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The Society
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December 14, 1992

Secretary Samuel J. Chilk
U.S. Nuclear Regulatory Commission
Washington, DC 20555
Attn: Docketing and Service BranchRE: 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 Secretary Chilk:

These comments are submitted on behalf of the over 14,000 members of the American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM). The ACNP and SNM support the NRC's efforts to address the petition for rulemaking docketed on February 28, 1992, PRM-170-3, and are confident any disagreement can be resolved with the approval of both parties. As the petition states, the NRC has addressed some inequities in the user fee schedule imposed by 10 CFR 170 and 171, however, these changes fail to prevent the extreme adverse effects felt by the medical community.

ACNP and SNM have continually expressed concern over the structure and application of the user fee schedule and the decision to increase the fees for facilities, materials licenses, and other regulatory services above and beyond the fiscal year 1991 annual fees. We continue to believe that the current fee inequities unfairly burden medical licensees and threaten the continuation of many nuclear medicine practices, as indicated by the cancellation of medical licenses since the fee schedule was implemented.

EXEMPTION GUIDELINES:

According to NRC regulations, nonprofit educational institutions are exempt from part 170 licensing and inspection fees, based on the reasoning that "many of these entities have limited ability to pass regulatory costs to their clients, assessing fees could affect the ability of these organizations to continue to perform the licensed services. In addition, these organizations provide broad national support and benefits to the education and health care fields".¹

¹ 56 Federal Register 31487.

ACNP and SNM do not disagree with the NRC's reasoning in regards to exempting certain licensees from the user fee structure and understand that according to the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) the NRC must recover 100% of its fees for each fiscal year. We do contend however that the majority of medical licensees that are currently outside of the exemption for nonprofit institutions, in fact meet the criteria that NRC has used to justify this exemption. The NRC cites information from the Office of Management and Budget Circular No. A-25, the implementing governmentwide policy guidance for the Independent Offices Appropriations Act (IOAA), Item 5.(b).(4) that an exception may be made from the payment of the full fee by a state, local government or nonprofit group when it would be in the interest of the program.²

Medical licensees meet the exemption criteria above based on the following:

- A substantial number of nuclear medicine physicians practice in hospitals because many of the hospitals are required to provide nuclear medicine services under requirements for Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation. Nuclear medicine physicians are dependent on the reimbursement from a federal agency, although the Health Care Financing Administration (HCFA) does not recognize the costs of other regulatory agencies in processing reimbursement requests. This forces the NRC licensee to find other methods of recovering the user fees. This often results in higher costs for radiopharmaceuticals used in hospitals, higher overhead costs that the hospital must pay out of pocket, and the termination of NRC licenses due to excessive user fees.
- The assessment of these fees correlates directly with the ability to deliver necessary health care services, especially in rural areas, to the people who rely on these services the most. In a time when the government is attempting to control health care costs, and limiting reimbursement for services rendered, the NRC has attached expensive user fees, driving up the costs for medical licensees beyond that of any other medical specialty. The indirect result of these user fees make it difficult for hospitals who conduct vital clinical testing, research and treatment to continue such practice. The NRC has the potential of destroying a valuable medical tool due to this artificial market pressure.

According to the NRC approximately 2,000 licensees have requested that their license be terminated or combined since the FY 1991 final rule was adopted, of which the majority can be attributed to the additional user fee costs.³ Unfortunately, the drastic reduction in the number of medical licensees, contained within the initial 2,000 terminations, directly affects the health and well being of those dependent on that medical licensee. The excessive fees also affect the hospitals ability to continue to perform the licensed service because of the additional strain of maintaining a nuclear medicine department. If nuclear medicine

² 56 Federal Register 31474.

³ 57 Federal Register 32697

becomes a loss-leader for health care organizations, rural hospitals that are already struggling under today's system are put under even more pressure to bring in revenue from other areas to cover the cost of the nuclear medicine department or risk shutting down all together. Surely in the eyes of the NRC, limiting health care arbitrarily was not an original intention of the user fee structure.

Nuclear medicine departments in both for-profit and not-for-profit in hospitals are essential to the complete delivery of health care services and the assurance of the well being of the American public. If for no other reason than an interest in making it possible for hospitals to provide the necessary health care benefits, the NRC should find hospital and medical facilities exempt under the same guidelines it uses for non-profit licensees.

INDIVIDUALIZED EXEMPTION CRITERIA:

ACNP/SNM continue to maintain the position presented in the petition filed on February 10, 1992 with the NRC, that exemption criteria should uniformly consider each licensee's particular circumstances. Medical licensees as well as others should not be denied the same consideration now given to power reactor licensees. It would also seem that granting uniform consideration would lower the administrative costs attributed to the investigation and consideration of each individual licensee.

In developing the uniform exemption criteria, one of the major factors the NRC should consider is the ability to pass on costs related to the user fees. (i.e. HCFA's denial to reimburse for user fees incurred as a practice expense after 1989, the last data year used in developing the technical component for the Resource Based Relative Value Scale (RBRVS).)

SLIDING SCALES FOR SMALL ENTITIES:

The equation for determining the amount of fees allocated to each licensee under part 170 and 171, again fail to take into account the method of collection by the licensee in order to cover those fees. Although the NRC has taken steps to alleviate the burden on small businesses by providing a cap on fees of not more than \$1,800, this does not eliminate the burdensome fees on medical licensees whose institutions don't qualify for this exemption. The criteria on which the NRC currently bases its fee structure revolve around the revenue of the entire institution, rather than just that of the licensee. It is difficult to see the rationale behind the NRC using the revenues of an entire hospital in evaluating which licensees qualify for the small entity exemption. Basing a fee schedule on the non-nuclear revenue of the hospital forces the hospital to allocate funds outside of the scope of the license in order to compensate for funds that are not raised through the activities of the licensee.

ACNP/SNM would like the NRC to reconsider basing its fees on the smaller nuclear medicine department entity rather than relying on the licensee's annual receipts. By focusing on the smaller entity within the license, many licensees would qualify for the small business exemptions and would pay fees based on the actual revenue generated under the license. This would grant the larger entity the freedom to maintain and potentially upgrade the capabilities of its nuclear medicine department and continue to provide the best patient care available.

Also, when determining the amount of fees to be charged for licensees, ACNP/SNM feel it is inappropriate to charge a flat fee for all small entity licenses. This system generates unfair charges for licensees that may be on the threshold of the exemption criteria. Rather than enforcing a flat fee capped at \$1,800, the NRC should adopt a sliding scale based on the revenue of the authorized users. This is the only way to fairly assess fees and create a definitive payment structure that allows licensees to pay what they can afford. It is obviously in the best interest of the NRC and the nation as a whole to encourage the continuation and development of nuclear medicine and quality patient care that results from such services, rather than placing obstacles in the way.

REGULATORY ACCOUNTABILITY

In accordance with 10 CFR 170 which designates a fee to cover services rendered beyond what is covered in the annual fee (10 CFR 171), ACNP/SNM is concerned that regulations will be promulgated in an effort to justify budgetary estimates within the various departments at NRC. Over the past two years ACNP/SNM has witnessed a considerable decline in the number of materials licensees regulated by the NRC. Yet the budget figures for the NRC continue to rise rather than decline in conjunction with licensee terminations. ACNP/SNM seeks a greater role in the development of new regulatory programs that could have a substantial impact on the economic status of a licensee or result in the termination of that license.

The easiest way to structure such a program is to implement the backfit rule for materials licensees. This rule as stated under 10 CFR 50.109, forces the NRC to justify additions or regulatory changes that could be costly to power reactor licensees. There is no reason why this same criteria should not apply to regulatory programs dealing with material licensees.

A perfect example of the implementation of a backfit rule applies to the NRC's Quality Management Rule. This regulation will result in significant fees assessed to medical materials licensees. Although ACNP/SNM have stated their displeasure with the implementation of the Quality Management Rule, we will not reiterate our complaints. It is however important to note that the Office of Management and Budget (OMB) reviewed the Quality Management Rule as part of the Paperwork Reduction Act before it was implemented, and found that the NRC had not justified the benefits of this program versus the obvious costs to the licensee. In a letter from OMB dated January 24, 1992, OMB stated concerns about the NRC's lack of justification for the benefits of the Quality Management Rule and gave NRC a series of issues to examine before passing a final rule (Appendix 1). In a final letter from OMB dated June 26, 1992, OMB, after careful review of all the material pertaining to the Final Quality Management Rule, determined that the

NRC had not established justification that this rule would solve the problem it was aimed at (Appendix 2). James MacRae, Acting Administrator and Deputy Administrator of the Office of Information and Regulatory Affairs states, "OMB believes that the reporting and recordkeeping requirements in this ICR have little if any practical utility. Therefore, the significant burdens imposed on the regulated community are unreasonable..." Despite this rejection from the Office of Management and Budget, the NRC continued on with the implementation of the Quality Management Rule, undeterred.

It is situations like this that justify the development of a modified backfit rule that would require the NRC to justify the costs and benefits of regulatory programs and be accountable for those decisions. Especially in a time when the government is attempting to cut back costs and evaluate the benefits of additional regulations, the NRC should heed the advice of other agencies and the professional community in evaluating the cost of future regulations. As was stated during a November 9, 1992 NRC public meeting, the Quality Management Rule will result in additional fees beyond the already high fees that are part of 10 CFR 171 (Appendix 3).

CONCLUSION:

"With regard to health and safety responsibility and national defense requirements of the Atomic Energy Act and the Energy Reorganization Act, there is insufficient evidence supporting the commenters' claims of significant adverse impacts. However, implementation of the rule will be monitored and action taken as necessary if there are clear health and safety problems that arise"

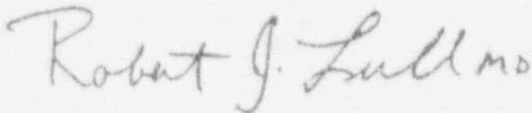
Based on this statement made in the July 10, 1991 Federal Register ACNP/SNM assumes that NRC will make the necessary changes in the allocation of fees for materials licensees. Over the past two years a significant amount of materials licensees have chosen to terminate their licenses because NRC user fees made it uneconomical to continue to practice. This has made a significant impact on the availability of medical services afforded to the public. If the NRC is truly interested in maintaining quality and a high standard of care in the area of nuclear medicine services, it will recognize the deteriorating effects the user fees are having on the medical community. Although we understand that the NRC is mandated by the Congress to recover 100% of its annual budget and seeks to find fair and equitable fee assessments for all licensees, the medical community presents an unusual situation that requires the NRC to reevaluate its fee structure for that group.

* 56 Federal Register 31476

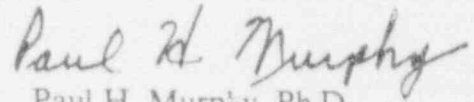
ACNP/SNM urge the Nuclear Regulatory Commission to reexamine the role the medical community plays in society, and the ability for that community to respond to NRC user fees. It would be a great loss to this nation if the specialty of nuclear medicine deteriorated as a result of user fees that were misapplied by the Nuclear Regulatory Commission.

ACNP/SNM appreciate the opportunity to provide additional comments on our petition. If you have any questions regarding our comments, please contact Kristen Morris, Director of Government Relations, in our Washington Office at (202) 429-5120.

Sincerely,



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President
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