

PHARMACEUTICAL MANUFACTURERS

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TDCS

PR-41

45 FR 13104

Director
Division of Waste Management
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Disposal of Low-Level Radio-
active Waste, Comments on
Preliminary Draft Regulation
10 CFR Part 61

Dear Sir:

The Pharmaceutical Manufacturers Association is a voluntary nonprofit association representing 148 manufacturers of prescription and ethically promoted drugs, medical devices and diagnostic products. Many PMA members manufacture therapeutic and diagnostic radioactive drugs as well as in vitro diagnostic products which employ radioisotopes. These products make an extremely important contribution to the diagnosis and treatment of many serious illnesses. However, their use also generates low-level radioactive waste. 1/ Because the continued availability of these very important products depends, at least in part, on the ability to dispose of the resulting waste, PMA's members are vitally interested in assuring that adequate disposal mechanisms remain available and at the lowest possible cost consistent with protection of the public health and the environment. Therefore, PMA welcomes this opportunity to comment on the Commission's draft regulation on the establishment and operation of low-level radioactive waste disposal sites which was the subject of the Notice of Availability published in the Federal Register on February 28, 1980 (45 Fed. Reg. 13104).

1/ A recent report by the Comptroller General estimates that approximately 25 percent of the volume of low-level radioactive waste generated in the United States is related to the use of radioactive isotopes to treat or diagnose illness. Report to the Congress by the Comptroller General on "The Problem of Disposing of Nuclear Low-Level Waste: Where Do We Go From Here?" March 31, 1980 at ii. PMA's members also generate a certain amount of low-level radioactive waste in connection with their manufacturing operations as well as their scientific investigations of new products.

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The proper handling of low-level radioactive waste is a complex matter involving not only what means of disposal is most appropriate for a particular kind of low-level radioactive waste but also what is the optimum means for providing each of these alternative disposal methods. PMA has the following comments on the general subject of disposal of low-level radioactive wastes.

1. PMA believes that the federal and state governments should assume a more active role in stimulating the development of additional low-level radioactive waste disposal sites. These activities should include the generation of a slate of potential wastes sites, developed from geological and other data accumulated for state and federally owned land. The Commission might also develop an overall plan for the establishment of regional sites which would correlate the needs of each area with the availability of appropriate sites and take into consideration such matters as efficient transportation routes. The Commission and state governments could also provide increased regulatory assistance to applicants including, for example, actively addressing such problems as rezoning.

2. In the Federal Register notice announcing the availability of the subject draft, the Commission indicated its interest in establishing a "de minimus level" of radioactivity in waste that was sufficiently low that the waste could be disposed of as ordinary non-radioactive trash. PMA strongly supports such a concept and believes that such an approach could, without any appreciable risk to the public health or the environment, significantly reduce the amount of low-level radioactive waste requiring regulated disposal. PMA believes this would be particularly so in the case of low level radioactive wastes generated by the health care sector. PMA also believes that this concept should be extended to allow for certain forms of low-level radioactive waste to be dealt with other than by "confinement, permanent isolation, or removal. . ." Such techniques could include storage of radioactive wastes with shorter half-lives for decay and ultimate disposal as non-radioactive trash and the incineration of low-level radioactive wastes such as scintillation vials, certain animal carcasses and certain solid wastes. These techniques could significantly reduce the volume of low-level radioactive waste generated by the health care sector requiring disposal in permanent shallow-land burial sites.

The proposed regulations relate to a particular form of disposal: land burial. PMA has the following specific comments on that particular proposal.

1. As noted in the recent GAO report cited above, the number of operational low-level radioactive waste burial sites has declined in the last five years, and there is some question as to the continued viability of the three remaining sites. PMA believes that new sites should be established as promptly as possible, not only to preclude the possibility of an acute shortage of disposal capability, but also to provide for more widely distributed sites and thereby reduce the cost of waste transportation. To this end, we urge that, wherever possible, the regulations governing the licensing of such sites be written to allow licenses to be reviewed and approved as promptly as possible, consistent with the protection of the public health and the environment.

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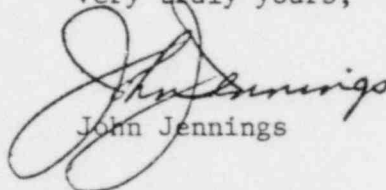
2. Although implied in the text of the current draft, PMA suggests that Subpart A Section 61.10 ("Purpose") specifically state that the regulations are intended to promote the efficient use of any newly licensed burial capacity.

3. Packaging requirements for low-level radioactive wastes should be consolidated in a single section concerning compaction, solidification of liquids, inactivation of biohazards, and similar matters. These requirements should be consistent with the requirements of the Department of Transportation and should be uniform for all Commission-licensed facilities.

4. The educational and safety criteria for employees at low-level radioactive waste disposal facilities should be those already established in 10 CFR Parts 19 and 20. Duplicative or slightly different requirements seem to PMA to be unnecessary and to create the possibility of confusion.

PMA welcomes this opportunity to comment on the draft regulations and is anxious and willing to work with the Commission and other interested parties in developing safe and economical techniques for dealing with low-level radioactive wastes.

Very truly yours,



John Jennings

JJ/cds