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TEXAS NATURAL RESOURCE CONSERVATION COMMISSION

Protecting Texas by Reducing and Preventing Pollution

March 21, 1997

Mr. Paul H. Lohaus, Deputy Director
Office of State Programs
Nuclear Regulatory Commission
Washington, D.C. 20666-0001

Re: SP-97-015 Rulemaking Plan, 10 CFR Parts 30 & 32,
C-14 Urea H. Pylori Diagnostic Test

Dear Mr. Lohaus:

We have received your request for comments regarding 10 CFR Parts 30 & 32, C-14 Urea H. Pylori Diagnostic Test. Please note that the Texas Department of Health (TDH), not the Texas Natural Resource Conservation Commission (TNRCC), has jurisdiction over this matter; therefore, TNRCC declines to comment on these rules.

Sincerely,

Minor Hibbs, P.E., Director
Industrial & Hazardous Waste Division

MH/KV/jb

cc: Mr. Richard Ratliff, TDH

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P.O. Box 13087 • Austin, Texas 78711-3087 • 512/239-1000

SP-A-4
SP-AG-27
Cross reference

Texas Department of Health

Patti J. Patterson, M.D.
Commissioner

1100 West 49th Street
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Carol S. Daniels
Deputy Commissioner for Programs

Randy P. Washington
Deputy Commissioner for Health Care Financing

Radiation Control
(512) 834-6688

Roy L. Hogan
Deputy Commissioner for Administration

March 26, 1997

Paul H. Lohaus, Deputy Director
Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C., 20555-0001

Dear Mr. Lohaus:

Staff members of the Texas Department of Health (TDH), Bureau of Radiation Control have reviewed the final rulemaking plan regarding a proposed rule which will allow the exempt distribution of capsules containing one microcurie of C-14 Urea to any person for diagnostic testing. We offer the following comments for consideration.

In response to the first question, although this will set a precedent for in vivo use of radioactive material under an exemption, the risks from use of this regulatory structure appear to be very low. Therefore, we agree with the staff recommendation of the U.S. Nuclear Regulatory Commission.

As for the second question, we are not aware of any other regulations that might be of concern if the capsules are authorized under an exempt distribution license, with a Division 1 level of compatibility for the users. However, we have forwarded the final rulemaking plan to the Texas Board of Pharmacy and to the TDH Drugs and Medical Devices Division.

We appreciate the opportunity to provide comments. If you have any questions or need further information, please contact me at (512)834-6688 or E-mail address rratliff@brc1.tdh.state.tx.us.

Sincerely,

Richard A. Ratliff, P.E., Chief
Bureau of Radiation Control

9704170287

STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION
Division of Radiological Health
Third Floor, L & C Annex
401 Church Street
Nashville, TN 37243-1532

March 13, 1997

Office of State Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Paul Lohaus, Deputy Director

Gentlemen:

We are in receipt of your March 7, 1997, All Agreement States letter (SP-97-015) concerning the **Rulemaking Plan - 10CFR Parts 30 & 32 C-14 Urea H. Pylori Diagnostic Test**. This letter requested a response to two questions concerning the rulemaking plan. We are happy to provide our response to these questions:

1. **What is the position of your State on the NRC's plan not to limit receipt of the drug to physicians, but to rely on FDA and State Boards of Pharmacy to decide who should administer the drug?**

   The State of Tennessee concurs with not limiting the use of this drug to physicians as long as the U.S. Nuclear Regulatory Commission (NRC) requires the distribution to and use by "any person who is permitted to receive and use the drug under an appropriate Federal or State law governing the distribution and use of the drug."

2. **Are there requirements in your State, that are mandated by regulations other than the radiation control program regulations, that might be of concern if the capsules are authorized under an exempt distribution license, with a Division 1 level of compatibility for the users?**

   The State of Tennessee is unaware of any requirements mandated by regulations other than radiation control program regulations that would affect the compatibility requirements for users. However, we encourage the NRC, as it proposes and accomplishes the necessary rulemaking, to recognize that an Agreement State such as Tennessee must follow a parallel course in order to make the necessary changes in its Regulations to accommodate an item of this significance. States may not be able to accomplish the rule change as expeditiously as NRC. Therefore, NRC should share the specifics of its intentions at each step of the process with the States as soon as the text of the Proposed Rule is available. This information sharing will help reduce the impact that potential delays in rule changes may have in the exempt distribution of this radioactive material to the public.

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L-4-1, IT30

L-4-1, IT32

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The Division appreciates the opportunity to address these questions on this final rulemaking plan, and looks forward to commenting on future topics.

Sincerely,

Michael H. Mobley, Director
Division of Radiological Health