

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

DOCKET NUMBER
PETITION RULE PRM 35-12
(59FR61831)

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OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Dear Secretary,

I have read the Tri-Med Specialties, Inc. Filing of Petition for Rulemaking and am writing to comment on this petition. As a member of the public, I am interested in bringing down the cost of health care in the United States of America, and I believe that new cost-effective diagnostic tests are one way to do this. I am aware that useful devices such as smoke detectors contain safe amounts of radioactivity and are already available for general use. 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 is very safe for patients. I understand that the amount of radiation exposure from the breath test is less than one day of normal background radiation, or about the same as the cosmic rays during one hour of airline flight. This is a very small risk, considering the benefits of the test. In comparison to other medical sources, a mammogram is about 300 breath tests and a chest x-ray is about 30 breath tests.

If the breath test is distributed under a general license, the test will be very inexpensive for patients. By minimizing the amount of radioactivity and devising very simple procedures, Tri-Med has been able to make the C14 breath test inexpensive. If physicians performing the test are required to have an N.R.C. licensed facility, the test will be more expensive and less available to the public. As a result, fewer people would benefit from the test and the public would find it necessary to choose less accurate alternatives.

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: Frances Renne
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