



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

December 14, 2004

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-04-0211

TITLE: FINAL AMENDMENTS TO 10 CFR PART 50, APPENDIX E,
RELATING TO (1) NUCLEAR REGULATORY COMMISSION
REVIEW OF CHANGES TO EMERGENCY ACTION LEVELS,
PARAGRAPH IV.B AND (2) EXERCISE REQUIREMENTS
FOR CO-LOCATED LICENSEES, PARAGRAPH IV.F.2

The Commission (with all Commissioners agreeing) approved a final rule in an Affirmation Session as recorded in the Staff Requirements Memorandum (SRM) of December 14, 2004.

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

A handwritten signature in black ink, appearing to read "Annette Vietti-Cook".

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-04-0211

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. DIAZ	X				X	11/19/04
COMR. McGAFFIGAN	X				X	12/9/04
COMR. MERRIFIELD	X				X	12/6/04

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved a final rule as noted in an Affirmation Session staff's and reflected in the SRM issued on December 14, 2004.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN DIAZ

SUBJECT: SECY-04-0211 - FINAL AMENDMENTS TO 10 CFR PART 50, APPENDIX E, RELATING TO (1) NUCLEAR REGULATORY COMMISSION REVIEW OF CHANGES TO EMERGENCY ACTION LEVELS, PARAGRAPH IV.B. AND (2) EXERCISE REQUIREMENTS FOR CO-LOCATED LICENSEES, PARAGRAPH IV.F.2

Approved xxj Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

Approve, subject to attached edits.

Annette Vietti-Cook
SIGNATURE

Nov 19, 04
DATE

Entered on "STARS" Yes No _____

requirements for co-located licensees, paragraph IV.F.2. A discussion of each of these revisions follows.

(1) NRC APPROVAL OF LICENSEE CHANGES TO EALs, 10 CFR PART 50, APPENDIX E, PARAGRAPH IV.B.

EALs are part of a licensee's emergency plan. There is an inconsistency in the emergency planning regulations regarding the ^{threshold for when} NRC approval of nuclear power plant licensee changes to EALs ^{is required.} Section 50.54(q) states that licensees may make changes to their emergency plans without Commission approval only if the changes "do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of §50.47(b) and the requirements of Appendix E" to 10 CFR Part 50. By contrast, Appendix E states that "emergency action levels shall be...approved by NRC." Current industry practice follows the provisions of §50.54(q). Industry has generally made and implemented revisions to EALs without requesting NRC approval after determining that the changes do not decrease the effectiveness of the emergency plan. When the determination is made that a change constitutes a decrease in effectiveness, licensees submit the changes to the Commission for approval. If a change involves a major change to the EAL scheme, for example, changing from an EAL scheme based on NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," guidance to an EAL scheme based on NUMARC/NESP-007, "Methodology for Development of Emergency Action Levels," or NEI-99-01, "Methodology for Development of Emergency Actions Levels," guidance or if the license proposes an alternate method for complying with the regulations, the industry practice ^{has been} to seek NRC review and approval before implementing the change.

X
X

X

The Commission believes that prior NRC approval of every EAL change is not necessary to provide reasonable assurance that EALs will continue to provide an acceptable level of safety. This final amendment focuses on EAL changes that are of sufficient significance that a safety evaluation by the NRC is appropriate before the licensee may implement the change. The Commission believes that EAL changes that have the potential to reduce the effectiveness of the emergency plan are of sufficient regulatory significance that prior NRC review and approval is warranted. This standard is the same standard that the current regulations provide for when determining whether changes to emergency plans (except EALs) require NRC review and approval. As such, this regulatory threshold has a long history of successful application. Therefore, this standard should also be used for EAL changes. On the basis of NRC's inspections of emergency plans, including EAL changes, the Commission believes that licensees have generally made appropriate determinations regarding whether an EAL change may potentially reduce the effectiveness of the emergency plan and that licensees have the capability to continue to do so. Limiting the NRC's approval to EAL changes that may reduce the effectiveness of emergency plans or to an alternate method for complying with the regulations will ensure adequate NRC oversight of licensee-initiated EAL changes. This both increases regulatory effectiveness (through use of a single consistent standard for evaluating all emergency plan changes) and reduces unnecessary regulatory burden on licensees (who would not be required to submit for approval EAL changes that do not decrease the effectiveness of the emergency plan).

The Commission believes a licensee's proposal to convert from one EAL scheme (e.g., NUREG-0654-based) to another EAL scheme (e.g., NUMARC/NESP-007 or NEI-99-01 based) or to a proposed alternate method for complying with the regulations will always involve a potential reduction in effectiveness. The potential safety significance of a change from one EAL scheme to another, or when proposing an alternative, is such that prior NRC review and

is of sufficient significance to

NRC review and approval for such major changes in EAL methodology is necessary

approval is appropriate to ensure that there is reasonable assurance that the final EAL change will provide an acceptable level of safety.

Accordingly, the Commission is revising Appendix E to 10 CFR Part 50 to provide that Commission approval of EAL changes is necessary for all EAL changes that decrease the effectiveness of the emergency plan and for changing from one EAL scheme (e.g., NUREG-0654-based) to another EAL scheme (e.g., NUMARC/NESP-007 or NEI-99-01-based) or for a proposal of an alternate method for complying with the regulations.

(2) EXERCISE REQUIREMENTS FOR CO-LOCATED LICENSEES, 10 CFR PART 50, APPENDIX E, PARAGRAPH IV.F.

The emergency planning regulations were significantly upgraded in 1980 after the accident at Three Mile Island (45 FR 55402; August 19, 1980). The upgraded 1980 regulations required an annual exercise of the onsite and offsite emergency plans. The regulations were amended in 1984 to change the frequency of participation of state and local governmental authorities in nuclear power plant offsite exercises from annual to biennial (49 FR 27733; July 6, 1984). The regulations were amended in 1996 to change the frequency of exercising the licensees' onsite emergency plans from annual to biennial (61 FR 30129; June 14, 1996). Appendix E to Part 50, Paragraph IV.F.2, currently provides that the "offsite plans for each site shall be exercised biennially" (emphasis added) with the full or partial participation of each offsite authority having a role under the plans, and that "each licensee at each site" shall conduct an exercise of its onsite emergency plan every two years, an exercise that may be included in the full or partial participation biennial exercise¹. Thus, Paragraph IV.F.2 is

¹ 10 CFR Part 50, Appendix E, IV.F.2, states:

2. The plan shall describe provisions for the conduct of emergency preparedness exercises as follows: Exercises shall test the adequacy of timing and content of implementing procedures and methods, test emergency equipment and communications networks, test the public notification system, and ensure that emergency organization personnel are familiar with their duties.

a. ***

b. Each licensee at each site shall conduct an exercise of its onsite emergency plan every two years. The exercise may be included in the full participation biennial exercise required by paragraph 2.c. of this section.***

c. Offsite plans for each site shall be exercised biennially with full participation of each offsite authority having a role under the plans, and that "each licensee at each site" shall conduct an exercise of its onsite emergency plan every two years, an exercise that may be included in the full or partial participation biennial exercise.

The Commission concludes that biennial full or partial participation exercises for each co-located licensee are not warranted and that this final regulation provides a sufficient level of assurance of emergency preparedness for the following reasons. First, the final rule is consistent with the current licensees' practice for the James A. FitzPatrick/Nine Mile Point plants. This practice has been reviewed periodically by the NRC, the Federal Emergency Management Agency (FEMA), and the State of New York. NRC has continued to find that there is reasonable assurance that appropriate measures could be taken to protect the public health and safety in the event of a radiological emergency based on NRC's assessment of the adequacy of the licensee's onsite Emergency Planning (EP) program, FEMA's assessment of the adequacy of the offsite EP program, and the current level of interaction between the onsite and offsite emergency response organizations in the period between full or partial participation exercises.

X

X

Second, the central requirement of a "partial participation" exercise under the current regulations is to test the "direction and control functions" between the licensee and the offsite authorities (i.e., protective action decision making related to emergency action levels and communications capabilities among affected State and local authorities and the licensee). The final rule contains a requirement that, in each of the three years between a licensee's participation in a full or partial participation exercise, each licensee shall participate in A&I with offsite authorities to test and maintain interface. By requiring that the licensee's emergency preparedness organization engage in activities and interactions with offsite authorities to exercise and test effective communication and coordination, the final rule provides the functional equivalent of a biennial exercise which tests the "direction and control functions" between the licensee and the offsite authorities. *Id.*

Third, the burden of requiring each licensee to participate biennially in a full or partial participation exercise with offsite participation falls most heavily on the offsite authorities

(i.e., the state and local authorities). The Commission's 1984 and 1996 rulemakings were specifically intended to reduce the schedule for offsite exercises to remove unnecessary burden on offsite authorities. However, the Commission did not explicitly address the unique circumstance of two plants located on a single site, with each plant owned by a different licensee. This final rulemaking addresses the undue burden placed upon offsite authorities in these circumstances.

The final rule defines co-located licensees as two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the following emergency planning and siting elements:

1. Plume exposure and ingestion emergency planning zones;
2. Offsite governmental authorities;
3. Offsite emergency response organizations;
4. Public notification system; and/or
5. Emergency facilities.

Paragraph-By-Paragraph Discussion of Changes to 10 CFR Part 50, Appendix E.

A. Paragraph IV. B - Assessment Actions.

This paragraph is amended by adding new language governing the type and scope of EAL changes that must receive NRC approval before implementation. The final amendment clarifies that the Commission approval of EAL changes is required for changes that decrease the effectiveness of the emergency plan when a licensee proposes an alternate method for complying with the regulations, when converting from one EAL scheme (e.g., NUREG-0654-based) to another EAL scheme (e.g., NUMARC/NESP-007 or NEI-99-01-based). The final

A new footnote 6 is also added to provide a definition of co-located licensees. There are two elements to the definition, both of which must be satisfied. First, co-located licensees^e are two different licensees whose licensed facilities are located either on the same site, or on adjacent, contiguous sites. Secondly, the co-located licensees^e must share most of the following emergency planning and siting elements.

X
X

1. Plume exposure and ingestion emergency planning zones;
2. Offsite governmental authorities;
3. Offsite emergency response organizations;
4. Public notification system; and/or
5. Emergency facilities.

The proposed rule did not actually specify that co-located licensees^e are those whose facilities either share the same site, or be located on adjacent contiguous sites, this is inherent in the concept of being "co-located." Nonetheless, the Commission believes that the rule should explicitly address this, and the final rule's language has been modified to include the concept of physical co-location as one of the criteria for a "co-located" licensee.

X

Comments on the Proposed Rule.

On July 24, 2003 (68 FR 43673), the Commission published a notice of proposed rulemaking and requested public comments by October 7, 2003. A total of seven comment letters were received. One comment letter was from a member of the public, six from utilities. All of the utility letters were in favor of the proposed changes, while the public commenter suggested that the changes were unnecessary. However, the comment letters did provide suggested clarifications to the proposed amendments. A detailed evaluation of each comment received is outlined below.

Comment

In Paragraph IV.B (Assessment Actions), ⁹ ~~(third sentence)~~ in lieu of adding "or licensee" in the third sentence, one commenter proposed that the following be added after the fourth sentence, "A revision to an EAL must be discussed and agreed on by the licensee and state and local government authorities prior to implementation." X

Response

The Commission disagrees with this comment because the Commission wants the original EAL submittals from applicants and licensees to be discussed and agreed on with the state and local governments and approved by the Commission. Additionally, the Commission continues to want EALs to be reviewed by the state and local government^s annually and not only when revisions are made to the EALs. X

Comment

"Reference is made throughout the proposed rule to NUMARC/NESP-007 as an alternative EAL scheme. Since the proposed rule was issued for public comment, NRC has endorsed NEI-99-01 as another acceptable EAL scheme. It is proposed that NEI-99-01 be referenced in addition to or in lieu of NUMARC/NESP-007."

Response

The Commission agrees with this comment and has referenced NEI-99-01 throughout the final amendment accordingly.

Comment

"The sixth and seventh sentences in the proposed Appendix E, Paragraph IV.B appear redundant to §50.54(q), ^{with regard} ~~regarding~~ to emergency plan revisions, and Appendix E Paragraph V, with regard to implementing procedure revisions. Furthermore, these additions might necessitate a complementary change to §50.4(b)(5) which explicitly references submittals X

The Commission agrees and has modified the list of activities and interactions A&I that are now contained in Regulatory Guide 1.101, Rev 5. X

Comment

The language in §50.54(q) could be further improved by establishing clear criteria for what constitutes a decrease in effectiveness of the Emergency Plan. Specifically, the following language should be revised, "*may make changes to these plans without Commission approval only if the changes do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of paragraph 50.47(b) and the requirements of Appendix E to this part.*"

The commenter suggested to add the words "a change to an emergency plan will not decrease the effectiveness of the plan if the change will not decrease the abilities of the emergency response organization, and/or supporting emergency response facilities and equipment, as required by paragraphs 10 CFR 50.47⁷(b) and Appendix E, or equivalent measures approved under 10 CFR 50.47(c), to reasonably assure the adequate protection of public health and safety in the event of a radiological emergency as stated in 10 CFR 50.47(a)(1). The change cannot delete any of the capabilities described in 10 CFR 50.47(b) and (d), or in Appendix E to 10 CFR Part 50." X

Response

While the Commission recognizes the merits of this comment, revising 10 CFR 50.54(q) to define what is meant by "decreasing the effectiveness" of the emergency plans was not published as part of the proposed rule and is therefore beyond the scope of this rulemaking.

Comment

One commenter believes that clarifying exercise requirements to allow alternating participation in exercises for co-located licensees will remove ambiguity that currently exists. The proposed exercise frequency, coupled with the detailed activities and interactions, will

REGULATORY ANALYSIS

The NRC has prepared a regulatory analysis on this regulations. This analysis examines the costs and benefits of the alternatives considered by the Commission.

I. Statement of Problem and Objectives

The Commission is making two changes to its emergency preparedness regulations contained in 10 CFR Part 50, Appendix E. The first amendment relates to the NRC approval of licensee changes to EALs, paragraph IV.B and the second amendment relates to exercise requirements for co-located licensees, paragraph IV.F.2. A discussion of each of these final amendments follows.

(1) NRC approval of licensee changes to EALs, 10 CFR Part 50, Appendix E, Paragraph IV.B.

EALs are part of a licensee's emergency plan. There is an inconsistency in the emergency planning regulations regarding the ^{threshold for when} NRC approval of nuclear power plant licensee changes to emergency action levels ^{is required}. Section 50.54(q) states that licensees may make changes to their emergency plans without Commission approval only if the changes "do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of 10 CFR 50.47(b) and the requirements of Appendix E" to 10 CFR Part 50. By contrast, Appendix E states that "emergency action levels shall be...approved by NRC." Current industry practice has been to make revisions to EALs and to implement them without requesting NRC approval, after determining that the changes do not reduce the effectiveness of the emergency plan in accordance with §50.54(q). When the determination is made that a final change constitutes a decrease in effectiveness, licensees submit the changes to the Commission for approval. If a change involves a major change to the EAL scheme, for example, changing from an EAL scheme based on NUREG-0654 guidance to an EAL scheme based on NUMARC/NESP-007 or NEI-99-01 guidance, or when proposing an alternate method

for complying with the regulations, it has been the industry practice to seek NRC review and approval before implementing the change.

(2) Exercise Requirements for Co-Located Licensees, 10 CFR Part 50, Appendix E, Paragraph IV.F.

The emergency planning regulations were significantly upgraded in 1980 after the accident at Three Mile Island (45 FR 55402; August 19, 1980). The updated 1980 regulations required an annual exercise of the onsite and offsite emergency plans. The regulations were amended in 1984 to change the frequency of participation of state and local governmental authorities in nuclear power plant offsite exercises from annual to biennial (49 FR 27733; July 6, 1984). The regulations were amended in 1996 to change the frequency of exercising the licensees' onsite emergency plans from annual to biennial (61 FR 30129; June 14, 1996). Appendix E, to 10 CFR Part 50, Paragraph IV.F.2, currently provides that the "offsite plans for each site shall be exercised biennially" with the full or partial participation of each offsite authority having a role under the plans, and that "each licensee at each site" shall conduct an exercise of its onsite emergency plan every two years, an exercise that may be included in the full participation biennial exercise. Thus, Paragraph IV.F.2 is ambiguous about the emergency preparedness exercise requirements where two nuclear power plants, each licensed to ^adifferent licensees, and meet the definition of being co-located. Specifically, it is ambiguous regarding whether each licensee must participate in a full participation exercise of the offsite plan every two years, or whether the licensees may alternate their participation so that a full participation exercise is held every two years and each licensee (at a two-licensee site) participates in a full participation exercise every four years.

X
X

Upon consideration of the language of the current regulation and the legislative history of the exercise requirements, the Commission believes that the ambiguity in the current regulations can be interpreted that each co-located nuclear power plant licensee must

Thus, each co-located licensee would participate in a full or partial participation exercise quadrennially. In addition, in the year when one of the co-located licensees is participating in a full or partial participation exercise, the final rule requires the other co-located licensee to participate in A&I with offsite authorities. For the period between exercises, the final rule also requires the licensees to conduct emergency preparedness activities and interactions. The purpose of A&I would be to test and maintain interface among the affected state and local authorities and the licensees.

The final rule defines co-located licensees as two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the following emergency planning and siting elements.

1. Plume exposure and ingestion emergency planning zones;
2. Offsite governmental authorities;
3. Offsite emergency response organizations,
- d. Public notification system; and/or
- e. Emergency facilities.

II. Background

(1) Emergency Action Levels (paragraph IV.B).

EALs are thresholds of plant parameters (such as containment pressure and radiation levels) used to classify events at nuclear power plants into one of four emergency classes (Notification of Unusual Event, Alert, Site Area Emergency, or General Emergency). EALs are required by Appendix E to 10 CFR Part 50 and §50.47(b)(4), and are contained in licensees' emergency plans and emergency plan implementing procedures.

Section 50.54(q) states that licensees can make changes to their emergency plans without Commission approval only if the changes "do not decrease the effectiveness of the plans and the plans, as changed, continue to meet the standards of §50.47(b) and the

requirements of Appendix E" to 10 CFR Part 50. However, Appendix E to 10 CFR Part 50 states that, "These emergency action levels shall be discussed and agreed on by the applicant and state and local governmental authorities and approved by NRC." Because EALs are required to be included in the emergency plan, the issue is whether changes to EALs incorporated into the emergency plan are subject to the change requirements in 10 CFR 50.54(q), or to the more restrictive requirement in Appendix E to 10 CFR Part 50.

(2) Exercise Requirements for Co-Located Licensees (paragraph IV.F.2).

The NRC's current regulations contained in Appendix E to 10 CFR Part 50, require that the offsite emergency plans for each site shall be exercised biennially with the full or partial participation of each offsite authority having a role under the plans and that each licensee at each site shall conduct an exercise of its onsite emergency plan every two years, an exercise that may be included in the full participation biennial exercise. This exercise requirement, though straightforward, has implementation and compliance problems when two or more licensees' facilities are located either on the same site or on adjacent, contiguous sites, thereby requiring the same state to conduct a full participation exercise with each co-located licensee every year.

There is currently only one site with two licensees, the Nine Mile Point and James A. FitzPatrick site. However, the nuclear industry has expressed the possibility of locating new plants on currently approved sites, possibly with different licenses^e, thus the need for this final rule change. X

III. Rulemaking Options For Both Amendments

Option 1 - revise the regulations to reflect current staff and licensee practices:

Option 2 - not ~~to~~ revise the regulations. X

to

IV. Alternatives

Impact(s)

Option 1 for the EAL revisions would amend the existing regulations to eliminate the inconsistency between the requirements of 10 CFR Part 50, Appendix E and §50.54(q) relating to approval of changes to EALs and reflect current staff and licensee practice. This would be done by amending Appendix E to 10 CFR Part 50 to require NRC to approve new EAL schemes, as well as proposals of alternate methods for complying with the regulations, and requiring Commission approval of revisions to EALs that ^{reduce} ~~diminish~~ the effectiveness of the emergency plans in accordance with §50.54(q). The rulemaking would provide a means for licensees to ^{make changes to} ~~improve~~ their EALs while reducing unnecessary regulatory burden. X

Once the rule is revised, licensees could make EAL changes that do not decrease the effectiveness of the emergency plan without a submittal for prior approval from the Commission. This approach would reduce the unnecessary regulatory burden on licensees. X

Option 2 for EAL changes would retain the inconsistency in the regulations, thereby increasing the unnecessary burden on licensees and the NRC staff in addressing questions on a case-by-case basis.

Option 1 (to amend the regulation) for co-located licensees would maintain safety because emergency planning exercises would continue to be required at the frequency which has provided reasonable assurance that the emergency plans can be implemented. The impact of Option 1 on the resources of licensees and offsite authorities would be minimal. Option 1 would reflect what licensees are currently doing and, therefore, there would not be a change in existing acceptable practices. Clarification of the regulatory requirements would modify wording that has resulted in an ambiguous understanding of the requirements. This option would require NRC resources to conduct the rulemaking. The activities and interactions that would test and maintain the interface for co-located licensees and offsite authorities in the

offsite authorities. For the period between exercises, the final rule requires each licensee to conduct emergency preparedness activities and interactions. Likewise each co-located licensee would log the activities and interactions with offsite authorities that are also conducted in the period between exercises. This final rule does not increase the burden on current co-located licensees because they have an emergency planning training regime consistent with the final rule. Future co-located licensees would keep a log of the A&I with offsite authorities which is estimated to average 30 hour^{g/g}(s) per co-located licensee per year. X

VI. Presentation of Results

As noted, the impact on a co-located licensee to implement the final rule change is 30 hour^{g/g}(s) per year per co-located licensee. This time would be used to maintain a log of the A&I with offsite authorities. At an assumed average hourly rate of \$156/hour, the total industry implementation cost is estimated at \$9,360. The cost for an individual co-located licensee is \$4,680 per year. X

With respect to the EAL rule change, licensees would save staff time by having explicit NRC requirements and guidance that will assist the licensees in the proper submittals of EAL changes. The impact of improved regulations on the NRC is a decrease in the amount of staff time needed to review licensee EAL changes. This is estimated to be about a 100 staff-hour reduction or a \$8,000 savings to the NRC per year (assuming a \$80 hourly rate for NRC staff time). However, it is uncertain as to how many EAL changes might have been received by the NRC.

There would be several additional benefits associated with these amendments. The greatest would be the increased assurance that the Commission's regulations are consistent and not ambiguous. Further, by addressing these issues generically through rulemaking rather than continuing the current case-by-case approach, it is expected that the burden on the NRC staff would be reduced by several hours for each licensee EAL change as well as future co-

located licensees' exercise requirements that NRC would need to approve. Another beneficial attribute to this final action is regulatory efficiency resulting from the expeditious handling of future licensing actions by providing regulatory predictability and stability for the EAL changes as well as the exercise requirements for co-located licensees.

VII. Decision Rationale for Selection of the Final Action

As previously discussed, the additional burdens on a licensee and the NRC are expected to be modest. However, a revision of the requirements is desirable to remove ambiguities in the current regulations while maintaining safety and reducing unnecessary regulatory burden.

VIII. Implementation

The final rule takes effect 90 days after publication in the *Federal Register*.

REGULATORY FLEXIBILITY CERTIFICATION

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The final rule would affect only States and licensees of nuclear power plants. These States and licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, or the size standards established by the NRC (10 CFR 2.810).

BACKFIT ANALYSIS

(1) NRC approval of EAL Changes

The final rule, which eliminates the need for NRC approval for certain EAL changes, does not constitute a backfit as defined in §50.109(a)(1). Although 10 CFR 50.54(q) permits licensees to make changes to the^r emergency plan^s which do not decrease the effectiveness of the plan^s, 10 CFR Part 50, Appendix E currently requires that all EALs shall be approved by

X
X

time that the NRC approved "alternating participation." However, these licensees have informally been implementing an emergency planning training regime since year 2000 that is consistent with the final rule. Accordingly, the NRC will not prepare a backfit analysis addressing the Nine Mile Point and James A. FitzPatrick licensees.

With respect to future holders of operating licenses (including combined licenses under Part 52) for nuclear power plants which meet the definition of being co-located, the Commission has indicated in various rulemakings that the Backfit Rule does not protect the prospects of a potential applicant.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of Office of Management and Budget (OMB).

LIST OF SUBJECTS IN 10 CFR PART 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act ^{of} 1954, as amended, the Energy Reorganization Act of 1974, as amended, the National Environmental Policy Act of 1969, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR Part 50. X

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATIONS FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132,

If two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the elements defining co-located licensees,⁶ each licensee shall:

- (1) conduct an exercise biennially of its onsite emergency plan; and
- (2) participate quadrennially in an offsite biennial full or partial participation exercise; and
- (3) conduct emergency preparedness activities and interactions in the years between its participation in the offsite full or partial participation exercise with offsite authorities, to test and maintain interface among the affected state and local authorities and the licensee. Co-located licensees shall also participate in emergency preparedness activities and interaction with offsite authorities for the period between exercises.

* * * * *

Dated at Rockville, Maryland, this __ day of _____, 2004.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,
Secretary of the Commission

⁶Co-located licensees are two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the following emergency planning, and siting elements:

- a. plume exposure and ingestion emergency planning zones,
- b. offsite governmental authorities,
- c. offsite emergency response organizations,
- d. public notification system, and/or
- e. emergency facilities



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 1.101, REVISION 5

EMERGENCY RESPONSE PLANNING AND PREPAREDNESS FOR NUCLEAR POWER REACTORS

A. INTRODUCTION

In §50.54, "Conditions of licenses," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," paragraph (q) states that, "A licensee authorized to possess and operate a nuclear power reactor shall follow and maintain in effect emergency plans which meet the standards in §50.47(b) and the requirements in Appendix E of this part." Likewise, 10 CFR 50, Appendix E, paragraph IV.F.2.c. requires:

"c. Offsite plans for each site shall be exercised biennially with full participation by each offsite authority having a role under the plan. Where the offsite authority has a role under a radiological response plan for more than one site, it shall fully participate in one exercise every two years and shall, at least, partially participate in other offsite plan exercises in this period.

For If two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the elements defining co-located licensees, each licensee shall:

- (1) conduct an exercise biennially of its onsite emergency plan; and
- (2) participate quadrennially in an offsite biennial full or partial participation exercise; and
- (3) conduct emergency planning activities and interactions in the years between its participation in the offsite full or partial participation exercise with offsite authorities to test and maintain interface among the affected state and local authorities and the licensee."

Whereas, "Partial participation" is defined in a footnote as "when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite authorities shall actively take part in the exercise sufficient to test direction and control

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the NRC staff in its review of applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Written comments may be submitted to the Rules and Directives Branch, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Regulatory guides are issued in ten broad divisions: 1 Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Single copies of regulatory guides (which may be reproduced) may be obtained free of charge by writing the Distribution Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to (301-415-2289), or by email to Distribution@NRC.GOV. Electronic copies of this guide and other recently issued guides are available at NRC's home page at WWW.NRC.GOV through the Electronic Reading Room, Accession Number

junctions; i.e., (a) protective action decision making related to emergency action levels, and (b) communication capabilities among affected State and local authorities and the licensee." Likewise, "co-located licensees" is also defined in a footnote as, "two different licensees whose licensed facilities are located either on the same site or on adjacent, contiguous sites, and that share most of the following emergency planning and siting elements:

- (a) Plume exposure and ingestion emergency planning zones,
- (b) Offsite governmental authorities,
- (c) Offsite emergency response organizations,
- (d) Public notification system, and/or
- (e) Emergency facilities"

This regulatory guide provides guidance to co-located licensees and co-located applicants on methods acceptable to the NRC staff for complying with the NRC's regulations for emergency response plans and preparedness relative to conducting emergency response planning activities and interactions (A&I) in the years between participation in the offsite full or partial participation exercises with offsite authorities. Licensees and applicants may propose means other than those specified by the provisions of the Regulatory Position of this guide for meeting applicable regulations. No new positions or requirements are being imposed by this regulatory guide.

The information collections contained in this regulatory guide increases the burden on co-located licensees to log activities and interactions with offsite agencies during the years that full or partial participation emergency preparedness exercises are not conducted and to prepare a one-time change to procedures to reflect the revised exercise requirements. The public burden for this information is estimated to average 30 hours per year. Because the burden for this information collection is insignificant, Office of Management and Budget (OMB) clearance is not required. Existing requirements were approved by the Office of Management and Budget, approval number 3150-0011. The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

B. Discussion

Revision 1 to NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," was published in November 1980 to provide specific acceptance criteria for complying with the standards set forth in 10 CFR 50.47. FEMA, NRC, and other involved Federal agencies use the guidance contained in Revision 1 of NUREG-0654/FEMA-REP-1 in their individual and joint reviews of the radiological emergency response plans and preparedness of State and local governments and the plans and preparedness of applicants for and holders of a license to operate a nuclear power reactor. Revisions 2 and 3 of Regulatory Guide 1.101 endorsed Revision 1 of NUREG-0654/FEMA-REP-1.

In January 1992, the Nuclear Utilities Management and Resource Council (NUMARC) issued Revision 2 of NUMARC/NESP-007, "Methodology for Development for Emergency

¹Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161; (telephone (703)487-4650; <<http://www.ntis.gov/ordernow>>. Copies are available for inspection or copying for a fee from the NRC Public Document Room at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; the PDR's mailing address is US NRC Public Document Room, Washington, DC 20555; telephone(301)415-4737 or (800)397-4209; fax (301)415-3548; email is PDR@NRC.GOV.

Action Levels,"² which contained guidance on EAL development that accounted for lessons learned from ten years of using the NUREG-0654 guidance. The NRC stated in Revision 3 of Regulatory Guide 1.101 (August 1992), that Revision 2 of NUMARC/NESP-007 was considered to be an acceptable alternative to the guidance provided in NUREG-0654 for development of EALs to comply with 10 CFR 50.47 and Appendix E to 10 CFR Part 50.

In Revision 3 to Regulatory Guide 1.101, the NRC stated that "Licensees may use either NUREG 0654/FEMA-REP-1 or NUMARC/NESP-007 in developing their EAL scheme but may not use portions of both methodologies." The staff stated in EPPOS No. 1, "Emergency Preparedness Position (EPPOS) on Acceptable Deviations from Appendix 1 of NUREG-0654 Based Upon the Staff's Regulatory Analysis of NUMARC/NESP-007, Methodology for Development of Emergency Action Levels,"³ that it recognizes that licensees who continue to use EALs based upon NUREG-0654 could benefit from the technical basis for EALs provided in NUMARC/NESP-007. However, the staff also recognized that the classification scheme must remain internally consistent. X

In January 2003, the Nuclear Energy Institute submitted guidance (NEI 99-01, Revision 4, January 2003, "Methodology for Development of Emergency Action Levels")⁴ for developing EALs applicable in the shutdown and refueling modes of plant operations. NEI 99-01 also provided new guidance for developing EALs for permanently shutdown reactors and dry cask spent fuel storage at nuclear power plants. In addition, improvements to the NUMARC/NESP-007 EAL guidance were incorporated into NEI 99-01; these improvements were first developed (and the rationale behind the revision discussed) in NEI 97-03, Draft Final Revision 3, "Methodology for Development of Emergency Action Levels" (December 1998). NEI 97-03 was not endorsed by the NRC because the NRC applied its resources to the review of NEI 99-01, which incorporates the guidance in NEI 97-03. X

Revision 4 endorsed the guidance in NEI 99-01 (Revision 4, January 2003), "Methodology for Development of Emergency Action Levels," as acceptable to the NRC staff as an alternative method to that described in Appendix 1 to NUREG-0654/FEMA REP-1 and NUMARC/NESP-007 for developing EALs required in Section IV.B of Appendix E to 10 CFR Part 50 and 10 CFR 50.47 (b)(4). X

The NRC is revising RG 1.101 to set forth guidance on the conduct of activities and interactions, (A&I) to reflect the provisions of the regulations addressing co-located licensees. X

The Commission finds that where two nuclear power plants are licensed to different licensees and meet the definition of being co-located, reasonable assurance of emergency preparedness exists where:

1. The co-located licensees would exercise their onsite plans biennially;
2. The offsite authorities would exercise their plans biennially; and,
3. The interfaces between offsite plans and the respective onsite plans would be exercised biennially in a full or partial participation exercise alternating between each licensee.

²Copies are available for inspection or copying for a fee from the NRC Public Document Room at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852; the PDR's mailing address is US NRC Public Document Room, Washington, DC 20555; telephone (301)415-4737 or (800)397-4209; fax (301)415-3548; email is PDR@NRC.GOV.

³Electronic copies (Accession Number ML022970165) are available in NRC's Public Electronic Reading Room, which can be accessed through the NRC's web site. <WWW.NRC.GOV>.

⁴Electronic copies (Accession Number ML030300486) are available in NRC's Public Electronic Reading Room, which can be accessed through the NRC's web site. <WWW.NRC.GOV>.

Thus, each co-located licensee would participate in a full or partial participation exercise quadrennially. In addition, when one of the co-located licensees is participating in a full or partial participation exercise, the final rule requires any other co-located licensees to participate in activities and interaction (A&I) with offsite authorities. For the period between exercises the final rule also requires the licensees to conduct emergency preparedness A&I. The purpose of these A&I would be to test and maintain the interface among the affected state and local authorities and the licensees.

Table 1 provides a graphical description of one possible way of meeting the requirements of the regulations.

Table 1 Example of Emergency Preparedness Training for Two (2) Co-located Licensees

Year	1	2	3	4	5	6	7	8	9
Licensee 1	X	A&I	A&I	A&I	X	A&I	A&I	A&I	X
Licensee 2	A&I	A&I	X	A&I	A&I	A&I	X	A&I	A&I

Notes: X = Full or partial participation exercise (with appropriate activities and interactions with offsite authorities).
A&I = Activities and interactions with offsite authorities

The substance of this guidance is set forth below:

1. When one licensee hosts the two-year full or partial participation exercise, the other licensee is involved in the following activities:
 - (a) Scenario preparation;
 - (b) Meetings with State, and local governmental personnel to develop extent of play document;
 - (c) Licensee to conduct training at state/local centers such as reception centers, congregate care centers, and local emergency operations center; and
 - (d) Provide controllers and observers for the full-participation exercise.
2. Provide for the staffing of the State and local emergency operations centers (EOC) such as dose assessment and communications personnel as well as the staffing of the Joint News Center.
3. Hospital drills are conducted with alternating localities; if applicable.
4. The notification process and the emergency action level scheme should be exercised.
5. Protective action recommendations methodology for the 10-mile emergency planning zone and the dose assessment methodology should be exercised.
6. Licensee/Offsite training:
 - Annual State/local training (Examples: Reactor Systems, Dry Cask Storage, EALs).
 - Licensee provided Fire Service Training.
 - Licensee provided Ambulance Training.
 - Licensee provided Hospital Training.
 - Licensee provided Dose Assessment training, including dose assessment software.
7. Licensee/Offsite Meetings and Conferences:
 - Ad hoc meetings with county emergency management staff.

X

- Local government emergency planning committee meetings.
 - Licensee security meetings with offsite law enforcement and other federal agencies. X
 - Licensee assistance in the development of the emergency planning public information booklet.
8. Licensee/Offsite drills and exercises:
- Local and/or State partial participation in licensee drills and biennial exercises.
 - Participation in local/State FEMA evaluated drill.
 - Local fire department support during licensee on-site fire drills.
9. Licensee/Offsite support services:
- Licensee support at local government reception center training and practice drills.
 - Licensee provides dosimeters and processing services to local government.
 - Licensee provides radiological instrument calibration services to local government. X
 - Licensee support of local government during public notification system test.
 - Licensee provides use of weapons firing range to local and state law enforcement (Sheriff, State Police), if available.

C. REGULATORY POSITION

The criteria and recommendations in this Regulatory Guide are methods acceptable to the NRC staff for complying with the requirements in 10 CFR Part 50, Appendix E, and the planning standards in 10 CFR 50.47(b) that must be met in onsite and offsite emergency response plans. These criteria provide a basis for NRC co-located licensees and State and local governments to develop acceptable radiological emergency plans and improve emergency preparedness.

D. IMPLEMENTATION

The purpose of this section is to provide information to co-located licensees and applicants regarding the NRC staff plans for using this regulatory guide.

Except when a co-located applicant or licensee proposes an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in this guide will be used in the evaluation of emergency plans and preparedness for co-located licensees.

AFFIRMATION ITEM

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: SECY-04-0211 - FINAL AMENDMENTS TO 10 CFR PART 50, APPENDIX E, RELATING TO (1) NUCLEAR REGULATORY COMMISSION REVIEW OF CHANGES TO EMERGENCY ACTION LEVELS, PARAGRAPH IV.B. AND (2) EXERCISE REQUIREMENTS FOR CO-LOCATED LICENSEES, PARAGRAPH IV.F.2

Approved Disapproved Abstain

Not Participating

COMMENTS:

Approved subject to edit of Chairman Deaz.

Edward Mc Caffigan Jr.

SIGNATURE
December 9, 2004

DATE

Entered on "STARS" Yes No

AFFIRMATION ITEM


RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: SECY-04-0211 - FINAL AMENDMENTS TO 10 CFR PART 50, APPENDIX E, RELATING TO (1) NUCLEAR REGULATORY COMMISSION REVIEW OF CHANGES TO EMERGENCY ACTION LEVELS, PARAGRAPH IV.B. AND (2) EXERCISE REQUIREMENTS FOR CO-LOCATED LICENSEES, PARAGRAPH IV.F.2

Approved Disapproved Abstain
Not Participating

COMMENTS:

Approved subject to the edits of Chairman Diaz, and one minor edit to be transmitted letter.



SIGNATURE
12/6/04

DATE

Entered on "STARS" Yes No



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

The Honorable Joe Barton, Chairman
Subcommittee on Energy and Air Quality
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The Nuclear Regulatory Commission (NRC) is amending its emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule amends 10 CFR Part 50, Appendix E to require NRC review of emergency action levels (EALs) for applicants for initial reactor operating licenses and initial combined licenses (COL) and for licensees who are converting from one EAL scheme (e.g., NUREG-0654 based) to another EAL scheme (e.g., NUMARC/NESP-007 or NEI-99-01 based), as well as revisions to EALs that decrease the effectiveness of the emergency plan. This practice has been shown to maintain safety and reduce unnecessary regulatory burden for licensees in revising their EALs. Licensees can make minor EAL changes promptly and efficiently without undue NRC oversight.

Additionally, the final rule codifies the current practice of co-located licensees alternating participation in the full (or partial) participation biennial exercises of the offsite plans, with the current level of other activities and interaction between the licensees and offsite authorities at the affected site as acceptable.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
Federal Register Notice

cc: Rep. Rick Boucher