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American College of Nuclear Physicians (202) 429-5120 Fax (202) 223-4579 The Society of Nuclear Medicine

August 29, 1994

The Honorable Ivan Selin
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Selin:

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM)[1] are writing to encourage the U.S. Nuclear Regulatory Commission (NRC) to initiate steps to implement the backfit rule provisions in 10 CFR 50.109 for all materials licensees. We feel that these additional provisions will provide the regulated community and the public with assurances that new regulations or changes in regulatory positions directly affecting materials licensees will be implemented only if the benefits both substantially increase safety and outweigh the costs. Because the costs and impacts of unnecessary and burdensome regulations affect material licensees at least as significantly as they affect reactor licensees, these backfit criteria are especially applicable to materials licensees. This is especially true now as medical facilities face an era of cost-cutting mandated by society. Under these conditions we would expect the NRC to make all efforts to reduce the regulatory burden placed upon its materials licensees.

Previous requests by ACNP and SNM regarding other issues have briefly mentioned that the implementation of the backfit rule would be beneficial in reducing the regulatory burden.[2] Unfortunately, these requests have been denied.[3] Further investigation of the regulatory structure governing materials licensees have reassured ACNP and SNM members that this policy change is justified. In this detailed letter we will outline the burdensome impacts from with the existing structure and a justification for implementation of backfit provisions. Thank you in advance for your consideration of the enclosed analysis.

I. Existing Regulatory Structure

Rulemaking affecting NRC materials licensees is currently governed by several federal regulations and an internal NRC policy. Principal regulations are the Administrative Procedure Act (APA) (5 U.S.C. 500 *et seq.*) the Paperwork Reduction Act (PRA) of 1980 (44 U.S.C. 3501 *et seq.*) and the Regulatory Flexibility Act (RFA) of 1980 (5 U.S.C. 601 *et seq.*). As part of its implementation of the APA, NRC has found it useful to conduct a detailed cost benefit analysis to provide a reasoned basis for most rulemaking efforts. In addition, the power licensees regulated by NRC are also protected by the Backfit Rule. These provisions are in place impart, to reduce and document the burden placed on the licensee.

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[1]The American College of Nuclear Physicians and the Society of Nuclear Medicine represent over 15,000 nuclear medicine physicians, nuclear pharmacists, nuclear scientists, and nuclear medicine technologists, involved in the delivery of essential health care.

[2]ACNP/SNM User Fee Petition (57 FR 20211)

[3]NRC denial of ACNP/SNM User Fee Petition (59 FR 12555)

The Paperwork Reduction Act of 1980 takes statutory steps needed to reduce and minimize the burden government paperwork imposes on the public. This public law ensures that paperwork required from the public is first checked to see whether the information requested is (1) Needed; (2) Not duplicative; and (3) Collected efficiently. Through information collection requests filed for public comment with the Office of Management and Budget, the Nuclear Regulatory Commission details cost estimates for the paperwork accompanying a rulemaking. These estimates include a time and monetary burden placed on the licensee to show compliance with an NRC regulation. ACNP and SNM have exercised their right to comment on information collection requests submitted by NRC but have been disappointed in the outcome. Very rarely do comments submitted to OMB result in a change to NRC's original paperwork request.

The Regulatory Flexibility Act of 1980 (P.L. 96-354) is another piece of legislation designed to reduce the regulatory burden on small licensees like many of NRC's materials licensees. This piece of legislation set up extensive guidelines for agencies, like the NRC, to use in reducing the burden on licensees. In the legislation it is clear that the congressional intent was to reduce this burden:

> *"It is the purpose of this Act to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration."*[4]

The RFA is carried out primarily through the guidelines set out in Executive Order 12866, signed by President Clinton on September 30, 1993, entitled Regulatory Planning and Review.[5] In the initial Statement of Regulatory Philosophy and Principles it states, "In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider."

The Executive Order goes on to outline a series of criteria that an agency must try and meet when proposing a rulemaking that will affect a significant number of small entities. (See Appendix 1) Upon publishing the criteria in the Federal Register and reviewing public comments the agency must then publish a final regulatory flexibility analysis. In this analysis, the agency must include (1) a summary of the needs and objectives for the rule; (2) a summary of the issues raised by the public comments, an assessment of those comments, and any changes in the proposed rule; and (3) a description of each of the significant alternatives to the rule consistent with the stated objectives of applicable statutes and designed to minimize any significant economic impact of the rule on small entities which was considered by the agency, as well as a statement of the reasons why each alternative was rejected. This Executive Order requires a detailed account of an agency's cost - benefit assessments and provides confidence to the public that an agency is doing everything possible to reduce regulatory compliance costs.

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[4]Section 2 (b) of P.L. 96-354, 94 Stat. 1165

[5]58 Federal Register 51735

The NRC also prepares cost-benefit analyses to justify any new regulatory requirements. This cost benefit is often prepared by outside contractors together with NRC staff.

In addition to the above mentioned protection for materials licensees, proposed rules affecting nuclear power licensees are also subject to the backfit rule. By definition a backfit is defined by NRC as "to require a modification or addition to systems, structures, components, or design of a facility, or the design, approval, or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position."[6] To justify this backfit, however, NRC must show that the backfit will result "in a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection."[7] This rule is currently only applied to nuclear power licensees.

All of the above cited rules and regulations are in place to guarantee that federal agencies, like the Nuclear Regulatory Commission, take the necessary steps to reduce the regulatory burden without compromising the health and safety of the public. These provisions are especially important to those involved with the use of byproduct material for medical purposes. With billing constraints placed on Nuclear Medicine by other federal agencies like the Health Care Financing Administration, any increase in regulatory compliance costs can have an adverse effect on the ability of a physician to deliver quality clinical service to his/her patients.

II. Inadequacies Within the Existing Regulatory Structure

Research done by the ACNP and SNM, shows a disturbing trend, by the NRC to use its authority as an independent agency to impose requirements that can not be justified by a cost-benefit analysis for new and existing regulations. This section describes some of the problems surrounding the existing structure.

Under the Paperwork Reduction Act of 1980, any agency conducting or sponsoring the collection of information must first meet with the approval of the Office of Management and Budget. The role of the OMB is to make sure that the agency reduces to the extent practicable the regulatory burden placed on the persons who will provide the information to the agency. When this law was originally passed in the Congress, there was concern over the intrusion into the regulatory jurisdiction of independent federal agencies. To resolve this concern the following section was added to the Act:

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[6] 10 CFR 50.109 (a)(1)

[7] 10 CFR 50.109(a)(3)

> *"Any disapproval by the Director, in whole or in part, of a proposed information collection request of an independent regulatory agency, or an exercise of authority under section 3504 (h) or 3509 concerning such an agency, may be voided, if the agency by a majority vote of its members overrides the Director's disapproval or exercise of authority. The agency shall certify each override to the Director (of OMB), shall explain the reasons for exercising the override authority. Where the override concerns an information collection request, the Director shall without further delay assign a control number to such request, and such override shall be valid for a period of three years."*[8]

Under definition, the Nuclear Regulatory Commission qualifies as an independent agency. In the area of materials licensees, we cite specifically one example where the NRC exercised its authority in the above section.

On December 24, 1991, the Nuclear Regulatory Commission (NRC) submitted to the Office of Management and Budget (OMB) an information collection request (ICR) for review under the Paperwork Reduction Act. This ICR would authorize the NRC to require those medical practitioners engaged in therapies using radioactive material to maintain records as evidence of a quality management program, submit copies of the quality management programs to the NRC, and report to the NRC when a misadministration occurs. During the review OMB contacted NRC for further clarification of several issues due to their concern that the burden imposed on the regulated community by these reporting and record keeping requirements was not justified by the limited practical utility of the requirements. After further review of the ICR's supporting statement, the OMB concluded that the limited practical utility of the requirements imposed on the regulated community do not justify their burden, and disapproved the ICR.

Under 44 U.S.C. § 3507 (c) the NRC exercised its right to overrule the OMB and continued with the implementation of the paperwork requirements. In comments to the OMB, ACNP and SNM calculated the cost of this rule to medicine alone at approximately $381 million the first year and approximately $ 189 million each subsequent year. In addition, despite the efforts of NRC, there is still substantial confusion regarding what is exactly required by this rule. Members of ACNP and SNM, despite following the regulatory guidance issued by NRC, are receiving notices that the quality management plans that they have submitted are inadequate.

ACNP and SNM members are concerned that, although a third party (OMB) does review the paperwork requirements of the NRC, that third party has no authority to enforce its decisions.

There are similar loopholes in the Regulatory Flexibility Act (RFA) that allow NRC to sidestep many requirements for rulemaking. The RFA requires significant documentation of the validity, cost, and actual benefit that a rule provides. However, according to 5 U.S.C. § 605 (b), the regulatory analysis required by the RFA, "shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities." ACNP and SNM members, for the most part, work in Nuclear Medicine and Radiology departments located within a hospital. The NRC defines small entities based on the gross receipts of the hospital, which is the licensee, and not the Nuclear Medicine department. The current size requirements are based on whether a facility has a net gross receipt of over $3.5 million or a private practicing physician who has a net gross receipt of over $1 million.

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[8] 44 U.S.C. § 3507(c)

Unfortunately, the budgets for many Nuclear Medicine and Radiology departments must include the fees associated with the NRC. Currently, hospitals recover most of their costs from the Nuclear Medicine department through reimbursement from insurance carriers, including Medicare and Medicaid. These insurance carriers do not cover the costs of capital equipment and fees associated with the Nuclear Regulatory Commission. In addition, there is no reimbursable avenue for the amount of time spent complying with NRC regulations. These costs that are incurred must come out of the hospital's direct operating budget. In today's era of health care reform we are seeing hospitals closing down their Nuclear Medicine departments because the cost of business is too great. Although the hospital, overall, has a stable operating budget, they can no longer afford to take the losses incurred by offering Nuclear Medicine services. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) also used to require a hospital provide Nuclear Medicine services in order to receive accreditation. This is no longer the case. Many facilities are choosing to operate in conjunction with several other hospitals and share Nuclear Medicine services. This unfortunately results in limited access to Nuclear Medicine procedures for the patient.

These current NRC size standards, as they are applied for medical licensees consider the overall receipts of the licensee hospital, rather than receipts associated with the operation of the Nuclear Medicine service. This presents an inaccurate portrayal of the impact that NRC regulations have on hospitals. Under the provisions of the RFA, the NRC must only provide a statement that the rulemaking will not affect a large number of small entities. What the NRC does not realize is that most of the rulemakings have a significant economic affect on the Nuclear Medicine department and the total funds that must be allocated for that department. Again, this is an example of where the NRC avoids the significant reporting requirements of the RFA, and forgoes additional cost-benefit analyses that portray an accurate representation of the effect that the rulemaking may have.

As an alternative to the above requirements of the PRA and RFA, the NRC does include a cost-benefit analysis. Moreover, these such analyses have been categorized as inaccurate even by reactor licensees. The above requirements don't clearly address the concerns which are the most important. Much of their cost benefit analysis is often vague and significantly under estimates the cost-impact of rulemakings. Two examples of this are the costs of the Quality Management Rule, which NRC stated, would have no cost impact on licensees. Also, the calculations of the cost of record keeping for the Criteria for Patient Release Proposed Rule, which was recently released, were incomplete. The NRC published a calculated cost of $33 per patient for the record keeping provisions. However, there is no explanation of how the NRC arrived at that figure in the cost-benefit analysis.

III. Justification for Implementation of the Backfit Rule for Materials Licensees

ACNP and SNM feel that experience with NRC cost-benefit analyses shows that they do not accurately reflect the actual costs of rulemaking so that the statements that NRC publishes for their rulemakings do not satisfy the APA. It is for this reason that we feel that the additional protection of the backfit rule would be a strong addition to the rulemaking process for materials licensees at NRC.

The NRC promulgates several major rulemakings a year that affect materials licensees. Most of these rulemakings require additional funds to be allocated for compliance. Whether it is for paperwork requirements, the modification of existing facilities, increased inspections, or additional staff and time necessary to insure compliance, these additions all require funding that is not necessarily available to these facilities. The result is the large number of materials licensees dropping their licenses. A structured requirement such as the backfit rule would help eliminate some of these regulatory burdens. Under the definition of the backfit rule now, it applies to a modification of the "procedures, or organization required to design, construct or operate a facility, any of

which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position."[9] This provision should include any rulemakings that have a similar effect on materials licensees.

By including material licensees in this definition, it would require the commission to implement new regulations only "when it determines, based on the analysis described in paragraph(c) of this section that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection."[10] Of course, there are provisions for an exemption from the backfit requirements, but even those include detailed documentation of the commission's position on why the backfit is necessary.

The ACNP and SNM also feel that by carrying out the backfit rule for all regulations concerning materials licensees it places them on equal footing with power reactor licensees. The effects that additional costs have on a facility may be equally onerous whether it is $33 for a materials licensee or $330,000 for a power reactor.

IV. Conclusion

The ACNP and SNM urge the Commission to give this request serious consideration as one of the most effective ways to control the escalating costs of the materials program. We have not filed this as an official petition to give the commission time to consider our request. However, if this request is not acted upon within a reasonable length of time we will proceed with an official petition to be filed with the Commission.

We look forward to hearing a response from the Commission on this important issue. In addition we would like to offer the services of the members of ACNP and SNM on working toward reducing compliance costs from NRC regulations. If you have any questions or comments feel free to contact Mr. David Nichols, Regulatory Affairs Coordinator, in our Washington office at (202) 429-5120.

Sincerely,

William H. McCartney

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cc: The Honorable E. Gail de Planque
The Honorable Kenneth C. Rogers
Dan Berkovitz

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[9] 10 CFR 50. 109(a)(1)

[10] 10 CFR 50.109 (a)(3)