



## **POLICY ISSUE** **(Notation Vote)**

**March 14, 1995**

**SECY-95-061**

**FOR:** The Commissioners  
**FROM:** James M. Taylor  
Executive Director for Operations  
**SUBJECT:** NEED FOR A BACKFIT RULE FOR MATERIALS LICENSEES

**PURPOSE:**

To perform a review of the pros and cons of developing a backfit rule for materials licensees and to provide a recommendation in this matter.

**CATEGORY:**

This paper covers a major policy question requiring Commission consideration.

**BACKGROUND:**

In August 1994, the presidents of the American College of Nuclear Physicians and The Society of Nuclear Medicine wrote to the Chairman of the NRC requesting that the NRC "...initiate steps to implement the backfit rule provisions in 10 CFR 50.109 for all materials licensees." The Chairman responded by indicating that the staff was to review the pros and cons of developing a backfit rule for materials licensees and to provide its recommendations to the Commission. The staff was so directed by a Staff Requirements Memorandum of November 16, 1994 (WITS No. 9400197).

The Backfit Rule, 10 CFR 50.109, governs the process by which the Commission determines whether to impose new requirements on existing nuclear power reactors. A similar provision applies to monitored retrievable storage installations and independent spent fuel storage installations under Part 72, and to gaseous diffusion plant certificates under Part 76. The backfit rule evolved in response to concerns raised by NRC power reactor licensees and a perceived need, in light of extensive backfits following the TMI-2 accident, to limit the imposition of backfits on these licensees. The rule is applicable to both generic actions (i.e., rulemakings, generic letters, and bulletins) and individual actions which might impose new requirements on

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licensees who are operating or intend to operate commercial power reactors. Neither the historical record on the development of the backfit rule, nor discussions with individuals directly responsible for the development of the backfit rule, provide a clear basis for a decision on whether it would be prudent to extend the backfit rule to materials licensees given the recent experience in the regulation of these licensees.

The staff is currently reevaluating its materials licensee programs. These efforts include a Regulatory Impact Survey and a materials licensing Business Process Reengineering study. Also, a special study involving a review of NRC's medical licensee regulatory program is currently underway at the National Academy of Sciences.

#### DISCUSSION:

Amend the backfit rule so that it applies to materials licensees:

**Pro:** The need to demonstrate a substantial improvement in public health and safety is already used by the NRC as a decision criterion in determining the need for new requirements for Part 50 licensees.

Equity argues that all NRC licensees, i.e., power reactor and materials licensees, should have the same protection against the imposition of backfits which do not result in a substantial improvement to the public health and safety.

Extending the backfit rule to materials licensees would promote a more consistent safety standard between power reactor and materials licensees, as well as over the diverse range of activities covered by materials licensees.

Such a rule would promote efficiency in that licensee and NRC resources would be expended only in those areas where substantial improvements in health and safety would be realized.

The growing government-wide interest in controlling regulatory burdens would be further satisfied by this rule.

Industry perception that the NRC imposes unnecessary requirements would be further alleviated.

**Con:** Unlike power reactor licensees, materials licensees are not a relatively homogeneous group. Hence, arriving at a consistent definition of "substantial" for use across the varied types of materials licensees (e.g., waste disposal, medical use, well-logging, etc.) is problematic. Further, the uncertainties associated with the quantification of risk and the definition of "substantial" as they apply to materials licensees would likely make any determination of "substantial" artificial or subjective.

The backfit rule requires the existence of "a substantial increase in the overall protection of the public health and safety..." for the

backfitting of a facility. While power reactors may use the results of the safety goal screening criteria and probabilistic risk assessments to define "substantial," there are no such tools currently available for materials licensees.

Problems with the current backfit rule as applied to power reactors exist, particularly when requirements cannot be translated into quantitative safety space. Examples include requirements involving security, personnel, emergency response, and fitness for duty. This is likely to be the norm, rather than the exception, if the Commission extends the backfit rule to materials licensee requirements.

There are serious concerns regarding a lack of experience in applying the backfit rule to materials licensees. This, coupled with the inherent difficulties in defining a "substantial increase in protection" and the potentially large number of individual licensing actions involving materials licensees, could result in a need for a significant increase in NRC resources.

An important objective of the "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," NUREG/BR-0058 and revisions is to prevent the imposition of generic requirements having marginal overall safety benefit or costs out of proportion to the benefits. Since the Guidelines' inception, NRC regulatory analysis requirements have become more effective, and to a large extent, already provide protection, similar in nature to that afforded by the backfit rule. Specifically, the Guidelines have been developed to implement the NRC policy that new generic requirements are justified on the basis of a cost-benefit analysis. Thus, the need for a backfit rule is less apparent today than when it was adopted.

The Commission readily can establish additional restraints (i.e., cost benefit analyses) on new requirements on individual materials licensees as a matter of policy without rulemaking.

#### RECOMMENDATION:

The staff believes that extending the backfit rule to materials licensees would create a number of technical problems and although these are not likely to be insurmountable, their satisfactory resolution would undoubtedly impose significant increased resource burdens on the staff. Further, the actual performance of backfit analyses for each regulatory initiative involving materials licensees would also increase NRC burdens at a time when resources are being reduced. In the staff's view, these increased burdens would provide a level of protection to materials licensees that is only marginally more effective than that currently afforded under the NRC's regulatory analysis requirements. Therefore, on balance, the staff sees little technical justification for extending the backfit rule to materials licensees.

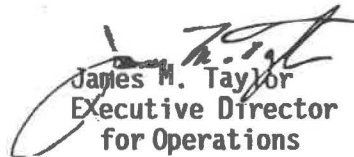
Another important consideration, however, is the need to address the appearance that the Commission does not treat all licensees equally in its

regulatory procedures. If the Commission felt that this issue was of overriding importance, the staff would still caution against taking action at this time. The staff is aware that Congress is currently considering new legislation to reform the regulatory process government-wide. This proposed legislation could have broad implications on the NRC's regulatory process, and in particular, our future need for a rulemaking requiring materials licensee backfit analyses. For example, a current version of this draft legislation requires certification of a substantial improvement in public health and safety. This would appear to effectively extend the backfit rule to materials licensees legislatively. Thus, given that reform of the regulatory process is currently in flux, any NRC decision or initiative in this area should await passage of the proposed legislation to allow the NRC to assess the full implication of the final legislation on this particular issue.

In making this recommendation to the Commission, the staff notes that it will be reporting to the Commission on NMSS's findings from the Regulatory Impact Survey, the materials licensing Business Process Reengineering, and on findings of the National Academy of Sciences review of medical licensees. When these studies have been completed, the staff may have new insights and will report back to the Commission at that time. Specific focus of that reconsideration will be on whether a Commission policy (i.e., conducting a cost benefit analysis) should be developed regarding the imposition of new requirements on individual licensees.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

  
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