



DOCKET NUMBER
PETITION RULE PRM 170-3
(57 FR 46818)

(54)

MOUNT CARMEL MEDICAL CENTER

703 WEST STATE STREET COLUMBUS, OHIO 43222 614-251-0000-8 P6:54

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USNRC
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Secretary, U.S. Nuclear Regulatory Commission
Washington, DC 20555

ATT: Docketing and Service Branch
RE: Docket Number: PRM-170-3

We, the administration of Mount Carmel Medical Center, a medical institution, agree with the petition submitted to the NRC by the American College of Nuclear Physicians and the Society of Nuclear Medicine.

We agree the NRC should:

1. Provide an exemption for a medical service similar to the exemption provided for a non-profit institution.
2. Provide for uniform consideration of each licensee's particular circumstances. For example, the petitioners suggest that the NRC develop a simple template for structuring exemption requests.
3. Adopt a sliding scale of fees depending on the size of an entity and not just providing a fee cap for those entities who qualify as "small entities."
4. Allow licensees a greater voice in the NRC's decision-making process for developing new programs where the development costs could have substantial economic impacts. The petitioners believe that if the NRC proposes to develop a regulation which is not necessary for the adequate protection of the public health and safety, the NRC should be required to show that the regulations would result in a substantial increase in safety and that the benefits exceed the costs.

This comment is submitted to the commission on October 31, 1992.

Lawrence Fulmer MD

Lawrence Fulmer, M.D.
Medical Director, Nuclear Medicine

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Proposed Rules

Federal Register

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Tuesday, October 13, 1992

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

[Docket No. PRM-170-3]

American College of Nuclear Physicians and Society of Nuclear Medicine; Request for Comment on a Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; request for comment.

SUMMARY: The Nuclear Regulatory Commission (NRC) requests public comment on a petition for rulemaking filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The petition has been docketed by the Commission and has been assigned Docket No. PRM-170-3. The petitioners request that the NRC amend its regulations governing the licensing, inspection, and annual fees charged to its licensees because of the recent increase in these fees.

DATES: Submit comments by December 14, 1992. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Attention: Docketing and Service Branch.

For a copy of the petition, write: Rules Review Section, Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-492-7758 or Toll Free: 800-368-5642.

FOR FURTHER INFORMATION CONTACT: C. James Holloway, Office of the Controller, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: 301-492-4301.

SUPPLEMENTARY INFORMATION:

Background

On February 18, 1992, the Nuclear Regulatory Commission (NRC) received a petition for rulemaking submitted by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The petition was docketed as PRM-170-3 on February 28, 1992. The petitioners requested that the NRC amend 10 CFR Parts 170 and 171 concerning fees for facilities, materials licenses, and other regulatory service under the Atomic Energy Act of 1954, as amended. The petitioners requested this amendment to mitigate the substantial adverse impacts experienced by its members because of the recent increase in the NRC's license and annual fees.

In the Federal Register of May 12, 1992 (57 FR 20211), the NRC published a notice of receipt of this petition. In that document, the NRC announced that it would consider the issues raised by the petitioners after the rulemaking action necessary to establish the license and annual fees for FY 1992 was completed. The NRC indicated that it would consider the petitioners' concerns within the context of the review and evaluation of the fee program for FY 1993 which will be conducted as part of the NRC's continued implementation of Public Law 101-508. As part of the review concerning the fee program for FY 1993 and succeeding years, the NRC now requests public comment on the issues raised in PRM-170-3.

Fee Schedule Rulemaking

On April 12, 1991 (56 FR 14870), the NRC published proposed amendments to its regulations governing the licensing, inspection, and annual fees charged to its licensees. The proposed revisions were necessary to implement Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508), passed by the Congress on November 5, 1990, which mandates that the NRC recover approximately 100 percent of its budget authority in Fiscal Year 1991, and the four succeeding fiscal years, through the assessment of license, inspection, and annual fees. The proposed rule affected all applicants, licensees, and holders of certificates of compliance, registrants of sealed sources and devices and approvals of quality assurance programs. The proposed revisions, when adopted, would increase fees substantially for those entities currently

subject to fees. Other entities previously exempt from fees would become subject to the fees in these proposed schedules.

In response to this rule, the American College of Nuclear Physicians and the Society of Nuclear Medicine submitted comments on May 13, 1991. The petitioners' comments discussed the issue of assessing user fees to medical licensees and what the petitioners believed would be the potential damage that could occur as a result.

On July 10, 1991 (56 FR 31472), the NRC published the final rule implementing the requirements of Public Law 101-508. This final rule, which became effective on August 9, 1991, revised the fees charged to NRC licensees for FY 1991. With regard to the impact on NRC licensees, the Commission concluded that "to eliminate the adverse effects, the annual fees would have to be eliminated or reduced. Because Public Law 101-508 requires the NRC to assess and collect approximately 100 percent of its budget authority, a reduction in the fees assessed for one class of licensee would require a corresponding increase in the fees assessed for another class. Therefore, the impact noted cannot be eliminated without creating adverse effects for other licensees. For this reason, consideration has been given only to the effects that NRC is required to consider by law (i.e., the Atomic Energy Act, the Energy Reorganization Act, and the Regulatory Flexibility Act)."

The NRC reconciled the mandate of Public Law 101-508 with the requirements of the Regulatory Flexibility Act to consider the impacts of its regulations on small entities by establishing a maximum small-entity fee for a licensee who qualifies as a small entity. In an effort to further mitigate the impact of the annual fee on a small entity, the NRC published a proposed rule (57 FR 847; January 9, 1992) to establish a lower-tier, annual fee for a small-entity licensee that has relatively low annual gross receipts or supporting populations. The final rule adopting this proposed amendment was published on April 17, 1992 (57 FR 13625), and became effective on May 18, 1992.

The proposed rule necessary to establish the license and annual fees for FY 1992 was published on April 29, 1992 (57 FR 18095). The comment period for this action closed on May 29, 1992. The

NRC published the final rule establishing the FY 1992 licensing and annual fees on July 23, 1992 (57 FR 32691). The provisions of the final rule became effective August 24, 1992. Now that the fee cycle for FY 1992 is complete, the NRC is beginning its evaluation of the fee program for FY 1993. As part of that action, the NRC is soliciting public comment on the petition submitted by the American College of Nuclear Physicians and the Society of Nuclear Medicine (PRM-170-3).

The Petitioners

The American College of Nuclear Physicians (ACNP) is an organization of 1,450 members, including 1,100 physicians who are qualified to use radioactive byproduct materials for diagnostic and therapeutic medical purposes. The Society of Nuclear Medicine (SNM) is an association of 11,300 members with about 4,750 physicians who practice nuclear medicine. Members of the ACNP/SNM who use byproduct radioactive materials must be licensed by either the NRC or an Agreement State.

Adverse Impacts on the Petitioners

The petitioners have submitted this petition for rulemaking because they believe they have been adversely affected by the current license fee rule. The petitioners state that the fees imposed by the NRC unfairly burden medical licensees and threaten the continuation of many nuclear medicine practices. The petitioners state that fees for its member physicians have increased by up to 1400% and that this constitutes a substantial, additional expense for the practice of nuclear medicine. The petitioners state that since the fee increase over 400 nuclear medicine licensees have either terminated or applied to terminate their NRC licenses.

The petitioners state that, in addition to the direct fee increase, they are also affected indirectly. Increased user fees are also reflected in the cost of radiopharmaceuticals due to the increase in fees for radiopharmaceutical manufacturers and radiopharmacy licenses. The petitioners state that this additional fee is passed on to the practitioner, thereby raising their operating costs.

The petitioners state that substantial numbers of their members practice in hospitals because these hospitals are required to provide nuclear medicine services. The petitioners also state that about 40% of all fees for nuclear medicine service are covered by Medicare. However, according to the petitioners, Medicare reimbursement

limits do not consider NRC license fee increases. Thus, the recent substantial increases in NRC license fees have had to be absorbed into the non-reimbursable costs of nuclear medicine practices.

The petitioners believe that the recent amendments to the license fee rule have had an inequitable impact on them. They believe they are in a unique situation and should be given special consideration similar to what the NRC has given to other limited categories of licensees. For example, non-profit educational institutions retained their fee exemption under part 170 and were given an additional exemption under part 171 in recognition of their unique contributions to society. The petitioners believe that their unique contributions to society should also warrant an exemption.

The petitioners believe that the NRC discounted the unique societal benefits provided by members of the ACNP/SNM, their unique circumstances regarding reimbursement, and the hardships imposed on individual physicians by the fee rules. In addition, the petitioners assert that fees for the remaining NRC medical licensees may rise substantially again under the present fee recovery policy because several hundred medical licensees have terminated their licenses. The petitioners believe the increases could further extend the competitive disadvantage in favor of alternative modalities and identical services in Agreement States. The petitioners indicate that the fee increase may also impact medical practice resulting in limiting patient choices in some geographical areas.

The Petitioner's Proposals

The petitioners request that parts 170 and 171 be amended to minimize the inequitable impacts of NRC-imposed fees on the practice of nuclear medicine. The petitioners request that the NRC amend its regulations in 10 CFR parts 170 and 171 to recognize factors the petitioners contend the NRC considers for other licensees. The petitioners' specific suggestions include the following items. The NRC should—

1. Provide an exemption for a medical service similar to the exemption provided for a non-profit institution.
2. Provide for uniform consideration of each licensee's particular circumstances. For example, the petitioners suggest that the NRC develop a simple template for structuring exemption requests.
3. Adopt a sliding scale of fees depending on the size of an entity and not just providing a fee cap for those entities who qualify as "small entities."

4. Allow licensees a greater voice in the NRC's decision-making process for developing new programs where the development costs could have substantial economic impacts. The petitioners believe that if the NRC proposes to develop a regulation which is not necessary for the adequate protection of the public health and safety, the NRC should be required to show that the regulation would result in a substantial increase in safety and that the benefits exceed the costs.

Petitioners' Conclusion

The petitioners have identified several significant adverse impacts which they assert have affected its members as a result of the recent increases in NRC license and annual fees. The petitioners believe that the fees imposed by the NRC unfairly burden medical licensees and threaten the continuation of many nuclear medicine practices, and request that the NRC consider its proposals to amend the rules in parts 170 and 171.

Dated at Rockville, Maryland, this 6th day of October 1992.

For the Nuclear Regulatory Commission,

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 92-24747 Filed 10-9-92; 8:45 am]

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