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

(6)

From: "Ratliff, Richard" <Richard.Ratliff@dshs.state.tx.us>
To: <lwc1@nrc.gov>, <jmm2@nrc.gov>
Date: Mon, Aug 28, 2006 12:44 PM
Subject: NARM Rulemaking (RIN 3150-AH84)

The Texas Department of State Health Services endorses and concurs with the comments offered to the NRC by the Organization of Agreement States Executive Board attached below.

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Subject:	NARM Rulemaking (RIN 3150-AH84)
Creation Date	Mon, Aug 28, 2006 12:47 PM
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Organization of Agreement States

August 23, 2006

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 Executive Board of the Organization of Agreement States (OAS) provides the enclosed comments in response to requests made in the subject document dated July 28, 2006. The first set of comments refers to the proposed rule, and the second set refers to the regulatory analysis for the proposed rule. The proposed rule 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 (EPAct).

The most significant concern expressed throughout the OAS Executive Board's comments is related to the extent to which the U.S. Nuclear Regulatory Commission (NRC) relied upon, and will authorize the continued use of, State regulations respecting NARM. These State regulations have been used for decades, and are based on the Conference of Radiation Control Program Directors, Inc.'s model *Suggested State Regulations for the Control of Radiation* (SSRs). The Agreement States are concerned that without an express recognition that the definitions derived from the SSRs, which are currently in use, are acceptable for continued use (so long as they provide the appropriate authority to regulate the materials coming under NRC's authority pursuant to the EPAct), there will be a significant impact upon the Agreement States' regulatory programs clearly not intended by the EPAct.

Specifically, the proposed rule has several definitions tailored to the NRC regulatory scheme (e.g., the definition of "byproduct material"), which are designated as "Health and Safety" (i.e., required for the purposes of program adequacy). The OAS Executive Board and the vast majority of the Agreement States would support this designation, if moderated by additional language in the final Statements of Consideration for this rule that include the following, or substantially similar, statements:

"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."

Another efficient and cost-effective solution to this dilemma would be for the NRC to recognize, in writing, an intent to continue to implement the long-standing practice of accepting alternative language (such as for definitions) used by the States, as described in NRC Management Directive 5.9, section VI. This recognition could be included in the final Statements of Consideration for this rule, and should clearly reflect that the States can continue to use the definition of the more generic term "radioactive material," rather than revise existing definitions in State statutes and regulations to conform to the NRC's newly created definitions. Without this continued recognition, expanded to recognize other definitions new to the NRC (such as "particle accelerators," and other terms that have been in use for decades due to the States' broader authority), the proposed rule could have a significant detrimental impact upon the Agreement States.

Alternatively, for this rulemaking, if the above suggestions cannot be implemented, the OAS Executive Board has no recourse but to recommend that the NRC designate the definitions it is changing (to bring its regulations in line with the EPAct) as compatibility category D.

Thank you for the opportunity to comment on these important documents and please contact me at Bhamrick@dhs.ca.gov or by telephone at 714-257-2031 if you have any questions.

Sincerely,

Original Signed by Barbara L. Hamrick

Barbara L. Hamrick, Esq., CHP, JD, Chair
Organization of Agreement States
1800 E. Lambert Road, Suite 125
Brea, CA 92821

Enclosures

Cc: Janet Schlueter, Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission

OAS Board

Pearce O'Kelley, Chair
Conference of Radiation Control Program Directors

Agreement States (by email)

OAS Executive Board Comments on the US NRC's

Proposed rule for

Requirements for Expanded Definition of Byproduct Material

Generally the NRC's proposed rule *Requirements for Expanded Definition of Byproduct Material* is well conceived and the Organization of Agreement States (OAS) Executive Board is in agreement with the stated objectives and methods proposed to implement the provisions by the NRC for the NRC, however, the proposed rules will be difficult to incorporate into existing states' NARM statutes and regulations. There are a number of specific concerns described in the following paragraphs that the NRC could address before the rule is finalized by —simply using the "model State standards in existence on the date of enactment of this Act," as referenced in the Energy Policy Act of 2005 (EPAct.), section 651(e)(4)(B)(ii).

Comment 1: The "proposed rule, *Requirements for Expanded Definition of Byproduct Material,"* has several definitions specific to the NRC regulatory scheme (e.g., "byproduct material") and which are designated as "Health and Safety" (H&S) (i.e., required for program adequacy). To ensure the smooth transition of authority required by the EPAct, the OAS Executive Board and a vast majority of the Agreement States recommend that the final Statements of Consideration for this rule contain the following, or substantially similar, language:

> "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."

Alternatively, the NRC could recognize, in writing, the intent to continue to implement the long-standing practice of accepting alternative language (such as for definitions) used by the States, as described in NRC Management Directive 5.9, section VI. This recognition could be included in the final Statements of Consideration for this rule, and should clearly state that the States can continue to use the definition of the more generic term "radioactive material," rather than revise existing definitions in State statutes and regulations to conform to the NRC's newly created definitions. Without this continued recognition, expanded to recognize other definitions new to the NRC (such as "particle accelerators," and other terms that have been in use for decades due to the States' broader authority), the proposed rule could have a significant detrimental impact upon the Agreement States.

Finally, if the above suggestions cannot be implemented, the OAS Executive Board has no recourse but to recommend that the NRC designate the definitions it is changing (to bring its regulations in line with the EPAct) as compatibility category D.

The NRC's added and amended definitions in the proposed rule are not only responsive to the requirements of the EPAct, but also consistent with NRC's current regulatory framework. While NRC regulations already use the term "byproduct material" generally to define two distinct categories of radioactive material, Agreement States typically use the term "radioactive material," as defined in the Conference of Radiation Control Program Directors, Inc.'s (CRCPD's) *Suggested State Regulations for Control of Radiation* (SSRs) to refer to the various

types of radioactive materials regulated, which still includes a broader range of materials than NRC has authority to regulate (e.g., Agreement States generally regulate diffuse as well as discrete sources of radium).

As noted in the Federal Register Notice (FRN) for this proposed rule, on pages 42953, 42954 and 42958, and in comment number 12 below, most of the States have regulated naturally occurring and accelerator produced radioactive material (NARM) in a manner consistent with the way the Agreement States and the NRC have regulated the more traditional "byproduct material" for decades. The States have done this using the term "radioactive material" and have not had any compatibility problems with the NRC in the past with regard to this difference. The OAS Executive Board is confident that the NRC's State and Tribal Programs (STP) staff who have worked many years with the CRCPD's SSRs would agree that the States' use of the terms "radioactive material," as well as other definitions included in the proposed rule (e.g., "particle accelerator") adequately provide the authority to continue to regulate these materials in a manner consistent with the NRC's newly granted authority, and there is no need for any wholesale change of State regulations to accommodate the new authority granted to the NRC by the EPAct. In most cases, the States do not need these definitions and adding them to the States' rules would only confuse readers of the States' statutes and regulations as the States have always used the term "radioactive material" rather than "byproduct material."

Comment 2: On pages 42953 and 42954 of the FRN the NRC indicates that it proposes to revise its rules to match the SSRs. We agree this proposal is consistent with the requirements of the EPAct, and will provide for the least disruption in the existing regulatory framework. In those cases in which the NRC is proposing a substitution for language in the SSRs, where a State has already adopted the existing SSR requirement, the OAS Executive Board recommends that the Statements of Consideration acknowledge that such States will not be required to revise statute or rule language, regardless of the compatibility category assigned, unless the existing language is demonstrated to be incompatible with the requirements of the EPAct.

Comment 3: The OAS Executive Board finds the proposed new general license for certain items containing radium (on page 42962 of the FRN) reasonable, with one possible exception regarding antiquities. The OAS Executive Board recommends that the NRC consider also offering a time-limited exemption for antiquities, until such time as a very substantive public outreach effort can be made to identify those persons that may possess these items, and adequate data exist to demonstrate these items pose a significant enough risk to require licensure. The experience of the OAS Executive Board is that many of the antiquities mentioned in the proposed Section 31.12(a) are held by members of the public or by organizations in private collections. These items are no longer being used for their original purpose; so do not pose the same risk that they would if used as originally intended. Most, if not all, of these items have not been proactively regulated for decades. An abrupt transition from exempt status to general licensure may be problematic since a) many of the possessors of these items likely are not following the regulatory proposals arising from the EPAct (unaware that these provisions may impact them), b) there is no comprehensive record of who may possess these items, and c) there is no specific data cited in the Statements of Consideration to the proposed rule that indicates these items pose significant enough risk to warrant licensure.

Comment 4: The proposed new general license for certain items containing radium would prohibit assembly, disassembly, and repair (see page 42963 of the FRN). Although there is no consensus of the States on this issue, the OAS Executive Board is aware of specific

circumstances in California, Illinois and Wisconsin that suggest that a prohibition of these activities under general licensure is appropriate. In this regard, the OAS Executive Board also believes that an outreach effort will be needed for these general licensees to provide them with sufficient information to bring their possession, use, transfer, distribution and disposal of these items into compliance with any new requirements. The NRC should collaborate with the States on this outreach effort.

Comment 5: On page 42963 of the FRN, the NRC makes the following requests to which index numbers have been inserted by the commenter in italics:

> "The Commission specifically requests comments to provide information that may assist the NRC to more fully evaluate potential impact to public health and safety and the environment due to activities involving radium-226 sources. *(1)* In particular, the Commission requests input on any quantitative or qualitative health and safety information regarding radium-226 sources that may be used to support a regulatory framework other than general licensing, such as an exemption. *(2)* The Commission also requests comments regarding the specific constraints in the proposed exemption in 10 CFR 30.15(a)(1)(viii) and *(3)* in its general license approach for certain items and self-luminous products containing radium-226 that were manufactured prior to the effective date of the rule, regarding under what circumstances an exemption is a more effective and viable approach, and *(4)* requests additional information for the technical basis supporting an exemption in lieu of a general license. *(5)* In particular, the Commission would appreciate input on whether this general license approach, and its allowances and restrictions, is reasonable while the Commission evaluates the products; *(6)* whether the general license should allow possession of radium-226 luminous items, such as individual watch hands, dials, gauge indicators and faces, etc., which are not contained in an intact product regardless of number; *(7)* whether commercial transfers should be restricted and require a specific license; or *(8)* whether data are available to justify an exemption for certain types of radium-226 sources, now or in the future."

With reference to the numbers inserted in the above quoted section of the proposed rule, the OAS Executive Board provides the following responses:

> *(1)* The comment period does not provide sufficient time to assess what information is available, and compile it so as to address this request. The OAS Executive Board recommends an NRC-Agreement State Working Group be formed to address this issue.
>
> *(2)* The OAS Executive Board is in general agreement with the approach.
>
> *(3)* An exemption, when justifiable, is a better approach than a general license. Please also refer to Comment 3, above regarding the recommendation for a time-limited exemption for antiquities, until further information can be developed, and adequate public outreach efforts are made.
>
> *(4)* The OAS Executive Board recommends an NRC-Agreement State Working Group be formed to address this issue, as noted in sub-item 1, above.
>
> *(5)* The approach is reasonable while the NRC evaluates the products. However, also refer to Comment 3, above, in this regard.

(6) There is a possession level beyond which a specific license is preferable, whether or not the items are "intact" (a number of items that is at least the exempt quantity value times ten to one hundred should be considered).

(7) Commercial transfers should not be treated in the same manner as mere possession and use. The OAS Executive Board recommends that a specific license be required for the commercial transfer of these items, but also notes that concerns provided in Comment 3 are relevant here also – i.e., a significant public outreach effort is required to identify and educate persons involved in the trade of these items.

(8) The OAS Executive Board is not aware of the existence of compilation of such quantitative data, and recommends, as noted in sub-items 1 and 4 above that an NRC-Agreement State Working Group be formed to address this issue.

Comment 6: On page 42963 of the FRN, the NRC describes its regulatory structure, which is set up for separate licenses for production, distribution, and possession and use. Some of the Agreement States have for many years combined the license authorizations as much as feasible for these activities, because there is only one radiation safety program to be evaluated at a facility and the additional authorizations take only the addition of a few lines of text to a license document, so the licensee should not have to pay two or three separate licensing fees for the authorization of work at one facility under one regulatory agency, for one radiation safety program under one management. Some other Agreement States have the same licensing structure as the NRC. The OAS Executive Board recommends that the NRC continue to allow this flexibility.

Comment 7: On page 42967 in the FRN, is a discussion regarding the potential for the existence of facilities currently contaminated from discrete sources of radium-226 and the NRC's proposal to address these situations on a case-by-case basis as they are identified following promulgation of the proposed new requirements. The OAS Executive Board reminds NRC that radium-226 was once relatively common and unregulated. Therefore, the NRC can reasonably expect radium-226 to turn up on a regular basis. This issue will require public outreach in both Agreement and non-Agreement States, and the OAS Executive Board suggests this effort be included in the efforts undertaken to resolve issues addressed in our comments 3, 4 and 5, above.

Comment 8: On page 42969 and 42970 of the FRN it states "The Commission specifically requests comments on the proposed effective date for the final rule and other implementation period to ensure the affected individuals have sufficient time to come into compliance with the new requirements and to apply for an appropriate license or license amendment for the material, if applicable." The OAS Executive Board agrees with the proposed timeframe; however, it is concerned about the ability of currently non-licensed persons who may, upon promulgation of the rule, be subject to a general or specific licensure, to be aware of the existence of the requirements. Please refer to Comments 3, 4, 5 and 7, in this regard.

Comment 9: On page 42971 of the FRN, referring to proposed changes to 10 CFR, Section 31.8(b), the OAS Executive Board recommends that the NRC provide a "grandfather clause" for the many items that may have been approved for manufacture many years before 10 CFR 32.57 was adopted in its current form. The States should be able to simply attest that the calibration or reference sources were manufactured to standards or criteria that have been demonstrated through years of use to be adequate to protect the public health and safety and the users of the sources. The NRC should clearly communicate what it plans to require for this,

if anything. The OAS Executive Board thinks that, unless the NRC has knowledge of problems of leaking sources of this type, it should be clearer in a written statement that these sources are acceptable as manufactured.

Comment 10: On page 42978 in the FRN, regarding Voluntary Consensus Standards, at the end of the section the NRC states, "To the maximum extent practicable, the NRC has incorporated the CRCPD's SSRs into the proposed rule." Based on the language and the NRC's stated intent this appears to be accurate; however, the proof will be in the NRC's implementation. The Agreement States were active in the development of the EPAct language requiring the NRC to use the CRCPD's SSRs. The OAS Executive Board is confident that the intent of the Agreement States and of the drafters of the EPAct language was to minimize the burden on the public and the States in the NRC's process of developing and implementing compatible provisions and the desire was that the NRC become compatible with the CRCPD's SSR language, which essentially should guarantee that the Agreement States would not need to make any statutory changes and few, if any, rule changes.

Comment 11: On pages 42981 through 42993 in the FRN, respecting the definitions, the OAS Executive Board Comments 1 and 2 apply.

Comment 12: On page 42986 in the FRN, referring to 10 CFR 32.72, the OAS Executive Board recommends that the NRC specifically recognize, in the Statement of Considerations for the final rule, that an Agreement State will not be required to amend their comparable regulation, so long as that comparable regulation (or other regulations) provide for the same control of the manufacture and initial distribution of radium-226 sources under a general license as the proposed regulation.

Comment 13: On pages 42987 and 42988 in the FRN, referring to 10 CFR 35.2 Definitions of *Authorized nuclear pharmacist*, *Authorized user* and *Positron Emission Tomography (PET),* the OAS Executive Board recommends, consistent with our Comments 1 and 2, above, that any Agreement State that has rule language essentially the same as the current CRCPD's SSRs provisions should be considered to have compatible rules and should not have to revise those rules as a result of this NRC rulemaking regardless of the compatibility category assigned by the NRC.

OAS Executive Board Comments on the Regulatory Analysis

1. On page 2, Section 1.1.2, second paragraph, second sentence, is the following:

   "Although the NRC has not regulated NARM, all 33 Agreement States and certain non-Agreement States have regulated programs for NARM."

   Comment: The second "regulated" should be "regulatory."

2. On page 3, under Non-Agreement States, second bullet, is the following:

   "...parallel the Suggested State Regulations for the Control of Radiation (SSRs) developed by the Council of Radiation Control Program Directors, Inc. (CRCPD)."

   Comment: "Council" should be "Conference"

3. On page 12, Section 2.3, near the end of the top paragraph on this page, is the following:

   "However, the SSRs do not specifically address certain categories of products and discrete sources containing radium-226 which are in the public domain but may not be otherwise covered under a license."

   Comment: The OAS Executive Board thinks that a statement should be added indicating that the reason these categories of products and discrete sources containing radium-226 were not specifically covered in the SSRs is that there was very little history of problems warranting regulation of them.

4. On page 12, Section 2.3, near the end of the second paragraph on this page, is the following:

   "However, no additional NORM has been identified at this time that has useful chemical properties and with attendant radiological risk subject to NRC regulation."

   Comment: The State of Florida has found sufficient radiation exposure rates in certain small accessible areas of certain phosphate fertilizer processing facilities to warrant a radiation protection program for workers in those areas. Such was implemented through specific licenses at the facilities.

5. On page 16, Section 3.1, Item 5., is the following:

   "Other Government. The proposed alternatives may impose a small cost to Agreement State governments with respect to additional reporting requirements for products that contain radium-226. This cost is insignificant and is not included in the analysis."

   Comment: Nowhere in this document or in the Federal Register Notice is there a clear statement that the Agreement States will not have to make extensive statutory and regulatory changes as a result of this rulemaking. Without such a written statement, as proposed in the OAS Executive Board's comments on the proposed rule, there is potentially a very significant cost to the Agreement States, and the NRC should provide a cost estimate for those statutory and regulatory changes. Adopting the suggested language provided in the OAS Executive Board's comments on the proposed rule would obviate the need for a cost assessment.

From: Lydia Chang
To: Evangeline Ngbea; SECY
Date: Wed, Aug 30, 2006 12:14 PM
Subject: Fwd: NARM Rulemaking (RIN 3150-AH84)

Van:

Please docket the following e-mail from TX. Thanks....

Lydia C.

CC: Mark Delligatti

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