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Samuel J. Chilk  
Secretary of the Commission  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

PROPOSED RULE PR 20  
45 FR 67018

Attention: Docketing and Service Branch, Re: Federal Register Vol. 45, No. 197  
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Dear Mr. Chilk:

These comments are filed on behalf of the nation's major research universities, medical schools and teaching hospitals that conduct the vast majority of the nation's biomedical research.

The Nuclear Regulatory Commission's proposed rule of October 8, 1980 (FR 45: 67018) would, if adopted with some relatively minor modifications, allow reasonable, safe, and publicly responsible solutions to the problem of the disposal of certain common wastes which contain extremely low levels of radioactivity. As the commission notes in the supplementary information, these wastes currently are subject to regulations which require unnecessary, costly, and ecologically unfeasible disposal as radioactive wastes.

We support the Commission's recognition of the problems inherent in current regulation and the solutions proposed. We have included, in our comments, suggestions for minor modifications of the rule in keeping with the intent of that rule which would allow for a total solution to the problems so accurately described in the supplementary information.

The first modification to the rule is proposed because certain misinterpretations are possible in the definition of "animal carcasses." Waste products of the animal (e.g. urine, feces, blood) even if separated from the carcass should logically be considered a part of the animal carcass and thus, if below the .05 $\mu$ C/ml or gm level, should be disposable without regard to their radioactivity. This should be clarified in the final regulations which should be extended to cover such wastes.

Second, in our judgement the rule does not go far enough toward accommodating the actual conditions commonly encountered in biomedical experimentation. It would seem eminently reasonable and consistent with the intent of the proposed regulation to exclude those disposable items of research paraphernalia (e.g. syringes, plastic and paper products, gloves) and also those derivatives of the carcass (e.g. isolated organs, homogenates, extracts), which contain radioactivity below the level of .05 $\mu$ C/gm or ml.

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To exemplify this situation further let us consider a typical experiment: the liver of a living, anesthetized dog is perfused with a carbon-14 labelled precursor using disposable surgical products most of which are minimally contaminated with radioisotope during the perfusion. The liver is removed from the animal, homogenized, extracted in a volume of 10 liters of fluid and subjected to column chromatography. One hundred liters of chromatographic fluid are obtained from which 100 1-ml samples are removed for counting in scintillation vials. It is found that samples from 80% of the chromatographic fluid falls well below the  $.05\mu\text{C}/\text{ml}$  level. Thus, 80 liters of the fluid could also be safely considered non-radioactive but under the rule as proposed only the 80 ml of scintillation samples and the animal carcass could be handled as ordinary wastes without regard to their radioactivity.

The proposed rule quite logically proposes to set a lower limit to define what should be considered "radioactive" but limits this definition in an unrealistic way. It would be logical and in keeping with the Commission's intent to extend the proposed rule so that all the experimental paraphernalia and the chromatographic materials having radioactivity below  $.05\mu\text{C}/\text{ml}$  or gm level should be excluded as well. We believe that an addition under paragraph 20.306 (a)(2) should be made as follows:

"(2) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue averaged over the weight of the entire animal and disposable experimental paraphernalia, excreta, organs and biological by-products derived from the carcass containing not more than 0.05 microcuries per gram or milliliter; provided however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans or as animal feed." (Added material underlined.)

We believe this proposed rule to be especially important and timely as it appears certain that current national radioactive waste disposal sites are likely to close in the near future. This makes it imperative that alternatives, consistent with the protection of the public health and safety, be found as soon as possible.

Sincerely,

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President

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