Decrease in Effectiveness

A. Definition of the Regulatory Problem.

Title 10, Section 50.54, "Conditions of licenses," of the *Code of Federal Regulations* (10 CFR 50.54) establishes a series of requirements that are deemed to be conditions in every license the U.S. Nuclear Regulatory Commission (NRC) issues pursuant to 10 CFR Part 50, "Domestic Licensing of production and Utilization Facilities." Furthermore, 10 CFR 50.54(q) establishes (1) that a licensee must maintain in effect and follow its emergency plan, and (2) a change process by which a licensee can modify its approved plan dependent on whether the change would "decrease the effectiveness" of the plan. The staff has identified the following three problems involving 10 CFR 50.54(q):

(1) This section lacks clarity in the regulatory intent of the phrase "maintain in effect." The current language does not adequately convey the NRC expectation that maintaining an emergency plan also requires maintaining the various capabilities and resources relied upon in the plan. If those capabilities and resources are to be reduced, the agency expects actions be taken to ensure that the plan continues to provide adequate protection of public health and safety following the change. The staff has identified several occurrences in which licensee personnel outside of the emergency preparedness group have changed the status of capabilities and resources under their cognizance without considering the impact on the effectiveness of the emergency plan or without alerting the emergency preparedness group.

(2) This section lacks a definition for the phrase "decrease the effectiveness" in the context of changes to emergency plans. This lack of regulatory clarity has led to varied implementation by licensees, several enforcement actions, and unnecessary precautionary submittals for NRC review resulting in inefficient and ineffective use of licensee and staff resources.

(3) There is a lack of clear process for proposing alternative approaches to the guidance of Regulatory Guide 1.101, "Emergency Response Planning and Preparedness for Nuclear Power Reactors." This guide endorses the criteria and recommendations in NUREG-0654/FEMA-REP-1, Revision 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," issued November 1980, as methods acceptable to the NRC staff for complying with the planning standards in 10 CFR 50.47(b) that must be met in onsite and offsite emergency response plans. As with all regulatory guides, methods and solutions different from those set out in the guide will be acceptable if the alternatives provide a basis for the findings requisite to the continuance of a license (e.g., the alternative will not decrease the effectiveness of the emergency plan). However, 10 CFR 50.54(q) does not require staff review of a licensee's proposed alternative approach for demonstrating compliance with one or more of the planning standards in 10 CFR 50.47(b). By its silence on the matter, the current language of 10 CFR 50.54(q) enables a licensee to implement an alternative approach to the methods identified in the regulatory guide without affording the staff the opportunity to make the requisite finding that the alternative will not decrease the effectiveness of the emergency plan. Also, in the absence of a prescribed process some licensees have erroneously submitted a proposed alternative method, deemed by the licensee to decrease the effectiveness of the emergency plan, as a

license amendment pursuant to 10 CFR 50.90, "Application for Amendment of License or Construction Permit." As a result, implementation of 10 CFR 50.54(q) has been inconsistent, potentially affecting the licensee's ability to adequately protect public health and safety.

B. Existing Regulatory Framework

Currently, 10 CFR 50.54(q) currently states, in part, the following:

> A licensee authorized to possess and operate a nuclear power reactor shall follow and maintain in effect emergency plans which meet the standards in section 50.47(b) and the requirements in appendix E of this part.... The nuclear power reactor licensee 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 section 50.47(b) and the requirements of Appendix E to this part.... Proposed changes that decrease the effectiveness of the approved emergency plans may not be implemented without application to and approval by the Commission.[1]

As permitted by 10 CFR 50.54(q), a licensee can make changes in its emergency plans without Commission approval if the changes do not decrease the effectiveness of the plans. The regulations do not define the term "decrease in effectiveness" or identify the type of changes that would constitute a decrease in effectiveness. In 1998, the NRC issued Emergency Preparedness Position (EPPOS) 4, "Emergency Plan and Implementing Procedure Changes," to provide guidance to NRC inspectors. The industry has a strong interest in this issue; in 2004, the Nuclear Energy Institute (NEI) submitted two white papers regarding the decrease in effectiveness for NRC consideration (see references below). The staff could not reach consensus with NEI and thus did not endorse the NEI guidance. In 2005, the NRC withdrew EPPOS-4 and issued Regulatory Issue Summary (RIS) 2005-02, "Clarifying the Process for Making Emergency Plan Changes," dated February 14, 2005, to (1) clarify the meaning of decrease in effectiveness, (2) clarify the process for making changes to emergency plans, and (3) provide some examples of changes that are not decreases in effectiveness. Although RIS 2005-02 provided pertinent guidance, the NRC and NEI continue to discuss how the 10 CFR 50.54(q) change process could be improved, including the use of a regulatory framework parallel to that of 10 CFR 50.54(a)(3), 10 CFR 50.54(p)(2), and 10 CFR 50.59, "Changes, Tests, and Experiments."

C. Preliminary Options Considered to Resolve the Problem.

1. Take no action.

   This option would maintain the status quo. There would be no definition of the "follow and maintain in effect." requirement in 10 CFR 50.54(q) and no definition of which emergency plan changes constituted a decrease in effectiveness. As a

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1 This proposed rulemaking would address concerns regarding emergency preparedness for power reactors. During the rulemaking effort, NSIR/DPR proposes to work with NRR/DPR/PRTB in determining which of the proposed changes to 10 CFR 50.54(q) would apply to research and test reactors. The staff is not proposing amended language for 10 CFR 50.54(q) provisions that are generic to all 10 CFR Part 50 licensees.

result, there would be continued inefficiencies and ineffectiveness in the use of licensee and staff resources in the absence of the proposed clarifications. There would be no defined process for changes that warrant NRC prior review, increasing the likelihood that changes unacceptable to the NRC may be implemented without the review deemed necessary, thereby potentially affecting the public health and safety. As such, the staff considered this option to be unacceptable.

2. Use voluntary program.

NEI has submitted two white papers that sought to clarify the characteristics of emergency plan changes that should be considered to be decreases in effectiveness. The staff did not reach consensus with NEI, which resulted in the staff's publication of RIS 2005-02. Although regulatory guidance, and perhaps industry guidance, may ultimately be part of the solution (as with the earlier revision of 10 CFR 50.59), the staff believes that the fundamental definitions and requirements need to be codified to ensure consistent and predicable implementation and enforceability. Similarly, the staff believes that proposed changes to define the term "maintain in effect," as well as the proposed change process for emergency plan changes requiring prior NRC review need to be codified to ensure consistent and predicable implementation and enforceability. Accordingly, the staff considered this option to be unacceptable.

3. Implement proposed regulation.

The staff believes that the proposed amendment to the regulations, supplemented as necessary by regulatory guidance, is the best course of action and will ensure that (1) the effectiveness of the EP plans are maintained, (2) changes to the approved emergency plan are properly evaluated, and (3) any change that decreases the effectiveness of the plan or that is an alternative approach to the methods identified in the regulatory guide, is reviewed by the NRC prior to implementation. The staff also believes that the proposed rule changes will promote consistent and predictable implementation and enforcement, while minimizing inefficient and ineffective use of licensee and staff resources. Although RIS 2005-02 provides pertinent guidance, the desirable changes in structure and content of 10 CFR 50.54(q) require rulemaking. The staff expects that the proposed rule will provide a definition of the phrase "decrease the effectiveness," supplemented by examples of those types of changes that would not decrease the effectiveness of the plan in a regulatory framework parallel to that of §§ 50.54(a)(3), 50.54(p)(2), and 50.59. The staff will also consider alternatives to the term "decrease the effectiveness."

4. Implement some other regulatory scheme.

It is possible that some other regulatory scheme would be more effective and efficient than the one proposed and would continue to provide the desired assurance that changes to emergency plans are made which conform with clear definitions of the terms "maintain in effect" and "decrease the effectiveness" of emergency plans. The NRC rulemaking process offers the opportunity for the public and the nuclear power industry to comment on the proposed changes to

the regulations. If another viable scheme is proposed during this process, the staff will review it and, if it could adequately protect public health and safety, propose its implementation to the Commission for consideration.

D. Technical References and Supporting Documents

- 10 CFR 50.47(b)
- 10 CFR 50.54(a)(3)
- 10 CFR 50.54(q)
- 10 CFR 50.54(p)(2)
- 10 CFR 50.59
- SECY-06-0200, “Results of the Review of Emergency Preparedness Regulations and Guidance”
- EPPOS-4, "Emergency Plan and Implementing Procedure Changes."
- RIS 2005-02, "Clarifying the Process for Making Emergency Plan Changes," February 14, 2005.
- NUREG-0654/FEMA-REP-1, Rev. 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," November 1980.
- NEI White paper “Emergency Plan Change Process 10 CFR 50.54(q),” March 2005
- NEI Comments on Draft “NRC Views for 50.54(q) Discussion,” July 14, 2004

E. Potential Response from Stakeholders

In informal draft correspondence, NEI indicated that the industry (1) endorses the concept of a consistent, repeatable definition of the types of change that decrease the effectiveness of the emergency plan, (2) suggested that terminology other than “decrease in effectiveness,” be used in the future, and (3) might submit a proposed industry definition. NEI also stated that RIS 2005-02 is unreasonably restrictive and increases unnecessary regulatory burden. The staff expects NEI to propose an alternative approach once this rulemaking plan becomes public. However, reaching a consensus may be challenging given the history of NEI-NRC interface on this issue, and NEI comments regarding RIS 2005-02.

The Federal Emergency Management Agency (FEMA) and State and local authorities will likely support this rulemaking initiative because the effectiveness of the onsite emergency plan is under the purview of the NRC. Furthermore, increased clarity regarding the change process for emergency plans provides increased assurance that the onsite plans will be an effective part of the overall onsite and offsite emergency preparedness.

Meetings with public advocacy groups and the public in general during the development of SECY-06-0200, “Results of the Review of Emergency Preparedness Regulations and Guidance,” dated September 20, 2006, did not bring out any concerns related to maintaining the effectiveness of the onsite emergency plan. The public will likely support this NRC rulemaking if it is perceived as strengthening the NRC oversight of the licensee’s EP program.