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## **RULEMAKING ISSUE**

(NEGATIVE CONSENT)

February 7, 1997

SECY-97-031

**TO:** The Commissioners

**FROM:** Hugh L. Thompson, Jr.  
Acting Executive Director for Operations

**SUBJECT:** FINAL RULEMAKING PLAN: EXEMPT DISTRIBUTION AND USE OF A  
RADIOACTIVE DRUG CONTAINING ONE MICROCURIE OF CARBON  
14 UREA (PARTS 30 AND 32)

**PURPOSE:**

To inform the Commission of the staff's rulemaking plan for amending Parts 30 and 32 to allow the distribution of a radioactive drug containing one microcurie of  $^{14}\text{C}$ -urea as an exempt material for "in vivo" diagnostic testing.

**BACKGROUND:**

On October 6, 1994, the Commission docketed a petition for rulemaking (Docket No. PRM-35-12) from Tri-Med Specialties, Inc. (Tri-Med). In a letter dated August 23, 1994, Tri-Med petitioned the NRC to amend its regulations "to allow for the general licensing and/or exemption for the commercial distribution by licensed pharmaceutical manufacturers of a capsule containing one micro-Curie ( $\mu\text{Ci}$ ) of  $^{14}\text{C}$ -urea for in vivo diagnostic testing." The purpose of this diagnostic test is to detect the presence of the bacterium *Helicobacter pylori* (*H.pylori*), a cause of peptic ulcers.

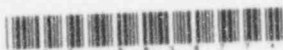
The petition for rulemaking was noticed for comment in the Federal Register on December 2, 1994. A total of 315 comment letters were received. There were 313 letters supporting the petition (mostly form letters) and 2 letters opposing the petition.

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE  
FINAL SRM IS MADE AVAILABLE

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130048 3/13/97

9702130193



DSH  
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Byproduct mat. license  
X 2-4-1 PT 32  
X Oem-u Comm

## DISCUSSION:

In accordance with the SRM-COMSECY-96-035 dated June 11, 1996, a copy of the draft rulemaking plan, recommending a general license approach, was provided to the Agreement States for review and comment. The comment period closed on October 31, 1996. Ten comment letters were received from Agreement States. Six States agreed with the staff's initial position to grant the petition by making the  $^{14}\text{C}$ -urea capsules available to any physician under a general license. However, three States - Georgia, Illinois, and New York - while agreeing that the petition should be granted, opposed the staff's recommendation and argued that the capsules should be made available as exempt material. One State, Oregon, stated that it would continue to require that any person who administers a radioactive drug be specifically licensed.

In addition, there were some comments related to the process of Agreement State involvement in NRC rulemaking that the staff believes were addressed in SECY-96-035, and, therefore, are not addressed in the memorandum to the Commission or in the final rulemaking plan.

After considering Agreement States' comments, the staff has changed its recommendation. We now recommend that manufacturers and distributors be permitted to distribute this radioactive drug as exempt material to "any person" who is permitted to receive and use the drug under the appropriate Federal or State law governing the distribution and use of the drug.

## AGREEMENT STATE COMMENTS ON DRAFT RULEMAKING PLAN:

In accordance with Management Directive 6.3, "The Rulemaking Process," the staff drafted a rulemaking plan in response to a petition for rulemaking submitted by Tri-Med Specialties, Inc. Under the draft plan, the staff would have developed a direct final rule amending 10 CFR Part 35 to permit, under a general license, any physician to administer to patients capsules containing one microcurie of C-14 as a diagnostic tool for detecting peptic ulcers caused by the *Helicobacter pylori* bacterium.

In accordance with COMSECY-96-035 dated June 11, 1996, a copy of the draft rulemaking plan was provided to the Agreement States on October 1, 1996, for a 30-day period of review and comment. Comments were received from ten Agreement States.

Six States (Kentucky, Nebraska, Colorado, Washington, Utah, and Louisiana) supported the staff's initial position to grant the petition via a general license to permit physicians who are not authorized users to receive and use capsules containing 1  $\mu\text{Ci}$  of  $^{14}\text{C}$ -urea. Kentucky indicated they already have provisions for a general license for "in vivo" use in their regulations.

One State, Oregon indicated that it would not permit administration of the capsules under a general license, but would continue to require that all physicians who administer radioactive drugs, including the C-14 capsules, be specifically licensed.

Three States, New York, Georgia and Illinois, opposed the general license approach recommended by the staff. Georgia and Illinois recommended that physicians who are not "authorized users" be permitted to receive and use capsules containing 1  $\mu\text{Ci}$  of  $^{14}\text{C}$  - urea

as exempt material. Georgia argued that their burden would be increased by distribution and use under a general license because of reports required from distributors, invoicing of physicians for general license fees, and possible amendment of all of their distribution licenses. Illinois stated that distribution of the capsules as exempt material is consistent with the NRC's technical evaluation and would ensure that physicians could have access to the capsules without a specific or general license. Illinois further stated that if the NRC were to require distribution and administration under a general license, Agreement States would need to incur the expense of modifying their regulations. Illinois seems to imply that they could avoid rulemaking if the NRC were to adopt the exemption approach. However, as Georgia correctly observed, the exemption approach would require States to make conforming changes in their regulations as well. New York stated that they agreed that the widespread medical use of the capsules would involve no risk to the public health and safety or the environment, and would provide significant medical benefits to the population. New York also stated that using a risk-based regulatory approach, there is no need to regulate the capsules for their radioactive content. Further, New York argued that a general license is an ineffective means of regulatory control in any case. New York also noted that the Food and Drug Administration will regulate the capsules as a drug.

There were further comments from the States addressing the process of Agreement State involvement in NRC rulemaking that the staff believes were addressed in SECY 96-035, and therefore are not addressed here. Copies of the comment letters are enclosed.

#### STAFF RESPONSE:

The staff initially recommended distribution of the capsules under a general license because if the capsules were to be distributed as an exempt material, manufacturers and distributors located in Agreement States would be required to obtain and maintain both an NRC and Agreement State license. Since the staff had concluded that there was no significant radiological safety or environmental risk, it did not intend that the general license would be used as a means of exercising regulatory control beyond limiting distribution to physicians. However, in light of the comments received from New York, Illinois, and Georgia, the staff changed its position from permitting distribution to any physician under a general license to permitting exempt distribution to any physician. After further consideration, the staff decided that manufacturers and distributors should be permitted to distribute this radioactive drug as exempt material to any person who is permitted to receive and use the drug under the appropriate Federal or State law governing the distribution and use of the drug. Permitting exempt distribution to "any person," rather than "any physician," would avoid the need for NRC to amend its regulations if other Federal or State authorities permit the distribution and use of the radioactive drug to persons who are not physicians. Moreover, the drug will be manufactured under a specific Part 32 license to ensure that capsules contain only one microcurie of carbon 14 and do not contain any other radioactive contaminants.

#### POLICY ISSUES:

NRC regulations specify that persons administering radioactive drugs containing byproduct material to patients or human research subjects must have specific authorization. Also,

there are no provisions in NRC regulations for the "in vivo" use of byproduct material as an exempt material. However, in light of the above, the staff is recommending the distribution of the capsules as exempt material to any person.

In addition, the Commission should note that current regulations (§ 35.6) addressing the use of byproduct material in research require licensees to meet specific provisions for the protection of human subjects. Under the staff's recommendation, the exempt distribution of the capsules for use in research involving humans subjects would not be authorized.

The Commission also should note that all of the options in the draft rulemaking plan given to the Agreement States for review in June, 1996, explicitly limited the use of the drug to physicians. Hence, the position of the Agreement States on the staff's recommendation in this final rule plan to not limit the use to physicians only, but rely on FDA and State Boards of Pharmacy regulations for determining use, is not known.

#### AGREEMENT STATE COMPATIBILITY:

Under the Atomic Energy Act, certain regulatory functions are reserved to the NRC. Among these are the distribution of exempt materials and quantities, as discussed in 10 CFR Part 150. Hence, the staff's recommended approach is a Division 4 matter of compatibility, with regard to the manufacture and distribution of the capsules (Part 32), and a Division 1 matter of compatibility with regard to possession and use (Part 30). All Agreement States will need to adopt regulations to allow any person to receive capsules containing 1  $\mu$ Ci of  $^{14}\text{C}$ -urea as an exempt material.

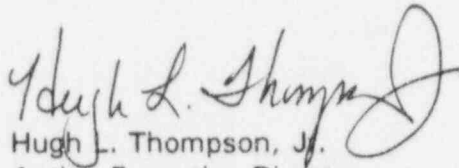
The Commission should note that under the staff's initial recommendation, Oregon (and possibly other States, since not all States commented) could have continued its current practice of requiring physicians administering radioactive drugs to humans to be specifically licensed, because the general license amendments would have been a Division 3 matter of compatibility.

#### COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer concurs that there will be no resource impacts beyond those currently budgeted. The Office of the Chief Information Officer concurs that there will be no information technology or management impacts beyond those needed for rulemaking.

RECOMMENDATION:

Unless the Commission directs otherwise within 10 days from the date of this paper, I will implement the rulemaking plan and direct the staff to begin development of a proposed rule to permit the distribution of the radioactive drug as an exempt material for distribution to any person.

  
Hugh L. Thompson, Jr.  
Acting Executive Director  
for Operations

Enclosures:

1. Final Rulemaking Plan
2. Agreement State Comment Letters

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on February 26, 1997 that the Commission, by negative consent, assents to the action proposed in this paper.

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## **RULEMAKING PLAN**

RULEMAKING PLAN FOR

EXEMPT DISTRIBUTION AND USE OF A RADIOACTIVE DRUG CONTAINING  
ONE MICROCURIE OF CARBON 14 UREA (PARTS 30 AND 32)

Lead Office: Office of Nuclear Regulatory Research

Staff Contact: S. Jones, RES/RPHEB

Concurrences: SIGNED 8/13/96  
D. Morrison, RES Date

SIGNED 9/19/96  
C. Paperiello, NMSS Date

SIGNED 9/20/96  
R. Bangart, OSP Date

(memo from Stuart Treby) 9/20/96  
W. Olmstead, OCG Date

(memo from David Meyer) 8/20/96  
D. Meyer, ADM Date

Approval:

H. L. Thompson 2-7-97  
H. L. Thompson, AEDO Date

FINAL RULEMAKING PLAN  
10 CFR PARTS 30 AND 32

EXEMPT DISTRIBUTION OF A RADIOACTIVE DRUG  
CONTAINING ONE MICROCURIE OF CARBON 14 UREA  
(PRM-35-12)

BACKGROUND

On October 6, 1994, the Commission docketed a petition for rulemaking (Docket No. PRM-35-12) from Tri-Med Specialties, Inc (Tri-Med). In a letter dated August 23, 1994, Tri-Med petitioned the NRC to amend its regulations "to allow for the general licensing and/or exemption for the commercial distribution by licensed pharmaceutical manufacturers of a capsule containing one micro-Curie ( $\mu$ Ci) of  $^{14}\text{C}$ -urea for in vivo diagnostic testing." The purpose of this diagnostic test is to detect the presence of the bacterium *Helicobacter pylori* (*H. pylori*), a cause of peptic ulcers.

"Peptic ulcer disease is a chronic inflammatory condition of the stomach and duodenum that affects as many as 10% of people in the United States at some time in their lives. The disease has relatively low mortality, but it results in substantial human suffering and high economic costs." (Source: Article included as an appendix to the petition, from JAMA, July 6, 1994-Vol 272, No. 1, "H. pylori in Peptic Ulcer Disease-NIH Consensus Conference").

In the petition dated August 23, 1994, the petitioner stated the following:

Recent medical research has found that peptic ulcers are commonly caused by a bacterium called *H. pylori*. This bacterium lives in the stomach of most ulcer sufferers. By treating ulcer patients with antibiotics, doctors can now cure most ulcer problems.

It is therefore necessary to detect the presence of *H. pylori* bacteria in ulcer patients so that the new treatment can be given appropriately. In the past, this was done by a gastroenterologist who took biopsy samples of the stomach lining at endoscopy, a procedure which was uncomfortable and expensive (\$1000).

With the new test, *H. pylori* can be detected non-invasively using a  $^{14}\text{C}$ -urea tracer.  $^{14}\text{C}$ -urea is broken down by *H. pylori* to form labeled  $\text{CO}_2$  which is expired in the breath. To do the test, a doctor asks the patient to swallow the capsule with 30 mls of water. After 15 minutes the patient blows 2 liters of breath into a collection bag (a Mylar balloon) which is mailed to a testing laboratory. If  $^{14}\text{C}$ - $\text{CO}_2$  more than twice background is present in the breath sample, then the patient must be infected with *H. pylori*.

CURRENT REGULATIONS

10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Materials," § 32.72, "Manufacture, preparation, or transfer for



commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35," provides for commercial distribution of radioactive drugs containing byproduct material for use by persons authorized pursuant to Part 35. Thus, the regulations currently would permit Part 32 licensees to commercially distribute capsules containing 1  $\mu$ Ci of  $^{14}\text{C}$ -urea to persons authorized pursuant to Part 35.

10 CFR Part 35, "Medical Use of Byproduct Material," sets forth radiation safety requirements, including requirements for the training and experience of authorized user physicians to assure the safe possession and use of radioactive drugs containing byproduct material.

Existing exemptions for use of byproduct material in § 30.14, "Exempt concentrations" and § 32.18, "Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license," do not permit the exempt transfer of byproduct material contained in any food, beverage, cosmetic, drug, or any product designed for ingestion or inhalation by, or application to, a human being.

### REGULATORY ISSUE

The regulatory issue is whether the  $^{14}\text{C}$ -urea capsules present a sufficiently small radiation risk that they can be safely distributed to and used by physicians who are not "authorized users" under 10 CFR Part 35.

### SAFETY ANALYSIS

Based on a safety analysis conducted by an NRC contractor, the staff has concluded that the human use of these capsules results in insignificant exposures as depicted below:

Scenario	Maximum Exposed Individual	Routine Exposure
Worker administering $^{14}\text{C}$ -urea breath tests	Full-time worker, 8,000 patients/yr	Less than 0.7 mrem/yr
Routine exposure of patients from $^{14}\text{C}$ -urea breath tests	Patient tests negative	0.38 mrem/capsule
	Patient tests positive	0.18 mrem/capsule
Release of 150 $\mu\text{Ci}$ of $^{14}\text{CO}_2$ into administration area	Member of public in the administration area	Less than 0.0002 mrem
Rupture of a capsule causing skin contamination of worker or patient	Skin (100 $\text{cm}^2$ ) exposed for one hour prior to washing	5.8 mrad skin dose 0.075 $\mu\text{Ci}$ skin absorption 0.029 mrem CEDE

### Pathways to the Environment

Based on an environmental report prepared by an NRC contractor, the staff concluded that the impacts associated with any releases of  $^{14}\text{C}$  to the surrounding environment are expected to be very small and the expected risks are minimal.

The earth's atmosphere contains an inventory of naturally occurring  $^{14}\text{C}$  of about 3.8 million curies (equivalent to the activity in 3.8 trillion breath tests), which is in addition to the huge inventory of about 240 million curies in the world's oceans. The  $^{14}\text{C}$  released into the atmosphere from the use of this test would mix with the global inventory and expose the public and other biotic components of the environment to  $^{14}\text{C}$  intakes from inhalation, drinking water, and all possible food pathways in the same manner as naturally occurring  $^{14}\text{C}$ . The current world inventory of naturally occurring  $^{14}\text{C}$  results in an average dose to the public of about 1.25 mrem/year, and the release of 0.6 curies of  $^{14}\text{C}$  from the total of 600,000 tests assumed to be administered annually (see the REGULATORY ANALYSIS section below) would result in an additional average annual dose of  $2 \times 10^{-7}$  mrem. This is far below the EPA reporting level of 1 mrem/year required under the Clean Air Act for routine exposures to a member of the public, or the 4 mrem/year EPA limit for public drinking water. In a total population of about 260 million people in the U.S., the collective annual dose from the breath tests would be about 0.051 person-rem. In addition, the doses from normal use of breath tests, or from any accidental release of  $^{14}\text{C}$  to the environment also are expected to be very small because the concentration of  $\text{CO}_2$  released is very low and it would mix immediately with the atmosphere.

### Collective Exposures to Members of the Public

The small doses from naturally occurring  $^{14}\text{C}$  are of little significance to human health and the environment. Potential long-term impacts from widespread releases of the long-lived  $^{14}\text{C}$  (5,730-year radiological half-life) from breath tests were concluded to be insignificant. Assuming that the testing in the U.S. would increase over a period of time to an average of a million tests per year for 50 years, the collective annual dose to the U.S. population would be about 5 person-rem over the next 50 years. This dose is very small when compared to the annual collective dose to the U.S. population from naturally occurring  $^{14}\text{C}$  of over 300,000 person-rem, and about 78,000,000 person-rem from all naturally occurring radiation. Clearly, an increase of a few person-rem will not significantly change these exposures, and thus there is no expected impact from the widespread use of the breath test on the entire U.S. population.

### COMMENTS FROM THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)

This petition was discussed with the ACMUI at the October 1995 meeting. The ACMUI indicated that it endorsed the wide availability of this diagnostic test and that the radioactive drug could be used under a general license or an exemption, whichever the NRC thought to be procedurally easier.

## COMMENTS FROM THE PUBLIC

The "Notice of receipt of petition for rulemaking" was published for public comment in the Federal Register on December 2, 1994 (59 FR 61831). A total of 315 public comment letters, 313 supporting (mostly form letters) and 2 opposing letters, were received.

The two letters opposing the petition made the following two comments:

- (1) The product should not receive an exempt status because the uncontrolled distribution and application of this product could lead to significant risk to the public, and
- (2) Medical uses should be restricted to short-lived isotopes because of disposal problems presented by long-lived isotopes.

The staff disagrees with both comments.

- (1) As shown in the "SAFETY ANALYSIS" section of this plan, the radiation dose to workers, patients, and the public is very low.
- (2) As discussed in the "Pathways to the Environment" section of this plan, the impacts associated with any releases of  $^{14}\text{C}$  to the surrounding environment are expected to be very small and the expected risks are minimal. Also, as discussed in the "Collective Exposures to Members of the Public" section of this plan, the small doses from naturally occurring  $^{14}\text{C}$  are of little significance to human health and the environment. Potential long-term impacts from widespread releases of the long-lived  $^{14}\text{C}$  (5,730-year radiological half-life) from breath tests were concluded to be insignificant.

## DRAFT RULEMAKING PLAN

In accordance with Management Directive 6.3, "The Rulemaking Process," the staff drafted a rulemaking plan in response to a petition for rulemaking submitted by Tri-Med Specialties, Inc. Three alternatives were considered in the draft rulemaking plan:

- |                 |   |
|-----------------|---|
| Alternative 1 - | Deny the petition.  |
| Alternative 2 - | Grant the petition via an exemption to permit physicians who are not "authorized users" to receive and use capsules containing 1 $\mu\text{Ci}$ of $^{14}\text{C}$ -urea.     |
| Alternative 3 - | Grant the petition via a general license to permit physicians who are not "authorized users" to receive and use capsules containing 1 $\mu\text{Ci}$ of $^{14}\text{C}$ -urea |

Under the draft plan, the staff would have developed a direct final rule amending 10 CFR Part 35 to permit, under a general license, any physician to administer to patients capsules containing one microcurie of C-14 as a diagnostic tool for detecting peptic ulcers caused by the *Helicobacter pylori* bacterium (Alternative 3).

Distribution of byproduct material as exempt material requires an NRC license, even in an Agreement State. Hence, manufacturers and distributors licensed by Agreement States would need to obtain and maintain both NRC and Agreement State licenses to distribute the  $^{14}\text{C}$  capsules as exempt material. This is not the case for byproduct material to be possessed and used under a general license. The staff viewed this potential dual licensing as an unnecessary burden with no safety benefit. Therefore, the staff did not recommend distribution to and use as exempt material in the draft rulemaking plan. In terms of public health and safety, either Alternative 2 or 3 could be adopted because the radiological risk is negligible.

In accordance with COMSECY-96-035 dated June 11, 1996, a copy of the draft rulemaking plan was provided to the Agreement States on October 1, 1996, for a 30-day period of review and comment. Comments were received from ten Agreement States.

#### AGREEMENT STATE COMMENTS ON DRAFT RULEMAKING PLAN

Six States (Kentucky, Nebraska, Colorado, Washington, Utah, and Louisiana) supported the staff's recommended approach (i.e., grant the petition, and permit physicians who are not authorized users to receive and use capsules containing 1  $\mu\text{Ci}$  of  $^{14}\text{C}$ -urea via a general license). Kentucky indicated they already have provisions for a general license for "in vivo" use in their regulations.

One State, Oregon indicated that it would not permit administration of the capsules under a general license, but would continue to require that all physicians who administer radioactive drugs, including the  $^{14}\text{C}$ -urea capsules, be specifically licensed.

Three States, New York, Georgia and Illinois, opposed the general license approach recommended by the staff. Georgia and Illinois recommended that physicians who are not "authorized users" be permitted to receive and use capsules containing 1  $\mu\text{Ci}$  of  $^{14}\text{C}$  - urea as exempt material. Georgia argued that their burden would be increased by distribution and use under a general license because of reports required from distributors, invoicing of physicians for general license fees, and possible amendment of all of their distribution licenses. Illinois stated that distribution of the capsules as exempt material is consistent with the NRC's technical evaluation and would ensure that physicians could have access to the capsules without a specific or general license. Illinois further stated that if the NRC were to require distribution and administration under a general license, Agreement States would need to incur the expense of modifying their regulations. Illinois seems to imply that they could avoid rulemaking if the NRC were to adopt the exemption approach. However, as Georgia correctly observed, the exemption approach would require States to make conforming changes in their regulations as well. New York stated that they agreed that the widespread medical use of the capsules would involve no risk to the public health and safety or the environment, and would provide significant medical benefits to the

population. New York also stated that using a risk-based regulatory approach, there is no need to regulate the capsules for their radioactive content. Further, New York argued that a general license is an ineffective means of regulatory control in any case. New York also noted that the Food and Drug Administration will regulate the capsules as a drug.

#### RECOMMENDED APPROACH

The staff has determined that the radiological risk of this drug presents such a small radiation hazard that the capsules can be treated without regard to their radioactivity. Hence, no control of the capsules is necessary for radiation safety after they are manufactured and distributed. In light of this, and in light of the comments from Illinois, and Georgia, the staff has decided not to recommend distribution and use of the  $^{14}\text{C}$ -urea capsules under a general license. Rather, the staff is now recommending that Part 30 be amended to permit the  $^{14}\text{C}$ -urea capsules to be distributed to and used by any person, without need of an NRC (or Agreement State) license, who is permitted to receive and use the drug under an appropriate Federal or State law governing the distribution and use of the drug. Thus regulation of receipt and use of the drug will be left to other Federal and State agencies with the responsibility and authority to regulate drugs (as is the case for other drugs that do not contain byproduct materials). The staff believes that permitting exempt receipt of the capsules by "any person who is permitted to receive and use the drug under an appropriate Federal or State law," rather than limiting receipt and use to physicians only will provide any controls needed for regulation of the capsules as a drug, and avoid the need for NRC to amend its regulations if other Federal or State agencies permit under their authority the distribution and use the radioactive drug to persons who are not physicians.

The staff believes that NRC should require the drug to be manufactured under a specific Part 32 license to ensure that capsules contain only one microcurie of carbon-14 and do not contain any other radioactive contaminants. Hence, conforming amendments would be made to Part 32 to provide requirements for a specific license to manufacture, process, produce, package, repackage, or transfer capsules containing one microcurie of  $^{14}\text{C}$ -urea, as a radioactive drug, to be distributed as an exempt material to any person for "in vivo" diagnostic testing. Licensees distributing the radioactive drug as an exempt material would not be relieved from other applicable Federal (e.g., FDA) or State drug manufacturing and distribution requirements.

#### PRELIMINARY REGULATORY ANALYSIS

In the letter dated August 23, 1994, the petitioner stated,

If exempted, the C-14 breath test could be done by most doctors for less than \$100 cost to the patient. This is a considerable savings over endoscopy and biopsy (\$1000).

In a letter on November 30, 1994, the petitioner stated:



... The test is 95% accurate and quite inexpensive because of its simplicity. The test would permit doctors to determine easily whether or not ulcer patients have been cured of their infection. By providing the public with an inexpensive, easily accessible diagnostic test, more individuals would be accurately diagnosed and treated for their *H. pylori* infection. This would save the United States an estimated \$500 million per annum over conventional therapy.

Tri-Med estimates annual benefits to be on the order of \$500 million/year. This assumes approximately 600,000  $^{14}\text{C}$ -urea breath tests/year, at an average cost of \$100, in lieu of performing endoscopy at an average cost of \$1000/test. It assumes that the lower cost and greater availability of an unregulated breath test would result in a complete substitution for endoscopy. Tri-Med's benefit analysis provides a measure of the total benefits associated with the test and does not focus on the incremental benefits of administering the test pursuant to 10 CFR 35.100 regulation (status quo) versus releasing the test to all physicians (NRC licensed and non licensed alike). Implicit in Tri-Med's estimated annual benefits is the presumption that none of these  $^{14}\text{C}$  tests and corresponding savings would accrue if the petition were denied. In reality, under the status quo, the test would be available and administered by physicians or clinics holding a license under NRC's Part 35. Further, Tri-Med's estimate did not allow for the substitution of other non-invasive tests (e.g., serological test for IgG antibodies to *H. pylori* antigens) for both endoscopy and  $^{14}\text{C}$ -urea tests. In addition, wire service articles dated September 19, 1996, stated that the FDA has approved a non-radiological diagnostic breath test using  $^{13}\text{C}$  for detecting the presence of *H. pylori* infections.

The staff's benefit analysis focuses on the incremental benefits of granting relief based on the petition. The analysis looks solely at changes relative to the base case or status quo. In this analysis, the comparison is between regulated and unregulated  $^{14}\text{C}$ -urea breath tests, not unregulated  $^{14}\text{C}$ -urea breath tests and endoscopies or other non-invasive tests. For the purposes of this regulatory analysis, the staff assumes that the same number of breath tests (i.e., 600,000 tests) will be administered regardless of the level of NRC regulatory control. This view is predicated on the belief that each physician's primary motivation is to provide the best possible care to his or her patients. If the breath test is judged preferable to endoscopy, or other procedure, any physician not authorized to use the test will refer his or her patient to authorized users who could perform the test under existing NRC regulations. This appears fully consistent with standard medical practice, whereby patients are referred routinely to laboratories and specialists for a wide array of tests and procedures.

In the NRC's analysis, the benefits of adopting the petition accrue as a result of reduced patient cost and reduced health care cost resulting from the elimination of the need for referrals from a physician who is not an authorized user (e.g., gastrointestinal specialist). There would also be some regulatory savings because the NRC would not have to expend resources reviewing new applications for specific medical use licenses. However, the NRC savings would be small because the staff expects that few physicians who are not authorized users would apply for a specific NRC license for use of this one product.

The staff's benefit calculation is based on the assumption that a significant portion of the 600,000 patients would receive the  $^{14}\text{C}$  breath test from physicians who are not

authorized users (e.g., gastrointestinal specialists) instead of authorized users (e.g., nuclear medicine specialists). The actual savings would be dependent on the number of tests ultimately administered by physicians who are not authorized users, thereby eliminating the need for a referral.

The annual savings could be as high as approximately \$20 million if there was a complete shift of the administration of the tests from physicians who are authorized users (i.e., base case) to physicians who are not authorized users.

The basis for this estimate is as follows.

Assuming adoption of the petition eliminates the need for 600,000 referrals, patient savings in averted travel expenses (transportation and personal time incurred with medical referral) would be:

Assuming round trip of 20 miles @ \$0.25/mile, and personal time of 0.5/hours/trip valued at \$25.00/hour

$600,000 \text{ trips/year} \times (20 \text{ miles/trip} \times \$0.25/\text{mile} + 0.5 \text{ hours/trip} \times \$25.00/\text{hour}) = \$10.5 \text{ million/year}$

Health Care Savings in averted administrative expenses (administrative costs incurred with medical referral) would be:

$600,000 \text{ patients/year} \times \$19.00/\text{patient} = \$11.4 \text{ million/year}$

Assuming \$19.00 (administrative cost/patient) as the differential between the cost of an office visit to a general family practice physician by an established patient (\$45.90), and the cost to a new patient (\$64.90 per visit) for completion of new patient paperwork, reviewing health history, maintaining medical records, etc. The patient who is referred to an authorized user (e.g., nuclear medicine specialist) for the  $^{14}\text{C}$ -urea breath test would most likely be a new patient for the authorized user.

Total Savings:

$\$10.5 \text{ million/year} + \$11.4 \text{ million/year} = \$21.9 \text{ million/year}$

Alternatively, if only 200,000 or 400,000 of the 600,000 tests were performed by a physician who is not an authorized user, the annual cost savings would be approximately \$7 million/year and \$15 million/year, respectively.

## COMPARISON OF ALTERNATIVES

### Alternative 1 - Deny the Petition

This alternative would maintain the status quo. Only physicians who are authorized users under Part 35 would be allowed to possess and administer the  $^{14}\text{C}$ -urea test. Any physician could apply to become an authorized user. However, the NRC expects few

physicians would apply for a Part 35 license for the sole purpose of using such capsules because of the requirement for training and experience and the associated costs of obtaining and maintaining a Part 35 license. Alternatively, physicians who are not authorized users could refer their patients to physicians who are authorized users to undergo the diagnostic test, but this would add expense, inconvenience, and delay to an otherwise straight-forward procedure.

Alternative 2 - Grant the petition to permit the  $^{14}\text{C}$ -urea capsules to be distributed to and used by any person, without need of an NRC (or Agreement State) license, who is permitted to receive and use the drug under an appropriate Federal or State law governing the distribution and use of the drug.

Parts 30 and 32 would be amended to permit the manufacture and distribution of capsules containing one microcurie of  $^{14}\text{C}$ -urea as an exempt material to any person. The staff has determined that the radioactive component of this drug presents a minimal radiation risk and, therefore, regulatory control of the human use of capsules for radiation safety is not necessary.

Alternative 3 - Grant the petition via a general license to permit physicians who are not "authorized users" to receive and use capsules containing  $1\ \mu\text{Ci}$  of  $^{14}\text{C}$ -urea for in vivo diagnostic testing.

This alternative would permit any physician to receive and use capsules containing  $1\ \mu\text{Ci}$   $^{14}\text{C}$ -urea for human use under a general license. The health and safety concerns for this alternative are the same as Alternative 2. However, if this alternative were adopted, there could be a burden to those Agreement States and Agreement State licensees in States that assess licensing or registration fees for general license holders.

### RECOMMENDED COURSE OF ACTION

The staff recommends proceeding with a rulemaking amending Parts 30 and 32 in conformance with Alternative 2 for the following reasons:

- Health and Safety

Based upon the analysis of the radiological impacts discussed above, there do not appear to be any safety or technical reasons why the capsules, breath test materials, counting fluids and vials, and urine from patients cannot be treated without regard to their radioactivity.

- Avoided Costs

Under Alternative 1, physicians who are not authorized users would have to refer patients to authorized users to undergo the diagnostic test. These referrals and

attendant expense could be avoided under either Alternatives 2 or Alternative 3. However, compared with Alternative 3, Alternative 2 appears to be less burden for Agreement States and their licensees.

#### AGREEMENT STATE IMPLEMENTATION

Rules pertaining to the distribution of products to persons exempt from NRC requirements fall into the class of regulatory functions reserved to the NRC pursuant to the AEA and delineated in 10 CFR Part 150. Therefore, the staff's recommended amendment to Part 32 pertaining to the manufacture and distribution of capsules containing 1  $\mu$ Ci of  $^{14}\text{C}$  - urea for "in vivo" diagnostic testing by persons exempt from licensing would be a Division 4 matter of compatibility. The amendment to Part 30 would be a Division 1 matter of compatibility since Agreement States would need to conform their regulations to recognize that possession and use of  $^{14}\text{C}$ -urea capsules is exempt from licensing. States (e.g., Oregon, and possibly others) would not be able to require that physicians administering radioactive drugs to humans be specifically or generally licensed.

#### OGC LEGAL SUFFICIENCY ANALYSIS DEMONSTRATING THAT NO KNOWN BASIS EXISTS FOR LEGAL OBJECTION

OGC has reviewed the rulemaking plan and has not identified any environmental issues that would present significant difficulties in pursuing the proposed rule.

Since this rulemaking would address the resolution of PRM-35-12, the staff will need to ensure that appropriate procedural actions are taken to close the actions associated with that petition. These actions include specifically granting or denying the petition for rulemaking, either in the Federal Register notice associated with the rulemaking or in a separate Federal Register notice, and informing the petitioner of the Commission's decision. The detailed procedures for responding to the rulemaking petition are contained in Part 11 of the Regulations Handbook (NUREG/BR-0053, Rev. 3).

#### ASSESSMENT OF LIKELY IMPACTS ON NRC AND AGREEMENT STATE LICENSEES

This rulemaking would not result in any additional regulatory burden to NRC medical use licensees. Authorized users would continue to be authorized to receive and use this product for medical use.

#### SUPPORTING DOCUMENTS

A regulatory analysis, an environmental assessment, and an OMB information collection approval package will be provided for this rulemaking.

#### RESOURCES

Resources to complete and implement this rule are included in the current budget.

#### LEAD OFFICE STAFF AND STAFF FROM SUPPORTING OFFICES

##### Staff-Level Working Group

RES - Sam Jones

NMSS - Donna-Beth Howe

OGC - Marjorie Rothschild

OSP - Lloyd Bolling

ADM - Mike Lesar

##### Concurring Official

Bill M. Morris

Donald A. Cool

Stuart A. Treby

Richard L. Bangart

David L. Meyer

#### STEERING GROUPS/WORKING GROUP

There is no need for a steering group for this rulemaking. The Working Group is identified above.

#### ENHANCED PUBLIC PARTICIPATION

This rulemaking will be placed on the electronic bulletin board at FedWorld and will also be published in the Federal Register.

#### EDO OR COMMISSION ISSUANCE

Because the amendment involves a policy issue (i.e., the capsules would be distributed to any person who would be exempt from NRC regulations), it is recommended that the Commission issue the rule.

#### SCHEDULE

Proposed Rule:

Weeks from the date EDO/Comm approves  
the Rulemaking plan

Send proposed rule to office for  
concurrence

2 weeks



Send proposed rule to EDO	6 weeks
Send proposed rule to Commission	8 weeks
Receive Commission approval	10 weeks
Publish in the <u>Federal Register</u> for a 75-day public comment period; and submit information collection approval package to OMB	13 weeks

## **AGREEMENT STATE COMMENT LETTERS**

DLD (SP07)

RL32

PHL

SLD

~~WRC~~

(RE: SP-96-107)

STATE OF ILLINOIS  
DEPARTMENT OF NUCLEAR SAFETY  
103 HORTER PARK DRIVE  
SPRINGFIELD, ILLINOIS 62704

Jim Edgar  
Governor

Thomas W. Ortiger  
Director

217-786-1333 (TDD)  
217-786-2611 (V)

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

NSP

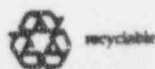
Re: Draft Rulemaking Plan entitled "Medical Use of Capsules Containing One Microcurie of Carbon-14."

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.

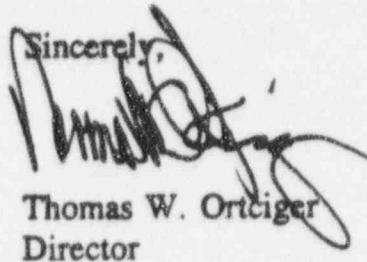


SP-A-4

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. Ortigier  
Director

TWO:meb

cc: Jim Lynch  
State Agreements Officer

From: Spell, Bill <bills@deq.state.la.us>  
To: Frazee, Terry <tcf0303@hub.doh.wa.gov>  
Date: 10/23/96 12:12pm  
Subject: RE: SP-96-107

We support your position on this matter completely. To the final paragraph, I would add, "It wouldn't hurt to involve the regulated community early in the rulemaking process. The result will be easier for those regulated to accept." We tried this in developing the well-logging regulations, and it worked well. The regulated community felt their views were adequately addressed.

CULater.....

Bill

-----  
From: Frazee, Terry  
To: lab  
Cc: phl; wpo{dhec4005.columbia34.autryvr}; rratliff; rquillin; ray.d.paris; paul.merges; mmoble; jvolpe; dm0020; dflater; 103075.1375; egrad.bsinclai; kxr01@albnydh2.bitnet; rrknybcrh; teff100w; davidson; ccmall.kwangler; robert.schell; hallisey; bill\_s; k\_allen; tom\_hill; hwl.ebailey; gdwa23a; rkelley  
Subject: SP-96-107  
Date: Tuesday, October 22, 1996 5:23PM

To: Lloyd Bolling, OSP, NRC

This is our response to your request for comments on the "Draft Rulemaking Plan for 10 CFR 35" received by FAX on October 1, 1996. Specifically, the draft plan, in "Pre-decisional" form, concerns "Medical Use of Capsules Containing One Microcurie of Carbon-14" and is based on PRM-35-12.

We have two summary comments: 1) we support alternative 3 which would establish a "general license" for use of this low risk diagnostic test; and 2) we believe "parallel rulemaking" with the CRCPD should have been considered rather than jumping immediately to a "direct final rule".

A general license similar to that for "in vitro" testing (10 CFR 31.11) is considered appropriate for this rulemaking. This includes a registration process. This will provide a method of "authorization" for a wide range of physician-users; will be low cost (where a registration fee is required); allows the manufacturers of the capsule to be fully licensed by an Agreement States if located therein; and provides the regulatory agency with some knowledge of usage within its jurisdiction plus a database for later use in evaluating a further relaxation in the degree of control over this new product (for instance, eliminating the registration requirement).

We agree with the choice of "Division 3" for Agreement State compatibility although a corresponding assessment should also be provided to relate it to the new classification expected under the implementation procedures for the Final Policy Statement on the Adequacy and Compatibility of Agreement State Programs.

Finally, while we support speedy resolution of PRMs and agency initiated rulemaking efforts, we have never supported the level of secrecy that NRC has employed in the various phases of its rulemaking effort. In the initial phase, it allows NRC staff to fixate on a solution of their own devising, and to establish themselves in a narrowly defined position which they then feel must be defended. At the final phase, it results in the Commission receiving a "decision" paper that tries to reflect the scope of an issue and the varying and often complex positions of other interested parties as interpreted by NRC





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

PHL  
SLO  
LAB

96 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.


SP-A-4  
SP-AE-20-3

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,

A handwritten signature in cursive script, appearing to read "Rita Aldrich".

Rita Aldrich  
Principal Radiophysicist

RA:jmp

From: Frazee, Terry <tcf0303@hub.doh.wa.gov>  
To: WND1.WNP9(lab)  
Date: 10/22/96 8:23pm  
Subject: SP-96-107

To: Lloyd Bolling, OSP, NRC

This is our response to your request for comments on the "Draft Rulemaking Plan for 10 CFR 35" received by FAX on October 1, 1996. Specifically, the draft plan, in "Pre-decisional" form, concerns "Medical Use of Capsules Containing One Microcurie of Carbon-14" and is based on PRM-35-12.

We have two summary comments: 1) we support alternative 3 which would establish a "general license" for use of this low risk diagnostic test; and 2) we believe "parallel rulemaking" with the CRCPD should have been considered rather than jumping immediately to a "direct final rule".

A general license similar to that for "in vitro" testing (10 CFR 31.11) is considered appropriate for this rulemaking. This includes a registration process. This will provide a method of "authorization" for a wide range of physician-users; will be low cost (where a registration fee is required); allows the manufacturers of the capsule to be fully licensed by an Agreement States if located therein; and provides the regulatory agency with some knowledge of usage within its jurisdiction plus a database for later use in evaluating a further relaxation in the degree of control over this new product (for instance, eliminating the registration requirement).

We agree with the choice of "Division 3" for Agreement State compatibility although a corresponding assessment should also be provided to relate it to the new classification expected under the implementation procedures for the Final Policy Statement on the Adequacy and Compatibility of Agreement State Programs.

Finally, while we support speedy resolution of PRMs and agency initiated rulemaking efforts, we have never supported the level of secrecy that NRC has employed in the various phases of its rulemaking effort. In the initial phase, it allows NRC staff to fixate on a solution of their own devising, and to establish themselves in a narrowly defined position which they then feel must be defended. At the final phase, it results in the Commission receiving a "decision" paper that tries to reflect the scope of an issue and the varying and often complex positions of other interested parties as interpreted by NRC staff alone. We believe rulemaking should be an open process throughout its course and, no matter what your rationalization, the use of "Pre-decisional" documents is viewed as "secrecy" and simply feeds the public's, the licensees' and, alas, some Agreement States' distrust of the NRC's actions. We recommend that the Commission seek independent views on issues brought before it and that the NRC staff publish (and/or actively distribute to a wide audience) issues and alternatives, responses and draft rule language, and proposed final rule language for public comment, each in turn, to be sure there is adequate public involvement. One step toward this goal is working with CRCPD in the proposed "parallel rulemaking" process.

If you have any questions about this e-mail:

\*\*\*\*\*

This message from: Terry Frazee

Quick ways to reach me:

Voice = 360-753-3461

FAX = 360-753-1496

Also, visit our Home Page at

--> <http://www.doh.wa.gov/ehp/rp>

From: Craig Jones <cjones@deq.state.ut.us>  
To: WND1.WNP9(lab)  
Date: 10/24/96 12:17pm  
Subject: Comments/SP-96-107

Hi Lloyd,

A number of staff within the Division of Radiation Control have reviewed the draft rulemaking plan for medical use of capsules containing carbon-14. We support option 3 as outlined in the pre-decisional rulemaking plan (docket No. PRM-35-12). Thanks for the early opportunity to comment.

CC: udl.internet3("BSINCLAI@deq.state.ut.us")

From: Joyce Davidson <davidson@nrcdec.nrc.state.ne.us>  
To: WND1.WNP9(lab)  
Date: 10/17/96 12:32pm  
Subject: Draft Rulemaking Plan (10 CFR Part 35)

Hi Lloyd:

Brian Hearty asked that I send you an E-Mail saying that we favor Alternative 3 and concur that NRC should proceed directly to final rule.

Should you have any questions regarding this E-mail message please contact Brian or me at my E-mail address or call (402) 471-2168.

Have a nice day!!!

Joyce



From: JAKE JACOBI <wejacobi@smtpgate.dphe.state.co.us>  
To: WND1.WNP9(lab)  
Date: 10/21/96 6:56pm  
Subject: Draft Rule for C-14 capsules

Greetings Lloyd

The proposed rule re "Medical Use of Capusles Containing one Microcurie of Carbon-14", PRM-35-12, appears appropriate, and should go forward.

If you have any questions, please call.  
Jake

CC: ud1.internet3("rquillin@smtpgate.dphe.state.co.us"...



CABINET FOR HEALTH SERVICES  
COMMONWEALTH OF KENTUCKY  
FRANKFORT 40621-0001

PHL  
SLO  
HAB

DEPARTMENT FOR PUBLIC HEALTH

October 4, 1990

LLOYD BOLLING  
U S NUCLEAR REGULATORY COMMISSION  
OFFICE OF STATE PROGRAMS  
WASHINGTON D C 20555

Dear Mr. Bolling:

Kentucky has no opposition to allowing use of carbon-14 in one microcurie amounts under a general license as proposed in the rulemaking plan for 10 CFR Part 35 (SP-96-107).

We already have provisions for a general license for in vivo use in our regulations under 902 KAR 100:050. This regulation would be required to be amended to include carbon-14 as an authorized material. In the interim of revising the regulation, we would allow the use under a general license as a licensing policy. A form is required to be submitted for this license; however, only a signature is required. No additional information is required to be submitted, thus a review is not required. A fee is charged, on an annual basis, for a general license.

Sincerely,

Vicki D. Jeffs, Supervisor  
Radioactive Materials Unit

96 OCT 10 PM 3:31

OSI

SP-A-4  
SP-A6-11

October 29, 1996

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

Dear Mr. Bolling:

This is in response to All Agreement States Letter SP-96-107 Draft Rule Making Plan 10 CFR Part 35. We support Alternative 2. Although this places an initial regulatory burden on the NRC, it reduces the burden on physicians, distributors and the Agreement States. This should not place any undue regulatory burden on Agreement State licensees wishing to distribute the one microcurie carbon 14 capsules. The capsules can be directly distributed by the manufacturer to physicians. As there does not appear to be any radiological impacts on patients, workers or the public, the analyzing laboratory would not need to be licensed. Agreement States are always amending their rules as a matter of compatibility. Therefore, we consider the regulatory burden to be minimal to include the exemption during rulemaking.

We do not agree with Alternative 3, granting a general license. Our regulatory burden is increased accepting Alternative 3. Although Alternative 3 may not cause a regulatory burden on NRC, it will impose greater paperwork cost to Georgia licensees, the distributors of the capsules, and will result in general license fees being assessed to physicians.

The specific regulatory burden on Georgia licensees would be as follows:

1. We would continue to require the distributor to send us a report quarterly as required under the rules for distribution under a general license.
2. We will be required to invoice the physicians for the general licensee fee, which would not be charged to a person receiving under an exempt distribution license.
3. We may have to amend all of our distribution licenses to allow for distribution of this product under a general license. This will add an additional cost to our licensees for the amendment fee that would not be caused by exempt distribution.

We recommend proceeding with a direct final rule amending Part 35 in conformance with Alternative 2.

Sincerely

Thomas E. Hill, Manager  
Radioactive Materials Program

TEH/klc

From: Martha G Dibblee <Martha\_G\_DIBBLEE@ohdmail.hr.state.or.us>  
To: WND1.WNP9(lab)  
Date: 12/6/96 4:05pm  
Subject: OSP FILE CODE: SP-A-4 (Petition for rulemaking for C-14 capsules for helicobacter)

Hello, Lloyd,

Oregon doesn't intend to authorize in vivo diagnostic procedures under general license. Persons who use this diagnostic procedure must be specifically authorized under 35.100 or equivalent regulations (uptake, dilution, & excretion). Oregon authorizes only in vitro procedures by general license.

Thank you for the transcript of the NRC Briefing that we all attended on Wednesday 13 November. I was glad to see the NUREG finally published.

Martha

CC: ud1.internet3("Christie\_L\_HINKLE@ohdmail.hr.state....