

March 31, 2005

Mr. Alex Marion
Senior Director, Engineering
Nuclear Generation Division
Nuclear Energy Institute
1776 I Street, Suite 400
Washington, DC 20006-3708

SUBJECT: INSTRUMENTATION, SYSTEMS, AND AUTOMATION SOCIETY S67.04
METHODS FOR DETERMINING TRIP SETPOINTS AND ALLOWABLE
VALUES FOR SAFETY-RELATED INSTRUMENTATION

Dear Mr. Marion:

The purpose of this letter is to provide the Nuclear Regulatory Commission (NRC) staff's response to your November 29, December 17, 2004, and March 18, 2005, letters related to the use of Method 3 of the Instrumentation, Systems, and Automation Society (ISA) ISA-S67.04, Part II, "Methodologies for the Determination of Setpoints for Nuclear Safety-Related Instrumentation," dated September 1994, to determine the trip setpoints and allowable values of safety-related instrumentation. The NRC staff agrees with your proposal to develop a Technical Specification Task Force (TSTF) technical specification change to address the issue. In the interim, the NRC staff proposes that certain commitments and technical specification changes be incorporated into license amendment requests (LARs) currently under NRC staff review so that these reviews can be completed.

In your November 29, 2004, letter you provided an update on the status of the "Method 3 Allowable Value" issue and expressed your concern with the regulatory process being imposed on licensees with pending LARs based on Method 3. In your December 17, 2004, letter you provided the results of an analysis conducted by MPR Associates on Method 3. Your March 18, 2005, letter provided feedback on a proposed approach for addressing this issue and additional information related to the MPR Associates analysis.

In your November 29, 2004, letter you indicated that the NRC staff should continue to process LARs in accordance with plant-specific licensing bases unless a regulatory analysis was performed supporting a new regulatory position in accordance with the backfit rule. You also noted that the NRC staff had previously stated that the use of Method 3 was not an immediate safety issue or a compliance issue and that licensees could continue to use Method 3 until long-term resolution is implemented. Further, you expressed concern that the NRC staff recently issued a request for additional information (RAI) that seems to reverse this position.

The NRC staff is continuing to process LARs related to instrumentation setpoints in accordance with plant-specific licensing bases. Contrary to your assertion that the NRC staff has stated that the use of Method 3 is not a compliance issue, the NRC staff's statements were intended to indicate that the staff had not yet determined whether the use of Method 3 raised a compliance issue. To ensure that the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 50.36(c)(1)(ii)(A) are satisfied on a plant-specific basis until a permanent resolution to this issue can be implemented, the NRC staff prepared an RAI for

those licensees requesting changes to LSSSs. As you noted in your November 29, 2004, letter, the RAI stated that Method 3 was not acceptable unless the method is modified. In February 2005, the NRC staff revised the RAI question (see the Enclosure for the revised RAI) to focus on compliance with the requirements of 10 CFR 50.36. This revised RAI was provided to all of the licensing project managers in the Division of Licensing Project Management with instructions to discuss the revisions with the affected licensees and to confirm that the content of the licensees' responses are consistent with the revised RAI. Further, the revised RAI will be sent to the affected licensees to clarify the NRC staff's expectations in regard to this issue.

In your December 17, 2004, letter you provided the results of an MPR Associates analysis of Method 3. In your letter you state "[t]he independent review (enclosed) concludes that ISA Method 3 provides adequate protection." The NRC staff believes that the overall conclusion of the MPR Associates analysis is best summed up by the last paragraph of the paper:

Safety channel operability is monitored and maintained both through periodic, measurement based surveillance testing and recalibration. *The Analytical Limit is protected by the trip setpoint, not the Allowable Value, and the setpoint drift is, in practice, kept small by a tight recalibration tolerance band.* Because of this and our Monte Carlo simulation results, we have no concern that the use of ISA Method 3 for establishing the Allowable Value for surveillance tests leads to a generic safety concern. (emphasis added)

The NRC staff agrees that the safety limit (SL) is protected by the practice of setting the instrument trip setpoint at, or more conservative than, the calculated trip setpoint (TSP_{cal}) that accounts for credible uncertainties, rather than the allowable value (AV). However, existing AV-based technical specifications do not require that licensees control the instrument setting based on TSP_{cal} . Therefore, any generic solution to this issue needs to include a requirement to return the as-left instrument setting to the TSP established to protect the SL (either TSP_{cal} or a nominal TSP that is more conservative than TSP_{cal}). With such a requirement in place, the limiting safety system settings (LSSS) becomes the setpoint limit rather than the AV, and the issue of whether Method 3 is acceptable for establishing an AV as an LSSS is moot since this approach is method independent. As such, the NRC staff believes that further discussion on this point is unnecessary as it would divert our limited resources from reaching the goal of improving the clarity and consistency of the technical specifications.

The NRC staff identified a broader concern with technical specifications with respect to assessing the operability of the instruments associated with systems for which LSSS values are established. To address the NRC staff's concern with respect to operability and satisfy 10 CFR 50.36(c)(1)(ii)(A), operability needs to be assessed, in part, based on the ability of the system to initiate automatic protective actions as required to protect the SL (i.e., satisfy its safety function). The NRC staff's view is that in order to meet this requirement, periodic testing or calibration must demonstrate that the performance of the instrument is within the expected range, accounting for uncertainties associated with the test or calibration. As stated in your March 18, 2005, letter you support the development of a TSTF technical specification change to address resetting automatic trip setpoints for LSSS and describing how setpoint methodologies are applied in practice to verify component operability. Incorporating requirements into technical specifications that assess operability based on the previous as-left setting and the credible uncertainties when testing or calibrating the instrumentation will address the broader NRC staff concern.

As you noted in your March 18, 2005, letter the systems these instruments are typically associated with are the reactor trip system (RTS) and engineered safety feature actuation system (ESFAS) for pressurized water reactors (PWRs) and the reactor protection system (RPS) and emergency core cooling system (ECCS) for boiling water reactors (BWRs). The NRC staff agrees that RTS and ESFAS, and RPS and ECCS are the typical systems, for PWRs and BWRs respectively, for which LSSS are established to protect the safety limits. However, there may be other plant-specific systems that could be included within the scope of systems covered by 10 CFR 50.36(c)(1)(ii)(A). To explicitly limit the scope of systems covered by any generic solution to these systems may not be consistent with some plant-specific licensing bases. Therefore, the TSTF technical specification change being developed should recognize that the requirements may also apply to systems other than RTS, ESFAS, RPS, and ECCS, based on the plant-specific licensing bases.

During the public meeting held on March 11, 2005, at the NRC Headquarters Office, you requested that the NRC withdraw the RAI question and continue its review of existing licensing actions pending finalization of the TSTF technical specification change to address this issue. You reiterated this request in your March 18, 2005, letter. As noted previously, the NRC staff is continuing the review of existing in-house LARs. To move forward with LARs that are currently under NRC staff review, an interim approach has been developed that addresses the NRC staff's concerns until the TSTF technical specification change is reviewed and approved. As part of these licensee specific reviews, the revised RAI question (see Enclosure) will remain outstanding, with the understanding that, in addition to a brief discussion of the licensee's methodology for establishing LSSS, the licensee's response to the question needs to contain the following in order for the staff to complete its review:

1. An explicit regulatory commitment to adopt the final TSTF technical specification change to come into conformance with the existing understanding of the requirements of 10 CFR 50.36.
2. An explicit regulatory commitment to assess the operability of tested instrumentation based on the previous as-left instrument setting and accounting for the uncertainties associated with the test or calibration.
3. A revision to the technical specifications for the LSSS being changed by the LAR to incorporate a footnote that states:

The as-left instrument setting shall be returned to a setting within the tolerance band of the trip setpoint established to protect the safety limit.

Once completed, the NRC staff plans to make the TSTF technical specification change available for adoption by licensees consistent with the consolidated line item improvement process (CLIIP).

On March 24, 2005, the interim approach described above was discussed with Mr. Michael Schoppman of your staff. During this discussion, Mr. Schoppman was also informed of the NRC staff's intent to issue a regulatory information summary (RIS) that documents the staff's position on the requirements of 10 CFR 50.36 as they relate to LSSS and periodic testing or calibration of instrumentation. The focus of the RIS will be to inform interested stakeholders

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that to meet the requirements of 10 CFR 50.36, licensees need to return the instrument to the TSP established to protect the AL (and, therefore, protect the SL) at the completion of testing or calibration and that during the periodic testing or calibration, operability needs to be assessed by comparison of as-found settings with the previous as-left instrument settings, considering the uncertainties associated with the test or calibration. For further interaction on the interim approach, please contact Mr. Christopher Gratton of my staff. You may reach Mr. Gratton at 301-415-1055 or email at cxg1@nrc.gov.

As you indicated in your March 18, 2005, letter the TSTF is preparing a technical specification change that may be generically applied in accordance with the CLIIP. You indicated that the current schedule is for the TSTF technical specification change to be submitted into the CLIIP in June 2005. This is consistent with the NRC staff's expectations for the generic resolution of concerns with setpoint technical specifications. As the NRC staff moves forward with implementing the generic resolution of this issue, it may issue a generic communication soliciting information from licensees regarding the methods being employed to establish LSSS values in technical specifications. As part of this generic communication, the NRC staff would note that the TSTF/CLIIP technical specification change would likely be an acceptable way to address concerns that may be identified. The NRC staff point of contact for the TSTF technical specification change will be Mr. Tom Boyce, or a member of his staff. Mr. Boyce may be reached at 301-415-0184 or email at thb@nrc.gov.

Sincerely,

/RA/

James A. Lyons, Deputy Director
Division of Licensing Project Management
Office of Nuclear Reactor Regulation

Enclosure: As stated

cc: Brian Sheron, ADPT Michael Mayfield, DE
Bruce Boger, DIPM Tad Marsh, DLPM
Dave Matthews, DRIP Suzanne Black, DSSA
Mike Schoppman, NEI

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As you indicated in your March 18, 2005, letter the TSTF is preparing a technical specification change that may be generically applied in accordance with the CLIP. You indicated that the current schedule is for the TSTF technical specification change to be submitted into the CLIP in June 2005. This is consistent with the NRC staff's expectations for the generic resolution of concerns with setpoint technical specifications. As the NRC staff moves forward with implementing the generic resolution of this issue, it may issue a generic communication soliciting information from licensees regarding the methods being employed to establish LSSS values in technical specifications. As part of this generic communication, the NRC staff would note that the TSTF/CLIP technical specification change would likely be an acceptable way to address concerns that may be identified. The NRC staff point of contact for the TSTF technical specification change will be Mr. Tom Boyce, or a member of his staff. Mr. Boyce may be reached at 301-415-0184 or email at thb@nrc.gov.

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REVISED METHOD 3 REQUEST FOR ADDITIONAL INFORMATION

The [insert plant name] technical specifications define Limiting Safety System Settings (LSSS) as an allowable value (AV). During reviews of proposed license amendments that contain changes to LSSS setpoints, the NRC staff identified concerns regarding the method used by some licensees to determine the allowable values (AV) identified in the technical specifications (TS). AVs are identified in the TS as LSSS to provide acceptance criteria for determination of instrument channel operability during periodic surveillance testing. The NRC staff's concern relates to one of the three methods for determining the AV as described in the Instrument Society of America (ISA) recommended practice ISA-RP67.04-1994, Part II, "Methodologies for Determination of Setpoints for Nuclear Safety-Related Instrumentation."

The NRC staff has determined that to ensure a plant will operate in accordance with the assumptions upon which the plant safety analyses have been based, additional information is required regardless of the methodology used to establish LSSS values in technical specifications. Details about the NRC staff's concerns are available on the NRC's public website under ADAMS Accession Numbers ML041690604, ML041810346, and ML050670025¹.

In Order for the NRC staff to assess the acceptability of your license amendment request related to this issue, the NRC staff requests the following additional information:

1. Discuss the setpoint methodology used at [insert plant name] to establish AVs associated with LSSS setpoints.
2. Regardless of the methodology used, the NRC staff has the following questions regarding the use of the methodology at [insert plant name]:
 - a. Discuss how the methodology and controls you have in place ensure that the analytical limit (AL) associated with an LSSS will not be exceeded (the AL is a surrogate that ensures the safety limits will not be exceeded). Include in your discussion information on the controls you employ to ensure the trip setpoint established after completing periodic surveillances satisfies your methodology. If the controls are located in a document other than the TS, discuss how those controls satisfy the requirements of 10 CFR 50.36.
 - b. Discuss how the TS surveillances ensure the operability of the instrument channel. This should include a discussion on how the surveillance test results relate to the technical specification AV and describe how these are used to determine the operability of the instrument channel. If the requirements for determining operability of the LSSS instrument being tested are in a document other than the TS (e.g., plant test procedure), discuss how this meets the requirements of 10 CFR 50.36.

¹ To access the document, go to www.nrc.gov, click on "Electronic Reading Room," then "Documents in ADAMS," then "Web-Based Access," then "Begin ADAMS Search," then "Advanced Search," and enter the Accession number into the Accession Number box near the top of the page. Click on the "Search" button near the bottom of the page. You will need to select "Image File" on the search results page to view the document. NOTE: You will need Adobe Acrobat Reader to open this file.

Enclosure