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STATE OF NEW YORK
DEPARTMENT OF LABOR
DIVISION OF SAFETY AND HEALTH
Radiological Health Unit
Building #12, Room 457
State Office Building Campus
Albany, NY 12240

95 OCT 17 AM 11:38 OSP

October 14, 1996

Mr. Lloyd Bolling
Office of State Programs
USNRC
Mail Stop 3 D 23
Washington, D.C. 20555

RE: Agreement States Letter SP-96-107 Draft Rulemaking Plan 10 CFR Part 35

Dear Mr. Bolling:

We agree with NRC's contractor's conclusion that the widespread medical use of capsules containing one microcurie of carbon-14 would involve no risk to public health and safety or the environment, and would provide significant medical benefits to the population.

Using a risk-based regulatory approach, there is, therefore, no need to regulate this product for its radioactive content. This is especially true since it will be regulated by the U.S. FDA as a drug. Therefore, it should be distributed as exempt, not as generally-licensed (GL).

The only reasons given by NRC for not exempting the recipients of this product from all further regulation, is that manufacturers (and initial distributors other than manufacturers) would have to obtain NRC licenses authorizing exempt distribution, and this would impose a regulatory burden on NRC.

Since it appears that there is only one manufacturer of this product at the present time, this would seem to be an inconsequential burden. The draft rulemaking plan also implies that there would be no regulatory burden resulting from a GL designation, and states that users under a GL would not have to register with NRC, as they did under the GL that used to be in Part 35 and Agreement State regulations. However, on page 11 of the plan it states that "in developing the actual rule language, consideration should be given to the issue of whether any general license conditions (such as those in the former 10 CFR 35.31, "General License for Medical Use of Certain Quantities of Byproduct Material") are appropriate." Therefore, the possibility of a regulatory burden on users of the product, and on regulatory agencies, under a GL is unknown at this time. This makes the comparison of regulatory alternatives in the plan invalid.

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SP-A-4
SP-AG-20-3

FAX: 518-457-5545

General Licenses always contain terms and conditions, since they are a means of exerting regulatory control over the users of a GL product. However, they are an ineffective regulatory tool that attempts to establish a gray area between exemption and specific licensing, and this often leads to inadequate control over hazardous radiation sources and over-regulation of trivial radiation sources.

Having concluded that this product needs no regulatory control after its distribution, it makes no sense to license end-users in any way. If decisions on whether a product should be distributed as exempt are to be based on the regulatory burden on NRC, rather than on an appropriate risk-benefit analysis, we will distort our entire regulatory system.

The product should clearly be exempt, and NRC's process re-engineering group should ensure a streamlined exempt-distribution licensing process for it.

Sincerely,

Rita Aldrich

Rita Aldrich
Principal Radiophysicist

RA:jmp

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