AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-99-279 - FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

Edward McGaffigan Jr.
SIGNATURE

February 15, 2000
DATE

Entered on "AS" Yes X No ____

Commissioner McGaffigan's Comments on SECY-99-279:

The staff is to be commended for its excellent and voluminous work on a difficult subject. I approve the draft final rule, with certain edits to the statement of considerations; the edits are attached. Their aim is to reflect my views on two backfit issues, discussed below. If the Commission adopts these edits, conforming changes will need to be made in Appendix F and elsewhere.

Aggregation of costs and benefits: A significant part of the staff's labor on this rule, labor disproportionate to any benefit I perceive, was expended in dealing with the backfit rule. The staff took the highly conservative approach -- urged by the industry but required neither by Commission decision nor law -- of considering each element of the rule under the backfit rule, rather than considering the aggregate under the rule, as the agency did when Part 26 was first promulgated.

It is easy to imagine cases that call for disaggregation. For example, the agency should not justify an expensive and useless rule by combining it with an unrelated enhancement to safety with large benefits and low costs. Even within a single rule, the agency should not promulgate a useless and costly section.

However, here we are not dealing with unrelated rules, or useless and expensive outliers. Indeed, so tightly woven and finely grained are the elements of this rule that the 36 items proposed as worthwhile exceptions to the backfit rule do not come into view until one has descended to the subsection, or even paragraph, level, and many of these items have no costs to justify (see Table 7 in Attachment E to the SECY paper).

Some rule of reason ought to apply when considering the parts of a proposed rule under the backfit rule. In most cases, it should be enough to set forth the reasons for each proposed provision, and, for purposes of a regulatory analysis, estimates of the costs of each such provision. It does not make sense to impose routinely on every small element of a large rule the requirement that it provide a substantial increase in public health and safety. For example, the proposed requirement that FFD program personnel be subject to testing (paragraph (4) of subsection (a) of section 26.2) makes such good sense that the agency thought it went without saying in the existing version of Part 26, but it is not easy to say that that single requirement will bring about a substantial increase in public health and safety.

"Substantial Increase": However, even if the 36 revisions proposed as worthwhile exceptions are taken in the aggregate, there is still the question of whether they, or all the revisions taken as a whole, meet the "substantial increase" standard, which for better or for worse, must be met even when there are, as here, in the aggregate, no costs to justify. In the proposed rule, the Commission took no firm position on the issue, instead inviting comment on it. The staff says, without argument, that it believes that the revisions, including those revisions proposed as worthwhile exceptions, do not, taken as a whole, add up to a substantial increase in safety, but the staff nonetheless firmly believes that even those portions that do not, in its opinion, comply with the backfit rule are "worthwhile" and should be promulgated as exceptions to the backfit rule. The staff thus pits the backfit rule against what is "worthwhile."

As a general matter, it may be better to interpret a law flexibly to include the reasonable and useful, rather than make the agency go outside existing law to do something reasonable. In the 1993 SRM to which the staff appeals in recommending that certain revisions to Part 26 be

treated as worthwhile exceptions, the Commission majority urged that the backfit rule be regarded as a flexible instrument.[1] The staff believes that the backfit rule is not flexible enough to cover all of the revisions before us, but I am not persuaded. The 1993 SRM harks back to the 1985 modification of the backfit rule, where the Commission said that the "substantial increase" standard

> is not intended to be interpreted in a manner that would result in disapprovals of *worthwhile* safety or security improvements having costs that are justified in view of the increased protection that would be provided.

(Emphasis added.) This is the right context for the word "worthwhile," not the context of exceptions. In the light of this quotation, it sounds strange to except something from the backfit rule because that something is "worthwhile." The 1985 interpretation of the phrase "substantial increase" shows us a reasonable flexibility in the standard. I believe that, considered as a whole, the staff's proposed changes to Part 26 -- even just the 36 proposed "worthwhile exceptions" considered as a distinct group -- meet this standard. The staff's analysis amply shows that they are "worthwhile safety or security improvements" that justify their costs.

If a majority of the Commission does not believe that the "substantial increase" standard has been met by the aggregate of the revisions, then I would support going forward with the revisions on the basis of the regulatory analysis alone, which, being a straightforward cost/benefit analysis, amply justifies the proposed revisions to Part 26 (see Appendix E to the SECY paper). In this case, I would support promulgating the 36 identified items as "worthwhile exceptions" to the backfit rule, but in the future we should avoid applying the backfit rule to every discernable provision of a proposed rule, and we should consider changing the rule to a straightforward cost-benefit rule (see the footnote). So many exceptions to a rule suggest either that the agency has become lax in following its own rules -- which is certainly not true in this case where the staff has expended great labor in applying the backfit rule -- or that the rule to which the exceptions are being made needs to be rethought.

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[1]Commissioner Curtiss, in the minority, advocated that the backfit rule be modified to directly address situations where a seemingly worthwhile change to regulations cannot be adopted because of difficulties in demonstrating that the change represents a "substantial increase in the overall protection of the public health and safety." That remains an alternative course in future cases like the one before us now.

NRC question 1(a): Would any of the proposed changes, groups of related requirements (e.g., modifications to prevent subversion of the testing process, further ensure the accuracy and integrity of testing, clarify actions for removal), or the rulemaking as a whole provide a substantial increase in the overall protection of the public health and safety or the common defense and security?

Summary of comments: Most commenters who responded to this question stated that the proposed changes, considered individually or as a whole, would not provide a substantial increase in the overall protection of the public health and safety. Three commenters stated that the changes as a whole would either provide an incremental improvement in the protection of the public health and safety or enhance the achievement of the objectives of the FFD program.

NRC response: The NRC has reevaluated the proposed changes in light of the public comments. In certain cases, the Commission concludes that ~~the~~ changes ~~should be adopted as a worthwhile change, even though they may not~~ represent a "substantial increase" in protection to public health and safety. ~~In other cases,~~ the Commission believes that the changes do constitute ~~such~~ "substantial increases." A discussion of each change with respect ~~to backfit~~ is contained in the "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)" which is available for inspection and copying for a fee at the NRC Public Document Room. This document is also available as Attachment F to SECY-99-279.

NRC question 1(b): Are the groupings and subgroupings of the changes contained in the Backfit Analysis section of the Federal Register notice appropriate and are the changes categorized properly?

Summary of comments: While not referring explicitly to the Commission's categorization of the proposed rule changes, several commenters expressed the opinion that most of the proposed changes would create reasonable and appropriate clarifications of rule requirements or reductions of licensee burden and should be adopted as soon as possible. Several commenters, however, said that proposed revisions that would increase licensee burden should be subject to backfit analysis. Several commenters expressed the opinion that the backfit rule applies only to new obligations imposed by the NRC. One of these commenters specifically said that it is the mandatory nature of the regulatory change that controls applicability of the backfit rule, and that, where a reduction in a regulatory requirement or the implementation of a revision is not made mandatory, but is instead left to licensees' discretion to continue implementing the current requirement or adopt the change, such changes are not backfits.

NRC Response: The NRC has thoroughly reviewed all of its proposed revisions with respect to the application of the backfit rule and has concluded that each revision fits into at least one of the following classifications:

1) Clarifications. Several revisions will clarify current requirements to assure consistent understanding and implementation of the Commission's original intent for these requirements. Without changing the requirements stated in these sections, these revisions would remove the ambiguities that produced the licensee's uncertainty. The backfit rule does not apply to revisions that leave current requirements unchanged.
2) Administrative matters. A few revisions make minor administrative changes, such as correction of typographic errors, correction of inconsistencies, relocating requirements from one section to another, and combining existing requirements into a single section. Administrative matters are not subject to Backfit Rule requirements.

3) Permissive relaxations. Several revisions permit, but not require, relaxations of current requirements (i.e., licensees are free to either comply with current requirements or adopt the relaxed requirements as an alternative). The backfit rule does not apply to rule revisions that provide permissive relaxations of current requirements.

4) Information collection and reporting requirements. A few revisions modify information collection and reporting requirements, which are not considered to be subject to the Backfit Rule.

5) Compliance exceptions. Several revisions are necessary to bring licensees into compliance with existing Commission requirements or the Commission's clearly stated intent in promulgating the requirement. In addition, some of the revisions modify current requirements where there is evidence that the current version of the standard is not achieving the purpose that the Commission had when it originally promulgated the rule. These revisions are exceptions to the backfit rule, as specified in 10 CFR 50.109(a)(4)(I).

6) ~~Worthwhile changes to be adopted as Backfit Rule Exceptions: Some of the revisions are recommended for consideration for adoption as an exception to the backfit rule because they are worthwhile changes.~~ The Commission indicated in the SRM dated June 30, 1993, that it would consider worthwhile changes on a case-by-case basis as an exception to the "substantial increase" in safety standard, as long as they have been subject to public notice and comment, as these revisions have.

The Commission has considered the need for the revisions, and the public comments regarding those revisions, and has concluded that the changes should be promulgated.

The NRC has prepared a detailed analysis of the backfitting applications of each of the proposed changes, which may be found in the "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)."

NRC question 1(c): Are the changes in Group III worthwhile and necessary to better accomplish the FFD rule's objective, clarify the rule's existing requirements, and reduce ambiguities?

Summary of comments: Although commenters did not specifically refer to the Commission's categorization scheme, some commenters supported the Commission going forward with those rule revisions that serve to better accomplish the rule's objectives and clarify current requirements. One commenter stated that the proposed revisions would significantly improve the effectiveness of the FFD program and that the backfit rule should not apply to this rulemaking. The remainder of these commenters stated that the backfit rule requires the NRC to conduct an analysis of the effects of those revisions that would create new licensee burden.

NRC response: The NRC has prepared a detailed analysis of the backfitting applications of each of the proposed changes, which may be found in the "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)."

NRC question 1(d): Do the rule revisions as a whole not constitute a backfit since the rule's cumulative effect is to ease licensee burdens or leave them essentially the same rather than to increase them?

Summary of comments: One commenter recommended that the backfit rule should not be applied to the proposed amendments because the rulemaking as a whole would provide an incremental improvement and reduce licensee burden. Another commenter contended that the proposed revisions would significantly improve the effectiveness of the FFD program and that the backfit rule should not apply to this rulemaking. This commenter justified that contention by

NRC response: After considering the alternative approaches suggested by some commenters, the NRC has concluded that rulemaking is the only effective vehicle for making these changes. Rule change is favored because clear regulatory requirements eliminate interpretive debates. Clear public policy is frequently needed to address legal challenges, ensure that individual rights are protected, and assure that State and local restrictions will not hinder the stringent drug and alcohol testing needed to protect public health and safety. Clear public policy in this area also facilitates collective bargaining. These points were discussed in more detail in the May 9, 1996, Federal Register notice on the proposed rulemaking at 61 FR 21106.

In response to the comments regarding increases in burden, the NRC reviewed the proposed rule revisions and made some changes to reduce potentially complicated processes. In so doing, the NRC noted that several commenters' examples of how the wording of the final rule would have to be implemented introduced complications not suggested by the proposed revisions. In these cases, the NRC has provided clarification of the intent of the revision.

41. Comments About Backfit.

The backfitting discussion in the SOC for the proposed rule, 61 FR 21105 (May 9, 1996), divided the proposed changes to Part 26 into three categories: (i) changes necessary to conform with HHS standards, (ii) changes representing reduction in licensee burden, and (iii) other worthwhile changes. Public comment was specifically requested on whether the changes in the proposed rule, considered individually or collectively, constitute a substantial increase in safety and if not, whether the rule should nevertheless be adopted by the Commission. In particular, the SOC requested comment on whether the rule's cummulative effect is to reduce licensee burden, consistent with the position that the Backfit Rule does not apply to relaxations in regulatory requirements. The SOC also requested comment on whether the rule could be adopted if there was no objection from those subject to the rule. Id. at 21128-29.

Twelve organizations provided comments on backfitting issues (comments were also made by an NRC employee; the rulemaking addresses those comments as if they were made by a private citizen). The comments can be summarized as follows: (1) most commenters thought the proposed revisions would not create a substantial increase in the overall protection of public health and safety, and (2) several commenters recommended that the NRC should segregate those revisions that would create reductions in requirements from those that would impose new requirements and immediately proceed with rulemaking for those rule revisions that would either reduce licensee burden or result in only minor administrative changes. Commenters also recommended that the proposed revisions that would create new requirements should be withdrawn from this rulemaking and, if still considered desirable by the NRC, should be processed for separate promulgation with appropriate backfit justification. NEI acknowledged that most of the proposed rule revisions would create only minor program adjustments, many of which will increase program effectiveness and efficiency and decrease licensee burden. However, NEI also cited several revisions that should require backfit justification because it believed the revisions would increase licensee burden or that additional reduction in burden should be provided.

After consideration of the public comments on both the desirability of the proposed changes and the backfitting issues, the Commission has decided that there was sufficient adverse comment on some of the changes that the proposed rule could not be promulgated on the basis of "non-objection" by affected parties. In addition, the Commission has decided that the proposed changes should be considered individually in determining whether the "cost-justified substantial increase" standard of Section 50.109(a)(3) has been met. Since the Commission has decided that it would not be appropriate in this rulemaking to aggregate the changes and view the rule as a whole for backfitting, the Commission has also decided not to rely upon a rationale that would consider the cumulative effect of the FFD rule as providing an overall reduction in licensee burden, and therefore not constituting a backfit (however, as

the adoption of the Backfit Rule "that regulatory impacts are assessed under established criteria in a disciplined process" is being met for the information collection and reporting requirements in the final FFD Rule.

(5) Compliance exceptions. Several revisions are necessary to bring licensees into compliance with existing Commission requirements or the Commission's clearly stated intent in promulgating the requirement. In addition, some of the revisions modify current requirements where there is evidence that the current version of the standard is not achieving the purpose that the Commission had when it originally promulgated the rule. Pursuant to Section 50.109(a)(4)(i), a backfit analysis need not be prepared.

(6) Worthwhile changes to be adopted as ~~Backfit Rule Exceptions~~. Some of the revisions are considered to be backfits, but ~~neither~~ fall into one of the exceptions in Section 50.109(a)(4)(i) through (iii), ~~nor~~ constitute a "substantial increase" in protection to public health and safety whose cost is justified in light of the increase in protection. ~~The Commission has previously indicated in a June 30, 1993, SRM that it would consider worthwhile changes on a case-by-case basis as an exception to the "substantial increase" in safety standard, as long as such changes have been subject to public notice and comment.~~ As discussed above, the SOC for the proposed FFD Rule stated that the Commission was considering adopting provisions of the proposed rule as "worthwhile improvements," and invited public comments on this proposal. After consideration of the public comments, the Commission has determined, for the reasons set forth in the "Analysis of the Application of the Backfit Rule to the Revisions to the Fitness-for-Duty Rule (10 CFR Part 26)," that the certain changes are "worthwhile improvements" to Part 26 and that the requirements of the Backfit Rule, 10 CFR 50.109, should not apply to the portion of this rulemaking adopting these changes. Therefore, the Commission hereby waives the application of the Backfit Rule to the portion of this final rulemaking adopting the following changes:

(1) *Section 26.2(a)(4): FFD program personnel to be covered by FFD rule.*

(2) *Section 26.20(a): Off-site involvement with drugs, subversion of the testing process, and refusals to test added.* Note: this revision consists of three parts and only the one part requiring FFD policies to address off-site involvement of drugs is recommended to be considered a worthwhile change.

(3) *Section 26.23(a)(2): Clarify that persons with a known (to the contractor or vendor) history of substance abuse must not receive assignments to the protected area without the knowledge and consent of the licensee.*

(4) *Section 26.24(a)(5): Clarify existing testing requirements for persons unavailable for testing for short periods and insure consistency with the access authorization program.* Note: this revision consists of three parts and only the one part concerning tests after extended absences is recommended to be considered a worthwhile change.

(5) *Section 26.24(a)(5): Require return-to-duty testing after extended absences or denial of access.* Note: this revision consists of two parts and only the one part concerning the testing of personnel returning to work after extended absences or after having been denied access under section 26.27(b) is recommended to be considered a worthwhile change.

(6) *Section 26.24(f): MRO to report FFD policy violation in writing.*

(23) *Section 2.7(g) of Appendix A: Require testing for d and l isomers of amphetamines.*

(24) *Section 2.7(i) of Appendix A: Specimens associated with subversion to be placed in long-term storage.*

(25) *Section 2.7(j) of Appendix A: Retesting of adulterated or diluted specimens need only confirm specimen not valid.*

(26) *Section 2.7(k) of Appendix A: Minimum time for requests by individuals to have split specimen tested at another HHS-certified laboratory.*

(27) *Section 2.7(p) of Appendix A: Laboratory shall not have a conflict of interest with licensee's MRO.*

(28) *Section 2.8(b) of Appendix A: Laboratory results on blind performance specimens must be evaluated and appropriate corrective actions taken.*

(29) *Section 2.8(e) of Appendix A: Require that blind quality control materials meet standards for preparation, certification, and stability.*

(30) *Section 2.8(e) of Appendix A: Assure regularity of submission of blind test specimens.*

(31) *Section 2.8(e) of Appendix A: Adulterate or dilute and spike some blind performance specimens.*

(32) *Section 2.8(e) of Appendix A: Specify that initial 90-day period for blind performance testing rate applies to all new contracts with HHS-certified laboratories.*

(33) *Section 2.8(f) of Appendix A: Investigation of testing process errors and inclusion of report of action taken.* Note: this revision consists of two parts and only the one part requiring licensees to investigate testing process errors is recommended to be considered a worthwhile change.

(34) *Section 2.8(f) of Appendix A: All false positive errors must be reported to NRC.* Note: this revision consists of two parts and only the one part requiring the licensee to require the HHS-certified laboratory to take corrective action is recommended to be considered a worthwhile change.

(35) *Section 2.9(b) of Appendix A: MROs shall not have a conflict of interest with certified laboratories.*

(36) *Sections 2.9(f) and (g) of Appendix A: Medical determination of fitness to perform duties defined.*

For the reasons set forth above and on the basis of the documents discussed above, the Commission finds that the requirements of the Backfit Rule have either been met or appropriately waived for the final FFD Rule.