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PETITION RULE PRM 170-3
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December 8, 1992

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Secretary Samuel J. Chilk
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attn: Docketing and Service Branch
Docket No. PRM-170-3

11/10/92 10:10 AM
DOCKETING & SERVICE
BRANCH

Ref: Nuclear Regulatory Commission; American College of
Nuclear Physicians and Society of Nuclear Medicine;
Request for Comment on a Petition for Rulemaking;
Federal Register, Vol. 57, No. 198, October 13, 1992,
pp. 46818-46819

Dear Mr. Chilk:

The American Hospital Association (AHA), on behalf of its nearly 5,300 member hospitals, welcomes this opportunity to comment on the American College of Nuclear Physicians and Society of Nuclear Medicine (ACNP/SNM) petition for rulemaking on licensing, inspection, and annual fees charged to licensees.

AHA expressed a number of its concerns about the licensing fees to the NRC on May 29, 1992, when the NRC announced its decision to raise the FY 1992 annual fees for materials users by approximately 50 percent over FY 1991 annual fees¹. We continue to believe the increases are tied to unnecessary and overly expensive regulation. Given the fact that a significant number of medical licenses have been terminated, the AHA would anticipate a corresponding reduction in NRC staff and activity devoted to this category of licenses, keeping fees at a manageable growth rate rather than spreading a larger budget over fewer entities.

AHA supports two of ACNP/SNM's proposals, that the NRC provide an exemption from the fees for medical service licensees similar to the exemption provided for educational institutions, and that the NRC allow licensees a greater voice in its decision-making process in developing new programs where the development costs could have substantial economic impacts. AHA agrees that NRC should be required to demonstrate the cost and benefit of regulations and programs.

¹Approximately 20 percent of this increase is attributed to the growth in the NRC budget for regulating materials users; another major component of the increase is the fact that licensees have dropped out, with the result that the program costs to be recovered must spread across fewer licensees.

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Exemption for Health Care Facilities

NRC should exempt health care facilities from licensing. The Office of Management and Budget Circular No. A-25, which implements the Independent Offices Appropriations Act, indicates that an agency may make exceptions from general policy for recipients engaged in activity designed for the public safety, health and welfare.² AHA believes it would be consistent with this guideline for the NRC to cap current fees for all hospital users of nuclear materials. As with nonprofit educational institutions, health care organizations have a limited ability to pass the costs of fees on to others. Medicare, a major payor for nuclear medicine procedures, does not take licensing cost increases into account in calculating reimbursement. Health care organizations, as well as educational institutions (as NRC stated in its July 10, 1991, final rule), provide an important benefit to "the public at large and should not be discouraged."

NRC Decision-making Process

AHA believes that the 20-percent increase in the NRC materials licensee budget from FY91 to FY92 was due primarily to the implementation of the quality assurance programs, or "medical improvement program" which the NRC has required over the last year. The NRC could decrease the amount of the budget attributable to materials licensees by scaling back this quality assurance program to focus on those procedures and treatments that have the highest risk for causing harm to patients.

In January 1990, the NRC published a proposed rule on a basic quality assurance program. On April 11, 1990, AHA submitted a letter to the Commission describing our concerns with the proposed quality assurance program. The key point of that letter was that the NRC had not demonstrated that there was a valid need for regulation. We now reiterate our earlier recommendations that the NRC evaluate the program in terms of:

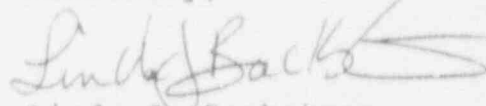
- . the actual administrative and cost burdens imposed;
- . whether the reporting requirements result in the identification of a greater number of serious and preventable quality problems than previously existing regulations;
- . whether the identified problems represent a breakdown in the institutional quality assurance program or simple human error; and
- . whether the program has reduced the improper administration of radiopharmaceuticals.

² Federal Register, July 10, 1991, p. 31474

Clearly, the cost burdens imposed by these rules have been significant and will be even higher in the next few years; the costs are now being passed on to materials users. To AHA's knowledge, the program has not been successful in identifying patterns in quality problems or reducing mishaps. AHA recommends that NRC: coordinate its quality assurance program with the Centers for Disease Control to identify the highest risk activities; and significantly scale back its program by targeting only the activities thus identified thereby reducing its current budget.

The lesson learned from the implementation of this program has been that a more vigorous review of NRC programs and regulations before they are implemented would have avoided an unnecessary and expensive program. Future programs should be demonstrated to be necessary, and documentation should be provided that would show the positive benefits and anticipated costs of the program for both the agency and regulated entities.

Sincerely,

A handwritten signature in dark ink, appearing to read "Linda J. Backstrom", with a stylized flourish at the end.

Linda J. Backstrom
Assistant Radiation Safety
Officer