

RULEMAKING ISSUE NOTATION VOTE

July 23, 2001

SECY-01-0134

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FINAL RULE AMENDING THE FITNESS-FOR-DUTY RULE

PURPOSE:

To (1) request Commission approval of the recommended option (Option 3) to address stakeholder concerns regarding 10 CFR Part 26, "Fitness-for-Duty Programs," and (2) request Commission approval of the staff's plans to propose an interim enforcement policy to exercise enforcement discretion to resolve concerns about inconsistent implementation of current Part 26 requirements pending rulemaking.

SUMMARY:

A proposed amendment to the Fitness-for-Duty (FFD) rule was published on May 9, 1996. After consideration of public comment, a final rule was affirmed by the Commission on December 4, 2000. When the NRC staff sought clearance from the Office of Management and Budget (OMB) to publish the affirmed final rule, the Nuclear Energy Institute (NEI) objected and expressed a number of concerns regarding the affirmed final rule.

The staff has identified three options for resolving issues with the affirmed final rule.

- Option 1 would involve obtaining OMB clearance and issuing the affirmed final rule essentially as it is. Revised guidance would then be issued to address some of the issues. The rule would be implemented 120 days after the revised guidance is issued.
- Option 2 would involve withdrawing the OMB clearance request, making changes to the affirmed final rule as necessary to address the issues, and publishing a supplemental notice of proposed rulemaking. The supplemental notice would request comments only on the changed provisions.

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- Option 3 would also involve withdrawing the OMB clearance request and making changes to the affirmed final rule as necessary to address the issues. However, under Option 3 the Commission would publish a new notice of proposed rulemaking. The new notice would request comments on all aspects of the rule.

Option 1 would limit the Commission's ability to deal with the issues. The staff recommends Option 3 because it provides the greatest benefits in terms of public confidence, as well as clarity, efficiency, and effectiveness of the rule, and does not involve significantly more delay than Option 2. Option 3 also provides an opportunity to combine the guidance that is common to both FFD and access authorization. Option 3 will take 6 months longer than Option 2 because (1) a proposed rule rather than a supplementary rule will be noticed for public comment and (2) the entire rule will be noticed as opposed to only the changed provisions being noticed for public comment.

In public meetings with stakeholders held this year, the staff has learned of two common practices which the staff contends are not in compliance with the current FFD rule. After reviewing these practices, the staff believes that in suitable cases enforcement discretion is appropriate, pending issuance of a final rule which addresses these matters. To be eligible for enforcement discretion, a licensee should meet or exceed two specific criteria, discussed in further detail below, which the staff believes to be acceptable for the long term. If the Commission approves this plan, the staff will prepare an appropriate enforcement policy statement for Commission approval.

The staff requests a Commission response by August 10, 2001, in order to provide timely information to OMB regarding withdrawal of the pending OMB clearance request.

BACKGROUND:

The proposed rule was published in the *Federal Register* on May 9, 1996 (61 FR 21105). The public comment period expired August 7, 1996. The final rule was submitted to the Commission on June 4, 1999 (SECY-99-141). However, SECY-99-141 was withdrawn to address three issues. The staff resubmitted the final FFD rule (SECY-99-279) to the Commission on December 6, 1999. By Staff Requirements Memorandum (SRM) dated July 5, 2000, the Commission returned SECY-99-279 to the staff. The Commission requested that the staff modify the FFD rulemaking package as follows: (1) remove the requirement imposing a more restrictive temperature range for an acceptable urine specimen (Sections 2.4(g)(13) and (15) of Appendix A) and (2) remove the requirement that a medical determination of fitness be performed to evaluate all employees tested for cause, including those who test negative, from the rulemaking package. In addition, the Commission directed that the staff should, in coordination with the Office of the General Counsel (OGC), modify the analysis on compliance with the Backfit Rule to consider all the changes separately, and also in the aggregate, including those previously proposed as "worthwhile" changes. The rulemaking package was modified and resubmitted to the Commission. In a SRM dated December 4, 2000, the Commission approved final rule changes to 10 CFR Part 26, "Fitness-for-Duty Programs" (SECY-00-0159).

The document announcing OMB review and requesting public comment on the information

collection requirement contained in the FFD final rule was published in the *Federal Register* on February 2, 2001 (66 FR 8812). By letter dated March 5, 2001, the NEI provided comments to OMB and objected to issuance of the final rule. Because of stakeholder concerns and questions about implementation of the final rule, the staff met with stakeholders March 20-22, 2001, to discuss implementation questions, and again on May 8, 2001, to more fully understand their concerns about the rule.

DISCUSSION:

OMB Clearance Issues

By letter dated March 5, 2001, NEI submitted comments to OMB on the FFD final rule clearance package, recommending that OMB withhold clearance because of several concerns. One of NEI's primary concerns was the NRC's estimate that the FFD rule would reduce the total industry-wide cost for all licensees by about \$27 million annually. NEI estimated that the rule would cause licensees industry-wide to spend approximately \$8 million more annually than they spend on their current programs. NEI also had the following objections to the final rule, claiming:

- The NRC changed its interpretation of an existing regulatory requirement that a suitable inquiry, that is, verification of employment history for FFD purposes, be conducted on all individuals covered by an FFD program.
- Proposed 10 CFR 26.27(a)(4) would require that a medical determination of fitness be performed for all individuals with a history of substance abuse, resulting in an unnecessary burden.
- The NRC maintained an opiate cutoff level of 300 nanograms per milliliter (ng/mL), whereas the Health and Human Services (HHS) opiate cutoff level is 2000 ng/mL.
- The NRC did not articulate a compelling basis for requiring licensees to audit laboratories that receive a certification from HHS.

The NRC staff met with the OMB desk officer on April 12, 2001, to discuss the NRC's plan for addressing NEI's comments and to request that OMB allow the NRC additional time to resolve the industry's concerns. The OMB desk officer granted additional time to engage stakeholders and obtain Commission direction on how to proceed with the clearance. On June 5, 2001, the NRC staff informed the OMB desk officer that the NRC was considering withdrawing the FFD rule clearance request, pending formal Commission guidance after review of the staff's written proposals.

Additional Stakeholder Issues

The NRC staff held a public workshop March 20-22, 2001, with NEI and other stakeholders. The purposes of the workshop were to: (1) convey the final rule changes; (2) identify implementation questions, issues, and concerns relative to the final FFD rule; (3) provide provisional answers to all the questions the staff had received from stakeholders before the workshop; and (4) receive comments on the rulemaking plan for reducing the scope of random

FFD drug and alcohol testing (SECY-00-0022). In addition to the issues raised in NEI's letter to OMB as summarized above, stakeholders raised the following concerns during the workshops:

- The rule allows authorization of access upon completion of 1 year's suitable inquiry, provided a suitable inquiry has been "initiated" for the remaining 4 years. A definition of the term "initiated" is needed.
- Stakeholders desire credit for prior suitable inquiries.
- Clarifications are needed for return-to-duty testing and suitable inquiry requirements for someone returning for duty after being absent from the program for more than 60 days.
- Increased requirements to check for history of substance abuse and to have a medical determination of fitness will create significant problems and costs.
- Consistency is needed between FFD and access authorization requirements.
- The revised guidance should be issued in parallel with the final rule.

After the March 20-22, 2001, workshop, the NRC received a letter dated April 2, 2001, from a former NRC employee, Mr. Loren Bush. Mr. Bush requested that the Commission restore the language of 10 CFR 26.10(c) prior to issuance of the final rule or consider his letter a petition for rulemaking under the provisions of 10 CFR 2.802. Currently 10 CFR 26.10(c) requires FFD programs to "have a goal of achieving a drug-free workplace and a workplace free of the effects of such substances." This objective was removed from the final rule. By letter dated April 24, 2001, the NRC staff responded to Mr. Bush's letter. The staff concluded that removal of 26.10(c) was appropriate and that, since the final rule had not been implemented, it would be inappropriate to treat Mr. Bush's letter as a petition for rulemaking.

On May 4, 2001, Mr. Bush sent a second letter objecting to the staff's conclusions and provided additional information in support of restoring the language of 10 CFR 26.10(c). By letter dated June 6, 2001, the staff informed Mr. Bush that it plans to address his concern regarding 10 CFR 26.10(c) along with the other stakeholders' concerns.

On May 8, 2001, the NRC staff and management held a second public meeting with NEI and other external stakeholders to better understand key issues that had been raised by the industry regarding changes to the FFD rule and how those issues might be resolved.

On June 12, 2001, the NRC staff and management held a public meeting with NEI personnel to discuss the industry's Personnel Access Data System (PADS). The NEI personnel explained that PADS is a standardized approach for in-processing of nuclear plant workers through the establishment of a computer-based national personnel data system. In addition, the NEI personnel discussed the following industry documents that provide guidance for implementing PADS and meeting the intent of NRC's fitness-for-duty and access authorization requirements: NEI 95-01, "Nuclear Power Plant Personnel Access Authorization Standards and Procedures"; NEI 94-02, "Standard Audit Process for Licensee-Approved Contractor/Vendor Access Authorization/Fitness-for-Duty Programs"; NEI 95-03, "PADS Health Physics Standards and

Procedures”; and NEI 95-04, “Guideline for General Plant Access Training.” The NEI personnel explained that NEI 95-01 was submitted to the NRC staff. However, because the NRC staff and NEI could reach agreement on only portions of NEI 95-01, it was not approved by the staff. This discussion helped to explain why the NRC staff and the industry have different interpretations of the Part 26 requirement for a suitable inquiry for periods of employment for less than 30 days as discussed further in the next section.

During the public meeting on June 12, 2001, the NRC staff and NEI personnel explored the possibility of stakeholders developing a document containing guidance for both FFD and access authorization. The guidance document would then be submitted to the NRC staff for review and, if approved, endorsed via a regulatory guide. This new approach would (1) supersede all previous guidance documents, (2) achieve consistency and greater clarity in FFD and access authorization requirements, (3) reduce unnecessary regulatory burden, and (4) eliminate the need for a cumbersome FFD question and answer document like NUREG-1385. The staff’s recommendations regarding other Part 26 activities (e.g., fatigue-related impairment as an FFD concern) are discussed below under “Options for FFD Final Rule.”

The Attachment summarizes key stakeholder concerns raised in NEI’s March 5, 2001, letter to OMB as well as the other stakeholder interactions described above. It also provides a summary of the staff’s response and proposed resolution for each concern.

Options for FFD Final Rule

In evaluating stakeholder concerns with the final rule, the staff identified three categories of concerns. Concerns in the first category may be resolved in a guidance document and/or by changing the rule without renoticing. The second category requires further stakeholder interaction to more fully understand the exact costs and benefits and to determine the appropriate resolution of the stakeholder issues. The third category requires rule changes that must be renoticed. The table in the attachment identifies key stakeholder concerns in each category. On the basis of this evaluation of stakeholder concerns, the staff developed the following three options for resolving stakeholder concerns:

- (1) Option 1—Obtain OMB clearance and publish the rule with an effective date of 120 days after the revised guidance is issued. It is estimated that the final rule would be issued by November 30, 2001, and the revised guidance would be issued by June 28, 2002. This option takes advantage of those burden reductions that are undisputed by stakeholders and enhancements of the approved rule at the earliest opportunity. Specifically, Option 1 would provide enhancements to the current rule earlier than the other options. Option 1 would resolve the issues regarding pre-access testing discussed below, but it would not address suitable inquiry. Also it would not address numerous other industry concerns, such as the clarity of certain requirements and the potential for unnecessary burdens resulting from unintended consequences of the rule.
- (2) Option 2—Withdraw the OMB clearance request, make changes to the rule with appropriate stakeholder interaction, and publish a supplementary notice (i.e., request comments only on the changed provisions). After obtaining OMB clearance, it is estimated that the final rule and guidance would be issued by December 31, 2002.

This option would take 6 months longer than Option 1 to rewrite sections of the rule, meet with stakeholders at least twice, and respond to public comments on changed provisions. This option allows the Commission to enhance public confidence by clearly resolving in the rule certain stakeholder concerns that cannot be addressed in the guidance. However, this option defers implementation of the burden reductions and enhanced protection (e.g., validity testing) of the approved rule and will result in a lengthy and complex final rulemaking package.

- (3) Option 3—This option would be similar to Option 2 because the NRC would withdraw the OMB clearance request and make changes to the rule with appropriate stakeholder interaction. However, under Option 3 the notice of proposed rulemaking would request comments on all of the rule's provisions. After obtaining OMB clearance, it is estimated that the final rule and guidance would be issued by June 30, 2003. This option would take 6 months longer than Option 2 to rewrite sections of the rule, meet with stakeholders at least three times, and respond to public comments on the entire rule. Additional time is needed to complete Option 3 to (1) address a greater number of public comments and (2) meet with stakeholders concerning a combined access authorization and FFD guidance document. As with Option 2, Option 3 allows the Commission to clearly resolve in the rule certain stakeholder concerns that cannot be addressed in the guidance. Since the public's opportunity to comment on the proposed rule ended five years ago, allowing public comment on the entire rule at this time (Option 3) would be more beneficial in terms of public confidence. This would also be more beneficial in terms of the clarity, efficiency and effectiveness of the rule, because commenters may suggest improvements in areas other than those that the staff proposes to change.

The NRC staff believes that Option 3 provides opportunities for combining efforts. As discussed previously, the NRC staff is currently reviewing a number of industry-proposed changes to the industry guidance that is endorsed by Regulatory Guide 5.66 (which applies to access control requirements in §73.56). Industry representatives have stated, and the staff agrees, that the access control guidance for §73.56 should be consistent with the access control guidance for Part 26. For example, it makes sense that the number of previous employers contacted for a background check under §73.56 should be the same as the number contacted for a suitable inquiry under Part 26. In addition, as discussed above, industry representatives are interested in drafting a combined guidance document, which could then be endorsed by the NRC in a regulatory guide. Under Option 3 the staff plans to pursue this approach.¹

The staff recommends that outstanding issues regarding the scope of Part 26 (SECY-00-0022) continue as a separate effort to be coordinated but not combined with the FFD rulemaking. The International Brotherhood of Electrical Workers (IBEW) has requested an exemption to the scope of Part 26 for certain workers at Diablo Canyon. The exemption would exclude clerical workers at Diablo Canyon from random drug and alcohol testing who have unescorted access to the protected area but who (1) do not perform any safety-related duties and (2) do not have unescorted access to the plant's vital areas. The current scope of Part 26 applies to persons with unescorted access to the protected area. Any advantages (e.g., a single *Federal Register* notice could address both efforts) or disadvantages (e.g., substantial industry opposition to reducing the scope of Part 26 may hinder issuance of an FFD final rule within the

¹ In the event this approach is not completed soon enough to support timely implementation of the final rule, the staff can issue enough guidance to support implementation.

proposed time frame) in combining the scope activity with the FFD rulemaking will ultimately depend on the Commission's decision on the exemption request.

The staff also recommends that the fatigue-related impairment effort (SECY-01-0113) continue as a separate activity, to be coordinated with the FFD rulemaking, but not combined with it. The fatigue-related impairment effort is at an early stage of development in that the Commission is reviewing a rulemaking plan. If the fatigue-related impairment effort were combined with the FFD rulemaking at this time, it would probably hinder issuance of the final FFD rule as a result of its early stage of development, as well as issues related to the backfit and regulatory analyses.

The staff does not plan to prepare a rulemaking plan in connection with any of these options for the following reasons. Option 1 would involve publishing the final rule that has been approved by the Commission. Under Option 2 or 3, the proposed (renoticed) rule would maintain most of the provisions of the previously approved final rule and, thus, would not represent a significant change in direction. If future developments result in a significant change in direction, such that Commission review and approval of a rulemaking plan is appropriate, the staff will submit one.

Goals of the NRC

The three options also were considered relative to the performance goals of the NRC Strategic Plan (NUREG-1614).

GOALS OF THE NRC	OPTIONS		
	1	2	3
	Issue Rule and Guidance	Revise Rule, Renotice Only the Changed Provisions of the Rule, and Issue Rule and Guidance	Revise Rule, Renotice All Provisions of the Proposed Rule, and Issue Rule and Guidance
Maintain Safety	X	X	X
Increase Public Confidence		X	XX*
Increase Efficiency and Effectiveness		X	XX*
Reduce Unnecessary Regulatory Burden	X	XX*	XX*

*XX indicates a stronger effect than X.

All three options would maintain safety and reduce unnecessary regulatory burden. The unintended consequences associated with Option 1 decrease the expected reductions in unnecessary regulatory burden, as compared to Options 2 and 3. Options 2 and 3 would both increase efficiency and effectiveness and increase public confidence by providing timely stakeholder involvement in the development of the rule and the implementing guidance and by achieving greater clarity in the final rule. Since the public's opportunity to comment on the proposed rule ended five years ago, allowing public comment on the entire rule at this time

(Option 3) would be more beneficial in terms of public confidence. This would also be more beneficial in terms of the clarity, efficiency and effectiveness of the rule because commenters may suggest improvements in areas other than those that the staff proposes to change.

Recommended Option

Option 1 would limit the Commission's ability to address several stakeholder concerns. Options 2 and 3 have similar merits that Option 1 does not provide (e.g., increase public confidence, clarity, efficiency, and effectiveness of the rule). The staff recommends Option 3 because it provides the greatest benefits in terms of public confidence, as well as clarity, efficiency, and effectiveness of the rule, and will not involve significantly more delay than Option 2. Option 3 also provides an opportunity to combine the guidance that is common to both FFD and access authorization. Option 3 will take 6 months longer than Option 2 because (1) a proposed rule rather than a supplementary rule will be noticed for public comment and (2) the entire rule will be noticed as opposed to only the changed provisions being noticed for public comment.

Staff's Approach to Address Inconsistent Implementation of 10 CFR Part 26 Requirements

As a result of discussions at the public workshop of March 20-22, 2001, discussed above, the staff identified concerns about whether licensee practices in two FFD areas met the current Part 26 requirements. These practices, and the staff's proposals for addressing them while the rulemaking is being completed, are as follows:

(1) Suitable Inquiry

In conducting a suitable inquiry prior to granting unescorted access, it appears that many licensees do not contact the employers where a candidate was employed for less than 30 days. The NRC staff contends that this practice conflicts with §§26.3 and 26.27(a)(2).

Paragraphs 26.3 and 26.27(a)(2) require that before granting unescorted access a licensee must conduct a suitable inquiry consisting of a "best-effort verification of employment history for the past five years, but in no case less than three years, obtained through contacts with previous employers to determine if a person was, in the past, tested positive for illegal drugs, subject to a plan for treating substance abuse, removed from, or made ineligible for activities within the scope of 10 CFR Part 26, or denied unescorted access at any other nuclear power plant or other employment in accordance with a fitness-for-duty policy." These paragraphs do not provide an exception regarding short-term employers.

In Regulatory Guide 5.66 (1991), "Access Authorization Program for Nuclear Power Plants," the NRC endorses the practice of contacting only employers where the candidate was employed for 30 days or more. Regulatory Guide 5.66 applies only to the requirement to conduct a background investigation pursuant to §73.56(b)(2)(i), rather than the suitable inquiry required by §26.27(a)(2). Although the requirements are separate, licensees have maintained, and the staff agrees, that it makes sense to follow the same practice for one rule as for the other. A suitable inquiry is very similar

to a background check. It merely involves asking questions about drug and alcohol use rather than questions about reliability. In fact, a licensee typically contacts a previous employer only once and asks both sets of questions at that time.

In addition, in the 1996 proposed amendment to Part 26, the NRC proposed to add language that would specifically exclude the need to contact employers of less than 30 days duration. The fact that the NRC had proposed to specifically endorse the practice may have contributed to some licensees' belief that it was acceptable to exclude contacting employers of less than 30 days duration.

The NRC staff is currently reviewing a number of industry-proposed changes to the guidance endorsed by Regulatory Guide 5.66, including an industry proposal to adopt the following practice: "If the applicant has periods of less than 30 days of contiguous employment/unemployment, at least one of the periods of employment/unemployment must be verified for each 30-day period." For example, assume that during the month of April a transient worker was: employed by Employer A for two weeks; employed by Employer B for one week; and unemployed for one week. Under the proposed guidance it would only be necessary to verify one of the following periods for the month of April: employment with Employer A; employment with Employer B; or unemployment.

Because this practice requires at least one contact for each 30-day period, the NRC staff believes it provides an acceptable method of conducting a suitable inquiry. Neither the current rule nor the affirmed final rule provides an exception for short-term employers. Nevertheless, by requiring at least one contact for each 30-day period, this practice would provide for a reasonable amount of inquiry in a cost-effective manner. Therefore, pending publication of a final revision to Part 26 which addresses this matter, the staff plans to propose an interim enforcement policy to authorize the exercise of enforcement discretion for licensees that follow this practice and issue a generic communication to make the NRC's expectations clear in this area. Consistent with the belief that this proposed practice provides an acceptable method of conducting a suitable inquiry, the staff plans to propose a relaxation in the wording of Part 26 to allow the practice. Since this would constitute a "voluntary relaxation" it would not be a backfit.

In a parallel activity, the staff is currently planning to endorse the proposed new practice via a revision to Regulatory Guide 5.66, which applies to Part 73. The proposed new practice involves more than licensees are currently required to do under Part 73, as documented in the current version of Regulatory Guide 5.66. Thus, backfitting considerations will need to be addressed in connection with the revision to Regulatory Guide 5.66 when it is proposed (assuming that events occur as currently planned).

(2) Pre-Access Testing

Prior to granting unescorted access to a candidate for reinstatement or transfer, some licensees apparently do not conduct a pre-access test for alcohol and drugs if the candidate has recently been covered by a Part 26 FFD program (e.g., within the past 30 days). But the fact that a candidate was recently covered does not necessarily mean the candidate was recently tested for drugs and alcohol. Thus, this practice conflicts

with §26.24(a)(1) and the applicable provisions of the NRC's guidance in NUREG-1385, "Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions." The rule and guidance state that an applicant must be tested for drugs and alcohol "within 60 days prior to the initial granting of unescorted access." They do not provide an exception for a reinstatement or transfer where there is little or no break in coverage under a Part 26 FFD program.

However, there is confusion among licensees regarding what is permitted under Part 26 to meet the pre-access testing requirement. Some licensees omit pre-access testing for candidates who have been covered by a Part 26 FFD program within the past 30 days because they view FFD initial screening as being the same as access authorization initial screening. Access authorization initial screening is completed once and, as long as continuous behavioral observation is maintained, the initial screening is not repeated.

It is reasonable that short breaks in coverage for a reinstatement or a transfer should be treated similar to the case of continuous coverage. For example, a worker who is continuously covered but absent from behavioral observation and the possibility of random testing while on vacation for two or three weeks is generally not given a pre-access test upon return. Also, the practice of omitting the pre-access test when the break in coverage is less than 30 days is similar to NRC's practice in related areas. For example, using the guidance endorsed by Regulatory Guide 5.66, licensees generally do not conduct a background check under §73.56 for a candidate for reinstatement or a transfer when the gap in coverage is less than 30 days. In another example, using the guidance in NUREG-1385, an individual covered by a contractor's FFD program may take a (reasonably short) period of time to transfer from one site to another without invoking the need for a pre-access test. Finally, the affirmed final rule (Part 26), if implemented, would allow a similar exception. It would state that: "Pre-access testing for drugs and alcohol must be conducted within 60 days before the granting of unescorted access to protected areas or assignment to activities within the scope of this part unless the individual: (A) Has been covered by a program meeting the requirements of this part for at least 30 days during the 60 days immediately previous to the granting of unescorted access, and (B) Has no history of substance abuse."²

On the basis of these considerations, the NRC staff has concluded that it is acceptable to omit the pre-access test for alcohol and drugs where a candidate for reinstatement or transfer has been covered by a Part 26 FFD program for at least 30 of the previous 60 days and has not, in the past, been: tested positive for illegal drugs; subject to a plan for treating substance abuse; removed from or made ineligible for activities within the scope of Part 26; or denied unescorted access at any other nuclear power plant or other employment in accordance with a fitness-for-duty policy. This is the equivalent,

2

History of substance abuse is a new term that is currently undefined but would be defined under the affirmed final rule if implemented. It is roughly equivalent to the following terminology under the current rule: "tested positive for illegal drugs; subject to a plan for treating substance abuse; removed from or made ineligible for activities within the scope of Part 26; or denied unescorted access at any other nuclear power plant or other employment in accordance with a fitness-for-duty policy."

under the current rule, of what the affirmed final rule would allow if implemented. Also, it is equivalent to the case where an individual is continuously covered and, as a result, drug and alcohol testing is not required when the individual returns to the site after a reasonable period of absence, such as a vacation. Thus, it fulfills the purposes of the current rule and, pending publication of a final amendment to Part 26 which addresses this matter, the staff plans to propose an interim enforcement policy to authorize the exercise of enforcement discretion for licensees that follow this practice and issue a generic communication to make the NRC's expectations clear in this area.

In the case of suitable inquiry, the allowed practice would require at least one contact for each 30-day period to provide a reasonable amount of suitable inquiry in a cost-effective manner. In the case of pre-access testing, the allowed practice, which applies to a candidate for reinstatement or transfer, would be the equivalent of allowing a continuously covered worker to return from a few weeks of vacation without taking a pre-access test. Also, it is the same as what would be allowed under the affirmed final rule. Based on these factors, and its judgment that both practices are fully acceptable, the NRC staff considers the risk associated with issuing an interim enforcement policy to authorize the use in suitable cases of enforcement discretion pending rulemaking to be insignificant. If the Commission approves this plan, the staff will prepare an interim enforcement policy statement for Commission approval. The staff plans to propose that the policy take effect upon issuance.

An alternative approach would be to grant exemptions rather than enforcement discretion. However, granting exemptions would be resource intensive because a separate exemption would have to be issued for each licensee that does not comply with the current rule.

Public/Industry Participation

This rulemaking will continue to use the interactive rulemaking Web site, as appropriate, and public meetings to encourage public participation.

COORDINATION:

OGC has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

RESOURCES:

The NRR resources to address the issues raised by stakeholders are estimated to be 1.5 FTE for Option 1 (rule expected to be completed by November 30, 2001, and guidance by June 28, 2002), 2.5 FTE for Option 2 (guidance and rule expected to be completed by December 31, 2002), and 3.0 FTE for Option 3 (guidance and rule expected to be completed by June 30, 2003). The NRR FTE stratified by fiscal year (FY) and option is:

OPTION	FY 01	FY 02	FY 03	TOTAL
1	0.4	1.1	-	1.5
2	0.4	1.7	0.4	2.5
3	0.4	1.4	1.2	3.0

The NRC resources (i.e., OGC, OE, and NMSS) are estimated to be 0.3 FTE greater than the NRR resources. In addition, contractor support is estimated to be about \$85,000 for Option 1, \$123,000 for Option 2, and \$168,000 for Option 3.

The NRR contractor support depicted by FY and option is:

OPTION	FY 01	FY 02	FY 03	TOTAL
1	\$21,250	\$63,750	-	\$85,000
2	\$20,910	\$81,180	\$20,910	\$123,000
3	\$21,840	\$80,640	\$65,520	\$168,000

The previously discussed resources are not currently budgeted and will be reprogrammed using the Planning, Budgeting, and Performance Management process.

NRR Technical Lead: Garmon West, Jr.

NRR Rulemaking Support: Dennis Allison and Sandra Frattali

OGC Contact: Geary S. Mizuno

RECOMMENDATIONS:

That the Commission:

1. Approve the recommended option (Option 3) as discussed above.
2. Approve the staff's plans to propose an interim enforcement policy to authorize the exercise of enforcement discretion pending rulemaking for licensees that follow certain practices as discussed above under the headings "Suitable Inquiry" and "Pre-Access Testing."
3. Note that:
 - a. The staff plans to propose that the interim enforcement policy take effect upon issuance.
 - b. Public comments would be requested at the proposed rulemaking stage concerning the request by Mr. Bush to restore the language of 10 CFR 26.10(c).
 - c. The staff will propose that the final rule become effective 120 days after issuance of the associated guidance (to be developed in parallel with the rule).
 - d. The staff is currently preparing a related paper for the Commission, "Fatigue of Workers at Nuclear Power Plants." The paper proposes options for responding to a petition for rulemaking (PRM-26-2) that requests amendment of Part 26 to address personnel fatigue as a fitness-for-duty concern. The staff will

coordinate, as appropriate, the resolution of PRM-26-2 with the revisions to 10 CFR Part 26 that are proposed in this paper.

SCHEDULE:

The staff requests a Commission response by August 10, 2001, in order to provide timely information to OMB regarding withdrawal of the pending OMB clearance request.

/RA by William F. Kane Acting For/

William D. Travers
Executive Director
for Operations

Attachment:
Industry's Major Issues With the FFD Rule

3. Note that:

- a. The staff plans to propose that the interim enforcement policy take effect upon issuance.
- b. Public comments would be requested at the proposed rulemaking stage concerning the request by Mr. Bush to restore the language of 10 CFR 26.10(c).
- c. The staff will propose that the final rule become effective 120 days after issuance of the associated guidance (to be developed in parallel with the rule).
- d. The staff is currently preparing a related paper for the Commission, "Fatigue of Workers at Nuclear Power Plants." The paper proposes options for responding to a petition for rulemaking (PRM-26-2) that requests amendment of Part 26 to address personnel fatigue as a fitness-for-duty concern. The staff will coordinate, as appropriate, the resolution of PRM-26-2 with the revisions to 10 CFR Part 26 that are proposed in this paper.

SCHEDULE:

The staff requests a Commission response by August 10, 2001, in order to provide timely information to OMB regarding withdrawal of the pending OMB clearance request.

/RA by William F. Kane Acting For/
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 Executive Director
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Attachment:

Industry's Major Issues With the FFD Rule

DOCUMENT NAME: C:\Program Files\Adobe\Acrobat 4.0\PDF Output\SP01-0134.wpd

OFFICE	Tech. Ed	RSS:DIPM	IQMB:DIPM	DRIP:NRR	PPRB:NRR	IOLB:DIPM	D:DIPM	OGC
NAME	PKleene*	GWest*	DDorman*	WBeckner*	MCase* via e-mail	GTracy*	BABoger*	STreby*
DATE	6/18/01	6/11/01	6/14/01	7/05/01	7/06/01	6/21/01	6/25/01	7/13/01
OFFICE	OCIO	OCFO	ADM	OE	A/D:IP:NRR	D:NRR	EDO	
NAME	BShelton* via e-mail	JFunches* via e-mail	MLesar*	JLuehman*	RBorchart*	SCollins*	WTravers	
DATE	7/02/01	7/06/01	6/28/01	7/13/01	7/ 18/01	7/18/01	07/23/01	

* = SEE PREVIOUS CONCURRENCE.

OFFICIAL RECORD COPY

ATTACHMENT

**INDUSTRY'S MAJOR ISSUES WITH
FINAL FITNESS-FOR-DUTY RULE**

MAY BE RESOLVED VIA GUIDANCE AND/OR RULE CHANGE WITHOUT RENOTICE	
Industry Issue	Staff Response
Rule should allow combining partial samples to get the required volume for HHS analysis. Otherwise, an added expense with reduced gain.	No change is required. NRC staff agreed with comments on the proposed rule that objected to combining because it may lower the concentration of a drug. Further, HHS guidelines do not allow this practice.
Medical professionals other than a licensed physician should be allowed to determine if a history of substance abuse “raises a concern.”	Clarify in revised guidance that the rule allows a medical person other than a state-licensed physician to evaluate whether a history of substance abuse “raises a concern.”
Reevaluate NRC’s regulatory analysis indicating \$27 million savings in light of industry’s estimate of \$8 million cost increase.	Detailed reevaluation still indicates <i>savings</i> of about \$15 million.
New rule requires audits of certified labs.	The current rule requires audits. The staff proposes to only require audits for areas not covered by the HHS certification process.
Rule includes FFD personnel in program.	The NRC staff continues to agree with the intent of the rule which was that personnel who administer FFD programs must be covered by Part 26. Address implementation aspects in guidance.
The term “history of substance abuse” is pejorative and may incorrectly label some workers in the nuclear industry as substance abusers.	The identification of individuals in this category is needed to provide the intended relief for persons with no history of substance abuse. The staff will consider minor changes to the term.

RESOLUTION REQUIRES FURTHER STAKEHOLDER INTERACTION	
Industry Issue	Staff Response
History of substance abuse creates a new class of workers and no relief.	The creation of a new class of workers provides relief from current requirement for negative test result before access for workers with no history. However, the cost-benefit is not clear. Industry perceptions of excessive cost may be partially based on misunderstandings.
History of substance abuse creates tracking burden.	The burden may be necessary to allow relaxation from a current requirement for negative test result before granting unescorted access for workers with no history of substance abuse.
Change opiate cutoff level of 300 ng/mL to HHS standard of 2000 ng/mL.	Reconsider 2000 ng/mL in light of the following information: <ul style="list-style-type: none"> a. Confirmed positives over the last 11 years run about 0.01% of all tests (mean of 21 per year). b. At a cutoff level of 2000 ng/mL, most of these would be missed. c. The cases missed would almost entirely be nonprescription use of prescription drugs such as Tylenol 3 or cough syrups with codeine.
It is impossible to complete all suitable inquiries within 72 hours.	This new requirement could be clarified in guidance. The intent was to provide relief in "return-to-duty" cases. Industry perceptions of excessive burden may be based on misunderstandings. Further dialogue is needed.

RESOLUTION REQUIRES RULE CHANGE WITH RENOTICE	
Industry Issue	Staff Response
Rule requires verification of all employment periods, including less than 30 days.	The staff believes this is currently required under Part 26. The industry's position is based upon Regulatory Guide on access authorization. Any revision would require a rule change.
Allow credit for prior licensee's suitable inquiry.	Credit is currently not allowed. Industry did not suggest credit during proposed rule comment period. Credit would require a rule revision.
Allow credit for prior licensee's medical determination of fitness.	Credit is currently not allowed. Credit would require a rule revision.
Requirements for FFD should be consistent with access authorization requirements.	Agree. Currently consistent except for suitable inquiry. NEI's proposal dated 12/2000 is under staff review.
Medical determination of fitness for <i>all</i> individuals with a history of substance abuse creates an unnecessary burden.	Clarify rule to state that a medical determination of fitness would only be required if there was a "concern about the person's history of alcohol or drug use."
Rule does not allow shared audits of HHS-certified laboratories.	Consider shared audits and revise rule to permit them.