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May 25, 1994

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BRANCH

Samuel J. Chilk
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Docketing and Service Branch

DOCKET NUMBER
59 FR 9146 PR 20
(59FR9146)

RE: 59 FR 9146; Advanced notice of proposed rulemaking "Disposal of Radioactive Material by Release into Sanitary Sewer Systems"

Dear Secretary Chilk:

The American College of Nuclear Physicians (ACNP) and The Society of Nuclear Medicine (SNM) applaud the use of an advanced notice of proposed rulemaking by the Commission for an issue such as this. However, we are concerned that this is another example of NRC moving forward on an issue with no justifiable scientific reasoning. ACNP and SNM represent over 15,000 nuclear medicine physicians, nuclear pharmacists, nuclear medicine scientists, and nuclear medicine technologists involved in the delivery of essential health care. We strongly urge the Commission to refrain from making any regulatory changes to the current exemption of the disposal of patient excreta into sanitary sewer systems.

The ACNP and SNM are extremely concerned that NRC is ignoring any type of cost-benefit analysis or risk assessment in proposing to change the limits on radionuclides disposed in municipal sewer systems. We see no evidence that there is any risk to either the public or the sewer system employees from the disposal of patient excreta. NRC must recognize that with the analytical equipment available today it is possible to pick up small traces of radioactivity in the sewer systems. This contamination has existed since 1936 when Nuclear Medicine began. However, as NRC acknowledges, Nuclear Medicine employs only trace amounts of radioactivity that then are disposed of through patient excreta in the sewer systems. To prevent this disposal it would require medical licensees to keep patients in the hospital until there was no chance of interaction with the municipal sewer system. It would also require the separation of excreta from all patients who have received a Nuclear Medicine procedure.

In Nuclear Medicine over 10,000,000 diagnostic and 50,000 therapeutic procedures are conducted annually. Of all those procedures only about 6,000 patients need to be hospitalized (thyroid carcinoma therapies), for an average of about two days or a total of 12,000 hospital days. If disposal of patient excreta into the sanitary sewer system were no longer exempt, then patients and their excreta would be required to remain under hospital control for the current requirement of ten effective half lives storage decay: 80 days for hyperthyroid and thyroid cancer patients receiving I-131, 140 days for leukemic and polycythemic patients receiving P-32, and 500 days for patients with metastatic cancer to bone receiving Sr-89. The corresponding required days of hospitalization would be 41,000 (80d) + 1,000 (140d) + 8,000 (500d) = 7.42 million hospital days compared to the currently required 12 thousand hospital days. At a cost of about \$800/day the annual cost would be more than \$5.9 billion compared to the current \$9.5 million. This is only for the 50,000 patients, and does not even cover the cost of new plumbing and disposal facilities for storage and decay of stool and urine.

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ACNP/SNM Comments to NRC

May 25, 1994

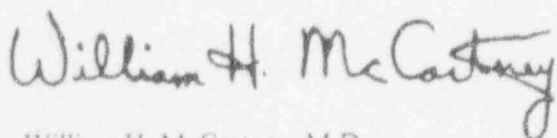
Page 2

We hope that these cost estimates will convince NRC that this rule would be far too expensive to implement and could cause the end of Nuclear Medicine. No hospital in the United States would be willing or able to meet these regulatory requirements and in all likelihood would stop offering Nuclear Medicine services. We would also like to point out that this would be a perfect example for a backfit rule. Currently, only regulations affecting the power reactors are subject to this rule. We would strongly urge the Commission to consider this rule for materials licensees as well. We are hard pressed to believe that Commission could justify any rulemaking of this sort if they were forced to meet the requirements of the backfit rule.

ACNP and SNM would also like to point out the lack of significant risk assessment by NRC in offering this advanced notice of proposed rulemaking. In the six case studies that NRC offers it clearly notes in most that there was no harm to the public or the employees in question and that there were no levels above the current requirements in 10 CFR 20. We feel that this is significant when considering changing the current regulations. NRC chooses to use extremely conservative estimates in determining TDE for the public by assuming that any member of the public would get their drinking water at the point of discharge. ACNP and SNM believe this to be an unrealistic assumption. In addition employees working with the municipal sewer system, although not specifically trained in the handling of radioactive material, are very conscious about the chemical and biological risks involved with sewer disposal. We believe that it is highly unlikely that a worker in a municipal sewer system would receive a harmful dose of radiation through the course of employment.

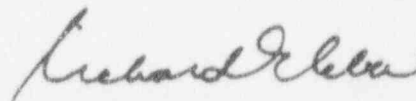
There is also concern about NRC considering the notification of local municipalities before discharging radionuclides into the sewer. In the area of patient care, currently most patients are discharged from the hospital after receiving a Nuclear Medicine procedure. To properly notify the local authorities in advance, medical licensees would be forced to keep patients in the hospital, creating extensive costs as mentioned before. We can understand how NRC may want licensees to notify the local municipality when a spill occurred above and beyond the regulations of 10 CFR 20, but unless that occurs, this proposed regulation would be extremely costly with no additional level of safety being achieved.

In conclusion, the ACNP and SNM strongly urge NRC to shelve any reconsiderations of disposal standards for municipal sewer systems until risk to the public or employees of municipal sewer systems can be determined. We believe that the current regulations of 10 CFR 20 are adequate to govern this area and that any additional changes would be too expensive for industry to bear. Thank you for the opportunity to comment on this important topic. If you have any additional questions please feel free to contact Mr. David Nichols in our Washington Office at (202) 429-5120.



William H. McCartney, M.D.
President
American College of Nuclear Physicians

Sincerely



Richard C. Reba, M.D.
President
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