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Hybritech INCORPORATED
TEAM EXCELLENCE

May 24, 1994

Dr. George E. Powers
The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington DC 20555

Re: Comments on the Advanced Notice of Proposed Rulemaking regarding Disposal of Radioactive Material by Release into Sanitary Sewer Systems, *Federal Register*, Vol. 59, No. 38, February 25, 1994, pg 9146-9149.

Dear Dr. Powers:

The NRC is considering changing the existing regulations governing the disposal of radioactive materials into the sanitary sewerage system, in particular 10 CFR Part 20. The following comments are presented to state Hybritech Incorporated's concerns regarding the proposed changes. In general, any proposed change in the regulations should 1) reflect proportionately the level of risk which the proposed regulations are attempting to address and 2) use sound science based upon actual measurements. We are concerned that regulations may be implemented before the true level of risk has been accurately ascertained.

(1) Comments - Form of Material for Disposal

a) Any changes to the current regulations should clarify and define "soluble" and "biologically dispersible" materials. The biotechnology industry uses and manufacturers many biological materials, yet can only respond with difficulty to customer questions about the solubility or biological dispersibility characteristics of our products. NRC Information Notice 94-07 is really not applicable or helpful in answering questions about the many different compounds biomedical companies manufacture, because all compounds are not listed in solubility tables. Also, the analytical methods described in the Information Notice are not applicable to all compounds. An Information Notice more appropriate to the uses of biological compounds in the biomedical business sector would be helpful.

Also, the proposed regulations should expressly provide that "medical diagnostic products in an aqueous mixture" containing less than 10 microcuries of isotope with a half-life of less than 61 days can be poured directly into the sewage system. Because of the sewage system dilution effect on the isotopes, the doses to individuals from this source are far below the NRC's dose limit for members of the public.

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(2) Comments - Total Quantity of Material

b) The current regulations set total annual activity limits for the disposal of these materials into the sewer. This is all that is needed. The nature and extent and the perceived problem, as illustrated in the examples in the Federal Register notice, do not demonstrate any need to place further restrictions of the disposal of radioactive materials.

c) The petition for rulemaking submitted by the Northeast Ohio Regional Sewer District addressing the disposal of radioactive materials into the sanitary sewerage system (PRM-20-22) would have an adverse impact on the biotechnology industry and those customers using its manufactured products. Medical diagnostic kits used by clinics, hospitals, labs, and universities all over the nation, containing microcuries of activity, are most often flushed down the drain. Notification of the sewage treatment plant every time one of the kit components is released into the sanitary sewage system would require hundreds of phone calls each week. This requirement would be impossible to meet.

To summarize, adding unnecessary restrictions on the disposal of radioactive materials into the sewer, will compromise the industry's ability to work with radioactive materials. Thus, the ability of the biomedical industry to provide adequate diagnostic health care product would be impaired. Unless a significant benefit to public health from such restrictions can be demonstrated, no further burden should be imposed on the manufacturers and providers of medical diagnostic products and services.

We appreciate this opportunity to comment on the advance notice of proposed rulemaking. I am available for any further discussion on Hybritech's comments or other provisions of the notice.

Sincerely,

Steve Bursik

Steve Bursik
Assistant Radiation Safety Officer
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