

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF HEALTH



Safe and Healthy Lives in Safe and Healthy Communities
14 June 1999

Paul H. Lohaus, Deputy Director
US Nuclear Regulatory Commission
Office of State Programs
Washington, DC 20555-0001

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OSP

Dear Mr. Lohaus:

This letter is in response to your 3 June 1999 letter to Charles McMahon, which provided NRC/OSP comments on proposed amendments to the RI Rules and Regulations for the Control of Radiation. The Radiation Control Agency staff has reviewed your comments and has recommended the following actions:

1. The Agency concurs that references to "individuals administered radioactive materials and released in accordance with Section C.8.24 of the Rhode Island regulations" were omitted from our definitions of "Occupational Dose" and "Public Dose". Upon receipt of Duncan White's verbal summary of this problem area, we requested an opinion from our Chief Legal Counsel on the possibility of including this additional text as a technical correction to our proposed amendments. However, we were informed that, in her opinion, the scope of these changes went beyond what was allowed as a technical correction under our Administrative Procedures Act. Consequently, if we wished to adopt the additional language, we would have to submit these changes for an additional Public Hearing. Given the time and effort associated with a Public Hearing, the very small likelihood that any substantive comment would be received, and the fact that the Agency will be submitting additional proposed regulations (10 CFR 35 equivalent, etc) for comment later this year, we have opted to defer adoption of this additional language until our next round of amendments. We believe that this will have minimal impact on public health and safety because changes to both Dose Limits for Individual Members of the Public [Subsection A.2.11(a)(1)] and the actual procedures for release of patients [Section C.8.39] have been adopted as part of this current rulemaking process.

2. While the Agency concurs that the overall changes to 10 CFR 32.72 should be assigned a Category B compatibility level, we respectfully disagree that the failure to adopt the language in 32.72 (b)(3)-(5) should be treated as a Category B deficiency. These subparagraphs only deal with "ministerial changes" which allow licensees to name their own nuclear pharmacists, as long as NRC is notified of the changes within the prescribed period of time. When NRC previously adopted a fairly broad definition of what constitutes a "ministerial change", RI elected to adopt a much narrower definition which still requires prior Agency review and approval of prospective new authorized users in non-broad scope licenses. In addition, nuclear pharmacists are also regulated by the RI Board of Pharmacy, which requires review and approval before any individual is allowed to practice pharmacy in Rhode Island. The Radiation Control Agency has an agreement with the Board of Pharmacy that neither agency will take any licensing action relating to nuclear pharmacies/nuclear pharmacists without prior consultation between both program staffs. Therefore, we respectfully request NRC/OSP to withdraw their determination that failure to adopt language equivalent to 10 CFR 32.72(b)(3)-(5) represents a Compatibility Level B deficiency and allow us to adopt this amendment as originally proposed.

3. The Agency believes that the previously adopted language contained in Section A.5.18 of the RI Rules and Regulations for the Control of Radiation meets the intent of 10 CFR 20.2205 and that no additional changes are required.

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Paul H. Lohaus
14 June 1999
Page 2

Other than replacing "INSERT EFFECTIVE DATE" with "1 July 1999" the final version of these regulatory changes is identical to the original proposed amendments forwarded to your Office on 29 March 1999. As per your request, we are enclosing an electronic (WordPerfect 6.1) version of the entire Rules and Regulation for the Control of Radiation. Because the size of this document (approx 1.8 MB) exceeds the capacity of a single disk, it has been formatted as a self-extracting ZIP file [raarg699.exe].

Agency staff will be reviewing the RATS data sheet included with your letter. If any discrepancies are noted, we will notify your Office under separate cover.

If you have any further questions concerning this letter or are unable to extract the document from the ZIP file, please contact William Dundulis at (401) 222-4948, Ext. 2107.

Sincerely,



Marie Stoeckel, MPH, CIH, Chief
Office of Occupational and
Radiological Health

pc: Duncan White, USNRC-Region I
Charles McMahon
William Dundulis