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PROPOSED RULE PR 20  
(59FR9146)

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USMRC

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May 25, 1994

The Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555  
ATTN: Docketing and Service Branch

OFFICE OF SECRETARY  
DOCKETING & SERVICE  
BRANCH



RE: **Advanced Notice of Proposed Rulemaking: Disposal of Radioactive Material by Release into Sanitary Sewer Systems** (Federal Register, Vol. 59, No. 38, pp. 9146 - 9149)

Merck & Co., Inc. is a large multinational pharmaceutical company with corporate headquarters in Whitehouse Station, NJ. The company pursues a rigorous research and development program in human and animal health through its research division, Merck Research Laboratories (MRL). The use of radionuclides is a critical component in many of MRL's research programs. The proper and safe use of radioactive material, as well as, the safe and efficient disposal of radioactive waste are primary goals of MRL's health physics program.

The MRL Department of Health Physics, Biosafety & Environmental Affairs doesn't believe that there is a need for additional restrictions to the current regulations governing the release of radionuclides to sanitary sewer systems. The current regulations have maintained the radiation dose to members of the public to well below the 100 mrem/year limit stipulated in 10 CFR 20.1302, *Compliance with Dose Limits for Individual Members of the Public*. The six case studies presented in the federal register indicate that no individual (even in these highly unusual situations) received a radiation dose in excess of the 10 mrem/y ALARA guideline recommended in Regulatory Guide 8.37, *ALARA Levels for Effluents from Materials Facilities*.

If the Commission feels compelled to amend the regulations in view of the findings of NUREG/CR-5814, *Evaluation of Exposure Pathways to Man From Disposal of Radioactive Material Into Sanitary Sewer Systems*, then the Commission should limit its changes to the handful of potentially problematic radionuclides. As presented in the table below, the range of potential radiation doses arising from the sewer disposal of radionuclides typically used in biomedical research are well within the Regulatory Guide 8.37 recommendations for ALARA effluents.

RADIATION DOSES CALCULATED IN NUREG/CR-5814 FOR RADIONUCLIDE DISCHARGES OF 1 CURIE PER YEAR TO A 5 MILLION GALLON PER DAY SEWAGE TREATMENT PLANT		
Radionuclide	Maximum Radiation Dose (mrem/y)	Minimum Radiation Dose (mrem/y)
H-3	1.6E-04	< 1.0E-07
C-14	4.1E-02	3.0E-06
P-32	1.2E+00	< 1.0E-07
P-33	1.2E-01	< 1.0E-07
S-35	4.4E-02	< 1.0E-07
I-125	6.8E-01	< 1.0E-07

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Changes in the sewer disposal regulations could have a detrimental impact on the management of certain radioactive waste streams. Therefore, Merck feels that it is necessary to comment on the topics published in the Federal Register notice. For clarity, the topics are presented in bold italics and our response follows.

***THE POTENTIAL IMPACTS ON LICENSEE'S OPERATIONS ASSOCIATED WITH ANY ADDITIONAL RESTRICTIONS REGARDING FORMS OF MATERIAL SUITABLE FOR DISPERSAL.***

Merck does not support any additional restrictions regarding forms of material suitable for dispersal. 10 CFR 20 states that only readily soluble or readily dispersible biological material is satisfactory for disposal by release into sanitary sewerage. Considering that the design of sewage treatment plants is to process readily dispersible biological material; the need to further restrict this waste form isn't clear. However, if the ability to dispose of this waste form to the sanitary sewer was restricted there would be a major impact on waste management practices. For example, in large animal *in-vivo* studies large volumes of excreta containing low radionuclide concentrations are directly washed into the sanitary sewer system (with proper evaluation and recordkeeping). If this disposal method was no longer available, the large volume of excreta (containing very little licensed material) would have to be contained, packaged, transported and stored prior to disposal. All of this extra handling increases the potential for personnel radiation dose from the raw, undiluted waste. The increased radiation exposure to caretakers and costs for waste handling do not appear to be outweighed by the slight reduction in calculated radiation doses to members of the public that are already far below federal limits.

Additionally, further restrictions in the sewer disposal regulations would lead to a sizable increase in the volume of radioactive waste for interim storage at biomedical research facilities. Since this increase wasn't foreseen, the existing facilities designated for interim storage may not have the necessary capacity. Therefore, it will be necessary for organizations to increase capital spending on storage facilities.

The suggestion of further restrictions on sewer disposal appears to contradict the ALARA philosophy, considering the increased radiation exposure to personnel and increased costs of waste handling at biomedical research institutions versus the minimal reduction in radiation doses to members of the public.

***THE POTENTIAL IMPACT ON LICENSEE'S OPERATIONS ASSOCIATED WITH FURTHER RESTRICTIONS ON THE TOTAL QUANTITY OF RADIOACTIVE MATERIAL THAT COULD BE RELEASED DURING A YEAR.***

Merck does not support further restrictions on the total quantity of radioactive material that could be released during the year. The same general arguments and conclusions presented above would apply to this proposal.

***TO REQUIRE AT LEAST 24 HOURS ADVANCE NOTICE TO THE APPROPRIATE SEWAGE TREATMENT PLANT BEFORE RELEASING RADIOACTIVE MATERIAL TO THE SANITARY SEWAGE SYSTEM.***

Merck does not support the idea of 24 hour notification prior to discharge. The utility of this proposal is not clear. What benefit is derived from this notification? What action would the

operator of a sanitary sewerage system take? This requirement would become burdensome to large facilities that have routine discharges, requiring almost daily notification of the appropriate sewage treatment plant.

*SHOULD THE COMMISSION CONSIDER LIMITATION USING A DOSE LIMIT APPROACH, AND PROVIDE TOTAL QUANTITY AND CONCENTRATION VALUES IN A REGULATORY GUIDE TO FACILITATE COMPLIANCE WITH THE DOSE LIMIT?*

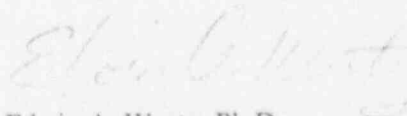
Merck supports the use of a dose limit approach to sewer disposal regulations. From the radiation dose values presented in NUREG/CR-5814, it appears that the current sewer disposal regulations are more restrictive than other effluent stream requirements. If the appropriate models are developed, like those in NUREG/CR-5814, there should be no reason for sewer disposal to be handled differently than any other facility effluent. Using this approach, facility discharges and associated public radiation doses could be controlled under the requirements of 10 CFR 20.1302, *Compliance with Dose Limits for Individual Members of the Public*, or the ALARA guideline recommended in Regulatory Guide 8.37, *ALARA Levels for Effluents from Materials Facilities*.

*THE APPROPRIATENESS OF CONTINUING THE EXEMPTION FOR PATIENT WASTES.*

Merck concurs with the Commission's assessment that the current regulation is adequate. We can not identify any benefit to regulating patient excreta; however, the cost of an extended hospital stay or the potential exposures to family members from the handling and storage of patient excreta are obvious.

I am sure that this comment will receive careful review and consideration before the publication of a proposed rule change. If you require additional information on this matter, I would welcome the opportunity to discuss this topic with a member of the NMSS staff.

Sincerely,



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