule is necessary to conform to the requirements of Section 651(e) of the Energy Policy Act of 2005.

The RAM Program has two major concerns related to the proposed rule:

- Health and Safety (H&S) adequacy designation of several key definitions and
- Regulation of Ra-226 Antiquities by General License.

The Department expresses its' appreciation to the NRC for the opportunity to comment on the draft proposed rule. If you have any questions please contact me at kim.wiebeck@arkansas.gov or by telephone at (501) 661-2173.

Sincerely

Kim C. Wiebeck, Program Coordinator
Radioactive Materials Program
Radiation Control Section

Enclosure

Cc: Janet Schlueter, Director
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U.S. Nuclear Regulatory Commission

Jared Thompson, Program Manager
Arkansas Radioactive Materials Program

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ARKANSAS COMMENTS

RIN 3150-AH84 Proposed Rule: 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171 "*Requirements for Expanded Definition of Byproduct Material*"

Health and Safety Adequacy Designation

The EP Act mandated that the NRC, "after consultation with States and other stakeholders, issue final regulations establishing requirements..." The FRN is in response to that mandate and includes "**significant contributions** (emphasis added) from many States that have regulated the naturally occurring and accelerator-produced radioactive material", the OAS, and the CRCPD. The FRN further states that the "...proposed rule was informed and guided by the CRCPD's applicable Suggested State Regulation for the Control of Radiation" (SSR). However, it seems that in the development of the proposed regulations, particularly the definitions, the "information and guidance" of the SSR was apparently not accepted by the NRC, as it relates to the States.

The NRC must continue to acknowledge the "**significant contributions**" and the successful history the Agreement States have in regulating all types of radioactive material, including NARM, over the past decades. Only now is the NRC beginning to regulate NARM that the States have regulated for years. The Agreement States have effectively regulated NARM with the same regulatory programs used with "AEA Materials" and have accomplished these "**significant contributions**" using the Suggested State Regulations.

Given this successful regulatory history, it is uncertain why the NRC is mandating the adoption of several new definitions (and other provisions) of the rule by the Agreement States through the compatibility process. These definitions and policies are adequately addressed in the SSR. It again is apparent that the NRC does not accept the language of the SSR. If the definitions that are being proposed are adopted by the NRC without recognition of the States regulations, it will ultimately require the States to amend statutes (enabling legislation before the State Legislature) and the rules and regulations. This is an unnecessary administrative and resource burden (and risk) to the States to accomplish what purpose? The States should not have to use very limited resources to make "minor changes" in the legislation and rules and regulations.

The NRC must reconsider the compatibility/adequacy designation of the rule. Following a review of Management Directive 5.9, specifically Parts I, II, VI, and the Glossary, the H&S adequacy designation does not seem appropriate for this issue, considering the definition of Health and Safety and categorization criteria (examples of program elements) contained in Parts I and II. Further, Part VI, Essentially Identical, addresses the language issue citing the use of the "...term 'radioactive material' in place of the term 'byproduct material')..." as acceptable language in Agreement States regulations.

The RAM Program strongly agrees with the position taken by the OAS on this issue for the NRC to either:

1. Include the following language in the Statement of Consideration for this proposed rule

   "The initial determination of the adequacy of definitions of terms arising from, or amended by, the EPAct, shall rely on the Governor's certification that a program is "adequate," as required by the EPAct. If the certification is accepted overall, no statutory or regulatory changes to those definitions will be required. The initial and all future assessments of adequacy in this regard will only be to ensure that the State has the statutory and regulatory authority in place to regulate the materials defined in Section 651 of the EPAct, without regard to the specific language used to provide that authority.", or

2. Designate the definitions of the proposed rule as Compatibility Category "D".

Preferably, as also discussed by the OAS, the optimum way to implement the proposed rule is for the NRC to continue its past practice described in Management Directive 5.9, Part VI of recognizing "essentially identical" language in the States regulations. The NRC must revise the compatibility/adequacy requirement for the proposed rule definitions (or any other requirement that a State may have included in the enabling legislation) to preclude States from having to revise the enabling legislation.

Regulation of Ra-226 Antiquities by General License

The proposed new General License for Certain Items and Self-Luminous Products Containing Ra-226, appears to be acceptable, except the Section covering the possession of antiquities. This Section should be withdrawn from consideration and these items should be exempted from regulation, as has been the unwritten practice in Arkansas and other States for many years, without being specifically addressed in the Rules and Regulations.

The basis for this comment includes the following:

1. In Arkansas, there is an absence of any knowledge in the State Radiation Control Program of a radiological safety event involving an antiquity over the past several decades. On a few occasions, assistance has been requested from the Radiation Control Program upon the discovery of an antique item bearing some type of radiological marking. In addition, a scrap metal dealer or a steel mill will occasionally notify the State that a radiological antique has been detected by a portal monitor. In these instances, the item is segregated and returned to the sender, or the item is confiscated by the State.

2. Considering the absence of known radiological safety events involving antiquities and the unknown number and location of individuals possessing radiological antiquities, what cost-benefit analysis has the NRC performed to justify the considerable expenditure of very limited resources at the State level that will be required to locate, identify, inform, and communicate with potential General Licensees of the future regulatory requirements? What were the results of the analysis? What dose savings does the NRC anticipate by implementing the General License on radiological antiquities?

3. The practical implementation of the proposed rule is of great concern. Because individuals (collectors) may not realize or understand they possess a radiological antique, and may not realize or understand the regulatory process of a General License issued by the NRC, it will be extremely difficult to locate radiological antiquities in the State. Has a process been developed to assist the NRC Regional Offices in locating and identifying radiological antiquities in the States, or a similar process that may be used to assist the States? How does the NRC propose to regulate radiological antiquities that are bought and sold on the Internet? As previously noted in written comments from Arkansas, "...it would be practical and prudent to regulate newly manufactured Ra-226 devices/sources, it will be an impossible task to attempt to regulate previously manufactured items that are in the public domain."

4. Radiological antiquities are collector items (both private and public) and are not used for their original purpose, nor should the items be considered useful for any malicious purpose.

5. What specific risks associated with the possession of radiological antiquities have been identified by the NRC that warrants the implementation of a new General License? Arkansas is unaware of any increased risk to public health and safety related to the possession of intact antiquities. It is understood that other States are also unaware of increased risk associated with the possession that truly justifies the General License. If no risks have been identified it seems that the NRC should apply an exemption, rather than a General License, to the possession of radiological antiquities while the NRC "...more fully evaluate potential impact to public health and safety and the environment due to activities involving Radium-226" (FRN, page 42963). Certainly, if disassembly, repair, and assembly work is performed on an antique, the risk increases, and this work must be authorized by a Specific License.

Additional Comments

The NRC is not assigned regulatory responsibility by the EP Act of 2005 for the manufacture of discrete sources and the proposed rule does not address radiological safety of manufacturing, waste management, etc., but it's responsibility is only applicable after a discrete source is produced. Will Agreement States be required to regulate the manufacturing and waste management aspects of source production? If the manufacturing occurs in a Non-Agreement State, who is responsible for the radiological safety?

A similar question exists for the "production" of accelerator-produced radioactive material. Who will regulate the accelerator in States, both Agreement and Non-Agreement States? Many States have implemented the SSR accelerator regulations; however, the regulatory responsibility for the radiation safety of the accelerator facility, the production of the radionuclides (licensing of accelerator targets), and the radioactive waste management (specifically, accelerator targets) is unclear, particularly in federal institutions, in Non-Agreement States. The proposed rule is silent on this issue; however, the radiation safety of the accelerator facility and its operation cannot be overlooked. This issue must be addressed and resolved prior to the implementation of the proposed rule.

Final Comment

The RAM Program does not agree with the statement contained in Paragraph VII, Voluntary Consensus Standards, which reads

> "In developing this proposed rule, the NRC has consulted with Agreement and non-Agreement States about their regulations. To the maximum extent practicable, the NRC has incorporated the CRCPD's SSR into the proposed rule".

Although considerable consultation with the States has apparently occurred in the development of the proposed rule, the draft final product leaves much to be desired. If the finally adopted rule requires the States to return to their State Legislatures to amend their enabling statutes (and resultant regulations) because of definitions and practices that the NRC unnecessarily mandates, then certainly the NRC has not fulfilled the requirement placed on them by the EP Act of 2005.

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Date: Wed, Aug 30, 2006 4:48 PM
Subject: Arkansas NARM Comments

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