February 5, 2004

Mr. Lew W. Myers
Chief Operating Officer
FirstEnergy Nuclear Operating Company
Davis-Besse Nuclear Power Station
5501 North State Route 2
Oak Harbor, OH 43449-9760

Dear Mr. Myers:

The Petition dated August 25, 2003, from Greenpeace and the other Petitioners (the Nuclear Information & Resource Service and the Union of Concerned Scientists), regarding Davis-Besse Nuclear Power Station, Unit 1 (Davis-Besse), has been reviewed by the Nuclear Regulatory Commission (NRC) staff pursuant to Section 2.206 of Title 10 of the *Code of Federal Regulations*. The staff's proposed Director's Decision on the Petition is enclosed.

The NRC was requested to take enforcement actions against FirstEnergy Nuclear Operating Company (FirstEnergy), the licensee for Davis-Besse, and the NRC was requested to suspend the Davis-Besse license and prohibit plant restart until certain conditions have been met. As basis for the request to have the NRC take enforcement actions against the licensee, the Petitioners stated that FirstEnergy has failed to complete commitments related to the NRC's 50.54(f) design basis letter (issued on October 9, 1996), and refer to numerous design basis violations dating back to plant licensing (corresponding to Requests 1 and 2 in the Petitioners' August 25 letter). The Petitioners also requested that the NRC suspend the Davis-Besse license and prohibit plant restart until all design basis deficiencies identified in response to the NRC's 50.54(f) design basis letter are adequately addressed, the plant probabilistic risk assessment is updated to reflect design flaws, and no systems are in a "degraded but operable" condition (corresponding to Requests 3, 4, and 5 in the Petitioners' August 25 letter).

The Petitioners' representatives met with the staff on September 17, 2003, to provide additional information in support of their Petition. The transcript of the September 17 meeting is considered a supplement to the Petitioners' August 25 letter. Both the August 25 letter and the transcript from the September 17 meeting are available at http://www.nrc.gov/reactors/operating/ops-experience/vessel-head-degradation/controlled-correspondence.html.

In the NRC's October 7, 2003, acknowledgment letter to the Petitioners' August 25 letter, we stated that the NRC staff would provide its findings on the Petitioners' requests for "immediate action" before the Davis-Besse plant is allowed to restart. The staff considered the Petitioners' requests to suspend the Davis-Besse license and prohibit plant restart until certain conditions have been met to be equivalent to "immediate action" requests because the Davis-Besse licensee might complete all necessary restart activities, and the NRC staff might complete all necessary oversight activities, before the staff could finalize the Director's Decision on this Petition.

Requests 3, 4, and 5 contained in the Petitioners' August 25 letter were considered immediate action requests, and the staff's evaluation of each of these requests was provided in its letter to the Petitioners dated November 26, 2003. This evaluation is repeated in the enclosed proposed Director's Decision. Both of these NRC letters are available at the Web site location referred to above.

The staff's proposed Director's Decision addresses the two remaining Petitioners' requests for enforcement actions (Requests 1 and 2 described in the Petitioners' August 25 letter). In Request 1, the Petitioners requested the NRC to "take enforcement actions against First Energy Nuclear Operating Company for failure to live up to their commitments made in response to the NRC's October 1996 10 CFR 50.54(f) letter. Since the 10 CFR 50.54(f) letter was issued in direct response to the problems at Millstone that netted its owner a record $2.1 million fine from the NRC, failure to heed the Millstone warning should carry at least an equivalent sanction." In Request 2, the Petitioners requested the NRC to "take enforcement actions against First Energy Nuclear Operating Company for the numerous design basis violations dating back to the date of licensure with penalties for each day that the licensee was out of compliance with NRC regulations."

I request that you provide comments to me on any portions of the proposed decision that FirstEnergy believes involve errors or any issues in the Petition that FirstEnergy believes have not been fully addressed. The staff is making a similar request of the Petitioners. The staff will then review any comments provided by you and the Petitioners and consider them in the final version of the Director's Decision with no further opportunity to comment. As specified in 10 CFR 2.206, within 25 days after the date of the final version of the Director's Decision being published, the Commission may on its own motion review that decision. If the Commission does not act on the Director's Decision within that 25 days (unless the Commission extends the review time), the Director's Decision becomes the final agency action on the Petition.

Please provide your comments by March 8, 2004. Consistent with the guidance in NRC Management Directive 8.11, "Review Process for 10 CFR 2.206 Petitions," if no comments are received, the proposed Director's Decision will be issued as the final Director's Decision shortly after the comment period ends.

Sincerely,

/RA/

Eric J. Leeds, Deputy Director
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Docket No. 50-346

Enclosure: Proposed Director's Decision

cc w/encl: See next page

Davis-Besse Nuclear Power Station, Unit 1

cc:

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Please provide your comments by March 8, 2004. Consistent with the guidance in NRC Management Directive 8.11, "Review Process for 10 CFR 2.206 Petitions," if no comments are received, the proposed Director's Decision will be issued as the final Director's Decision shortly after the comment period ends.

Sincerely,
/RA/
Eric J. Leeds, Deputy Director
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Docket No. 50-346
Enclosure: Proposed Director's Decision
cc w/encl: See next page

Incoming: G20030508 - ML032400435 PKG.: ML040280005
Letter: ML040300096 *See previous concurrence **Concurred by phone

OFFICE	PDIV-2/PM	PDIII-2/LA	PDIII-1/SC	OE	RIII
NAME	*MFields	*THarris	*AMendiola	*JLuehman	**JGrobe
DATE	1/27/04	1/27/04	1/29/04	2/02/04	2/02/04

OFFICE	PDIII/PD	DLPM/DD	ADPT	NRR/D	DLPM/DD
NAME	*WRuland	*ELeeds	*BSheron	*JDyer	ELeeds
DATE	2/02/04	2/02/04	2/03/04	2/05/04	02/05/04

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JCraig
JGoldberg
DB0350

DD-04-0X

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION

J. E. Dyer, Director

In the Matter of	)	Docket No. 50-346
	)	
FirstEnergy Nuclear Operating Company	)	License No. NPF-3
	)	
	)	
(Davis-Besse Nuclear Power Station, Unit 1)	)	
	)	

DIRECTOR'S DECISION UNDER 10 CFR 2.206

I. Introduction

By letter dated August 25, 2003, Greenpeace filed a Petition pursuant to Section 2.206 of Title 10 of the *Code of Federal Regulations* (10 CFR) on behalf of the Nuclear Information & Resource Service and the Union of Concerned Scientists (collectively, the Petitioners). The Petitioners requested that the Nuclear Regulatory Commission (NRC) take enforcement actions against FirstEnergy Nuclear Operating Company (FirstEnergy), the licensee for Davis-Besse Nuclear Power Station in Oak Harbor, Ohio, and also requested that NRC suspend the Davis-Besse license and prohibit plant restart until certain conditions have been met. As basis for the request to have the NRC take enforcement actions against the licensee, the Petitioners stated that FirstEnergy has failed to complete commitments related to the NRC's 50.54(f) design basis letter (issued on October 9, 1996), and referred to numerous design basis violations dating back to plant licensing (corresponding to Requests 1 and 2 in the Petitioners' August 25 letter). The Petitioners also requested that the NRC suspend the Davis-Besse license and prohibit plant restart until all design basis deficiencies identified in response to the NRC's 50.54(f)

design basis letter are adequately addressed, the plant probabilistic risk assessment (PRA) is updated to reflect design flaws, and no systems are in a “degraded but operable” condition (corresponding to Requests 3, 4, and 5 in the Petitioners’ August 25 letter).

In a letter dated October 7, 2003, the NRC informed the Petitioners that the issues in the Petition were accepted for review under 10 CFR 2.206 and had been referred to the Office of Nuclear Reactor Regulation for appropriate action. A copy of the acknowledgment letter is publicly available in the NRC’s Agencywide Documents Access and Management System (ADAMS) under Accession No. ML032690314. A copy of the Petition is publicly available in ADAMS under the Accession No. ML032400435.

The Petitioners’ representatives met with NRC staff on September 17, 2003, to provide additional details in support of this request. This meeting was transcribed and the transcript is publicly available on the NRC Web site as a supplement to the Petition (http://www.nrc.gov/reactors/operating/ops-experience/vessel-head-degradation/controlled-correspondence.html).

The licensee responded to the Petition on October 20, 2003 (ML033421458). This response was considered by the staff in its evaluation of the Petition.

In a letter dated November 26, 2003 (ML033010172), the NRC provided to the Petitioners its evaluation of their “immediate action” requests. The staff considered the Petitioners’ requests to suspend the Davis-Besse license and prohibit plant restart until certain conditions have been met to be equivalent to "immediate action” requests because the Davis-Besse licensee might complete all necessary restart activities, and the NRC staff might complete all necessary oversight activities, before the staff could finalize the Director’s Decision on this Petition. Requests 3, 4, and 5 in the Petitioners’ August 25 letter were considered immediate action requests, and the staff’s November 26 evaluation is repeated in Section II.D for completeness.

Proposed

II. Discussion

This section contains a discussion of the agency's regulatory oversight process, relevant NRC enforcement policies, the NRC staff's response to the Petitioners' requests for enforcement action (Requests 1 and 2 in the Petitioners' August 25, 2003, letter), and for completeness, the staff's November 26, 2003, response to the Petitioners' immediate action requests (Requests 3, 4, and 5 in the Petitioners' August 25, 2003, letter).

The objective of the descriptive information presented below on the agency's processes and policies is to provide an clear understanding of the basis for the staff's findings with respect to the Petitioners' two requests for enforcement action. These findings are summarized below.

° With respect to the first request for enforcement action, the NRC staff finds that the Petitioners' request for enforcement based solely on failure of the licensee to complete commitments represents a misinterpretation of the agency's enforcement policies regarding commitments. As will be discussed later in this Director's Decision, reasonable assurance of adequate protection of public health and safety is, as a general matter, defined by the Commission's health and safety regulations themselves. In most cases, the agency cannot take enforcement actions solely on the basis of whether licensees fulfill commitments, as failure to meet a commitment in itself does not constitute a violation of a legally binding requirement. However, when failures to meet commitments result in violations of the Commission's health and safety regulations, the staff will take the appropriate enforcement actions. Although the staff has not taken any enforcement actions against FirstEnergy solely for failure to meet commitments, the staff has taken enforcement actions against the licensee for noncompliance with NRC

requirements, including enforcement actions for failure to meet design-related requirements.

° With respect to the second request for enforcement action, the NRC staff finds that the Petitioners' request for enforcement based on numerous design basis violations (i.e., the LERs submitted by the licensee) is in effect being granted by the actions already taken by the staff as will be evident by the discussions of our processes for reviewing and evaluating LERs presented later in this Director's Decision.

A. Reactor Oversight Process

This section provides a brief overview of the process by which the staff inspects and assesses licensees' compliance with the Commission's rules and regulations. This overview is intended to provide an understanding of what the current regulatory oversight of the Davis-Besse plant consists of, and why this oversight was imposed on this licensee. It is important to note that the agency has been utilizing its process for the highest level of staff oversight for plants with performance problems or operational events in inspecting and assessing the Davis-Besse licensee activities since May 3, 2002. Any additional enforcement actions, as requested by the Petitioners, would not increase this level of staff oversight, which is directed at assuring that the plant is capable of safe operation in accordance with the Commission's rules and regulations.

The fundamental building blocks that form the framework for the regulatory oversight process are seven cornerstones of safety: initiating events, mitigating systems, barrier integrity, emergency preparedness, occupational radiation safety, public radiation safety, and physical protection. These cornerstones are grouped into three strategic areas: reactor safety, radiation safety, and safeguards. This framework is based on the principle that the agency's

mission of assuring public health and safety is met when the agency has reasonable assurance that licensees are meeting the objectives of the seven cornerstones of safety.

The Reactor Oversight Process (ROP) integrates the NRC's inspection, assessment, and enforcement programs. Along with performance indicators (PIs), assessment, and enforcement, the reactor inspection program is an integral part of the ROP. Acceptable performance in the cornerstones, as measured by the PIs and the risk informed baseline inspection program, is indicative of overall performance that provides for adequate protection of public health and safety.

Another principle of the framework is that there is a level of performance above which the NRC does not need to engage the licensee beyond some baseline level of oversight. Performance indicators reported by power reactor licensees and the NRC's inspection program provide the information used in comparing licensee performance against the cornerstones of safety. The risk-informed baseline inspection program is designed to be the inspection oversight that provides indications of performance within areas of the cornerstones of safety that are not measured by the PIs or not adequately measured by PIs.

The Operating Reactor Assessment Program evaluates the overall safety performance of operating commercial nuclear reactors and communicates the results to licensee management, members of the public, and other government agencies.

This assessment program collects information from inspections and PIs in order to enable the agency to arrive at objective conclusions about the licensee's safety performance. Based on this assessment information, the NRC determines the appropriate level of agency response, including supplemental inspection and pertinent regulatory actions ranging from management meetings up to and including orders for plant shutdown. The assessment information and agency response are then communicated to the public. Followup agency

actions, as applicable, are conducted to ensure that the corrective actions designed to address performance weaknesses were effective.

In general, when significant performance problems are identified in one or more of the seven cornerstones in the areas of reactor safety, radiation safety, or security, as defined by NRC Inspection Manual Chapter (IMC) 0305, “Operating Reactor Assessment Program, “ the level of NRC actions are governed by the Action Matrix (Exhibit 5 of IMC 0305). The Action Matrix was developed with the philosophy that, within a certain level of safety performance (e.g., the licensee response band), licensees would address their performance issues without additional NRC engagement beyond the baseline inspection program. Agency action beyond the baseline inspection program will occur only if assessment input thresholds are exceeded. The Action Matrix identifies the range of NRC and licensee actions and the appropriate level of communication for varying levels of licensee performance. The Action Matrix describes a graded approach in addressing performance issues. The possible approaches could include additional supplemental inspection, a demand for information, a confirmatory action letter, or issuance of an order, up to and including a plant shutdown. The highest level of staff oversight of licensee activities for plants with performance problems or operational events is governed by IMC 0350, “Oversight of Operating Reactor Facilities in a Shutdown Condition With Performance Problems.”

By letter dated April 29, 2002, the NRC informed FirstEnergy that its corrective actions at Davis-Besse would receive enhanced NRC oversight as described in IMC 0350. The decision by the staff to place the Davis-Besse licensee in the highest level of staff oversight was based on the identified performance deficiencies, and also to assure close coordination between NRC and licensee personnel on the corrective actions needed to assure safe plant restart. That enhanced monitoring began on May 3, 2002, and included the creation of an

oversight panel to provide the required oversight during the plant shutdown and any future restart and following restart until a determination is made that the plant is ready for return to the NRC's normal Reactor Oversight Process.

When a plant is under the IMC 0350 process, the routine ROP is suspended. However, the ROP continues to be used as guidance. The oversight panel will assess inspection findings and other performance data to determine the required level and focus of followup inspection activities and any other appropriate regulatory actions. The focus of this manual chapter is to provide oversight of the licensee's performance until a return to the routine oversight under the ROP is warranted.

All of the documents referenced in Section II.A are available at the NRC Web site, www.nrc.gov.

B. Relevant Enforcement Policies

This section provides a brief overview of the NRC's scope and authority relative to the enforcement policy, and the processes by which the staff takes enforcement actions relative to licensees' compliance with the Commission's rules and regulations. This overview is intended to provide a general understanding of how and why enforcement actions are taken against licensees, as well as an understanding of the appropriate enforcement actions relative to the specific requests from the Petitioners.

Background

The Atomic Energy Act of 1954, as amended, establishes "adequate protection" as the standard of safety on which NRC regulations are based. In the context of NRC regulations, safety means avoiding undue risk or, stated another way, providing reasonable assurance of

adequate protection of workers and the public in connection with the use of source, byproduct, and special nuclear materials.

While safety is the fundamental regulatory objective, compliance with NRC requirements plays an important role in giving the NRC confidence that safety is being maintained. Under Atomic Energy Commission and NRC case law, reasonable assurance of adequate protection of public health and safety is, as a general matter, defined by the Commission's health and safety regulations themselves. That is, unless otherwise provided, there is reasonable assurance of adequate protection of public health and safety when the applicant or licensee demonstrates compliance with the Commission's regulations. NRC requirements, including technical specifications, other license conditions, orders, and regulations, have been designed to ensure adequate protection—which corresponds to "no undue risk to public health and safety"—through acceptable design, construction, operation, maintenance, modification, and quality assurance measures. The regulations were established using defense-in-depth principles and conservative practices which provide a degree of margin to unsafe levels. In the context of risk-informed regulation, compliance plays a very important role in ensuring that key assumptions used in underlying risk and engineering analyses remain valid.

While adequate protection is presumptively assured by compliance with NRC requirements, circumstances may arise where new information reveals that an unforeseen hazard exists or that there is a substantially greater potential for a known hazard to occur. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety.

The NRC also has the authority to exercise discretion to permit continued operations—despite the existence of a noncompliance—where the noncompliance is not

significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When noncompliance occurs, the NRC must evaluate the degree of risk posed by that noncompliance to determine if specific immediate action is required. Where needed to ensure adequate protection of public health and safety, the NRC may demand immediate licensee action, up to and including a shutdown or cessation of licensed activities.

Based on the NRC's evaluation of noncompliance, the appropriate action could include refraining from taking any action, taking specific enforcement action, issuing orders, or providing input to other regulatory actions or assessments, such as increased oversight (e.g., increased inspection). Since some requirements are more important to safety than others, the NRC endeavors to use a risk-informed approach when applying NRC resources to the oversight of licensed activities, including enforcement activities.

The primary purpose of the NRC's Enforcement Policy is to support the NRC's overall safety mission in protecting the public health and safety and the environment. Consistent with that purpose, the policy endeavors to:

- deter noncompliance by emphasizing the importance of compliance with NRC requirements, and
- encourage prompt identification and prompt, comprehensive correction of violations of NRC requirements.

Therefore, licensees, contractors, and their employees who do not achieve the high standard of compliance which the NRC expects will be subject to enforcement sanctions. Each enforcement action is dependent on the circumstances of the case. However, in no case will licensees who cannot achieve and maintain adequate levels of safety be permitted to continue to conduct licensed activities.

Relevant Enforcement Policies

The Petitioners' requests for enforcement actions against the Davis-Besse licensee are related to commitments made by the licensee in response to the NRC's 1996 50.54(f) letter, and to the licensee event reports (LERs) submitted by the licensee (these two requests are explained more fully in Section II.C).

With respect to the issue of enforcing commitments, the agency in most cases cannot take enforcement actions solely on the basis of whether licensees fulfill commitments, as failure to meet a commitment in itself does not constitute a violation of a legally binding requirement such as a rule, order, license condition, or technical specification. However, when failures to meet commitments result in violations of the Commission's health and safety regulations, the staff will take the appropriate enforcement actions.

With respect to the issue of taking enforcement related to LERs, the staff has processes in place for reviewing LERs submitted by nuclear power plant licensees, and that process includes determining appropriate enforcement actions if violations are identified. A brief description is provided below of how the staff reviews and dispositions LERs. This process is part of the Reactor Oversight Process, described in Section II.A.

NRC inspectors conduct inspections of licensed nuclear power plants following guidance in the NRC Inspection Manual, which contains objectives and procedures to use for each type of inspection. Inspection Procedure 71153, "Event Followup" requires inspectors to review LERs and related documents for accuracy of the LER, appropriateness of corrective actions, violations of requirements, and generic issues.

If an LER involves a finding or noncompliance which the licensee entered into its corrective action program, IMC 0612, "Power Reactor Inspection Reports," directs the

inspectors to include in the inspection report a description of the safety significance of the event and any appropriate enforcement actions.

The safety significance of LER findings is determined by using the Significance Determination Process (SDP) as defined in IMC 0609, "Significance Determination Process." Each SDP analysis supports a cornerstone associated with the strategic performance areas as defined in IMC 2515, "Light-Water Reactor Inspection Program - Operations Phase." The SDP is primarily used to assess the significance of NRC inspection findings, but is also used for other purposes, including the assessment of LER findings.

Depending on their significance, LER findings are assigned colors of:

° green (very low safety significance),

° white (low to moderate safety significance),

° yellow (substantial safety significance), or

° red (high safety significance).

If the LER findings are associated with violations of regulatory requirements, enforcement actions are processed in accordance with the current revision of NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions." The significance of the LER findings are considered in the determination of the appropriate enforcement action.

All of the documents referenced in Section II.B are available at the NRC Web site, www.nrc.gov.

C. Staff Response to Petitioners' Requests To Take Enforcement Action

Response to First Request for Enforcement

The first of the two specific requests for enforcement action by the Petitioners was for the NRC to "take enforcement actions against First Energy Nuclear Operating Company for

failure to live up to their commitments made in response to the NRC's October 1996 10 CFR 50.54(f) letter. Since the 10 CFR 50.54(f) letter was issued in direct response to the problems at Millstone that netted its owner a record $2.1 million fine from the NRC, failure to heed the Millstone warning should carry at least an equivalent sanction."

The purpose of the 1996 10 CFR 50.54(f) letter was to require information that would provide the NRC added confidence and assurance that U. S. nuclear power plants are operated and maintained within the design bases and any deviations are reconciled in a timely manner. As stated in the staff's response to the Petitioners' requests for immediate action (see Section II.D), the adequacy of safety-significant structures, systems, and components is being assessed by the staff's oversight activities and must be adequately addressed before the NRC will allow the plant to restart. The staff's oversight activities since the Davis-Besse plant has been shutdown will provide the level of confidence and assurance that this plant meets the objectives stated in the 10 CFR 50.54(f) letter. These oversight activities have included system health assurance inspections, inspections of design-basis issues, and an inspection of the licensee's actions associated with the completeness and accuracy of required records and submittals to the NRC (Inspection Report 50-346/03-19, dated January 28, 2004).

In Inspection Report 50-346/03-19, the staff stated that, based on the documents and corrective actions reviewed during this inspection and the results of previous NRC inspections of licensee activities under the Davis-Besse Return-to-Service Plan, the NRC has reasonable confidence that important docketed information is complete and accurate in all material respects and that future submittals will be complete and accurate. This inspection identified no widespread noncompliances of regulatory requirements or current programmatic concerns associated with the completeness and accuracy of submittals to the NRC. The inspection report identified three findings, including a noncited violation and an apparent violation, which is

being considered for escalated enforcement. The apparent violation involves failure to provide the NRC complete and accurate information as required by 10 CFR 50.9 in the licensee's November 11, 1998, response to NRC Generic Letter 98-04, "Potential for Degradation of the Emergency Core Cooling System and the Containment Spray System After a Loss-of-Coolant-Accident Because of Construction and Protective Coating Deficiencies and Foreign Material in Containment." Specifically, information pertaining to unqualified protective coatings and the likelihood of clogging of the containment emergency sump screen was not provided to the NRC in a complete and accurate manner. The licensee has been offered an opportunity to either respond to the apparent violation or request a predecisional enforcement conference before the NRC makes its enforcement decision.

As stated in the previous section, the agency in most cases cannot take enforcement actions solely on the basis of whether licensees fulfill commitments, as failure to meet a commitment in itself does not constitute a violation of a legally binding requirement.

Although the staff has not taken any enforcement actions against FirstEnergy solely for failure to meet commitments, the staff has taken enforcement actions against the licensee for noncompliance with NRC requirements, including enforcement actions for failure to meet design-related requirements.

Two recent enforcement actions taken against the Davis-Besse licensee were for systems, structures, and components (SSCs) not configured or maintained in accordance with the plant's design and licensing basis. On October 7, 2003, the NRC issued a final significance determination for a yellow finding associated with potential clogging of the emergency sump following a loss-of-coolant accident. In addition, on October 8, 2003, the NRC issued a preliminary significance determination for a greater-than-green finding for a design issue involving the high-pressure injection pumps. The NRC is presently performing a more refined

risk analysis for the high-pressure injection pump design issue based on information provided by FirstEnergy to the NRC on December 5, 2003. The licensee submitted LERs to the NRC on both of these issues and more detailed discussions of these two issues are included in the staff's response below to the Petitioners' second request for enforcement action.

In response to the Petitioners' reference to the enforcement actions taken against the Millstone licensee, those enforcement actions were for noncompliance with NRC requirements, not solely related to any failures to fulfill commitments. With respect to the civil penalty assessed to the Millstone licensee, it should be noted that the agency's Enforcement Policy has changed since that time in conjunction with adopting the ROP.

Instead of using civil penalties as a deterrent, the NRC uses enforcement actions under the ROP as but *one part* of the agency's overall regulatory response. The ROP's Action Matrix will cause the staff to consider specific regulatory actions based on the risk significance of the issue. Actions might include increased inspections, demands for information, or orders.

However, civil penalties (and the use of severity levels) will be considered for issues with actual consequences, such as an overexposure to the public or plant personnel above regulatory limits, failure to make the required notifications, impacting the ability of Federal, State and local agencies to respond to an actual emergency preparedness (site area or general emergency), transportation event, or a substantial release of radioactive material. Civil penalties and severity levels will also be used to address violations that are willful or that have the potential for impacting the regulatory process.

The use of civil penalties in these instances remains appropriate as a deterrent for these types of issues. To the extent that the SDP can provide an assessment of the significance of the underlying violation or issue, it will be used as a first step in determining the significance of the violation. This will ensure a consistent approach for significance determinations. The staff

considers the SDP output in conjunction with the guiding principles for assessing significance and the guidance included in the supplements to the Enforcement Policy to determine the appropriate severity level. For example, a procedural violation associated with an inspection finding characterized by the SDP as green may be categorized at Severity Level IV based on the risk significance and ultimately assigned a Severity Level III categorization because the violation was willful.

There are ongoing NRC activities that may lead to civil and/or criminal proceedings against the Davis-Besse licensee. NRC's Office of Investigations (OI) completed an investigation to determine whether the Davis-Besse licensee willfully violated NRC requirements and whether the licensee willfully misled the NRC. The results of the OI investigation were provided to the U.S. Department of Justice (DOJ) in accordance with the Memorandum of Understanding (MOU) between the NRC and DOJ. The federal investigation into these matters continues under the leadership of the U.S. Attorney in Cleveland supported by the NRC Office of Investigations and the DOJ.

In accordance with Section III.C. of the MOU, after notifying DOJ, the NRC may take immediate actions necessary to protect the public health and safety. Absent such circumstances, the NRC shall normally defer actions such as civil penalties until DOJ concludes its activities. The staff concluded that immediate actions to protect the health and safety of the public are not necessary at this time. A senior NRC manager is monitoring the ongoing federal investigation for any emerging safety concerns. Because this is an ongoing federal investigation that may lead to civil and/or criminal proceedings, information regarding the investigation is not currently available for public release.

Response to Second Request for Enforcement

The second specific request for enforcement action by the Petitioners was for the NRC to "take enforcement actions against First Energy Nuclear Operating Company for the numerous design basis violations dating back to the date of licensure with penalties for each day that the licensee was out of compliance with NRC regulations." As basis for this request, the Petitioners cite the LERs submitted by the licensee since the plant was licensed, and they specifically cite seven LERs that have been submitted by the licensee since mid-2002.

Based on the NRC's evaluation of each noncompliance reported in the LERs (and other sources such as NRC inspection reports), the appropriate action could include refraining from taking any action, taking specific enforcement action, issuing orders, or providing input to other regulatory actions or assessments, such as increased oversight (e.g., increased inspection).

The NRC endeavors to use a risk-informed approach when applying NRC resources to the oversight of licensed activities, including enforcement activities. As described in the Commission's Enforcement Policy, varying levels of significance using either one of four severity levels or one of four risk levels derived from the ROP are applied to documented violations. Civil penalties can be applied to Severity Levels III, II, and I, but are not normally applied to ROP findings that constitute violations. The ROP utilizes other mechanisms, such as increased inspection oversight, to motivate compliance and corrective actions.

As stated in Section II.B, the staff's findings on individual LERs are discussed in resident inspection reports. Of the seven LERs specifically cited by the Petitioners in support of their request for enforcement action, the staff has published inspection reports providing its findings on four of these LERs. To illustrate how the staff implements the agency's Enforcement Policy in regard to LER findings, summaries from these published inspection reports for the four LERs

are provided below. The remaining LERs mentioned by the Petitioners will be addressed by the same process, but these inspection reports have not yet been issued.

LER 2002-004, "Containment Isolation Closure Requirements for Reactor Coolant Pump (RCP) Seal Injection Valves MU66A-D"

This LER documented a condition where the pressure regulating valve setpoint for the RCP seal injection valves was inadequate to ensure closure of the valves upon receipt of a containment isolation signal. This condition represented a potential common-mode failure. As a result of this condition, during postulated accident conditions, a potential for uncontrolled radioactive leakage outside containment could be created. This condition had apparently existed since original plant construction, and is a violation of Technical Specification (TS) 3.6.3.1 for Modes 1-4. The TS requires that "all containment isolation valves shall be operable with isolation times less than or equal to required isolation times" for Modes 1, 2, 3, and 4. Contrary to this, the pressure regulating setpoint for the RCP seal injection valves was inadequate to ensure closure of the valves upon receipt of a containment isolation signal. In addition, the valves were determined to be installed inconsistent with design assumptions.

However, downstream of these isolation valves are check valves that are designed to prevent flow out of the reactor coolant system, thereby isolating the flow path regardless of whether the RCP seal injection valves are closed. The reliability of the check valves was determined to be high based on test history (no test failures in the past 10 years had occurred). The regional senior reactor analyst performed a Phase 3 assessment in accordance with IMC 0609 and determined that the issue had very low safety significance (green) due to the low initiating event frequency of an interfacing system loss-of-coolant accident (ISLOCA), 1E-7, coupled with the check valve's probability of failure to prevent a potential ISLOCA if the RCP

seal injection valve failed. The Senior Reactor Analyst also reviewed the licensee's risk assessment and determined that the calculation was conservative given the assumptions used. The licensee's analysis determined that the change in core damage frequency was in the 1E-8 per year range.

Based on the above evaluation of risk, this LER was closed in Inspection Report 50-346/02-17 as a licensee-identified noncited violation of TS 3.6.3.1.

LER 2002-005, "Potential Clogging of the Emergency Sump Due to Debris in Containment"

On September 4, 2002, with the reactor defueled, FirstEnergy determined that the existing amount of unqualified containment coatings and other debris (e.g., insulation) inside containment could have potentially blocked the emergency sump intake screen, rendering the sump inoperable following a loss-of-coolant accident. The unqualified coatings and existence of other debris had existed since original construction. FirstEnergy declared the emergency sump inoperable and entered the deficiency into its corrective action program. With the emergency sump inoperable, both independent emergency core cooling system (ECCS) trains and both containment spray (CS) system trains were inoperable, due to both requiring suction from the emergency sump during the recirculation phase of operation. This could prevent both trains of ECCS from removing residual heat from the reactor and could prevent CS from removing heat and fission product iodine from the containment atmosphere.

FirstEnergy reported this information in LER 2002-05 on November 4, 2002. On December 11, 2002, FirstEnergy submitted Supplement 1, which provided additional information regarding corrective actions for the sump strainer and coatings issues. In this supplement, FirstEnergy stated that a debris generation and transport analysis would be performed. Supplement 2, dated May 21, 2003, provided additional information regarding

additional corrective actions. On May 28, 2003, FirstEnergy informed the NRC that a further review of past significance of these issues would not be performed.

FirstEnergy obtained information on at least two occasions prior to issuance of the LER that should have alerted them to the unqualified coatings. First, a 1976 letter from Babcock and Wilcox (B&W) informed the Davis-Besse licensee that B&W had no data regarding design basis accident testing for particular coatings. The equipment coated with unqualified paint identified in the letter included the RCP motors, reactor vessel, steam generators, pressurizer, and reactor coolant system piping. Second, NRC Generic Letter 98-04, "Potential for Degradation of the Emergency Core Cooling System and the Containment Spray System After a Loss-of-Coolant Accident Because of Construction and Protective Coating Deficiencies and Foreign Material in Containment," dated July 14, 1998, was issued to operating reactors specifically requesting information about the potential effects of containment coating deficiencies.

On July 3, 2003, a Significance and Enforcement Review Panel meeting was held regarding the significance of the failure to effectively implement corrective actions for design control deficiencies regarding containment coatings, uncontrolled fibrous material, and other debris inside containment. This deficiency resulted in the inability of the ECCS sump to perform its safety function under certain accident scenarios due to clogging of the sump screen. The NRC staff determined that several combinations of factors lead to core damage frequency increases in the 1E-4 (yellow) range.

On July 30, 2003, the NRC issued the preliminary yellow finding in Inspection Report 50-346/03-15. FirstEnergy provided a written response dated August 29, 2003, acknowledging the performance deficiency. FirstEnergy did not contest the Finding and their response provided no new information to change the NRC's preliminary conclusion. On

October 7, 2003, the NRC issued the Yellow Final Significance Determination, which included a Notice of Violation of 10 CFR Part 50, Appendix B, Criterion XVI, “Corrective Actions,” for the failure to promptly identify and correct significant conditions adverse to quality involving the potential to clog the emergency core cooling and CS system sump with debris following a loss-of-coolant accident.

As corrective actions, FirstEnergy performed extensive modifications during the current outage on the sump. FirstEnergy replaced the previous emergency sump strainer with a much larger strainer. The unqualified coatings and other debris, including fibrous insulation remaining in containment, have been walked down, verified, and documented. Much of the fibrous insulation has been removed from containment, and most of the containment internal surfaces and surfaces of equipment inside containment have been re-coated with qualified paint. Debris generation, transport, strainer head loss, and strainer integrity analyses were performed for the emergency sump to return the emergency sump to full qualification and operability. The NRC inspection of FirstEnergy's new sump is documented in Inspection Report 50-346/03-06. The NRC identified no significant issues with the new sump.

<u>LER 2003-002, “Potential Degradation of High-Pressure Injection Pumps Due to Debris in Emergency Sump Fluid Post Accident”</u>

On October 22, 2002, with the reactor defueled and in an extended outage, FirstEnergy identified a design deficiency regarding internal clearances of the high-pressure injection (HPI) pumps. This deficiency resulted in operation of the HPI pumps being affected by debris that may be entrained in the process fluid during some post-accident scenarios. Specifically, it was determined that small ports in the HPI pumps that supply lubricating water to the hydrostatic bearing in the pump were smaller than the designed openings in the emergency sump screen. During certain accidents when the reactor coolant system is at high pressure, the HPI pumps

are needed to maintain the core cooled by operating in the high-pressure sump recirculation mode of operation taking suction from the containment sump via the low-pressure injection pumps. It was during this mode of operation that the potential existed for debris from the sump (fibrous insulation, paint chips, and smaller debris such as containment floor dirt) to be transported to the HPI pumps and cause blockage of the ports and loss of lubricating water to the hydrostatic bearing. This could result in failure of the pumps due to excessive vibration/overheating.

This deficiency was an original design flaw that had existed since initial plant operation. On April 7, 2003, FirstEnergy reported this issue to the NRC in accordance with 10 CFR 50.72. Subsequently, on May 5, 2003, FirstEnergy submitted LER 2003-02. FirstEnergy modified both HPI pumps during the current extended outage to eliminate the potential for blockage of the ports.

On September 4, 2003, a Significance and Enforcement Review Panel determined the issue to be greater than green because of the large uncertainty in determining the most likely failure probability of the HPI pumps and the contribution to risk from fires. On October 8, 2003, the NRC issued Inspection Report 50-346/03-21 transmitting the preliminary greater-than-green finding to the licensee. On November 7, 2003, FirstEnergy requested an extension on the response to the preliminary significance determination. On December 5, 2003, FirstEnergy provided its analysis showing risk to be in the yellow range of importance. The NRC is presently reviewing the analysis and plans to conduct another Significance and Enforcement Review Panel at the completion of its review.

Proposed

LER 2003-005, "Containment Gas Analyzer Heat Exchanger Valves Found Closed Rendering the Containment Gas Analyzer Inoperable"

This LER reported the failure by the licensee to establish an appropriate operational test, for a time period from original plant startup until May 2003, to ensure that sufficient cooling water flow is provided to the hydrogen analyzer heat exchangers during operational modes that require the hydrogen analyzers to be operable. The hydrogen analyzers are part of the containment hydrogen control system, which is designed to control the concentration of hydrogen which may be released into containment following a LOCA. In accordance with IMC 0609, Appendix A, Attachment 1, the inspectors performed a SDP Phase 1 screening and determined that the issue affected the Reactor Safety Strategic Performance Area. The finding was more than minor because it (1) involved the configuration control attribute of the barrier integrity cornerstone; and (2) affected the cornerstone objective of providing reasonable assurance that physical design barriers protect the public from radionuclide releases caused by accidents or events.

This finding is unrelated to SSCs that are needed to prevent accidents from leading to core damage. To determine if this finding had an effect on large early release frequency (LERF), the inspectors used IMC 0609, Appendix H, "Containment SDP." The finding was characterized as a Type B finding (having no impact on core damage frequency) and was then compared to Table 3 in Appendix H. The inspectors determined that the hydrogen analyzer had no impact on the containment-related SSCs listed in Table 3 (i.e., containment penetration seals, containment isolation valves, or purge and vent lines) and would not influence LERF. Based on this, the finding has very low safety significance.

Because of the very low safety significance and because the issue was entered into the licensee's corrective action program, it was treated as a noncited violation, consistent with

Section VI.A of the NRC Enforcement Policy. The details of the staff's evaluation is contained in Inspection Report 50-346/03-17 dated September 29, 2003.

This LER also discussed a second issue which involved a condition that would potentially render the moisture trap on the gas analyzer sample line inoperable. This condition could have lead to premature operation of the hydrogen dilution system or the hydrogen purge in conjunction with hydrogen dilution. Premature operation of these systems would have no adverse effect on the accident mitigation process. The licensee provided a supplement to this LER dated January 23, 2004, that described the modifications made to prevent the moisture trap from becoming inoperable. LER 2003-005 remains partially open pending final closeout of this second issue by the staff.

Although the above discussion on the individual LERs is meant to demonstrate how the staff implements the agency's inspection process and Enforcement Policy in regard to LER findings, the staff's first priority is to assure that the issues involved will not adversely impact future plant safety. The staff then reviews the licensee's analysis for accuracy and completeness, and conducts its own risk assessment of the condition reported by the licensee. Once the safety implication are well understood, the staff imposes the appropriate enforcement actions in accordance with the Enforcement Policy.

D. Staff Response to Petitioners' Immediate Action Requests.

The NRC staff provided its findings on the Petitioners' requests for "immediate action" in a letter dated November 26, 2003. The staff considered the Petitioners' requests to suspend the Davis-Besse license and prohibit plant restart until certain conditions have been met to be equivalent to "immediate action" requests because the Davis-Besse licensee might complete all necessary restart activities, and the NRC staff might complete all necessary oversight activities,

before the staff could finalize the Director's Decision on this Petition. Requests 3, 4, and 5 contained in the Petitioners' August 25 letter are considered to be the immediate action requests, and the staff's evaluation of each of these requests contained in its November 26 letter is repeated verbatim below.

> In Request 3, the Petitioners requested the NRC, "suspend the license and prohibit restart of the Davis Besse reactor unless and until First Energy Nuclear Operating Company has addressed all 1000 design basis deficiencies identified in 1997." The NRC staff agrees that design basis issues need to be addressed before plant restart. The NRC's oversight activities of the licensee's ongoing programs related to the design adequacy of the Davis-Besse plant are focused on plant safety. The licensee has initiated, and is still implementing, extensive corrective actions to address hardware, programmatic, and human performance issues to assure compliance with its license and NRC regulations. Compliance includes evaluating, testing, or inspecting safety-related systems to ensure that they are able to perform their design basis functions as defined in the plant's technical specifications (TS) and updated final safety analysis report. The staff's oversight activities include independent NRC inspections and NRC reviews of the licensee's evaluations to ensure conformance of safety systems and programs to the design and licensing bases. The adequacy of safety-significant structures, systems, and components is being tracked under NRC Restart Checklist Item 5.b, "Systems Readiness for Restart" and must be adequately addressed before the NRC will allow the plant to restart.
>
> The Petitioners' Request 3 is based on information contained in the NRC's February 26, 2003, inspection report on Davis-Besse design-related activities, which reported that approximately 200 of the more than 1000 design basis deficiencies identified in response to the NRC's 50.54(f) design basis letter had not been corrected. The licensee had agreed, prior to the Petitioners' August 25, 2003, letter, to place all remaining unresolved design basis deficiencies identified in response to the NRC's 50.54(f) design basis letter in its corrective action program. Information on how the remaining unresolved design basis deficiencies will be dispositioned can be found in the licensee's October 20, 2003, letter responding to this Petition, and in the licensee's letter dated November 20, 2003, providing supplemental information related to the NRC's 50.54(f) design basis letter. In these letters, FirstEnergy stated that, while it had been slow to implement corrective actions for those issues identified in response to the NRC's 50.54(f) design basis letter, FirstEnergy has determined that these issues either were corrected or have been documented in condition reports and entered into the Davis-Besse corrective action program. Each condition report generated by FirstEnergy was evaluated for potential impact on the operability of systems, structures, or components (SSCs). Those conditions classified as restart action items require evaluation for needed corrective actions prior to restart. Conditions that are not classified as restart action items will remain in

the licensee's corrective action program and will be prioritized for resolution, which may occur after plant restart. The licensee stated in these letters that the number of open items has been reduced to approximately 100, with only a small number designated as restart items.

Appendix B of 10 CFR Part 50 requires operators of nuclear power plants to maintain an effective corrective action program. The process described above by the licensee to evaluate and disposition the remaining design basis deficiencies conforms with this regulatory requirement. The NRC's oversight of the licensee's activities includes specific inspections of the corrective action program to assure that this process is being followed correctly. The NRC will not allow the plant to restart until the licensee has demonstrated the capability to adequately manage the resolution of unresolved design basis deficiencies.

Therefore, the staff considers these activities, initiated prior to receiving the Petition, to completely satisfy the Petitioners' immediate action request to prohibit plant restart until the licensee has addressed all 1000 design basis deficiencies. The staff also concludes that the Petitioners immediate action request to suspend the plant license until the licensee has addressed all 1000 design basis deficiencies is in effect being granted by the actions already taken by the staff. These actions include our confirmatory action letter of March 13, 2002 (which confirmed the licensee's agreement that NRC approval is required for restart of the Davis-Besse plant), the enhanced NRC oversight as described in NRC Inspection Manual Chapter 0350, and compliance with the regulatory requirements imposed on all U.S. nuclear power plants. If the licensee had not agreed to obtain NRC approval before restarting the Davis-Besse plant, the NRC would have taken appropriate regulatory actions to assure restart would not occur unless NRC approval was received.

In Request 4, the Petitioners requested the NRC, "suspend the license and prohibit restart of the Davis Besse reactor unless and until First Energy has updated its Probabilistic Risk Assessment to reflect the flaws in it[s] design and licensing basis." The Petitioners provided clarifying information related to this request during the September 17, 2003, meeting. The Petitioners are requesting that the Davis-Besse PRA be revised to include the known design flaws, which will be corrected before the plant is allowed to restart, to account for unknown design flaws that may currently exist or may exist in the future.

The NRC's policy statement on PRA encourages greater use of this analysis technique to improve safety decisionmaking and improve regulatory efficiency in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy. However, for the specific purpose of assuring that all restart issues have been satisfactorily addressed, the staff does not intend to rely on the Davis-Besse PRA to determine if there is reasonable assurance of adequate protection of the public health and safety.

On a more general level, while the staff recognizes that a PRA is a useful analysis tool, there are currently no regulatory requirements for licensees to develop a plant PRA, nor are there requirements to maintain or update a plant PRA. As explained in Management Directive 8.11, requests for changes to existing NRC regulations should be submitted as a petition for rulemaking and are not considered valid requests under 10 CFR 2.206. Therefore, the staff will not consider taking any action under Section 2.206 in regard to the Petitioners' request that the NRC suspend the license and prohibit restart of the Davis-Besse reactor until the plant PRA is updated to reflect design flaws, and this request is therefore denied.

In Request 5, the Petitioners requested the NRC, "suspend the license and prohibit restart of the Davis Besse reactor with any systems in a 'degraded but operable' condition." It is the staff's judgement that the processes and programs in place for the Davis-Besse restart effort (described above in the staff's response to Request 3) will provide reasonable assurance that all safety-related systems will be capable of performing their intended safety function and will be in compliance with the plant license and TS. The NRC has issued generic guidance (Generic Letter 91-18, "Information to Licensees Regarding Two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and on Operability") which provides a process for licensees to develop a basis to continue operation or to place the plant in a safe condition and take prompt corrective action. This process assures that issues affecting the operability of SSCs that are subject both to 10 CFR Part 50, Appendix B, and 10 CFR Part 50.59 are corrected promptly, and that SSCs in degraded but operable conditions are returned to full functional capability in a timely fashion. Each licensee is authorized to operate its plant in accordance with the NRC's regulations and the plant license. If an SSC is degraded or nonconforming but operable, the licensee must establish an acceptable basis to continue to operate. The licensee must, however, promptly identify and correct the condition adverse to safety or quality in accordance with 10 CFR Part 50, Appendix B, Criterion XVI. The basis for this authority to continue to operate is that the plant license and TS contain the specific characteristics and conditions of operation necessary to ensure that an abnormal situation or event does not pose an undo risk to public health and safety. Thus, if the TS are satisfied and required equipment is operable, and the licensee is correcting any degraded conditions in a timely manner, allowing a plant to restart or to continue operation does not pose an undue risk to public health and safety. This generic guidance applies to all U.S. nuclear power plants, including Davis-Besse, and the NRC will continue to monitor licensees to assure that this guidance is followed appropriately. Therefore, the Petitioners Request 5 is not needed to assure plant safety nor is it consistent with established staff regulatory requirements, and is therefore denied.

III Conclusion

The NRC staff has carefully considered the Petitioners' arguments regarding why the NRC should take enforcement actions against FirstEnergy. In summary, the Petitioners stated that FirstEnergy has failed to complete commitments related to the NRC's 50.54(f) design basis letter (issued on October 9, 1996), and refer to numerous design basis violations dating back to plant licensing (corresponding to Requests 1 and 2 in the Petitioners' August 25 letter). As noted earlier, the Petitioners' requests for immediate actions (corresponding to Requests 3, 4, and 5 in the Petitioners' August 25 letter) were evaluated in the staff's November 26, 2003, letter and this evaluation is repeated in Section II.D of this Director's Decision for completeness.

With respect to the first request for enforcement action, the NRC staff finds that the Petitioners' request for enforcement based solely on failure of the licensee to complete commitments represents a misinterpretation of the agency's enforcement policies regarding commitments. As stated earlier, reasonable assurance of adequate protection of public health and safety is, as a general matter, defined by the Commission's health and safety regulations themselves. In most cases, the agency cannot take enforcement actions solely on the basis of whether licensees fulfill commitments, as failure to meet a commitment in itself does not constitute a violation of a legally binding requirement. However, when failures to meet commitments result in violations of the Commission's health and safety regulations, the staff will take the appropriate enforcement actions. Although the staff has not taken any enforcement actions against FirstEnergy in direct response to any failures to meet commitments, the staff has taken enforcement actions, as discussed in the previous section, against the licensee for noncompliance with NRC requirements.

Therefore, the Petitioners' request for enforcement actions based solely on any failures on the part of the licensee to not fully comply with commitments made in response to the 50.54(f) letter, is denied. Enforcement actions are taken when there is a noncompliance with

NRC requirements, and the severity of those actions are based in part on the degree of risk posed by that noncompliance.

With respect to the second request for enforcement action, the NRC staff finds that the Petitioners' request for enforcement based on numerous design basis violations (i.e., the LERs submitted by the licensee) is in effect being granted by the actions already taken by the staff as evidenced by the earlier discussion of our processes for reviewing and evaluating LERs.

It is also important to note that the highest level of staff oversight of licensee activities for plants with performance problems or operational events is governed by IMC 0350, and that the agency has been overseeing the licensee's activities using this process since May 3, 2002. The decision by the staff to place the Davis-Besse licensee in the highest level of staff oversight was based on the identified performance deficiencies, and also to assure close coordination between NRC and licensee personnel on the corrective actions needed to assure safe plant restart. Any additional enforcement actions, as requested by the Petitioners, would not increase this level of staff oversight, which is directed at assuring that the plant is capable of safe operation in accordance with the Commission's rules and regulations.

As provided in 10 CFR 2.206(c), a copy of this director's decision will be filed with the Secretary of the Commission for the Commission to review. As provided for by this regulation, the decision will constitute the final action of the Commission 25 days after the date of the decision unless the Commission, on its own motion, institutes a review of the decision within that time.

Dated at Rockville, Maryland, this day of 2004.

FOR THE NUCLEAR REGULATORY COMMISSION

J. E. Dyer, Director
Office of Nuclear Reactor Regulation

Proposed