May 27, 2009

MEMORANDUM TO: Ralph Archtizel, Senior Reactor Engineer
Safety Issue Resolution Branch, Division of Safety Systems
Office of Nuclear Reactor Regulation

FROM: Eric J. Leeds, Director **/RA/**
Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL OPINION DECISION CONCERNING CLOSURE PROCESS FOR GENERIC SAFETY ISSUE -191 (DPO-2008-001)

On October 1, 2008, in accordance with Management Directive 10.159, "The NRC Differing Professional Opinions Program", you submitted a differing professional opinion (DPO) concerning the NRC staff closure process for Generic Safety Issue (GSI)-191, including associated activities to review licensee submittals in response to Generic letter (GL) 2004-02. Specifically, your DPO is focused on part of the closure process for GL2004-02, which is documented in an internal memorandum, "NRC Staff Process for Review of Licensee Supplemental Responses to GL2004-02", dated March 25, 2008. You indicated that your DPO, "essentially is that the staff procedure and process outlined above [in the March 25, 2008 memorandum] has resulted in a review that is unnecessarily focused on compliance versus a determination that the underlying safety issue has been satisfactorily addressed." You also indicated that the staff's approach is inconsistent with Commission guidance provided in two Staff Requirements Memoranda and that the staff's review process is inefficient and may result in focusing on non-safety significant issues. The purpose of this memorandum is to respond to your DPO.

On November 4, 2008, I established a DPO Ad Hoc Review Panel (the Panel) and tasked it to meet with you, review your DPO submittal, and issue a DPO report, including conclusions and recommendations to me regarding the disposition of the issues presented in your DPO. The Panel initially met with you on November 26, 2008 to establish a concise statement of your concerns and indicated that it completed that statement on December 22, 2008. On March 29, 2009, after reviewing the applicable documents, completing internal interviews of relevant individuals and completing its deliberations, the Panel issued its report to me.

Following receipt of the panel's report, I provided a copy of the report to you for your review. On April 13, 2008, I met with you to discuss the Panel's report and to get your insights and comments. You provided me additional insights into your concerns and your thoughts for resolving the technical issues associated with GSI-191.

A-1

In order to make a decision with regard to your DPO, I reviewed the DPO Panel=s report, met with the DPO Panel, met with you, discussed the issues with the relevant Division Director and then re-considered your comments to me.

The DPO Panel agreed with your first concern that the resolution of GSI-191 is focused on compliance. The Panel stated that compliance with the regulatory requirements presumptively assures that adequate safety is maintained and, therefore, the current approach is appropriate. Based on my review, I concur with the Panel that in this case, compliance with the regulatory requirements will provide reasonable assurance of safety. For your consideration, I am including a COMSAJ-97-008, dated August 25, 1997, a Commission approved discussion describing the nexus between compliance and safety.

You also raised the concern that the staff's current approach does not comport with Commission guidance provided in two staff requirements memoranda (SRM). To paraphrase, the Commission direction to the staff and the Advisory Committee on Reactor Safeguards (ACRS) was that both entities focus their attention, resources, and additional research, if needed, on evaluating realistic scenarios rather than all possible scenarios. Here again, I concur with the Panel in that the staff is not assessing all possible scenarios and that through the establishment of an integrated review team (IRT), of which you are a member, a holistic review is being conducted on a plant-by-plant basis, balancing the safety margins among the various technical review areas, where possible.

Based on my understanding of the general thrust of your comments and the Panel's recommendations concerning the review of all possible scenarios, I believe it is appropriate for the staff to re-evaluate its approach to determine whether excluding scenarios based on low probability or risk is feasible.

Your DPO highlighted a need to ensure that the staff continue to follow the Commission's guidance on evaluating realistic scenarios rather than all possible scenarios. In that the staff has just begun its review of in-vessel downstream effects, I want to ensure our continued adherence to the SRM. Your sensitivity to the Commission's direction and willingness to raise the potential for the staff to overlook this key issue is laudable and I thank you for your feedback.

The third concern that the Panel addressed was your view that the staff's review process is inefficient and may result in focusing on non-safety significant issues. The Panel agreed with you that the staff's approach has been inefficient as detailed guidance has evolved as staff and licensees have learned from ongoing industry and NRC-sponsored testing. As you note, staff guidance has only stabilized over the last year or so. However, the Panel also found that the staff's approach resulted in improved plant safety because it required that licensees enact some initial, rapid improvements to address the risk associated with the potential for inadequate safety system performance. I am concerned that the staff's review was not as efficient as it could be and that we should improve our process based on lessons learned from our review of PWR sump performance. One of the Agency's strategic objectives is that NRC actions are high quality, efficient, timely and realistic, to enable the safe and beneficial use of radioactive materials. Again, thank you for raising this issue so that we can focus on improving our regulatory process going forward.

In addition to your stated concerns, you proposed an alternative approach which would assess whether the plants have adequately resolved the risks associated with GSI-191, without making clear-cut compliance determinations. When we met and discussed this specific issue, you emphasized that you did not think a rigorous risk assessment was necessary but that the staff was more likely to find issues with BWR sump performance and its impact on ECCS systems than the staff had found with PWRs. I agree that it is important to determine, to the extent feasible, the risks posed by sump/strainer performance issues for PWRs and BWRs, such that resources can be focused on the most safety-significant aspects of the issue.

Based on their review of your DPO, the Panel also recommended the staff consider two additional activities to ensure that the risk associated with GSI-191 related issues is acceptable. In short, the Panel recommended, (1) that the staff perform an integrated review of the test results from all licensees to ensure that the results are as consistent as practical given the differences in testing approaches and (2) that the staff assess the consequences associated with ECCS inoperability.

Therefore, I am assigning the following tasks to the Director, Division of Safety System (DSS), in consultation with appropriate staff and management in NRR and RES:

1. Review and revise, as necessary and appropriate, NRC's guidance to its technical review staff in its review of issues relating to GSI-191, to ensure that the guidance follows the intent of the Commission's direction in its June 30, 2004, and November 16, 2006, SRMs. In particular, evaluate whether and how focus can be increased on realistic scenarios, for example by using risk tools.

2. Conduct an interim lessons learned from the staff's review of GSI-191 to date to determine improvements to the process that can be incorporated into the ongoing review of PWR sump issues and in going forward with the review of BWR sump performance.

3. Consider the Panel's recommendations that the staff perform an integrated review of the test results from all licensees to ensure that the results are as consistent as practical given the differences in testing approaches and that the staff assess the consequences associated with ECCS inoperability.

4. Provide a memorandum to me, through the Associate Director for Engineering and Safety Systems, and with a copy to you, the DPO submitter, providing the results of the three assigned actions by September 30, 2009.

Thank you for raising your DPO and for your active participation in the DPO process. An open and thorough exploration of how we carry out our regulatory process is essential to keeping these programs effective. Your willingness to raise concerns with your colleagues and managers and ensure that your concerns are heard and understood is admirable and vital to ensuring a healthy safety culture within the Agency.

Enclosure 1: DPO Panel report Dated March 19, 2009.
Enclosure 2: COMSAJ-97-008, Staff Requirements, Discussion on Safety and Compliance, Dated August 25, 1997.

cc: M. Bailey, NMSS
K. Karwoski, NRR
R Tregoning, NRR
R. Pedersen, OE

Safety and Compliance

As commonly understood, safety means freedom from exposure to danger, or protection from harm. In a practical sense, an activity is deemed to be safe if the perceived risks are judged to be acceptable. The Atomic Energy Act of 1954, as amended, establishes "adequate protection" as the standard of safety on which NRC regulation is based. In the context of NRC regulation, safety means avoiding undue risk or, stated another way, providing reasonable assurance of adequate protection for the public in connection with the use of source, byproduct and special nuclear materials.

The definition of compliance is much simpler. Compliance simply means meeting applicable regulatory requirements.

What is the nexus between compliance and safety?

1. Safety is the fundamental regulatory objective, and compliance with NRC requirements plays a fundamental role in giving the NRC confidence that safety is being maintained. 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. 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.

2. Adequate protection is presumptively assured by compliance with NRC requirements. Circumstances may arise, however, where new information reveals, for example, 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.

3. The NRC 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 non-compliances occur, the NRC must evaluate the degree of risk posed by that non-compliance 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. In addition,

in determining the appropriate action to be taken, the NRC must evaluate the non-compliance both in terms of its direct safety and regulatory significance and by assessing whether it is part of a pattern of non-compliance (i.e., the degree of pervasiveness)that can lead to the determination that licensee control processes are no longer adequate to ensure protection of the public health and safety. Based on the NRC's evaluation, 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).

4. Where requirements exist that the NRC concludes have no safety benefit, the NRC can and should take action, as appropriate, to modify or remove such requirements from the regulations or licenses. Requirements that are duplicative, unnecessary, or unnecessarily burdensome can actually have a negative safety impact. They also can tend to create an inappropriate NRC and licensee focus on "safety versus compliance" debates. As the Commission states in its Principles of Good Regulation, "There between regulations and agency goals and objectives, whether explicitly or implicitly stated."

5. Since some requirements are more important to safety than others, the Commission should use a risk-informed approach wherever possible when adding, removing, or modifying NRC regulations, as well as when applying NRC resources to the oversight of licensed activities (this includes enforcement). Based on the accumulation of operating experience and the increasing sophistication of risk analysis, the NRC should continue to refine its regulatory approach in a manner that enhances and reaffirms our fundamental safety objective.

These principles attempt to describe the nexus between compliance and safety. The misperception that compliance and safety are somehow incompatible or unrelated arises when the principles just outlined are not understood or are wrongly applied. When understood and applied correctly, the result should be a consistent, credible regulatory approach—as applied to licensing, inspection, enforcement, performance assessment processes, and rulemaking.