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From:  
NEI

TACs:  
MC5405

To:  
James Lyons

\*\*\* YELLOW \*\*\*

For Signature of:

Routing:

Dyer  
Borchardt  
Sheron  
Carpenter  
NRR Mailroom

Description:

ISA S67.04 Methods for Determining Trip Setpoints and Allowable Values for  
Safety-Related Instrumentation

Assigned To:

DLPM

Contact:

MARSH, LEDYARD (TAD) B

Special Instructions:



NUCLEAR ENERGY INSTITUTE

Alexander Marion  
SENIOR DIRECTOR, ENGINEERING  
NUCLEAR GENERATION DIVISION

November 29, 2004

Mr. James E. Lyons  
Deputy Director, Division of Licensing Project Management  
Office of Nuclear Reactor Regulation  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**SUBJECT: ISA S67.04 Methods for Determining Trip Setpoints and Allowable Values for Safety-Related Instrumentation**

Dear Mr. Lyons:

This letter provides a status report on the "Method-3 Allowable Value" issue and expresses our concern with the regulatory process that is being imposed on licensees with pending License Amendment Requests (LARs) based on Method 3.

During the past year, the NEI Setpoint Methods Task Force (SMTF) has been working with the NRC staff to resolve staff concerns about the use of Method 3, as defined in ISA-RP67.04-1994, to establish operability limits for safety-related instruments. Since October 2003, four public meetings have been held on this issue, NEI has submitted a technical white paper in defense of Method 3, and the NRC staff has published a formal problem statement to express its continuing concerns.

The SMTF is currently developing a response to the NRC problem statement dated June 17, 2004. We anticipate submitting the response in January 2005. The SMTF is also working with the Technical Specification Task Force (TSTF) and the NSSS Owners Groups to identify potential generic changes to the Standard Technical Specifications. Proposed changes, if any, will be processed using the established regulatory process for TSTF Travelers.

The SMTF believes that Method 3, as documented in plant-specific licensing bases, provides sufficient assurance that plants will continue to operate safely, pending long-term resolution of NRC generic concerns. We agree that the technical issues raised by NRC should be resolved and believe that long-term generic resolution can be achieved by implementing the regulatory processes defined by NRR Operating Instructions. Pending generic resolution, NRC should continue processing License Amendment Requests (LARs) in accordance with plant-specific licensing bases



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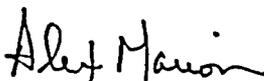
unless the staff conducts a mandatory regulatory analysis supporting a new regulatory position in accordance with 10 CFR 50.109, the backfit rule. NRC has previously stated in letters and during public meetings that the use of Method 3 is not an immediate safety issue or a compliance issue and that licensees could continue to use Method 3 until long-term resolution is implemented. However, a recent Request for Additional Information (enclosed) that is being sent to licensees with pending Method-3 LARs indicates that NRC staff reviewers have reversed position and will no longer review Method-3 LARs unless the licensee modifies (i.e., backfits) its method to alleviate staff concerns.

True?

This is a significant process issue that warrants NRC management attention. To paraphrase the NRC Regulatory Analysis Guidelines, NRC decision-making should be systematic, disciplined, transparent, and based on adequate information about the value and impact of new regulatory positions. The licensing process is not stable if licensees cannot rely on documented licensing bases and the protections afforded by the backfit rule. Further, the ad hoc imposition of regulatory requirements without appropriate regulatory analysis, conducted in accordance with prescribed procedures, is a violation of NRC regulations.

If you have questions or require additional information, please contact Mike Schoppman at (202) 739-8011; [mas@nei.org](mailto:mas@nei.org).

Sincerely,



Alex Marion

Enclosure

c: Brian W. Sheron, NRC  
Richard J. Barrett, NRC  
Ledyard B. Marsh, NRC  
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Sher Bahadur, NRC CRGR  
Christopher Gratton, NRC  
NEI Administrative Points of Contact  
NEI Licensing Contacts List.

**Allowable Value Generic Concern  
Interim RAI for Current License Amendment Requests**

***For Method 3-Based Changes to Setpoint-Related  
Technical Specifications Only***

Staff has determined that setpoint Allowable Values (AV) established by means of ISA 67.04 Part 2 Method 3 do not provide adequate assurance that a plant will operate in accordance with the assumptions upon which the plant safety analyses have been based. These concerns have been described in various public meetings. The presentation used in public meetings in June and July, 2004 to describe the staff concerns is available on the public website under ADAMS Accession Number MLO41810346<sup>1</sup>. (Note: Public access to ADAMS has been temporarily suspended so that security reviews of publicly available documents may be performed and potentially sensitive information removed. Please check the NRC Web site for updates on the resumption of ADAMS access).

Staff is currently formulating generic action on this subject. It is presently clear, however, that staff will not be able to accept any requested Technical Specification changes that are based upon the use of Method 3, unless the method is modified to alleviate the staff concerns. In particular, each setpoint limit in the Technical Specifications must ensure at least 95% probability with at least 95% confidence that the associated action will be initiated with the process variable no less conservative than the initiation value assumed in the plant safety analyses. In addition, the operability of each instrument channel addressed in the setpoint-related Technical Specifications must be ensured by the Technical Specifications. That is, conformance to the TS must provide adequate assurance that the plant will operate in accordance with the safety analyses. Reliance on settings or practices outside the TS and not mandated by them is not adequate.

Staff has determined that AV computed in accordance with ISA Method 1 or 2 do provide adequate assurance that the safety analysis limits will not be exceeded. Staff has also determined that an entirely different approach, based upon the performance of an instrument channel rather than directly upon the measured trip setting, can also provide the required assurance. This alternative approach, designated Performance-Based Technical Specifications, sets limits on acceptable nominal setpoints and upon the observed deviation in the measured setpoint from the end of one test to the beginning of the next. This approach has been accepted

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<sup>1</sup> Go to [www.nrc.gov](http://www.nrc.gov), click on "Electronic Reading Room," then "Documents in ADAMS," then "Web-Based Access," 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. Click on the icon under "Image File" on the search results page. NOTE: You will need Adobe Acrobat Reader to open this file.

for use at Ginna, and is discussed in a Safety Evaluation available via ADAMS as Accession Number ML041180293. The referenced Safety Evaluation is specific to Ginna, and is cited here only as a general example for other plants. It is up to the licensee to modify the approach as necessary to meet the indicated objectives for the particular plant(s) in question. In addition, licensees are welcome to propose alternative approaches that provide the indicated confidence, but such alternative approaches must be presented in detail and must be shown explicitly to provide adequate assurance that the safety analysis assumptions will not be violated.

NEI has indicated an intent to submit a white paper concerning this matter for NRC consideration. Receipt of that white paper is anticipated in late October or early November, 2004. Licensees may choose to endorse whatever approach and justification is described in that white paper, or to act independently of the NEI. If the NEI approach is found to be acceptable to staff, it will be necessary for each licensee who chooses to use it to affirm that the salient conditions, practices, etc. described in it are applicable to their individual situations.

Please indicate how you wish to proceed in regard to the Setpoint-Related Technical Specification changes addressed in your request. Following are some examples of acceptable actions:

- 1 Demonstrate that the approach that you have used to develop the proposed limits provides adequate assurance that the plant will operate in accordance with the safety analyses. Show that Operability is ensured in the Technical Specifications.
- 2 Suspend consideration of setpoint-related aspects of your request pending generic resolution of the staff concern.
- 3 Revise your request to incorporate Method 1, Method 2, or Performance-Based Technical Specifications.
- 4 Revise your request to incorporate some other approach that you demonstrate to provide adequate confidence that the plant will operate in accordance with the safety analyses and show that Operability is ensured in the Technical Specifications.