



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

November 2, 1999

MEMORANDUM TO: William D. Travers  
Executive Director for Operations

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

SUBJECT: MINUTES OF THE CRGR MEETING NUMBER 346

The Committee to Review Generic Requirements (CRGR) met on Tuesday, September 14, 1999, from 8:30 a.m. to 10:45 a.m., to hold its 346th meeting. Attachment 1 contains a list of attendees.

Item 1

B. Boger, M. Bugg, and D. Dorman (all of NRR) presented for CRGR review and endorsement draft generic letter 88-18 Supplement 1, "Guidance on Managing Quality Assurance Records in Electronic Media" (CRGR Item No. 225). Attachment 2 contains the staff's presentation material.

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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. Additionally, the cognizant staff is encouraged to keep the CRGR staff informed when a proposed generic action is issued final so that the affected portions of the CRGR meeting minutes can be placed in the NRC Public Document Room.

Questions concerning these meeting minutes should be referred to George Lanik (415-7490).

Attachments: As stated

cc (w/atts.):

Commission (4)

SECY

- C. Paperiello, DEDMRS
- R. Borchardt, OE
- K. Cyr, OGC
- H. Miller, R-I
- J. Dyer, R-III
- W. Kane, NMSS
- S. Collins, NRR
- F. Miraglia, DEDO
- H. Bell, OIG
- J. Larkins, ACRS
- L. Reyes, R-II
- E. Merschoff, R-IV
- A. Thadani, RES
- B. Boger, NRR

Distribution: (via email w/atts)

- J. Moore, OGC
- G. West, NRR
- G. Lanik, RES
- D. Dorman, NRR
- M. Bugg, NRR

Distribution: (hard copy w/atts.)

- CRGR RF
- CRGR SF
- B. Sheron
- J. Murphy
- M. Virgilio
- M. Federline
- C. Rossi
- J. Johnson
- B. Mallett, RII
- R. Tripathi

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NAME	GLanik:act		JMurphy
DATE	10/5/99		10/5/99

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A. Thadani, RES

S. Collins, NRR

B. Boger, NRR

**Attendance List**  
**CRGR Meeting No. 344**  
**(August 14, 1999)**

**CRGR MEMBERS**

J. Murphy (Chairman) *video*  
B. Mallett for J. Johnson (via teleconferencing)  
B. Sheron  
M. Virgilio  
C. Rossi for M. Federline  
J. Moore

**NRC Staff**

B. Boger, NRR  
M. Bugg, NRR  
G. West, NRR  
D. Dorman, NRR

**CRGR STAFF**

G. Lanik

**PRESENTATION TO CRGR**

**GENERIC LETTER 88-18, SUPPLEMENT 1:  
“GUIDANCE ON MANAGING QUALITY ASSURANCE RECORDS  
IN ELECTRONIC MEDIA”**

Date: 9/14/99

**ATTACHMENT 2**

## PURPOSE

- To provide updated 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
- Office of the Chief Information Officer consultation (ADAMS)

## 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 and NIRMA TG11-1989

## SCOPE

- Holders of operating licenses and construction permits; also decommissioning plants
- **Not for safeguard records**
- Licensee maintains QA records. **No records sent to NRC**

## METHOD

- Endorses NIRMA TG11-1998, “Authentication of Records and Media”
- Endorses TG15-1998, “Management of Electronic Records”

- Endorses TG16-1998, "Software Configuration Management and Quality Assurance"
- Endorses TG21-1998, "Electronic Records Protection and Restoration"

### **UNIQUE CONSIDERATIONS OF ELECTRONIC RECORDS**

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

### **EXPECTATIONS OF ADDRESSEES**

- Describe treatment of electronic records in QA program
- Description does not have to be a reduction in commitment (NRC review should not be needed)



### **COMMENT RECEIVED FROM PREVIOUSLY PROPOSED GENERIC LETTER**

- 11 respondents, comprising 8 power reactor licensees, 2 industry groups, and 1 consulting firm
- Endorse NIRMA 1998 documents instead of 1993 document
- Remove electronic signature requirements develop by the FDA methodology

### **CHANGES TO PREVIOUSLY PROPOSED GENERIC LETTER**

- New name of generic letter
- Now endorses NIRMA TG11-1998, TG15-1998, TG16-1998, and TG21-1998
- No longer use a conditional endorsement (electronic signatures)

### **REQUEST CRGR APPROVAL**

- Issue generic letter in Federal Register as soon as possible

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**RULEMAKING PLAN:  
REDUCTION IN THE SCOPE OF RANDOM  
FITNESS-FOR-DUTY TESTING REQUIREMENTS  
FOR NUCLEAR POWER REACTOR LICENSEES  
(10 CFR PART 26)**



**CRGR BRIEFING**

**Bruce A. Boger, Director  
Division of Inspection Program Management  
Office of Nuclear Reactor Regulation  
OVERVIEW**

- Background
- Proposed Amendment
- Benefits
- Backfit Considerations
- Schedule

## BACKGROUND

- IBEW Union Court Request February 12, 1992
- Court Denial of IBEW Request June 11, 1992
- NRC Solicitor Recommended Reevaluation July 20, 1992
- SRM, COMSECY-92-018 August 18, 1992
- IBEW New Exemption Request December 6, 1993
- SECY-94-016 January 24, 1994
- *Federal Register* notice May 11, 1994

**PROPOSED AMENDMENT TO  
10 CFR 26**

- Require random drug and alcohol testing of only those persons with unescorted access to vital areas.
- Eliminate random drug and alcohol testing for employees who must physically report to the TSC or EOF during an emergency.

## BENEFITS

- Decrease unnecessary regulatory burden.
- Decrease exemption requests.
- Contribute to risk-informing Part 26.
- Provide balance of safety and privacy issues.

## BACKFIT CONSIDERATIONS

Provide an opportunity for licensees to:

- Continue random FFD testing for personnel who are granted unescorted access to the protected area or who physically report to the TSC and EOF during an emergency.
- Reduce the scope of personnel subject to random FFD testing under 10 CFR Part 26 without prior NRC review and approval.

## SCHEDULE

Brief CRGR on rulemaking plan	September 14, 1999
Rulemaking plan to the EDO	October 29, 1999
Proposed rule for office concurrence	Three (3) months
Proposed rule to the EDO	Seven (7) months
Proposed rule to the Commission	Eight (8) months
Proposed rule published in <u>Federal Register</u> with a 75-day comment period	Nine (9) months
Publication of final rule	Eighteen (18) months





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