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January 30, 2006

Lydia Chang
U.S. Nuclear Regulatory Commission
Two White Flint North/Mail Stop 8A23
11555 Rockville Pike
Rockville, MD 20852

Dear Ms. Chang:

Reference is made to NRC's Draft Federal Register Notice (FRN) for regulations to implement the EPAct of 2005. Enclosed is a copy of the OAS Board's comments on the Draft FRN. Please accept this letter and the enclosure as Iowa's comments on the Draft FRN.

Thank you for the opportunity to comment. If there are any questions please contact me.

Sincerely,

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DAF/rk

Enclosure

cc: B. Hamrick
L. Bolling

OAS Board Comments on the US NRC's

draft proposal for

Requirements for Expanded Definition of Byproduct Material

Generally the NRC's draft proposed rule *Requirements for Expanded Definition of Byproduct Material* is well conceived and the Organization of Agreement States (OAS) Board is in agreement with the stated objectives and methods proposed to implement the provisions by the NRC for the NRC. There are a number of specific concerns described in the following paragraphs, which the NRC could address before the rule is proposed by following the EPAct--using "model State standards in existence on the date of enactment of this Act." (A quote from the EPAct.)

Comment 1: The *Requirements for Expanded Definition of Byproduct Material* has several definitions specific to the NRC regulatory scheme (e.g., types of new byproduct material) that are in the draft proposed rule with a Category B compatibility level assigned. The OAS Board is confident that the NRC's State and Tribal Programs (STP) staff who have worked many years with the Conference of Radiation Control Program Directors' (CRCPD) Suggested State Regulations (SSR) system would agree that the States' use of the terms "radioactive material" and "particle accelerator" as defined in the SSRs already cover all the material that NRC has to add to its rules by use of these definitions. In most cases, the States do not need these definitions and adding them will only confuse readers of the States' statutes and regulations as the States have always used the term "radioactive material" rather than "byproduct material." It would be preferable if NRC clearly stated in writing that the States can continue to use "radioactive material" rather than revising the States' statutes and regulations to use "byproduct material" throughout the States regulations, and that the States do not have to add definitions of terms that the States do not use in the States regulations. The assigned compatibility Category B level as the NRC typically administers compatibility will not allow the rational solution that the OAS is suggesting. For this rulemaking, the NRC should designate the definitions it is changing to bring its regulations in line with the EPAct and the CRCPD's SSRs as compatibility Category C. The NRC is adding the terms not only because the EPAct has the terms, but because its regulations use the term "byproduct material" generally and defining two more categories of radioactive material to be "byproduct material" efficiently resolves the NRC's regulatory issues. The States have used the term "byproduct material" typically only with reference to mill tailings and the term "radioactive material" for all that the NRC is proposing to define to be "byproduct material" except for mill tailings. As noted in the FRN on pages 31, 32 and 61 and in comment number 23, the States use of "radioactive material" has always included NARM and discrete radium as the NRC proposal defines these terms.

Comment 2: On page 15 in the first sentence of the second paragraph, there needs to be clarification of working group and task force representation and resource persons. Illinois has provided assistance only through a resource person.

Comment 3: On page 21 in the last line of the center paragraph, The OAS Board recommends that "any" be "an" in ..."an inextricable part of any accelerator operation."

Comment 4: On page 23 the sentence at the end of the first paragraph indicates that the NRC is seeking comments on the extent, if any, that accelerators are used to intentionally produce radioactive material and to provide beams for basic science research. The OAS is not providing comments on this but encourages specific States comments because there are so few States to which this applies and those States and the licensees themselves should comment on it.

Comment 5: At the end of page 23 and continuing on page 24, the NRC requests comments "on the decommissioning of accelerator facilities, specifically addressing the extent to which accelerator components and facility building materials may become activated, the need to remove and properly dispose of such activated material during decommissioning in order to meet the radiation dose limits in 10 CFR Part 20 Subpart E—Radiological Criteria for License Termination, the cost of the decommissioning and disposal, if required, and the need for financial assurance by accelerator facilities to guarantee sufficient funding for proper decommissioning."

In the experience of the OAS Board, medical treatment accelerators (generally, linear accelerators referred to as linacs) and non-medical linacs (generally, industrial radiography use) have no real decommissioning issues regardless of the energy level because the induced radioactive is usually short lived and the machines are so valuable that older machines are traded in on newer machines or are refurbished by knowledgeable persons who know what components may be activated, how to measure the radiation level, and how to safely work with the "hot" components during the refurbishment process. The half-life of the "hot" components is so short that there is no "disposal" issue with regard to "low level radioactive waste" and there should be no export issues due to radioactivity. The NRC should clearly focus the application of its efforts on "production accelerators"—those used to produce radioactive materials for medical or other use. The States have licensed these types of accelerators, have required decommissioning cost estimates and, in some cases, have completed the decommissioning process for licensed accelerator facilities. Current information from one State that requires "Persons who use particle accelerators to manufacture radionuclides for distribution to other licensees or customers" to submit a reclamation plan and cost estimate for approval by the Agency; and, secure a financial arrangement in the amount specified on the Agency-approved cost estimate." The Reclamation Plans outline the types of machines and activated hardware that must be dispositioned and estimates the amount of concrete from the target vaults that require removal for disposal. These types of facilities

reconfigure their operations from time to time based on product needs and changes. Sometimes the shielding material is reused. The number of vaults, targets, etc. drive the costs of decommissioning. For financial assurance cost estimating, most licensees plan on removing all of the concrete shielding.

CONFIDENTIAL—NOT for Public Disclosure follows in brackets [ ]

CONFIDENTIAL—NOT for Public Disclosure above in brackets [ ]

Comment 6: On pages 30 and 31 the NRC indicates that it proposes to revise its rules to match the SSRs. We agree that this is the right way to go. For cases in which NRC is proposing a revision and a State has already adopted a comparable requirement that has stood the test of time; the States want a written statement by the NRC that the States do not have to revise the rule language to be like NRC even if it the NRC assigns a compatibility Category B or Category A.

For the column breakthrough limit (see page 31) the OAS Board recommends that the NRC state that the proposed criterion is from the US Pharmacopoeia, which is the criterion the States have used.

Comment 7: On page 33 and 34 there is a discussion under the title Definition of Discrete Sources that could be expanded to clearly state that residuals from treatment of water to meet drinking water criteria and residuals from treatment of waste water from public sewer treatment facilities are not discrete sources of radium regardless of the concentration of radium; however, some of these residuals may become licensable quantities of "source material" due to the concentration of uranium (and thorium).

Comment 8: On page 36 there is a discussion of the NRC's intent to accommodate existing products and materials that were previously regulated by the States under similar provisions. The OAS Board would like the NRC to clearly state that the wording in the States rules that covered this prior to the NRC receiving its new authority will not have to be revised because the NRCs phrases used to accomplish the same purpose may be different and the rule has a compatibility Category B or Category A assigned by the NRC.

Comment 9: On page 37 in the center of the page is a sentence that states "Some time ago, tritium and then promethium-147 replaced radium in self-luminous products." The memory of some States' older regulatory personnel is that promethium-147 and then tritium replaced radium in self-luminous products.

Please confirm the historical accuracy of the statement. These States' older personnel do not claim to possess perfect recall of such information.

Comment 10: On the bottom of page 41, the NRC proposes to "accommodate generally licensed devices meeting the restrictions of the general license that were previously approved by the States under comparable provisions to 10 CFR 32.51." The OAS Board supports this approach. The OAS Board requests the NRC to clearly state that the States with provisions comparable to the NRC proposal, as evidenced by the fact that the rule was on the States' books and other States had not objected to it prior to this rulemaking by the NRC, will not have to revise the comparable provisions in order to be compatible with the NRCs new rule language even if the NRC rule is a compatibility Category B or Category A.

Comment 11: On page 42 the NRC discusses the registration requirement for radium-226 sources under a general license that are 0.1 mCi or more. Illinois searched its database and found that there were two known to be in Illinois. North Carolina has no such sources under a general license. It would be good if other States with a database that tracks these were checked to see if any exist and if so what are they and how much activity is there per device.

Comment 12: On page 44 is the term "revigarators" but a check of a device clearly showed the spelling to be "revigators" instead. Check the historical records and use correct term or, if both terms were used, then use both terms here and elsewhere in this FRN where the term is used. Also, the examples used were made of uranium ore rather than radium. This sentence could be deleted or new examples are needed.

Much more importantly is the proposed new general license for certain items and self-luminous products containing radium, which makes sense with one possible exception: antiquities. The experience of the OAS Board is that many of the antiques mentions in the proposed Section 31.12(a) are held by members of the public or by organizations in private collections. These items are collected and thus no longer being used for their original purpose. Most, if not all, of these items have been considered as practically exempt from regulation by the States for decades. The transition from exempt to a general license may be problematic since a) many of the owners of these items are likely unaware of the radioactive content and thus unaware of regulatory requirements - current or future and b) we do not know the details of who has them - just the big picture. We are also unaware of any data that suggests these items pose significant enough risk to warrant regulation. The NRC should consider including these antique items under an exemption, as has been the State practice for decades.

Comment 13: On page 45 is a discussion of a proposed general license that would prohibit ...assembly, disassembly, repair... of products containing radium-226. There is not a consensus of the States on this issue. These folks have not been regulated in the past for radiation safety purposes. There have been a few

problems because of this. Contact California, Illinois or Wisconsin for examples. Given the uncertainty of who may be performing service of radium-226 items, it seems appropriate to the OAS Board to recommend that the NRC require a specific license at this point. In order to be sensitive to the cost issue, the NRC could establish a separate, lower cost license category or fee reduction while still requiring a license. Finally, we also believe the NRC proposed regulations may (likely will) impact some facilities that have not previously been regulated by NRC or the states, such as facilities that restore antique aircraft containing radium dial gauges. We believe that an outreach effort will be needed to educate previously unregulated entities prior to implementation of the new NARM regulations. The NRC should collaborate with the States on this outreach.

Comment 14: On page 45 at the center of the page, end of first full paragraph is a statement that persons possessing these devices under a general license are to respond to written requests for information from the NRC. It appears that this sentence should end with "from the NRC or the appropriate Agreement State."

Comment 15: On page 46, 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 its general license approach for certain items and other self-luminous products containing radium-226, *(3)* asks for comments on whether 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."

(1) Other than anecdotal information from State Radiation Control Programs seasoned staff members, that there have been only a small percentage of leaking or failed sources, there is no information known to exist.

(2) The OAS Board is in general agreement with the approach; however, see Comment 12.

(3) An exemption, when justifiable, is a better approach than a general license. We therefore recommend using exemptions rather than general licenses.

(4) Other than the qualitative statement that the States are not aware of significant problems with the sources, the States do not have technical data supporting an exemption in lieu of a general license or vice versa.

(5) The approach is reasonable while the NRC evaluates the products; however, see Comment 12.

(6) There is a possession level beyond which a specific license is preferable (possibly, a number of items that is at least the exempt quantity value times ten). The NRC should propose a value in the FRN and ask for comment.

(7) Commercial transfers are nearly the same considerations as for quantities needing a specific license for dials. It is case specific and would require knowledge and experience. In some cases the answer is yes, but could be costly and also urgent, as professionals with direct knowledge of radium are becoming aged.

(8) The OAS Board is not aware of the existence of such data.

Comment 16: On pages 47 and 48 the NRC describes its regulatory structure that is set up for separate licenses for production, and distribution, and possession and use. Some of the Agreement States have for many years combined the license authorizations as much as feasible for these because there is only one radiation safety program to be evaluated at a facility and the authorization takes 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 Agreement States have the same licensing structure as the NRC. The OAS recommends that the NRC continue to allow this flexibility.

Comment 17: On page 53, the second sentence of the last paragraph on the page states in part "The intent of this provision is that the compacting process implemented in accordance with the LLWPA is not to be affected by"... It appears that the word "compacting" should be "Compact."

Comment 18: On page 58 at the end of the first paragraph, the document states ..."a facility-specific decommissioning plan that addresses the current contamination and any previous disposals." It appears that this should state ..."any previous on-site disposals."

Comment 19: On page 58, at the center of the page, 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 new requirements. The OAS Board reminds NRC that radium-226 was once relatively common and unregulated. Therefore, NRC can reasonably expect radium-226 to turn up on a regular basis. NRC should be prepared to address voluminous situations requiring the NRC's technical, public relations, and political resources.

Comment 20: On page 59 in the discussion of the transition plan, is specified "The statement of the Commission is subject to a certification provided by the Governor of the State to the Commission on the date of publication of the transition plan"... The States would like a clear statement that the date of publication of the transition plan will be provided well in advance so the States can get the certifications provided on the exact date of publication of the plan.

Comment 21: On page 61 in the fourth line from the top is stated ..."and a 12-month period from the effective date for the affected individuals to apply for a new license application." This should indicate "apply for a new license with an application" or something similar rather than "apply for a new license application."

Comment 22: On page 61 in the middle of the page and last sentence of the paragraph, the FRN 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 Board agrees with the proposed timeframe found at the top of this page 61; however, it is concerned about the ability of currently non-licensed persons and those who will have a new general license to be aware of the existence of the requirements.

Comment 23: On the bottom of page 61 in the last paragraph is the statement that inspires many of the OAS Boards concerns regarding compatibility and the NRC's implementation of its new authority, which took away what the Agreement States had been doing in a fairly uniform comparable manner for decades and now gives it back with requirements that include the NRC's concept of "make the States regulations read exactly like our new ones." The OAS Board suggests that the FRN include a statement that the NRC will accept as compatible each Agreement States regulations that were essentially the same as the CRCPD's SSR on the date of the NRC's final rule. It may help the NRC to understand the States' concern if the NRC views this process as the NRC becoming compatible with the Agreement States and living up to the requirement in the Atomic Energy Act that NRC also must use its best efforts to maintain compatible programs when it signed each of the agreements.

Comment 24: On page 65 Section 30.34, perhaps there should be a reference to the US Pharmacopoeia as the source of this requirement for element breakthrough in the eluant on the first elution of a generator.

Comment 25: On page 66 Section 31.8 reference to Paragraph (b), the OAS Board hopes that the States do not have to demonstrate that its provisions were comparable to 10 CFR 32.57 because some of these may have been done 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 in the FRN what it plans to require for this, if anything. The OAS Board thinks that, unless the NRC has knowledge of problems of leaking sources of this type that it should be clearer in a written statement that these sources are acceptable as manufactured.

Comment 26: On page 67 Section 31.12, were luminous devices for ships considered for inclusion in this GL, and if so, were they excluded because of higher activities involved? Marine compasses are mentioned in another current rulemaking. It might be helpful to address marine compasses in this section perhaps by reference to the section where they are addressed.

Comment 27: On page 68 Section 31.12 in the last paragraph before Part 32, the OAS Board wishes to know if the NRC plans to monitor this for compliance by a strictly reactive process.

Comment 28: On page 70 Section 35.2 Definitions, the proposed changes are because of the NRC's use of the term "byproduct material" and the NRC should clearly state that States who use the term "radioactive material" as defined by CRCPD's SSRs do not need to amend their definitions to be compatible even if the compatibility Category B or Category A is assigned because the States definitions already include what NRC is including with the proposed revision. Perhaps the NRC could designate the 11e(3) and 11e(4) additions to the definition as compatibility Category C to resolve the issue.

Comment 29: On page 81 at the top of the page is the statement "NRC specifically requests comments on the Compatibility designation. In particular, NRC request comments on whether the definition of *Discrete source* is correctly designated as Compatibility Category B, considering the procedures in Management Directive 5.9 and that Congress assigned NRC the task of defining *Discrete source* in the EPAct." The OAS Board suggests that the FRN include a statement acknowledging that the CRCPD SSR and Agreement States term *Sealed source* is comparable and the Agreement States do not have to change their definitions to incorporate the definition of *Discrete source* or that the term is Category C.

Comment 30: On page 81 at the top of the Table for 20.1003 for the Definition of *Byproduct Material* and Sections 20.2006 (e) and 20.2008 the OAS Board wants NRC to acknowledge the Agreement States use of the term "Radioactive material" instead of "Byproduct material" and that the term "Radioactive material" includes what the NRC is including with its change in its definition of "Byproduct product" and that regardless of whether the compatibility is designated Category A, Category [A], Category B, or Category C the Agreement States do not have to revise their regulations to be compatible with the changes NRC has to make to include what the Agreement States already include in "Radioactive material." This comment also applies to the other Sections where the same terms are defined.

Comment 31: On page 82 Section 30.4 Definitions of *Accelerator-produced radioactive material, Byproduct material, Positron Emission Tomography (PET)* and *Particle Accelerator*, the OAS Board suggests that the FRN state that the NRC will accept as compatible regardless of the Compatibility Category the current Agreement States definitions of the terms as long as they are consistent with the current CRCPD's SSR. This statement applies to the other Sections where the same terms are defined.

Comment 32: On pages 82 through 87 for all Sections not regarding the Definitions discussed in Comments 30 and 31, the OAS Board suggests that the FRN include an acknowledgement that the NRC is becoming compatible with the Agreement States by using language similar to that of the CRCPD's SSR and that any Agreement State that has rule language essentially the same as the current SSR provisions has compatible rules and does not have to revise those rules as a result of this NRC rulemaking regardless of the compatibility Category assigned by the NRC.

Comment 33: On page 88 at the top of the page the NRC states "The NRC requests comments on this proposed rule specifically with respect to the clarity and effectiveness of the language used. With the exception of the actions required of the Agreement States to be compatible with these rules, the OAS Board finds the FRN for the proposed rule is extremely well written, clear and easy to understand and effective in communicating requirements. The OAS Board has suggested substantive improvements to the FRN throughout this comment paper.

Comment 34: On page 88 in VII. Voluntary Consensus Standards at the bottom of the page 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 Suggested State Regulations (SSR). The OAS 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 many rule changes. Needlessly forcing the States to change statute and/or rules that currently mirror the SSRs does not meet the letter or spirit of the EPAct.

Comment 35: On page 90 in the second line the word "Agreement" needs to be deleted because some of the States who developed the ARM rules were not Agreement States but were States who regulated only NARM.

Comment 36: On page 95 under X. Regulatory Analysis in the beginning of the second paragraph is stated "The Commission requests public comment on the draft regulatory analysis." The OAS Board currently does not have time to look at this.

Comment 37: On pages 102 through 104 for the Definitions the OAS Board Comments 30, 31 and 32 apply.

Comment 38: On page 104 in Section 20.1003 Definitions and the definition of *Waste* the OAS Board that the last sentence that starts with the word "However" should not be in the definition. The sentence should be in rule text with requirements or a note or deleted but not in the definition. Including it in the definition may cause unnecessary rulemaking to add explanatory material that could be in a note or guidance or in the rule where requirements are specified. Either delete it or put it in somewhere as a compatibility Category C.

Comment 39: On page 105 in Section 20.2008 (a) the OAS Board recommends adding a phrase similar to the phrase "if acceptable to the Compact for that State" to the end of the first sentence.

Comment 40: On page 116 in Section 32.51 (c)(13)(i) for the last sentence the OAS Board recommends that the last sentence be deleted and leave this as an option for each State to do as it determines is in the best interest of the State. Some States find it more advantageous to allow multiple addresses for location of use for one general licensee, such as gauges at coal fired power plants. This is an item that may be addressed in the GL petition.

Comment 41: On page 121 in footnote 2 the items named "revigarators" should be referred to as "revigators." This term was used in one or two other places of the FRN.

Comment 42: On page 122 in the first sentence of Section 31.12 (c)(1) the OAS Board thinks that "Shall notify the NRC" should state "Shall notify the NRC or Agreement State where the damaged product is currently located.

Comment 43: On page 122 in the second sentence of Section 31.12 (c)(1) the OAS Board thinks that "disposed of" could be "dispositioned" or "disposed of or transferred" because transfer to a specific licensee is acceptable.

Comment 44: On page 127 for 32.72 the Agreement States do not need to amend their regulations or licenses because the terms used by the Agreement States already authorize all the things that NRC is including its regulations with these changes. The NRC is becoming compatible with the Agreement States and as long as the Agreement States has rule language comparable to the current CRCPD's SSR the Agreement State should not have to revise its regulations regardless of the NRC compatibility Category assigned.

Comment 45: On pages 131 through 133 for Section 35.2 Definitions of *Authorized nuclear pharmacist*, *Authorized user* and *Positron Emission Tomography (PET)*, Any Agreement State that has rule language essentially the same as the current SSR provisions has 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.

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