DOCKET NUMBER
PROPOSED RULE PR 20
(68FR09595)

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DOCKETED
USNRC
1892
June 27, 2003 (3:59PM)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

June 28, 2003

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: Rulemaking on Controlling the Disposition of Solid Materials: Scoping Process for Environmental Issues and Notice of Workshop; Federal Register, February 28, 2003.

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing over $30 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures. The research, development, clinical and quality control laboratories of our member companies utilize radionuclide testing and diagnostic equipment in their drug discovery and drug development endeavors and are, therefore, vitally interested in the NRC consideration of appropriate alternatives for appropriately controlling the disposition of solid materials with no, or very small amounts of, radioactivity resulting from licensed operations.

PhRMA offers its strong support for an NRC rulemaking on alternatives for controlling the disposition of solid materials described by the Nuclear Regulatory Commission (NRC) in the subject proposal. PhRMA concurs with the National Academy of Science report that the current regulatory approach is incomplete and inconsistent, and that the NRC's approach should be risked-based. The NRC's proposed rulemaking provides a set of alternatives that support a logical framework for developing a risk based approach for protecting the health and safety of the public in regard to the appropriate disposition of solid materials. Only solid materials that warrant the highest level of public isolation should be required to be disposed of at an NRC/Agreement State licensed low-level waste (LLW) disposal site (alternative 5). Solid materials that contain very small amounts of radioactive material could safely be isolated from the public through disposal in an EPA regulated landfill (alternative 4).

The application of such a risk based approach to facilities in both the industrial, and the research sectors would be of enormous significance. For our members, the successful acceptance of the proposed rule would allow for much needed flexibility in the management and disposal of very low-level radioactive waste (LLRW) at their drug research facilities.

Specifically, PhRMA supports the EPA regulated landfill disposal alternative for the disposal of solid materials with very small amounts of radioactivity. Allowing the disposal of very low levels of radioactive waste in RCRA Subtitle D landfills, and very low levels of radioactive waste containing hazardous materials in RCRA Subtitle C landfills would assure the protection of public health and safety while decreasing the regulatory burden for NRC and Agreement State licensees. In addition, the utilization of such regulated landfills is consistent with the NRC's broad performance goals listed in the proposed rulemaking. The use of a regulated landfill will also contribute to public confidence, by way of informing the public that the risks from extremely low levels of radioactive materials can be adequately controlled and the materials can be safely disposed of in this manner. The current approach which requires that solid materials containing only trivial amounts of radioactive material be disposed of at a LLW site only serves to elevate public concerns over radiation risks and contributes to public misperception or misunderstanding of the actual associated risks.

The NRC's implementation of Alternative 4 would be of enormous significance to the research-based pharmaceutical industry. For our members, the ability to utilize regulated landfills would allow for much needed flexibility, and significantly lower costs, in the management and disposal of very LLRW at their drug research facilities. When materials are no longer in use at licensed facilities, or when materials are a byproduct of licensed operations, the material is often cleaned to very low levels. But, at present, since 10 CFR Part 20 does not have a *de minimus* release level the material must be disposed in a licensed radioactive waste landfill. Few licensed waste facilities exist throughout the country; only two are currently accepting waste from out-of-compact facilities. The Barnwell, SC LLRW landfill is reducing its accepted volumes of out-of-compact waste so that in the very near future only one 10 CFR Part 61 NRC licensed facility will be available for radioactive waste disposal from out-of-compact generators.

The use of industrial landfills to safely dispose of very LLRW will benefit the public by reducing the burden for allocating burial space at scarce licensed LLW facilities. In addition the cost for disposal at a LLW facility is significantly higher than at an industrial, or hazardous waste landfill. For example, the costs for disposal at a Subtitle D landfill is approximately $1.50 to $3.70 per cubic foot, versus, a cost of approximately $300 to $315 per cubic foot at a LLW site. This represents a more than 100-fold increase in cost, and if projected across the entire industry could amount to millions of dollars of annual cost savings. The estimated cost savings for a 200 lb 55 gallon drum containing

compacted solid materials would be in excess of $2200. Such cost savings would benefit the public through lower operating costs that results in lower product costs.

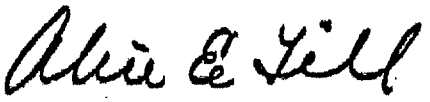
PhRMA recommends that the method of implementation of alternative 4 be simple and straightforward. For example, the NRC should develop specific radionuclide concentrations and total radionuclide activity limits per drum or container that can safely be disposed of in a Subtitle D and Subtitle C landfill. These radionuclide limits should be based upon realistic pathway analysis such that potential maximum doses to which members of the public and landfill operators are exposed are below acceptable limits.

Finally, PhRMA recommends that the NRC should select a dose limit that is consistent with international standards that are being developed for such activities. A dose limit in the range of 1 to 10 mrem/yr is safe and reasonable when compared to variances in natural background radiation exposures throughout the U.S.

PhRMA commends the NRC on publishing the proposed rule for comment. In our view it is an example of how the NRC is providing a clear risk-informed direction on controlling the disposition of solid materials.

Thank you for the opportunity to comment on this proposed rule.

Sincerely



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