



OFFICE OF THE  
GENERAL COUNSEL

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

April 11, 1995

PDR  
AF-10-2  
#3B

MEMORANDUM TO: Stephen A. McGuire  
Office of Nuclear Regulatory Research

FROM: Bradley W. Jones *Bradley W. Jones*  
Senior Attorney

SUBJECT: TECHNICAL REVIEW OF FINAL RULE ON "MEDICAL ADMINISTRATION OF  
RADIATION AND RADIOACTIVE MATERIAL"

I have reviewed the draft final FRN on the wrong patient rule provided to the working group in your April 5, 1995 Memorandum. The attached two pages contain two suggested revisions to the language in the draft final FRN. I will forward the final rulemaking package to OGC management for review upon receipt of the Office Concurrence version of the package.

cc: S. Treby

*done*  
*4/17*

The existing § 20.1301(a) also excludes dose contributions from the licensee's disposal of radioactive material into sanitary sewerage. That exclusion was not ~~be~~ added to §§ 20.1002 and 20.1003 because the question of dose from sewer disposal of radioactive material is now under consideration by the NRC. When that issue is resolved, it is intended that the wording concerning dose from sewer disposal will be made consistent in §§ 20.1002, 20.1003, and 20.1301(a).

A recently published proposed rule (June 15, 1994; 59 FR 30724), which deals with criteria for the release of individuals administered radioactive material, would also amend § 20.1301(a)(1). When that amendment of § 20.1301(a)(1) is published in final form, the wording on what is excluded from the dose limit will be inserted in §§ 20.1002 and 20.1003 (in the definitions of public dose and occupational dose) so that the same parallelism will exist throughout.

#### IV. Consistency with the 1979 Medical Policy Statement and Coordination with ACMUI.

On February 9, 1979 (44 FR 8242), the NRC published a Statement of General Policy on the Regulation of the Medical Uses of Radioisotopes. The first statement of the policy states, "The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public." The rule is consistent with this statement because it continues to provide for administrations of radioactive materials to be regulated under 10 CFR Part 35. The rule further clarifies that additional regulations are not considered necessary.

This rulemaking was discussed with representatives of Agreement States at a meeting in Portland, ME, on October 24, 1994. The States were polled on how they regulated an administration to the wrong individual, and it was found that they <sup>appear to</sup> regulate <sup>such</sup> the administration <sup>is consistent with</sup> ~~the same way as~~ in this rule. Two States commented on the rule, and both fully supported the rule.

The NRC believes that the modification of Part 20 should be a Division 1 matter of compatibility consistent with past practice of requiring basic definitions to be uniform for effective communication of basic radiation concepts. The only Agreement State commenting on the compatibility issue supported a Division 1 level.

#### VI. Finding of No Significant Environmental Impact.

The NRC has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of Part 51, that this rule is not be a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

The NRC prepared an environmental assessment for the proposed rule, which was contained within the Federal Register Notice for that rule. That assessment continues to stand for the final rule.

#### VII. Paperwork Reduction Act Statement.

This rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1980