



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 29, 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 329

The Committee to Review Generic Requirements (CRGR) met on Tuesday, October 13, 1998, from 9:00 a.m. to 4:30 p.m., to hold the Committee's 329th meeting. Attachment 1 contains the list of attendees. J. Murphy presided over the meeting as Acting Chairman.

E.Q. Ten Eyck (NMSS) presented for CRGR review and endorsement the NMSS Policy and Procedures Letter (PPL) 1-53, "GDP Plant Specific and Generic Backfit Management." This PPL contains formal guidance for the staff on implementation of the backfit provisions of Title 10 Code of Federal Regulations (10 CFR) Part 76.76, specifically on identification and justification of potential backfits. It also contains guidance for the certificatees on the NRC's backfit appeal process. Attachment 2 contains the staff's presentation material. Via e-mail, dated January 12, 1999, the staff provided a redline/strikeout version of the revised PPL incorporating the Committee's comments and recommendations. In a subsequent meeting between the cognizant staff and the CRGR staff, additional minor changes to the PPL were identified. On January 15, 1999, a further modified version of PPL 1-53 was received from the staff, which had the required sponsoring Division-Director-level consensus. However, the CRGR endorsement of these procedures has been held back because the Committee wishes to re-review these procedures in light of the staff requirements memorandum (SRM)¹, dated December 1, 1998. In this SRM, in the context of Part 70 related actions, the Commission indicated that it

"...supports a requirement that any new backfit pass a cost-benefit test, without the "substantial" increase in safety test. The Commission believes that modest increases in safety at minimal or inconsequential cost could be justified on a cost benefit basis."

The re-review of the GDP backfitting procedures is scheduled at CRGR Meeting No. 337, to be held on February 9, 1999. Following Committee's discussion, the revised procedures will be attached to the minutes of that meeting. Additionally, the Committee recommended that before issuing the PPL final, the staff revise all those appendices, which have been directly excerpted from the CRGR Charter, Revision 6, and will be affected by the Charter revision in progress.

¹ Staff Requirements Memorandum, SECY-98-185 - Proposed Rulemaking - Revised Requirements for the Domestic Licensing of Special Nuclear Material, dated December 1, 1998.

Rec 1

W. D. Travers

T. Essig (NRR), R. Auluck (NRR) and S. Frattelli (NRR) presented for CRGR review and endorsement the draft final rule titled, "Frequency of Reviews and Audits for Emergency Preparedness Programs, Safeguard Contingency Plans, and Security Programs for Nuclear Power Reactors (Part 73)," which was developed in response to two petitions for rulemaking submitted by Virginia Power Company. This was the first CRGR review of this rulemaking. The staff's presentation material is included in Attachment 3. Since this rulemaking affects both nuclear power reactors as well as nuclear materials facilities, in response to an issue raised earlier by the CRGR staff, the cognizant staff confirmed at the meeting that NMSS had concurred (with comments) on the draft final rule. As required by Section IV.B(iv) of the CRGR Charter, the staff provided the Committee with a copy of the NMSS correspondence.

The Committee made various comments and recommendations on the Part 73 rulemaking package. Specifically, this rulemaking, as proposed, would result in a substantial burden on licensees as it would involve (1) efforts to develop performance indicators (PIs); (2) change in frequency of audit reviews; (3) change in procedure(s); and (4) change in scope and frequency of inspections. Most importantly, the Committee believes that as proposed, this action is a backfit, and recommended that it should be made voluntary. The Committee further recommended that this rule not be issued until the staff has articulated guidance on PIs, and by using objective criteria has established examples of what some acceptable PIs may look like. The Committee also noted an inconsistency in the language used in the Statement of Considerations and that of the rule, and recommended that inconsistencies in the rule package need to be resolved. Additionally, because no PIs or guidance on PIs currently exists, the Committee expressed a concern from the inspection and enforcement standpoint, and urged that the staff issue interim guidance to aid the NRC inspectors. Finally, the Committee asked the staff to return with the revised draft rule package for formal CRGR review and endorsement.

T. Essig (NRR) and M. Jamgochian (NRR) presented for CRGR review and endorsement the draft proposed rule titled, "Changes to 10 CFR 50.47 Relating to the Use of Potassium Iodide (KI) for the General Public." This proposed rulemaking would require the States to consider KI, in addition to evacuation and sheltering, as one of the protective measures in their emergency plans. Currently, 10 CFR 50.47(b)(10) does not identify any specific protective actions, but indicates that a range of protective actions should be developed. The staff's presentation material is included as Attachment 4-A. The Committee's comments and recommendations were as follows:

- (1) The Committee noted that, the proposed rule, was under inter-office review at the time of CRGR review; however, to support the staff's schedule commitments, the Committee agreed to a review before formal office concurrences were received. Additionally, the staff indicated that OGC was expected to provide its comments in the near term. The CRGR asked the staff to notify the Committee of any changes in the concurrence status.
- (2) The Committee recognized Commission direction on this item and commented that, as proposed, the rule appeared to be a backfit, and that the backfit issue should be clarified before the rule is issued for public comment. Initially, the Committee explored consideration of including a sentence after the first sentence in 10 CFR 50.47(b)(10):

W. D. Travers

"In developing this range of actions, consideration [emphasis added] has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

The Committee's rationale for this recommendation was that with the use of the word "consider" in the proposed rule change, it would appear that no new requirements are being placed on either the States or licensees. However, the staff further explained to the Committee that if a State considers the KI option and decides against it, then no new requirements will be placed on licensees. In contrast, if a State considers the KI option and decides in favor, then licensees will in fact have some new requirements imposed on them. Licensees, for example, may be required to develop new procedures for administering KI to the public. Consequently, the Committee concluded that consideration of KI indeed involves a backfit for the reactor licensees. The Committee, therefore, recommended that the staff prepare an appropriate backfit analysis in accordance with the provisions of 10 CFR 50.109. The staff, in subsequent e-mail exchanges with the Committee, re-iterated its position as to why this rule was not a backfit.

The CRGR membership (as configured on the day of the meeting, and ensuring a quorum) met again in the coming days to re-consider the backfit aspects of the rule. The Committee further noted that 10 CFR Part 50 regulations impose requirements on licensees, and not on States. However, with this rulemaking, the staff intends to impose requirements on the States, and since NRC does not regulate and impose requirements on the States, why would the proposed Part 50.47 be applicable to them? The rule applies to licensees and, as proposed, it basically says that a licensee would have to work with its State and get that State to "consider KI" in its emergency preparedness. If the State were to refuse to consider the KI option, then the NRC could find the licensee in non-compliance. Based on ensuing discussion at this follow-up meeting, the Committee did not accept the staff's argument, and concluded that the proposed rule, as drafted, is a backfit. On October 23, 1998, in a memorandum to the EDO (Attachment 4-B), the Committee articulated its concerns. The proposed rule, as drafted, was not endorsed.

- (3) The Committee asked the staff to clarify the issue as to who will bear the cost of KI stockpiling, distribution and subsequent replenishment. The CRGR review package did not have the CFO's concurrence. The Committee particularly noted that the *Federal Register* Notice states (page 33) that "...the Federal government (most likely NRC) will fund the purchase of a stockpile of KI for the States upon request." Specifically, the Committee asked the staff to address whether NRC's budget would be affected once the shelf-life of procured KI expires. The Committee also asked the staff to quote directly from the applicable Federal Drug Administration (FDA) document in the *Federal Register* Notice response to Issue 4 (page 28); the response discusses FDA's approval of KI as an over-the-counter drug. The Committee also stressed that a direct quote would most accurately describe FDA's position on KI.

W. D. Travers

- (4) The CRGR also asked the staff to appropriately address comments provided by various offices. The members were provided with AEOD comments (Attachment 4-C).

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.

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	M. Springer, ADM
	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
	E. Ten Eyck, NMSS	T. Essig, NRR

W. D. Travers

- (4) The CRGR also asked the staff to appropriately address comments provided by various offices. The members were provided with AEOD comments (Attachment 4-C).

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.

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	M. Springer, ADM
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
E. Ten Eyck, NMSS	T. Essig, NRR

Distribution:

File Center (w/attch)	PDR (NRC/CRGR) (w/o attch. 4-B and 4-C)
CRGR SF	CRGR CF
DDambly	JMurphy
MVirgilio	BSheron
GWest	RTripathi
CRossi	JMitchell
RPierson	MGalloway
AMohseni	FKantor
RAuluck	SLewis
DMatthews	MJamgochian

DISK/DOCUMENT NAME: S:\CRGR\DMTS-329.WPD

To receive a copy, indicate: "C" = Copy w/o attachment/enclosure; "A" = Copy with attachment/enclosure; "N" = No copy. NO MARK = NO COPY!

OFC	CRGR	C	CRGR	C	C:CRGR	C
NAME	GWest:jc <i>ew</i>		RTripathi <i>ew</i>		JMurphy <i>ew</i>	
DATE	1/29/99		1/29/99		1/29/99	

OFFICIAL RECORD COPY

Attendance List
CRGR No. 329 Meeting
(October 13, 1998)

CRGR MEMBERS

1. J. Murphy (Acting Chairman)
2. C. Rossi for T. Martin
3. C. Haughney for M. Knapp
4. B. Sheron for F. Miraglia
6. D. Dambly
6. J. Dyer

CRGR STAFF

1. R. Tripathi

NRC STAFF

1. L. Ten Eyck, NMSS
2. R. Pierson, NMSS
3. C. Cox, NMSS
4. M. Galloway, NMSS
5. T. Essig, NRR
6. F. Kantor, NRR
7. A. Mohseni, AEOD
8. C. Miller, NRR
9. S. Lewis, OGC
10. R. Auluck, NRR
11. S. Frattelli, NRR
12. G. West, NRR
13. M. Jamgochian, NRR

PRESENTATION MATERIALS USED BY THE STAFF

GDP Plant Specific and Generic Backfit Management

Policy and Procedures Letter (PPL) 1-53

Background

- March 17, 1997** Draft PPL 1-53 published in FR for public comment
- May 27, 1997** USEC and NEI submit only public comments
- June 1998** Revised PPL 1-53 based on comments received
- June 29, 1998** FR Notice of Availability issued

Modeled after NRR process

- **Identification of Potential Backfit**
- **Determination**
- **Documented Evaluation**
- **Regulatory Analysis**
- **Appeals**
- **Backfit Implementation**
- **Record Keeping and Reporting**

Differences:

- **One policy for generic and plant specific backfit**
- **Cost benefit not based on person-rem**
- **Looks at worker exposure to chemicals**
- **Additionally looks at safeguards**

Public Comment Areas of Disagreement

- **SARUP issues not subject to backfit determination**
- **Cost/benefit analysis not based upon person-rem**
- **Qualitative estimate for chemical hazard from regulated material**
- **Chemical exposure of workers considered in increased protection**
- **All correspondence to GDPs should not require CRGR review**
- **Safeguards issues will be considered during backfit analysis**

SUMMARY

- **Likelihood of requiring a backfit: slim**
- **Issues identified in SARUP and existing compliance plan items should be the main modifications required for these facilities. Backfit analysis is not required.**
- **These facilities have a 10 year maximum life left. This would be considered in the backfit analysis, again making potential backfits unlikely.**

PRESENTATION MATERIALS USED BY THE STAFF



**Final Rule - Frequency of Reviews and Audit for
Emergency Preparedness Programs,
Safeguards Contingency Plans, and
Security Programs for Nuclear Power Reactors
(PRM 50-59 and PRM 50-60) - 10 CFR Part 50 and
73**

Presentation to CRGR

October 13, 1998

**Thomas H. Essig, Acting Chief
Generic Issues and Environmental Projects
Branch
Division of Reactor Program Management
Office of Nuclear Reactor Regulation**

HISTORY

- **Petitions for rulemaking submitted by Virginia Power Company, January 7th and 19th, 1994 (PRM 50-59 and PRM 50-60).**
- **Petitions published for public comment (59 FR 23641, April 1994, and 59 FR 17449, May 1994).**
- **Proposed rule published July 31, 1997 (62 FR 40978).**

CURRENT REGULATIONS

- **Requirements for review of safeguards contingency plans by licensees contained in § 50.54(p)(3) and in Appendix C to Part 73.**
- **Requirements for security program review contained in § 73.55(g)(4) and § 50.54(p)(3).**
- **Requirements for review of the emergency preparedness program by licensees**

contained in § 50.54(t).

- Requires these reviews to be performed yearly.

PROPOSED CHANGES

- Licensees shall ensure that all program elements are reviewed at least every 24 months.
- Reviews performed as necessary in response to program performance indicators or soon after a change in personnel, procedures, equipment, or facilities, that potentially could compromise emergency preparedness or security, but no longer than 12 months after the change.
- Promote performance-based rather than compliance-based review and audit activities.
- Reduce the regulatory burden on licensees.

PUBLIC COMMENTS

- **Ten public comments were received**
 - **an Agreement State,**
 - **a utility industry group, and**
 - **eight licensees.**
- **All except one supported the proposed changes.**
- **State of Illinois did not support the changes and restated its comments on the published petition which were addressed in the proposed rule FRN.**
- **Specific comments on performance indicators were requested in the proposed rule. Only one suggested specific performance indicators.**

COMMENT AREAS

- **Performance Indicators**
- **Audit Frequency**

- **Audit Procedures**
- **Definitions and Clarifications**

PERFORMANCE INDICATORS

Comments:

- **One commenter suggested each utility to be allowed to develop its own performance indicators.**
- **Two commenters stated their interest in developing industry guidance.**

Response:

- **It is the responsibility of the individual utilities to define their own performance indicators, subject to review and acceptance by the NRC.**
- **Any guidance developed within the industry on performance indicators is to be encouraged.**
- **NRC may decide to develop performance**

indicators in the future.

AUDIT FREQUENCY

Comment:

- **The State agency felt a review every 24 months was not sufficiently frequent to ensure that all aspects of an emergency preparedness plan remain current.**

Response:

- **This concern was addressed by clarifying that more frequent, focused program reviews and audits may be required, based on an assessment of security or emergency preparedness by the licensee against performance indicators or after a change in personnel, procedures, equipment, or facilities that potentially could compromise emergency preparedness or security, but in no case less frequently than every 24 months.**

Comment:

- **Although some commenters felt that there should be no maximum audit period specified, most of the commenters had no problem with a frequency no less than 24**

months

Response:

- **Frequency no less than 24 months remains.**

AUDIT PROCEDURES

Comment:

- **Comments related to adding an additional layer of requirements and on the qualifications of persons conducting the reviews.**

Response:

- **The rule does not add an additional layer of requirements and it is the licensee who determines when a review is necessary.**
- **NRC expects these audits to be conducted by individuals who are qualified (technically competent) in the subjects being audited and are independent of the program to ensure objectivity and no conflict of interest.**
- **At the licensee's option, the QA organization may perform, lead, or assist in these audits.**

DEFINITIONS AND CLARIFICATIONS

Comment:

- **Consistent use of the terms “review” and “audit”**

Response:

- **These amendments do not change the use of any of these terms from the previous text of the rule, and are consistent with other NRC regulatory usage of these terms.**

DEFINITIONS AND CLARIFICATIONS (Continued)

Comment:

- **Define the terms “significant,” “significant change,” “as necessary,” and “reasonably practical.”**

Response:

- **The terms “significant” and “significant change” in the rule language were replaced with the words “a change that potentially could compromise emergency preparedness or security.”**
- **The term “as necessary” is a function of the change. The scope and depth of the review would be expected to vary with the change. Thus judgement will need to be exercised in making the decisions. Similarly “reasonably practicable” is a function of the significance of the change and needs to be factored into the scope and depth of review.**

REGULATORY ANALYSIS

- **Potential cost savings for licensees because of anticipated decrease in the number of audits.**
- **If each element of the program is audited at least once every 2 years, instead of yearly, potential maximum savings is**
 - **\$30,000 per licensee every 2 years**
 - **\$1.1 million to the industry per year**
- **Limited focused audits that address significant problems or changes will cost about \$5,000 per licensee year if they are needed.**
- **Even if some elements of the programs are audited more frequently, the cost to the licensee will likely be less than auditing the entire program every year.**
- **No additional cost anticipated for collecting and analyzing program performance indicators since most licensees already do so in some fashion.**

INSPECTION AND ENFORCEMENT

- **The NRC will review the performance**

indicators developed by licensees and observe whether and to what extent these performance indicators are assisting licensees in conducting their program reviews.

- **The NRC will use this experience to determine if specific and additional guidance should be developed.**
- **Licensees will need to exercise judgement in view of the difficulty of defining in advance, except in general terms, the threshold of changes that potentially could compromise emergency preparedness and security.**
- **If licensee has made a good faith effort in making the judgements needed to comply with this rule, the staff intends not to issue notices of violation unless the licensee's actions were clearly unreasonable.**
- **In the absence of willfulness, these violations are expected to be Severity Level IV violations.**

BACKFIT

- **The frequency with which licensees conduct independent reviews and audits of their emergency preparedness programs, safeguards contingency plans, and security programs is reduced.**
- **This action does not impose any new or increased requirements in this area.**
- **It is a decrease of burden on licensees.**
- **No backfitting is intended.**
- **Therefore, no backfit analysis has been prepared.**

PRESENTATION MATERIALS USED BY THE STAFF

CRGR PRESENTATION

POTASSIUM IODIDE (KI) RULEMAKING – GRANTING PETITIONS FOR RULEMAKING 50-63 AND 50-63A

Mike Jamgochian
301-415-3224

October 13, 1998

COMMISSION VOTE

June 26, 1998 - SRM 98-061; Granting the Petitions for Rulemaking

- Change 10 CFR 50.47(b)(10) by

Inserting the following sentence, after the first sentence: In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate.”

- In addition, the Federal Register notice and the statement of considerations for the proposed rules include a statement to the effect that State and local decision makers, provided with proper information, may find that use of KI as a protective supplement is reasonable and prudent for specific local conditions.

Background

- September 1995 - PRM 50-63 Submitted
- October 1997 - Option Paper to Resolve Petition (SECY-97-245)
- November 1997 - Commission Briefed by Petitioner, NRC and FEMA Staffs
- November 1997 - PRM 50-63A Submitted

Petition Requested

A statement be made clearly recommending stockpiling of KI as a “reasonable and prudent” measure, and

A proposed rule change to 10 CFR 50.47(b)(10), which would be accomplished by inserting the following sentence after the first sentence: “In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate”

Public Comments

On PRM 50-63:

- 73 Comment Letters Received
 - Against Granting Petition:
20 Utilities; 9 States; 2 Utility Interest Associations; 2 State Universities; 12 Health Physicists; 1 Member of the Public
 - For Granting the Petition:
5 Environmental Group
22 Members of Public American Thyroid Association

On PRM 50-63A:

- 82 Comments Letters Received

- Against Granting Petition:

13 Utilities; 3 States; 1 Utility Association; 1 Member of the Public

- For Granting Petition:

8 Public Interest Groups; 46 Members of the Public;
2 Public Interest Groups; 2 U.S. Sentators;
1 State Representative; 3 Physicians;

**CRGR MEMORANDUM TO THE EDO,
DATED OCTOBER 23, 1998**

MEMORANDUM TO:

William D. Travers
Executive Director for Operations

October 23, 1998

FROM:

Thomas T. Martin, Chairman
Committee to Review Generic Requirements

Original signed by
Thomas T. Martin

SUBJECT:

PROPOSED AMENDMENTS TO 10 CFR 50.47 — RULE
CHANGE RELATED TO THE USE OF POTASSIUM IODIDE FOR
GENERAL PUBLIC

The Committee to Review Generic Requirements (CRGR) met on Tuesday, October 13, 1998, from 9:00 a.m. to 3:30 p.m. to hold the Committee's 329th meeting. Mr. Joseph A. Murphy presided as Acting Chairman. At this meeting, the staff presented for CRGR review and endorsement the proposed rule relating to use of potassium iodide (KI) by the general public. Please note that at the time of the CRGR review, this proposed action did not have OGC and other office concurrences as required by the CRGR Charter. However, to support the staff's schedule commitments, the Committee agreed to review this rulemaking with the understanding that the staff would submit to the Committee the revised proposal clearly indicating the changes made in response to office (including OGC) concurrences, concurrences with comments, and indicate any non-concurrences.

Subsequently, the CRGR membership (as configured on the day of the meeting on October 13th) met again to discuss the backfit issue. Mr. Francis Cameron (OGC) was present at this meeting. Pending issuance of the final minutes of the meeting, the purpose of this memorandum is to raise to your attention the Committee's backfit-related concerns and other comments and recommendations:

1. As proposed, this rule appears to be a backfit. The CRGR recommends that an appropriate backfit analysis should be performed in accordance with the provisions of 10 CFR 50.109.
2. The staff should clarify the issue of resources as to who will bear the cost of KI stockpiling, distribution and subsequent replenishment.
3. Finally, the Committee indicated that it would have no other objections to the staff proceeding with the issuance of this rulemaking for public comment if the comments provided by various offices during the concurrence process are appropriately addressed.

As always, I am available to discuss this matter further.

cc: F. Miraglia J. Murphy D. Dambly
B. Sheron J. Dyer C. Rossi
M. Knapp

MEMORANDUM TO: Jack W. Roe, Acting Director
Division of Reactor Program Management
Office of Nuclear Reactor Regulation

FROM: Thomas T. Martin, Director
Office for Analysis and Evaluation
of Operational Data
Original signed by T. T. Martin
October 7, 1998

SUBJECT: OFFICE REVIEW AND CONCURRENCE OF A
PROPOSED RULEMAKING (PRM 50-63 AND 50-63A)

In response to your request, we have completed our review of the subject document and provide AEOD's concurrence subject to the changes described in the attachment.

If you have any questions, please contact me or Aby Mohseni of my staff at 415-6409.

Attachment: As stated

MEMORANDUM TO: Jack W. Roe, Acting Director
Division of Reactor Program Management
Office of Nuclear Reactor Regulation

FROM: Thomas T. Martin, Director
Office for Analysis and Evaluation
of Operational Data

SUBJECT: OFFICE REVIEW AND CONCURRENCE OF A
PROPOSED RULEMAKING (PRM 50-63 AND 50-63A)

In response to your request, we have completed our review of the subject document and provide AEOD's concurrence subject to the changes described in the attachment.

If you have any questions, please contact me or Aby Mòhseni of my staff at 415-6409.

Attachment: As stated

Distribution:
AEOD R/F
IRD R/F
ER R/F
File Center
CMiller
MJamgochian

DISK/DOCUMENT NAME: A:\MOHSENI\RULEMAKG.WPD

* See previous concurrence

To receive copy, indicate: "C" = Copy w/o attachment/enclosure; "A" = Copy with attachment/enclosure; "N" = None. NO MARK = NO COPY!!!

OFC	IRD:AEOD	A	D:IRD:AEOD	A	D:AEOD					
NAME	AMohseni		FJCongel		TTMartin					
DATE	10/05/98*		10/06/98*		10/ /98					

OFFICIAL RECORD COPY

AEOD COMMENTS ON THE PROPOSED FEDERAL REGISTER NOTICE ON KI RULEMAKING

1. We recommend that "could" in the last sentence in the Commission Response to Issue 2 (page 18) be changed to "should."
2. We recommend that the third sentence in the second paragraph of the Commission Response to Issue 3 be deleted (page 19). We realize that the entire Commission Response was taken out of Draft NUREG-1633. It was pointed out in the comment period that that statement is not substantiated.
3. We recommend that the last sentence of the "Conclusion from Polish Experience" be revised or deleted (page 25). It is inconsistent with the last sentence of the "Polish Experience" on page 24. If you choose to revise it, it is suggested that you revise it as follows: "Because of the low iodine concentrations in Poland and the protective actions implemented, Poland has not detected excess cancers resulting from intake of radioiodines."
4. The first paragraph under "Overall Chernobyl Conclusion" on page 26 is not accurate. For the same reasons cited above, the low iodine concentrations, the ingestion pathway protective actions, such as banning the consumption of fresh milk, etc. were significant factors. The Polish experience had to do more with mass use of KI and its safety implications than with actually accounting for preventing excess thyroid cancer. We recommend that the paragraph be revised or deleted.
5. The Commission Response to Issue 4 on page 28 is not accurate. The FDA's position about safety in the context of thyroid exposure to inhaled radioiodines is more cautious than what is in this paragraph. The sentence should also be revised to state that the Polish experience reported two significant adverse reactions and 36,000 medically significant reactions.
6. We recommend that "could" in the last sentence in the Commission Response to Issue 5 (page 29) be changed to "should."
7. We suggest that the Commission Response to Issue 6 on page 29 be revised as follows: "With the limited Federal stockpiles of KI for terrorist events and the willingness of the Federal Government to provide a stockpile of KI for any State that decides to use it as a supplemental protective measure for the general public, the Commission believes that a supply of KI could be obtained."
8. Section A of "Commission Evaluation of Issues Raised by the Petitioner and Public Commenters" leads the reader to believe that the Commission agrees with the Petitioner that the reason for not observing excess thyroid cancer in Poland was the timely distribution of KI. That clearly should not be the case, as described in the previous pages of the package. We propose that the paragraph be revised.

ATTACHMENT

MEMORANDUM TO: William D. Travers
Executive Director for Operations

AM - to
October 23, 1998

Meeting minutes
for 329

FROM: Thomas T. Martin, Chairman
Committee to Review Generic Requirements
Original signed by
Thomas T. Martin

SUBJECT: PROPOSED AMENDMENTS TO 10 CFR 50.47 — RULE
CHANGE RELATED TO THE USE OF POTASSIUM IODIDE FOR
GENERAL PUBLIC

The Committee to Review Generic Requirements (CRGR) met on Tuesday, October 13, 1998, from 9:00 a.m. to 3:30 p.m. to hold the Committee's 329th meeting. Mr. Joseph A. Murphy presided as Acting Chairman. At this meeting, the staff presented for CRGR review and endorsement the proposed rule relating to use of potassium iodide (KI) by the general public. Please note that at the time of the CRGR review, this proposed action did not have OGC and other office concurrences as required by the CRGR Charter. However, to support the staff's schedule commitments, the Committee agreed to review this rulemaking with the understanding that the staff would submit to the Committee the revised proposal clearly indicating the changes made in response to office (including OGC) concurrences, concurrences with comments, and indicate any non-concurrences.

Subsequently, the CRGR membership (as configured on the day of the meeting on October 13th) met again to discuss the backfit issue. Mr. Francis Cameron (OGC) was present at this meeting. Pending issuance of the final minutes of the meeting, the purpose of this memorandum is to raise to your attention the Committee's backfit-related concerns and other comments and recommendations:

4. As proposed, this rule appears to be a backfit. The CRGR recommends that an appropriate backfit analysis should be performed in accordance with the provisions of 10 CFR 50.109.
5. The staff should clarify the issue of resources as to who will bear the cost of KI stockpiling, distribution and subsequent replenishment.
6. Finally, the Committee indicated that it would have no other objections to the staff proceeding with the issuance of this rulemaking for public comment if the comments provided by various offices during the concurrence process are appropriately addressed.

As always, I am available to discuss this matter further.

cc: F. Miraglia J. Murphy D. Dambly
B. Sheron J. Dyer C. Rossi
M. Knapp

Distribution: CRGR SF CRGR CF JMitchell RTripathi JRoe Central Files
MJamgochian TEssig RAuluck CMiller GWest SLewis

DISK/DOCUMENT NAME: S:\CRGR\KILTREDO.WPD

*Previously concurred.

To receive a copy of this document, indicate in the box: "C" = Copy w/o attachment, "E" = Copy w/attachment, "N" = No copy

OFC	CRGR	CRGR	D: AEOD					
NAME	RTripathi*	JMurphy*	TMartin					
DATE	10/23/98	10/23/98	10/23/98					

As always, I am available to discuss this matter further.

Attachment: As stated

cc: F. Miraglia
B. Sheron
M. Knapp
J. Murphy
D. Dambly
J. Dyer
C. Rossi

Distribution: CRGR SF CRGR CF J Mitchell RTripathi JRoe
MJamgochian TEssig RAuluck C Miller GWest SLewis

DISK/DOCUMENT NAME: S:\CRGR\KILTREDO.WPD

To receive a copy of this document, indicate in the box: "C" = Copy w/o attachment, "E" = Copy w/attachment, "N" = No copy

OFC	CRGR	CRGR	D: AEOD						
NAME	RTripathi	J Murphy	TMartin						
DATE	10/23/98	10/23/98	1/ /98						

OFFICIAL RECORD COPY