



OFFICE OF THE GOVERNOR

STATE CAPITOL

SANTA FE, NEW MEXICO 87503

August 1, 1996

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GARY E. JOHNSON  
GOVERNOR

Chairman Shirley Ann Jackson  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-001



(505) 827-3000

Dear Chairman Jackson:

The Institute of Medicine's (IOM) recommendation that NRC's regulatory authority for medical use be removed, that Federal guidance shift to the Department of Health and Human Services, and that the states increase their regulatory responsibility to include byproduct material for medical use is looked on with great interest by New Mexico as a potential regulator of all aspects of medical programs.

A review of the prepublication copy of the IOM report, "Radiation in Medicine" A Need for Regulatory Reform," by program staff in the Environment Department has resulted in the following comments pertaining to the NRC's Committee for Review of Evaluating on the Medical Use Program's recommendations on policy, legislative rulemaking and guidance issues:

1. Committee Recommendation A1. "The committee recommends that Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses."

Department's Comment:

Since there is split regulatory authority at the federal level, and the NRC has no apparent interest in seeking jurisdiction over all sources of ongoing radiation, Department staff agrees with the committee recommendation that Congress remove regulation of the possession and use of those radioactive materials subject to the federal Atomic Energy Act from the purview of the NRC.

2. Committee Recommendation A2. "The committee recommends that Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine;
  - a. Supporting the operation of the Conference of Radiation Control Program Directors;
  - b. Providing a venue for the review and evaluation of Suggested State Regulations for Control of Radiation;

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- c. Assisting states in the implementation of their regulations;
- d. Aiding in assessment of the effectiveness of state programs through the collection and analysis of data;
- e. Helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be increased;
- f. Monitoring the effects of deregulation;
- g. Enhancing, training, and standards for health care personnel; and
- h. Investigating future significant radiation medicine incidents.

Department's Comments:

Department staff supports this recommendation so long as all states maintain radiation regulatory programs that measure comprehensive standards of performance and effectiveness.

3. Committee's Recommendation B1. "The committee recommends that the NRC immediately relax enforcement of 10 CFR 35.32 and 35.33 through the present mechanisms."

Department's Comments:

Staff believes that the Quality Management rule should be replaced with a more reasonable performance based rule that can be implemented at both the licensing and inspection stages.

4. Committee's Recommendation B2. "The committee recommends that the NRC initiate formal steps under the Administration Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above."

Department's Comments:

Department staff believe that 10 CFR Part 35 should be totally revised if Congress does not respond to the recommendations regarding removing the regulatory responsibility and authority for the use of radioactive materials in medicine from the purview of the NRC.

5. Committee's Recommendation B3. "The committee recommends that the NRC separate the costs of formulating regulations from the costs of administering those regulations."

Department's Comments:

Department staff endorses this recommendation of the committee.

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6. Committee's Recommendation C3. "The committee recommends that the Conference of Radiation Control Program Directors and the states continually re-evaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine."

Department's Comments:

Department staff believe that constant re-evaluation of programs is essential to maintain relevant, cost-effective regulations.

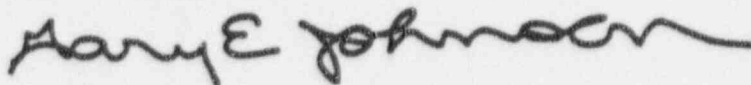
New Mexico appreciates the opportunity to provide its perspective on the important issues raised in the report.

Please contact the New Mexico Environment Department, Radiation, Licensing and Registration Section staff at (505) 827-1564 should you have any questions.

12:06 <sup>B</sup> 12. 96

Sincerely,

Mr. Benito Garcia



Gary E. Johnson  
Governor

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committee would be

considered by the Commission

Statute Amendment & Rebooting Initiative

over him some of telephone if he desired further  
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