July 25, 2000

COMMISSION VOTING RECORD

DECISION ITEM: SECY-00-0111
TITLE: FINAL RULE TO AMEND PART 70, DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

The Commission (with all Commissioners agreeing) approved the subject paper as noted in the Affirmation Session and recorded in the Affirmation Session Staff Requirements Memorandum (SRM) of July 25, 2000.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

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Annette Vietti-Cook
Secretary of the Commission

Attachments: 1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

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VOTING SUMMARY - SECY-00-0111

RECORDED VOTES

| | APRVD | DISAPRVD | ABSTAIN | NOT PARTICIP | COMMENTS | DATE |
|---|---|---|---|---|---|---|
| CHRM. MESERVE | X | | | | X | 7/6/00 |
| COMR. DICUS | X | | | | X | 6/29/00 |
| COMR. DIAZ | X | | | | X | 7/19/00 |
| COMR. McGAFFIGAN | X | | | | X | 7/11/00 |
| COMR. MERRIFIELD | X | | | | X | 6/29/00 |

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendations to apply the backfit provisions upon approval of the ISA, agreed that ISAs should be approved through the use of SERs, and agreed that the rule should be effective 30 days after publication. In addition, the Commission agreed to allow multiple ISAs to be submitted for each facility. The Commission agreed (with Chairman Meserve and Commissioners Dicus and Diaz agreeing and Commissioners McGaffigan and Merrifield disagreeing) to include "substantial" in the backfit requirement. The Commission disapproved (with Commissioners Diaz, McGaffigan, and Merrifield agreeing and Chairman Meserve and Commissioner Dicus disagreeing) the staff's recommendation for quarterly reporting on safety items at the facility. Subsequently, the Commission affirmed the final rule in an Affirmation Session as reflected in the Affirmation Session SRM issued on July 25, 2000.

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## Commissioner Comments on SECY-00-0111

### Chairman Meserve

I approve the notice of final rulemaking for publication in the Federal Register, subject to the following comments. I also

support the certification that the rule will not have a negative economic impact on a substantial number of small entities. Although I suggest certain modifications of the final rule, I commend the staff for its efforts in this rulemaking. The revision of Part 70 is a very significant undertaking and the fact that there are relatively few controversial issues associated with the final rule reflects well on the staff's efforts to understand and, as appropriate, to accommodate the suggestions of the various stakeholders.

1. The proposed rule contains a backfit provision (§ 70.76) that presents two issues. One concerns the timing of the effectiveness of the backfit provision. The other relates to the standard that must be satisfied in order to justify a backfit.

a. The final rule proposed by the staff provides that the backfit provision established by the rule will apply only after the staff approves the Integrated Safety Analysis (ISA) Summary. Industry has argued that the backfit requirements of section 70.76 should instead be effective at the time the rule becomes final.

The differing perspectives on this issue may not have much real significance. The proposed backfit rule provides that a modification to bring a facility into regulatory compliance is not subject to examination under the backfit rule. See §§ 70.76(a)(4)(i) and (ii). Presumably most of the changes that would be required of licensees at the time of implementation of the rule would be to achieve compliance with the new rule (which itself is not subject to backfit analysis), and, if so, the applicability of backfit considerations would be irrelevant. Nonetheless, I concur with the staff's recommendation that the backfit provision be applied to the requirements in Subpart H after the ISA Summary is approved. Because the ISA for a facility might be expected to provide insights on baseline safety issues that were not previously considered thoroughly, it is desirable to avoid possible disputes as to whether changes that are justified by the ISA fall within the compliance exception to the backfit rule. Moreover, postponing the applicability of the backfit provision until the ISA Summary is completed and approved will ensure that such analyses are available to illuminate any future backfit decisions that must be made.

At the Commission meeting on Part 70 it was suggested that, rather than one ISA Summary to encompass the entire facility, there might be multiple ISAs, each prepared for a separate subsystem, and that the staff might undertake the piecemeal review and approval of the resulting segmented ISA Summaries. If so, the backfit rule might become applicable to a given subsystem after the relevant ISA Summary is approved. This is acceptable to me, but only so long as the staff develops appropriate guidance to limit excessive or inappropriate segmentation. An ISA, after all, is intended to provide an integrated safety analysis and any segmentation should not be allowed to undermine the evaluation of the interdependence of systems and of possible synergistic effects. Moreover, the rule should not create incentives for excessive segmentation in order to obtain the benefit of early backfit protection for some subsystems.

b. The backfit provision, like the counterpart provision governing reactors (10 C.F.R. § 50.109), does not require a backfit analysis if the change is required to achieve compliance with a regulatory requirement or is necessary to provide adequate protection of public health and safety. For requirements of lesser significance, the proposed rule would require showings that there is "an increase in the overall protection" of the public health and safety, and that the costs of implementation of the backfit are justified by the benefits. See § 70.76(a)(3). Industry argues that the rule should require a "substantial increase" in overall protection in addition to the cost-benefit test.

The Commission previously provided guidance to the staff that any new backfit proposal for Part 70 should not require a showing of a "substantial" increase in safety. See SRM for SECY-98-185 (Dec. 1, 1998). Nonetheless, I believe that the word "substantial" should be introduced into the backfit test. The point of the backfit rule is to provide a measure of regulatory stability so that licensees are not required to undertake investments to comply with a newly minted regulatory requirement absent a convincing showing that the application of the new requirement is justified. The elimination of the word "substantial" would effectively reduce the barrier to the imposition of backfits for Part 70 licensees. In fact, any requirement that could pass the cost-benefit component of the backfit test would necessarily provide some (albeit perhaps slight) increase in protection and therefore would of necessity also pass a mere "increase-in-protection" requirement. Thus the staff's proposal, in effect, would reduce the backfit rule to a cost-benefit test. In other contexts in our rules -- notably 10 CFR §§ 50.109 and 76.76 -- we require a heightened showing of benefit and I see no reason for a departure from this approach for Part 70 licensees. As Commissioner Dicus has noted, there is a benefit in consistency in our rules so that predictability is enhanced. And, although there is admitted ambiguity as to the increase in protection that is sufficient to constitute a "substantial" increase, there is a benefit in specifying that more than a trivial increase in safety is needed to justify requiring our licensees to undertake the expense of a backfit.

2. The proposed rule would require prior NRC approval upon the removal or modification of "items relied on for safety" (IROFS) under certain particularly safety-significant circumstances, quarterly reporting as to changes that affect IROFS in other circumstances, and reporting of other revisions of the ISA Summary on an annual basis. See § 70.72. Industry has objected to the burden of quarterly reporting, claiming that each quarterly reporting may require a filing covering 20-30 items. Staff responds that modifications to the IROFS are like changes to technical specifications in the reactor context and more frequent reporting than annual reporting is justified.

The staff's analogy to technical specifications is not completely appropriate because changes to technical specifications must be pre-approved by the NRC. Nonetheless, there is a certain parallelism between the definition of technical specifications (§ 50.36) and the definition of IROFS (proposed § 70.4): both serve to define the safety envelope for the facility. Moreover, the different risk characteristics of a reactor and a facility licensed under Part 70 serve to justify the different approaches to prior approval of changes. Given the safety significance of changes to IROFS, I approve the staff's requirement for quarterly reports.

I am troubled by the perception of industry that the routine operation of a facility might require as many as 30 changes to IROFS to be reported each quarter. I understand that the staff does not anticipate that a quarterly reporting requirement should be so burdensome. Accordingly, I urge the staff to review and revise the guidance and/or the statement of considerations so that the changes to IROFS that are subject to quarterly reporting are more sharply and more narrowly delimited.

3. Industry has argued that there is no justification for staff approval of an ISA Summary because there is no procedural action, such as the issuance of a license amendment, that is hinged to the approval. Based on the discussion at the Commission Meeting on June 20, however, it is apparent that the staff approval of an ISA Summary will result in the staff producing a Safety Evaluation Report that will be the foundation for licensing actions (as well as the trigger and the foundation for application of the backfit rule). I approve the staff's approach.

4. The development of the Standard Review Plan (SRP) is critically important to the successful implementation of the rule. The process can and should serve as a vehicle for assuring that the staff and the licensees, as well as other stakeholders, are fully informed of each other's understanding of the rule and each other's expectations for its implementation. As a result, staff should continue to work with stakeholders to ensure that the SRP contains sufficient detail as to provide concrete guidance, but not such prescriptive requirements as to interfere with a performance-based approach to compliance. Given that the rule already provides for the phased applicability of the new requirements, I conclude that the rule should become effective 30 days after publication, rather than after completion of the SRP.

## Commissioner Dicus

I want to commend staff for the hard work and effort put forth in developing the Part 70 draft final rule. I am aware of the complexities addressed and resolved in this rulemaking effort, and I soundly believe that the regulatory requirements of Subpart H and its specific performance requirements, adequately protects the worker, the public, and the environment. I also believe that Subpart H and the Standard Review Plan (SRP) guidance provides the appropriate level of requirements and information that will provide our fuel cycle licensees the opportunity to facilitate safety enhancements, or confirm the safety of existing conditions/controls, to their current programs. These requirements and guidance methods provide reasonable assurance that items relied on for safety (IROFS) will be available, reliable, and will perform as designed or intended, if operational challenges and/or process deviations are confronted. With respect to the few remaining issues, i.e., Backfit implementation for Subpart H requirements, ISA Summary approval, Quarterly Reporting, and Chapters 3 and 11 of the SRP, I have carefully considered these issues and the views presented by staff, the Nuclear Energy Institute (NEI EXIT), and our fuel cycle licensees, and I've derived the following positions:

### 1. Backfit and ISA Summary Approval

Both staff and industry have presented logical positions concerning these issues. However, based on the safety significance of the information to be provided in the ISA Summary documents, the number of projected submittals per licensee, and the projected timing of these submittals, I support staff's recommendation for review and approval of each ISA Summary submittal and the subsequent issuance of a safety evaluation report (SER) per approval. At the time of approval and SER issuance, the applicability of Backfit should be immediately effective for the Subpart H requirements. Additionally, my position also includes modifying the Backfit draft final rule language, as stated in Part 70.76(a)(3), to re-incorporate "substantial increase" into the regulation. I believe that this modification provides the generic consistency across our existing regulations, as identified in Part 50.109(a)(3) and Part 76(a)(3), and further ensures predictability in our regulations, as well as our regulatory interpretations and positions. However, I do recognize that the term "substantial," as utilized in our regulations is neither qualified or quantified, but does provide a level of differentiation between the stand-alone term of "increase."

I also want to share a general observation that I've concluded concerning the interpretation of the ISA concept by staff, NEI, and our licensees. At the June 20 Commission meeting one licensee informed the Commission that the NRC could expect to receive approximately 15 separate ISA Summaries for that facility's existing operations, which was also indicated at my June 19 meeting with NEI and our licensees. From my perspective, it appears to be a disconnect between the ISA process and the related Process Hazard Analysis (PHA), which is the major input portion to the ISA. Typically, facilities conduct individual PHA's for each process unit operation, with the results of the PHA becoming the infrastructure of the ISA. As the process indicates, the objective of the ISA is to evaluate the comprehensive risks and impacts in an integrated manner. The results of this process provides plume effect information, which evaluates the accident sequence and impacts of one process unit operation on another, thereby, providing the data needed to identify and implement appropriate engineering and administrative controls, and bolstering the facility's level of defense-in-depth. This approach would end-up with a number of PHAs and possibly one to three ISAs, which would significantly reduce the number of SERs issued per licensee. In this regard, I recommend to the degree necessary, that clarification be provided to our licensees. This information should address the type of information needed to demonstrate regulatory compliance, so that one could establish appropriate methods to efficiently and effectively evaluate operations safety, and the adequacy of measures taken concerning worker and public health and safety. This clarification could be addressed in Chapter 3 of the SRP, the rule language, or in the statements of consideration (wherever staff believes it would appropriately fit). As licensees begin to submit their ISA Summaries, it is essential for staff to ensure that the information appropriately addresses accident sequences, risks, and impacts in a comprehensive and integrated manner, so that a sound safety basis can be established.

### 2. Quarterly Reporting of IROFS not requiring NRC pre-approval

Both staff and industry have presented logical positions concerning this issue, and I believe the merits of these positions warrant equal consideration. Based on the expected safety and health importance that quarterly reporting will provide, I support staff's recommendation requiring quarterly reporting of IROFS that do not require NRC approval prior to making process changes. However, as both Commissioner McGaffigan and industry pointed out, the language currently in Part 70.72(c)(4)(d)(1) should be clarified to better explain what type of changes meet this reporting threshold and the value of that threshold to the NRC. Recognizing that there will be fundamental differences in facility operations, once the rule language and if necessary the statements of consideration are modified, the usage of License Conditions, as appropriate, would also provide an effective vehicle to cover the uniqueness of these differences.

The issue that I struggle with, is not the quarterly reporting of IROFS, but the types of IROFS that would fall into the quarterly reporting range. By following the unresolved safety question (USQ) process, it's quite clear that changes impacting IROFS that fall within the USQ range must be pre-approved by the NRC prior to implementing any change. However, I do not get the same sense of clarity or what the safety significance is, with the types of IROFS that fall outside of the USQ range. In response to my question to NEI and our licensees during my June 19 meeting, and as stated in the June 20 Commission meeting, industry believes that a range of 20 to 50 items per licensee will have to be reported per quarter. Also mentioned by our licensees, is that they believe this category of items is down in the grass with respect to safety significance. In contrast, I firmly believe that if the PHAs and ISAs are appropriately carried-out, that the number of IROFS reported per quarter should be minimal to none, with the annual report being the main vehicle of reporting . From a regulatory burden perspective, I do not support industry's position that quarterly reporting to the NRC presents unnecessary regulatory burden, because each licensee, through their configuration management change control process, is responsible for appropriately documenting changes that take place. Mere reporting of these changes should not present a significant burden on any of our licensees, since the burden of evaluating and documenting these changes have already taken place. Additionally, at the time of completing the ISA process, the licensee should have a well established safety basis, and except for new processes or significant modifications to existing processes, I would not foresee numerous changes to the established safety basis. Therefore, this is why further clarification is warranted in the rule language and/or statements of consideration addressing the quarterly reporting of IROFS.

### 3. SRP - Chapters 3 (ISA Guidance) and 11 (Management Measures)

I recognize that as lessons are learned and experiences are gained, general and specific changes to the SRP will probably take place. As both staff and industry indicated during the June 19 and 20 meetings, a revised Chapter 3 is being developed by NEI and coordinated for NRC review and comment, and an introductory statement to Chapter 11, addressing the level of suggested detail, has been drafted and tentatively agreed upon. I believe that staff is taking the right approach in refining the SRP guidance document and has done an excellent job in doing so. Therefore, I do not support endorsement of NEI's Chapter 3 guidance in the Part 70 rule or delaying the implementation of the rule until Chapter 11 issues are resolved, as recommended by NEI and our licensees.

## Commissioner Diaz

I approve publication of the final rule to amend 10 CFR Part 70, Domestic Licensing of Special Nuclear Material, subject to the following comments on the rule.

I am especially pleased to see that the final rule includes a backfit provision, which I supported in my earlier comments on the proposed rule. I believe that the Commission has an obligation to ensure that the agency promulgate "reasonable" regulations for the protection of public health and safety and, consequently, I support re-introducing the word "substantial" into the backfit requirement in § 70.76(a)(3). I agree with the Chairman that "there is a benefit in specifying that more than a trivial increase in safety is needed to justify requiring our licensees to undertake the expense of a backfit." That is, a substantial increase in protection of the public's health and safety would need to be demonstrated before the NRC imposes a backfit. The U.S. nuclear fuel facilities have much lower risks than nuclear power plants, with small public health and safety consequences even for large accident scenarios. They have a demonstrably sound safety record. It is, therefore, necessary to prevent the imposition of additional burden without justifiable safety improvements, both in absolute and relative terms. NRC must provide clear guidance on what is considered a "substantial" increase, as used in this part, to ensure consistent application of the requirement and to prevent unnecessary future expenditures of industry and NRC resources trying to resolve the term's meaning. When possible, I prefer quantification of the increase, but when necessary, qualification is often sufficient. Therefore, I recommend that the following language be added to § 70.76(a)(3):

> Substantial increase, as used in this part, means that there would be a qualitative or quantitative increase in the overall health and safety protection of the public if the backfit is imposed. Likewise, failure by licensees to perform the backfitting could potentially result in an increase in the health and safety consequences to the public that is outside of the acceptable range of potential consequences associated with the use of SNM.

In other words, the determination of whether there is a "substantial increase" in protection, if backfitting of the facility were required, would be tied to the acceptable level of consequences NRC considers during licensing the use of SNM, i.e., the acceptance criteria in the Standard Review Plan (SRP).

Consistent with the above statements on the safety and risks of SNM licensees, I disagree with the requirement that any changes that affect the list of the items relied on for safety in the Integrated Safety Analysis (ISA) summary be submitted quarterly. We have a continuous inspection process at the fuel cycle facilities. I believe that this oversight is more effective in providing real-time reports on safety than a requirement for submission of quarterly reports. Therefore, I believe that the

reports on safety changes, which do not require pre-approval, be submitted annually.

Both the SECY paper and the briefing of the Commission showed that there are still numerous details to be worked out between the NRC and the industry regarding the ISA and the SRP. Based on the progress to date, I encourage staff to continue working to resolve the remaining issues, such as the level of detail in the ISA summary.

**Commissioner McGaffigan**

I approve the draft final rule amending Part 70 for certain licensees authorized to possess a critical mass of special nuclear material (SNM) subject to the following comments on specific rule provisions and the Standard Review Plan (SRP). I commend the staff and industry representatives for their tireless efforts over the past few years to reach consensus on a more risk-informed and performance-based rule.

***Rule Provisions*:**

1. Approval of the Integrated Safety Analysis (ISA) summary (10 CFR § 70.62(c)(3)(ii) - I support the current language which requires existing licensees to demonstrate compliance with the new rule requirements by submitting an ISA summary to NRC for approval. While industry argues that the ISA and the summary document are "living documents" and therefore should not be "approved" by NRC but rather should be reviewed by NRC for the purpose of determining whether the licensee is in compliance with applicable requirements, the intent of the review process described by the staff is the same and as such use of the word "approval" appears to be somewhat an issue of semantics. Moreover, the approval of the ISA summary is the trigger for any application of the backfit provision (70.76), which industry desires.

2. Quarterly reporting of certain changes that affect the list of items relied on for safety (10 CFR § 70.72(d)(1) - I do not support the proposed quarterly reporting frequency for certain changes to the list of IROFS and instead support an annual reporting frequency. I do not agree that staff has made the case for the analogy to nuclear power reactor technical specifications. If the staff truly considered these items to be directly comparable in safety significance to reactor tech specs, then the changes to the list of IROFS should require pre-approval by NRC. I do not believe that the staff will have a need to, or will actually perform, quarterly reviews of these reports. In addition, it is not clear why ISA Summary change information, if of interest to NRC, could not be reviewed during a routine or reactive inspection. Therefore, in the absence of a health and safety basis or concern with such changes, it is not clear that the burden to the licensee for quarterly reporting can be justified. The reporting frequency for these changes should be annual.

3. Backfit (10 CFR § 70.76) - I approve the staff's approach, both with regard to the timing of the applicability of the backfit provision (with one minor exception), and with regard to the standard that must be met for imposition of a backfit. For reasons discussed below, I would remove rulemaking from the definition of backfit. As to the timing, I would make whatever rule language modification is required to allow for the possibility that ISAs will be submitted and approved on a "piecemeal" basis. In such cases, the backfit provision may become effective at the time of NRC approval of each ISA summary for that portion of the facility. However, I share the concern expressed by Commissioner Merrifield and Chairman Meserve that the ISA was intended to provide an integrated analysis of all of the hazards at the facility, and this purpose should not be allowed to be frustrated by unnecessary segmentation.

   As for the standard that must be met for imposition of a backfit, I strongly oppose the addition of the word "substantial" to the test. As I wrote in previous votes, I believe in applying cost-benefit analysis to backfits, but the substantial increase test in 50.109 has proven to be an impediment to worthwhile regulation, regulation that provides modest increases in safety at minimum or inconsequential costs. The Chairman in his vote notes the "admitted ambiguity as to the increase in protection that is sufficient to constitute a "substantial increase." This is an understatement in my view.

   If one goes back to the 1985 revision of the 50.109 backfit rule (adopted by a 3 - 2 vote), the Commission majority attempted to explain the substantial increase standard in the Statements of Consideration as follows:

   "Substantial means 'important or significant in a large amount, extent, or degree.' Under such a standard, the Commission would not ordinarily expect that safety improvements would be required on backfits which result in an insignificant or small benefit to public health and safety or the common defense and security, regardless of implementation costs. On the other hand, the 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."

   The last sentence of this explanation is on its face inconsistent with the words in the rule. "Substantial" clearly connotes something more than a worthwhile improvement passing a cost-benefit test. Otherwise, the word "worthwhile" should have been substituted in the rule language. Commissioner Asselstine in his dissent dismissed the Commission majority's explanation of the substantial increase standard as "so unclear as to be useless." Ever since, as Commissioner Asselstine warned, this standard has proven to be a barrier to improved safety. It has put us at odds with foreign nuclear regulators, who do not have so strong an obstacle to worthwhile cost-beneficial backfits. It has the potential to make the two-edged sword of risk-informed regulation a single-edged sword, as critics argue.

   Commissions have periodically contemplated bringing the 50.109 rule into conformity with the worthwhile standard in the 1985 Statements of Consideration explanation. We had a recent reminder of the difficulty with the 50.109

substantial increase standard in the staff's analysis of, and our voting on, the final fitness-for-duty rule (SECY-99-279). As I noted in my vote on SECY-99-279, Commissioner Curtiss in 1993 advocated that the 50.109 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 public health and safety."

Given this history, adopting the substantial increase standard in a Part 70 backfit should not be done simply for consistency with Part 50 or Part 76. In SECY-99-147, the staff argued at some length why the "Part 70 regulations are much different than regulations to which backfit currently applies." One of the key parts of that discussion bears on the industry's desire for any backfit provision to be implemented using quantitative backfit analysis versus the staff's intent to use a qualitative backfit analysis. The staff stated their belief that "a quantitative determination of incremental risk may require a Probabilistic Risk Assessment, which the industry has strongly opposed in the past." We are adopting a final Part 70 rule which does not require quantitative PRA-quality ISAs. I support that (despite the concerns of ACNW and ACRS on this matter). But the substantial benefit standard for backfits, if adopted contrary to the staff's recommendation, implies a quantitative approach to backfit analysis. I continue to support the staff's proposal to use a qualitative non-monetary methodology to derive the value of safety/safeguards improvements. Industry should not be granted qualitative ISAs, but quantitative backfit methodology. Even under the rule as proposed, the staff warns us in Attachment 6 to SECY-00-0111 that "the staff anticipates that developing guidance on this issue (qualitative vs quantitative methodology) may be challenging and controversial." We will compound the controversy with a "substantial" increase standard.

Finally, I would remove rulemaking from the definition of a backfit. Commissioner Bernthal in his dissent on the 1985 50.109 rule eloquently presented the case against including rulemaking in that rule's definition of backfit. The heart of his argument (which I attach and associate myself with for purposes of this vote) is that there are very clear statutory procedures for rulemaking that ensure a disciplined process which is entirely in the Commission's hands already. There is no need for the addition of a backfit rule on top of that.

In crafting a backfit provision for Part 70, the Commission should not look merely for consistency with Part 50 (or the largely untried provision in Part 76). There are good and substantial reasons why a Part 70 provision should be different. There may well be good and substantial reasons to revisit the 50.109 rule (both its backfit standard and applicability to rulemaking) in light of 15 years experience with it as well.

4. § 70.62(d) minor edit - The word "graded" appears to have been inadvertently omitted from the rule language in the second sentence of subsection 70.62(d) as indicated here: "The measures applied to a particular engineered or administrative control system may be **graded** commensurate with the reduction of the risk attributable to that control or control system." (See the discussion of comment C.4 on page 20 which indicates the comment C.4 proposed text including "graded" was accepted into the rule text, and staff confirms this was inadvertently omitted.)

**Standard Review Plan (SRP):**

The staff should continue to work diligently with stakeholders to promptly finalize an SRP that reflects solid guidance on implementation of the new rule, but that avoids an overly prescriptive approach. I believe that continuation of the current process will lead to an effective guidance document, and that the effective date of the rule should not be delayed pending completion of the SRP. The SRP should be submitted to the Commission for information when finalized.

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## Attachment
## to Commissioner McGaffigan's Comments on SECY-00-0111

---------- Excerpt from 50 FR 38097, pages 38110-38111

**Views of Commissioner Bernthal**

I had fully expected to support the Commission's final rule on backfitting. Unfortunately, an eleventh-hour decision by the majority has added a destructive provision that at best can only confuse the public and our licensees by its misrepresentation of the role and options of the Commission in rulemaking; at worst it contains the seeds for rulemaking chaos, with litigative risks, unpredictability, and lengthened timetables that will result in more, rather than less uncertainty in the Commission's entire licensing and regulatory process. Such a backfitting rule is surely not in the public interest or in the interest of our licensees.

In a word, my principal quarrel with the rule adopted by the Commission is its inclusion of rulemaking in the definition of backfitting. Indeed, the mere idea of imposing its own rule on the statutory procedures for rulemaking as set forth in the Administrative Procedures Act should have given the Commission majority long pause, to say the least.

But in its apparent desire to appear to have voluntarily circumscribed its own authority and flexibility for rulemaking (when it cannot, of course, ultimately do so), the Commission has instead chosen to run the risk of creating new, legally binding requirements for rulemaking, requirements which will only widen the target for anyone seeking to challenge a final rule.

It is not even clear just who it is the Commission believes will be served by this action. Far from lending discipline and order to the rulemaking process, what the Commission majority has done will help insure that our often long and tortured consideration of rules will become even longer, more tortured, and more confusing. More ominously, should a future Commission find common-sense public health and safety measures unduly confused and obstructed by the backfit rule, it may in frustration choose simply to begin issuing by order "rules" that today would be subjected to the careful, disciplined process set forth in the Administrative Procedures Act.

The only rationale the majority has offered for wanting to include rulemaking under the backfit rule is to "discipline" the Commission (i.e., to protect the Commission from itself). If the Commission is incapable of disciplining itself in the rulemaking [pg 38111] process as it stands (what with the existing Committee to Review Generic Requirements and the Commission's incontestable authority and ineluctable responsibility to instruct the staff), then I doubt that rule laid upon rule will do much to teach the Commission the virtue of self-discipline.

More specifically, the Commission majority presumably knows that the backfit threshold criteria applied to rulemaking would apply not just on a plant- specific basis (which it should be recalled was the intent of the original backfitting initiative), but to generic decisions that may affect dozens of plants, and in fact to rulemaking on all but procedural matters, rulemaking that may or may not have the remotest connection to what the public and our licensees normally consider a plant "backfit". The scope of Commission rulemaking responsibilities thus often involves broad public policy considerations, and those considerations can rise above elements as simple as cost-benefit analysis to reach issues as fundamental as fairness and individual rights. The Commission's backfit rule, if applied to rulemaking itself, will thus serve only to trivialize in appearance and confuse in practice the many factors to be weighed in rulemaking.

As one small example of the morass into which the Commission majority has wandered, consider (as the Commission currently is considering) whether there should be a requirement that radiation workers be provided their dose records annually. The "benefit" of this "backfit" of Commission rules may seem clear, but it might very well never pass the cost-benefit test. Indeed, it is difficult to imagine a rule that would involve the human-factors element of plant operations, and that would also be amenable to straightforward cost- benefit analysis.

Rulemaking as it exists involves numerous inherent procedural checks and balances to insure that each proposal is carefully considered prior to adoption. Indeed, rulemaking is the forum which provides the greatest number of checks against arbitrary action by the Staff or Commission. Much of the analysis (including cost-benefit) which the new backfitting rule would require is already done informally throughout the process of considering and adopting new regulations.

If the Commission wishes to insure still more structure in the rulemaking process, structure which could take into account every single factor set forth in the backfit rule and more, there are ample means of doing so by simple internal agency management. Such methods would reaffirm existing Commission guidelines to the Staff without opening the door to additional needless litigation as a consequence of vague new, legally enforceable, Commission- created rights added to those already available to all parties under the APA.

The entire backfit rulemaking was undertaken to bring order and accountability to plant modifications heretofore sometimes imposed without the benefit of systematic evaluation and justification. In rulemaking per se, that objective has always been well within the Commission's grasp--it is, after all, the Commission that makes rules. For good measure, the Commission also has the Administrative Procedures Act as a matter of law, and its own Committee to Review Generic Requirements as a matter of internal administrative policy to assist it in carrying out such considered decision-making. Casting the net of the new backfit rule over Commission rule-making (almost as an afterthought, as it happened in this case) is thus at best an exercise in pointless symbolism, and at worst potentially destructive of the Commission's entire rule-making process.

Unneeded law is bad law, and unneeded regulation is bad regulation. The Commission majority has imposed on this agency new regulatory obligations in rulemaking that are not only unneeded, but which the Commission majority itself hopes and trusts will be of little practical (i.e. legally enforceable) consequence. To the extent that this rule will affect rulemaking, it will therefore be a bad rule. In sum, the Commission majority has inexplicably insisted on fixing not only what is, but what ain't broke. I will not be a party to such poor judgment.

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## Commissioner Merrifield

I approve, with modifications provided in the following paragraphs, the staff recommendations in SECY-00-0111 to publish a final rule amending 10 CFR Part 70, Domestic Licensing of Special Nuclear Material. But first, I want to commend the staff for its efforts to involve the public in both drafting the final rule and standard review plan to date. I recognize this task involved a great deal of extra effort on the part of the staff. But by allowing the public to have access to and make comments on the draft documents in an almost interactive mode involving both public meetings and the internet, I believe the staff has produced a far superior product over the initial draft.

A majority of the rule is fully satisfactory. However, there are a few sections requiring Commission guidance and my comments on those sections are as follows:

1. I approve the staff position that the ISA summary should be approved as part of the overall review process. In addition, I approve the staff position that the backfit provisions of the rule should not become effective for subpart H until the NRC approves the ISA summary. However, these two decisions are somewhat related. Strictly from reading the paper, my impression was that the staff anticipated one approval of the ISA summary at the end of the process. However from

the public meeting, presentations by the industry indicated that there were multiple, non-coupled ISAs anticipated to be submitted for each site. The staff indicated that they could do an individual approval for each independent ISA. I support the concept that if an individual ISA summary approval can be issued by the staff, then the backfit provisions should become effective at the time of issuance of the staff safety evaluation report for that specific ISA. My initial impression is that it would be more efficient for both the staff and the licensee to seek one approval at the end of the review. But if the licensee or applicant wants to seek individual approval for each ISA and the staff believes such an approach is feasible, I would support allowing the flexibility for approval of specific individual ISAs in the rule. However, I have a caveat to this support. Although it was portrayed at the meeting that these multiple ISAs for the site were non-coupled and therefore independent, the staff review should also focus on the site as a whole to ensure there are no synergistic effects that are not being properly addressed between the "independent" ISAs. The staff should make changes to the rule and/or statement of considerations, as appropriate, to clearly reflect this position.

2. Continuing with the backfit provision, industry has asked the Commission to add the term "substantial" as part of the qualifier for determining when changes providing an increased level of protection should be considered. I support the previous Commission decision to delete the term "substantial" from this definition. I recognize that the industry desires a qualifier when changes are necessary for increases in safety. I do not believe the word "substantial" provides a clear qualifier and only serves as an additional point of debate on whither a particular change is necessary. In fact, as part of the discussions on equivalent regulations for power reactors, the Commission extensively debated the differences in such words as "substantial" and "minimal". Industry is concerned about decisions the staff may make on marginal issues. However, there are provisions for appealing staff decisions through the EDO level and to the Commission, if appropriate. In addition, there are provisions for requesting exemptions to regulations, where appropriate. Given these two provisions, I believe industry has the ability to challenge marginal calls and the word "substantial" does not need to be added to this section of the regulations.

3. At the public meeting, NEI requested that the Commission consider publishing the final regulation but delaying its effective date until the Standard Review Plan is completed. After careful consideration, I approve leaving the effective date as proposed by the staff. I prefer a date certain for the rule. This is an important regulation and its effective date will initiate actions requiring four years or longer to complete. The current discussions between the industry and NEI do not significantly impact initial actions required of licensees. I prefer that the clock start on implementing these actions. However, the discussions between industry and the staff on the SRP should be completed in a timely manner; and the staff should report back to the Commission, by an information paper or a less formal mechanism, when the SRP is finalized. If significant disagreements raise between the staff and industry, they should be reported to the Commission.

4. As a final area for discussion, the staff has proposed a formal quarterly report to the NRC of changes to items relied on for safety when the changes do not require prior NRC approval. I believe these reports should be submitted on an annual basis, but additional effort is needed by the staff in two distinct areas. Staff makes a novel argument using the technical specifications for power reactors as an analog to require reporting of these changes quarterly. I have a problem with this analog because changes to technical specifications require prior NRC approval. If staff really believed changes to items relied on for safety were equivalent to technical specifications, the staff should have proposed that such changes require prior NRC approval. However, the staff stated that there were changes that could be made to items relied on for safety without prior NRC approval. If these changes do not require prior NRC approval, they should be treated in a manner equivalent to any change that does not require prior NRC approval, and an annual report is appropriate.

   The staff does have a valid concern that licensees may inappropriately make changes without prior NRC approval when in fact the change should have required prior NRC approval, particularly the first year or so after the ISA summary is approved. Typically the staff waits until it receives the annual report from a licensee (concerning changes made without prior NRC approval) before auditing the changes to determine if indeed they could be made without prior NRC approval. The staff may wish to consider conducting more frequent site audits until the staff has confidence that licensees are appropriately making changes under their authority. If licensees are inappropriately making changes that should require prior NRC approval, I would expect appropriate corrective action to occur.

   However, at the public meeting, information was provided that raises additional concerns and I would like staff follow-up for this issue. At the meeting, industry stated that, although they had no actual data to provide an exact response, they would expect 20 to 50 changes per quarter per site to items relied on for safety. This may be an issue of semantics, but I want the staff to follow-up with industry to obtain a better understanding of the statements. I can conceptually agree that for a new process there may be considerable adjustments during the first year of its operation. However, for existing processes that have been in operation for some period of time and which just had an ISA performed, I have a conceptual problem visualizing the need for 80 to 200 changes per year per site. If the licensee is making this many changes per year for items relied on for safety, where is the stability for the worker to know how to use this equipment? If the site is evolving this much, what is the reasonable assurance that equipment relied on for safety will be available when needed? As I stated, this may be an issue of semantics because the industry may have been thinking of changes so trivial that the NRC may have no concerns. However, I would like the staff to follow-up with industry to obtain a clearer understanding of this matter. As part of informing the Commission that the SRP is finalized, the staff should also inform the Commission of the results of its discussions on this matter and, if appropriate, any concerns or recommendations from the staff.