

DLD (SP07)

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(RE: SP-96-107)

STATE OF ILLINOIS  
DEPARTMENT OF NUCLEAR SAFETY

1035 OUTER PARK DRIVE  
SPRINGFIELD, ILLINOIS 62704

Jim Edgar  
Governor

217-785-9900  
217-782-6133 (TDD)

Thomas W. Ortziger  
Director

October 28, 1996

Paul Lohaus  
Deputy Director  
Office of State Programs  
Mail Stop 3D23  
Office of Governmental and Public Affairs  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555

96 NOV -5 PM 2:22

OSP

Re: Draft Rulemaking Plan entitled "Medical Use of Capsules Containing One Microcurie of Carbon-14."

Dear Mr. Lohaus:

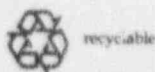
The Illinois Department of Nuclear Safety (the Department) hereby submits its comments on the referenced rulemaking plan. The proposed rulemaking represents changes to 10 CFR Part 35 to authorize the commercial distribution and use of a one micro-Curie C-14 capsule for *in-vivo* diagnostic testing for peptic ulcers under a General License.

The Department believes the best option is Alternative 2, in which the NRC would only need to issue a license for the manufacture and distribution of the C-14 capsules in accordance with 10 CFR Part 32. Distribution to persons exempt is consistent with the NRC's technical evaluation and would ensure that physicians could have access to this material without a specific or general license. The number of new manufacturer/distributor exempt distribution licenses will be far fewer than the number of licenses (or registrations) that would be issued nationwide to physicians who would potentially use this material.

Implementation of Alternative 3 would require the NRC and each of the 29 Agreement States to have costly rulemaking proceedings to add a general license to the regulations of each agency. General licenses should be used only when some level of control is desired for the product. The NRC's technical analysis indicates that no controls are warranted, so Alternative 2 is appropriate and the least costly approach.

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PDR



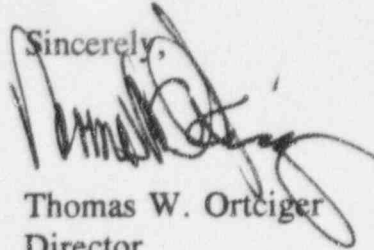
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SP-A-4

SP-AG-8

Paul Lohaus  
Page 2  
October 28, 1996

The Department appreciates the opportunity to provide its perspective on this draft rulemaking plan. If you have questions regarding these items, please contact me or Steven C. Collins at (217) 785-9948.

Sincerely,  
  
Thomas W. Ortiger  
Director

TWO:meb

cc: Jim Lynch  
State Agreements Officer

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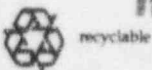
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SP-A-4

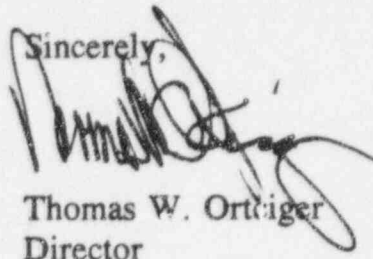
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Page 2  
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Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas W. Ortiger', is written over the typed name and title.

Thomas W. Ortiger  
Director

TWO:meb

cc: Jim Lynch  
State Agreements Officer