Mendiola, Doris

Subject: FW: Comments on Draft Regulatory Guide DG-1141, "Setpoints for Safety-Related Instrumentation," Federal Register Notice (79FR133); Docket ID NRC-2014-0163

Attachments: 10-09-14_NRC_Request for Industry Comments on Draft Regulatory Guide DG-1141, Setpoints for Safety-Related Instrumentation.pdf; 10-09-14_NRC_Request for Industry Comments on Draft Regulatory Guide DG-1141, Setpoints for Safety-Related Instrumentation_Attachment.pdf

From: HUTCHINS, Steven [mailto:sph@nei.org]
Sent: Thursday, October 09, 2014 9:11 AM
Subject: Comments on Draft Regulatory Guide DG-1141, "Setpoints for Safety-Related Instrumentation," Federal Register Notice (79FR133); Docket ID NRC-2014-0163

October 9, 2014

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Ms. Cindy K. Bladey
Office of Administration
Mail Stop: 3WFN 06A-A44M
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001

Subject: Comments on Draft Regulatory Guide DG-1141, "Setpoints for Safety-Related Instrumentation," *Federal Register* Notice (79FR133); Docket ID NRC-2014-0163

Project Code: 689

Dear Ms. Bladey:

The Nuclear Energy Institute (NEI), on behalf of the industry, provides the attached comments for NRC consideration. In a July 11, 2014, *Federal Register* Notice (79FR133), the U.S. Nuclear Regulatory Commission (NRC) requested public comments on Draft Regulatory Guide DG-1141, "Setpoints for Safety-related Instrumentation."

NEI encourages further interactions between the industry and the NRC that would result in an NRC endorsement of existing industry standards on setpoints.

The industry has some concerns with the proposed guidance that could be finalized in a Regulatory Guide (RG). Some of the more significant comments are as follows:

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E-RIDS= ADM-03
Add= P.J. Rebstock (PJR1)
M. Orr (mp01)

1. The DG incorrectly indicates that the Limiting Setpoint (LSP) has to be set with margin to the Analytic Limit (AL) which permits only 2.5% probability of exceeding the AL.
    a. This is not consistent with the established fundamental setpoint methodology basis that states that a setpoint margin to the AL that allows 5% probability of exceeding the AL is acceptable.
    b. This 5% probability basis is in the NRC approved setpoint methodology document, NEDC-31336P-A, and is similar to the basis used for several other NRC approved Monte Carlo safety analyses.

2. While the linear extrapolation is the preferred method of determining time related uncertainties, there are times when this is not practical or is non-conservative.
    a. When time-related uncertainties are established over a short interval, extrapolating to a much longer interval can produce uncertainties that are overly large.
    b. The RG should not disallow "Square-Root-Sum-of-Squares" extrapolation of time-related uncertainties that has proven to be successful.

3. Treating analytical limits as surrogate safety limits has ramifications in the definition of safety limits in Technical Specifications (TS).
    a. Equating analytical limits with safety limits can lead to confusion in the application of the safety limit exceedance requirements in standard TS 2.0.
    b. This could occur whenever a setpoint is found to have exceeded its as-found tolerance during surveillance testing.

4. The 95/95 criterion in the DG applies to instrument error around the setpoint but does not define the margin of the setpoint to the AL. The instrument error around the setpoint and margin to the AL are two different concepts.
    a. The setpoint for an instrument, with same error, can be calculated to be an arbitrary number of sigmas (or standard deviations) away from the AL.
    b. The DG statement that the consequence of applying the 95/95 error criterion is to provide a 2.5% margin beyond the AL is inconsistent with the statistical definition and interpretation of 95/95 given in NUREG-1475 Section 9.12 and 9.13.

Since there is not a significant safety issue being addressed by this draft regulatory guide and an industry consensus standard already exists, NEI encourages further interactions between the industry and the NRC in workshops, teleconferences and meetings to further refine the guidance and achieve endorsement of the existing industry standards.

If you have any questions or require additional information, please contact me.

Sincerely,

Steven P. Hutchins

Senior Project Manager,
Engineering and Operations Support

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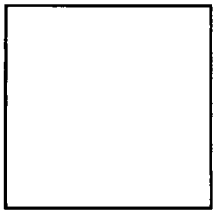

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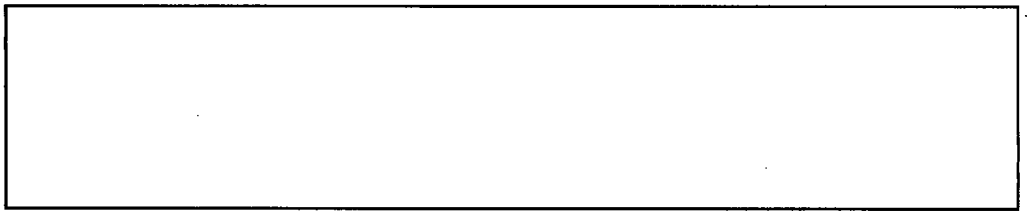

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NUCLEAR ENERGY INSTITUTE

October 9, 2014

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Office of Administration
Mail Stop: 3WFN 06A-A44M
U.S. Nuclear Regulatory Commission
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    a. This is not consistent with the established fundamental setpoint methodology basis that states that a setpoint margin to the AL that allows 5% probability of exceeding the AL is acceptable.

[1] The Nuclear Energy Institute (NEI) is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

   b. This 5% probability basis is in the NRC approved setpoint methodology document, NEDC-31336P-A, and is similar to the basis used for several other NRC approved Monte Carlo safety analyses.

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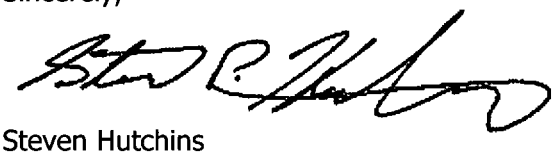
Sincerely,



Steven Hutchins

Attachment

c: Mr. Paul J. Rebstock, Jr., RES/DE/ICEEB, NRC
Mr. Mark P. Orr, RES/DE/RGGIB, NRC

DTE Comments Regarding Draft DG-1141

Comment Category (General, Technical, or Editorial)	Section, Paragraph Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
General	N/A	Sufficient guidance on decimal place usage and rounding guidelines is not provided.	Provide guidance on the number of decimal places to be used in error and setpoint calculations, and define the conservative rounding direction (up or down) for the calculated error and setpoint values relative to the new terms contained in the RG.	Lack of guidance regarding decimal places and rounding in the draft RG.
Technical	Section A, Page 4, First paragraph Sentence 1	Draft Regulatory Guide (RG) states: "This RG applies to all instrument setpoints that are included in plant technical specifications in accordance with the requirements of 10 CFR 50.36, whether the requirements concerning those setpoints are presented directly in the technical specifications or are incorporated by reference." Providing examples of the setpoint requirements (SL/AL) that have been incorporated by reference into TS would be beneficial.	Provide examples of the setpoint requirements (SL/AL) that have been incorporated by reference into TS.	No examples of setpoint requirements in compliance with 10 CFR 50.36 are provided in the Draft Regulatory Guide.
Technical	Section A, Page 4, Second paragraph Sentence 1	Draft RG states: "Appendix B to 10 CFR Part 50 requires that programs and administrative controls be in place to provide adequate assurance that systems associated with significant safety functions be designed to perform satisfactorily in service." No definition is provided for the term "significant safety function" and potential impacts on non Tech Spec instrumentation.	Define the term "significant safety function" to bound the scope of the RG.	Terminology lacks clarity.

DTE Comments Regarding Draft DG-1141

Comment Category (General, Technical, or Editorial)	Section, Paragraph Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
Technical	Section B.2, Page 8, Fifth paragraph Sentence 2	Draft RG states: "It also describes criteria and objectives that the NRC staff believes to be applicable to the uncertainty analyses used to determine suitable setpoint related limits and allowances." The setpoint related limits and parameters depicted on page 10 in Figure 1 do not align with the approved GEH Setpoint Methodology.	Provide guidance for the use of the new analyses to determine suitable setpoint limits and allowances.	The approved General Electric Hitachi (GEH) Setpoint Methodologies were developed based on the consideration of sufficient margins between the allowable limit (AL) and calculated setpoints, TS AV and NTSP, to ensure that there is a high probability that the AL will not be exceeded for all limiting events. The terminology used in this Draft RG differs from current practices.
Technical	Section B, 5.2, Page 17, Third paragraph Sentence 1	Draft RG states: "One consequence of the 95/95 criterion is that there will be a 95 percent probability that the actual trip point for an instrument loop will differ from the As-Left setting by as much as – but not more than – the total loop uncertainty. Figure 2 illustrates this point for an As-Left setting equal to the limiting setpoint and with bias in the actual trip point (ATP) distribution." Conformance to the 95/95 criterion using the one-sided probability distribution method is not addressed in the Draft RG. The margins for the setpoint calculation using one-sided distribution are decreased by a factor of 1.645/2.	Include the one-sided probability distribution method for conformance to the 95/95 criterion.	The approved GEH Setpoint Methodology uses one-sided probability distribution in the development of nominal trip setpoints.
Technical	Section C Page 20 paragraph 1.a	Draft RG states: "Analytical limits and other limits which prevent safety limits from being exceeded constitute surrogate safety limits." The term surrogate safety limit is not defined.	Clarify the application of the term "surrogate safety limits," especially for cases with no analytical limit.	In accordance with GEH Setpoint methodology, the AL is the process variable value in the safety analysis established to prevent reaching the SL.

DTE Comments Regarding Draft DG-1141

Comment Category (General, Technical, or Editorial)	Section, Paragraph Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
Technical	Section C Page 21 paragraph 4.c.(2)	Draft RG states: "Time related uncertainties should be determined by linear extrapolation of the uncertainty specification, not by the Square Root of the Sum of the Squares (SRSS) of multiple intervals." This stipulation is not consistent with the approved GEH Setpoint Methodology.	Clarify the acceptability for use of the SRSS method with respect to 6-month interval calculations.	The approved GEH Stepoint Methodology allows the application of the SRSS calculation method to account for multiple 6-month intervals.
Technical	Section D, Page 28, First paragraph Sentence 2	Draft RG states: "In addition, it describes how the NRC staff complies with 10 CFR 50.109, "Backfitting" and any applicable finality provisions in 10 CFR Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants." The RG should provide guidance on current licensing basis impact and the acceptability of future license amendment requests referencing the GEH Setpoint Methodology.	Confirm the currently approved methodologies remain applicable for determining the Technical Specification (TS) allowable values (AVs) and related nominal trip setpoints (NTSPs).	The terminology and calculation methods outlined in this draft are not equivalent to those used in the NRC approved GEH Setpoint Methodology, NEDC-31336P-A.

Industry Comments on Draft Regulatory Guide DG-1141,
"Setpoints for Safety-Related Instrumentation"
(Docket ID NRC-2014-0163)

By Michael Carroll (Duke Energy)

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
?	C.4.c.(2)	RG should not disallow SRSS extrapolation of time related uncertainties.	Delete "not by the SRSS of multiple intervals" and "not SRSS(1%,1%) = ..."	While the linear extrapolation is the preferred method of determining time related uncertainties, since this is conservative for the calculation of the TLU, there are times when this is not practical or is non-conservative. When time related uncertainties are given over a short interval, extrapolating to a much longer interval can produce uncertainties that are overly large. Generally, common sense would tell us that these excessive extrapolated uncertainties are not suitable for calculation of the TLU, even though it would be conservative to do so, since the impact to plant operational margin could be significant. Also, overly large time related uncertainties would be non-conservative for calculating Allowable Values and/or As-Found Tolerances, as this would tend to hide instrument degradation during surveillances. The SRSS extrapolation method can be used under certain conditions to provide a more realistic and conservative (for AV or AFT) time related uncertainties.

Comments on Industry Comments on Draft Regulatory Guide DG-1141,
"Setpoints for Safety-Related Instrumentation"
(Docket ID NRC-2014-0163)

By NuScale Power

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section A, Scope, Page 4	Reason for Change: The scope discussion is not consistent with the with the DG title. It is also not aligned with the reason for the revision described in Section B.1, which is to resolve the issues described in Regulatory Information Summary (RIS) 2006-17, *NRC Staff Position on the Requirements of 10 CFR 50.36, "Technical Specifications," Regarding Limiting Safety System Settings During Periodic Testing and Calibration of Instrument Channels*. The RIS is specifically focused on Limiting Safety System Settings (LSSSs). As a separate note, it should be clear that the methods specified in DG-1141 should not be applied to Emergency Operating Procedure (EOP) setpoints. Specifically, the application of 95/95 criteria (in Section C.6) can lead to actions points that may lead to premature operator actions. The appropriate criteria for the EOPs are to use best-estimate data.	Modify the first paragraph as follows: This RG applies to Limiting Safety System Settings~~all instrument~~ setpoints that are included in plant technical specifications or a setpoint control program in accordance with the requirements of 10 CFR 50.36~~, whether the requirements concerning those setpoints are presented directly in the technical specifications or are incorporated by reference~~.	The typical industry methods used by vendors and utilities result in conservative calculations for establishing the basis for the analytical limits that the LSSS is designed to protect. Vendors typically retain margin between Analytical Limits and Safety Limits, such that they will not be the same values. Two examples illustrate the point. For core related limits, the Analytical Limits are largely based on the worse time in core life. For cycle burnup dependent limits, there can be substantial margin most of the time. For non-LSSS TSs such as the ultimate heat sink temperature limit, the limit is based on the bounding accident demand coincident with the bounding single failure using the ASME degraded pump curve with the worst-case heat exchanger fouling along with the maximum ambient temperature and minimum heat sink reservoir level. The expansive treatment of the small instrument errors for these cases focuses additional industry resources in areas of little safety significance.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section B.2, Definitions, Page 8	The definition of setpoint does not capture the essential characteristic of this term as a reference value to initiate a protective action. It would be more clear and appropriate to included it in the trip point definition rather than in the setpoint definition.	Change the definitions as follows: Setpoint: the value of the process variable at which a channel is ~~*observed* to trip[1] under *test or calibration* conditions, or is~~ *intended* to trip under *operating* or *design basis* conditions. Trip point: the value of the process variable at which a channel *actually does* trip under *operating* conditions (including design basis conditions). The trip point is observed under test and calibration conditions to ensure that the safety functions will be initiated within approved setpoint related limits and tolerances.	The two-fold purpose of this RG is to define the methodology for establishing and maintaining setpoints. The setpoint is a reference value established using the methodology determined using the guidance provided in this RG. The "observed trip under test or calibration conditions" is not a reference value, but an actual trip point also subject to measurement errors associated with test equipment and equipment conditions at the time of the test. The observed trip point under test conditions is subject to the limits defined in this RG as guidance for maintaining setpoints.
	B.2 Background and Overview, Pages 8-9	Revise sentence for clarity.	Modify the last sentence on Page 8 as follows: Plant technical specifications[2] are designed to prevent plant safety limits from being exceeded. Plant safety analyses[3] show that safety limits will not be exceeded if certain actions are initiated before the limits established in the safety analyses (called analytical limits)~~certain other limits~~ are exceeded. ~~Those other limits are called "analytical limits."~~	

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	B.2 Background and Overview, Pages 9	Treating Analytical Limits as surrogate Safety Limits has ramifications in definition of Safety Limits in TSs.	Modify the paragraph at the top of Page 9 as follows: Because protection of analytical limit is used to ensure protection of safety limits, ~~the NRC staff considers analytical limits to be surrogate safety limits and therefore to be subject to the same requirements and guidance as safety limits (Section C.1 of this RG). S~~setpoint related technical specification limits are therefore selected so as to provide adequate protection of analytical limits.	Equating Analytical Limits with Safety Limits can lead to confusion in the application of the Safety Limit violation requirements in Standard TS 2.0 whenever a Setpoint is found to have exceeded its As-Found Tolerance during surveillance testing.
	B.3 Industry Standards, Page 9	Make it consistent with the previous paragraph.	Revise the following sentence: The NRC staff does not endorse, and has not previously endorsed, the ISA's 67.04 series documents other than ISA-S67.04-1994~~ANSI/ISA 67.04.01~~ and earlier versions of that standard.	
	Figure 1: Setpoint Parameters of Regulatory Interest, Page 10	Revise the two notes related to AFT.	Revise the two notes related to AFT as follows: Potentially Excessive Deviation (see notes 3 and 4)	Both notes are related to AFT.

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	Figure 1: Setpoint Parameters of Regulatory Interest, Page 10	Revise for correctness.	Revise the parenthetical statement as follows: (This figure is used instead of~~supersedes~~ the figure in Section 4 of ISA 67.04.01.)	The RG does not supersede the ISA standard. It only explains an acceptable way to use the standard.
	Section B.4.1, Setpoint Related Limits and Parameters, Note 2, Page 11	Revise for clarity.	Modify Figure 1, Note 2, as follows: 2. Setpoint deviation may be computed as the difference between the as-found value (AsF) of the setpoint and the nominal setpoint (NSP) if all the conditions listed in Section C.7b~~.~~ of this RG are met. ~~addresses the acceptability of the evaluation of setpoint deviation relative to the nominal setpoint (NSP).~~ If the indicated conditions of Section C.7b are not met, setpoint deviation should be evaluated relative to the previous as-left setpoint (pAsL).	

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section B.4.1, Setpoint Related Limits and Parameters, Note 3, Page 11	Revise for clarity.	Modify Figure 1, Note 3, as follows: 3. If the magnitude of an observed deviation exceeds the as-found tolerance (±AFT), the deviation should be evaluated in accordance with ANSI/ISA 67.04.01-2006 Section 6.1 and Section C.7c of this RG. The AFT should be established in accordance with Section C.7.d of this RG. If the actual setting (as-found setpoint) of the channel is found to be conservative with respect to the Allowable Value but is beyond the as-found tolerance band, the channel is operable, but degraded. ~~Section C.7c of this RG addresses the acceptability of occasional deviation in excess of the as-found tolerance (±AFT), provided that the deviations are neither too large nor too frequent. Section C.7c(3) of this RG recommends that the deviation should be deemed excessive if the as-found value (AsF) of the setpoint is less conservative than the allowable value (AV) regardless of whether or not the as-found tolerance is exceeded and whether or not the occurrence of this condition is chronic.~~	Provides consistency with the language used in the approved version of TSTF-493, revision 4 (see Federal Register Volume 75, Number 90, Pages 26294-26295), and the guidance provided in RIS 2005-20, *Revision to Guidance Formerly Contained in NRC Generic Letter 91-18, "Information to Licensees Regarding Two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and on Operability"*.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section B.4.1, Setpoint Related Limits and Parameters, Note 4, Page 11	Revise for clarity.	Modify Figure 1, Note 4, as follows: 4. The use of an allowable value (AV) in Technical Specifications is optional. An AV may be used as an additional basis for assessment of the as-found setpoint; but, it is not suitable as a substitute for the as-found tolerance assessment specified in Section C.7c of this RG. Use of an AV alone would ignore excessive deviation in the conservative direction and, therefore, is not adequate as an indication of proper channel operation.~~The relationship of allowable value to analytical limit, limiting setpoint, and the as-found tolerance limit is methodology dependent. The allowable value might be more or less conservative than the as-found tolerance limit. See allowable value definition and discussion and Section C.7e later in this RG.~~	

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	B.4.1 Setpoint Related Limits and Parameters, Page 11	Editorial comment.	Modify the third paragraph after Note 4 as follows: The overall objectives in the selection of setpoint related limits are • to provide adequate assurance that safety limits will not be exceeded, • to provide adequate assurance that the criteria and data on which those limits have been based are consistent with the observed operation of the equipment associated with each setpoint, and • to support an assessment as to whether the equipment associated with a setpoint has been functioning as expected and required.	

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	B.4.1 Setpoint Related Limits and Parameters, Page 11	Make the discussion consistent with the definitions provided in Section 5 of the RG. The AV discussion should be deleted in this section so that the two primary considerations (LSP and AFT) are emphasized.	Modify last paragraph as follows: This RG addresses two primary considerations regarding acceptability limits on measured values for instrument setpoints: 1. Limits on the acceptable measured value of a setpoint: *Limiting Setpoint (LSP)*: the least conservative acceptable value for an as-left setpoint~~a limit on the value to which a setpoint may be adjusted (see definition and discussion later in the RG)~~ ~~*Allowable Value (AV)*: a limit on the value at which a setpoint may be found (see definition and discussion later in this RG)~~	One of the goals of the RG is to clarify the use of terminology used in setpoint documents. The RG considers the AV concept to be optional and endorses only limited use in Sections B.5.1 and C.7.e. Including the AV in this list of primary considerations for acceptability limits incorrectly promotes its importance.

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	B.4.1 Setpoint Related Limits and Parameters, Page 12	Make the discussion consistent with the definitions provided in Section 5 of the RG.	Modify Item 2 as follows: 2. Limits on the acceptable change in the measured value of a setpoint during the interval between scheduled measurements: *As-Found Tolerance (AFT)*: the maximum amount by which the measured setpoint is expected to change over the course of a calibration interval~~a limit on the amount by which a measured setpoint may differ from the previous setting, in either the positive or the negative direction (see definition and discussion later in this RG)~~	One of the goals of the RG is to clarify the use of terminology used in setpoint documents.
	B.4.1 Setpoint Related Limits and Parameters, Page 12	Delete the second bullet.	Delete the second bullet: ~~• The allowable value can provide additional assurance that a channel would trip at an appropriate value at the time the setpoint is measured, with additional margin for environmental changes etc. that might exist at the time the associated safety function is needed. See Section C.7e of this RG.~~	This unqualified statement, without the limits specified in Section C.7.e, provides ambiguous guidance with regard to the use of the allowable value. Section 5.1 clearly states that the allowable value alone cannot provide adequate assessment of setpoint deviation. Sections 5.1 and C.7.e provide adequate guidance on the optional, limit use of the allowable value.

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	Section B.4.2 Uncertainty Analyses: Establishing Margins and Limits, Page 13	The proposed insertions are made for clarity and a typographical error is corrected.	Modify last paragraph as follows: It is usually understood that, in establishing a limiting value for a setpoint, it is better to overestimate uncertainties than to underestimate them. <u>This point is illustrated in Figure 1, which shows that the relationship between the analytical limit (AL) and the limiting setpoint (LSP) is determined by the total loop uncertainty (TLU). Overestimating uncertainties increases the value of TLU, which results in a more conservative LSP.</u> However, when establishing a limiting value for acceptable setpoint deviation, it is better to underestimate uncertainties. The objective of deviation assessment is to confirm that a setpoint has not changed by more than the anticipated amount. <u>This point is illustrated by the as-found tolerance (AFT) shown in Figure 1.</u> Excessive deviation could indicate equipment malfunction or problems with the uncertainty analysis on which the anticipated deviation and other setpoint related limits and parameters have been based. If the magnitude <u>of</u>~~or~~ the anticipated deviation were overestimated, the effectiveness of the assessment would be reduced.	This paragraph also makes a very important distinction. It would be helpful to include an example to illustrate the concept of overestimating versus. underestimating uncertainties. For example, it is conservative to overestimate temperature effects using the maximum anticipated ambient temperature changes when calculating TLU to determine the limiting setpoint value; however, it is conservative to underestimate temperature effects in determining setpoint deviation limits since calibration is typically performed at nominal ambient temperature. Including any temperature uncertainty in the latter case, unless it can be justified, would reduce the effectiveness of the deviation limit.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section B.5.1 Setpoint Deviation: Evaluating the As-Found Setpoint (AFT, AV), Page 15.	Modify the last two sentences of the fourth paragraph.	Modify the last two sentences of the fourth paragraph as follows: The NRC staff considers this to be an appropriate balance between detection efficiency and the avoidance of false detections~~spurious actuations~~. The use of nominal set point based deviation assessment rather than previous as-left value based assessment can result in a significant increase in the likelihood of false detections~~spurious actuations~~.	There is no basis for linking "false detections" to "spurious actuations."
	Section B.5.2 Constraining the As-Left Setpoint (LSP, NSP, ST), Page 16	The RIS 2006-17 definition of LSP should be retained as the basis for this regulatory guide.	Change the Limiting Setpoint (LSP) definition as follows: *Limiting Setpoint (LSP)*[8]: the limiting setting for the channel trip setpoint (TSP) considering all credible instrument errors associated with the instrument channel~~the least conservative acceptable value for an as-left setpoint~~.	The Limiting Setpoint (LSP) definition does not address the basis for establishing the setpoint value. The focus on setpoint maintenance ignores the basic relationship between the LSP and the Analytical Limit (AL) shown in Figure 1. Limits on the as-left value of the limiting setpoint are equally important, but the discussion in this section stresses the importance of the total loop uncertainty (TLU) in establishing the LSP.
	Section B.5.2 Constraining the As-Left Setpoint (LSP, NSP, ST), Page 17	Delete last sentence in the last paragraph in the subsection on Limiting Setpoint.	Delete last sentence in the last paragraph in the subsection on Limiting Setpoint as follows: ~~Reduction in the separation between the analytical limit and limiting setpoint to anything less than the full value of total loop uncertainty, however, should be strongly avoided.~~	To be consistent with statements earlier in the subsection that the limiting setpoint should be separated from the analytical limit by an amount not less than the total loop uncertainty, and that it is not appropriate to reduce the total loop uncertainty to any value less than the total loop uncertainty.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section 5.2 Constraining the As-Left Setpoint (LSP, NSP, ST), Page 18	The two-sided statistical approach effectively establishes a 97.5% probability of getting channel trip before the process variable reaches the Analytical Limit. It is not consistent with established regulatory practice for treatment of important parameters with a statistical basis.	Modify the discussion associated with Figure 2 related to two-sided statistics to reflect use of a one-sided statistical basis for providing reasonable assurance that Analytical Limits are not exceeded.	The established regulatory practice is to use the 95% confidence level (the so-called 95/95 statistical approach). NuScale believes that implementation of the more restrictive limits could increase plant trip/transient probability, since operating margins would be reduced. This unintended consequence was not considered in the Regulatory Analysis for DG-1141.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section C.4 Uncertainty Analyses, Page 22	Inclusion of dynamic effects within the setpoint methodology, as required by Section C.4.c(3), is inconsistent with industry practice.	Delete Item c.(3): ~~(3) Section 4.4g: Consideration of dynamic effects should include dynamic effects related to the relationship between the parameter of interest and the parameter actually sensed by the instrument, as well as consideration of the time required for a demand signal to result in the needed action. Some examples include: transport delays associated with the sensing line; delays related to the physical process whereby the parameter of interest is realized at the sensing instrument; and time required for actuated equipment (such as a large gate valve) to perform its safety function. Delays already accounted for in the safety analyses should be recognized in the uncertainty analyses, with a brief description of how they have been accounted for.~~	Time delays and dynamic effects associated with protective actions of safety systems should not be treated as an instrument uncertainty in the calculation of TLU. Protection system response time is treated as a separate category of instrument channel performance in the Technical Specifications. The examples of dynamic effects in this section are addressed in determining the acceptance criteria for response time testing required by Technical Specifications.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section C.4 Uncertainty Analyses, Page 22	Add clarification to Item c.(4.	Add clarification to Item c.(4) as follows: (4) ... suitability of that method for the particular application should be explained and justified. <u>It is expected that the setpoint calculation preparer evaluates for any known dependence; however, a formal analysis to demonstrate that all Square Root Sum of the Squares parameters are independent it not required.</u>	Clarification of expectations that the evaluation of independence uses reasonable engineering judgment rather than a formal proof of independence.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section C.4 Uncertainty Analyses, Page 23	Revise for clarity.	Modify Paragraph as follows: i. Setpoint related limits that are not generally subject to NRC review – such as for setpoints in a setpoint control program under NRC Technical Specifications Task Force Traveler TSTF-493, "Clarify Application of Setpoint Methodology for Limiting Safety System Settings," option B, (Ref. 20) controlled under 10 CFR 50.59, "Changes, Tests, and Experiments" – should be developed in accordance with a methodology that conforms to this ~~or a later version of this~~ RG. Prior NRC reviews not based on this or a later version of this RG might have been application specific, and might not have addressed these provisions adequately to support applications outside the original context.	Make the discussion consistent with the limitations described in Section D of the RG.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section C.6 Uncertainty Data and the 95/95 Criterion, Page 25	To encompass the small sample size environmental qualification testing required for digital I&C equipment by RG 1.209.	Modify Item (e) as follows: e. For channel performance uncertainty data that are typically not based on a large number of observations, such as device performance data relating to qualification type tests (e.g., digital system environmental, post-accident, or seismic conditions), the NRC staff expects licensees and applicants to account for such values in the form of bounding estimate values, accompanied by supporting analyses that demonstrate the bounding values to be appropriate.	It would be helpful to have additional discussion on what the NRC staff expects in the way of supporting analyses that demonstrate the bounding values are appropriate.
	Section C.7 Setpoint Deviation: Evaluating the As-Found Setpoint, Page 25	It would be both impractical and inappropriate to require that all past deviations be addressed.	Modify Paragraph as follows: c. ... the magnitude of the present deviation and of past deviations, in particular addressing all relevant past deviations in excess of the as-found tolerance. The justification should include consideration ...	At some point historical data loses relevance and data related to equipment that has been replaced or modified is not relevant.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section C.7 Setpoint Deviation: Evaluating the As-Found Setpoint, Paragraph d. (2), Page 26	This section of the draft RG should be made consistent with Branch Technical Position (BTP) 7-12.	Modify item, d.(2) as follows: (2) The as-found tolerance should include only those uncertainty components which are applicable to the as-found value measurement at the time the measurement is taken. <u>If testing is performed in an environmentally controlled area at essentially the same ambient temperature as the previous test, it is not conservative to include maximum temperature effect uncertainties in the as-found tolerance.</u>	This section cautions that to provide a high degree of assurance that setpoint deviation will be detected the as-found tolerance should include only those uncertainty components which are applicable at the time measurements are taken. Branch Technical Position (BTP) 7-12 Section 3.A contains a definition of Acceptable as-found band with a list of uncertainties that could be included in the as-found tolerance. This list of possible uncertainties includes normal environmental effects. Neither the DG nor the ISA standard address when it is appropriate to include normal temperature effects in the as-found tolerance. If testing is performed in an environmentally controlled area at essentially the same ambient temperature as the previous test, it is not conservative to include maximum temperature effect uncertainties in the as-found tolerance.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section Glossary, Page 30	Reason for Change: The definition of setpoint does not capture the essential characteristic of this term as a reference value to initiate a protective action.	Change the definitions as follows: ~~**Actual trippoint (ATP)** – the value of the process variable at which a channel actually does trip under operating conditions (including design basis conditions). Because of the unavoidable presence of measurement uncertainty, ATP is a random, rather than a fixed, value. *(See related discussion under "Setpoint Related Limits and Parameters") Sometimes referred to as "Trippoint." Compare with "setpoint." The "actual trippoint" should not be confused with the phrase "Actual Trip Setpoint" that appears in ISA 67.04.01-2006 and refers to a related but not identical concept.*~~	The two-fold purpose of this RG is to define the methodology for establishing and maintaining setpoints. The setpoint is a reference value established using the methodology determined using the guidance provided in this RG. The "observed trip under test or calibration conditions" is not a reference value, but an actual trippoint also subject to measurement errors associated with test equipment and equipment conditions at the time of the test. The observed trippoint under test conditions is subject to the limits defined in this RG as guidance for maintaining setpoints. As such, it would be more clear and appropriate to included it in the trippoint definition rather than in the setpoint definition.

Comment Category	Section, Paragraph, Sentence	COMMENT	PROPOSED RESOLUTION	BASIS FOR COMMENT OR RESOLUTION
	Section Glossary, Page 31	The definition of setpoint does not capture the essential characteristic of this term as a reference value to initiate a protective action.	Change the definitions as follows: **Setpoint** – the value of the process variable at which a channel is ~~*observed* to trip[1] under *test or calibration* conditions, or is~~ intended to trip ... **Trippoint** - ~~See "Actual Trippoint."~~ the value of the process variable at which a channel *actually does* trip under *operating* conditions (including design basis conditions).~~–~~The trippoint is observed under test and calibration conditions to ensure that the safety functions will be initiated within approved setpoint related limits and tolerances. Because of the unavoidable presence of measurement uncertainty, ATP is a random, rather than a fixed, value. *(See related discussion under "Setpoint Related Limits and Parameters") Sometimes referred to as "Trippoint." Compare with "setpoint." The "actual trippoint" should not be confused with the phrase "Actual Trip Setpoint" that appears in ISA 67.04.01-2006 and refers to a related but not identical concept.*	The two-fold purpose of this RG is to define the methodology for establishing and maintaining setpoints. The setpoint is a reference value established using the methodology determined using the guidance provided in this RG. The "observed trip under test or calibration conditions" is not a reference value, but an actual trippoint also subject to measurement errors associated with test equipment and equipment conditions at the time of the test. The observed trippoint under test conditions is subject to the limits defined in this RG as guidance for maintaining setpoints. As such, it would be more clear and appropriate to included it in the trippoint definition rather than in the setpoint definition.

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SOUTHERN COMPANY

October 3, 2014

NL-14-1512

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Comments on Draft Regulatory Guide DG-1141, "Setpoints for Safety Related Instrumentation" (Docket ID NRC–2014–0163)

Dear Mr. Hutchins:

Your letter dated August 19, 2014 to Nuclear Energy Institute Administrative Points of Contact requested industry comments on Draft Regulatory Guide DG-1141, "Setpoints for Safety Related Instrumentation" (Docket ID NRC–2014–0163). Accordingly, you will find enclosed comments from Southern Nuclear Operating Company in the format requested by your August 19, 2014 letter.

As general comments, SNC offers the following as overarching issues which need to be addressed:

- Broadened Scope – The scope of this regulatory guidance is increased to include all setpoint values associated with plant Technical Specifications. In the past, the guidance was limited to setpoints which were safety-related, associated with a protection system, and associated with plant Technical Specifications.
- Endorsement of ANSI/ISA 67.04.01 – As proposed, the guidance takes numerous exceptions to the ISA standard. Our recommendation is that ISA and the NRC staff continue to resolve differences in this ISA standard. The preference is to have an ISA standard which the NRC staff can endorse.
- Terminology – This proposed regulatory guidance adds new terms and provides alternative definitions for others. Our recommendation is that ISA and the NRC staff continue to resolve differences which prevent endorsement of a common set of terminology.
- 95/95 Criterion – Compliance with the 95/95 criterion cannot be achieved in some cases due to a small statistical population size. Our recommendation is to develop additional guidance that provides an acceptable method to comply with the 95/95 criterion when only small statistical population sizes exist.

If you have any questions or comments, please contact Doug McKinney at (205) 992-5982.

Respectfully submitted,

C. R. Pierce

C. R. Pierce
Regulatory Affairs Director

CRP/DN/cbg

Enclosure: SNC Comments on Docket ID NRC–2014–0163

cc: Southern Nuclear Operating Company
Mr. B. L. Ivey, Vice President – Regulatory Affairs
Mr. B. J. Adams, Vice President – Engineering
SNC Document Services - RType: CGA02.003

Enclosure 1

Comments on Draft Regulatory Guide DG-1141, Setpoints for Safety Related Instrumentation"
(Docket ID NRC–2014–0131)

By Southern Nuclear

#	Section, Page, Line #	Comment	Proposed Resolution	Basis for Comments or Resolution
1	General	In general, the guide is too lengthy covering topics already discussed in ANSI/ISA RP67.04, Part 1. This redundancy of guidance documents leads to the potential for contradicting information. Reference to the ANSI/ISA S67.04 document is adequate for a large part of the sections.	Recommend endorsing ISA documents or sections and remove the redundant sections from DG-1141.	Elimination of redundant guidance.
2	Page 4, "Scope" Section	At the August 14th public meeting, the scope as defined on page 4 was discussed. The Industry challenged that the scope of this regulatory guide had been substantially increased because it was no longer limited to safety-related setpoints used for protection systems which are addressed in the Technical Specifications. The Staff stated that it was not their intent to increase the scope for the regulatory guide.	Recommend clarifying the scope on page 4 so that it is limited to only safety-related setpoints used in protection systems which are addressed in the Technical Specifications. Currently the scope is increased to include any instrument setpoint that is included in plant technical specifications.	The scope of this regulatory guide needs to be maintained instead of increased.

3	Page 8, Section 2	While the definition and discussion of "trippoint" is factual, there is not a need to add this material to this version of the regulatory guidance. The approved uncertainty methodologies address contributors to the trippoint such as readability and measurement errors. In addition trippoints cannot be measured. If the trippoint is not measurable by the licensee, then this guidance does not need to create this new term. Furthermore, trippoints are not addressed in the plant Technical Specifications, the discussion in this regulatory guidance is not appropriate and complicates this guidance.	Recommend removing the discussion of trippoints from this guidance. Since trippoints are not addressed in the plant Technical Specifications, the discussion in this regulatory guidance is not appropriate and complicates this guidance.	Since trippoints are not addressed in the plant Technical Specifications, the discussion in this regulatory guidance is not appropriate and complicates this guidance.
4	Page 9, Section 2	The discussion of "analytical limits" being considered as "surrogate safety limits" generates questions which are not answered in Section 2 or Section C.1. For example, it is not clear how much margin is required between an analytical limit and a safety limit. It is not clear whether these two terms are now interchangeable in design bases or licensing bases documentation.	Recommend clarifying if "safety limit" and "analytical limit" are now interchangeable terms or if there is a requirement to have margin between these terms.	Clarifying how the terms "safety limit" and "analytical limit" will be used will reduce confusion in the future.
5	Page 9, Section 2	Since the guidance discusses "surrogate safety limits" both on pages 8 and 9 as well Section C.1 on page 20, recommend combining the discussion into one place in the guidance. Since the staff's guidance is provided in Section C.1, recommend moving the information on "surrogate safety limits" from pages 8 and 9 to Section C.1 on page 20.	Recommend transferring the information on "surrogate safety limits" from the "Discussion" Section on pages 8 and 9 to the "Staff Regulatory Guidance" Section C.1 on page 20.	Delete information that is repeated in the two different sections of this guidance.

6	Page 9, Section 3	Recommend only listing which ISA documents have been endorsed and which documents have not been endorsed by the NRC. The bullets describing the content of documents which are not endorsed is not required and distracts from the purpose of the guidance.	Recommend deleting the bullets which describe the content of documents which are not endorsed. This additional information is not important to the purpose of this guidance.	Removal of unnecessary information improves the guidance.
7	Page 10, Section 4.1	Acknowledging that terminology is not consistent throughout the industry is not a valid justification for providing an additional set of definitions. It would be better to work with ISA to provide a common set of definitions instead of introducing new definitions. An alternative solution is to endorse ISA terminology with certain exceptions. Then describe the exceptions.	Recommend working with ISA to develop a common set of definitions. An alternative is to endorse the ISA definitions with certain exceptions and then describe the exceptions.	A common terminology is needed to improve alignment within the industry.
8	Page 10, section 4.1, Figure 1	Since Figure 1 of this draft RG is presenting more detail than the figure in Section 4 of ANS/ISA 67.04.01-2006, and is to be used in lieu of that figure, it would be helpful to provide a table or mapping diagram of which terms within the draft RG are considered "new" or "re-defined" with respect to the ANS/ISA standard and which terms could be considered unchanged or matching.	Recommend mapping of proposed new terminology to the terminology used in the ANS/ISA 67.04.01-2006 standard.	Terminology consistency
9	Page 11, Section 4.1, Figure 1, Note 4	In explanation of Figure 1, note 4 states that the allowable value (AV) may be more or less conservative than the as-found (AF) tolerance limit. That statement combined with Section C.7e will confuse personnel trying to develop clear guidance for operators performing an immediate determination of operability (IDO).	Recommend revising Figure 1, note 4 to align with Section C.7e and to improve clarity.	Improve alignment of figure 1 with Section C.7e.

10	Page 12, general comment	Since the RG discusses "acceptable amount that a measured setpoint might change over the course of a calibration interval" and "anticipated errors" over periods between measurements, it may be helpful to discuss the level of documentation or pedigree needed to validate these assumptions. It would be assumed that a large portion of this information would be supplied via manufacturer/vendor data and product literature, but in many cases the detailed calculations and methodology used by the vendor may vary. This is mainly concerning the selection of setting tolerance and as-found tolerance.	Recommend discussing the reliance of vendor data to validate assumed or anticipated error.	Improve clarity of guidance associated with vendor data.
11	Page 12, Section 4.1	Consider removing the italicized statements under bullets 1 and 2. While the statements are true, the additional commentary only restates information in the bullets.	Recommend deleting the italicized statements on page 12 underneath bullets 1 and 3.	Redundant statement need to be removed.
12	Pages 12 and 13, Section 4.1	Under the "In Summary" heading, there are 3 bullets which address "limit" and "limiting values". Recommend revising these terms to "limiting setpoints" and "limiting safety values" to maintain consistency in terminology. The wording in these bullets is ambiguous and can cause confusion about which type of "limit" is being discussed. It could a "limiting setpoint", "safety limit", and/or "analytical limit".	Recommend revising these terms to "safety limits" and "limiting safety values" to maintain consistency in terminology.	Maintain consistency of terminology.

13	Page 13, "In summary" section, 3rd bullet	This bullet states that the limit on the acceptable measured value for a setpoint at calibration should include consideration of anticipated error in the actual trippoint over the entire period between measurements. Then reference is made to Section C.8 of the RG. The way the "anticipated error" over the entire period is discussed, it sounds like instrument/setpoint drift. It would be helpful to delineate or further explain this "anticipated error" as it relates to total loop uncertainty. While instrument drift is included in the loop uncertainty, it is not clear whether "anticipated error" should be taken to be equivalent. While the discussion in section C.8 is clear with regards to including the TLU at a minimum for margin to the analytical limit, the term "anticipated error" is not mentioned in C.8.	Recommend providing clarification on what is meant by "anticipated error in the actual trippoint" and how this relates to the discussion in section C.8 with regard to TLU.	Document is not consistent on this terminology
14	Page 13, Section 4.1	In the last paragraph of Section 4.1, the following statement is made: "The presence of unavoidable measurement error makes it impossible to know the exact value of the actual trippoint at the time of measurement or at any other time." Based upon that statement, the discussion of "trippoints" needs to be removed from this guidance. If a licensee cannot measure a trippoint, then trippoints should not be a value which is discussed in regulatory guidance. The licensee and the staff cannot prove or disprove compliance with a value which cannot be quantified.	Recommend removing the discussion of "trippoint" since a trippoint cannot be measured. Recommend this regulatory guidance remain focused on values which can be quantified and measured.	The term "trippoint" cannot be measured.

15	Page 13, Section 4.2	Section 4.2 can be deleted. The establishment of a setpoint is independent of the type of technology. The type of technology is addressed during the calculation of uncertainty but the establishment of a setpoint is not impacted by the use of digital components.	Recommend deleting Section 4.2	The type of technology is addressed during the calculation of uncertainty but the establishment of a setpoint is not impacted by the use of digital components.
16	Page 13, Section 4.2	While Section 4.2 can be deleted because establishment of setpoints are independent of the type of technology, nevertheless Section 4.2 contains valuable information which needs to be captured in the ISA documentation. Recommend working with ISA to include the information in Section 4.2 into the ISA standard. Also consideration should be given to addressing control and configuration of setpoints electronically. This is especially important with the increased number of digital upgrade projects and new plant designs relying primarily on digital control systems.	Recommend working with ISA to include the information in Section 4.2 into their standard.	
17	Page 13, Section 4.3 last paragraph	The last paragraph on this page refers to "establishing a limiting value for acceptable setpoint deviation". It is not clear whether this is referring to setting tolerance or as-found tolerance. Recommend using the corresponding terminology from Figure 1.	Recommend referring to actual terminology used in Figure 1 for the "acceptable setpoint deviation."	Terminology consistency

18	Page14, Section 4.4	At the August 14th public meeting, the issue of 95/95 criterion was discussed. The industry stated that compliance with the 95/95 criterion is so costly in certain circumstances that the best option from a nuclear safety standpoint is not chosen. Industry stated it often has to purchase a much larger lot of components to have a sample size large enough to comply with this criterion. The staff responded by stating that an acceptable method to maintain compliance was to essentially take a penalty (use a larger value) for the uncertainty value. Since the purpose of a regulatory guidance document is to provide acceptable methods for the industry to use in their licensing bases, then it is recommended to document this alternate method of compliance with the 95/95 criterion.	Recommend that the Staff document the acceptability of licensees using a larger uncertainty to comply with the 95/95 criterion when an adequate population size is not achievable without purchasing a much larger sample size of components. This was discussed at the August 14th public meeting.	Providing an acceptable method to comply with regulation is the purpose of the regulatory guidance. Therefore providing an acceptable method to comply with the 95/95 criterion when a population size is insufficient is a tremendous value for both the staff and the licensees.
19	Page 18, Figure 2	The Note to Figure 2 states that the figure is constructed using a simple Gaussian distribution for the actual trippoint. It also states that the actual trippoint distribution will be wider than this idealized Gaussian distribution and the trip probability curve will be lower. It would be useful to show the ideal case followed by an example of the non-idealized Gaussian (real-world) case to effectively illustrate the importance of TLU with respect to the wider distribution. Recommend providing a real world example along with the ideal case for a Gaussian distribution.	Recommend adding another figure for the non-idealized Gaussian case to show the wider trippoint distribution.	Further explanation and visualization of the statistical terminology

20	Page 20, Section C.1	The term "surrogate safety limit" is introduced in this regulatory guidance. From statements in C.1.a and C.1.b, it is not clear which analytical limits would be "surrogate safety limits". For example, the term surrogate safety limit could be applied to technical specification setpoints or to analytical limits assumed or described in safety analyses. Recommend further refinement on the discussion of surrogate safety limits is required.	Recommend revising the definition "surrogate safety limit" further to delineate whether all or a subset of analytical limits are considered surrogate safety limits.	Clarification of terminology
21	Page 21, Section C.3.b(6) and C.3.b(7)	Since Section C provides the Staff's regulatory guidance, recommend Section C.3.b(6) and C.3.b(7) provide guidance on how the licensees should use Sections 4.4. 4.5, 4.6, and 6 from ANSI/ISA 67.04.01-2006. Currently, the licensee does not know if the staff endorses these sections of the ISA document or if the sections in the ISA document are superseded by this guidance. Recommend revising Section C.3.b(6) and C.3.b(7) to provide regulatory guidance to the licensee instead of stating that these are "addressed" in a different section.	Recommend revising Section C.3.b(6) and C.3.b(7) to provide regulatory guidance to the licensee instead of stating that the specific sections in ANSI/ISA 67.04.01-2006 are "addressed" in a different section. An alternative solution is to move Section C.4.c to Section C.3.b(6) and (7).	Stating that a section is addressed does not provide usable guidance.
22	Pages 24 and 25, Section C.6.e	It would be helpful if the staff provided additional guidance on development of bounding values when the population size is small.	Recommend increasing the guidance associated with the development of bounding values when the population sizes are small.	Compliance with the 95/95 criterion when the population size is small is an area of interest and concern by the industry. Additional guidance on methodology in developing bounding values is important to licensees.

23	Page 30, Glossary	In the glossary section there are multiple terms that are covered in ANSI/ISA RP67.04, Part 1, yet the definition is not worded the same. More potential for contradiction and misinterpretation. Even if the staff does not endorse ANSI/ISA RP67.04, Part 1, it can still use the same terminology and definitions.	Recommend using standard definitions.	Clarification of terminology

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
1	General	The RG attempts to provide clarification but instead introduces ambiguity and potential misinterpretation.	Verifiy consistency and accuracy. DO not introduce new terms. Consider indorcement of exidting Industry Consenses Standards.	Draft RG containes many areas open to misinterpretation.
1	Purpose	Includes statement: "... RG addresses the selection ...and of limits useful in the assessment of channel operability." However, "operability" is not mentioned anywhere else in the RG.	Section C.7 does mention evaluating the as-found setpoint, but does not make any connection to operability as suggested in the noted paragraph. Recommendation: replace word "operability" in noted paragraph with word such as "acceptability"	Provide consistency throughout the document.
1	General	The biggest technical concern with the Draft RG is that it has decreed that the Limiting Setpoint (LSP) has to be located with margin to the Analytic Limit (AL) which permits only 2.5% probability of exceeding the AL. This directly violates the GEH fundamental setpoint methodology basis that states that a setpoint margin to the AL that allows 5% probability of exceeding the AL is OK. This 5% basis was in the GEH NRC approved setpoint methodology document NEDC-31336P-A, and is similar to the basis that GEH has used for several other NRC approved GEH Monte Carlo safety analyses.	The draft does not directly state that the previous 5% requirement has been reduced to 2.5%, but Fig 2 and the accompanying discussion clearly implies this conclusion.	The current GEH setpoint methodology, which is highly conservative and technically well developed, provides two separately calculated margins. The first margin is between the setpoint and the AV and the second is a margin between the AV and the AL. These should be continued to be used for new BWR licenses. Setpoints developed by this licensed methodology have enabled plants to operate successfully for many years.
2	2nd and 3rd paragraphs of section 4.4	"probability" NUREG-1475 Rev 1, "Applying Statistics" uses the word "confidence", perhaps only semantics.	Suggest a reference to NUREG-1475.R1.	Well established guidence.
2	3rd ¶	"...these limits can provide assurance..." The purpose is to provide assurance. This implies that just passing these limits will still require more evaluation or something to provide the assurance that they function as intended.	Recommendation: delete the word "can"	
2	3rd ¶	"... *to constitute a limiting safety system setting...*" This appears to be an increase in scope of the definition. If it was obviously a LSSS, it would have been included in previous revisions of this RG. As stated on page 6 of the current revision of this RG (R3), "Section 4.3 of ISA-S67.04-1994 states that the limiting safety system setting (LSSS) may be the trip setpoint, an allowable value, or both. For the standard technical specifications, the staff designated the allowable value as the LSSS. "With this revision, the as-found tolerance (not just the AV) is stated as "constitute[ing] a limiting safety system setting"	*This is an expansion of the definition without a rulemaking.* Recommendation: don't backfit	
2	4th ¶	"The use of an allowable value in..." This is contrary to all the standard technical specifications described in the NUREGs referenced earlier in the RG.	A RG is not the place to place to establish TS content – revise the referenced NUREGs and use the rulemaking process if it needs to be changed.	Align with already published NRC Documents.
2	End of 4th ¶	"This is independent of the shape of the actual trippoint distribution." The basis for using 95% throughout this RG is a normal distribution. For practical purposes that is the easiest to find tables of confidence, portion of population, and probability. However, to now make a statement that 2½% is independent of shape is inconsistent with prior insistence on normal distribution. What is required for 2½% as compared to the 5% is that the distribution be symmetric – so shape does matter, at least one characteristic.	Recommendation: Reword sentence to state "This is true for symmetric trippoint distributions."	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
2	Reason, 4th bullet	"... use of an "Allowable Value" for a setpoint, ..." The word limit is used more consistently as what is included in TS.	Suggestion: change the word "setpoint" to "limit"	
2	Scope	"... or are incorporated by reference" What does this mean? If a setpoint is part of a program listed in section 5, Administrative Controls, is that "incorporated by reference. Appears to be an increase in scope of RG coverage. If a setpoint is part of an approved program, then doesn't the approved program control the method?	Recommendation: Clarify what is meant "incorporated by reference". If it is to include any such setpoint, then I recommend that it be reworded as "... or are specifically stated as being incorporated by reference."	This seems to be a scope increase.
3	3rd bullet, italics paragraph	"In addition, if a setpoint changes by more..." The second sentence is not really "in addition", it is the why behind the first sentence. In this case, "In addition" is not a good transition phrase.	Suggestion: Use a different linking or transition phrase.	Second sentence is the "why" behind the first sentence.
3	4th ¶ of section 4.4	"Use of such data as if it were 95/95 should be justified. ...to support a statistical analysis to develop an equivalent population value that does meet the 95/95 criterion." This seems to indicate that if a vendor is not able to confirm 95/95 then the station might be able to receive enough vendor data to do a statistical analysis themselves. What is the problem being solved with this analysis? Is there reason to consider the vendor data suspect? At least the uncertainties related to normal operations and testing conditions are validated to some degree at every calibration or functional test (depending on station specific criteria).	Similar comment as page 7 #1. What is the problem being solved? If there is no problem, then how can there be a benefit for any cost-benefit analysis?	
3	definition	This definition again makes the assumption that the setting tolerance is a bias (see BA4 on page 10) and not a random term included in the TLU to define the LSp. Again this is a throw-back to an old practice, as noted in comment #1 for page 11.	Recommendation: Recognize that the setting tolerance can be random, and be included in the TLU used to establish LSp. That is, recognize that ISA use is acceptable.	
3	large bullet #2	Includes statement: "This RG addresses the means by which such limits should be established." Various terms are included, such as AV, LSp, and AFT. However, no statement in section C is made as to which of the various limits should be used in the TS. For example, section C.2.a discusses limits, but makes no indication of which could be used. The first sentence of section C.7.e indicates that AV alone is not sufficient. There are statements in section B, where a statement to the effect "the NRC staff considers to be an LSSS". However, as noted these differ from past NRC publications. This appears to be an attempt to change what constitutes an LSSS, without actually saying so in the Regulatory Guidance section.	Recommendation: make a clear statement somewhere in section C as to which parameters are acceptable options for TS limits. And be consistent with prior NRC publications (e.g. NUREGs listed in this RG), and other established processes.	
3	Scope, 2nd ¶	Paragraph makes a statement about 10 CFR 50 Appendix B that is not related to scope. Combine it with the Appendix B paragraph on page 3, as desired. There were words in a previous draft that expanded the scope of the RG. They were deleted (appropriately) leaving an unneeded single sentence paragraph.	Recommendation: delete entirely the 2nd paragraph from RG.	
3	top ¶, from previous page	Includes statement: "This RG includes assessment of an as-found setpoint as one element of confirmation that an instrument channel is functioning as expected." However, later pages try to call AFT an LSSS. If it is not sufficient to confirm instrument is functioning as expected, should the attempt to call it an LSSS even be considered.	Recommendation: delete later reference to AFT as a potential LSSS.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
3	Trippoint	Inconsistent use of "trippoint" or "actual trippoint" throughout RG.	Suggestion: use either "trippoint" or the ISA term "actual trip setpoint" consistently.	
3		Reference to IEEE 279 and 603 will be changing due to rulemaking so this will be impacted	Hold RG until current draft rule is issued for use.	Potential impact due to current rulemaking
4	2nd ¶ from bottom	"...NRC staff considers the limiting setpoint to constitute a limiting safety system setting..." This is different from the position on revision 3 of this RG, where the AV is the LSSS. (page 6 of rev 3, "For the standard technical specifications, the staff designated the allowable value as the LSSS.")	Recommendation: make up your mind (without a backfit) is AV or LSp the LSSS? See also comment #2 for this page.	
4	5th ¶	"...if certain criteria are met..." The discussion in C.7.b is much more than "slightly different" from the RIS discussion. This is a good place to discuss those criteria.	Recommendation: include a criteria discussion here and have it conform to RIS 2006-017.	
4	Deviation	Again a bias against the information presented in RIS 2006-017.	Recommendation: Align with concepts discussed in the RIS.	
4	Footnote	The footnote indicates a definition for "setpoint deviation". However, "deviation" is what is provided in the glossary.	Suggestion: consistent use of terms	
4	Scope	"... all instrument setpoints that are included in plant technical specifications..." This appears to include **all** numbers measured using instruments in TS, include sections such as 3.4 Reactor Coolant System and 3.8 Electrical Power Systems. This is an expansion of scope from those just in section 3.3 Instrumentation. Also not all in section 3.3 are safety related; so even requiring it for section 3.3 is an expansion.	Recommendation: Clarify which setpoints are intended, and do not expand scope from previous revisions of the RG.	
4	Section Scope Page 4, Section C1	The RG Draft has broadened its scope to not only consider safety margin to the AL, but also includes performance monitoring requirements. The RG Draft also states that it is applicable to all Tech Spec setpoints (Section Scope Page 4, Section C1), so all the RG compliance requirements cover all the Tech spec setpoints regardless of whether or not the setpoints have a safety function. The Draft RG performance monitoring requirements are also not totally consistent with the performance monitoring requirements put out separately by the NRC a few years ago via TSYTF-493.	The performance monitoring requirements in TSTF-493 only applied to a specified list of Tech Spec setpoints, whereas the RG applies to all Tech Spec setpoints even those that have no safety analysis. Applying the rigors of NRC methodology to all setpoints including those that have no safety function appears to put an unnecessary burden on all operating plants. The RG should follow the requirement outlined in TSTF-493.	Implementation of the requirements in this RG Draft to all Tech Spec setpoints will result in a significant increase in plant operating costs and regulatory compliance costs without any increase in plant safety. Moreover, the inconsistency between RG and TSTF performance monitoring requirements could impact the GEH LTR written in response to TSTF-493, which was reviewed and recently approved by the NRC.
4		The Scope is unclear - Appendix B to 10 CFR Part 50 requires that programs and administrative controls be in place to provide adequate assurance that systems associated with significant safety functions be designed to perform satisfactorily in service. Therefore setpoints not directly related to safety limits but still associated with significant safety functions must ensure that automatic protective actions are initiated in accordance with the design bases. Such setpoints are therefore within the scope of this RG.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
4		Scope - With the references to Tech Spec limits, are compliance limits and Backup control room in the scope of the RG?	Clarify wording.	
4		This Reg Guide Rev 3 Page 2 states that the methods are acceptable to the NRC staff for complying with the NRC's regulations for ensuring the setpoints for safety-related instrumentation are initially within and remain within the Technical Specifications. In Draft Rev 4, Page 4, the scope is listed as applicable to all instrument setpoints that are included in the plant Technical Specifications..... This does not concur with the title of the Reg Guide, "Setpoints for Safety-Related Instrumentation."	The scope increase has to be justified in the safety-analysis basis. A number of Tech Spec setpoints do not come from the safety analysis (Example: SG high level on a PWR).	Un-neccesary scope increase.
5	6th ¶	"The interval should be constructed so as to encompass 95 percent of the deviations that are anticipated when there is no malfunction induced deviation." This appears to indicate that there should be 5% failure, that is, 5% of the as-found values will be outside the AFT. This also appears to assume that instrument failures will be primarily a gradual degradation of accuracy, only detectable by a finely tuned AFT, instead of outright failure or at least a large deviation.	If, according to the 3rd paragraph on this page, the as-found tolerance is an LSSS, 5% of all surveillance tests would need to indicate a violation of an LSSS? Revise to clarify.	
5	Drift	This is not a definition.	Recommendation: provide a definition, perhaps from ISA.	
7	6th ¶	"...spurious actuations." What are spurious actuations? Are these the 5% false failures? If the intent is that these are the 5% that actuate outside the AFT, but the equipment is functioning properly, then there are better words to use.	Recommendation: define "spurious actuations", or use other words such "false failure" related to "false detection" earlier in the paragraph.	
7	Reason, 3rd bullet	"95/95 criterion" What is the problem? Is there an NRC concern that the uncertainties are unacceptably small and that the limits are not adequately protected? The industry concern is that we have to prove 95/95, when there has not been an issue with acceptable uncertainties. I know the "95/95" label and (sometimes vague) idea has been used extensively for years. Clarification of concepts is fine.	Recommendation: Provide answer to "What is the problem that extensive testing, documentation, and statistical analysis will solve?"	
7		New "trippoint" definition creates confusion.	RG should used ISA terms. The equation Measured + unknown error is double dipping on some normal uncertainties such as reference accuracy, M&TE, etc. that is in the measured error.	
7		First paragraph after bulleted items. Draft Rev 4 acknowledges extensive discussions with various stakeholders from 2004 and 2006, and then ignores the continuation of the dialog that occurred after the issuance of RIS 2006-017 in 2006 and the joint acceptance of TSTF-493, Rev 4 in 2009.	Incorporate the agreement made after the issuance of RIS 2006-017 and the joint acceptance of TSTF-493.	
8	6th ¶	"The use of nominal set point based deviation assessment rather than previous as-left value based assessment can result in a significant increase in the likelihood of spurious actuations." If the setting tolerance is random, then false failures are no more likely.	Recommendation: delete sentence since it does not recognize the random nature discussed in RIS 2006-017. OR provide basis for why you think this is true. Others of us, who also think we understand statistics, disagree.	
8	7th block text	... and trippoint" is a random variable bearing..." The relation between "setpoint" and "trippoint" is variable, but it is not only random. It will have a random component, but there are important bias terms that can affect the trippoint.	Recommendation: delete the word "random"	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
8	C.1.a	Pages 8-9 state that the Safety Limits (SLs) won't be exceeded if actions are initiated before certain other limits (i.e., Analytical Limits (ALs)) are exceeded.	The wording of "before" excludes the action being initiated when the AL is reached. The GEH safety analysis assumes a setpoint that causes automatic actions (e.g., Reactor Scram, Group 1 Isolation) when the measured parameter is equal to the AL. The NRC's wording now excludes the action taking place at the AL.	
8	**C.1.b**	Also, it conveys the idea that if an AL is exceeded, the NRC considers the SL to have been exceeded. That would mean the plant would have to shut down and remain so until explicit permission is given by the NRC to start again.	This could exclude having only 95% protection of the AL, and appears to me to now be 100% protection of the AL. (Note that it's very difficult in statistics to achieve 100% probability.)	
8	Definitions	This is the definition of "actual trippoint" as given in the glossary. The glossary does not give a definition for trippoint.	Suggestion: add the word "actual" to be consistent with definitions; OR use just "trippoint" throughout the RG - be consistent.	
8	trippoint Eq	{trippoint} = {measured setpoint} + {unknown error} The measured setpoint includes some of the *unknown errors in the overall channel. Appears to have some aspects redundant with "unknown error".*	Recommendation: use the word "intended" instead of "measured". It *will be consistent with a part of the definition given above this* equation.	
9	1st ¶	... the NRC staff considers analytical limits to be surrogate safety limits and therefore to be subject to the same requirements and guidance as safety limits... There a couple differences between ALs and SLs. (1) SLs have a legal and operation factor that ALs do not. This statement appears to be an attempt to expand the scope of SL. (2) ALs are not developed in the same method as SLs. ALs are developed in a safety analysis (SA) and do not necessarily represent the limit of the parameter before a SL is exceeded. A common practice it to use an AL (or Analysis Setpoint, AS) and if the SA results are acceptable then no further analysis is performed. In this way it is the limit of what was analyzed, not the limit on the parameter for safety considerations. There can easily be margin between an AL and the related SL. A similar type of margin is the basis of being able to perform Operability Determinations on degraded equipment - there is margin. The definition for AL as given in the glossary is reasonable for the definition of Analysis Setpoint, but not necessarily for the limit of the parameter before exceeding a SL. The use of the words "surrogate" and "requirements" are of particular concern.	Recommendation: reword sentence to be something like "the NRC staff considers the analytical limits to be an important means of ensuring safety limits are protected and recommend using the same guidance as for safety limits..."	
9	2nd ¶	"...typically invoke a limiting setpoint..." A review of the NUREGs listed on page 4 (standard TS) indicates that only Westinghouse plants would have a setpoint, and that is listed as "nominal" and includes a footnote that site specific TS may have only AV.	Therefore, based on the NUREGs, it appears that typical is there are no sites have a "limiting setpoint", and the majority of types (by vendor) will have only AV. The standard TS do not include an as-found value, but rather have a footnote which references a "predefined as-found tolerance".	
9	**C2**	Page 9 states that the Tech Specs limit (I read this to mean the Allowable Value) is selected to provide adequate protection of the AL, without defining "adequate." My understanding in the past is that the AV (and Nominal Trip Setpoints (NTSPs)) provide 95% or greater probability of protecting the AL.	That definition seems to have disappeared.	
9	Industry Std, 2nd ¶	"... documents other than ANSI/ISA 67.04.01 and earlier versions ..."	Suggestion: add "1994" after 67.04.01 to say "67.04.01-1994"	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
9	RIS 2006-17	Later paragraphs show that what was included from the RIS is minimal. Any reference to previous as-left value, without a corresponding consideration of nominal setpoint, as discussed on page 5 of the RIS, is an error of not including the results of specifically related prior NRC staff discussions and publications.	Just a comment.	
9	Section 2, 9th paragraph:	Section 2, 9th paragraph: Analytical limits are not surrogates for safety limits. Additional margin is provided in many fuel vendors safety analysis, so exceeding an AL doesn't mean a SL is exceeded. For example Safety Limit avoidance is provided for at the worst point in the fuel cycle. The 5% of the trips which occur after the AL, doesn't directly correlate with SL violations.	All NRC SL guidance and requirements should not apply to events where the trip did not occur at the AL. If a change is made in this area it should state the existing NRC requirements and specifically how they are changed.	
9		The RIS applied to a subset of Tech Spec instruments.	Is it being expanded by the RG to all?	
9		Reg Guide States that the NRC endorsed the 1994 version of the standard (with clarifications and limitations) in Rev 3 of the Reg Guide. The NRC did not endorse the 2000 version of the standard. Then on page 10, the staff said that the latest version of the standard ANSI/ISA 67.04.01-2006 presents criteria for computing the uncertainty associated with an instrument setpoint. "Various staff regulatory positions in Section C of this RG address the suitability of this standard for use in developing limits for setpoints that fall within the scope of this RG. " This does not provide an endorsement of the ISA standard at all. There is no reference to Draft Rev 4 endorsement of the 1994, 2000 or 2006 standard with clarifications.	This is a major deviation from the NRC direct in the past. In accordance with government directives, the NRC is to endorse industry standards, where applicable, and provide clarifications, instead of developing a whole new NRC document. This is clearly not the case with the Draft Rev 4 which has 32 pages of guidance in place of Rev 3's 9 pages. There needs to be a safety-case justification for the additional guidance and scope expansion as noted in the above comment. I don't believe there is a safety case for the very large addition. In addition, in the past, NRC and industry have worked together to establish coordination between the ISA standard and the associated Reg Guide. Again, this is not the case for the first time with Rev. 4 of this Reg Guide.	
9		First paragraph. Draft Rev 4 states NRC staff considers analytical limits to be surrogate safety limits and therefore to be subject to the same requirements and guidance as safety limits. Analytical limits that protect safety limits typically use methodologies approved by the NRC. Such methods of analysis typically include significant conservatism such that the selected analytical limits contain significant conservatism.	Therefore, analytical limits are not surrogate safety limits and should not be subject to the same requirements and guidance as safety limits.	
10	C3	Figure 1 Note number 3 seems to be in conflict with the discussion on page 16 in the last paragraph of Section 5.1. Fig. 1 Note #3 discusses how deviation is excessive if an As-found instrument setting is less conservative than the AV, regardless of whether the As-Found Tolerance (AFT) is exceeded. But on page 16, it then states the use of an AV is optional, because the AFT-based assessment of the setpoint deviations provides a similar function.	Clarify wording.	
11	Bottom of page	"This RG addresses two primary considerations regarding acceptability limits on measured values for instrument setpoints:" This appears to be a pre-discussion of what will be discussed in section 5.2 (LSp), and 5.1 (AFT & AV). As such is appears redundant.	Recommendation: delete redundancy. Remainder of section 4.1 should be deleted and relevant information moved to the sections where the parameter is already discussed.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
11	Bottom of page	"This RG addresses two primary considerations regarding acceptability limits on measured values for instrument setpoints:" This appears to be a pre-discussion of what will be discussed in section 5.2 (LSp), and 5.1 (AFT & AV). As such is appears redundant.	Recommendation: delete redundancy. Remainder of section 4.1 should be deleted and relevant information moved to the sections where the parameter is already discussed.	
11	Figure 1 Note 1	"The As-Left setpoint should be no less conservative than limiting setpoint (LSP)." This uses BA4 from page 10. With that it makes some sense. For sites that have setting tolerance that is random (that is, ST (ALT) = reference accuracy) and the accuracy is included in TLU, then the nominal setpoint must be <= LSp, but requiring that the As-Left setpoint also be <= LSp is a contradiction of the understanding of random and inclusion in TLU. It is also inconsistent with what appears in RIS 2006-017. This appears to be throw-back to an old industry approach of having a TS setpoint and then lowering the installed setpoint (e.g. 20mV and then having an as-left tolerance of around that installed setpoint (perhaps also 20 mV).	Recommendation: Include both perspectives	
11	Figure 1 Note 2	Evaluation relative to the previous as-left setpoint, again assumes that there is a setting tolerance much broader than reference accuracy (BA4 on page 10). The consideration of page 5 of RIS 2006-017 has not been included. Since one of the stated reasons for revision (pages 7 & 9) is RIS 2006-017, the perspective discussed there should be included.	Recommendation: Include both perspectives.	
11	Figure 1 Note 3	"...the deviation should be deemed excessive if the as-found value (AsF) of the setpoint is less conservative than the allowable value (AV) regardless of whether or not the as-found tolerance is exceeded..." Part of the definition of AV, from the glossary is "the least conservative as-found value for a setpoint, as measured under test conditions..." Using this definition, any as-found value (AFV) that exceeds AV, must also exceed the as-found tolerance (AFT). That is, the (As-Found Reference + ALT) must be <= AV. If not, then AV fails to meet the definition. If a station has a region of the AFT less conservative than the AV, they are expecting the as-found value to sometimes exceed AV. This is inconsistent with the definition.	Recommendation: Delete the words "regardless of whether ..." to the end of the sentence.	
11	Figure 1 Note 4	"The allowable value might be more or less conservative than the as-found tolerance limit." This is inconsistent with the definition of AV.	Recommendation: Change the sentence to read "The allowable value is the same as or less conservative than the as-found tolerance limit."	
11	Figure 1 Note 4	"The allowable value might be more or less conservative than the as-found tolerance limit." This is inconsistent with the definition of AV.	Recommendation: Change the sentence to read "The allowable value is the same as or less conservative than the as-found tolerance limit."	
11		Note 2 requires the evaluation of exceeding As Left tolerance. This is not appropriate.	Note 2 requires the evaluation of exceeding As Left tolerance. This is not appropriate.	
11		Note 3 - New fuzzy terms "excessive and chronic"?	Note 3 - New fuzzy terms "excessive and chronic"?	
11		Note 4 - How can Av be less conservative than AF?	Note 4 - How can Av be less conservative than AF?	
11		LSP - Does LSP include the As Left tolerance? This has been a pass Tech Spec compliance issue.	LSP - Does LSP include the As Left tolerance? This has been a pass Tech Spec compliance issue.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
12	3rd ¶	"...these limits can provide assurance..." The purpose is to provide assurance. This implies that just passing these limits will still require more evaluation or something to provide the assurance that they function as intended.	Recommendation: delete the word "can"	
12	3rd bullet, italics paragraph	"In addition, if a setpoint changes between tests by more..." The second sentence is not really "in addition", it is the why behind the first sentence. In this case, "In addition" is not a good transition phrase.	Suggestion: Use a different linking or transition phrase.	
12	4.1, In Summary, bullets 2 and 3 /pg 12 & 13	Subtle difference between bullets 2 and 3 is unclear.	Clarify.	
12	AFT	The definition is different from what is given in the glossary. Also this is redundant with what is presented on page 15.	Recommendation: delete redundancy	
12	AFT	The definition is different from what is given in the glossary. Also this is redundant with what is presented on page 15.	Recommendation: delete redundancy	
12	In Summary	Why is there a need to summarize an introduction before the primary parameters are discussed (sections 5.1 & 5.2)?	Suggestion: Delete as redundant	
12	Section 2, 2nd bullet	Section 2, 2nd bullet - Only one cause, degraded component, is listed.	Should be complete by adding maintenance error (present or previous), bad M&TE, statistical occurrence, etc.	
12	section 4.0 BA4	Some the later paragraphs in section 4 appear to be based on a fundamental assumption about the setting tolerance that is not stated. This comment is provided here because this is where a possible solution could be provided. The assumption seems to be that a significant majority of the industry uses a setting tolerance (ST = as-left tolerance, ALT) that is much larger (broader) than the reference accuracy of an instrument as given by the vendor. The basic reference accuracy is commonly considered to be a random variable. Broadening the tolerance beyond reference accuracy introduces a bias error. For an extreme example, if the reference accuracy of a bistable is 0.10% CS, but the ALT is allowed to be 1.0% CS then any given as-left value (ALV) is effectively a bias, with a small random variation (0.10%) around it. If the assumption above is a correct understanding of the NRC staff perspective then, it should be clearly stated. It affects many of the details later in section 4.	For the NRC staff to use this assumption and only the perspective based on this assumption, it needs to know that a significant majority of the industry uses this practice. If numerous sites have setting tolerances that are close to the reference accuracy then basing all the discussion on only this assumption is inappropriate – both perspectives should be included. Palo Verde is one that typically uses references accuracy as the ALT. Close to reference accuracy is intended to be random as described in condition (1) in the first paragraph on page 5 of RIS 2006-017. This assumption of this comment will be called Basic Assumption 4 (BA4) for reference back from other paragraphs. With this assumption more of the following make some sense. Without it, there appears to be an important misunderstanding of the difference between bias and random. Recommendation: Include the basic assumption, or if it is not the basis for much what follows, then correct many of the following paragraphs.	
13	1st ¶	In structure, this paragraph is part of the heading "In Summary" from the previous page. However, it does not summarize anything discussed previously in this section (4.1). It appears to be an "orphaned" paragraph. This discusses information presented in section 5.2. Also, what is the point of using the word "trippoint" instead of "actual trip setpoint"?	Recommendation: Move this paragraph to section 5.2 and rewrite as needed.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
13	1st ¶	In structure, this paragraph is part of the heading "In Summary" from the previous page. However, it does not summarize anything discussed previously in this section (4.1). It appears to be an "orphaned" paragraph. This discusses information presented in section 5.2. Also, what is the point of using the word "trippoint" instead of "actual trip setpoint"?	Recommendation: Move this paragraph to section 5.2 and rewrite as needed.	
13	4.1, last para / pg 13	Unclear why splitting hairs is necessary. During testing, the process value or equivalent that the trip occurs, is an actual value. Incorporating a concept of "actual trippoint" to accommodate what is basically measurement error or M&TE accuracy appears to be inconsistent with the "as-left band" section C.7 and shown in Fig. 1.	Clarify wording.	
13		The first paragraph - The description of actual setpoint is confusing. The ISA LTSP and NTSP are the setpoints defined in our Tech Specs.	Clarify wording.	
13		Section 4.2 - Digital signal converter should be digital signal converter/s. Plural for input and output A/D and D/As.	Need to address in ISA 67.04	
13		Software programming can cause errors. Need to address in ISA 67.04	Need to address in ISA 67.04	
13		M&TE uncertainties -	*The staff needs to reference to RP specific to M&TE. They do not have to endorse the complete RP document.*	
14	1st ¶ in section 4.4	"...for very large sample sets, this difference might be small enough to be ignored." If the sample size is, in fact, "very large" then the difference is small enough to be ignored, not just "might be". This assumes that other criteria of obtaining a meaningful sample are met.	Recommendation: delete either "very large" or "might be".	
14	1st ¶ in section 4.4	"...for very large sample sets, this difference might be small enough to be ignored." If the sample size is, in fact, "very large" then the difference is small enough to be ignored, not just "might be". This assumes that other criteria of obtaining a meaningful sample are met.	Recommendation: delete either "very large" or "might be".	
14	2nd and 3rd paragraphs of section 4.4	"probability" NUREG-1475 Rev 1, "Applying Statistics" uses the word "confidence", perhaps only semantics.	Suggest a reference to NUREG-1475.R1.	
14	4.4, 2nd paragraph.	4.4, 2nd paragraph. The second 95 is the confidence level used in determining the 2nd 95. In this paragraph they are not differentiated properly, one is "probability" the other "percent of members of the population". Unclear if the population is the tested sample or population of events challenging the AL.	It would be more clear to define and use the statistical term "confidence level" which is used in C.4.e.2. Then the sentence can be : ... 95% of the population falls within the criteria at 95% confidence level, where confidence level is based on the sample size.	
14	Section 4, last paragraph.	Section 4, last paragraph. Only an Instrument vendor can supply data supporting a 95% confidence level statement. The probability 95% (or 90% or 97.5% is a function of the statistical factor applied in the calculation or from a Monte Carlo analysis (reference statistics textbook).	95/95 in this section should be changed to 95% confidence. Reference EPRI TR 1025301, "Advanced Nuclear Technology: Regulatory Performance Requirements for Safety-Related Instrumentation"	
14		First paragraph of section 4.4 conflicts with next to last paragraph of 4.3 concerning excessive deviation.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
14		Last paragraph - So if the vendor cannot provide 95/95 data what do you do? Suggest that RG reference NUREG/CR-3659, PNL-4973, A Mathematical Model for Assessing the Uncertainties of Instrumentation Measurements for Power and Flow of PWR Reactors - Manufacturer Specifications These specifications are the main sources used in performing calculations.	The use of this type of data in an uncertainty analysis for normal environmental conditions is conservative. Since all data should fall within the bounds set by the manufacturer, using these specified limits for a 95% or even a 99% tolerance interval analysis will lead to a conservative estimate of the error.	
15	5.1 / 15	Basis for ""significant increase in the likelihood of spurious actions" unsupported.	Clarify wording.	
15	Sec 5.1	The terms excessive and chronic are fuzzy and should be eliminated such as the TSTF note wording.	Clarify wording.	
15		4th paragraph - The following statement is not support and should be deleted - The use of nominal set point based deviation assessment rather than previous as-left value based assessment can result in a significant increase in the likelihood of spurious actuations.	The statement is not support and should be deleted -	
15		Page 15 paragraph 4 (paraphrased) states that normally functioning instrument channels can be expected to exceed as-found limits that are based on the principles of 95-95 and that acceptance of a particular instance of deviation requires the use of judgment. This is a point that both the NRC Staff and industry can agree upon. However, on Page 20, Staff regulatory guidance C.2.b states that failure to meet a setpoint as-found or as-left criterion should be taken as an indication that the instrument channel is not functioning as required, and that appropriate corrective actions should therefore be initiated.	From review of 10 CFR50, Appendix B, Criterion XVI, Corrective Action, an as-found value exceeding an as-found tolerance would be a deviation and the event should be entered into the corrective action program (CAP). Since this condition is an expected event from a normally functioning instrument channel, a particular instance of deviation would not rise to the level of a significant condition adverse to quality and would not require corrective action be taken to preclude repetition. Page 20, Section C.2.b should be revised to delete the comment about appropriate corrective actions being initiated and should conform to 10 CFR50, Appendix B, Criterion XVI. Likewise, the second sentence Figure 1, Note 3 on page 11 should also be revised to conform to Appendix B, Criterion XVI.	
16	2nd ¶	"If an allowable value is established..." Without specifically stating the preferred method of determining the AV, the words indicate a bias toward methods 1 or 2, as described in ISA-RP-67.04 Part II, of 1994.	Clarify wording.	
16	5.1 top of page	The RG includes the definition of "Allowable Value" which is part of GEH's & ESBWR setpoint methodology, but not in ISA 67.04.01. It incorporates the performance monitoring requirements of RIS 2006-017. It provide (limited endorsement of a more recent version of ISA 67.04.01, 2006.	Clarify wording.	
16	5.2/pg 16/3rd para	Unclear what "Section 4.5 of Reference 7 of ANSI/ISA 67.04.01-2006" refers to since Reference 7 contains a number of references.	Clarify wording.	
16	C.4	Page 16 defines the AV stating that it will provide adequate assurance that the AL will not be exceeded.	"adequate" is not defined.	
16	Definition	Should state that the NTSP includes Drift and the AV does not GEH definition of LSSS is AV. This definition is actionable in the real plant as a comparison of the As Found tripoint from a measurement to the AV.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
16		If Av is not in Tech Spec, is AFT required to be in Tech Specs? How is operability to be determined?	The use of an allowable value in technical specifications is optional, because the as-found tolerance based assessment of setpoint deviation provides a similar function. The allowable value need not be computed if it is not used.	
16		What is being stated for LSP? Too complex.	Should just reference ISA 67.04	
16		First, disagree that LSP is post cal (ALT should be allowed). Also ALT should be allowed in calc because the previous ALT is in the present measured AF.	Clarify wording.	
17	5.2	There seems to be an error in section 5.2, which states: The 95/95 criterion thus results in a probability of not more than 2½% that the analytical limit will be exceeded as a result of measurement error. This statement and Figure 2 is a change to require a "double sided" statistical factor, which is unnecessarily conservative relative to "single sided" statistical factor. NRC is requested to revise the draft, to provide 5% probability that analytical limit will be exceeded, consistent with the statistical definition of 95% probability /95% confidence level.	Section 5.2 and Figure 2 are 97.5/95 not 95/95. This is unnecessary "conservatism", which contributes to spurious trips.	
17	3rd ¶	"Because the limiting setpoint..." This is continued evidence of the bias against the possibility that setting tolerance is random and can be included in TLU and that the LSp is a nominal value with a setting tolerance around it..	Recommendation: Recognize the position of RIC 2006-017 that nominal setpoints with random setting tolerances are effectively the same as the as-left setpoint.	
17	4th para	Where is NRC "using" setting tolerance?	It would be non-conservative to not use the setting tolerance.	
17	B.5.2	Page 17 states that the 95/95 criterion results in the AL being protected to 97.5%, in different words.	This is a huge change from the previously accepted 95% probability of protection.	
17	B.5.2 last para / pg 17, Fig. 2 Note / pg 18	"full magnitude" not consistent with 95/95 explanation in previous paragraph. Plus this phrase is used in the last sentence with the cravat that this "should be strongly avoided". "Total Loop Uncertainty" actually applicable bias terms plus (97 ½ /2) part of the random uncertainty.	Clarify wording.	
17	B.5.2 next to last para / pg 17	Statement "This is independent of the shape of the actual trippoint distribution." Is statistically unclear and appears to be in conflict with the statistical use of 95/95 concept.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
17	B.5.2, page 17, paragraph starting "One consequence of the 95/95 criterion	Last sentence states the 95/95 criterion thus results in a probability of not more than 2½% that the analytical limit will be exceeded..."95/95 means there is a 95% probability with 95% confidence actuation will occur before the analytical limit (AL) is exceeded. Almost all PPS setpoints are approached from a single side. To meet 95/95, there must be 95% assurance of actuation prior to reaching the AL. This implies a 5% probability of exceeding the AL. There are instances where accuracy requirements expressed as ± some value must be demonstrated met by rigorous uncertainty methods. Those cases generally require consideration of a two-tailed probability distribution where there is 95% probability the module meets the acceptance + and - values; with 2½% probability of exceeding the + and 2½% probability of exceeding the – value. Imposing a one-sided 2½% probability of actuation exceeding the AL implies the probability of actuation prior to exceeding the AL must be 97.5%. The overall increase in nuclear safety by imposing the increase in actuation probability is demonstrated below: Objective is to initiate a PPS response. Typically safety channels require 2 out of 3 safety channels to actuate. Using binomial distribution (ref Practical Engineering Statistics, Schiff/D'Agostino) and defining successful PPS actuation as 2/3 or 3/3 channels actuating before the AL is reached, probability of successful PPS actuation is summarized below:	Clarify wording.	
17	B.5.2, page 17, paragraph starting "One consequence of the 95/95 criterion	**Single Channel 95% probability** / **Single Channel 97.5% probability** **Only 2/3 channels actuate or** **13.5375%** **7.1296875%** **All 3/3 channels actuate** **85.7375%** **92.6859375%** **Total probability** **99.275%** **99.816%**		

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
17	Section 4.4	The RG Draft has defined 95/95 criterion to be the error of the instrument to be used in setpoint calculations. In simple terms, for a normal distribution of random errors always assumed in setpoint analysis, the first 95% corresponds to 2-sigma value of the error, and the second 95% corresponds to the "confidence" with which we know this 2-sigma error. The RG Draft states that a consequence of the 95/95 criterion is that the probability in the tail above the AL is 2.5% (Section 5.2 page 17 para 4).	It needs to be noted that the 95/95 criterion in the RG Draft applies to instrument error around the setpoint but does not define the margin of the setpoint to the AL. The instrument error around the setpoint and margin to the AL are two different concepts, because the setpoint for an instrument with same error can be located an arbitrary number of sigmas (or standard deviations) away from the AL. The RG statement that the consequence of applying the 95/95 error criterion is to provide a 2.5% margin beyond the AL is inconsistent with the statistical definition and interpretation of 95/95 given in NUREG-1475 Section 9.12 and 9.13. The fact that the RG Draft requires the instrument errors around the setpoint to be determined using 95/95 criterion is one decision, but requiring the setpoint/AL margin to be such that probability of exceeding the AL is only 2.5% is a separate decision independent of the 95/95 error criterion.	
17	Section 4c1, Section 5.2, para 2, Section 4.4	The RG Draft states emphatically in several places (Section 4c1, Section 5.2 page 17 para 2, Section 4.4) that the margin between the LSP and AL can be no less than the Total Loop Uncertainty (TLU), and TLU is the SRSS of the 95/95 errors of the components. The 95% corresponds to 2-sigma margin which leads to a 2.5% tail probability beyond the AL, whereas GEH licensed single sided methodology uses 1.645-sigma margin which leads to a 5% tail probability beyond the AL. The use of single sided statistics to determine margin between the setpoint and the AL is statistically and technically correct and is endorsed in the ISA 67.04.02 standards (see for example ISA 2007 Standard Draft Section 7.3) for setpoints approached from one direction.	Need to clearly state whether the Draft RG is stating that the requirement for exceeding the AL is now 2.5%, and ask them to justify why this is changed from the previous 5% requirement. The previous approved GEH methodology and the historical basis for the 5% requirement based on the conservatism in the GEH safety analyses. The RG Draft Section C4f states that the uncertainty analysis should be consistent with the plant safety analyses, so stating that for the licensed BWR GEH safety analysis a 5% probability of exceeding the AL is justified, is a strong argument against applying the 2.5% requirement to GEH safety setpoints. It needws to be noted that using the 2.5% criterion will require the GEH setpoints to be lowered which is unnecessary from the safety standpoint because operating experience at BWRs that use setpoints by GEH methodology has shown that the setpoints are already conservative, and this change would likely increase the probability of spurious scram which is undesirable from an operational and safety point of view].	
17	Section 5.2 para 4	i.The first decision to use 95/95 errors is ingrained in the NRC and will be difficult to challenge, although its implementation involves a lot of data and statistical analysis and will be very difficult and costly because most nuclear instrumentation accuracy specifications are generally not supported by statistical analysis which can stand the rigors of NRC scrutiny. Moreover the Draft RG already acknowledges that demonstrating 95/95 errors for all errors needed for calculating the total loop uncertainty, is not possible, and that engineering judgment is required. We should ask the NRC to confirm that when 95/95 data is not available, plants can use engineering judgment and historical records of setpoint performance to show that the error values used in the setpoint calculations are conservative and meet the requirement to a high degree of confidence, as was approved by the NRC in NEDC-31336P-A.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
17	Section 5.2 para 4	The NRC should provide the basis for the second decision which leads to the controversial 2.5% tail probability, since from a technical point of view, the requirement for the error around the setpoint does not translate to a requirement for the margin between the setpoint and the AL. The NRC needs to clarify a hypothetical question that if the specified instrument sigma error is large enough to be conservatively equal to or greater than the instrument population sigma error at 100% confidence , then would the RG still require 2.5% tail probability of exceeding the AL or would they agree that 5% tail probability of exceeding the AL is OK.		
17	Section 5.2 para 4	The NRC needs to clearly define the probability requirement (with justification) for exceeding the AL, since that is the main purpose of the RG.	Assuming there is no clear basis for this, it is recommend that RG 1.105 permit the use of the historical 5% probability of exceeding the AL since it has a historical basis and can be justified.	
17	Section B.5.2, page 17, paragraph starting "One consequence of the 95/95 criterion	The net increase to safety is only 0.541%. For 4 channel 2/4 configurations, the increase to safety is smaller: 0.042%. This increase is negligible compared to the potential percent decrease in safety that could result by diverting plant resources from more safety significant issues to address the imposed 97.5% probability requirement.	Clarify wording.	
18	C.6.a	Page 18: Figure 2 also shows a 97.5% probability of protection of the AL	Clarify wording.	
18	C.6.b	Also, note that the display of how the bias errors would affect the Limiting Trip Setpoint (LSP & LTSP) does not mention that only non-conservative bias errors are included (unless I missed that somewhere in the document)	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
18	Note	The GEH Safety Analysis application methodologies use the same 95/95 definition (ODYN NRC letter in Adams). The NRC's own NUREG-1465 Statistical handbook indicates single sided is preferred in some cases. This procedure provides for a statistical determination of the pressurization transient such that there is a 95% probability with 95% confidence (95/95) that the event will not cause the critical power ratio to fall below the MCPR Fuel Cladding Integrity Safety Limit.". 95 is the non-exceedance %/probability. 5% probability the CPR exceeds the Safety Limit. GEH has consistently used this 95/95=95% non-exceedance definition in analysis of Anticipated Operational Occurrences. For some reason a different branch of NRC has a different definition of 95/95. For normally distributed 95% probability uncertainties, standardized area distribution tables show that 95% of the population will have uncertainties between ± 1.96 sigma, with 2.5% falling below – 1.96 sigma and 2.5% falling above +1.96 sigma. If there are increasing and decreasing trip limits, the appropriate limits to use are ± 1.96 sigma. Using this technique, a positive uncertainty that has been calculated for a symmetrical case can be reduced while maintaining 95% coverage of the population when a single parameter is approached from only one direction. For example, if the original symmetric value was based on 2 sigma members, the reduction factor is 1.645/2.00 = 0.8225; if the original symmetric value was based on 1.96 sigma values, the reduction factor is 1.645/1.96 = 0.839.	Observation: Areva initially used single sided statistics in their setpoint methodology. When NRC was giving GEH a hard time, we pointed out they had approved an Areva LTR using one –sided statistical factor. Then they asked Areva this RAI, and Areva conceded to NRC: http://pbadupws.nrc.gov/docs/ML1006/ML100670007.pdf Similarly GEH made a concession to NRC in out ESBWR setpoint methodology	
18	Note	Fig 2 - previous NRC position was that approaches where 95% of population is contained are also appropriate. GEH position is the population is the trips which occur at or before AL. NRC October 2010 presentations http://pbadupws.nrc.gov/docs/ML1029/ML102980536.pdf illustrate the issue in Slides 13-16 They show the difference between the new NRC position and the statistical basis to contain 95% of the population, tripping at or before the parameter reaches the analytical limit (the later is the 1.645 sigma statistical factor, marked "NEDC-31336" on slides 13 & 16).. (Note the link is to the NRC slides from the meeting.) In Slide 17 NRC indicates other approaches are acceptable where "the appropriate tolerance interval contains 95% of the population of interest." I didn't see any statements like that in the draft RG.		
18		Do not understand what is being stated in Figure 2 and note.	Clarification is needed.	
19		Section 7 - Please state and list any secondary references endorsed.	Section 7 - Please state and list any secondary references	
20	B.1, 2nd bullet/ pg 7 C.2a/pg 20	DG-1141 seems to be "cherry picking" acceptable methods from RP67.04, thus expanding the purpose and intent of RG1.105.		
20	C.1	C.1 "AL constitute surrogate safety limits". Safety Limits are as defined in the technical specifications. They are not analytical limits. The criteria which apply to SL shouldn't apply to AL. Plant should not shut down and wait for NRC permission to restart (which is the case for SL violation) in the event of an AL violation. This is justified because there is not a SL violation. If changes being made or proposed to NRC requirements they should be spelled out.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
20	C.1.a	See comment #1 on page 9. The idea of "surrogate" safety limits is an expansion of the definition.	Recommendation: Delete C.1 as regulatory guidance as an inappropriate expansion of definitions.	
20	C.1.a	Revise to "Analytical Limits that protect Limiting Safety System Settings (10 CFR 50.36)" The rigorous 95/95 requirement is defined for LSSS trip settings and not for other limits or settings in the Technical Specifications.	Where there is not a limit established to a 95/95 confidence interval then it is inappropriate for the setpoint calculation to attempt to document a higher probability or confidence interval.	
20	C.1.b	*This is an expansion of safety limit. The principles can be applied to ALs, but they should not be* requirements.	*Recommendation: Delete C.1 as regulatory guidance as an* inappropriate expansion of definitions.	
20	C.2.a	Revise to "This RG describes an acceptable method for the development of Setpoints that protect Limiting safety system settings. "	Revise to "This RG describes an acceptable method for the development of Setpoints that protect Limiting safety system settings. "	
20	C.2.b	"...reevaluated..." This implies for each case of exceeding the AFT, but prior discussion indicates that 5% of the tests are expected to exceed the AFT. See comment #7.	Recommendation: Clarify that this is needed only for a trend of tests exceeding the AFT.	
20	C.2.b	Section 2.b - AFT and ALT have replaced Av. Not acceptance. TSTF criterion more reasonable. Also, this is scope expansion from the TSTF.	Clarify wording.	
20	C.2.b	Evaluation of as-found and as-left tolerances is controlled by the corrective action program and only where the trip function is lost would entry into the LCO be required for plant shutdown.	Delete second sentence "Such actions may be established in the plant technical specifications and may include immediate shutdown of the reactor"	
20	C.3.b.(1)	As noted on page 4, there appears to be an attempt at inappropriate scope expansion.	Clarify wording.	
20	C.3.b.(4)	What is the value of term "trippoint" as compared to "actual trip setpoint"?	Suggestion: provide a reason for terminology change.	
20	C.3.b.1	Section 3.b.1 - Please state what was broaden.	Clarify wording.	
20	C.3.b.2	Section 3.b.2 - RG needs to use ISA definitions.	Clarify wording.	
20	C.3.b.2	Use the industry terminology defined by ISA and Technical Specifications. Defining new terms that other than the ones defined by ISA standards is not the job of the NRC simplify because they like a new term. The industry terms have been used for 50 years and no new definitions are required.	Clarify wording.	
20	C.7	Page 20 states that Setpoints that prevent surrogate SLs from being exceeded are treated the same as setpoints that protect SLs directly. Based on the explanation at the top of page 9, that means if the ALs are exceeded. See my comment C1b. Again, 95% protection of ALs is excluded.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
20	General	Section c.3 applies to overall 67-04-01 many new concepts based on NRC's unique interpretation of terms and statistical methodology. Let's just go back to algebraic combination of errors. Allowable Value c.7e	Clarify wording.	
21	3. The Applicability of ANSI/ISA 67.04.01-2006 (4).	Ob: This is an improvement, as there is no "set" in the determination of this, so it makes sense to remove "set" from the term.	Clarify wording.	
21	C.4	Combination of multiple drift observations over the defined interval by SRSS should be allowed. Extrapolation to a longer interval seems appropriate.	Clarify wording.	
21	C.4.c.(2)	Drift is a part of both TLU and AFT. This formula is conservative for determination of TLU, perhaps overly. However, it is not conservative for determination of AFT. It also disallows the possibility that there are other mechanisms for drift than straight linearity. This is inconsistent with other expectations on determination of AFT. Recommendation: decide the greater need – conservative AFT or larger TLU to protect the AL.	Clarify wording.	
21	C.4.c.(2)	Draft Rev 4, Section C.4.c.(2) on page 21. Our experience with drift is that it is seldom linear. Evaluations performed consistent with EPRI TR-103335R1, "Statistical Analysis of Instrument Calibration Data," and Revision 2 of the EPRI report, often demonstrate that drift is not time dependent. This also applies to Section C.4.e.(6).	Clarify wording.	
21	C.4.c.(2)	Module manufacturers generally express time drift as a random effect. Random effects are combined by SRSS. Combination of consecutive time periods to derive drift over a calibration period would therefore be an acceptable method. Also, time drift is used to determine as-found tolerances. Linear extrapolation would make the AFT non-conservative (too large) to determine if the module is functioning correctly.	Clarify wording.	
21	C.4.c.(2)	The linear relationship is not supported by any drift trending or drift analysis results produced by the industry and reported to the NRC for surveillance extensions. Unless there is new evidence that a time to drift relationship exists then this is a baseless requirement. In fact drift has shown a random deviation over time for almost all instruments.	Delete this section	
21	C.4.c.(2)	The RG Draft requires the drift error to be extrapolated linearly, which is very conservative and unrealistic (Section 4c2).	Based on past experience, the linear extrapolation is an inaccurate model leading to unnecessarily large drift errors. Note that during licensing of NEDC-31336P-A, GEH showed that if the drift for 6 months was known, the drift for 2 years could be conservatively estimated by taking SRSS of 4 6 month drift errors. GEH also showed that when drift specification for a suitably long period was not available, assuming that the drift for 6 months is equal to the reference accuracy, is a conservative assumption. The RG Draft should be rewritten to permit use of this approximation and the SRSS extrapolation method, if it can be justified based on plant performance data].	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
21	C.4.c.(3)	What is purpose of this section? Are there plants that do not include them. Seems that time response testing is well established throughout the industry, and that it will be included in the safety analyses. Is this just a catch-all to ensure somebody does consider time response?	Suggestion: clarify the purpose of this section.	
21	C.4.c.(3)	The Draft states that the dynamic effects of the process, such as transport delays be included in the uncertainty analysis (Section C4c3).	Within the GEH methodology the use of dynamic effects are already considered in establishing the Analytic Limit, so they need not be considered in the calculating the setpoint margin from the AL].	
21	C.4.c.(7)	This section assumes that the various items are inputs to an uncertainty analysis. They can also be what is directed by the analysis.	Clarify wording.	
21	C.4c(2)	If as-found/as-left analysis determines that "drift" is not , time dependent, is "drift" then not a "time related uncertainty".	Clarify wording.	
21		Section 4.b - Refer to NUREG	Clarify wording.	
22	C.4.c.(3)	Draft Rev 4, Section C.4.c.(3) on page 22. Instrument setpoint evaluations should not discuss delays already accounted for in the safety analyses as the method of analysis used in the safety analysis is typically already approved by the NRC. This also applies to C.4.e.(1), C.4.f, and perhaps to other sections.	Clarify wording.	
22	C.4.c(.6)	Section 4.c.6 - This is an open violation statement due to its vagueness - Section 6.1, paragraph 3: In addition: If observations suggest that assumed distributions or statistical parameters do not accurately represent instrument performance, those distributions and parameters should be corrected as appropriate, the affected uncertainty analyses should be revised on the basis of the corrected information, and the setpoint related limits and technical specifications should be modified accordingly.	Clarify wording.	
22	C.4.c.(3)	Dynamic effects should not be in the scope of uncertainty analysis. Extending scope to consider response time affects plant programs already in place and directed by other design/licensing documentation.	Clarify wording.	
22	C.4.c.(3)	The safety analysis models consider the time response of the measured variable and the required operational times for the equipment. Surveillance tests confirm the capability of systems including electrical power supplies to be available and to functioning during the required time to mitigate a DBE or limiting transient. A detailed understanding of the safety analysis that generated an Analytical limit is necessary for every setpoint calculation that protects an LSSS. A note stating that these uncertainties should be confirmed to be contained in the safety analysis may be appropriate, but not the automatic evaluation in every setpoint calculation.	Delete this section	
22	C.4.c.(3)	C.4.c.3, dynamic effects, "consideration of the time required for a demand signal to result in the needed action". This is an expansion of the setpoint calculation documentation scope. The instrument setpoint calculation stops with the trip determination, it typically doesn't address time delays accounted for in the safety analysis.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
22	C.4.c.(4)	"...statistically independent and are based on normal probability distributions..." SRSS is not dependent on normal distribution. It is dependent on random. Standard deviations from any random distribution can be combined SRSS. It will still be a standard deviation. However, what portion of the sample or population it represents may not be known. Since normal distributions have been analyzed, we have better tables to describe the meaning behind a standard deviation of a normal distribution. If the variables are not independent there will be covariance terms. These covariance terms will affect the end result, and can greatly complicate knowing the confidence of those results. However, it does not conceptually prevent use of SRSS. For practical uses of SRSS, independence is needed. See chapters 2 & 4 in the book "Data Reduction and Error Analysis for the Physical Sciences", by Philip R. Bevington, Library of Congress number 69-16942.	Recommendation: replace the word "normal" with "random", delete the word "statistically"	
22	C.4.c.(4)	Section 4.c.4 - Random is missing from SRSS criterion.	Clarify wording.	
22	C.4.c.(5)	Section 4.c.5 - The staff should endorse what parts of the RP they concur with. This would be very valuable.	Clarify wording.	
22	C.4.c.(6)	Rigorous statistical vendor data is typically unavailable for existing nuclear setpts and exceptionally costly to obtain. The application of "multipliers" to convert sample statistics to population estimates will result in un-operable plants due to protection setpoint overlapping normal operating conditions. Appears the intended NRC position is for each utility to implement an "approved" as-found/as-left analysis for all installed equipment and to require validated vendor performance data for all new equipment.	Clarify wording.	
22	C.4.c.(7)	Section 4.c.7 - The requirement is backwards. The Design basis calcs drive the plant test, M&TE, etc. This should be written that Design provides controls to ensure design basis requirements are in place that the the plant has to conform to.	Clarify wording.	
22	C.4.c.(7)	No business case to change anything ever.	Clarify wording.	
22	C.4.c.(8)	This reduction the AFT has a basis in logic, but then can result in inconsistent terms for AFT and TLU. This is similar to the inconsistency noted in comment #2 and page 21.	Clarify wording.	
22	C.4.d	Section 4.d - Why is this needed.	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
23	C.4.c(4)	The argument is made that 95/95 is merely "recommended" for existing plants, and is a target but not required, etc. However, as noted, it is increasingly presented as a necessity going forward. EPRI 3002000864 issued in 2013 for Advanced Nuclear Technology states that 95/95 is required by RG 1.105 R3. Also, those plants attempting to take advantage of TSTF-493 must commit to 95/95. This is unfortunate because *saddling any plant with a costly, low-value and ultimately unattainable instrumentation commitment is not in anyone's best interest*. To summarize: The 95/95 criterion should not be promoted as desirable and much less as a requirement for nuclear plant instrumentation. It diverts the cognizant station staff from considering far more important factors in instrument selection, usage and setpoint development. It makes them hesitant to employ the long-successful techniques described earlier and for decades exemplified in the ISA standards. It leads to on-going confusion between these standards and NRC guidance, and within these documents themselves.	Because 95/95 makes sense only as a mathematical concept, people cannot see how to address it in practice. This creates concern over how to "justify" not meeting this criterion, since all the guidance in that event eventually reduces to being impractically more conservative. These justifications will all be different since there is no guidance at all on that, and there will be endless worry and debate over acceptability. Far from assisting the industry in doing a better job, driving it towards the 95/95 criterion will impair the good work already being done, will discourage or delay progress towards real improvements that can be made, and cannot ultimately accomplish anything worth even a small fraction of its cost.	
23	C.4.c.(4)	The push for a 95/95 criterion has been underway for some time and gets more embedded with each new revision of the various industry guidance documents. *It is undesirable in real-world nuclear for the following reasons*: (1) 95/95 has only a minuscule positive effect on the likelihood that redundant safety trains will actuate when required (2) 95/95 cannot be met by or back-fit to existing instrument loops. Thousands of these have for decades been installed and operating in nuclear safety systems. Replacing any such 'Q' equipment for any reason is a significant cost. Replacing a whole loop would be very costly. Replacing whole structures of loops would be impossibly so.(3) 95/95 data and certification on new components will be very expensive, on top of the usual surcharges for Appendix B-compliant manufacturing. Vendors must recover the large costs of determining and backing the 95/95 numbers from a very small market.(4) Even where vendors can be paid now to supply such equipment, future procurement of replacement parts will be very difficult when those specialty vendors have gone.	Obtaining 'Q' part replacements has been a well-known problem for decades already. Requiring 'Q + 95/95' will make this much harder. (5) Even if new equipment is procured and all components in a measurement loop have factory 95/95 certification, the environment in which these will be installed will not be so well mathematically defined. This includes the skill of the engineers designing the installation, the accuracy of the drawings they're using, the skill of the craft maintaining these loops, the knowledge of the analysts setting surveillance intervals etc. These will all be more than adequate, with numerous checks and verifications, but there are generally no 95/95 or better statistical certifications on such factors. So the 95/95 mathematical model will be immediately debased.	
23	C.4.e.(1)	Page 23: Paragraph e.(1) lists info for the setpoint calculation document that GEH does <u>not</u> include the basis for the selection of the AL(s). That info is in the Safety / Transient Analysis document(s).		
23	C.4.e.(1)	This is in the scope of the safety analysis, not the setpoint calculation. The Tech Spec basis often includes this basis.		
23	C.4.e.(1)	Delete this section. Analytical limits are defined in the safety analyses and not open to selection since they protect LSSS.	Delete this section	
23	C.4.e.(2)	While appropriate for a methodology, these modeling considerations and distributions should not change from calculation to calculation	Delete this section	
23	C.4.e.(3)	This implies that even the Calculation or Analysis procedure should be referenced. Also seems to expect that these procedures are inputs to the analysis instead of results determined in the analysis and then implemented in the various procedures.	Recommendation: Recognize the perspective that Engineering is directing the various aspects of instrument uncertainty instead of just reacting to external changes.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
23	C.4.e.(6)	Technical Specifications allow for extension of surveillance intervals by 25%, otherwise the surveillance has been missed and corrective actions are required to verify that the channel is still operable. All calculations consider this required additional time period for TS COTs TADOTS and CHANNEL CALIBRATIONS.	Delete "such time periods should include allowance for delays beyond the established normal time periods."	
23	C.4.f	Section 4.f - Calcs should not have assumptions. Change wording to requirements.	Clarify wording.	
23	C.4.g	Section 4.g - Not sure how to show independence. I could state that no dependencies are noted.	Clarify wording.	
23	C.4.g.	Parts of item g are redundant with C.4.c.(4).	Recommendation: Combine C.4.g and C.4.c. (4) for more complete description of use of SRSS in one location.	
23	C.4.h	The first sentence is redundant with C.4.e.(2) (distributions and parameters). Nor does it relate to the remainder of section "h."	Recommendation: delete first sentence, or combine with C.4.e.(2)	
23	C.4.h	Section 4.h - A histogram for each uncertainty parameter. Too costly and overkill. Use NUREG and vendor specs should address bias.	Clarify wording.	
23	C.4.h	Last sentence "A calibration monitoring program should be in place..." is not needed. This is already mandated by the NRC in accordance with 10CFR Appendix B section XVI. The statement seems to imply an additional program is required.	Clarify wording.	
23	C.4.h	Should reference requirements for a calibration program which is a different T/S section than the setpt T/S section. Refer to section 4.3, para 2.	Clarify wording.	
23	C.4.h	TSTF-493 requires the trending of as-found and as-left data the calibration monitoring would be redundant to this requirement	delete this section.	
23	C.4.i	"Setpoint related limits that are not generally subject to NRC review..." If they are not generally subject to NRC review, why include anything about them?	Recommendation: delete this section	
24	C.4.j	Section 4.j - I don't disagree with the concept but there are different levels of conservatism based upon engineering judgment and also so many variations that are application specific. It is difficult to cookbook all variables.	Clarify wording.	
24	C.5	Section a states that all setpoints in scope are to be full rigor, and section d does not endorse and grading criteria, but then section b allows an exception. This is exception appears to be of low value because it seems to indicate that a full rigor analysis is needed to show that a simplified analysis still give acceptable results.	Recommendation: delete redundant statements of rigor, decide whether exceptions to full rigor are allowed	
24	C.5.b	delete or provide a realistic acceptability criteria	Clarify wording.	
24	C.5.c	Appears redundant with section C.5.a. Recommendation: delete C.5.c	Clarify wording.	

Page	Section	Comment	Proposed Resolution	Basis for Comment or Resolution (If Needed)
24	C.5.c	LSSS are calculated by safety analysis methodologies that have a 95% probability and 95% confidence requirement. Other Setpoints or limits do not have these requirements and therefore it is impossible to produce a setpoint calculation with a 95% probability and 95% confidence level when the primary starting point does not have the same probability and confidence interval.	Revise to Grading should not be applied to Setpoints that protect LSSS functions.	
24	C.6.b	Does this section provide the basis for the assumption of normality or does the utility have to justify each and every variable as described in C.6c and C.6e.	Clarify wording.	
24	C.6.c	The goal of the uncertainty analysis is given here "...to achieve assurance that analytical limit will be protected." I agree. Much of the other information about 95/95 appears to be excessive statistical analysis without any real gain. If this goal (staff intent) is presently being achieved what is the problem major statistical analyses will solve.	Recommendation: Provide the problem being solved.	
24		Section 5 - Since the scope of the RG may have expanded to more than LSSS functions such asnon safety compliance and backup control room indication, EOP setpoints, a graded approach is warranted. Realistic (not 95/95) analyses are warranted for correct/appropriate operator actions and definition of appropriate compliance limits (ultra conservative uncertainty analysis can result in excessive costs for the life of the plant. If scope of RG is Safety Related Tech Spec setpoints, I am good with not having a graded approach.	Clarify wording.	
24		Section 6.b - The 95/95 and normal distribution proofs of all data will increase the costs of calculations by orders of magnitudes. An average calc for TVA is 80 to 120 mhrs at $100/hr to $150/hr which is $80K to $180K. This will at least double the cost per calc and multiple this over 200 calcs per unit result in cost increase of $3M to $16M per unit with no benefit to safety. Actually, it will reduce safety but robbing needed funding from critical plant upgrades. Based upon many calibration history evaluation, our present methods provide utlra conservative results which bound the desired 95/95 goals.	Clarify wording.	
24		Section 6.b - An additional resultant of this requirement will be the elimination of an already limit number of nuclear supplier because they cannot or will not provide these data.	Clarify wording.	
24		Section 6.d - Why? Only if interference is being made beyond the sampled population to a larger population.	Clarify wording.	
24		Section 6.e - I agree with these requirement but the requirement to justify the bounding values is left open for any interpretation. Not good for anyone. Suggestion is to use worst deviation applied in both directions and summed. This could be view as conservative since it bounds the worst case test results. An unacceptable method would be to use a 95/95 tolerance limit with a multiplier for 3 samples.	Clarify wording.	

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25	6.e	Suggested adding a reference to EPRI TR above for obtaining 95% confidence level data	Clarify wording.	
25	C.6	The argument is made that 95/95 is merely "recommended" for existing plants, and is a target but not required, etc. However, as noted, it is increasingly presented as a necessity going forward. EPRI 3002000864 issued in 2013 for Advanced Nuclear Technology states that 95/95 is required by RG 1.105 R3. Also, those plants attempting to take advantage of TSTF-493 must commit to 95/95. This is unfortunate because *saddling any plant with a costly, low-value and ultimately unattainable instrumentation commitment is not in anyone's best interest*.	To summarize: The 95/95 criterion should not be promoted as desirable and much less as a requirement for nuclear plant instrumentation. It diverts the cognizant station staff from considering far more important factors in instrument selection, usage and setpoint development. It makes them hesitant to employ the long-successful techniques described earlier and for decades exemplified in the ISA standards. It leads to on-going confusion between these standards and NRC guidance, and within these documents themselves. Because 95/95 makes sense only as a mathematical concept, people cannot see how to address it in practice. This creates concern over how to "justify" not meeting this criterion, since all the guidance in that event eventually reduces to being impractically more conservative. These justifications will all be different since there is no guidance at all on that, and there will be endless worry and debate over acceptability. Far from assisting the industry in doing a better job, driving it towards the 95/95 criterion will impair the good work already being done, will discourage or delay progress towards real improvements that can be made, and cannot ultimately accomplish anything worth even a small fraction of its cost.	
25	C.6	The push for a 95/95 criterion has been underway for some time and gets more embedded with each new revision of the various industry guidance documents. *It is undesirable in real-world nuclear for the following reasons*: (1) 95/95 has only a minuscule positive effect on the likelihood that redundant safety trains will actuate when required (2) 95/95 cannot be met by or back-fit to existing instrument loops. Thousands of these have for decades been installed and operating in nuclear safety systems. Replacing any such 'Q' equipment for any reason is a significant cost. Replacing a whole loop would be very costly. Replacing whole structures of loops would be impossibly so.(3) 95/95 data and certification on new components will be very expensive, on top of the usual surcharges for Appendix B-compliant manufacturing. Vendors must recover the large costs of determining and backing the 95/95 numbers from a very small market.(4) Even where vendors can be paid now to supply such equipment, future procurement of replacement parts will be very difficult when those specialty vendors have gone. Obtaining 'Q' part replacements has been a well-known problem for decades already. Requiring 'Q + 95/95' will make this much harder. (5) Even if new equipment is procured and all components in a measurement loop have factory 95/95 certification, the environment in which these will be installed will not be so well mathematically defined. This includes the skill of the engineers designing the installation, the accuracy of the drawings they're using, the skill of the craft maintaining these loops, the knowledge of the analysts setting surveillance intervals etc.	To summarize: The 95/95 criterion should not be promoted as desirable and much less as a requirement for nuclear plant instrumentation. It diverts the cognizant station staff from considering far more important factors in instrument selection, usage and setpoint development. It makes them hesitant to employ the long-successful techniques described earlier and for decades exemplified in the ISA standards. It leads to on-going confusion between these standards and NRC guidance, and within these documents themselves. Because 95/95 makes sense only as a mathematical concept, people cannot see how to address it in practice. This creates concern over how to "justify" not meeting this criterion, since all the guidance in that event eventually reduces to being impractically more conservative. These justifications will all be different since there is no guidance at all on that, and there will be endless worry and debate over acceptability. Far from assisting the industry in doing a better job, driving it towards the 95/95 criterion will impair the good work already being done, will discourage or delay progress towards real improvements that can be made, and cannot ultimately accomplish anything worth even a small fraction of its cost.	

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25	C.6	**SRSS and 95/95:** For the past four decades, in accordance with the applicable ISA standards, it has been common practice in the nuclear industry to determine an instrument's uncertainty in two steps: (1) identify all biases (errors with predictable sign) and treat them additively; then (2) combine all other errors (those with no evident interdependence) via Square Root of the Sum of the Squares (SRSS). The use of SRSS has long been found reasonable and effective in this industry, and for much longer in other industries, because such independent and generally random errors will in many cases offset each other. The SRSS is a simple, methodical, recognized, and proven way to capture this effect. Nuclear plants complement this with procedural feedback mechanisms to evaluate and account for real, observed instrument performance in the field. Used as it is, SRSS gives a demonstrably good estimate of what error magnitudes can and should be expected. It is true that SRSS can also be applied with statistical rigor to large data sets having known distributions - but that has no bearing on the value or use of SRSS for data that is less regular. SRSS still does what it is supposed to do in such cases: provide an effective, easily understood, widely accepted, and standard method of combining uncertainties that are not additive.	It is therefore a fallacy to conclude that any use of SRSS should entail all the knowledge of populations and distributions that attend formal statistical analyses. It is even more wrong to say that if that knowledge is lacking, SRSS cannot be used! Or to say that it can be used but only in ways that remove all its value e.g. over-conservatively bounding error contributors that cannot be proven to be normal. In spite of this, DG-1141 Pg. 23 Sec. C.4.c.(4) states that SRSS is acceptable "only if the uncertainties are statistically independent and are based on normal probability distributions that provide adequate coverage of the underlying data". The reason for this statement is the evident intent to impose the "95/95" criterion, which inherently requires rigorous statistical techniques. DG-1141 Pg. 25 Sec. C.6 states throughout that meeting 95/95 is important. Deficiencies in this regard are to be justified either based on some knowledge of the equipment distributions or by applying correction factors or using bounding value estimates. However, these methods are either impractical or are so conservative that they differ little from treating all errors as additive.	
25	C.6.e	Seismic qualification is for post event safe shutdown and not for accident response or accident mitigation. Post accident monitoring is also for post event trending. Neither is based on a detailed LSSS value and cannot be calculated to 95/95 in any case. The setpoints for these conditions are based on multiple worst case evaluations and do not support a 95/95 confidence interval.	delete this section.	
25	C.7.b & footnote	The difference between the presentation here and RIS 2006-017 appears to be much larger than "slightly". If the footnote wasn't there, the discussion on page 5 of the RIS would not likely be is not recognized.	Recommendation: conform more to the RIS discussion.	
25	C.7.b.(1)	Setting tolerance was eliminated in TSTF-493 and RIS 2006-17 this conflicts with current NRC guidance	Delete this section.	
25	C.7.b.(2)	Section C.4.c.(1) states: For the purpose of establishing the limiting setpoint, the total loop uncertainty does not need to include the setting tolerance. See "Limiting Setpoint (LSP)" in this RG.	Delete this section.	
25	C.7.b.(3)	Delete this section.	Delete this section.	
25	C.7.c	Not a part of the setpoint calculation process, these actions would be a part of the corrective action process and not reflected in the calculations.	Delete this section.	
25	C.7.d.(3)	"... high incidence of false detections..." This is related to comment #8 on page 15.	Recommendation: provide basis for why you think this is true. Others of us, who also think we understand statistics, disagree.	
25	C.7.d.(3)	Section 7.d.3 - Experience demonstrates this as not being a problem. Where did this come from (state a real basis for the requirement).	Clarify wording.	

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25	C.7.e.(3)	Section 7.e.3 - What is this stating? Av is a worthless value. AFT will always be used for Operability?	Clarify wording.	
25		Where is the RIS criteria for AFT and ALT?	Clarify wording.	
26	C.7.d.(3)	The staff assumes that the as-found trip points are close to the as-found tolerance limits most of the time and that there would be a high incident of false detections. This has not been the case for plants that have implemented TSTF-493 and is not expected. A false positive in this case is conservative and the statement is simply to push utilities to use the as-found minus as-left method for deviation calculation.	Delete this section.	
26	C.7.d.(3)	"suitable practices" is undefined and unclear.	Clarify wording.	
26	C.7.e.	Related to comment #1 on page 16	Clarify wording.	