ENCLOSURE 4

**Letter Dated August 23, 2005 Mr. Alex Marion**

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

**Meeting Summary of November 4, 2008 Meeting with NRC/TSTF**

August 23, 2005

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

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

Dear Mr. Marion:

The purpose of this letter is to respond to the information provided to the U.S. Nuclear Regulatory Commission (NRC) staff in your letter of May 18, 2005, during a public meeting on June 2, 2005, with the Nuclear Energy Institute (NEI) Setpoint Methods Task Force (SMTF), and in Mr. Michael Coyle's letter of June 30, 2005. This information discusses instrument settings and the technical specifications (TSs) required for limiting safety system settings (LSSSs) related to plant safety limits (SLs). In the letter dated May 18, 2005, the NEI SMTF proposed seven concepts that could be used in the development of a Technical Specification Task Force (TSTF) change traveler that would address these issues generically. These concepts were clarified during the public meeting on June 2, 2005, and are further clarified in this letter.

The NRC staff believes that implementation of these concepts as described in this letter will satisfactorily address both the staff's and industry's concerns with instrument settings, and ensure compliance with Part 50 of Title 10 of the Code of Federal Regulations (10 CFR) section 50.36, "Technical Specifications." The staff does not anticipate further changes to these concepts, and intends to follow them in its current reviews of plant-specific license amendment requests. The staff believes that the NEI SMTF should incorporate these concepts into the TSTF that is planned to be submitted to NRC in late September 2005.

During the June 2, 2005, public meeting, the NRC staff and the NEI SMTF reached agreement on five of the seven concepts discussed in the letter of May 18, 2005. Specifically, agreement was reached on concept 1 ([limiting] trip setpoint (TSP)); concept 2 (as-found trip setpoint), with a minor change that exceeding the predefined test acceptance criteria band "must" (vice "may") require additional evaluation; concept 3 (reset setpoint), and concept 6 (single-column vs. multiple-column TS). The staff and industry reached tentative agreement on concept 4 (limiting TSP vs. nominal TSP), but adjourned the meeting in disagreement on concept 5 (allowable value). Following the meeting, the staff developed an additional option for concept 5 that is acceptable to satisfy the requirements of 10 CFR 50.36. These agreements are discussed in more detail in Enclosure 1.

Subsequently, Mr. Coyle's letter of June 30, 2005, to Mr. James Dyer (NRC) appeared to limit the scope of the concepts to be incorporated into the TSTF to only "resetting an instrument when the 'as found' setting is outside a predetermined tolerance band," and to tie the resolution to Method 3 as described in ISA-RP67.04-1994, Part II, "Methodologies for the Determination of Setpoints for Nuclear Safety-Related Instrumentation." Mr. Coyle's letter stated that this was industry's current understanding based on discussions with the NRC staff. We agree that Mr. Coyle's statement resolves many of the staff's concerns. However, it does not capture all of the concepts discussed in your May 18, 2005, letter, as clarified in the June 2 public meeting and the subsequent discussions that are documented in Enclosure 1. For example Mr. Coyle's statement does not address concept 2 (as-found trip setpoint), which states that, if the as-found TSP exceeds the predefined test acceptance criteria band during periodic surveillances, additional evaluation and potential corrective action is warranted as necessary to ensure continued performance of the specified safety function. The NRC staff believes that implementation of all of the concepts is required to address the requirements of 10 CFR 50.36(c)(1)(ii)(A), and to address staff and industry concerns with instrument settings, including allowing continued use of Method 3 by licensees.

During the June 2 meeting, the NEI SMTF requested that the NRC staff provide additional information regarding its concerns with the analysis on Method 3 conducted by MPR Associates, which was provided to the staff in your letter of December 17, 2004. This additional information is in Enclosure 2.

The NRC staff intends to issue a generic communication in the near future to document and facilitate implementation of the concepts in this letter. The staff intends to reference the TSTF in the generic communication, provided it is submitted in a timely manner and accurately implements the concepts. In the interim, the staff intends to continue to process plant specific licensing amendment requests (LARs) consistent with the concepts. In the letter of May 18, NEI requested that the staff withdraw all requests for additional information for LARs associated with operability of instrument settings. As stated above, the staff believes that implementation of all of the concepts is required to address the requirements of 10 CFR 50.36. The staff believes that licensee responses to the RAIs that include TS requirements which implement the concepts described in the Enclosure to your May 18, 2005, letter (as discussed in Enclosure 1 of this letter) will be acceptable. A discussion related to NRC staff requests for additional information is provided in Enclosure 3.

The NRC staff points of contact for this issue are Mr. Tom Boyce and Mr. Christopher Gratton.

Mr. Boyce may be reached at 301-415-0184 or email at thb@nrc.gov; Mr. Gratton may be reached at 301-415-1055 or email at cxg1@nrc.gov.

Sincerely,

***/RA/***
Bruce A. Boger, Director
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

Enclosures: As stated

cc: James Dyer, NRR
Brian Sheron, ADPT
Michael Mayfield, DE
Dave Matthews, DRIP
Tad Marsh, DLPM
Jim Lyons, DSSA
Mike Schoppman, NEI

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

Dated: August 23, 2005

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Agreements on Concepts
in the NEI Letter of May 18, 2005

In a letter to Mr. James Lyons (NRC) of May 18, 2005, the Nuclear Energy Institute (NEI), based upon information developed by the Setpoint Methods Task Force (SMTF), proposed seven concepts that could be used in the development of a Technical Specification Task Force (TSTF) change traveler that would address issues regarding instrument setpoint and plant Technical Specifications (TS) generically.

During the June 2, 2005, public meeting, the NRC staff and the NEI SMTF reached agreement on five of the seven concepts discussed in the letter of May 18, 2005. Specifically, agreement was reached on concept 1 ([limiting] trip setpoint (TSP)); concept 2 (as-found trip setpoint), with a minor change that exceeding the predefined test acceptance criteria band "must" (vice "may") require additional evaluation; concept 3 (reset setpoint), and concept 6 (single-column vs. multiple-column TS).

For concept 4 (limiting TSP vs. nominal TSP), the NRC staff agreed that a nominal TSP may be established that is more conservative than the limiting TSP. When a nominal TSP is used, the NRC staff agreed that the as-left TSP must be set to within the setting tolerance of the nominal TSP consistent with its agreement on concept 3. However, the NRC staff questioned the idea that the predefined test acceptance criteria band for as-found values be maintained around the nominal TSP versus the previous as-left TSP. As expressed during the meeting, the NRC staff's view was that these predefined test acceptance criteria bands should be based on the as-left TSP from the most recently completed surveillance. Basing the predefined test acceptance criteria band on the previous as-left TSP ensures that the assumptions in the uncertainty analysis used to determine the limiting TSP remain unchanged.

During the meeting, the SMTF indicated that because of the small setting tolerance used when setting the TSP for the instrument channel, there would be little effect on the predefined test acceptance criteria band by using the nominal TSP versus the previous as-left TSP. The SMTF indicated that it would provide the NRC staff with information supporting this position. The NRC staff acknowledged that the use of the nominal TSP was acceptable provided detection of performance problems would be as effective as if the previous as-left TSP were used.

For concept 5 (allowable value), there was disagreement and extended discussions regarding the methodology used to calculate the allowable value designated as the limiting safety system setting (LSSS) in TS. The NRC staff proposed several options for follow-on discussion to resolve the issue, but the SMTF did not agree that any of these were an appropriate resolution. The staff agreed to reconsider the NEI SMTF proposal to retain a single column TS format that uses allowable values (AVs) determined using any of the three methods described in ISA-RP67.04, Part II-1994, "Methodologies for the Determination of Setpoints for Nuclear Safety-Related Instrumentation."

Subsequently, the NRC staff developed an additional option for concept 5 that it found acceptable to satisfy the requirements of Part 50 of Title 10 of the Code of Federal Regulations (10 CFR) section 50.36. The option retained the concept of the AV based in a single column TS format, and the AV could be determined based on any of the methodologies in ISA-RP67.04, Part II-1994. Under this option, the instrument channel must be reset to within

the setting tolerance of the nominal TSP, which may also be the limiting TSP, but is usually more conservative, and the capability of the instrument channel to function as required within the predefined test acceptance criteria band (consistent with concept 4) must be assessed. Further, the AV is an operability limit for the channel, and would not be designated as the LSSS. The LSSS would be the limiting TSP which accounts for the credible uncertainties associated with the instrument channel.

The specifics on how to designate the LSSS in TSs should be developed as part of a TSTF implementing these concepts. The concepts call for the limiting TSP to be the LSSS, vice the AV. Since 10 CFR 50.36 requires that the LSSS be included in the TS, either the limiting TSP value or a reference to the method for determining the limiting TSP value needs to be specified in the TS. The value or the description of the factors used to determine the value would be determined consistent with a licensee's current setpoint methodology. The method of determining the limiting TSP, the as-found instrument channel setpoint acceptance criteria band, and the as-left instrument channel setpoint tolerance band would be specified in the Updated Final Safety Analysis Report (UFSAR) or a document incorporated into the UFSAR such as the technical requirements manual.

Significant discussions were held during the June 2 meeting regarding concept 7 (operability). As clarified below, the NRC staff and the NEI SMTF agreed on concept 7:

1) If the as-found TSP is found to be non-conservative with respect to the AV specified in TSs, the channel is required to be declared inoperable and the associated TS action statement must be followed.

2) If the as-found TSP is found to be conservative with respect to the AV, and outside the predefined test acceptance criteria band, but the licensee is able to determine that the instrument channel is functioning as required and the licensee can reset the channel to within the setting tolerance of the limiting TSP, or a value more conservative than the limiting TSP, then the licensee may consider the channel to be operable. If the licensee cannot determine that the instrument channel is functioning as required, the channel is required to be declared inoperable and the associated TS actions must be followed.

3) If the as-found TSP is outside the predefined test acceptance criteria band, the condition must be entered into the licensee's corrective action program for further evaluation.

NRC Staff comments on MPR Associates Analysis on Method 3

An area of discussion between the NRC staff and the Setpoint Methods Task Force (SMTF) relates to the analysis on Method 3 conducted by MPR Associates provided in the NEI letter of December 17, 2004. In that letter, it is stated "[t]he independent review (enclosed) concludes that ISA Method 3 provides adequate protection." 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 [AL] 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.

The NRC staff agrees with the conclusion that the AL is protected by resetting the instrument trip setpoint (TSP) at, or more conservative than, the limiting setpoint (LSP) during surveillance testing and recalibration. The MPR report mathematically supports the staff and industry agreement that a properly-derived LSP ensures adequate protection of the AL if the channel setpoint is returned to the LSP at the beginning of each test interval. Note that each Monte Carlo simulation trial in the report begins with the channel setpoint equal to the LSP. This is based on the fact that the LSP accounts for the credible uncertainties associated with the instrument channel (e.g., total loop uncertainty).

However, the NRC staff notes that licensees with allowable value (AV) based technical specifications (TSs) do not currently have a regulatory requirement for the licensee to reset the instrument to the LSP (within a specified tolerance). Since licensees are not required to control the instrument setting based on the LSP, they could potentially leave an instrument setpoint set at the AV after periodic operational testing or calibration. This would not be consistent with the assumption of the MPR Associates analysis (in which the instrument was reset to the LSP that accounts for the credible uncertainties at the beginning of each monte carlo simulation). The staff understands from your input that resetting is consistent with typical industry practices. However, without a clear regulatory requirement to reset the instrument to the LSP, the NRC staff assumes in its regulatory decision making process that the AV becomes the de facto worst-case setpoint and therefore, the total loop uncertainty must be added to the AV when assessing whether the instrument is capable of protecting the SL.

Stated in more analytical terms, since the report assumes instruments are reset to a nominal setpoint, it does not analyze the influence of instruments where as-left setpoints can vary up to the AV. Therefore, it does not yield a quantitative assessment of the effectiveness of AVs determined either using Method 2 (AV2) or Method 3 (AV3) by themselves as a limiting value for the protection of the AL. Because the as-found setpoint is permitted to vary stochastically around a nominal setpoint, rather than being fixed at the AV being investigated, many trials are deemed successful in support of the AV when, in fact, the as-found value is unrelated to the AV. This artificially inflates the fraction of trials that appear to be successful, and, therefore, dilutes the assessment of the fraction that fail. Trials having as-found values that are not equal to the AV do not test the AV and should not be counted at all. The resulting statistics therefore

apply to the efficacy of the combination of LSP and AV together in the protection of the AL, rather than to the efficacy of the AV itself. Those statistics relate to the overall probability that the channel will protect the AL (absent hardware failures). Applying the 95/95 criterion to this overall effectiveness statistic, rather than just to the AV effectiveness statistic, would constitute acceptance of a significant increase in the overall likelihood of failure to protect the AL.

The report confirms that an AV based on AV2 provides more certain protection of the AL than does AV3, and therefore that AV2 is more conservative than AV; however, it does not demonstrate the effectiveness of either AV2 or AV3 in protecting the AL.

License Amendment Requests
for changes to TS Setpoint Allowable Values

In the NEI letter of May 18, 2005, the NRC staff was requested to withdraw all requests for additional information (RAIs) for licensing action requests (LARs) associated with operability of instrument settings. The staff believes that demonstration of the operability of instruments is required to ensure compliance with the requirements of Part 50 of Title 10 of the Code of Federal Regulations (10 CFR) section 50.36(c)(3) which requires that TS surveillances demonstrate that the plant is operating within its safety limits. Verification that the instrument is functioning as required is an integral part of this periodic testing. In addition, Section 50.36(c)(1)(ii)(A), which discusses the requirements for limiting safety system settings (LSSS), states that "If, during operation, it is determined that the automatic safety system equipment does not *function as required* (emphasis added), the licensee shall take appropriate action, which may include shutting down the reactor." This latter requirement is unique to automatic safety system equipment.

The staff's position is that simply resetting an instrument whose setpoint is found outside the predefined test acceptance criteria band back to its nominal setpoint and entering the data into a corrective action program, without a prompt evaluation of the condition, is not sufficient to determine the operability of the instrument that is being placed back into service. This is because an instrument may be degraded or fail due to conditions other than statistical variations in uncertainties, including drift. The staff and the NEI SMTF reached agreement on this issue during the June 2 meeting as part of Concept 2 (as-found trip setpoint) of the May 18, 2005, letter. This letter states that, if the as-found TSP exceeds a predefined test acceptance criteria band during periodic surveillances, additional evaluation and potential corrective action *"is"* (emphasis added) warranted (a change from "may be warranted" was agreed to during the meeting) as necessary to ensure continued performance of the specified safety function. Incorporating this requirement into TS provides reasonable assurance that at the next surveillance the as-found value of the TSP will continue to protect plant safety limits.

Concept 7 (Operability) discusses factors that could be considered in this evaluation. It should be noted that, although the TS would contain a note to verify that the as-found TSP was within the predefined test acceptance criteria band and that exceeding the limits would warrant additional evaluation, the detailed discussion of the evaluation process and the factors to be considered would not be required in either the TS or the Bases, and that the process for evaluation is consistent with the guidance that has recently been developed by the staff and the NEI Operability Determination Process Task Force as part of the effort to revise the operability guidance in Generic Letter 91-18.

More broadly, the staff will continue to issue RAIs similar to those in the enclosure to its letter to NEI from James Lyons (NRC) dated March 31, 2005, (Agencywide Documents Access and Management Systems, Accession No. ML050870008) for LARs that change LSSSs, but do not include the TS requirements described above for the LSSSs. This information is necessary in order for the NRC staff to determine whether the LAR complies with NRC rules and regulations, a finding needed to support the issuance of the LAR. The staff believes that licensee responses to the RAIs that include TS requirements which implement the concepts described in the Enclosure to the May 18, 2005, letter (as discussed in Enclosure 1 of this letter) will be

acceptable. One of the RAIs requested that the licensee provide a brief description of the methodology used to determine its setpoints. The purpose of this request was to solicit information from the licensee to determine whether TSPs were calculated in a manner that accounted for credible uncertainties associated with the instrument channel. This could be accomplished by referring to Regulatory Guide 1.105, “Setpoints for Safety-Related Instrumentation,” or an NRC approved plant-specific setpoint methodology. In addition, a predefined test acceptance criteria band should be developed consistent with the assumptions and uncertainties associated with the tested portion of the instrument channel and the determination of the TSP calculated to protect the safety limits. This information is necessary for the NRC staff to conclude that the TSP provides reasonable assurance that the safety limits will be protected, a finding necessary to support issuance of the LAR.