



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

PDR

April 1, 1999

MEMORANDUM TO: William D. Travers  
Executive Director for Operations

FROM: Joseph A. Murphy, Chairman  
Committee To Review Generic Requirements *Joseph A. Murphy*

SUBJECT: MINUTES OF THE CRGR MEETING NUMBER 315

The Committee To Review Generic Requirements (CRGR) met on Friday, February 13, 1998, from 9:00 a.m. to 12:00 p.m. Attachment 1 contains a list of attendees.

J. Roe and L. Bush, both of NRR, briefed the Committee on the historic perspectives and backfit aspects of the proposed final amendments to the Fitness For Duty Rule (10 CFR Part 26). Attachments 2-A and 2-B contains the material distributed by the staff at the meeting. The Committee made various comments and expressed an interest in a formal review at a later date.

R. Lee Spessard and M. Bugg, both of NRR, presented for CRGR review and endorsement the proposed generic letter on guidance on the storage, preservation, and safekeeping of quality assurance records in electronic media. Attachment 3 contains the presentation material used by the staff. The Committee endorsed the proposed generic letter subject to minor comments.

R. Lee Spessard, S. Black and R. Correia, all of NRR, briefed the CRGR on the proposed amendments to 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." Attachment 4 contains the presentation material used by the staff. The Committee offered various comments and recommendations, and to support the expedited schedule, accepted the staff's request to review the proposed amendments at the final rulemaking stage.

In accordance with the EDO's July 18, 1983 directive concerning "Feedback and Closure of CRGR Review", a written response is required from the cognizant office to report agreement or disagreement with the CRGR recommendations in these minutes. The response is to be forwarded to the CRGR Chairman and if there is disagreement with the CRGR recommendations, to the EDO for decision making.

Roal

PDR REV G.P.

William D. Travers

- 2 -

Questions concerning these meeting minutes should be referred to Raji Tripathi (415-7584).

Attachments: As stated

cc:	Commission (5)	SECY
	M. Knapp, DEDE	F. Miraglia, DEDO
	J. Lieberman, OE	H. Bell, OIG
	K. Cyr, OGC	J. Larkins, ACRS
	H. Miller, R-I	L. Reyes, R-II
	J. Dyer, R-III	E. Merschoff, R-IV
	C. Paperiello, NMSS	A. Thadani, RES
	S. Collins, NRR	W. Kane, NRR

**CRGR Meeting No. 315**

**Attendance List**

**February 13, 1998**

**CRGR MEMBERS**

T. T. Martin (Chairman)  
F. J. Miraglia  
D. F. Ross  
W. F. Kane for M. Knapp  
D. C. Dambly

**CRGR STAFF**

R. Tripathi

**NRC STAFF**

R. L. Spessard, NRR  
J. Roe, NRR  
L. Bush, NRR  
J. Shapaker, NRR  
M. Bugg, NRR  
S. Black, NRR  
R. Correia, NRR  
J. Peralta, NRR

Minutes of CRGR Meeting No. 315, February 13, 1998

**PRESENTATION MATERIAL USED BY THE STAFF**

ATTACHMENT 2-A

## **Chronology of Interfaces Between FFD and Backfit**

1. August 5, 1982 - Proposed FFD Rule
2. August 4, 1986 - Policy Statement
3. December 16, 1987 - SRM directed staff to prepare a proposed rule after NUMARC and staff briefed the Commission on implementation experience with the Policy Statement. Key problems were:
  - a. not all licensees random testing, some due to union intervention or State laws
  - b. cutoff levels varied significantly, some inadequate
  - c. sanctions imposed varied due to local tolerances
  - d. training and awareness programs needed improvement.
4. September 22, 1988 - Proposed FFD rule, over 3,000 comments
5. March 22, 1989 - SRM approved final rule and specifically directed the staff to:
  - a. make it clear that the rule may be amended in the future in response to advances in technology, additional experience, or other factors as identified by HHS or the NRC (SRM item 4);
  - b. assure adequate data collection so that licensees programs can be analyzed, the effectiveness of the rule can be assessed, and, if necessary, make appropriate improvements or changes (SRM item 7),
  - c. revisit the need for changes to the final rule by July 91 (SRM item 12).
6. June 7, 1989 - Final FFD rule with implementation date of January 3, 1990.
7. March 7, 1991 - Commission briefed on implementation of rule.
8. March 27, 1991 - SRM directed the staff to further investigate potential changes to the rule in regard to:
  - a. extrapolation of test results
  - b. requiring FFD program personnel be tested
  - c. specifying individuals be provided copies of drug test records, and
  - d. being more explicit in followup testing requirements.
9. September 17, 1991 - SECY-91-293 reported the staff's assessment of the implementation of the rule and need for changes to the rule.
10. November 7, 1991 - SRM directs the staff to:

- a. prepare proposed amendments as proposed by SECY-91-293
  - b. continue to consider further experience with implementation of the rule to identify possible areas where amendments may be needed.
  - c. adhere to the HHS Guidelines absent a compelling reason why a departure is necessary to address a unique situation in the nuclear industry. Specifically, the staff should not reduce the required specimen quantity, reduce the marijuana screening cutoff levels, and eliminate batch reporting, because they go beyond what the HHS Guidelines currently endorse. NOTE: HHS changed those requirements, and many others, on June 9, 1994, and DOT adopted those changes a few weeks later.
11. September 2, 1992 - SECY-92-308 proposed amendments to the FFD rule.
  12. September 30, 1992 - Commissioner Remick asked questions about the application of the Backfit Rule to the proposed amendments to Part 26.
  13. October 29, 1992 - SRM requested that the staff develop recommendations concerning possible changes to 50.109.
  14. November 19, 1992 - Memo from Taylor and Parler to Commissioner Remick makes the following points:
    - a. The changes proposed in SECY-92-308 were to achieve the intent of the original rulemaking in that testing results are accurate, the testing process is valid, and the licensees can meet the general performance objectives of the rule.
    - b. The Commission recognized that the rule might need to be updated and instructed the staff to inform it of any changes that may be needed, which the staff has done through a series of briefings and Commission papers.
    - c. The Commission directed the staff to proceed with rulemaking and to continue monitoring implementation experience to find other areas where amendments may be needed.
    - d. The rule changes proposed are only relatively minor modifications, clarifications, or adjustments to existing provisions. While the proposed changes are important and would improve the program in a manner consistent with the rule's original performance objectives, none of the changes satisfy a rigorous application of the backfit standards of a substantial increase in safety.
  15. February 19, 1993 - EDO withdraws SECY-92-308 because changes do not meet the "substantial increase" standard.
  16. March 1, 1993 - SRM instructs the staff to resubmit the proposed FFD rule changes when the backfit issues in response to the SRM of 10/29/92 are resolved.
  17. April 1, 1993 - SECY-93-086 provided the staff's evaluation of the backfit rule and its recommendations.

18. June 30, 1993 - SRM provided the staff with flexibility in implementing the backfit rule and provided for promulgation of rules for nonsafety reasons where the rules do not meet a flexible application of the "substantial increase" standard. Reasonable, well justified changes will be considered on a case-by-case basis as exceptions to the backfit rule.
19. October 31, 1995 - SECY-95-262 provided the staff's recommended changes. (This was updated version of SECY-92-308).
20. March 18, 1996 - SRM approves publication of proposed amendments.
21. May 9, 1996 - Proposed amendments published. Nearly 1100 comments received.

Minutes of CRGR Meeting No. 315, February 13, 1998

**PRESENTATION MATERIAL USED BY THE STAFF**

ATTACHMENT 2-B

**ANALYSIS OF THE APPLICATION OF THE BACKFIT RULE TO THE REVISIONS TO THE FITNESS-FOR-DUTY RULE (10 CFR PART 26)** may be standard is

This paper presents the staff's analysis of the application of the NRC's Backfit Rule (10 CFR 50.109) to the proposed revisions to the Fitness-for-Duty rule (10 CFR Part 26). In publishing the proposed revisions to Part 26 on May 9, 1996 (61 FR 21105), the NRC listed the revisions in three groups to facilitate the public's consideration. Group I included revisions that would conform Part 26 requirements to other national standards, including the Department of Health and Human Services' *Mandatory Guidelines for Federal Workplace Drug Testing Programs*. Group II included revisions that would reduce licensee burden and Group III revisions included revisions that would be worthwhile for other reasons. Minor edits that make no substantive change are not included in this analysis. This paper describes each of the proposed Part 26 revisions in the order that they were listed in these three groups. It should be noted that the staff is now recommending, based on public comments or new information, some modifications to the rule revisions that were published in the NRC's May 9, 1996 Federal Register notice. For the revisions that have been modified, the description of the revision notes the nature and reason for the modification and the application of the Backfit Rule to the modification.

## **BACKGROUND**

The Backfit Rule, 10 CFR 50.109, defines backfitting as "... the modification of or addition to ... the procedures or organization required to ... operate a facility...." Backfitting can result from "a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position...." The rule also requires that a backfit analysis be conducted, including consideration of associated implementation costs, for all proposed backfits except when backfits fit within one or more of three specific exceptions. One of these, the "compliance exception," exempts modifications that are "necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee...." According to the NRC's *Backfitting Guidelines* (NUREG-1409, July 1990), the Backfit Rule applies to actions that impose positions or requirements on licensees; it does not apply to requested actions that are optional or voluntary. Also, the rule generally does not apply to relaxations in requirements.

A Staff Requirements Memorandum (SRM) dated June 30, 1993 (SECY-93-086) contains additional guidance regarding Backfit Rule implementation. In that SRM the Commission stated that it expects the Backfit Rule's "substantial increase" criterion to be flexibly administered. Accordingly, qualitative as well as quantitative arguments can be made to demonstrate that a given proposed rule would substantially increase safety. The Commission also noted that this approach is flexible enough to allow for arguments that proposed rules that would make NRC requirements consistent with national and international standards, or would incorporate widespread industry practices, can either directly or indirectly

create a substantial increase in safety. The Commission also recognized that there may be proposed rules which, in the staff's opinion, do not meet the "substantial increase" standard but should be promulgated mainly for non-safety reasons. The Commission stated that it is willing to consider, on a case-by-case basis, whether such proposed rules should be promulgated as exceptions to the Backfit Rule as long as the proposal not to apply the Backfit Rule has been the subject of public notice and comment.

Based on the guidance provided by these two documents, the staff has concluded that none of the rule revisions is subject to further backfit analysis because each revision fits into at least one of the following classifications:

- 1) Clarifications. Several revisions would clarify current requirements to assure consistent understanding and implementation of the Commission's original intent for these requirements. Inquiries from licensees, attorneys, and NRC inspectors during the past eight years about the specific meaning of certain rule sections indicate that the current wording of those sections does not clearly convey the Commission's original intent. The staff has responded to these inquiries by providing verbal guidance as to the Commission's intent and the staff is confident that most or all licensees are now properly implementing these requirements. However, since the inquiries continue, clarifications are deemed necessary. Further, the staff is aware that some licensee FFD programs do not currently fully comply with certain Part 26 requirements, because of differences in interpretation of ambiguous language in the regulations. Therefore, the purpose of some of the proposed revisions is to clarify the requirements so that these licensees' FFD programs may be brought into compliance with those particular requirements. Without changing the underlying requirements stated in these sections, these revisions would instead remove the ambiguities that produced the licensees' uncertainty. The revisions would minimize the possibility for any future confusion, uncertainty, and misperception. According to an OGC memo interpreting the Backfit Rule, the rule applies to revisions or changed staff positions that create more stringent requirements. It does not apply to rule revisions that leave current requirements unchanged, as these clarifying revisions would do (memo from M. G. Malsch to Comm. Asselstine, January 23, 1986). Because they do not change current requirements, the staff concludes that these particular revisions are not covered by the Backfit Rule.
- 2) Relaxations. These revisions are not subject to the Backfit Rule's requirements because they are permissive relaxations of current requirements. Several revisions will provide licensees with the opportunity to reduce costs but do not require licensees to adopt a change. As the *Backfitting Guidelines* notes, the Backfit Rule does not apply to optional relaxations of regulatory burden.
- 3) Administrative matters. These revisions are administrative matters which, as the *Backfitting Guidelines* notes, are not subject to Backfit Rule requirements.

- 4) Compliance exceptions. These revisions fit under the Backfit Rule's compliance exception. This exception encompasses rule revisions that are necessary to bring licensees into compliance with the Commission's original intent in promulgating the requirement. In addition, some of the proposed revisions modify current requirements where there is evidence that the current version of the standards is not achieving the purpose that the Commission had when it originally promulgated the rule. In both these cases, some licensees will have to change some of their current FFD practices/procedures to bring their FFD programs into compliance with the Commission's rules.
- 5) Information collection and reporting requirements. Information collection and reporting requirements are not considered to be backfits per the CRGR charter.
- 6) "Non-safety" exceptions. The staff recommends that the Commission consider a relatively few revisions for promulgation as non-safety exceptions to the Backfit Rule. In the June 30, 1993 SRM, the Commission reiterated that it will consider, on a case-by-case basis, whether rule revisions that do not meet the Backfit Rule's "substantial increase" standard should be promulgated for non-safety reasons as exceptions to the Backfit Rule. A relatively few of the proposed rule revisions will, in the staff's view, substantially enhance the effectiveness of licensee's FFD programs without increasing licensee burden. For example, some of these revisions will make certain Part 26 requirements consistent with the HHS Mandatory Guidelines or other national standards or otherwise conform the rule to current industry practice. These revisions do not readily fit within any of the five previous classifications and, instead, should be promulgated as exceptions to the Backfit rule for non-safety reasons.

For each of the changes listed the following is provided:

- *Revision:* A brief description of the rule change.
- *Purpose:* A discussion of why the rule change is necessary.
- *Licensee Cost Reduction/Increase:* An estimate of the cost impact on licensees.
- *Backfit Rule Considerations:* A discussion of how the Backfit Rule applies to the revision, sometimes including public comments on the Backfit Rule implications<sup>1</sup>.
- *Staff Conclusion:* The staff's conclusion as to the application of the Backfit Rule to the proposed revision.

---

<sup>1</sup>It should be noted that NEI prefaced some of its suggested changes and objections to particular rule revisions as requiring backfit analyses if its recommended change was not adopted. Hence, many of NEI's recommended substantive rule revisions that are actually unrelated to backfit issues are included as public comments on backfit issues.

Minutes of CRGR Meeting No. 315, February 13, 1998

**PRESENTATION MATERIAL USED BY THE STAFF**

ATTACHMENT 3

**PRESENTATION TO CRGR**

**PROPOSED DRAFT GENERIC LETTER ON  
"GUIDANCE ON THE STORAGE, PRESERVATION, AND SAFEKEEPING  
OF QUALITY ASSURANCE RECORDS IN ELECTRONIC MEDIA**

Date: 2/13/98

## PURPOSE

- To provide guidance on an acceptable method, and NRC staff expectations, for storing, preserving, and safekeeping quality assurance records in electronic media

## BACKGROUND

- Previous staff positions on acceptable methods to satisfy requirements of Appendix B to 10 CFR Part 50 have been established in RG 1.28, RG 1.88, and GL 88-18
- GL 88-18 was issued to provide guidance on appropriate quality controls for an optical disk document imaging system. It supplemented the guidance in RG 1.28 and RG 1.88

## NEED FOR UPDATED GUIDANCE

- 10 CFR 50.71, "Maintenance of Records, Making of Reports," promulgated that Part 50 records "may also be stored in electronic media with the capability of producing legible, accurate, and complete records during the required retention period."
- Although the guidance in GL 88-18, RG 1.88, and RG 1.28 **remains acceptable and relevant**, licensees and NSSS suppliers suggested and requested that NRC provide additional guidance to address the acceptability of new information management technologies
- Proposed endorsement of Nuclear Information Records Management Association, Inc. (NIRMA) document

## RESEARCH

- 10 CFR 50.71(d)(1) and Criteria XVII, Appendix B, 10 CFR 50
- 21 CFR Part 11 "Electronic Records; Electronic Signatures" FDA
- 36 CFR Part 1234 - Media storage
- NIRMA TG15-1993, NIRMA TG11-1989

## SCOPE

- Holders of operating licenses and construction permits
- Decommissioning plants
- Licensee maintains QA records. **No records sent to NRC**

## METHOD

- Endorses NIRMA TG15-1993
- Additional Authentication Guidance

## **UNIQUE CONSIDERATIONS OF ELECTRONIC RECORDS**

- Long Term Storage
- Legibility
- Security
- Authentication
- Alteration Detection

## **EXPECTATIONS OF ADDRESSEES**

- Describe treatment of electronic records in QA program
- Follow guidance on this generic letter

## **REQUEST CRGR APPROVAL**

- Place generic letter in public docket for 30 day comment period

Minutes of CRGR Meeting No. 315, February 13, 1998

**PRESENTATION MATERIAL USED BY THE STAFF**

ATTACHMENT 4

**MAINTENANCE RULE CHANGE**  
**(a)(3) SAFETY ASSESSMENTS "SHOULD TO SHALL"**

**BACKGROUND**

- SECY 97-055 (3/97) Maintenance Rule status report discussed problems with "should" provision (unenforceable)
- SRM 97-055 (4/97) asked staff to consider clarifying (a)(3) and provide examples of weak programs found during baseline inspections (MRBI)
- SECY 97-173 (8/97) provided three options for (a)(3): (1) no changes; (2) should to shall only; (3) comprehensive change (PRA based) - staff recommended option 2
- SRM 97-173 (12/97) directed staff to change (a)(3) per option 2 and prepare proposed rule:
  - limited reg analysis of option 1 (i.e., no change)
  - clarify rule applies during all normal plant conditions including shutdown (add preamble)
  - make two editorial changes (edits to other parts of (a)(3))
  - change (a)(3) to (a)(4) with prescribed language
  - ensure consistency with other rulemaking efforts (e.g., 50.59)
  - limit reg analysis of option 3 (PRA based) but consider future (a)(4) rulemaking to propose RG 1.160/NUMARC 93-01 safety assessment methods be incorporated by reference
  - issue final rule change by 12/15/98 followed by revision to RG 1.160
- NEI letter to NRC endorsing should to shall rule change (10/97)

**MAINTENANCE RULE CHANGE**  
**(a)(3) SAFETY ASSESSMENTS "SHOULD TO SHALL"**

**STAFF PROPOSAL**

- Rulemaking Plan (per Directive 6.3.) may not be necessary:
  - SECYs 97-055 and 173 discussed issues and options for rule change including advantages and disadvantages of each option
  - RES, AEOD OGC, CIO and CFO concurred on SECYs
  - SRM 97-173 essentially dictated proposed rule change language
  - (a)(3) to (a)(4) rule change is not a major change (clarification)
  - impact on licensees relatively minor: RG 1.160/NUMARC 93-01 guidance addresses assessments for shutdown conditions; licensees' programs in place including shutdown safety assessment process
  - rule change consistent with original rule SOC "intent" of provision
  - ACRS briefed on maintenance rule status (5/97) including weaknesses found during MRBIs and unenforceability of provision
  - industry supports change
- CRGR and ACRS would receive draft proposed rule prior to public comment period
- CRGR and ACRS would be briefed during public comment period and prior to issuance of final rule change
- RG 1.160, EGM and IPs revised after rule change issued

# MAINTENANCE RULE AMENDMENT

<b>RULEMAKING ACTIVITY (NORMAL)</b>	<b>TIME TO COMPLETE (MONTHS)</b>	<b>TOTAL ELAPSED TIME (MONTHS)</b>
Receipt of SRM from Commission	0	0
Prepare rulemaking package	5	5
Proposed rule to NRR Office Director	1	6
Proposed rule to Office Directors	1	7
Proposed rule to CRGR and ACRS	2	9
Proposed rule EDO	1	10
Proposed rule to Commission	1	11
Proposed rule issued for public comment (60 days)	2	13
Resolution of public comments	2	15
Final rule to Division Director(s)	2	17
Final rule to NRR Office Director	1	18
Final rule to Office Directors	1	19
Final rule to CRGR and ACRS	2	21
Final rule to EDO	1	22
Final rule to Commission	1	23
Final rule to Federal Register	1	24

<b>RULEMAKING ACTIVITY</b> (Per SRM)	<b>TIME TO COMPLETE</b> (MONTHS)	<b>TOTAL ELAPSED TIME</b> (MONTHS)
Receipt of SRM from Commission	0	0
Prepare rulemaking package	2	2
Proposed rule to NRR Office Director	½	2 ½
<del>Proposed rule to Office Directors</del>	n/a	n/a
<del>Proposed rule to CRGR and ACRS</del>	n/a	n/a
Proposed rule EDO	½	3
Proposed rule to Commission/ACRS/CRGR	½	4
Proposed rule issued for public comment (45 days)	1 ½	5 ½
Resolution of public comments	1	6 ½
Final rule to Division Director(s)	1	7 ½
Final rule to NRR Office Director	½	8
Final rule to Office Directors	½	8 ½
Final rule to CRGR and ACRS	2	9 ½
Final rule to EDO	½	10
Final rule to Commission	½	10 ½
Final rule to Federal Register	1	11 ½

James M. Taylor

cc: Commission (5)  
SECY  
J. Milhoan  
H. Thompson  
J. Lieberman  
P. Norry  
D. Williams  
K. Cyr  
J. Larkins  
Office Directors  
Regional Administrators  
L. Shao  
C. Paperiello  
CRGR Members