

Secretary U.S. Nuclear Regulatory Commission
Attention: Docketing and Service Branch
Washington, D.C. 20555
RE Docket No. PRM-35-12

DOCKETED
USNRC

DOCKET NUMBER

PETITION RULE PRM 35-12

(59FR61831)

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Dear Secretary:

I have read the Tri-Med Specialties, Inc. Filing of Petition for Rulemaking and am writing to comment on this petition. I am a patient who has been investigated for *Helicobacter pylori* and I feel that the new, low dose C14-Urea Breath Test would be very beneficial.

The following are a few reasons why I believe the 14C-Urea Breath Test should be distributed under a general license and/or exempt status.

The test offers very accurate diagnosis of *H. pylori*. The recent N.I.H. consensus conference stated that the urea breath test (both ¹⁴C and ¹³C) was the best non-invasive test to confirm eradication of *H. pylori* after therapy. In many studies around the world, researchers have shown the C14-Urea Breath Test to be one of the most accurate tests developed to date. Since *H. pylori* is a common disease with a considerable death rate due to ulcer complications, the presence of an accurate test such as the C14-Urea Breath Test would be beneficial to the community.

Appropriate use of the test may be a major part in reducing stomach cancer. In recent publications, much evidence has been printed showing that *H. pylori* is a major risk factor for stomach cancer. Also, the World Health Organization recently put *H. pylori* in the same group of cancer causing chemicals as tobacco smoking. According to studies on *H. pylori*, approximately one patient out of every hundred will develop stomach cancer. If the breath test was free of restrictive licensing requirements, most physicians would be able to detect *H. pylori* accurately and easily, allowing them to treat the infection and reduce the risk of stomach cancer.

The test is rapid, simple and convenient. The C14-Urea Breath Test can be performed in about 15 minutes with no need for expensive new equipment. The patient only has to take a capsule then blow up a balloon, which is mailed to a testing lab for analysis. Because the test is so fast, labor time is also reduced. Since the test is so safe, current regulations would waste valuable resources by restricting the usage of such a safe test. Furthermore, all alternatives to the breath test take more time, are more complicated, and are far less convenient, leading me to believe that the availability of this test should not be limited.

Sincerely,

Signature: Gene Lupo

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