



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

Das
PDR

November 25, 1998

EGM 98-009

MEMORANDUM TO:

Hubert J. Miller, Regional Administrator
Region I
Luis A. Reyes, Regional Administrator
Region II
James L. Caldwell, Acting Regional Administrator
Region III
Ellis W. Merschoff, Regional Administrator
Region IV
Samuel J. Collins, Director
Office of Nuclear Reactor Regulation
Bruce Boger, Acting Associate Director for
Projects, NRR
Brian W. Sheron, Acting Associate Director for
Technical Review, NRR
Elizabeth Q. Ten Eyck, Director, Division of Fuel Cycle
Safety and Safeguards, NMSS
Donald A. Cool, Director, Division of Industrial and Medical
Nuclear Safety, NMSS
John T. Greeves, Director, Division of Waste Management, NMSS
William Kane, Director, Spent Fuel Project, NMSS

FROM:

James Lieberman, Director
Office of Enforcement

SUBJECT:

ENFORCEMENT GUIDANCE MEMORANDUM - USE OF
REGULATORY SIGNIFICANCE FOR ESCALATED
ENFORCEMENT ACTION

The purpose of this Enforcement Guidance Memorandum is to address the use of regulatory significance in the regulatory process. It is an important concept as it allows for increasing the severity levels of individual Severity Level IV violations into a Severity Level III problem where these violations represent fundamental performance problems which may be precursors to more significant problems. Thus, application of the concept of regulatory significance has formed the basis for staff and licensee management discussions, in the context of a set of violations, to emphasize the need for licensee's management to better control licensed activities to avoid adverse impact on the public health and safety. However, while there is value in using this concept, the subjective nature of the concept of regulatory significance requires careful management oversight to apply it in a consistent and predictable manner.

The staff recognizes the need to evaluate the use of regulatory significance and relationship between it and the reactor assessment process. This is being done as part of the ongoing reassessment of the reactor oversight program. Until that effort is completed, the staff will be increasing its oversight effort, to better control the use of judgment in regulatory significance determinations.

9812080073 981125
PDR ORG NE SEN
PDR

1/0
TEH

BACKGROUND

Regulatory requirements have varying degrees of safety, safeguards, or environmental significance. The Enforcement Policy (Policy) provides that the first step in the enforcement process is to determine the relative importance of the violation by evaluating its technical significance and regulatory significance. Technical significance addresses the actual and potential consequences of a violation including appropriate consideration of risk information.

Regulatory significance is not defined by the Policy. It is appropriately used to categorize the cumulative significance of one or more violations when the degree of agency concern is greater than the individual violation(s) actual or potential safety, safeguards, or environmental consequence. While regulatory significance addresses a wide variation of violations, it is used in three basic types of cases:

Type 1 - Impacting the Regulatory Process

Cases where there are violations that have safety implications from the impact or potential impact on the NRC's ability to carry out its statutory mission. Examples of cases under this category would include non-willful violations of 10 CFR 30.9, 50.9, etc (completeness and accuracy of information), 50.59, 76.68, etc (change, tests and experiments), and Subpart M of Part 20, 30.50, 50.72-73, etc (reporting requirements).

Type 2 - Integrity

Cases where there are violations that have safety implications associated with the integrity of the licensees and their employees, including the ability to maintain a safety conscious work environment. Examples of cases under this category would include willful violations of 10 CFR 30.10, 50.5, etc (deliberate misconduct), 30.7, 50.7, etc (discrimination), 30.9, 50.9, etc (completeness and accuracy of information) and other regulatory requirements.

Type 3 - Aggregation of Violations

Cases where the cumulative effect of a number of less significant violations has greater potential consequences than the individual issues treated separately. The issues are normally grouped together due to common root causes and surrounding circumstances. A common application of regulatory significance is for significant programmatic violations described in the various Policy Supplements as violations associated with recurring or related violations demonstrating a breakdown in the control of licensed activities such as a grouping of violations demonstrating by their nature and number a breakdown in the licensee's corrective action program involving safety systems.

In accordance with the Policy, the severity level of a violation is defined by the level of regulatory concern. The Policy does not specifically define the term, regulatory concern. However, the Policy uses it to describe the breadth of NRC regulatory responsibilities, i.e., safety, safeguards, and the environment, and the relative importance of the violation in those areas based on the technical and regulatory significance. The degree of regulatory concern is based on an evaluation of the involved violations, their root causes, and surrounding circumstances. When violations arise to a significant regulatory concern and are categorized at a Severity Level III, in essence the NRC is saying that the violations are of significant safety, safeguards, or environmental concern.

GUIDANCE

This EGM addresses Type 3 cases, Aggregation of Violations.

The severity level of an enforcement action must have a direct relationship to the violation's actual, potential, or regulatory significance. Therefore, **when the staff aggregates a number of individual Severity Level IV violations into a Severity Level III problem, the problem must demonstrate a significant safety, safeguards, or environmental concern.** More is needed than a grouping of violations. It is not the number of violations, but the number and nature of the violations that are important. In light of the judgement needed to apply the concept of regulatory significance, it is necessary in applying the concept to articulate clearly why the violations in the aggregate are significant from a safety, safeguards, or environmental perspective. Its use should be reserved for those violations that represent fundamental performance problems which may be credible precursors to more significant problems.

The Policy emphasizes the need to exercise judgment in making severity level decisions and provides examples in the Policy's eight supplements to aid in making those judgments.¹ Several of the examples in the supplements provide assistance in categorizing violations based on regulatory significance such as examples C.7 of Supplement I, C.8 of Supplement II, C.13 of Supplement IV, C. 7 of Supplement VI, etc. But the existence of these examples do not remove the subjectivity and the need to exercise considerable judgment to make sure there are sufficient safety implications to warrant a Severity Level III classification. As previously noted, it is not enough to have just a multitude of violations or a programmatic issue. There must be a nexus to safety, safeguards, or the environment. If the staff relies on a specific example from a supplement for a Severity Level III categorization based on regulatory significance, the staff still must be able to make a case that there is a significant safety, safeguards, or environmental concern.

The need to have a nexus to safety, safeguards, and the environment may narrow the application of examples in the Supplements. For example, in Supplement I, example C.7 should be limited to situations with clear safety implications such as:

breakdown in the control of licensed activities, including programmatic failures, involving recurring or multiple violations that demonstrate a significant lack of attention or carelessness towards a licensed activities **that have a significant and credible potential for impacting safety if not promptly addressed**

¹ The policy states that the examples in the supplements:

are neither exhaustive nor controlling. In addition, these examples do not create new requirements. Each is designed to illustrate the significance that the NRC places on a particular type of violation of NRC requirements. Each of the examples in the supplements is predicated on a violation of a regulatory requirement. The NRC reviews each case being considered for enforcement action on its own merits to ensure that the severity of a violation is characterized at the level best suited to the significance of the particular violation.

Enforcement actions should minimize the use of the term "regulatory significance" and focus on the safety implications of the violations. Enforcement notifications based on cases involving regulatory significance should address the safety implications.

The Office of Enforcement (OE) has increased its oversight of reactor cases involving regulatory significance to ensure that the grouping of violations demonstrate a sufficient nexus with safety, safeguards, and the environment to warrant escalation to Severity Level III. All future cases, based on regulatory significance, will require full OE review and concurrence. OE will seek the views of NRR and NMSS for each case. Reactor cases will also require concurrence by the Deputy Executive Director for Regulatory Effectiveness.

If there are questions on the use of regulatory significance, please contact your enforcement coordinator or OE.

cc: Chairman Jackson
 Commissioner Dicus
 Commissioner Diaz
 Commissioner McGaffigan
 Commissioner Merrifield
 W. Travers, EDO
 H. Thompson, DEDR
 M. Knapp, DEDE
 C. Paperiello, NMSS
 S. Collins, NRR
 E. Adensam, NRR
 L. Chandler, OGC
 J. Goldberg, OGC
 SECY

Distribution:

JLieberman
 RWBorchardt
 OE Staff
 Enforcement Coordinators by E-mail
 WEB (1-week after issuance)
 NUDOCS
 PDR (1-week after issuance)
 Day File
 EGM File

OE:DD
 RWBorchardt
 11/ /98

OE:D
 JLieberman
 11/28/98

egm98009.rev