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May 13, 1991

Mr. Samuel J. Chilk
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Attention: Docketing and Service Branch

Reference: Federal Register Notice
Vol. 56 No. 71 Page 14870
Revision of Fee Schedules;
100% Fee Recovery

Dear Mr. Chilk:

These comments are submitted on behalf of the U.S. Council for Energy Awareness Committee on Radionuclides and Radiopharmaceutical (the "Committee"). The Committee is comprised of representatives of major manufacturers of radiopharmaceuticals, radioactive sources and research radionuclides used in the USA for medical, therapeutic and diagnostics applications, and for biomedical, environmental protection and industrial, research and development.

The proposed fee schedule applies to manufacturers supporting biomedical activities. These functions should be exempt from the proposed rule to be compatible with the Congressional mandate to cap health care costs.

It is clear that the proposed fee schedule will severely affect manufacturers' operations. There has not been adequate time to make a detailed analysis of this proposed rule. We request that the NRC grant a 30-day extension to the comment period to allow manufacturers to collect financial impact estimates and to develop alternative proposals.

1. We agree with the intent of the NRC to ensure that annual charges reasonably reflect the cost of NRC services to licensees.

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2. We agree that non-profit educational institutions should be exempt from increased fees. The costs of NRC services to these institutions should be shared by all non-exempt licensees because all licensees benefit from the training and education these institutions provide.

3. There is concern that the proposed rule places an excessive financial burden on medical licensees, life science research and development, and on manufacturers who directly support biomedical activities.

   a. There are a hundred or more small licensees, who provide services to hospitals, that will not be able to afford the proposed increases.

   b. Many nuclear medical services utilize supplies and equipment that require the services of a chain of licensees. A typical flow might be: Radionuclide Production, Radiopharmaceutical Manufacturer, Distributor, Nuclear Pharmacy, Nuclear Medicine Department, each step involving a separate licensee and each licensee adding incremental costs due to proposed increases in fees.

   c. This chain of licensees is greatly extended when research and development to improve services and to advance life sciences are included.

   d. Consequently, the proposed rule will significantly impact health care costs.

   e. This is incompatible with the Congressional mandate to cap health care costs.

   f. All licensees and the public at large benefit from a affordable health care.

   We therefore, recommend that medical and life science research licensees, and manufacturers who support biomedical activities be exempt from increases in fees.

4. In the proposed rule, the costs of the Advisory Committee on Reactor Safeguards has been included in calculating the overhead for establishing a professional hourly rate charged to all non-exempt licensee. This cost is not relevant to non-reactor licensees and should not be included in the general overhead.

5. We agree with the proposal to add the costs of 10CFR20 updates and the Incident Response Center to power reactor costs.

   a. Although they apply to other licensees, they would exist for power reactors even if they were not used to support other licensees.

b. They essentially duplicate similar services provided by most states for non-power reactor licensees.

c. Non-fuel cycle licensees have too little radioactive material to require the services of a federal emergency response center.

6. Certain broad-scope non-reactor licensees are required to maintain a radiological contingency plan. The cost of this function is significant for both the licensee and the NRC. However, the need for these contingency plans for non-reactor facilities has only been demonstrated in facilities where uranium hexafloride is handled. Other licensees do not process enough radioactive material to deliver substantial off-site doses in a maximum credible accident scenario. (In past assessments the NRC has determined correctly that the maximum credible scenario for these facilities will involve a major building fire. However, these assessments did not take into consideration that a major fire would create thermal buoyancy which would reduce maximum off-site dose by more than an order of magnitude.) Consequently, we recommend that the part of the NRC costs due to non-reactor licensees' emergency contingency plans be allocated to facilities where uranium hexafloride is handled.

7. It is inevitable that some of the NRC costs are due to regulations which duplicate those of other federal agencies. Of particular concern are duplicate FDA requirements on medical practice and duplicate EPA regulations on emission standards and mixed waste. We urge that federal agencies take action to remove these duplications. In these cases, we believe the NRC should not regulate medical practice and the EPA should not regulate by-product material emissions and waste.

8. We are concerned that the Congressional mandate to the NRC for 100% fee recovery might be misconstrued as a release from Congressional controls. We urge that the NRC should maintain a sensitivity to the concerns and requirements of Congress. This is of particular importance with regard to public perception and the need of the NRC to both understand public concerns and take a more pro-active role in educating the public to appreciate the benefits to society from the activities that the NRC regulates.

9. We are also very concerned with the NRC proposed rule becoming effective upon publication. As holders of a number of licenses, we would want to know the final cost prior to making a decision on whether to continue to hold the licenses or to discontinue them on the basis of economic impracticality. If the NRC responds favorably to our comments, we will continue to hold the various licenses, however, if there is little or no change, we would probably be forced to terminate specific licenses. We, therefore,

strongly recommend that the effective date of the final rule be at least one month from the date of publication in the Federal Register.

The U.S. Council for Energy Awareness Committee on Radionuclides and Radiopharmaceutical, appreciates the opportunity to comment on the proposed rule. If you have any questions concerning our comments, require additional information, or would like to meet with representatives of the Committee, please contact Felix M. Killar, Jr , Director, Nuclear Programs, U.S. Council for Energy Awareness at 202-293-0770.

Sincerely,

Marvin S. Fertel