

July 9, 2004

Mr. John L. Ferruolo
Supervising Radiological Health Specialist
Office of Occupational and Radiological Health
Department of Health
3 Capitol Hill
Providence RI 02908-5097

Dear Mr. Ferruolo:

Thank you for your participation in the June 16, 2004 teleconference with John Zabko, of my staff, to discuss the Nuclear Regulatory Commission (NRC) comments on proposed changes to the Rhode Island regulations and other items contained in your June 4, 2004 letter. Changes in our review procedures to improve efficiency and effectiveness, as well as collegial interactions between the Agreement States and the Office of State and Tribal programs, have helped to make our redesigned, regulation review program a success.

The purpose of this correspondence is to respond to your letter and to summarize the NRC actions and Rhode Island proposed actions resulting from the teleconference. As discussed during the teleconference, we agree with your plans for addressing the comments in our May 4, 2004 letter. We believe that we addressed all of your items of concern and that the actions documented in the enclosed summary, both NRC's withdrawal of comments and Rhode Island's proposed actions resolve issues related to the regulation review.

If we have misunderstood or mis-characterized your planned actions, please contact me so that we can ensure that the comments on your draft regulations are adequately addressed. In addition, we will pursue the items of non-compatibility identified in Part T of the Suggested State Regulations, with the Part T committee chair and CRCPD.

The additional item discussed in the call, credit for adopting the amendment, RATS ID # 1997-2 "*Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State*", is under review. We will provide you with the results of that review when completed.

If you have any questions regarding the enclosure, the compatibility categories, or any of the NRC regulations used in the review, please contact me, or John Zabko of my staff at (301) 415-2308 or JGZ@NRC.GOV.

Sincerely,

IRA By J.M. Piccone

Josephine M. Piccone, Deputy Director
Office of State and Tribal Programs

Enclosure:
As stated

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SUMMARY OF PROPOSED ACTIONS FROM THE JUNE 16, 2004 TELECONFERENCE

Number	State Regulation	NRC Section	RATS ID	Category	Subject and Comments
1	A.0	71.4	1996-1	B	<p>a) The State's proposed regulation does not include the following definition:</p> <p>Certificate Holder</p> <p>b) In addition, the State's proposed regulations includes the phrase "or other form" in their proposed definition for Normal Form - Radioactive Material</p> <p>The state needs to include this definition and remove the phrase "or other form" from their proposed definition for Normal form radioactive material to meet compatibility.</p> <p>The previous comment on this section concerning the addition of the following definitions is withdrawn:</p> <p>Definition of A₁ and A₂ Conveyance Package</p> <p>The state makes reference to 49CFR173.401, in it's radiological rules, which includes these definitions.</p> <p><u>Rhode Island Action:</u></p> <p>The State will incorporate part (a) and (b) of this comment into its regulations, but will wait until their next transportation rule revision so as to engage in only one rulemaking.</p>

2	C.8.30	35.200	2002-2	H&S	<p>Use of Unsealed Byproduct Materials for Imaging and Localization Studies for which a Written Directive is not Required.</p> <p>In paragraph (a) the State’s proposed regulations use the phrase “involving measurements of the uptake, dilution or excretion studies,” instead of “for imaging and localization studies for which a written directive is not required.”</p> <p>The State needs to replace the phrase “involving measurements of the uptake, dilution or excretion studies,” with the phrase “for imaging and localization studies for which a written directive is not required.”</p> <p><u>Rhode Island Action:</u></p> <p>The State will submit this change as a technical correction to this current rule making.</p>
3	C.7.6	71.12	1996-1	B	<p>General License: NRC-approved package.</p> <p>The State’s proposed regulations did not include this requirement.</p> <p>The State needs to revise their regulations to include the requirement for an NRC approved Quality Assurance Program in sections C.7.6 - C.7.11. to meet this requirement as stated in 71.12 - 71.20</p> <p><u>Rhode Island Action:</u></p> <p>The State will incorporate this comment into its regulations, but will wait until their next transportation rule revision so as to engage in only one rulemaking.</p>

4	C.7.10	71.18	1996-1	B	<p>General License: Fissile Material, limited quantity per package</p> <p>The State's proposed regulations did not include paragraphs d & e for fissile materials. Also the transport index calculation appears to be in error. State defines a 15 gram minimum requirement for fissile material which is not discussed in this section of NRC regulations, and the multiplier for plutonium beryllium sources is noted as 0.026. NRC regulations state 0.025.</p> <p>The State needs to amend their regulations to incorporate the essential objectives of the text of 71.18.</p> <p><u>Rhode Island Action:</u></p> <p>The State will submit this change as a technical correction to this current rule making.</p>
5	C.7.7	71.13	1996-1	B	<p>The State's proposed regulations at C.7.7.(b)(2) contains the phrase, "approval except approved under special arrangement in accordance with," instead of "approval as defined in."</p> <p>The State needs to revise its regulations and replace the phrase, "approval except approved under special arrangement in accordance with," with the phrase "approval as defined in."</p> <p><u>Rhode Island Action:</u></p> <p>The State will incorporate this comment into its regulations, but will wait until their next transportation rule revision so as to engage in only one rulemaking</p>

6	C.7.14	71.87	1996-1	B	<p>Routine Determinations</p> <p>The State’s proposed regulations did not include the words “with its contents”</p> <p>The State needs to add the words, “with its contents” as noted in 71.87, thereby incorporating the essential objectives of the text of 71.87</p> <p><u>Rhode Island Action:</u></p> <p>None, this comment has been withdrawn. The word “package” is defined as the packaging and the radioactive material inside per 10CFR71. Therefor the phrase, “with its contents” is redundant in 71.87.</p>
7	C.7.19	71.101 71.103 71.105	1996-1	C	<p>Quality Assurance Requirements; Quality Assurance Organization; Quality Assurance Program</p> <p>The State’s proposed regulations regarding Quality Assurance did not include the language contained in 71.101(a), (b), (c) and (g) which specifies quality assurance requirements and organization, including specific requirements for radiography containers.</p> <p>State needs to revise their regulations to include design, purchase, fabrication, handling, storing, cleaning, inspection ,testing, operations, maintenance, repair and modification activities under a QA program. State should also include a discussion of QA organizations and programs similar to 71.103 in order to incorporate the essential objectives of the text of 71.101; and 71.103, including requirements for radiography containers as discussed in 71.101(g).</p> <p><u>Rhode Island Action:</u></p> <p>See Rhode Island action in comment 3. The addition of the requirement for an NRC approved QA program in sections C.7.6 - C.7.11 will adequately address this comment.</p>

8	N/A	40.36 H&S-- paragra phs (a), (b), (d), and (f).	1997-6 2003-1	H&S	<p>Financial assurance and recordkeeping for decommissioning (source material)</p> <p>The State's proposed regulations define financial assurance requirements for radioactive materials using the 30.35 model (Appendix B to Part 30 values times a multiplier). This approach does not work for source material (uranium and thorium). The 10 mCi and 100 mCi thresholds in 40.36 are not met with the 30.35 methodology.</p> <p>As written in 40.36 and 40.42 the specific threshold for source material needs to be explicitly stated in the State regulation or other legally binding requirement to establish a compatible financial assurance system for source materials.</p> <p><u>Rhode Island Action:</u></p> <p>The State will reevaluate its financial assurance and decommissioning requirements for source material licensees for compatibility with 40.36 and 40.42. Due to the small number of licensees involved, the State may use license conditions or conduct a full rulemaking to ensure compatibility. The State will begin the license condition process as soon as possible and will include this item in their next regularly scheduled rulemaking if they choose the rulemaking option.</p>
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9	C.5.8	40.42	1997-6	H&S	<p>Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas</p> <p>The State's proposed regulations did not explicitly include the regulatory requirements defined in 40.42 paragraphs (c), (d), (e), (f), (g), (h), (i), (j), & (k)(1), (2), (3) regarding source material.</p> <p>The State needs to revise its regulations to include the regulatory requirements defined in 40.42 paragraphs (c), (d), (e), (f), (g), (h), (i), (j), & (k)(1), (2), (3) regarding source material.</p> <p><u>Rhode Island Action:</u></p> <p>The State actions in response to comment #8 will also address this comment.</p>
10	A.2.3	20.1201	2002-1	A	<p>Occupational dose limits for adults</p> <p>The State's proposed regulations added the phrase "shallow dose equivalent" to the first sentence in paragraph A.2.3.c, and to the second sentence after the word, "assigned"</p> <p>The State also omitted the sentence, "The deep-dose equivalent, lens-dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable."</p> <p>The State needs to remove the two references to shallow-dose equivalent in paragraph A.2.3.c, and add the sentence noted above in order to incorporate the essential objectives of the text of 20.1201</p> <p><u>Rhode Island Action:</u></p> <p>The State will submit this change as a technical correction to this current rule making.</p>