DG-1363 Nonconcurrence Support Documents

Caveats and Limitations Concerning Documents Released to the Public

Limits on Interpretation and Regulatory Significance

THE DOCUMENT TO WHICH THIS NOTICE IS ATTACHED HAS NOT BEEN ISSUED, APPROVED, OR ENDORSED BY THE UNITED STATES NUCLEAR REGULATORY COMMISSION.

THE SUBJECT DOCUMENT PRESENTS THE IMPRESSIONS AND OPINIONS OF THE AUTHOR AS OF THE TIME OF ITS PREPARATION, CIRCA 2015.

THE SUBJECT DOCUMENT HAS NO REGULATORY SIGNIFICANCE.

The United States Nuclear Regulatory Commission (NRC) has issued revision 4 to regulatory guide 1.105 (RG 1.105), "Setpoints for Safety-Related Instrumentation," (Agencywide Document Management System (ADAMS) Accession No. ML20330A329). The NRC issued draft regulatory guide (DG)-1141 (ADAMS Accession No. ML081630179) in June 2014, as proposed revision 4 of RG 1.105. Interested persons and organizations outside the NRC submitted a substantial number of comments concerning DG-1141. NRC staff prepared draft responses to all of the comments, and updated the draft regulatory guide in preparation for final issue. In anticipation of a significant revision to the industry standard associated with the regulatory guide, the American National Standards Institute (ANSI)/International Society of Automation (ISA) Standard 67.04.01, "Setpoints for Nuclear Safety-Related Instrumentation," the NRC terminated all efforts related to DG-1141 and to the comments provided in response to it. The revised regulatory guide and comment responses related to DG-1141 were not issued. After the revised standard was issued, the NRC produced DG-1363 (ADAMS Accession no. ML20055G823), a second draft of revision 4 to RG 1.105. The issued revision 4 to RG 1.105 is based on DG-1363 rather than on DG-1141.

The principal author of DG-1141 indicated disagreement with two specific aspects of DG-1363, and documented the disagreement in a nonconcurrence statement. The nonconcurrence statement is available in ADAMS, at Accession No. ML20181A524. The nonconcurrence lists several reference documents that were not, at the time, available for public access. The NRC has determined that those documents should be made available to the public, with minor modifications to ensure that they are not interpreted as NRC policy or positions.

The document to which this notice is attached is one of the documents cited in the nonconcurrence statement, and has been modified and released for public access as described above. The changes to the document as released for public access, as compared with the document as it existed at the time of the nonconcurrence, are not germane to the nonconcurrence.

Response to Public Comments on Draft Regulatory Guide DG-1411, Setpoints for Safety-Related Instrumentation Proposed Revision 4 of Regulatory Guide 1.105

On July 11, 2014, the NRC published a notice in the Federal Register (79 FR 40163) announcing that Draft Regulatory Guide (DG)-1411, "Setpoints for Safety-Related Instrumentation," (Proposed Revision 4 of RG 1.105), was available for public comment. A second announcement was made on August 8, 2014 (79 FR 46469) to make minor editorial changes. The public comment period ended on October 10, 2014. The NRC received over 600 comments from 11 different groups or individuals. The NRC has combined the comments and NRC staff responses below.

In some cases, comments from multiple sources are sufficiently similar to warrant consolidation into a single "Common Theme" for response. In some cases, NRC staff has deemed it appropriate to paraphrase a comment to focus attention to what seems to be the salient point, or to more clearly indicate staff's interpretation of the comment statement. Similarly, comments presented in a single statement may be broken into multiple comments in cases where NRC staff has determined that individual treatment is warranted.

Two separate listings are presented:

- The first list presents the comment packages as received, including individual listing of attachments provided by the originator where appropriate. In cases where the originator has not uniquely identified each attachment, NRC staff has assigned an identifier to facilitate reference.
- The second list presents the comments themselves, along with the NRC responses. Each individual comment is presented. Comments that are similar to one another are referred to a "Common Theme" for response, rather than being answered individually. Duplicated comments are answered once, and the other instances are referenced to that one response. Individual comments may be numbered or sub-numbered by NRC staff, to facilitate identification.

COMMENT SUBMITTALS:

(All submittals are available to the general public in ADAMS[1] at the indicated ADAMS Accession Number.)
(All submittals were received in calendar year 2014)

Primary Commenter	Affiliation (if specified)	Submittal Date (or document date, if appropriate)	ADAMS[1] Accession Number
Aaron Adamczyk		**August 31**	**ML14254A178**
R. Baker		**October 10**	**ML14293A048**

This submittal consists of expository statements and assertions followed by unnumbered comments. NRC staff has extracted and paraphrased the comments and provided responses to them. Statements and assertions that are not directed to specific aspects of the draft regulatory guide are not explicitly addressed in the NRC's responses.

The comments in this submittal are essentially duplicated in comments submitted by the ISA and by NEI. The duplicated comments are cross-referenced and are addressed under the Baker submittal.

Mark Burzynski	**New Clear Day, Inc.**	**September 21**	**ML14281A263**
James Barstow	**Exelon**	**October 10**	**ML14300A407**

This letter endorses comments by others without additional comment or limitation. It is therefore not included among the comments addressed below.

Patricia Campbell	**General Electric - Hitachi**	**September 30**	**ML14281A265**

NOTE 1: These are identified by the commenter as "Preliminary" comments, and are therefore presumed to be superseded by the GE-Hitachi comments submitted October 8 on behalf of Jerald Head by Timothy Enfinger. They are therefore not explicitly addressed among the NRC responses.

NOTE 2: The comment submittal states that these comments, which are in the form of presentation slides, were presented at the public meeting of August 14. These slides were not included in the meeting record because the presentation was abandoned after only a few slides had been presented. The slides are, however, included in the ADAMS record identified for this submittal.

Jerald Head	**General Electric - Hitachi**	**October 8**	**ML14283A501**

Comment letter from Jerald Head, transmitted via October 8 EMail from Timothy Enfinger.

1 The NRC's **A**gencywide **D**ocuments **A**ccess and **M**anagement **S**ystem, available at: http://www.nrc.gov/reading-rm/adams.html

Jerry Voss, Peter VandeVisse **ISA (International Society of Automation)**
Subcommittee 67.04, *Setpoints for Safety-Related Instrumentation Used in Nuclear Power Plants*
October 9 **ML14288A242**

Disclaimer, from the comment transmittal letter:

The comments are from the ISA SP67.04 ''Nuclear Instrumentation Setpoints" Committee. They are not comments from Instrument Society of America, and have not been reviewed by the ISA S&P board.

The ISA comment submittal consists of a letter with three unnumbered and 5 numbered comments, plus a 19-page tabulation of unnumbered comments.

The ISA tabulation includes three comments that closely resemble comments submitted separately by R. Baker and also duplicated among the comments submitted by NEI. The various versions of those comments are cross-referenced, and are addressed in connection with the Baker submittal.

Comments from the ISA tabulation are identified here by means of the page number followed by the sequential count on that page — for example: the 3rd comment on page 4 is identified as comment number ISA-4.3. The unnumbered comments in the letter are identified as ISA-L1, ISA-L2, and ISA-L3. The numbered comments in the letter are identified simply by means of the ISA-provided comment numbers.

Steven Hutchins **NEI (Nuclear Energy Institute)** **October 9** **ML14289A017**

The NEI submittal consists of a letter with two unnumbered and four numbered multi-part comments, plus an enclosure. The enclosure consists of:

1. A 48-page tabulation of unnumbered comments. Some of the comments are attributed to other sources and bear originators' page numbers as well as NEI page numbers. Comments that do not appear to have been submitted to the NRC separately by others are treated as NEI comments regardless of attribution within the tabulation — the NEI (rather than originator) page numbering is cited for identification of individual comments.
2. A letter from C. R. Pierce of Southern Company to Stephen P. Hutchins of NEI is embedded between pages 23 and 24 of the tabulation. The letter is dated October 3, 2014, and includes 4 bulleted comments and a 9-page enclosure presenting 23 numbered comments.
3. Comments from NuScale that had already been submitted directly to the NRC on September 30. These are included in the NEI tabulation as pages 5 through 23.

The NEI tabulation includes three comments that closely resemble comments submitted separately by R. Baker and also duplicated among the comments submitted by the ISA. The various versions of those comments are cross-referenced, and are addressed in connection with the Baker submittal.

The Pierce letter and its attachment bear no NEI identification or numbering. Because it is not fully integrated into the NEI comments despite its location among the NEI comment pages, the Pierce letter is treated as a separate submittal. It is listed separately in this listing and among the NRC responses.

The NuScale comments are addressed in connection with the direct submittal by NuScale.

Comments from the 48-page NEI tabulation are identified here by means of the NEI page number followed by the sequential count on that page — for example: the 3rd comment on page 4 is identified as comment number NEI-4.3. The identifiers and page numbers provided by the NEI correspondents are not used here. The unnumbered comments in the NEI letter are identified as NEI-L1 and NEI-L2. The numbered comments in the NEI letter are identified by means of the NEI-provided comment numbers.

Frank Laratta **August 22** **ML14239A031**

Letter with attachments — all comments are contained in the letter. The attachments provide supplementary information and are not explicitly addressed in the responses, and therefore are not listed individually here.

Steven Mirsky **NuScale Power, LLC** **September 30** **ML14281A264**

Comment letter submitted via Regulations.gov. The submittal consists of a letter with no comments and an attachment with 26 numbered comments.

Ken Scarola **Nuclear Automation Engineering, LLC** **September 5** **ML14259A342**

a. comment listing
b. mark-up of draft RG

C. R. Pierce **Southern Company** **n/a** **n/a**

These comments are included in the October 9 submittal from Steven Hutchens of NEI (ADAMS ML14289A017). They are embedded in the enclosure to the NEI letter, but are not fully integrated into the NEI comments. They are available in ADAMS as part of the NEI submittal — there is no separate presentation in ADAMS.

The Pierce letter includes four bulleted comments and an enclosure with 23 numbered comments. The comments in the Pierce letter are identified herein with Southern Company rather than with NEI. The four bulleted comments in the Pierce letter are identified as SC-L1 through SC-L4. The 23 numbered comments attached to the Pierce letter are identified by means of the numbers assigned by Southern Company.

James Gresham **Westinghouse Electric Company** **October 1** **ML14293A047**

Comment letter signed by James Gresham, submitted to Regulations.gov by Camille Zozula.

Technical contacts: Charles Tuley, Terrance Williams

GUIDE TO RESPONSES[2]

COMMENTS AND RESPONSES

Comments are generally presented in text as close to the original as deemed reasonable, but may be altered to suit consistent presentation in this context, to support consolidation of similar comments, or to clarify the staff's interpretation of the original wording. Spelling, punctuation, grammar, and other editorial errors are not generally corrected unless such corrections are needed to resolve ambiguity. Substantive changes to the wording in the original comments are acknowledged and explained.

2 As indicated in the detailed listing of comment submittals, some comment sets do not warrant individual response and are therefore not included in this summary or in the responses provided below.

3 Comments from large organizations are identified with the organization rather than with the person who submitted them.

Comments are referenced to the specific documents in which they were submitted. Sequential comment numbering is assigned by the NRC. Commenters' numbering is included in the comment reference when appropriate. The comment numbering and referencing scheme is described below.

There is substantial duplication among comments, both within individual submittal packages and among comments provided by different commenters. A set of "Common Themes" has been developed to provide responses to sets of comments that are similar in terms of the underlying subject and substance. The Common Themes are presented as the first set of responses below. Comments which are essentially identical in substance but which are not addressed in Common Themes are addressed once and the duplicate comments are referenced to that response. In some cases, a comment from one commenter duplicates only part of a comment, and so is marked as a partial duplicate.

Planned NRC staff actions in response to individual comments are explicitly indicated in the responses. Such actions are highlighted ***in the manner demonstrated in this example***. If no action is presented, then no action is intended.

Comments and responses are presented in the following three-part structure:

1. xyz-1, B5.2>NSP, p18b2: Comment, quoted or paraphrased as appropriate. Each comment is numbered (sequential numbers, assigned by NRC). **(1)**

   The text between the sequential number and the colon presents citation information, usually in the format described below. The presentation of this information may be omitted or modified, as appropriate in the context of individual comments.

   The citation fields presented in this example are:

   xyz-1 unique commenter identifier and commenter's comment number:
   If the commenter has not assigned comment numbers, the NRC will assign numbers on the basis of some scheme appropriate to the presentation. Details concerning NRC-assigned numbering are presented in the description of each comment package.

   B5.2>NSP reference to a section of DG-1141:
   The text following ">" is a reference to an unnumbered section within the referenced section. This detail may be omitted if not applicable or if deemed not helpful.

   p18b2 reference to a specific page and text block in DG-1141:
   Text blocks are blocks of text counted from the top of the page but excluding titles and headers. A text block may include only a single line or a partial line of text. The first text block on a page may be a continuation of a paragraph from the previous page. Page and block references may be omitted in cases where other information is sufficiently specific — such as for paragraphs in Section C, or for definitions in the Glossary.

   Additional comment paragraphs as needed — not numbered. **(2)**

NRC response: one or more unnumbered paragraphs as needed. **(3)**

The comment and response are set off by indent and typeface, as shown in this example. A horizontal line marks the end of the final paragraph of a response.

Common Themes

This section consolidates sets of similar comments presented by multiple commenters. The comment text presented here is the staff's interpretation of the common aspects of the similar comments. In many cases, the need for explicit comment text is obviated by the title of the Common Theme together with the wording of the NRC's response or explanation. In most cases the consolidated comments apply to multiple sections of DG-1141, and so specific citations are omitted.

1. **Common Theme #1:** ***Technical Specifications***

   The regulatory guide should not present guidance for technical specifications, and it should not address considerations related to technical specifications.

Staff agrees that the regulatory guide should not provide guidance concerning the form and content of technical specifications. This is asserted in footnote 2 on page 8 of the current draft, cited near the end of Section B2, near the bottom of page 8.

Nevertheless, there is a clear nexus between the technical specifications and the guidance provided in this regulatory guide: the guidance provides means for reliably determining the numerical values for the limits that are codified in the technical specifications. In a practical sense, then, the guidance addresses aspects of the technical specifications in order to establish the manner of determination of the associated limits. The guidance does not address the question of what limits should be included in the technical specifications, but rather only establishes means for determining appropriate values for those limits. The text of the guidance does include information related to the technical specifications, in the interest of demonstrating or highlighting the importance of various aspects of the analyses addressed in the guidance. The text is intended to describe the reason that various limits are important, and to describe the implications of an inability or failure to comply with them.

The draft regulatory guide does presume that the technical specifications will have requirements relating to the As-Found setpoint and to the As-Left setpoint, and provides guidance as to how the associated limits may be determined.

Paragraph C2b of the draft guidance was revised to remove the sentence concerning technical specifications and reactor shutdown.

10CFR50.36 presents requirements concerning Limiting Safety System Settings (LSSS). The draft guidance recognizes two LSSS for each setpoint: a limit on the As-Found setting, to support a determination that the instrument channel has been functioning as expected during the time since its last assessment, and a limit on the As-Left setting, to provide assurance that the instrument channel will function properly during the upcoming operation interval. The As-Found limit in particular supports an operability determination, in that a setting found to deviate excessively from the expected value can be an indication of equipment problems. The As-Left limit also provides some degree of operability assessment, in that a channel that cannot be set to within the setting tolerance of the nominal setpoint would warrant further investigation. The objective of the guidance in this regard is not to establish a definition or comprehensive criteria for a formal operability determination — that is strictly a matter for technical specifications — but rather to highlight the relevance of these conditions in assessing operability. There are, of course, many other things to be taken into consideration in establishing operability in regard to technical specification requirements.

2. **Common Theme #2: *Calibration Criteria vs Setpoint Limits***

   Some comments express concern regarding perceived discrepancies between the calibration process for instrument loops and the calibration-related criteria and assumptions in the draft guidance.

The guidance addresses the overall calibration of an instrument loop, without regard to the manner in which the calibration is actually accomplished. Staff is aware that instrument loops are typically calibrated in parts, usually with the sensor calibrated separately from the electronics and with different processes for different types of equipment. This results in different criteria — including different kinds of criteria — for different parts of the instrument loop. The guidance establishes the overall calibration objectives and limits, with the understanding that the associated uncertainty allowances will be distributed among the loop components as needed. The guidance focuses on "the big picture" concerning overall loop performance, and does not address the details applicable to each individual device. The guidance also addresses phenomena that might not be included in the calibration details for any particular device, such as process- or connection-related considerations.

Staff is also aware that settings established in software have no tolerance, do not drift, and are not subject to random error. Such phenomena could be excluded from the uncertainty analyses altogether, or they could be included with uncertainty values of zero as applicable. The guidance is mute on this point, with the exception of asking that the approach be documented, with the intention that licensees address this as appropriate for their own particular needs and approaches.

The guidance does not specifically address device calibration, other than to say that the impact of the calibration process, tolerances, equipment, and schedule should be addressed in the uncertainty analysis that is used to establish the setpoint-related limits. The calibration procedures and the associated settings and tolerances will impact the operation of the loop as a whole, regardless of how the calibration is actually accomplished. That impact should be taken into consideration in the development of the limiting setpoint and of the as-found tolerance computed for the loop. Similarly, the calibration process, limits, equipment, and schedule should be consistent with the overall loop targets — the limiting setpoint and the as-found tolerance — established in response to the guidance.

C4f of the draft guidance indicates that the uncertainty analyses should be consistent with surveillance test procedures and criteria, among other things. This means that each computed limit should be based upon all — and only — those devices and conditions applicable to that particular limit. For example, if a TS limit on setpoint deviation applies only to the rack electronics and not to the sensor, then the associated uncertainty analysis should not include the sensor characteristics in the computation of that particular limit. ***C4f was modified to state this point explicitly***.

3. **Common Theme #3: *Scope***

   Some commenters claim that the scope of this draft guidance is too broad, and exceeds the scope of the previous revision to this regulatory guide. They say that the guidance should apply only to a limited selection of the setpoints presented in technical specifications, and should not apply to non-TS setpoints at all. At least one commenter indicates that the scope statement may be read as too *narrow*, excluding some setpoints that should be included. At least one commenter requests clarification regarding the role of regulatory guides in general. Some comments suggest that the scope of the guidance should be linked to the provisions of TSTF-493.

This guidance addresses only the manner of determining the numerical values of setpoint-related limits used in technical specifications or for other purposes. The guidance is intended to provide a rigorous basis for establishment of setpoint-related limits, regardless of the way those limits are used. Staff does not intend *any* increase in the scope or content of technical specifications, nor

rework concerning setpoint limits already established. The scope statement correctly indicates that the guidance can be applied to any setpoint, but does not mandate application to any setpoint in particular.

The scope section and other related statements was modified to more clearly indicate that the staff intends this guidance to address the manner in which setpoint-related limits expressed in the technical specifications for automated safety functions are computed, and not to influence the selection of which limits or setpoints are to be addressed in the technical specifications. For example, if the technical specifications concerning a given setpoint do not include an allowable value, then this guidance should not be construed as indicating that an allowable value should be added to the technical specifications. Or if a given function is not addressed in the technical specifications, then this guidance should not be construed as suggesting that it should be added. On the other hand, if the plant technical specifications do impose some limit concerning a setpoint for an automatic safety function — the reason for establishing such a limit would be outside the scope of this guidance — then staff believes that that limit should be developed in accordance with this guidance.

Staff recognizes that some settings or operating decision points not involved in automatic safety function actuation, such as some EOP action points, may warrant best-estimate analysis rather than the rigorous and conservative approach described in the guidance. The ***provisions concerning graded uncertainty analyses*** was modified in consideration of this recognition. Nevertheless, the guidance is acceptable for voluntary use as broadly as any licensee may wish to apply it.

TSTF-493 addresses the content of technical specifications, and the safety significance of setpoints contained therein. This is a scoping issue for the technical specifications, which, as already indicated in the draft guidance, is outside the scope of this regulatory guide. Therefore Staff believes that reference to TSTF-493 in this regulatory guide would be neither necessary nor appropriate.

As stated under "Purpose of Regulatory Guides" on Page 5 of the draft guidance, regulatory guides express an acceptable approach for compliance with applicable regulations but do not constitute regulations themselves. It is not necessary to comply with regulatory guidance, provided the alternative approach is shown to be in conformance with the applicable regulations and to provide an adequate degree of protection. This is true of all regulatory guides.

4. **Common Theme #4: *The Role of Industry Standards***

   Some comments advocate that NRC work with ISA to add needed details to 67.04.01 and obviate the need for the level of detail presently included in the draft guidance.

   Some comments indicate that ISA 67.04.02 includes, or could be modified to include, various aspects of the draft guidance, and recommend that it be endorsed in this regulatory guide.

   Some comments claim that there is a mandate for NRC to endorse industry standards.

While NRC does provide comments concerning, and in many cases has voting rights concerning, various industry standards, the standards themselves are rightly under the control of the organizations that issue them. From a regulatory standpoint, NRC can endorse a standard once it has been issued, and can limit that endorsement to exclude or modify specific provisions as we have done in regard to ISA-67.04.01 in the draft guidance. But our influence over the standard itself is limited. If the standard is revised to more closely reflect the draft guidance, then it might be possible for us to modify the guidance to rely more heavily on the industry standard and to reduce the level of detail in the guidance itself.

The draft guidance indicates endorsement of ISA 67.04.01 with specific exceptions. Provisions of the standard that are not explicitly excluded from endorsement and are not explicitly altered or contradicted in the draft guidance should be taken as acceptable to the NRC.

ISA-67.04.02 is a "Recommended Practice" document, not an industry "Standard." "Recommended practices" are not generally endorsed in regulatory guides. And if we were to endorse this particular recommended practice, the endorsement would require a very large number of clarifications. NRC Staff has determined that the best approach is to include suitable detail directly in the RG.

The National Technology Transfer and Advancement Act of 1995 requires, with some exceptions, that "… all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments." (Public Law 104-113, Section 12(d)(1)). It does not require unrestricted acceptance of any standard. In the present case, the industry standard includes many provisions that the NRC is able to accept, but it lacks important details and it includes material that the NRC considers ambiguous or to require enhancement for other reasons. Therefore it has been necessary for the NRC to provide a substantial amount of supplementary information in the guidance. Staff agrees that it would be preferable to have a standard that could be endorsed with little or no comment, but this is not presently the case. The ISA 67.04 Subcommittee acknowledges this in the second paragraph of their comment transmittal letter, addressed in this response document as comment ISA-L1.

NRC is represented on the committee responsible for ISA-67.04.01, and is open to requests for general discussions of these matters independently of or in conjunction with further development of that standard. See Common Theme #14: *Additional Meetings*

5. **Common Theme #5: *Terminology***

   Some comments indicate that the ISA terminology should be used throughout this guidance. Some comments request a mapping of the terminology used in the guidance into the ISA terminology, and in particular that the terminology used in guidance figure 1 be mapped into the corresponding terms in the corresponding figure in ISA 67.04.01. Some comments suggest that NRC and ISA should work together to develop common terminology. Some comments point out that the terminology used in the draft guidance differs from the terminology used in documents that have already been accepted by the NRC. Some comments express confusion over the term "trippoint."

Although the ISA terminology is useful, it does not address some of the concepts that are germane to this guidance. Simply adding new terms for those concepts would yield inconsistent ways of naming things within the guidance, potentially leading to confusion. Section B4.1 of the draft guidance points out that there is considerable variation in terminology across the industry. The ISA terminology is not used universally, and in some cases some terms are used by licensees in ways that differ from the ISA usage. Also, some of the definitions in the standard are not fully consistent with the needs of the regulatory guide.

Therefore staff determined that creation of a set of consistent terminology was warranted. The terminology used in the draft guidance is consistent with the terminology used in the extensive public discussions and correspondence leading up to the issuance of the setpoint RIS (2006-017).

Mapping the terminology in the guidance into the terminology in the ISA standard might be feasible for some terms, but differences in the terminology would render such a mapping incomplete. Staff does not agree that an attempt at such mapping would generate more benefit than confusion.

See Common Theme #14: *Additional Meetings* concerning joint efforts with ISA or any other entity.

Staff does not believe differences in terminology between the guidance and already-accepted documentation to be of concern. It is likely that there are also differences among different documents that have also already been accepted by the NRC. The terminology used within the guidance is designed for consistency and clarity within the guidance. Terminology used for other

purposes but consistent and clear within those contexts does not need to match that in the guidance.

The term "trippoint" describes a concept that is not addressed explicitly in the industry standard. The meaning and importance of this term are described on page 8 of the draft guidance.
See also Common Theme #16: *Setpoint vs Trippoint*.

6. **Common Theme #6: *Surrogate Safety Limits***

   Some respondents expressed concern over provisions in the guidance regarding the treatment of analytical limits as "surrogate safety limits." They suggested that exceeding a surrogate safety limit is not the same as exceeding the associated safety limit itself, and therefore should not be treated in the same manner. This comment was often linked to the common theme concerning the scope of the draft guidance. Some comments confuse the role of Limiting Safety System Settings in the protection of safety limits.

The Limiting Safety System Settings of 10CFR50.36 protect safety limits. Analytical limits are limits used in the safety analyses to show that safety limits will not be exceeded, and they provide the bases for the establishment of the LSSS. Safety limits related to PWR fuel temperature, for example, cannot be addressed directly by plant equipment, because fuel temperature cannot be measured in the present generation of PWR. Safety limits related to PWR fuel temperature are therefore protected by the analytical limits placed on other (measurable) variables. Those analytical limits therefore substitute for the fuel temperature safety limit, and so are of great importance in the protection of the reactor core and hence of public safety. As a result, the setpoint limits associated with those analytical limits should be derived with great mathematical and statistical rigor.

The term "surrogate safety limit" is used in recognition of the status of these analytical limits in protecting safety limits. Staff recognizes that there is margin in the safety analyses, and that exceeding an analytical limit will not necessarily result in exceedance of the associated safety limit. But that margin is not quantified, and plant behavior beyond the analyzed limits is not necessarily linear. Therefore it does not seem reasonable to rely upon, or to try to utilize, that "extra" -- but unknown -- margin.

Staff recognizes, however, that the foregoing reasoning applies more to the development of technical specifications, and less to the computation of the numerical values to be included in those technical specifications. This regulatory guide is intended to address the computation of the numerical values, and specifically avoids addressing the TS content. Therefore the ***references to surrogate safety limits was removed from the guidance***.

Some of the comments addressing surrogate safety limits include assertions and implications with which the staff does not agree. But in keeping with the focus on computation rather than technical specification content, we will not address those matters here.

The guidance is not intended to specify the actions to be taken in the event a setpoint-related limit is exceeded, although some description is provided for information and clarity. The plant technical specifications specify the needed limits and the actions to be taken if those limits are exceeded. The guidance only addresses the manner of determination of those limits. We will ***modify the statements concerning consequential actions*** to ensure that they are presented only as points of information and not as guidance concerning the content of the plant technical specifications.

7. **Common Theme #7: *AV***

   Some commenters indicate that allowable value is widely used and should not be deprecated. Some question the statements in the guidance concerning the relationship between the allowable value, the analytical limit, and the deviation limit in the nonconservative direction.

RIS 2006-017 indicates that Allowable Value is not an adequate criterion for the assessment of operability, because it does not provide for assessment of excessive deviation in the conservative direction. AV can provide assurance that deviation in the nonconservative direction has not caused a setpoint to become nonconservative, but the AFT limit in the nonconservative direction performs this same function and therefore renders the AV unnecessary. The use of an Allowable Value is not considered mandatory, but if one is specified then it should be respected.

The relationship between an allowable value and the associated nonconservative limit related to the As-Found tolerance will depend upon the manner in which AV is determined, and upon the basis for assessment of the As-Found setpoint. In a general conceptual sense, AV would be expected to be the same as the AFT-based limit. But there are multiple ways to compute an allowable value and the limits associated with the As-Found tolerance. Therefore AV may be more conservative or less conservative than the LSP limit, depending upon the particular combination of approaches used in any particular analysis. C7e3 in the draft guidance is consistent with the provision in the RIS that says that the AV should be respected if it is specified, but also recognizes that the AFT-based limit may be more conservative and would then supersede the AV-based limit.

The "Method 3" issue, addressed some time ago in extensive discussions and correspondence between the NRC and industry representatives, concerned one of the methods for computation of an allowable value as described in ISA "Recommended Practice" 67.04.02, which has not been endorsed by the NRC. The ISA has subsequently removed all three methods from the document. NRC demonstrated Method 3 to be inherently nonconservative.

8. **Common Theme #8: *95/95***

   Several comments point out difficulties in obtaining uncertainty data that can be shown to meet the 95/95 criteria. Several comments point out that the multipliers needed to convert sample statistics to population statistics can be large enough to result in uncertainty estimates that exceed the available operational margins, and thereby result in unacceptably large numbers of spurious actuations or even in an inability for a plant to function normally at all. Some comments assert that 95/95 should be applied only to setpoints of the highest level of safety significance, and some assert that it should not be applied to manual actuation points, such as those in SAMG, at all. Some comments suggest that the 95/95 provisions in the draft guidance are inconsistent with the provisions of Generic Letter GL-91-04.

   NOTE: Some comments appear to confuse the 95/95 criteria with a 95% probability of successful operation: Concerns related to the probability of successful operation are more appropriately addressed under the Common Theme on Single-Sided Setpoints, even though the comments themselves may be presented as "95/95" concerns. In addition, some comments nominally addressing 95/95 are actually better addressed under the Common Theme on SRSS. Individual comments are referenced to the appropriate Common Theme regardless of the nominal topic expressed in the comment.

The 95/95 criteria relate to the determination of the numerical values to be used in the uncertainty analysis. It affects the probability of successful initiation of a safety function because it governs the statistical characteristics of the underlying limits, but does not apply directly to the probability of initiation. The objective of the 95/95 or alternative criteria in this guidance is to establish the degree of credibility of the computed results: use of data that do not have appropriate statistical credibility would lead to results that also lack statistical credibility. The draft guidance presents a

succinct definition of the 95/95 criteria, but some comments express confusion as to what exactly is meant by the terms "sample" and "population." ***Section 4.4 was modified*** to more clearly explain what is intended by these terms.

While setpoint limits are clearly one-sided — from a safety standpoint, too high may be bad but too low may be acceptable — those limits are intended to accommodate anticipated errors. And errors are equally likely to be high or low. Note that error allowances are commonly presented in the form "±10psi," for example. Therefore the data upon which the composite error estimates are based are clearly two-sided, and so the composites themselves are two-sided. The "single-sided" statistics presented in some texts, such as NUREG-1475 Table T-11b, play no role here.

Staff recognizes that it will be difficult in many cases to demonstrate 95/95 confidence in uncertainty data, and that obtaining vendor information to support a claim of 95/95 or even obtaining a positive assertion of 95/95 will be difficult or impossible in many cases. Staff sees attainment of 95/95 confidence as a desirable goal rather than a necessary condition. For this reason Sections B4.4 and C6 of the draft guidance include provisions for the use of data that cannot be shown to meet the 95/95 criteria.

While staff understands the difficulties involved in strict application of the 95/95 criteria, staff does not believe outright abandonment of this goal to be consistent with the need for adequate assurance of plant safety. Data that do not meet this objective are likely to be nonconservative: as stated in some comments, strict adherence to 95/95 could require some uncertainty estimates to be so large as to drive some setpoints into the region of normal operation — moving them out of that region would then necessarily be less conservative.

Staff believes, and the draft guidance allows, that the uncertainty analyses used to establish setpoint limits should employ the best available data. If 95/95 cannot be demonstrated, the analyst should at least have some good reason for using the data that are available and should be able to articulate and document the reasoning behind the use of those data. The ***guidance was modified*** to more clearly indicate that the "justification" requested does not refer to formal analysis but rather to documentation of this reasoning.

Generic Letter GL-91-04 indicates that historical calibration data may be used to establish drift uncertainty in the determination of instrument setpoint limits. The draft guidance is consistent with this position. Item 1 of enclosure 2 of the generic letter indicates that a licensee should confirm that a drift value derived from historical data "has not, except on rare occasions, exceeded acceptable limits." Item 2 of enclosure 2 of the generic letter indicates that the drift values should be "determined with a high probability and a high degree of confidence." Staff believes that the draft guidance is consistent with both of these provisions. Note that the generic letter indicates a need for considerable and explicit documentation in support of the use of historical data in the determination of instrument drift. In addition, see above for a discussion of the provisions of the draft guidance in regard to strict adherence to the statistical provisions of the 95/95 criteria.

C6d and C6e were combined into a single provision addressing the use of historical data, qualification test data (typically having a very small sample size), and other data derived from sample sets that are not sufficiently large for sample size to be ignored. They will also be adjusted to indicate a need for justification — as opposed to specific mathematical analysis — for the approach and numerical values used in the uncertainty analyses.

Some uncertainty data are necessarily based upon a limited amount of test data. It has been suggested that in such a case the value of the uncertainty be taken as the largest observed error and treated as representing three standard deviations. Three standard deviations to both sides of the mean would encompass 99.73% of the population. Two standard deviations would encompass 95.95%. Staff agrees that it would make sense to use the largest, rather than mean or median, value, but observes that this value is influenced by the stochastic conditions at the time of the measurement and is not necessarily representative of the population statistics as a whole.

Therefore treatment as 3-sigma — which would entail reducing the value by a factor of ⅔ to be consistent with the other (2-sigma) data — is not obviously justified. Staff believes that the largest observed value should be used unaltered, but a licensee or applicant is welcome to provide a quantitative analyses to demonstrate that a modified value should be considered acceptable. ***C6e was modified*** to address this consideration.

Staff observes that the publically-available EPRI Report 3002000864, while neither endorsed nor reviewed by the NRC, does address this topic and may provide useful information in this area.

9. **Common Theme #9: *Single-Sided Setpoints***

NOTE: Some comments appear to confuse the 95/95 criteria with a 95% probability of successful operation: Concerns related to the probability of successful operation are more appropriately addressed under the Common Theme on Single-Sided Setpoints, even though the comments themselves may be presented as "95/95" concerns. In addition, some comments nominally addressing 95/95 are actually better addressed under the Common Theme on SRSS. Individual comments are referenced to the appropriate Common Theme regardless of the nominal topic expressed in the comment.

All measurements include some amount of error. Therefore the exact value of a measured variable at which an automated action will occur (the actual trippoint, ATP) cannot be known with certainty. The limiting setpoint (LSP) is established so as to provide adequate assurance that the actual trippoint will be conservative with respect to the value used in the plant safety analysis.

Staff has long accepted the 95/95 criteria as adequate for establishing setpoints related to safety functions. Measurement errors are typically distributed symmetrically about the mean value, and so half of the errors will be in the nonconservative direction and half will be in the conservative direction. Therefore only half of the errors that are larger than some threshold value will be nonconservative. 95/95 establishes the statistical distribution for each component of random error, and proper accumulation of those components into the total loop uncertainty results in a similar distribution for the net error in consideration of all of the components. If the underlying data meet the 95/95 criteria, and if the data are combined properly, then the result will also meet the 95/95 criteria. The total loop uncertainty represents that band about the mean error that can confidently be claimed to encompass 95% of all errors in the actual trippoint. Since the distribution is symmetrical and only half of those errors are nonconservative, the probability that any particular instance of error will be greater than TLU *and also nonconservative* is only 2½%, not 5%. So if the mean trippoint is conservative relative to the analytical limit by an amount equal to the total loop uncertainty, then the probability of violation of the analytical limit is only 2½%. This is a consequence of the manner in which the total loop uncertainty and the limiting value for the setpoint are established, as described in the industry standard (ISA 67.04.01). This is not a staff dictate or a "new provision" in the draft guidance.

The final sentence of p17b4 was modified to avoid the implication that this holds for asymmetrical distributions. There is no need for the distribution to be Normal, just that it be symmetrical

ISA 67.04.01-2006 clearly indicates — and has clearly indicated through multiple earlier editions — that the limiting setpoint should be removed from the analytical limit by an amount not less than the total loop uncertainty. Arguments to the effect that LSP may be separated from AL by less than TLU, however they may be justified, are clearly contrary to this provision of the industry standard and therefore contrary to the provisions of NRC guidance, which has endorsed this provision of the standard for roughly three decades.

The most common argument in favor of single-sided setpoints replaces the provisions described above with a particular, and, staff believes, erroneous, interpretation of the 95/95 criteria. That

argument hinges on the 95/95 provision that deems it acceptable for 5% of errors to be greater than TLU. But it ignores the distribution of errors, which places half of that 5% on the conservative side of the limiting setpoint. The argument claims that the 95/95 criteria allow the whole 5% to be nonconservative, thus reducing the separation between AL and LSP to something less than TLU. This interpretation ignores the symmetry in the distributions of the components from which the total loop uncertainty is derived. Staff does not accept this interpretation of the 95/95 criteria. In addition, this argument advocates violation of a key NRC-endorsed provision of the industry standard — that the limiting setpoint should be separated from the analytical limit by no less than the total loop uncertainty.

Staff recognizes that some instances of single-sided setpoints have been accepted by the NRC in the past. Staff does not believe, however, that those past acceptances necessarily express an abandonment of the provisions of past guidance or constitute a precedent for blanket acceptance of single-sided setpoints in the future. Those past acceptances were based upon particular details concerning the proposed scope and practices. Future applications may or may not include whatever additional provisions may have been taken into account in those past acceptances, and so the applicability of those past acceptances to future applications is an open question.

Staff also recognizes that the considerations expressed here and in the revised guidance should not necessarily impact past acceptance of single-sided setpoints. Staff does not presently intend to revisit past acceptances as a result of the revised guidance or of the foregoing discussion.

Some instructional texts, such as the NRC's own NUREG-1475[4], address the question of single-sided vs double-sided statistical limits in connection with 95/95 confidence or other confidence criteria. Some comments point out that the single-side criteria establish the 95/95 confidence limit at 1.645 standard deviations, in contrast to the 1.96 standard deviations needed for two-side criteria.[5] The single-side factor of 1.645 standard deviations does indeed seem to support the goal of 95/95 confidence, and would result in a 95% probability that the actual trippoint does not exceed the analytical limit.

But the random uncertainty elements that comprise the total loop uncertainty are clearly two-sided, and the 95/95 criteria place the tolerance limits for those random components of uncertainty at about two standard deviations on both sides of the means of the respective distributions. Therefore the limits for the random component of the total loop uncertainty are also about two standard deviations to either side of the mean of the composite distribution.

Section 4.4 of ISA 67.04.01-2006 clearly states that the limiting setpoint should be established as "AL – TLU" — that is, at a value removed from the analytical limit by the full amount of the total loop uncertainty.

Therefore the use of single-sided setpoints may meet the 95/95 criteria in some limited sense, if the symmetry in the distributions is ignored, but it fails to meet the requirement of Section 4.4 of 67.04.01. As indicated in Sections 4.4 and C6 of the draft guidance, and as further acknowledged and clarified in these responses to public comments, Staff recognizes that strict adherence to the 95/95 criteria may be difficult or impossible in many cases. Indeed, many of the comments from the public also assert the difficulty of compliance with the 95/95 criteria. Therefore use of 95/95 considerations to override the more specific and explicit "AL – TLU" requirement expressed in the industry standard is not, in the opinion of the staff, appropriate.

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4 NUREG-1475, revision 1, March 2011, Applying Statistics, by Dan Lurie, Lee Abramson, and James Vail, United States Nuclear Regulatory Commission. Available as NUREG/CR-1475, Rev. 1 from the Superintendent of Documents, U. S. Government Printing Office, P.O. Box 37082, Washington, DC 20013-7082 National Technical Information Service, 5285 Port Royal Road, Springfield, VA, 22161.

5 See, for example, Tables 11a and 11b on pages 558 and 559 of NUREG-1475 (both of the quoted factors apply to population standard deviations rather than to sample-set standard deviations)

Some comments assert that current practice allows for a 5% probability that a channel trippoint will exceed the analytical limit, and that the draft guidance seeks to reduce this probability to 2½%. Staff disagrees with both of these claims. There has never been, and the revised guidance does not establish, any specific requirement as to the numerical value of this probability. The 5% claim appears to come from a misreading of the 95/95 criterion concerning the probability that the assumed limits include 95% of the population, leaving 5% outside the limits. Such a reading ignores the fact that the excluded portion is distributed symmetrically about the mean, and so only half of that 5% is in the nonconservative direction. As discussed above, the 2½% probability is a consequence of other factors — it is not a provision mandated by the staff.

Some comments cite provisions of ISA-67.04.02 that allow for the limiting setpoint to be removed from the analytical limit by less than the total loop uncertainty. The NRC does not endorse ISA-67.04.02, and has not endorsed any earlier version of that document. Staff notes that such provisions contradict the requirements of ISA-67.04.01.

Some comments indicate that plant safety analyses include conservatisms that reduce the amount of conservatism needed in the margin between LSP and AL. Staff intends that AL as used in the determination of LSP be based on the actual value used in the safety analysis. If the safety analysis specifies the value of AL as "x" but then uses "1.05x" in the numerical analysis, then it may be appropriate for LSP to be based upon 1.05x rather than upon x. Other conservatisms in the safety analyses might also facilitate adjustment of the AL value used in the determination of LSP, but it would be necessary to quantify the conservatism and show that the value used in the determination of LSP is indeed consistent with the safety analysis assumptions and results.

An informal estimate of the composite probability that a two-out-of-four logic system will initiate a safety function at a process value that is nonconservative relative to the analytical limit (neglecting hardware failures) indicates that the use of a single-sided setpoint will increase this probability by a factor of about 7.85. Staff believes this increase in the failure rate to be too large for casual acceptance.

10. **Common Theme #10: *Temporal Extrapolation***

    Several comments question the need for linear extrapolation of uncertainty due to drift when a drift specification is for a time interval smaller than what is needed in the uncertainty analysis. Some comments indicate that drift specified over small intervals should be combined using SRSS for the number of intervals needed. Some comments assert that drift is not related to time at all. Some comments indicate a preference to use experience-related information to establish the amount of uncertainty that should be used to account for drift. Some comments point out that overestimation of drift would be conservative in regard to the limiting setpoint, but would be nonconservative in regard to the as-found tolerance.

It is important to recognize the difference between "drift" and "deviation:" "Drift" is the change in calibration over time that cannot be attributed to any other phenomenon. The measured change in a setpoint from one point in time to another includes the effects of drift, but it also includes other effects such as environmental changes or M&TE uncertainty. Therefore use of experience-related information would constitute an estimate of deviation, not drift.

Since deviation includes drift as well as other effects, use of deviation in lieu of drift would tend to be conservative for establishing a limiting setpoint but nonconservative for establishing the as-found tolerance. With suitable analysis and justification, this practice may be acceptable. The guidance was revised to ***explicitly recognize that alternative approaches*** to the determination of drift-related uncertainty may be acceptable.

Drift is typically specified on some arbitrary time base that may not be equal to the time interval needed in a particular uncertainty analysis. A drift rate specified as "1% per year" might be

specified just as accurately as "½% per 6 months." But if it is specified as "½% per 6 months" and extrapolated by SRSS, the resulting specification would only be 0.71% per year — almost 30% short of the actual value. If it could be shown that drift is truly non-constant over any arbitrary time interval, then it might be possible to justify an SRSS combination of time-related drift elements. But it would then be necessary to justify the selection of the duration of the time interval and the expected drift over such an interval, as well as to demonstrate the randomness of the amount of drift to be expected over each interval.

Staff is aware of industry efforts relating to the correlation of drift with time, and with preliminary results that suggest that the relationship between drift and time might be nonlinear for some devices. Although it seems unlikely that these efforts would justify SRSS-based extrapolation, it is possible that they could support alternatives to the linear extrapolation advocated in the current draft. ***The guidance was modified*** to recognize the possibility that alternative approaches may be justified, and to indicate that linear extrapolation should be used if no other approach can be adequately justified in any particular application.

Drift is time-related by definition. Nevertheless it is possible that some devices may be shown not to change with time, in which case the drift-related uncertainty could be specified as zero or could simply be omitted from the uncertainty computation.

The final paragraph on page 13 of the draft guidance points out the difference between conservatism in regard to the limiting setpoint and conservatism in regard to the assessment of setpoint deviation.

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11. **Common Theme #11: *Deviation Assessment***

Comments concerning deviation assessment fall into a few broad categories:

NSP vs pAsL

Several comments point out an error in the statements concerning the possibility of an increased rate of spurious detections of excessive deviation in the penultimate paragraph on page 15. Several comments also question the likelihood of an increase in false detections of excessive deviation when deviation is assessed on the basis of the nominal setpoint rather than the previous as-left setting. At least one comment asserts that the criteria for acceptance of NSP-based assessment of observed deviation differ significantly from the similar criteria on page 5 of RIS-20016-017.

We will ***change "spurious actuations" to "spurious detections"*** in the final two sentences of the penultimate paragraph on page 15. The references to "…actuations" are typographical errors.

NSP-based assessment of the as found setpoint will result in an increased incidence of false detection of excessive deviation. For example, if the previous As Left setpoint is near the +ST limit, then an otherwise-acceptable amount of deviation in the positive direction could be seen as "excessive" when compared to NSP whereas it would be seen as "acceptable" if AsF were compared to pAsL. In addition, there could also be an increase in the failure to detect excessive deviations: an As Left setting near the -ST limit followed by excessive deviation in the positive direction would be detected with pAsL based assessment but could appear to be acceptable when compared with NSP. Informal analysis suggests that NSP-based assessment would increase the false detection rate by about 250%, and would reduce the true detection rate by less than 10%. Staff believes that licensees who choose to use NSP-based assessment should be aware of, and prepared to deal with, the change in false detection rate regardless of the exact amount by which it might be affected.

The criteria in C7b for assessing an As-Found setting against the nominal setpoint rather than against the previous as-left setting differ in substance from the similar criteria at the top of page 5 of the RIS only in that C7b1 accepts AFT as the limit for comparison whereas item (1) in the RIS

specifies a particular selection of uncertainties. C7b2 and C7b3 are mathematically identical to their counterparts in the RIS. The slight increase in the limit on the setting tolerance is consistent with the analysis that led to the acceptance of NSP-based assessment in the RIS.

C7d3 was modified to remove the references to "suitable practices" and "high incidence of false detections" and instead to simply convey the expectation that a licensee would be aware of the possibility of an increase in the rate of false detections and be prepared to deal with them.

Reconsideration of the Analysis

Several comments question the need for reconsideration of setpoint-related analyses and of the associated data when discrepancies between the analyses and observed behavior are noticed.

AFT is a statistical value sometimes based upon limited data and a considerable amount of engineering judgment. When equipment is found not to behave in accordance with the analysis, it should be recognized that the problem may lie in the analysis rather than in the equipment. Whether an observed discrepancy is due to equipment problems or to analytical or data-related problems is not obvious. NRC staff therefore deems it reasonable for the RG to point out the need to be vigilant and aggressive in the assurance that the data and analyses are sufficiently accurate.

Chronic, Acute, or Expected Deviations

Some comments question the use of "fuzzy language" concerning the evaluation of deviations found to be in excess of the as-found tolerance. Some comments assert that the terms "excessive," "acute," and "chronic" are used in connection with the assessment of observed deviation, but are not defined within the guidance.

These terms are used in the standard sense of modern English, without qualification. This is already addressed near the middle of page 15 of the draft guidance: An acute deviation is a single instance of a large deviation. A chronic deviation is a repeated occurrence of small deviations that might not be significant individually but that become important because of the repetition. This is consistent with Note 3 to Figure 1, and with the provisions of C7c. It is a matter of good-faith best-estimate judgement to determine whether a single instance of deviation is larger than might reasonably be expected for normally-functioning equipment, or that an accumulation of lesser deviations has an occurrence frequency greater than might be reasonably expected. These judgements should be based on an understanding of the uncertainty analyses and of the underlying data used within it.

It would not be reasonable to take a single instance of a small amount of excessive deviation to constitute a "failure." Instrument behavior is to some limited extent stochastic, and occasional limited excursions are to be expected. This is the reason that "fuzzy" criteria are used in lieu of strict deterministic limits.

Miscellaneous

As stated near the middle of page 15 of the draft guidance, the LSSS related to the As-Found setting is the AFT "in combination with the reference value with which it is associated" — it is not the AFT itself. Although a setting found to be within the acceptable range does not confirm all aspects of operability, a setting found to be outside that range gives reason to question the operability of the instrumentation. The limits of this range constitute LSSS because an As-Found value outside the limits gives cause for further assessment of operability.

The final paragraph on page 13 of the draft guidance was modified to refer explicitly to the As-Found Tolerance, rather than to "acceptable setpoint deviation."

C2b was revised to remove the reference to corrective actions etc. The provisions for consideration of whether an observed deviation is excessive or chronic will be retained, because

that determination is intimately tied to the details of the statistical analysis concerning the operation of the instrument loop.

12. **Common Theme #12: *As-Left Limits***

    Clarify the intended significance of the Limiting Setpoint. Clarify the relationship among the Limiting Setpoint (LSP), the Nominal Setpoint (NSP), the Setting Tolerance (ST), the Analytical Limit (AL), and the Total Loop Uncertainty (TLU). Some commenters believe that LSP should apply to NSP rather than to the as-left setting. Under some circumstances, ST should be treated as a bias rather than as a Gaussian random variable. The value of ST is sometimes related to the value of the reference accuracy of the instrumentation. Add a reference to GL 91-04 as additional guidance related to instrument drift assessment.

The published draft establishes LSP as a limit on the As-Left setpoint, and allows the setting tolerance to be excluded from the margin between LSP and AL. Various comments indicate a preference that LSP be considered a limit on the nominal setpoint rather than on AsL, and that AsL in excess of LSP should be considered acceptable provided NSP is no less conservative than LSP and AsL differs from NSP by no more than ST.

For digital systems, ST is typically zero so there is no substantive difference between these two approaches.

If the limiting setpoint is to be considered a limit on the nominal setpoint rather than on the As-Left setting, then the setting tolerance will need to be included in the total loop uncertainty. If ST is to be included in TLU, then the distribution of AsL about NSP must be established. It does not seem reasonable to model this distribution as Gaussian — a uniform distribution seems more likely. In fact, there is incentive for AsL near the nonconservative edge of NSP±ST, in the interest of leaving as much "room" as possible for operational variations without the initiation of the protective function — this would introduce a bias component into the ST distribution, which would then need to be added algebraically to the SRSS of the Gaussian terms.

Ultimately, the distribution of AsL about NSP is a matter of the individual practices and perceptions of individual technicians, together with the rules and procedures under which they operate. It is not clear that any particular distribution can be credibly assumed for universal application. On the other hand, it may be possible to show in at least in some cases that ST is so small compared with the other components of TLU as to have negligible effect upon the ultimate value of TLU — this would then resemble the case of digital systems, where ST=0 and there is no substantive difference between the two approaches. If ST needs be treated as a bias rather than included in the SRSS, then demonstration that it could reasonably be ignored would require a somewhat smaller value and so be more difficult to achieve.

C8, along with associated provisions in ***Sections B and C and in the Glossary*** was modified to more clearly accept LSP as a limit on either the As-Left setting (as in the present draft) or the nominal setpoint, (as some commenters have requested). The associated discussions of and limitations concerning NSP, ST, and TLU was revised accordingly. Note that the guidance does not establish the nominal setpoint directly — instead, it establishes criteria that influence the selection of the nominal setpoint or of the as-left setting, depending on the approach taken as described above.

Setting tolerance is a tolerance associated with the physical act of setting the setpoint. Reference accuracy is related to the uncertainty associated with the basic nature of an instrument. Setting Tolerance may sometimes be selected in consideration of reference accuracy or other uncertainty considerations, but ultimately it is an arbitrary value based largely upon engineering judgement. Regardless of how the value of the setting tolerance is selected, the uncertainty associated with it is distinct from all other uncertainties and should be treated independently from them.

Operability considerations related to difficulties in establishing As-Left settings consistent with the setting tolerance — or related to any other consideration, for that matter — may utilize information related to the quantities developed in accordance with this regulatory guidance, but the determinations themselves are outside the scope of this guidance.

Some comments suggest that the limiting safety system setting for the As-Left setpoint should be the nominal setpoint (NSP) rather than the limiting setpoint (LSP). NSP can be an arbitrary value that includes an unspecified amount of margin. LSP is a fixed value computed in such a manner as to provide enough separation from the analytical limit to give reasonable assurance that the associated automatic actuation will occur at a value of the measured variable that is no less conservative than the value used in the associated plant safety analysis. LSP is thus a limiting value for NSP — or for the as-left setting, depending upon the approach taken as described above. NSP is not a limiting value, and therefore cannot constitute a limiting safety system setting.

Generic Letter 91-04 addresses considerations related to instrument drift within the context of extended calibration intervals. While GL 91-04 presents insights and considerations that may be useful in the context of this regulatory guide, it is not directly applicable and Staff does not agree that it would constitute an appropriate reference. Staff believes that most entities interested in this guidance are already cognizant of the generic letter, and so the lack of mention in this guidance will not significantly detract from its use.

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13. **Common Theme #13: *Dynamic Effects***

    Several comments express concern regarding the provision for consideration of dynamic effects in Section C4c3 of the Draft Guidance. At least one comment cites the related provision in item 4.4g of the associated industry standard, ISA 67.04.01.

Both 4.4g of the industry standard and C4c3 of the draft guidance already explicitly acknowledge that dynamic effects are usually addressed in the plant safety analyses. Effects addressed in the safety analyses influence the selection of the analytical limit derived from those analyses, and so further consideration in regard to the determination of setpoint limits is clearly unnecessary.

Section C4c3 of the draft guidance does not indicate that these effects need to be accounted for in the uncertainty analyses, it simply indicates that they need to be accounted for somewhere. For the most part, timing considerations are addressed in the development of the analytical limit that is used as an input to the uncertainty analyses, rather than in the uncertainty analyses themselves. Nevertheless, it is possible that details of the instrument implementation could introduce delays not addressed in the safety analyses, and those delays, if they exist, need to be accounted for.

Response time testing acceptance criteria are used to confirm that the equipment is operating in accordance with expectations. The plant safety analyses and/or the instrument uncertainty analyses show that that expected performance, together with the established setpoint limits, will provide adequate protection of the associated safety limits.

C4c3 was modified to clearly indicate that it applies only to delays associated with instrumentation, and not to delays related to the process or process equipment. The example concerning actuated equipment ***was deleted***.

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14. **Common Theme #14: *Additional Meetings***

    Some commenters suggest that additional public meetings on this regulatory guide would be helpful. The first public meeting on this revision was held shortly after the publication of the draft regulatory guide, on August 14, 2014.

Staff is amenable to the possibility of additional public meetings on this subject, but this comment/response effort is not the appropriate forum for establishing meetings. If staff

determines that one or more additional meetings would be appropriate, it/they will be scheduled and announced in the normal manner.

15. **Common Theme #15: *SRSS***

Some comments indicate confusion over the definition of SRSS in the glossary.

Some comments suggest that the demonstration of statistical independence among the various elements of uncertainty should be based upon engineering judgement rather than requiring formal mathematical analysis.

Some comments advocate the use of SRSS more broadly than described in the guidance, indicating a preference to use SRSS to reduce uncertainty estimates without applying the criteria that justify its use.

NOTE: Some comments appear to confuse the 95/95 criteria with a 95% probability of successful operation: Concerns related to the probability of successful operation are more appropriately addressed under the Common Theme on Single-Sided Setpoints, even though the comments themselves may be presented as "95/95" concerns. In addition, some comments nominally addressing 95/95 are actually better addressed under the Common Theme on SRSS. Individual comments are referenced to the appropriate Common Theme regardless of the nominal topic expressed in the comment.

The "Square Root of the Sum of the Squares" (SRSS) combination of independent uncertainties stems from statistical considerations related to the individual uncertainties themselves. Each element of instrument error (reference accuracy, thermal effects, measurement and test equipment error, etc.) is represented by some statistical distribution. "Uncertainty" refers to some parameter of that distribution. In the vast majority of cases, the errors are modeled as Gaussian distributions and each individual element of uncertainty is taken to be a combination of the mean and standard deviation of the corresponding distribution. The overall uncertainty is some combination of all of the individual elements of uncertainty. The combination of the means is straightforward summation. The combination of the standard deviations is more complex.

Mathematically, the key parameter is really the variance of each distribution rather than the standard deviation. When multiple independent random variables are combined, the variances are added — the variance of the sum is the sum of the variances. Note the need for the random variables to be statistically independent: if the variables are not independent of one another, then the combination of the variances is more complex than simple summation and so much of the remainder of this discussion is not applicable. The standard deviation is the square-root of the variance. Therefore, the combination of the random variables has a variance equal to the sum of the variances and a standard deviation equal to the square root of the variance — or the SRSS of the individual standard deviations. If the random variables all have the same statistical distribution (for example, all are normal), then the sum will retain that same distribution. If there are multiple distributions (for example, some normal and some uniform), then the sum will be a convolution integral of the individual distributions.

C4c4 was revised to eliminate the implication that the distributions must be Gaussian. ***The guidance will also be modified*** to indicate that the assessment of independence among the various elements of uncertainty may be based upon engineering judgement and does not require a formal proof of independence.

The standard deviation is a property of the statistical distribution of a random variable — in the present case, of the individual elements of uncertainty and of the actual trippoint. From an I&C engineering standpoint, however, it is usually considered more useful to work with uncertainty than with standard deviations. By convention, uncertainty is usually taken to be the distance in both the positive and negative directions from the mean that will cause the intervening space to

contain about 95% of the distribution. For a Gaussian random variable, this amounts to about 2 standard deviations to either side of the mean. The interval is symmetrical because the error distribution is symmetrical. For example, the uncertainty in the measurement from a pressure sensor would usually be stated as ±10psi rather than as as +15/-5 psi. Since the uncertainty is proportional to the standard deviation, the individual uncertainties can be combined in the same manner as the individual standard deviations. (Note that the selection of 95% here is a matter of convention and is not related to the 95/95 criterion.)

The definition of SRSS in the glossary was revised for clarity, to address uncertainty as well as standard deviations, and to include reference to the need for statistical independence.

16. **Common Theme #16: *Setpoint vs Trippoint***

    Several comments question the need for the term "trippoint" as defined and used in the draft guidance. Some comments attempt to draw an equivalency between this term and the term "Actual Trip Setpoint" as defined and used in the industry standard.

There is an important distinction between the terms "setpoint" and "trippoint" as defined and used in the draft guidance: "setpoint" refers to an observed or intended setting at which some action is to be initiated, whereas "trippoint" refers to the actual value of the measured variable when the action actually is initiated. "Setpoint" is associated with the environmental and other conditions at the time the measurement is made or the setting is established. "Trippoint" is associated with the conditions when the actuation actually occurs. A trippoint cannot be known with arbitrary certainty because any attempt to measure or infer it will necessarily include an unknown amount of measurement error. In addition, the important thing about a trippoint is not its current value, but its value at some time in the future, when the associated actuation is actually needed. Therefore the trippoint will be influenced by process, environmental, and other conditions as they exist at that time in the future rather than at the time of measurement. What can be measured is a setpoint — the associated trippoint will have some statistical relationship to that measured value. The trippoint is an unknowable random variable that has some statistical distribution related to the associated setpoint.

This distinction is important because it is important that the *trippoint* be consistent with the plant safety analyses, and the only way to provide adequate assurance that that is so is to establish the *setpoint* in such a manner as to accommodate the statistical distribution of the trippoint.

As already addressed in the definition of "actual trippoint" in the glossary (page 30), "actual trippoint" is not the same as the ISA term "Actual Trip Setpoint." The similarity in the terms is unfortunate. The ISA term refers to a measured value, which necessarily includes uncertainty due to measurement error and from other sources. "Actual Trippoint" is a random variable with a statistical relationship to the measured value but with a value that cannot be known with arbitrary precision.

The terms "trippoint" and "actual trippoint" are equivalent. The modifier "actual" is sometimes used to emphasize that this is an actual, rather than intended, value.

Aaron Adamczyk (AA)

17. AA-1: IEEE STD 279 is no longer active standard and is only available in electronic format.

IEEE-279 is addressed in this regulatory guide because it remains in the licensing basis for several nuclear power plants.

18. AA-2: Update IEEE STD 603 reference to the 2009 edition.

The 1991 version of this standard is the version cited in the Code of Federal Regulations. The Code of Federal Regulations is presently under revision to address the 2009 version, but the revision is not yet complete.

19. AA-3: Update reference to ASME NQA 1 2012 edition.

NQA-1 is referenced in this draft only through the reference to regulatory guide 1.28 on page 3. The version cited by RG1.28 is controlled in RG1.28 and cannot be modified in this draft.

20. AA-4: All ANSI/ISA references need to reference ISA only.

ANSI-endorsed standard are typically referenced to both ANSI and the originating entity.

R. Baker (RB)

21. RB-1:

    For four+ decades the nuclear industry has determined instrument uncertainty by (1) add up all biases (errors with known sign); (2) combine all other errors (with no evident interdependence) via Square Root of the Sum of the Squares (SRSS). This has long been found reasonable and effective in many industries because independent errors often cancel each other. SRSS is a simple, methodical, recognized, proven way to capture this effect. It gives a demonstrably good estimate of what error magnitudes can and should be expected. Nuclear plants complement this with procedures to evaluate and account for real, observed instrument performance.

    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 use of SRSS for data that is less regular! SRSS still provides an effective, easily understood, widely accepted, and standard method of combining uncertainties that are not additive.

    So it is incredible to hear that to use SRSS one must have rigorous knowledge of populations and distributions! Or that it can be used but only in ways that remove all its value e.g. over-conservatively bounding errors that can't be proven to be normal. But DG-1141 Pg. 23 Sec. C.4.c.(4) states exactly that.

    The reason is the NRC intent to impose the "95/95" criterion, which requires rigorous statistics. This push gets more serious with each new rev of the various industry guidance documents. DG-1141 p25 Sec C.6 again reinforces this.

See Common Theme #15: *SRSS*

22. RB-2:

    95/95 is a terrible idea for real-world nuclear because:

    (I) 95/95 has only a minuscule 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 are 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 hugely expensive, on top of the usual surcharges for Appendix B 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 95/95 certification, the environment in which they're used will not be "95/95". This includes the skill of the engineers designing the installation, the accuracy of the drawings used, the skill of the craft maintaining the instruments, the knowledge of the analysts setting surveillance intervals etc etc etc. These will all be adequate, with numerous checks and verifications, but there are no 95/95 or

better statistical certifications on such factors. So the hugely expensive 95/95 math model will be immediately debased and lost!

See Common Theme #8: *95/95*

23. RB-3:

    The argument is made that 95/95 is merely "recommended" for existing plants, and is a target but not required, etc. But it is increasingly presented as a necessity going forward. EPRI 3002000864 (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.

    Saddling any plant with a costly, low-value and ultimately unattainable instrumentation commitment is not in anyone's interest and does NOT serve the public.

    Summary: The 95/95 criterion should not be promoted as desirable and much less as a requirement for nuclear plant instrumentation. It diverts the 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 exemplified in the ISA standards (such as SRSS). 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 differ 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 continue to discourage and delay progress on real improvements, and cannot ultimately accomplish anything worth even a small fraction of its cost.

See Common Theme #8: *95/95*

Mark Burzynski (MB)

24. MB-1, A>Scope, p4b7: The first paragraph is inconsistent with the document title, and is not aligned with RIS2006-017 as described among the reasons for revision as presented in Section B1. The RIS is specifically focused upon Limiting Safety System Settings (LSSS).

See Common Theme #3: *Scope*

25. MB-2, B2, p9b1: Treating Analytical Limits as surrogate Safety Limits has ramifications in definition of Safety Limits in TSs. 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.

See Common Theme #6: *Surrogate Safety Limits*
See also Common Theme #1: *Technical Specifications*

26. MB-3, B4.1>Notes, p11b3: Replace the note with the following text:

    "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."

    The purpose of the recommended change is for clarity and 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".*

Section B of a regulatory guide provides general information. Regulatory positions are to be presented only in Section C, which is already cross-referenced in the note. Also, this regulatory guide presents information concerning the establishment of limits applied in the technical specifications, but specifically avoids issues concerning the content and interpretation of the TS themselves, including interpretations of "operability." See Common Theme #1: *Technical Specifications*. Finally, B4.1 is just an introduction establishing terminology. Details concerning AFT are presented in B5.1 and in the associated regulatory positions in C7.

27. MB-4, B5.2>LSP, p16b5: The definition for LSP should be changed from "the least conservative acceptable value for an as-left setpoint" to "the limiting setting for the channel trip setpoint (TSP) considering all credible instrument errors associated with the instrument channel." The RIS-2006-017 definition of LSP should be retained as the basis of this regulatory guide.

See Common Theme #12: *As-Left Limits*

28. MB-5, B5.2, p17b4 (commenter cited p18): 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 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. 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.

See Common Theme #9: *Single-Sided Setpoints*

29. MB-6, C4c3, p22: Delete this item. Inclusion of dynamic effects within the setpoint methodology, as required by Section C.4.c(3), is inconsistent with industry practice. 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.

See Common Theme #13: *Dynamic Effects*

30. MB-7, C4c4, p22: Append "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." to the existing text. This is to clarify the expectation that the evaluation of independence uses reasonable engineering judgment rather than a formal proof of independence.

The existing text does not indicate that formal analysis is required. It simply states that the reasoning behind the conclusion should be explained. ***The guidance was modified*** to indicate that the uncertainty analysis should include a description of the reasoning behind the selection of the method used.

31. MB-8, C4i, p23: Delete the reference to later versions of this regulatory guide, for consistency with the limitations described in Section D.

The reference was deleted. Future revisions can reach back to rev. 4 as appropriate, but staff concedes that it is not necessary for rev. 4 to look forward to future revisions.

32. MB-9, C6d, p24: Append "Alternately, historical calibration data can be used to inform the setpoint drift analysis, as allowed by Generic Letter 91-04, Changes in Technical Specification Surveillance Intervals to Accommodate a 24-Month Fuel Cycle." to this paragraph. The specific discussion on 95/95 criterion in Section C.6 is not consistent with the use of calibration history to inform the setpoint drift analysis, as allowed by the Generic Letter.

See Common Theme #8: *95/95*

33. MB-10, C6e, p25: Insert underlined text as follows: "…relating to qualification type tests, (e.g., digital system environmental, post-accident…conditions) …" To encompass the small sample size environmental qualification testing required for digital I&C equipment by RG 1.209. 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.

See Common Theme #8: *95/95*

34. MB-11, C7c, p25: Evaluation of past deviations should be limited to *relevant* deviations. It would be both impractical and inappropriate to require that all past deviations be addressed. At some

point historical data loses relevance and data related to equipment that has been replaced or modified is not relevant.

Past deviations of equipment that has already been replaced may not seem to be relevant, but may ultimately be due to factors other than the equipment itself and therefore should be taken into consideration. The justification in question is already necessarily an issue of judgment, and that judgment would also address the reasoning behind the determination of what information should be considered.

35. MB-12, D, p28: During the August 14, 2014 public meeting NRC was asked about the implementation of the new guidance proposed in DG-1141. The NRC response was that the implementation is voluntary and it does not expect any existing licensee to use or commit to using the guidance in DG-1141, unless the licensee makes a change to its licensing basis, as stated in Section D. NRC confirmed in a clarifying question that changes to Technical Specification setpoints for whatever reason (e.g., power uprates or fuel changes) would be a basis for imposing the new guidance. The industry countered that they envision an increase in the number of cases where applicants will have to propose alternatives because of the practical constraints that exist with plant designs and equipment records. NRC should address this situation in the Section C, Staff Regulatory Guidance, since one cannot readily impose the 95/95 criteria on old installed equipment.

See Common Theme #8: *95/95*

36. MB-13, Glossary: DG-1141 introduces new and altered terminology rather than invoking ISA 67.04 industry standard terminology. No uniform transition path to the new terminology is defined in DG-1141. Consequently, conflicting sets of definitions will necessarily introduce confusion into the industry. It is recommended that the ISA terminology should be used.

See Common Theme #5: *Terminology*

General Electric – Hitachi (GEH) (comments submitted by Jerald Head)

37. GEH-1, B5.2>NSP, p18: Trip Probability

DG-1141

Figure 2 on page 18 of DG-1141 shows that, assuming no bias error and assuming that the error around the Limiting Setpoint (LSP) is the 95% confidence population error, the LSP is located such that the margin to the Analytical Limit (AL) provides a probability of 97.5% that the trip for a single channel will occur before the AL is reached.

GEH Comment

The Draft DG-1141 appears to impose a requirement of 97.5% probability of single channel trip before the AL is reached. This is inconsistent with the current and previous revisions of RG 1.105 (Revision 3 and earlier) which clearly define the requirement of trip before AL is reached to be 95% probability. The previous 95% probability requirement is the basis of the licensed GEH safety analyses, and the basis of the NRC-approved GEH setpoint methodology (Reference 2). Thus, using the 95% probability criterion (rather than the 97.5% criterion) would be consistent with the statements in Draft DG-1141 that the setpoint should be determined in accordance with the requirements of the safety analysis.

The GEH safety analysis application methodologies use the same 95/95 definition. This is evidenced by a letter from the NRC to GE (Reference 3) which states, in part, "This procedure provides for a statistical determination of the pressurization transient ΔCPR/ICPR 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." Thus, 95% is the non-exceedance %/probability. GEH has consistently used this 95/95=95% non-exceedance definition in analysis of Anticipated Operational Occurrences. The 97.5% probability is a different definition of 95% probability/95% confidence level from that already being applied by the NRC.

Note that locating the setpoint with respect to the AL based on the 95% probability criterion for a single channel provides a much higher trip probability for the trip function because the safety systems generally have 4 multiple channels with 2-out-of-4 trip logic, or 1-out-of-2 twice trip logic. GEH calculations show that for the case when the LSP is based on the single channel 95% probability criterion, the probability of trip before AL is reached is 99.95% for 2-out-of-4 trip logic, and 99.5% for 1-out-of-2 twice trip logic for the multiple channel configuration. The calculations also show that for the case when the LSP is based on the single channel 97.5% probability criterion, the probability of trip before AL is reached increases slightly to 99.99% for 2-out-of-4 trip logic, and 99.88 % for 1-out-of-2 twice trip logic for the multiple channel configuration. These results show that the increase in this multiple channel trip probability when the LSP is based on the single channel 97.5% trip probability criterion, when compared to when the LSP is based on the single channel 95.0% trip probability criterion, is insignificant from the safety point of view.

Note also that basing the setpoint on the 97.5% probability criterion instead of the 95% probability criterion could also decrease the margin between the setpoint and the normal operating limit (OL), and that would result in an undesirable increase in the spurious trip probability. GEH calculations show that the margin between the setpoint and the OL would decrease by 0.315 times the error standard deviation if the setpoint was based on the 97.5% probability criterion instead of the 95% probability criterion, assuming that the LSP is the final setpoint and the measurement errors that

determine the probability of tripping before the AL is reached are the same as the errors that determine the probability of spurious trip avoidance.

Number of Channels/Coincidence	Approximate Increase in Spurious Trip Probability	Change in Spurious Trip Probability
Single channel spurious trip	1.7	from 10% to -16.7%
2-out-of-4 multiple channel spurious trip	2.5	from ~5.2% to ~13.2%
1-out-of-2 twice multiple channel spurious trip	2.6	from 3.6% to ~9.4%

This assumes that the OL is such that the margin between the setpoint based on the 95% probability criterion and the OL provides 10% spurious trip probability. The reduced setpoint/OL margin is for the case where the setpoint is based on the 97.5% probability criterion.

These calculations show that basing the LSP on the 97.5% probability criterion rather than the historical 95% probability criterion results in an insignificant increase in probability of tripping before the AL is reached, but could lead to a significant detrimental increase in spurious trip probability. Moreover, the licensed GEH safety analyses are based on LSPs that meet the 95% probability criterion, so no increase in trip probability is required from the safety point of view.

The 97.5% probability criterion is the consequence of using ''two-sided" statistics, whereas using "single-sided" statistics would correctly locate the setpoint such that it meets the historical 95% probability requirement for not exceeding the AL. Note that the NRC's statistical handbook (Reference 4,NUREG-1475 Rev 1,"Applying Statistics") indicates that use of single-sided statistics is appropriate for the usual case where the variable approaches a safety related setpoint, or limit, in one direction from the safe side (see description of Critical Power Ratio in example 9.4 of Reference 4. and see Section 9.13 of Reference 4 for a description of how to determine with high confidence the upper limit of the population standard deviation from the standard deviation obtained from a limited size sample).

Proposed Resolution #1

It is proposed that the Draft DG-1141 replace Figure 2 with one that shows that the LSP margin to the AL be such that the probability of trip before AL is reached is 95%. Note that this change would allow the use of both the 95% and the 97.5% probability criteria. The Draft DG-1141 should also replace the definition of the required margin between the AL and the LSP to be the margin that provides 95% probability with high confidence (>95%) that the trip for a single channel will occur before the AL is reached.

DG-1141 should include a reference to NUREG-1475 for an expanded definition of the 95/95 criterion applied to locating the LSP with respect to the AL.

See Common Theme #8: *95/95*
See Common Theme #9: *Single-Sided Setpoints*

NUREG-1475 was added as a reference.

38. GEH-2, B4.4 & B5.2>LSP, p14 & p17b4 : 95/95 Criterion

DG-1141

Section 4.4 of DG-1141 (page 14) describes the 95/95 criterion as the criterion for estimating the population error around the setpoint, and Section 5.2, page 17, states that a consequence of the 95/95 criterion is that the probability in the tail above the AL is 2.5%.

GEH Comment

The 95/95 criterion described in Section 4.4 of DG-1141 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 the same error can be located an arbitrary number of sigmas away from the AL. A detailed explanation of this has been with the NRC (see Reference 5 and the related documents). The fact that DG-1141 indicates the instrument errors around the setpoint should be determined using 95/95 criterion is one requirement, but requiring the setpoint/AL margin to be such that probability of exceeding the AL is only 2.5% is a separate requirement.

(1) The first requirement to use 95/95 errors to determine the total measurement error (or uncertainty) is technically a valid approach, though it will be difficult to implement in practice and to rigorously enforce. As explained in DG-1141, this requirement calls for obtaining the error for a population by multiplying the error (or standard deviation) measured for a limited number of samples by a statistical factor that depends on the number of samples, and the confidence level to which the population error is to be determined. For 95% confidence, this multiplication factor could be much larger than one. For a normal population error distribution (which is typical of random instrument errors as stated in DG-1141, item C6) the 95/95 error is approximately the 2-sigma population error, where the standard deviation (or 1-sigma error) for the population error distribution is known to 95% confidence. Note that for the typical normal distribution, 95% of the population error data is between the plus 2-sigma and minus 2-sigma limits, but these are error limits around the setpoint, and have no relationship to how conservatively the setpoint itself is located relative to the AL or what the margin is between the AL and the setpoint.

(2) The second requirement to locate the setpoint relative to the AL is not a consequence of the first requirement to use 95/95 error data, but a separate requirement that should be based on the probability of assuring that the trip will occur before the AL is reached. Locating the setpoint relative to the AL so that 2.5% of the tail of the population error distribution is beyond the AL (as shown in Fig 2 of DG-1141) implies that 97.5% of the population error data is on the conservative side of the AL. Since the population error (or standard deviation) is known to be 95% confidence, this means that DG-1141 is using a 97.5/95 criterion to determine the margin between the setpoint and the AL. Use of this 97.5/95 criterion in DG-1141 implies that the probability that the trip will occur before the AL is reached is 97.5%, and there is 95% confidence in that assertion. This is different from the 95/95 criterion historically used to determine the margin between the LSP and the AL

(3) The last paragraph of DG-1141, Section 4.4, indicates that instrument suppliers must elaborate in the specific definition of accuracy and other specifications based on test results. This is necessary for correct, unambiguous use of instrument vendor data in setpoint calculations. For example, an instrument vendor can specify the instrument uncertainty at a 2-sigma level, or at a 95% probability. The confidence level associated with the accuracy statement is needed to meet the requirement of DG-1141. Because multiple factors are considered in setpoint calculations, it is

usually necessary to convert specifications at different probabilities or standard deviations to obtain the required 95% probability of trip at or before reaching the AL.

Proposed Resolution #2

It is proposed that DG-1141 technically distinguish between the 95/95 criterion used for the error around the setpoint, and the 95/95 criterion used to determine the margin between the setpoint and the AL, and both criteria should be defined in the Glossary to avoid confusion. The criterion for the margin between the setpoint and the AL should be changed from 97.5/95 currently implied in DG-1141, to 95/95 as used historically in the past, which is consistent with the plant safety analyses.

The comment correctly recognizes that the 95/95 criterion is associated with the distribution of errors about the setpoint. The margin between the limiting setpoint and the analytical limit is based upon the total loop uncertainty. The random portion of the total loop uncertainty will also meet 95/95 if the underlying data meet 95/95 and the data are combined appropriately. The 95/95 criterion is only indirectly related to the margin between the analytical limit and the limiting setpoint: it influences the value of the total loop uncertainty, which is used to establish the smallest acceptable margin, but it is not used directly in the determination of the margin.

If the limiting setpoint is removed from the analytical limit by an amount equal to the total loop uncertainty, the probability of exceeding the analytical limit will be 2½%: this is a consequence of the 95/95 criterion and the establishment of the limiting setpoint in accordance with the industry standard. It is not an a priori objective.

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39. GEH-3, C6c & C6e, p24 & p25: Practical Implementation of 95/95 Error Requirement

DG-1141

Section C.6 on page 24 of DG-1141 states that the errors used in the setpoint calculation must meet the 95/95 criterion, or provide a means for justifying the use of statistical estimates or parameters that do not meet the 95/95 criterion when such data are not available.

GEH Comment

The means of justifying 95/95 errors needs clarification. It is noted that imposition of 95/95 requirement for all the errors used in the setpoint calculation will be practically difficult to conform to and monitor. This is because the measurement error needed for setpoint calculations is a statistical square root of the sum of the squares (SRSS) combination of many independent instrument random error components (e.g., temperature effect, pressure effect, radiation effect, and power supply effect) and producing statistically valid 95/95 data by instrument vendors for all these errors could be very difficult and costly, with limited benefits to improving safety.

Section C.6.e is important because it acknowledges that specifying a confidence level for some of the uncertainties involved in setpoint calculations (indicating that channel performance uncertainty data are typically not based on a large number of observations) adds the expectation that licensees and applicants will account for such values in the form of bounding estimate values and supporting analyses, which increases the cost of procurement of instruments. The quantification of confidence level was introduced in RG 1.105 coincident with concerns with the use of drift data, but it was not previously clear to which types of uncertainties it applies. DG-1141 recognizes that some errors cannot be measured with enough sample data to provide a 95/95 error from a statistical point of view, because the use of sample size dependent statistical factors to multiply the measured error (or standard deviation) would not produce meaningful estimate of the population error. However, DG-1141 does not clarify how to provide justification for the error to use when statistically valid 95/95 error data is not available. The use of bounding error values for a population that can be

justified is a valid approach. Note that a conservative bounding value could be considered as a 3-sigma error with high confidence (>95%). Another approach would be to use engineering judgment and historical records of setpoint performance to show that the error values used in the setpoints are conservative and meet the requirement to a high degree of confidence, as was approved by the NRC in NEDC-31336P-A (Reference 2).

Proposed Resolution #3

It is proposed that DG-1141 clarify that when statistically based 95/95 population error data is not available, then bounding errors can be used as 3-sigma errors with high confidence (>95%) in the setpoint calculation, assuming that these bounding errors can be properly justified. Section C.6.e should be expanded to clarify that data obtained through IEEE type testing, e.g. harsh environment uncertainties, will be limited in sample size, and direct application of the data is allowed. This is appropriate considering the quality standards applied to 1E equipment and the sample size (one sample) applied in functional testing.

See Common Theme #8: *95/95*

40. GEH-4, C4c2, p21: Drift Calculation

DG-1141

Section C.4.c of DG-1141 discuses certain provisions related to uncertainty analyses in in industry standard ANSI/ISA 67.04.01-2006 as providing a reasonable approach. Section C.4.c(2) of DG-1141 states, however, that time related uncertainties (i.e., the drift error for a long calibration time interval) should be determined by linearly extrapolating the uncertainty specification (drift error specified for smaller time intervals) rather than by the SRSS of multiple intervals. An example is provided in DG-1141.

GEH Comment

The linear extrapolation method and example described in DG-1141 is very conservative and provides unrealistically high drift errors, which would unnecessarily make the setpoint more conservative, increase the spurious scram probability, and make it difficult to determine if the module was performing correctly. During licensing of GE setpoint methodology (Reference 2), GEH showed that the time dependent drift of instruments was generally a random error, and that if the drift for 6 months was known (or specified), the drift for 2 years could be conservatively estimated by taking SRSS of four 6-month drift errors. GEH drift evaluations have also shown that when the time interval for which the drift error is specified is much less than 6 months, it is unrealistically conservative to use the SRSS method to extrapolate this specified drift error to determine drift error for intervals greater than 6 months. For this case, GEH drift evaluations show that the drift error for 6 months can be conservatively taken to be the specified accuracy of the device, and extrapolated beyond 6 months when necessary using the SRSS method. GEH has used this drift methodology in BWR setpoint calculations for many years, and is not aware of any case where this method has not produced an adequately conservative estimate of drift error.

The DG-1141 Glossary definition of Deviation includes a note which states, in part, "Drift is generally measurable only under strictly controlled laboratory conditions." Although the qualifier "generally'' is included, this seems to limit the use of operational data in evaluating drift. When environmental conditions and the accuracy of calibration equipment are accounted for, operational data can be used to quantify drift, and increase the sample size used to achieve 95% confidence

level. Drift is a particular area where operational data can contribute to attaining 95% confidence level.

Proposed Resolution #4

It is proposed that DG-1141 remove the requirement for calculating drift for a longer calibration time interval by linearly extrapolating the drift specified for smaller time interval, and replace that by a requirement to use a method for extrapolation that can be justified based on plant performance data and drift evaluations.

DG-1141 should continue to allow appropriate use of operational drift data. The TSTF-493 performance monitoring requirements (Reference 6) facilitate the use of operational data.

See Common Theme #10: *Temporal Extrapolation*

41. GEH-5, C4c3, p22: Use of Dynamic Effects in Setpoint Calculations

DG-1141

Section C.4.c of DG-1141 discuses certain provisions related to uncertainty analyses in in industry standard ANSI/ISA 67.04.01-2006 as providing a reasonable approach. DG-1141, Section C.4.c(3) states, however, that the dynamic effects of the process, such as transport delays, be included in the uncertainty analysis, and that the delays already accounted for in the safety analysis be listed in the uncertainty analysis.

GEH Comment

In most setpoint methodologies (and specifically the GEH setpoint methodology), dynamic effects are already considered in establishing the AL. GEH setpoint calculations refer to the source of the AL and the accompanying transient analysis. Thus, the pertinent dynamic effects are already listed in verifiable documents, and there is no need to repeat them in the setpoint calculation. Repeating such information can lead to unnecessary errors since setpoint calculations are generally done by different engineering organizations than the AL and transient analysis calculations.

Proposed Resolution #5

It is proposed that DG-1141 remove the requirement for identifying the dynamic effects of the process as long as the licensed methodology covers these effects in establishing the AL, and the setpoint calculation refers to the AL calculation.

See Common Theme #13: *Dynamic Effects*

42. GEH-6, A>Scope & C2a, p4 & p20: Application of Regulations to All Technical Specification Setpoints

DG-1141

The wording in the "Scope" section on page 4 of DG-1141 states that the guidance in DG-1141 applies to all instrument setpoints that are included in the Technical Specification. Section C.2 of

DG-1141 states that all setpoint related Technical Specification limits should be as conservative as values derived in this RG.

GEH Comment

The scope statement and the statement in Section C.2 imply that the guidance in DG-1141 applies to both setpoints that protect a safety limit (SL) and have an AL, and also to those that do not. This needs more clarification.

From the safety point of view, the guidance in DG-1141 cannot be applied to both setpoints that protect an SL and have an AL, and setpoints that do not protect a SL and have no AL. For setpoints that do not have an AL, the LSP has no meaning. For example, all BWAs have Average Power Range Monitor (APAM) rod block setpoints in the Technical Specifications. The APAM rod block function is to block rod movement and alert the operator when the APRM power gets close to the scram setpoint. The APAM scram setpoint has an AL but the rod block setpoint has no AL, and the positioning of rod block setpoint relative to the scram setpoint is arbitrary and based on historical and operational factors specific for that BWR plant. Establishing an LSP for the APRM rod block setpoint by back-calculating the LSP from the setpoint would result in a meaningless LSP.

From the performance monitoring point of view, the guidance in DG-1141 appears to apply to all Technical Specification setpoints. This is quite different from the performance monitoring requirements in TSTF-493 (Reference 6) which apply only to a limited number of safety-related setpoints with ALs. Thus, DG-1141 and TSTF-493 are not compatible, and the requirements in the two documents are not totally consistent. Moreover, applying the DG-1141 performance monitoring guidance to setpoints with no safety function appears to put an unnecessary burden on all BWR and PWA operating plants with no gain in plant safety.

In summary, implementation of the guidance in DG-1141 to all Technical Specification setpoints results in a significant increase in plant operating costs and regulatory compliance costs without a requisite increase in plant safety.

Proposed Resolution #6

It is proposed that DG-1141 limit the application of the regulations to only those setpoints that have ALs. It is also proposed that the performance monitoring guidance be made consistent with TSTF-493, and to clarify the role of TSTF-493 once DG-1141 is finalized and RG 1.105 R4 is issued.

See Common Theme #3: *Scope*
See also Common Theme #1: *Technical Specifications*

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43. GEH-7, B2, p9b1: Use of Analytical Limits as Surrogates for Safety Limits

Section 2, 9th paragraph of DG-1141 (see page 9) indicates that the NRC staff considers ALs to be surrogates for SLs. Analytical limits are not surrogates for safety limits and it is not appropriate to treat them the same. Additional margin is provided in many fuel vendors' safety analyses; therefore, exceeding an AL does not mean an SL is exceeded. For example, SL avoidance is provided for or assessed at the worst point in the fuel cycle. The 5% of the trips which occur after the AL do not directly correlate with SL violations. 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.

The same issue occurs in C.1 of DG-1141 regarding AL constituting surrogate safety limits. SLs are as defined in the technical specifications. They are not ALs. The criteria which apply to SLs should not

apply to ALs. A plant should not shut down and wait for NRG permission to restart (which is the case for SL violation) in the event of an AL violation, which is not an SL violation.

Proposed Resolution #7

It is proposed that DG-1141 not expand the actions required when an SL is violated to include channels which do not trip when an AL is reached. If broader changes are being made or proposed to NRG requirements they should be spelled out. If it is not the NRC's intent to imply that all requirements and guidance (including enforcement guidance) applicable to SLs be applied to ALs, then the wording could be modified to more clearly state the point or to explain which specific guidance is considered important for ALs.

See Common Theme #6: *Surrogate Safety Limits*

44. GEH-8, Glossary>SRSS: Glossary Definition of Square Root of the Sum of the Squares (SRSS)

In the DG-1141 Glossary definition of SRSS (page 31), it appears that in order to use the SRSS method for combining random uncertainties of 3 independent parameters B, C, D to give the uncertainty of the combined variable A, the variables must be random and added algebraically to give the total variable A. This is confusing and may be a terminology issue, since the variables need to be independent and only the uncertainties need to be random. DG-1141, page 16, refers to Section 4.5 of ANSI/ISA 67.04.01-2006 as addressing the use of SRSS as an acceptable method for combining uncertainties to find the total loop uncertainty under certain conditions. SRSS is discussed in other instances in DG-1141 in terms of combining uncertainties.

Proposed Resolution #8

Consider clarifying that the SRSS methodology applies only to the random errors of independent variables, and that when a sum variable is made by adding several independent constituent variables, the standard deviation error for the sum variable can be obtained by taking the SRSS of the standard deviation errors for the constituent variables.

See Common Theme #15: *SRSS*

ISA SP67.04 (comments submitted by Jerry Voss)

Disclaimer, from the comment transmittal letter:

The comments are from the ISA SP67.04 ''Nuclear Instrumentation Setpoints" Committee. They are not comments from Instrument Society of America, and have not been reviewed by the ISA S&P board.

45. ISA-L1: We realize that the Regulatory Guide (RG) is focused on expanding the specificity of the development of setpoint calculations and that part of this has been due to the limited direction provided in our Standard (ANSI/ISA-67.04.01-2006, "Setpoints for Nuclear Safety-Related Instrumentation"). However, the expanded Regulatory Guide ignores many of the concepts in the Standard and does not acknowledge ANSI/ISA-67.04.02 which clarifies the process of setpoint development.

See Common Theme #4: *The Role of Industry Standards*

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46. ISA-L2: As noted in our attached comments from numerous industry reviewers, the proposed RG develops new terminology and different concepts for the combination of error terms. The industry has devoted an exceptional effort in resolving setpoint and instrument performance trending with the NRC, and most if not all of those agreements are not indorsed by the proposed Regulatory Guide. We believe it is not possible to resolve some of our differences in comment process. We need to gather as a working group and seek to understand the regulatory mandate for some of the specifics in the RG.

See Common Theme #5: *Terminology*
See also Common Theme #14: *Additional Meetings*

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47. ISA-L3: The ISA Standards subcommittee would be pleased to support public meetings with the NRC to ensure that comments provided are well understood and to develop agreements on improvements to the setpoint calculation process. The subcommittee will be revising the Standard in the near future, and could also add specificity (where we all agree on the application) to the Standard.

See Common Theme #14: *Additional Meetings*

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48. ISA-1: Scope of the Proposed Regulatory Guide

    The industry has used the terms Safety Limit, Analytical Limit, and Limiting Safety System Setting as defined values. The proposed RG introduces surrogate Safety Limits and adds the limitation that setpoints for surrogate safety limits are subject to the same criteria as setpoints that protect actual safety limits directly. Surrogate Safety Limits, by their definition, could include any setting in the Technical Specifications and require a level of evaluation not consistent with the safety of the setpoint or plant actuation.

    The NRC, industry via the Technical Specification Task Force, and ISA spent considerable time and performed detailed analysis to identify the specific setpoints that directly protect Safety Limits. For these critical setpoints, TSTF-493 Rev. 4 required that Technical Specifications be changed to verify that the instruments were "functioning as expected." Expansion of the scope beyond the setpoints protecting Safety Limits with the same criteria would produce no increase in plant safety.

See Common Theme #6: *Surrogate Safety Limits*

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49. ISA-2: Trip Criteria

    The proposed RG now states that the 95/95 criterion 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 that actuation will occur before the analytical limit (AL) is exceeded. To meet 95/95, there must be 95% or more assurance of actuation prior to reaching the AL. This implies a 5% or less probability of exceeding the AL. 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% or more. Change to the basic trip probability requirements does not seem appropriate at the Regulatory Guidance level.

See Common Theme #8: *95/95*
See also Common Theme #9: *Single-Sided Setpoints*

50. ISA-3: Random Error Evaluation

    The proposed RG changes traditional methods of error combination without any basis provided. Section C.4.c. (2) requires linear extrapolation of time related uncertainties. This is inconsistent with practices used to justify calibration extension and the extrapolation of non-dependent time related uncertainties.

See Common Theme #10: *Temporal Extrapolation*

51. ISA-4: DG-1141 acknowledges that some data for setpoint calculations is obtained with limited sample size (e.g., from IEEE type testing) versus drift and accuracy data which usually offers large sample size. The members would like to develop this concept with the NRC.

See Common Theme #8: *95/95*
See also Common Theme #14: *Additional Meetings*

52. ISA-5: Standard Terminology — the proposed RG identifies new terminology for existing calculation and calibration values. Standards committees generally provide consensus definitions for terms so that all of the industry uses the same definition where possible. Changes in terms or attempting to map existing terms to new terms could lead to confusion for developers and reviewers. We have a strong interest in consistent, clear and concise industry terminology.

See Common Theme #5: *Terminology*

53. ISA-1.1: The RG attempts to provide clarification but instead introduces ambiguity and potential misinterpretation. This is evident based on review of comments received so far. Station perceived compliance to the Guide may not be the NRC's interpretation of the Guide. Based on Entergy's prior interaction with the NRC and the ACRS on power uprate activities, there is a 95/95 probability the NRC interpretation will prevail. This of course could likely force costly correction to the station's methods for a minimum gain or even reduction in actual safety due to diversion of resources from other safety significant tasks.

See Common Theme #3: *Scope*

ISA-1.2: This is a partial duplicate of NEI-24.3.

54. ISA-1.3: The Draft starts out by saying it is not a substitute for regulation, and compliance with the RG is not required. Methods and solutions different than the RG will be deemed acceptable if they provide a justifiable basis for issuance of NRC license. This position needs more clarification.

See Common Theme #3: *Scope*

55. ISA-1.4, A(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"

See Common Theme #1: *Technical Specifications*

ISA-1.5 partial duplicate of NEI-25.6
ISA-1.6 partial duplicate of NEI-25.8
ISA-1.7 partial duplicate of NEI-26.2

56. ISA-1.8, A>Scope, p4b7: "… 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? This seems to be a scope increase.

Yes, setpoints addressed in Section 5 of the Technical Specifications, such as setpoints in a Setpoint Control Program, are "incorporated by reference" and should be developed in accordance with RG1.105. The approved Setpoint Control Program should specify a methodology for determination of setpoint-related limits that is consistent with the guidance.
See Common Theme #3: *Scope*

ISA-1.9: This is a partial duplicate of NEI-26.7.

57. ISA-2.1 A>Scope, p4b8: 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.

See Common Theme #3: *Scope*. ***A statement to the effect that this RG describes means suitable for meeting the Appendix B requirement was added to this paragraph***.

58. ISA-2.2, A>Scope and C1, p4, p20: 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. Note that 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. 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.

See Common Theme #3: *Scope*

59. ISA-2.3, A>Related, p4b2: Why put the Standard Technical Specifications NUREGs in? Will have to revised for new plants.

Regulatory guides typically list related guidance for the convenience of the user. Note that this is reference information only and does not address any staff position.

ISA-2.4: This is a duplicate of NEI-26.9.

60. ISA-2.5, A>Scope, p4b7: With the references to Tech Spec limits, are compliance limits and Backup control room in the scope of the RG?

See Common Theme #3: *Scope*

ISA-2.6: This is a duplicate of NEI-27.2.
ISA-2.7: This is a duplicate of ISA-2.6.

61. ISA-2.8, B1, p7b3: DG-1141 seems to be “cherry picking” acceptable methods from RP67.04, thus expanding the purpose and intent of RG1.105.

The NRC does not endorse ISA Recommended Practice 67.04.02. The Recommended Practice does not influence the scope of the regulatory guide.
See Common Theme #3: *Scope*

62. ISA-2.9, B1, p7b4: "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.

See Common Theme #8: *95/95*

63. ISA-2.10, B1, p7b5: "… 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"

The phrase was changed to “…use of a setpoint ‘Allowable Value,’ in consideration of the removal of ‘Allowable Value’ from…”

64. ISA-2.11, B2, p8b4&6: 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.

See Common Theme #5: *Terminology*.

65. ISA-2.12, B1, p7b7: 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.

See Common Theme #3: *Scope*

66. ISA-2.13, B2, p8b7: … 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"

A "random variable" is a nondeterministic variable whose value can only be described statistically and cannot be known explicitly. See, for example, Section 6.2 "Random Variables" on page 90 of revision 1 of NUREG-1475, *Applying Statistics* by Lurie, Abramson, and Vail.

67. ISA-3.1, B2, p8b11: 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.

The wording is already consistent with the requested change. If action is taken when the AL is reached, then it is taken before the AL has been exceeded. (The comment presentation associates this comment with C1a, which is not on the cited page and is not directly related to the comment.)

68. ISA-3.2, B2, p8b11: 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.)

See Common Theme #6: *Surrogate Safety Limits*
See also Common Theme #8: *95/95* concerning statistical considerations related to the protection of the analytical limit. (The comment presentation associates this comment with C1b, which is not on the cited page and is not directly related to the comment.)

69. ISA-3.3, B2, p8b4: 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.

The glossary indicates that "trippoint" is sometimes used in place of "actual trippoint."

70. ISA-3.4, B2, p8b6: 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 (on page 8).

See Common Theme #16: *Setpoint vs Trippoint*

71. ISA-3.5, B2, p9b1: ... 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.

See Common Theme #6: *Surrogate Safety Limits*

72. ISA-3.6, B2, p9b2: "…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".

The statement will be modified to indicate that this is one approach set forth in RIS 2006-017.

73. ISA-3.7, B2, p9b1: 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.

"Adequate protection" is standard terminology. The reference to 95% as a quantification of "adequate" is not accurate. The statement in the draft guidance refers to whatever limits might be expressed in the technical specifications. This might be AV, but might also be other limits as well. For the most part these would be limits on the As-Left setting, rather than on the As-Found setting. The comment presentation cites C2 rather than B2. C2 is not on the cited page.
See Common Theme #8: *95/95*.

74. ISA-3.8, B3, p9b5: "… documents other than ANSI/ISA 67.04.01 and earlier versions …" Suggestion: add "1994" after 67.04.01 to say "67.04.01-1994"

The statement was changed to "…67.04.01-2006 and selected earlier versions…"

75. ISA-3.9, B2, p9b3: 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.

The requested information is provided in the discussion of AFT in B5.1 (block 5, page 15), and in C7b.

ISA-3.10: This is a partial duplicate of GEH-7.

76. ISA-3.11, B2, p9b3: The RIS applied to a subset of Tech Spec instruments. Is it being expanded by the RG to all?

See Common Theme #3: *Scope*

77. ISA-4.1, B3, p9b4: 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.

See Common Theme #4: *The Role of Industry Standards*
See also Common Theme #3: *Scope*

ISA-4.2: This is a duplicate of ISA-4.1.

78. ISA-4.3, B2, p9b1: 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.

See Common Theme #6: *Surrogate Safety Limits*

79. ISA-4.4, B4.1, p11b3: 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.

See Common Theme #7: *AV*. (The comment presentation cites C3, which is not directly associated with this comment.)

ISA-4.5: This is a partial duplicate of NEI-31.8.

80. ISA-5.1, B4.1, p11b8: "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, it is redundant. The relevant information from this introduction should be moved to the sections where the parameters are already discussed.

The statement is indeed intended to be a preview of what follows, and to explain why what follows matters.

ISA-5.2: This is a partial duplicate of NEI-30.2.

81. ISA-5.3, B4.1, p11b2: 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 (see comment for 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 inclusion of RIS 2006-017, the perspective discussed there should be included.

See Common Theme #11: *Deviation Assessment*

82. ISA-5.4, B4.1, p11b3: 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

See Common Theme #7: *AV*

83. ISA-5.5, B4.1, p11b4: 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."

See Common Theme #7: *AV*

84. ISA-5.6, B4.1, p11b2: Note 2 requires the evaluation of exceeding As-Left tolerance. This is not appropriate.

Note 2 refers to the previous as-left setting, not to the As-Left tolerance.

85. ISA-5.7, B4.1, p11b3: Note 3 - New fuzzy terms "excessive and chronic"?

See Common Theme #11: *Deviation Assessment*

86. ISA-5.8, B4.1, p11b4: Note 4 - How can Av be less conservative than AF?

See Common Theme #7: *AV*

87. ISA-5.9, B4.1, p11b10: LSP - Does LSP include the As-Left tolerance? This has been a past Tech Spec compliance issue.

See Common Theme #12: *As-Left Limits*

88. ISA-5.10, B4.1, p12b3: "…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"

The limits alone are not sufficient. Operability is established through the technical specifications, and involves observation of other aspects of instrument behavior. For example, intermittent problems and "noisy" operation may interfere with the ability of a channel to perform its safety function even if the limits are met at the time of testing.

89. ISA-5.11, B4.1, p12b8 (in italics): "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.

Staff will reconsider the wording of this statement. The point is that excessive deviation can result in inadequate protection but it can also be an indication of problems with the equipment or uncertainty analysis.

90. ISA-5.12, B4.1>Summary, p12: Subtle difference between bullets 2 and 3 is unclear.

The second bullet addresses criteria for the assessment of an as-found setpoint, and cites C7 which addresses assessment of an as-found setting. The third bullet addresses criteria for establishing a limit on an as-left setpoint, and cites C8 which addresses limiting the as-left setting. Both bullets involve consideration of the amount by which a setpoint might change between calibrations, but the third bullet also involves consideration of other quantities. ***The bullets will both be modified*** to more clearly indicate that they refer to the As-Found and As-Left setpoints.

91. ISA-5.13, B4.1, p12b2: The definition is different from what is given in the glossary. Also this is redundant with what is presented on page 15.

This is a general description, not a definition. As indicated in the cited text, the definition is provided later in the regulatory guide. The definition on page 15 does match that in the Glossary.

92. ISA-5.14, B4.1>Summary, p12: Why is there a need to summarize an introduction before the primary parameters are discussed (sections 5.1 & 5.2)? Suggestion: Delete as redundant.

These three bullets provide a succinct description of the primary limits discussed in Section B4.1. Section B5 further describes these limits and the means for protecting them.

93. ISA-5.15, B4.1, p12b7: Only one cause, degraded component, is listed. Should be complete by adding maintenance error (present or previous), bad M&TE, statistical occurrence, etc.

This text was modified to remove reference to the possible physical sources of the observed discrepancy. The key point — that apparently excessive deviation could be the result of problems with the analysis — will be retained. (The comment presentation cites the wrong paragraph.)

94. ISA-5.16, B4.1, p12b7: AFT does not allow for variation between a +/- limit, only reference to previous calibration ALT.

The as-found tolerance is associated with the previous as-left setting. It is not related directly to the as-left tolerance. Under certain circumstances, the as-found setting may be evaluated against the nominal setpoint rather than against the previous as-left setting.
See Common Theme #11: *Deviation Assessment*

95. ISA-6.1, B4.1>Summary, p13b1: 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.

The final paragraph of B4.1 was moved to precede the "In Summary" material in B4.2. This clarification of terminology is not related to the intent of B5.2.
In addition, see Common Theme #16: *Setpoint vs Trippoint*

96. ISA-6.2, B4.1, p13b1: 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.

A Trippoint cannot be measured because all measurements include error. The error may be small enough to be unimportant, but that is a matter to be addressed in the uncertainty analysis. The measured value at which the trip appears to occur is "actual" in the sense of the observation, but

the value still includes unknown measurement error. The distinction is between this unknowable random variable and the measurements intended to quantify it.

As stated near the end of B5.2 (p18b3), the nominal setpoint and setting tolerance (the "as-left band" described in the comment) are of regulatory concern only under the limited circumstances described in C7b. Note that C7 addresses the assessment of the As-Found setting. The As-Left setting is addressed in C8.

97. ISA-6.3, C6b, p24: 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.

NRC expects that any uncertainty analysis would be based upon credible data and reasonable statistical methods. C6b provides guidance for ensuring that statistical data assumed to be normal are adequately enveloped in the uncertainty analysis. It does not override the other provisions of C6. Meeting C6c may or may not imply that the other provisions of C6 have been met, depending upon the details of the data and analysis in question.
See Common Theme #8: *95/95*

98. ISA-6.4, B4.1, p13b1: The description of actual setpoint is confusing and geeky. The ISA LTSP and NTSP are the setpoints defined in our Tech Specs.

NRC assumes that the comment was intended to refer to "trippoint." "Actual setpoint" is not used in the cited paragraph. "Actual Trippoint" is contrasted with "Actual Trip Setpoint" in the cited paragraph, but it is defined succinctly in the Glossary. LTSP and NTSP are addressed in footnotes 8 and 10 on pages 16 and 17 respectively, and are also addressed in the definitions of "Limiting Setpoint" and "Nominal Setpoint" in the Glossary.

99. ISA-6.5, B4.2, p13: 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

The guidance provision is correct as stated. A minimal loop would have one sensor and one A/D converter. A protection loop would not typically include a D/A converter. The output relay would not introduce measurement or conversion error, and so would be excluded from the considerations of this guidance.

100. ISA-6.6, B4.2, p13: Software programming can cause errors. Need to address in ISA 67.04

This regulatory guide addresses statistical considerations in the establishment of instrument setpoint-related limits. Software errors are not amenable to similar statistical analysis, and can affect operation in ways far more far-reaching than simple calibration error. While the possibility of software errors and the associated impacts on operation must be considered, these matters are well outside the scope of this regulatory guide.

101. ISA-6.7, B4.3, p13b5: M&TE uncertainties - The staff needs to reference to RP specific to M&TE. They do not have to endorse the complete RP document.

We do not endorse 67.04.02, and should not reference it here.

ISA-6.8: This is a duplicate of ISA-10.9.

102. ISA-6.9, B4.4, p14b2: "…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".

Whether the difference can actually be ignored or not depends upon the size of the sample set and consideration of other aspects of the analysis and the relative magnitudes of other uncertainty elements. It is not sufficient to say that the difference can simply ignored outright if the sample is "very large" without defining what "very large" means. According to NUREG-1475 rev. 1, page559, a sample set of 1,000 elements could be too small to permit the effect to be ignored.

See Common Theme #8: *95/95*

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103. ISA-6.10, B4.4, p14b3-4: "probability" NUREG-1475 Rev 1, "Applying Statistics" uses the word "confidence", perhaps only semantics. Suggest a reference to NUREG-1475.R1.

The wording is correct within the specific context. ***Reference to NUREG-1475 was added as an aid to readers***, but it must be noted that NUREG-1475 is not a regulatory document and has no regulatory authority.
See Common Theme #8: *95/95*

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104. ISA-6.11, B4.4, p14b3: 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.

See Common Theme #8: *95/95*

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105. ISA-6.12, B4.4, p14b5: "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 for 3rd bullet of Reason for Revision. What is the problem being solved? If there is no problem, then how can there be a benefit for any cost-benefit analysis?

See Common Theme #8: *95/95*

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106. ISA-6.13, B5.1, Footnote #6, p14: The footnote indicates that a definition for "setpoint deviation" is to be found in the glossary. However, "deviation" is what is provided in the glossary.

The Glossary includes "Setpoint Deviation" in the entry for "Deviation." ***The footnote was modified to clarify the reference***.

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107. ISA-7.1, B4.4, p14b5: 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"

See Common Theme #8: *95/95*. 95/95 is correct as used. These statistical data do not typically involve Monte Carlo analyses.

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108. ISA-7.2, B4.4, p14b2: First paragraph of section 4.4 conflicts with next to last paragraph of 4.3 concerning excessive deviation.

B4.3 contrasts conservatism in AsL with conservatism in AFT. B4.4 addresses the question of how to estimate the properties of a statistical distribution of the basis of a finite set of data.

109. ISA-7.3, B5.1, p14b6: 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.

See Common Theme #8: *95/95*

ISA-7.4: This is a duplicate of NEI-33.2

110. ISA-7.5, B5.1>AFT, p15b3: "… 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.

Definitions are not changed, and rulemaking is not required. The rule (10CFR50.36) defines LSSS. By that definition, affected setpoints have two LSSS: one for the as-left setting, to ensure proper operation over the upcoming operation interval, and one for the as-found setting, to confirm operability at the time of the test. This is consistent with the provision for an as-found limit and an as-left limit as described in RIS-2006-017.
(Commenter associated this comment with B4.4, but cited text in B5.1)

111. ISA-7.6, B5.1>AFT, p15b4: "…neither acute…" One of the common uses of "acute" is related to short-term (see dictionary.com particularly #3 "(of disease) brief and severe (opposed to chronic)." It is also used this way on Rad Worker training). Chronic is long-term. (see dictionary.com, particularly #4 "(of a disease) having long duration (opposed to acute)." A different word such as "large", "excessive", or "severe" might better communicate your intent. This is similar to the way "excessive" is used in note 3 to Figure 1.

See Common Theme #11: *Deviation Assessment*

ISA-7.7: This is a duplicate of ISA-7.4.

112. ISA-7.8, B5.1>AFT, p15b5: "…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 and then conform to RIS 2006-017.

See Common Theme #11: *Deviation Assessment.*

113. ISA-7.9, B5.1>AFT, p15b6: "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, do you intend to have 5% of all surveillance tests indicate a violation of an LSSS? 10 CFR 50.36(c)(1)(ii)(A) includes the following words "…the cause of the condition and the basis for corrective action taken to preclude recurrence." If 5% are supposed to fail, then what is the corrective action to prevent recurrence? The idea that the AFT is an LSSS does not appear to be well thought through.

See Common Theme #11: *Deviation Assessment*

114. ISA-7.10, B5.1>AFT, p15b6: "…for previous as-left value based evaluations." Continuing expectation of setting tolerance being a bias and failure to include the discussion from RIS 2006-017, page 5.

See Common Theme #11: *Deviation Assessment*

115. ISA-7.11, B5.1>AFT, p15b6: "…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.

In this context, spurious actuations are actuations that occur when they are not needed.
See Common Theme #11: *Deviation Assessment*

116. ISA-7.12, B5.1>AFT, p15b6: "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. RIS 2006-017 recognizes the random nature. This RG seems opposed to the idea of random for setting tolerances.

See Common Theme #11: *Deviation Assessment*

117. ISA-7.13, B5.1>AFT, p15b7: The term excessive is fuzzy. AFT should define excessive.

See Common Theme #11: *Deviation Assessment*

118. ISA-8.1, B5.1>AFT, p15b4-7: The terms excessive and chronic are fuzzy and should be eliminated such as the TSTF note wording.

See Common Theme #11: *Deviation Assessment*

119. ISA-8.2, B5.1>AFT, p15b6: The following stated 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.

See Common Theme #11: *Deviation Assessment*

ISA-8.3: This is a partial duplicate of NEI-33.5.

120. ISA-8.4, B5.1>AV, p16b2: "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.

NRC does not endorse 67.04.02-2010 or any of the previous versions of that recommended practice, including RP-67.04 Part 2 from 1994. Staff notes that Method 3, as presented in past versions of the recommended practice, has been determined to yield nonconservative results and should be avoided.

ISA-8.5: This is a duplicate of NEI-26.3.

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121. ISA-8.6, B5.1>AV, p16b4: "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. I understand the logic; however, a RG is not the place to place to establish TS content – revise the referenced NUREGs and use the rulemaking process if you want it changed.

The statement was revised to say that allowable value need be determined only if it is used in technical specifications, and to avoid the appearance of guidance concerning the content of technical specifications. Revision of the associated NUREGs is not within the scope of this effort.
See Common Theme #7: *AV*

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122. ISA-8.7, B5.1>AV, p16b1: 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.

This comment does not request any change or response. Allowable value is addressed in the draft guidance because of its extensive use in existing technical specifications.
See Common Theme #7: *AV*

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123. ISA-8.8, B5.2>LSP, p16b8: 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.

The citation was corrected to refer to Section 4.5 of ISA67.04.01-2006.

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124. ISA-8.9, B5.1>AV, p16b1: defines the AV stating that it will provide adequate assurance that the AL will not be exceeded. Similar to my comment C2, "adequate" is not defined.

Cross-reference to ISA-3.7.

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125. ISA-8.10, B5.2>LSP, p16b5: This definition again makes the assumption that the setting tolerance is a bias 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 for page 11 Note 1 of Figure 1

(The referenced comment is identified herein as ISA-5.2)
See Common Theme #12: *As-Left Limits*

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126. ISA-8.11, B5.1>AV, p16b1: 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 trippoint from a measurement to the AV.

See Common Theme #7: *AV*

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127. ISA-8.12, B5.1>AV, p16b4: 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.

Technical specification content is not within the scope of this guidance.

128. ISA-8.13, B5.2>LSP, p16: What is being stated for LSP? Too complex. Should just reference ISA 67.04

See Common Theme #12: *As-Left Limits*

129. ISA-8.14, B5.2, p16: 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.

See Common Theme #12: *As-Left Limits*
See also Common Theme #11: *Deviation Assessment*

130. ISA-9.1, B5.2>LSP, p17b4: 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.

See Common Theme #8: *95/95*
See also Common Theme #9: *Single-Sided Setpoints*

131. ISA-9.2, B5.2>LSP, p17b3: "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.. This does not recognize the position of RIC 2006-017 that nominal setpoints with random setting tolerances are effectively the same as the as-left setpoint.

See Common Theme #12: *As-Left Limits*

ISA-9.3: This is a duplicate of NEI-24.8.

132. ISA-9.4, B5.2>ST, p17: Where is NRC "using" setting tolerance? It would be non-conservative to not use the setting tolerance. (The paragraph citation in the original comment appears to be incorrect.)

See Common Theme #12: *As-Left Limits*

133. ISA-9.5, B5.2>LSP, p17b4: 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.

See Common Theme #9: *Single-Sided Setpoints*

134. ISA-9.6, B5.2>LSP, p17b4: 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.

See Common Theme #8: *95/95*
See also Common Theme #9: *Single-Sided Setpoints*

135. ISA-9.7, B5.2>LSP, p17b5, also "NOTE" on p18: "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.

Staff does not observe any discrepancy between the final two paragraphs of the Section 5.2 discussion of LSP on page 17 of the draft guidance. The point of the final paragraph is to point out that if the operational margin is too small to adequately accommodate the total loop uncertainty, then steps should be taken to reduce the uncertainty rather than to reduce the safety margin.
See Common Theme #8: *95/95*
See also Common Theme #12: *As-Left Limits* for additional information

ISA-9.8: This is a duplicate of ISA-9.5.

136. ISA-9.9, B5.2>LSP, p17b4: 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:

	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%

The probabilities presented in the comment show an increase in the failure probability by a factor of 3.94 for single sided setpoints as compared with "two sided" setpoints. Staff does not consider this to be insignificant. Note that the factor is nearly twice as high for 2/4 systems as for 2/3 systems.

See Common Theme #8: *95/95*
See also Common Theme #9: *Single-Sided Setpoints*

137. ISA-9.10

The 10th entry on page 9 of the ISA comment tabulation is presented as a separate comment, but appears to be a continuation of the comment that precedes it. It is therefore included in the ISA-9.9 comment statement.

138. ISA-10.1, B4.4, p14: 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 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). Note that the 95/95 criterion in 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. Moreover, implying 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 for setpoints approached from one direction.

See Common Theme #9: *Single-Sided Setpoints*
See also Common Theme #8: *95/95*

ISA-10.2: This is a partial duplicate of NEI-36.2

139. ISA-10.3: Use of statistically based 95/95 for all errors used in a setpoint calculation is impractical, and the Draft RG acknowledges this but does not provide a method for doing so.

See Common Theme #8: *95/95*
The comment cites B5.2>LSP p17b2, but is not related to the text at that location.

140. ISA-10.4: The current Draft RG does not clarify the basis for why the traditional use of 95% probability of not exceeding the AL is being changed to 97.5%. Note that 95% probability of not exceeding the AL means 95% probability that the trip will occur before AL is reached, which was the traditional requirement. Use of 95/95 errors around the setpoint does not justify the change from 95% to 97.5% 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.

See Common Theme #8: *95/95*

The comment cites B5.2>LSP p15b2, but is not related to the text at that location.

141. ISA-10.5, B5.2>LSP, p17b2: The current Draft RG requirement of increasing the probability that the trip will occur before AL is reached from 95% to 97.5% for a single channel will lower the setpoint and could lead to undesirable increase in spurious scram probability without significant improvement in plant safety.

See Common Theme #9: *Single-Sided Setpoints*

142. ISA-10.6, B5.2>LSP, p17b4: 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.

See Common Theme #9: *Single-Sided Setpoints*

143. ISA-10.7, B5.2>LSP, Fig2, p18: Figure 2 also shows a 97.5% probability of protection of the AL

This observation is correct.

144. ISA-10.8, B5.2>LSP, Fig2, p18: 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)

The figure shows a hypothetical distribution for the Actual Trippoint for the instrument loop as a whole. If the net bias could credibly be quantified and shown to be conservative, then one could take advantage of that. Such a demonstration may be challenging.

145. ISA-10.9, B5.2>LSP, Fig2 Note, p18: 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.

See Common Theme #8: *95/95*

ISA-10.10: This is a duplicate of ISA-9.7.

146. ISA-11.1, Fig2 Note, p18b4: 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. From a Sept. 2010 NRC meeting meeting, here is the GEH side of the story: http://pbadupws.nrc.gov/docs/ML1029/ML102980517.pdf Yogi also answered followup questions from the meeting: http://pbadupws.nrc.gov/docs/ML1029/ML102980533.pdf This link gives an example from 1986 of GE's application of 95/95: http://pbadupws.nrc.gov/docs/ML0618/ML061880457.pdf see the bottom of pg US.C-207 "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. I found this statement in the following NEI document on Method 3 "The probability of protecting the AL during an AOO is 95%." This GE's position. The same statement appears in the Method 1, Method 2 and Method 3 sections on pg 8. Reference: ISA S67.04 Methods for Determining Trip Setpoints and Allowable Values for Safety-Related Instrumentation" December 5, 2003, Alex Marion NEI letter to Eric Leeds NRC NRR. ISA RP 67.04.02-2010 allows use of single side statistical factor in section 7.3: For normally distributed 95% probability uncertainties, standardized area distribution tables (see M.R. Spiegel Reference) 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. For normally distributed uncertainties, the same tables show that 95% of the population will have uncertainties less than +1.645 sigma (50% below the median and

45% between the median and +1.645 sigma) and that 95% of the population will have uncertainties greater than -1.645 sigma. If interest is only in the probability that a single value of the process parameter is not exceeded and the single value is approached only from one direction, the appropriate limit to use for 95% probability is +1.645 sigma or −1.645 sigma as appropriate. 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

NRC does not endorse any version of ISA-67.04.02. Note that NRC has determined that "Method 3" as expressed in that document (Method 3 has been removed from the current edition) is nonconservative and should not be used.
See Common Theme #8: *95/95*
See also Common Theme #9: *Single-Sided Setpoints*

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147. ISA-11.2, Fig2 note, p18b4: 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.

See Common Theme #8: *95/95*
See also Common Theme #9: *Single-Sided Setpoints*
Note that regulatory guides only contain guidance, and that an applicant is free to propose alternative means for compliance with applicable regulations. This is addressed under "Purpose of Regulatory Guide" on page 5 of the draft.

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148. ISA-11.3, Fig2 Note, p18b4: Do not understand what is being stated in Figure 2 and note. Clarification is needed.

Page 17 Block 4 provides additional information. ***The note on page 18 was modified*** to more clearly describe the intent and basis for the figure.

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149. ISA-11.4, B6, p19: Should ISA look at conformance with the IEC standard?

This is a comment for ISA, not for NRC.

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150. ISA-11.5, B7, p19: Please state and list any secondary references endorsed.

This request for licensing research assistance is outside the scope of the efforts relating to completion of this regulatory guide revision.

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151. ISA-11.6, C3b, p20: Need to check each of these

NRC carefully reviewed the industry standard before finalizing the draft guidance. The subject provisions result from that review.

ISA-11.7: This is a duplicate of ISA-2.8.
ISA-12.1: This is a duplicate of NEI-38.6.

152. ISA-12.2, B2(p9b1), C1a(p20): See comment on page 9 for first paragraph. The idea of "surrogate" safety limits is an expansion of the definition and this is not a rulemaking.

See Common Theme #6: *Surrogate Safety Limits*

153. ISA-12.3, C1a, p20: Revise to "Analytical Limits that protect Limiting Safety System Settings (10 CFR 50.36)" The rigorous 95/59 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.

See Common Theme #6: *Surrogate Safety Limits*
See also Common Theme #3: *Scope*

ISA-12.4: This is a duplicate of NEI-39.3.

154. ISA-12.5, C1b, p20: Delete this section. we have Setpoints that protect LSSS settings there is no regulatory bases for defining surrogate safety limits

See Common Theme #6: *Surrogate Safety Limits*

155. ISA-12.6, C2a, p20: Revise to "This RG describes an acceptable method for the development of Setpoints that protect Limiting safety system settings."

See Common Theme #3: *Scope*

ISA-12.7: This is a duplicate of ISA-2.8.

156. ISA-12.8, C2b, p20: "…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. This makes sense only for a trend of tests exceeding the AFT.

An observed deviation will exceed the as-found tolerance on occasion, even though there is nothing wrong with the equipment, calibration, or analysis. In most cases, such excessive deviation could be an indication of serious problems. C7c provides for a determination that an observed deviation in excess of the as-found tolerance is neither excessive nor chronic, and that further action is therefore not needed. C2b is intended to describe this aspect of the relationship between the guidance and the technical specifications.
See Common Theme #1: *Technical Specifications*

157. ISA-12.9, C2b, p20: AFT and ALT have replaced Av. Not acceptance. TSTF criterion more reasonable. Also, this is scope expansion from the TSTF.

See Common Theme #1: *Technical Specifications.*
See also Common Theme #3: *Scope*

158. ISA-12.10, C2b, p20: Delete second sentence "Such actions may be established in the plant technical specifications and may include immediate shutdown of the reactor" 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.

See Common Theme #1: *Technical Specifications*

159. ISA-12.11, C3b1, p20: As noted on page 4, there appears to be an attempt at inappropriate scope expansion.

See Common Theme #3: *Scope*

160. ISA-12.12, C3b1, p20: Please state what was broaden.

The statement was changed to indicate that the purpose and scope are as described in the guidance, not as described in the industry standard.

161. ISA-12.13, C3b2, p20: RG needs to use ISA definitions.

See Common Theme #5: *Terminology*

162. ISA-12.14, C3b2, p20: Use the industry terminology defined by ISA and Technical Specifications. Defining new terms 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.

See Common Theme #5: *Terminology*

163. ISA-12.15, C1b, p20: 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.

See Common Theme #6: *Surrogate Safety Limits*

164. ISA-12.16, C3, p20: 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

A simple algebraic combination of uncertainties would be excessively conservative in many cases. Section B5.1 of the draft guidance discusses the limitations of allowable value as a sole assessment of setpoint deviation.

165. ISA-12.17, C3b4, p21: This is an improvement, as there is no "set" in the determination of this, so it makes sense to remove "set" from the term.

The terms “setpoint” and “trippoint” are both defined in the guidance, and they refer to two very different things. The term “actual trip setpoint” in the industry standard refers to a measured value for the setpoint at a particular point in time — it is a measurement, and therefore includes uncertainty despite the addition of the term “actual.”

166. ISA-12.18, C3b4, p21: What is the value of changing terms, "trippoint" as compared to "actual trip setpoint"?

"Actual trip setpoint" is a measured value that necessarily includes measurement error. "Trippoint" is the value at which action actually occurs. Trippoint does not include any error, because it is the value at which action actually occurs, but it is unknowable, because any attempt to measure it will include unknown error. Trippoint is statistically bounded though, and the whole point of the computations and margins addressed in the guidance is to provide reasonable assurance that its value is consistent with plant safety.

167. ISA-12.19, C4c2, p21: Combination of multiple drift observations over the defined interval by SRSS should be allowed. Extrapolation to a longer interval seems appropriate.

See Common Theme #10: *Temporal Extrapolation*

168. ISA-13.1, C4c2, p21: 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.

See Common Theme #10: *Temporal Extrapolation*
(This comment appears to be related to ISA-14.7.)

ISA-13.2: This is a duplicate of NEI-40.5.

169. ISA-13.3, C4c2, p21: 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.

See Common Theme #10: *Temporal Extrapolation*

170. ISA-13.4, C4c2, p21: Delete this section 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.

See Common Theme #10: *Temporal Extrapolation*

171. ISA-13.5, C4c2, p21: The RG Draft (Section 4c2) requires the drift error to be extrapolated linearly, which is very conservative and unrealistic, and does not agree with drift data from the sites

See Common Theme #10: *Temporal Extrapolation*

172. ISA-13.6, C4c2, p21: If as-found/as-left analysis determines that "drift" is not, time dependent, is "drift" then not a "time related uncertainty".

See Common Theme #10: *Temporal Extrapolation*

173. ISA-13.7, C4c3, p22: The Draft states that the dynamic effects of the process, such as transport delays be included in the uncertainty analysis (Section C4c3). This requirement is confusing because these effects are already considered in the AL determination.

See Common Theme #13: *Dynamic Effects*

ISA-13.8: This is a duplicate of NEI-41.5.

174. ISA-13.9, C4c3, p22: 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.

See Common Theme #13: *Dynamic Effects*
C4e1 indicates that the source of the analytical limit should be expressed. C4f indicates that the uncertainty analysis should be consistent with related analyses and procedures, etc. Neither of these is related to the substance of this comment.

175. ISA-13.10, C4c6, p22: 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."

See Common Theme #11: *Deviation Assessment*

ISA-13.11: This is a duplicate of NEI-41.1.

176. ISA-13.12, C4c3, p22: 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.

See Common Theme #13: *Dynamic Effects*

ISA-13.13: This is a partial duplicate of NEI-41.9.

177. ISA-13.14, C4c3, p22: 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.

See Common Theme #13: *Dynamic Effects*

178. ISA-14.1, C4c4, p22: "…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"

See Common Theme #15: *SRSS*

179. ISA-14.2, C4c4, p22: Random is missing from SRSS criterion.

See Common Theme #15: *SRSS*

180. ISA-14.3, C4c5, p22: Section 4.c.5 - The staff should endorse what parts of the RP they concur with. This would be very valuable.

See Common Theme #4: *The Role of Industry Standards*

ISA-14.4: This is a duplicate of ISA-10.9. (The commenter associates this comment with C4c6, but staff has determined that it more closely relates to C4b.)

181. ISA-14.5, C4c7, p22: This section assumes that the various items are inputs to an uncertainty analysis. They can also be what is directed by the analysis.

The point is that the uncertainty analysis and these items should be consistent with one another, regardless of which one changes first. ***The provision was modified*** to focus on the need for consistency and to eliminate the implication of sequencing.

182. ISA-14.6, C4c7, p22: 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.

See response to ISA-14.5.

183. ISA-14.7, C4c8, p22: This reduction in 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 for page 21.

(The reference appears to be to ISA-13.1)
AFT and TLU would be expected to be different, since TLU includes terms that would not be in effect when AFT is used (such as effects associated with the post-accident environment). C4c8 points out that the conceptual bases for AFT and TLU are different, and that while it might not be necessary to adjust the limiting setpoint as a result of instrument improvements, those improvements might result in a reduction of expected deviation and hence in a need to reduce AFT.

184. ISA-14.8, C4d, p22: Why is this needed?

This is one of the several things that should be taken into consideration in the development of uncertainty analyses.

ISA-14.9: This is a duplicate of RB-3.
ISA-15.1: This is a duplicate of RB-2.

185. ISA-15.2, C4e1, p23: lists info for the setpoint calculation document that GEH does not include the basis for the selection of the AL(s). That info is in the Safety / Transient Analysis document(s).

See response to ISA-15.3

186. ISA-15.3, C4e1, p23: This is in the scope of the safety analysis, not the setpoint calculation. The Tech Spec basis often includes this basis.

The statement is intended to mean that the source of the analytical limit, or of the value used in lieu of an analytical limit, should be documented in the uncertainty analysis. If the value is quoted from some other analysis or credible source, then a simple reference to that source would suffice. If the value as presented in the source is modified for use in the uncertainty analysis, then that modification should be explained. ***C4e1 was modified to clarify this intent.***

187. ISA-15.4, C4e1, p23: Delete this section. Analytical limits are defined in the safety analyses and not open to selection since they protect LSSS.

See response to ISA-15.3

188. ISA-15.5, C4e2, p23: Delete this section While appropriate for a methodology, these modeling considerations and distributions should not change from calculation to calculation

This information should be quantified and documented for each analysis. Reference to a methodology that applies to many separate analyses could serve this function.

189. ISA-15.6, C4e3, p23: 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. This does not recognize the perspective that Engineering is directing the various aspects of instrument uncertainty instead of just reacting to external changes.

Each calculation and analysis should reference the procedure(s) upon which it is based. It is understood that the procedures may be altered on the basis of experience, and that the citations within the calculations and analyses should therefore cite the particular versions with which they are associated.

190. ISA-15.7, C4e6, p23: Delete "such time periods should include allowance for delays beyond the established normal time periods." 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.

Consideration of the 25% extension of the normal surveillance interval is consistent with the draft provision as written, assuming that that 25% is the maximum amount by which the time interval may be extended. The draft provision also indicates that this should be documented in the uncertainty analysis.

191. ISA-15.8, C4f, p23: Calcs should not have assumptions. Change wording to requirements.

All calculations have assumptions — for example, there are typically (sometimes tacit) assumptions that the equipment configuration analyzed in the calculation is representative of the actual configuration, and that the ambient temperature will not exceed some limiting value.

192. ISA-15.9, C4g, p23: Not sure how to show independence. I could state that no dependencies are noted.

See response to MB-7.

193. ISA-15.10, C4g, p23: 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.

C4g was merged into C4c4.

194. ISA-15.11, C4h, p23: 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)

The first sentence of C4h was deleted.

195. ISA-15.12, C4h, p23: A histogram for each uncertainty parameter. Too costly and overkill. Use NUREG and vendor specs should address bias.

This comment does not relate to the cited paragraph. No provision of the draft guidance indicates a need for development of histograms. Use of vendor information to address bias (and uncertainty in general) is already included in the draft guidance.

196. ISA-15.13, C4h, p23: 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.

The reference was deleted.

197. ISA-16.1, C4h, p23: Should reference requirements for a calibration program which is a different T/S section than the setpoint T/S section. Refer to section 4.3, para 2.

See response to ISA-15.13

198. ISA-16.2, C4h, p23: delete this section. TSTF-493 requires the trending of as-found and as-left data the calibration monitoring would be redundant to this requirement

Some licensees might not adopt TSTF-493, but should meet the provisions of this paragraph. In any case, the TSTF does not constitute agency guidance.

ISA-16.3: This is a duplicate of ISA-16.1.

199. ISA-16.4, C4, p23: No business case to change anything ever.

Regulatory guides address technical issues, not business cases. The paragraph cited in the comment ("C.4.g.h") does not exist. The comment cites page 23, which contains elements of C4, including C4g and C4h, but this comment is unrelated to the specific content of those paragraphs.

200. ISA-16.5, C4i, p23: 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?

As already indicated in the draft, some setpoints such as those included in a setpoint control program are not necessarily reviewed by the NRC. Such setpoints nevertheless are of sufficient importance that they should be developed in accordance with this regulatory guide to ensure that they include adequate margin to account for measurement errors and other influences.

201. ISA-16.6, C4j, p24: 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.

Comment accepted.

202. ISA-16.7, C5, p24: 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. There are redundant statements of rigor, and appear to have contradictory statements for whether exceptions are allowed.

C5b allows for conservative simplification of the uncertainty analysis. For example, it might be convenient in some particular instance to use an ambient temperature variation that is greater than the variation actually expected, rather than to adjust the corresponding uncertainty value in consideration of the details of the expected variation. This provides an "exception" only in that the computed uncertainty is sure to exceed the actual uncertainty and therefore to be conservative. There is no contradiction with the other provisions of C5.

203. ISA-16.8, C5b, p24: delete or provide a realistic acceptability criteria

See the response to ISA-16.7.

204. ISA-16.9, C5c, p24: Appears redundant with section C.5.a. Recommendation: delete C.5.c

C5c was combined into C5a.

205. ISA-16.10, C5c, p24: Revise to Grading should not be applied to Setpoints that protect LSSS functions. 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.

The statistical basis for the analytical limit or other applicable limit is distinct from the statistical basis for the uncertainty analysis, and is outside the scope of this regulatory guide. This regulatory guide seeks to ensure that the setpoint-related limits are statistically sound.

206. ISA-16.11, C6a, p24: Why is there a need to apply 95/95 to the individual uncertainty elements for each device and all intermediate results? Is there a concern that the existing methods do not adequately protect the Safety Limits?

C6a points out that proper application of the 95/95 criterion applies to the entire uncertainty calculation, including both the data and the analytical technique. It is possible to combine uncertainties in ways that do not preserve 95/95.

ISA-16.12: This is a duplicate of ISA-6.3.

207. ISA-16.13, C6c, p24: 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?

See Common Theme #8: *95/95*

208. ISA-16.14, C5, p24: Since the scope of the RG may have expanded to more than LSSS functions such as non 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.

See Common Theme #3: *Scope*

209. ISA-17.1, C6b, p24: 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.

The guidance is intended to provide adequate assurance of safety, not economics. Note that if it can be shown that the existing calculations already bound 95/95 then there would be no need to revise them.

210. ISA-17.2, C6b, p24: 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.

See the response to ISA-17.1. Also, note that regulatory guides provide guidance, not requirements.

211. ISA-17.3, C6d, p24: Why? Only if interference is being made beyond the sampled population to a larger population.

See Common Theme #8: *95/95*

212. ISA-17.4, C6e, p25: 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.

See Common Theme #8: *95/95*

213. ISA-17.5, C6e, p25: Suggested adding a reference to EPRI TR above for obtaining 95% confidence level data.

The reference is not specific. In general, staff is open to consideration of alternative approaches developed by industry groups.

ISA-17.6: This is a duplicate of RB-1.

214. ISA-17.7, C6e, p25: delete this section. 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.

Staff agrees that the reference in this context to seismic effects may be confusing or misleading and ***should be deleted***. Nevertheless, it is possible that in some cases seismic effects *should* be included in some uncertainty analyses, depending upon the details of the application.

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215. ISA-17.8, C7b & footnote, p25: 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 recognized. One of the stated goals of the revision of the RG is to incorporate the RIS. It doesn't.

The wording in C7b differs slightly from the equivalent provisions of the RIS. Both C7b and the corresponding provisions in the RIS are intended to allow for assessment of the AsFound setting against the nominal setpoint rather than against the previous AsLeft setting, which would be more mathematically rigorous. Staff has determined that the impact of using ST rather than pAsL as a reference for AsF is sufficiently small if the indicated provisions are enforced, but may be excessive if these provisions are not enforced. Staff believes the revised wording to be a reasonable evolution of the wording in the RIS in the interest of enhanced clarity.

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216. ISA-17.9, C7b1, p25: delete this section. setting tolerance was eliminated in TSTF-493 and RIS 2006-17 this conflicts with current NRC guidance

ST is needed only if it is to be used as a basis for assessment of the as-found setpoint. If AsF is to be assessed against pAsL — which is more mathematically rigorous — then there is no regulatory significance to ST.

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217. ISA-17.10, C7b2, p25: Delete this section. 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.

C4c1 indicates that TLU does not need to include ST as far as establishment of the limiting setpoint is concerned. C7b2 indicates that TLU *does* need to include ST if the as-found setpoint is to be assessed against ST rather than against the previous as-left setpoint. These two provisions address different concepts, and are not in conflict with one another. C4c1 will be amended to address the potential need for inclusion of ST in TLU for other reasons.

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218. ISA-18.1, C7b3, p25: Delete this section. See above.

See the response to comment ISA-17.10

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219. ISA-18.2, C7c, p25: "…acute…"

This comment is too cryptic to answer.

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220. ISA-18.3, C7c, p25: Delete this section. 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.

Although not a part of the setpoint calculation process, C7c does relate to the statistical basis on which the calculation should be based and it allows for recognition that those bases result in a possibility that the associated limits could be exceeded on occasion in a properly-functioning installation. It also provides clarification of a provision in the associated industry standard, which would otherwise need to be excluded altogether from the NRC's endorsement.

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221. ISA-18.4, C7d3, p26: Experience demonstrates this as not being a problem. Where did this come from (state a real basis for the requirement).

See Common Theme #11: *Deviation Assessment*

222. ISA-18.5, C7e3, p26: What is this stating? Av is a worthless value. AFT will always be used for Operability?

See Common Theme #7: *AV*

223. ISA-18.6, p25: Where is the RIS criteria for AFT and ALT?

Some of the RIS criteria apply to Technical Specifications and not directly to the subject of this regulatory guide.
See Common Theme #1: *Technical Specifications*

224. ISA-18.7, C7d3, p26: "… high incidence of false detections…" This is related to comment on page 15 about "spurious actuations". If the setting tolerance is random as discussed in RIS 2006-017, then there won't be a high incidence. This statement is inconsistent with statics for a random setting tolerance.

See Common Theme #11: *Deviation Assessment*

225. ISA-18.8, C7d3, p26: Delete this section. 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.

See Common Theme #11: *Deviation Assessment*

226. ISA-18.9, C7d3, p26: "suitable practices" is undefined and unclear.

See Common Theme #11: *Deviation Assessment*

227. ISA-18.10, C7e, p26: Related to comment on page 16 about allowable value.

The reference is ambiguous. See the responses to all related previous comments.

228. ISA-18.11, C8b, p27: delete "the limiting value for the as-left setpoint" the statement could be interpreted that the as-left setpoint must be separated from the analytical by an amount no less than the TLU. This would double count the as-left tolerance in the TLU equatioadd n.

The statement will not be deleted. The commenter's interpretation is correct, but note that C8d allows for modification of the TLU to avoid double-counting the setting tolerance (also known as the As-Left tolerance).

229. ISA-18.12, C8c, p27: delete this section. Same justification as C.8.b.

See the response to ISA-18.11.

230. ISA-18.13, C8c, p27: This again is evidence of a bias against a random setting tolerance. RIS 2006-017 recognizes that random setting tolerances (ALT essentially equal to reference accuracy) are acceptable and an offset in the setpoint is not needed.

Common Theme #12: *As-Left Limits*

231. ISA-18.14, C8d, p27: Establishing a "limiting setpoint" by backing the setting tolerance out by reverse SRSS will likely result in a meaningless limit, especially if the TLU is large due to seismic and environmental effects.

Removal of setting tolerance from TLU is acceptable under the conditions noted, but is optional. A licensee who does not believe that there would be any advantage to this does not need to do it.

232. ISA-18.15, C8d, p27: Add nothing, bug dust.

This comment is too cryptic for response.

233. ISA-18.16, D, p28: Use by NRC Staff. Paragraphs 3, 4 and 5 of this section are inconsistent with and contrary to paragraphs 1 and 2. Utilities should be able to revise their current licenses consistent with their current licensing basis and not be forced to comply with newer revisions of Regulatory Guides without there being a corresponding change to NRC Regulations that were approved by the regulatory process.

This comment concerns backfitting as it applies to new Regulatory Guides. As the commenter correctly notes, this Regulatory Guide (RG) is not being imposed as a requirement on current licensees, and a licensee will not be cited for violations of the RG unless it has been incorporated into the licensing basis of the facility. This does not prevent NRC staff from discussing the RG with a licensee or applicant as one way to meet regulatory requirements.

However, the commenter is not correct that current licensees will be "forced to comply" with the RG in the event of a license amendment. Paragraph 3 of the section referenced in the comment states that, if a licensee seeks a license amendment that is relevant to the subject matter of the RG, and where the subject matter of the RG is essential to the staff's determination of the acceptability of the licensee's request, "then the staff may request that the licensee either follow the guidance in this RG *or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements."* The licensee has the choice of whether to follow the RG, thereby taking advantage of the staff's previous determination that following the guidance is one way of complying with regulatory requirements, or of providing an alternative process to demonstrate compliance with the same regulations.

Because the RG does not impose new requirements, but rather describes one way of complying with existing requirements, it does not constitute backfitting as defined in 10 CFR 50.109(a)(1). However, Paragraph 4 of the referenced section states that, in the event that the NRC does, imposes new requirements in the future, then the backfitting provisions of 10 CFR 50. 109 apply. Paragraph 5 describes for backfitting issues.

No change is needed in responses to this comment.

234. ISA-18.17, D, p28: Second paragraph - It is very important that all utilities establish their RG 1.105 and ISA 67.04 design basis for their calculations in their plant SARs otherwise, no design basis exist and you are at the NRC mercy.

This is a comment to industry --- no NRC response.

235. ISA-18.18, D, p28: This section allows significant scope increase beyond the existing Safety Related LSSSs. Future Tech Spec LARs should be held to the plant's original licensing basis.

Regulatory requirements for technical specifications related to limiting safety system settings are set forth in 10 CFR 50.3(c)(1). This Regulatory Guide neither increases or decreases regulatory requirements in this area. In the even that a licensee requests a license amendment that seeks to change technical specifications, the NRC staff would review the application to determine whether the proposed amendment complies with all relevant regulatory requirements.

No change is needed in response to this comment.

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236. ISA-18.19, Glossary>95/95: 95/95 the definition is incomplete. It does not in any way explain what is meant by the numbers 95, while the body does expect proper use of 95/95. NUREG-1475.R1, section 9.12, "Statistical tolerance limits for a normal population" provides some information that might be useful.

95/95 is discussed in detail in B4.4.

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237. ISA-19.1, Glossary>AL: AL This is more of a definition of Analysis Setpoint (AS). Ideally, and as implied by the use of "surrogate" in other sections, the AL would be the least conservative AS that will have an acceptable result in the safety analysis. However, this is not necessarily what happens. A safety analysis (SA) is run only a few times with some AS. The least conservative AS is not found. Therefore, there may be margin between the AS in the SA and the ideal AL. In this case the AL is simply the limit of what has been analyzed; not the limit of what could be.

The analytical limit (AL) is indeed the limit used in the safety analyses, as opposed to the limiting value beyond which deleterious effects are known to occur. It is true that it might include unknown margin that cannot be used because it has not been evaluated. A licensee is free to perform analyses that show that a less conservative value is adequately safe, and then to designate that new value the analytical limit. The term "Analysis Setpoint" is not used or defined in the draft guidance, in the associated RIS, or in the associated industry standard.

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238. ISA-19.2, Glossary>Deviation: Deviation This appears (again) to be a bias against the information presented in RIS 2006-017.

This comment is too cryptic for response.

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239. ISA-19.3, Glossary>Drift: Drift this is not a definition. Recommendation: provide a definition, perhaps from ISA.

The draft is correct as-is. Note that the referenced term, "deviation," does address and contrast the more common but not equivalent term, "drift."

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240. ISA-19.4, Glossary: Footnote 3 What footnote does this mean? Note 3 of Figure 1 does not relate.

Footnote 3 is located on page 9 of the present draft.

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241. ISA-19.5, Glossary: Provide textbook or NIST reference or reference to NUREG-1465.

This comment is too cryptic for response. Also, NUREG 1465 is titled "Accident Source Terms for Light-Water Nuclear Power Plants" — perhaps the commenter intended to cite NUREG-1475?

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242. ISA-19.6, Glossary>SRSS: This might merely be a terminology issue, but I think it is an issue. The definition of SRSS on page 31 combines the standard deviations (we call them Sigmas) of random

errors and then adds the errors algebraically, if I read their equations correctly. Regardless, it is confusing to me. It seems incorrect to add the random errors algebraically (i.e., "A = B+C+D") and to combine the Stnd. Deviations using the SRSS (i.e., a = SRSS (b,c,d)," where the lower case letters are the corresponding Stnd. Deviations.

(This comment is associated with C8a by the commenter, but actually addresses the SRSS entry in the Glossary.)
See Common Theme #15: *SRSS*

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243. ISA-19.7, Glossary>SRSS, ST: The definition of SRSS on page 31 might be incomplete, as the last thing is an equal sign. Did the NRC leave something out? Or, is it a typographical error? Editorial: The definition of setting tolerance states that it is sometimes "…referred to as 'As-Left Tolerance,' or 'ALT.'" The word "or" should be "and," as both are used to mean the same thing. "ALT" is the abbrev.

The SRSS definition on p31 of the draft guidance is complete, and does not end with an equals sign. Perhaps there is a printing error in the reviewer's copy.
In the definition of Setting Tolerance, "or ALT" will be changed to "or as ALT." Sometimes "As-Left Tolerance is used, and sometimes "ALT" is used.

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244. ISA-19.8, Glossary>SRSS: Definition of SRSS - the first equation should be stated in words, the combination uncertainty A, of multiple terms, of B, C, D. Also suggest using sigma to indicate which are standard deviations, i.e. change to Sigma a= SRSS(Sigma b, Sigma c, Sigma d)

See Common Theme #15: *SRSS*

Although commonly used and understandable to most practitioners, ther term "sigma" is not defined and may be confusing to persons less familiar with this subject.

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245. ISA-19.9, Glossary>ST: The note does not recognize random variables for Setting Tolerance, as discussed in RIS 2006-017.

We interpret this comment as referring to the note in the Glossary entry for "Setting Tolerance."
See Common Theme #12: *As-Left Limits*

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246. ISA-19.10, Glossary>ST: Editorial: The definition of Setting tolerance states that it is sometimes "…referred to as 'As-Left Tolerance,' or 'ALT.'" The word "or" should be "and," as both are used to mean the same thing. "ALT" is the abbrev.

A person discussing "setting tolerance" might refer to "As-Left Tolerance" or to "ALT." These terms might be used interchangeably or independently.

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247. ISA-19.11, Glossary>TLU: This definition of TLU includes a bias toward a bias setting tolerance. It does not include the discussion in RIS 2006-017.

RIS 2006-017 addresses considerations related to the content of technical specifications and to operability determination as well as to the criteria for instrument setpoint limits. This regulatory guide does not directly address the content of technical specifications, nor does it directly address operability determination.
Common Theme #12: *As-Left Limits*

ISA-19.12: This is a duplicate of NEI-26.1.

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248. ISA-19.13, References, p33: no reference to Generic Letter 91-04 which is included in BTP 7-19 Rev 5. This is important guidance for calibration extensions.

See Common Theme #12: *As-Left Limits*

ISA-19.14: This is a duplicate of ISA-19.13.

Frank Laratta (FL)

249. FL-1: Setpoints should be adjusted dynamically, in consideration of the particular conditions existent in the plant in real time. The present practice of establishing fixed setpoints on the basis of safety analyses is fundamentally flawed. (This is the NRC's distillation of the considerably more detailed statements contained in Mr. Laratta's submittal.)

These comments refer to selection of the desired actuation point — the Analytical Limit, as described in this regulatory guide and in the associated industry standard, ISA-67.04.01. This regulatory guide addresses the treatment of uncertainties in the selection of a setpoint intended to protect an Analytical Limit that has already been selected. These comments are therefore not applicable to this regulatory guide. Licensees who wish to propose alternative methods for the determination of fixed or variable Analytical Limits are free to do so, and the proposed methods will be given due consideration by the staff. Note that, for example, PWR overpower and overtemperature delta-T setpoints are, in fact, variable. They are set dynamically on the basis of current and recent operating conditions.

NEI (comments submitted by Steven Hutchins)

250. NEI-L1: NEI encourages further interactions between the industry and the NRC that would result in an NRC endorsement of existing industry standards on setpoints.

See Common Theme #14: *Additional Meetings*

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251. NEI-L2: 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.

See Common Theme #14: *Additional Meetings*

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252. NEI-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.

See Common Theme #9: *Single-Sided Setpoints*

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253. NEI-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.

See Common Theme #10: *Temporal Extrapolation*

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254. NEI-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.

See Common Theme #6: *Surrogate Safety Limits*

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255. NEI-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.

Staff agrees that the 95/95 criterion and margin to the analytical limit are two different concepts, and that the margin between the limiting setpoint and AL can be increased to any desired value larger than the total loop uncertainty. The guidance does not address any "margin beyond AL." See Common Theme #9: *Single-Sided Setpoints* for a discussion of the probability of an actual trippoint in excess of the analytical limit.

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256. NEI-1.1: Sufficient guidance on decimal place usage and rounding guidelines is not provided.

    Proposed Resolution

    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.

    Basis for Comment or Resolution

    Lack of guidance regarding decimal places and rounding in the draft RG.

Criteria concerning numerical precision and rounding conventions are well-known and are beyond the level of detail appropriate to this guidance. These are among the many elements of uncertainty analysis.

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257. NEI-1.2, A>Scope, p4b7: "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.

    Proposed Resolution

    Provide examples of the setpoint requirements (SL/AL) that have been incorporated by reference into TS.

    Basis for Comment or Resolution

    No examples of setpoint requirements in compliance with 10 CFR 50.36 are provided in the Draft Regulatory Guide.

Setpoints that are not expressed directly in the technical specifications, but that are instead included in a Setpoint Control Program that is incorporated into the technical specifications by reference, are "included by reference."

See Common Theme #3: *Scope*

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258. NEI-1.3, A>Scope, p4b8: "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.

Proposed Resolution

Define the term "significant safety function" to bound the scope of the RG.

Basis for Comment or Resolution

Terminology lacks clarity

The applicability of Appendix B is already well-established, and is addressed in Appendix B itself.

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259. NEI-2.1, B.2, p8b10: "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.

Proposed Resolution

Provide guidance for the use of the new analyses to determine suitable setpoint limits and allowances.

Basis for Comment or Resolution

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.

See Common Theme #5: *Terminology*

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260. NEI-2.2, B5.2>LSP, p17b4: "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.

Proposed Resolution

Include the one-sided probability distribution method for conformance to the 95/95 criterion.

Basis for Comment or Resolution

The approved GEH Setpoint Methodology uses one-sided probability in the development of nominal trip setpoints.

See Common Theme #9: *Single-Sided Setpoints*

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261. NEI-2.3, C1a, p20: "Analytical limits and other limits which prevent safety limits from being exceeded constitute surrogate safety limits."

The term surrogate safety limit is not defined.

Proposed Resolution

Clarify the application of the term "surrogate safety limits," especially for cases with no analytical limit.

Basis for Comment or Resolution

In accordance with GEH Setpoint methodology, the AL is the process variable value in the safety analysis established to prevent reaching the SL.

See Common Theme #6: *Surrogate Safety Limits.*

262. NEI-3.1, C4c, p21: "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.

Proposed Resolution

Clarify the acceptability for use of the SRSS method with respect to 6-month interval calculations.

Basis for Comment or Resolution

The approved GEH Setpoint Methodology allows the application of the SRSS calculation method to account for multiple 6-month intervals.

See Common Theme #10: *Temporal Extrapolation*

263. NEI-3.2, D, p28: "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.

Proposed Resolution

Confirm the currently approved methodologies remain applicable for determining the Technical Specification (TS) allowable values (AVs) and related nominal trip setpoints (NTSPs).

Basis for Comment or Resolution

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.

The paragraph following the cited text, as well as "Purpose of Regulatory Guides" on page 5 of the draft (near the end of Section A), clearly indicate that the provisions of the regulatory guide are not mandatory. In particular, the final sentence of the second paragraph of Section D states: "Current licensees may continue to use guidance that NRC found acceptable for complying with the identified regulations as long as their current licensing basis remains unchanged."

264. NEI-4.1, C4c2, p21: RG should not disallow SRSS extrapolation of time related uncertainties.

Proposed Resolution

Delete "not by the SRSS of multiple intervals" and "not STSS (1%, 1%) = …"

Basis for Comment or Resolution

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.

See Common Theme #10: *Temporal Extrapolation*

265. NEI-5.1 through 23.1

These comments duplicate a submittal from Nu-Scale Power, and are addressed by NRC staff in response to the Nu-Scale submittal rather than here.

NEI-24.1: This is a duplicate of ISA-1.1.
NEI-24.2: This is a duplicate of ISA-1.4.

266. NEI-24.3: 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.

Proposed Resolution

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.

Basis for Comment or Resolution (If Needed)

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.

See Common Theme #9: *Single-Sided Setpoints*

NEI-24.4 duplicates ISA-6.10
NEI-24.5 duplicates ISA-5.10
NEI-24.6 duplicates ISA-7.5

267. NEI-24.7, B5.1>AV, p16b4: 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.

Proposed Resolution

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.

Basis for Comment or Resolution (If Needed)

Align with already published NRC Documents.

The cited paragraph was revised to address the problem with AV without implying guidance as to technical specification content.

268. NEI-24.8, B5.2>LSP, p17b4: "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.

Proposed Resolution

Recommendation: Reword sentence to state "This is true for symmetric trippoint distributions."

See Common Theme #9: *Single-Sided Setpoints*

NEI-25.1 duplicates ISA-2.10
NEI-25.2 duplicates ISA-1.8
NEI-25.3 duplicates ISA-5.11
NEI-25.4 duplicates ISA-6.12
NEI-25.5 duplicates ISA-8.10

269. NEI-25.6, A>Regulations, p2b6: "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.

Proposed Resolution

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.

See Common Theme #1: *Technical Specifications*

NEI-25.7: This is a duplicate of ISA-2.1.

270. NEI-25.8, A>Regulations, p3b1: "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.

Proposed Resolution

Recommendation: delete later reference to AFT as a potential LSSS.

See Common Theme #11: *Deviation Assessment*

271. NEI-26.1: Inconsistent use of "trippoint" or "actual trippoint" throughout RG.

Proposed Resolution

Suggestion: use either "trippoint" or the ISA term "actual trip setpoint" consistently.

See Common Theme #16: *Setpoint vs Trippoint*

272. NEI-26.2, A>Regulations, p3b3: Reference to IEEE 279 and 603 will be changing due to rulemaking so this will be impacted

Proposed Resolution

Hold RG until current draft rule is issued for use.

Basis for Comment or Resolution (If Needed)

Potential impact due to current rulemaking

Staff is aware of this issue. The final version of the guidance will be consistent with the regulation. Delaying the issue of the guidance to better address the revised regulation is a possibility, but the advisability of such delay will depend upon various scheduling considerations that would be better addressed as the guidance and rule revision near completion.

273. NEI-26.3, B5.2>LSP, p16b7: "…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.")

Proposed Resolution

Recommendation: make up your mind (without a backfit) is AV or LSp the LSSS? See also comment #2 for this page.

The guidance is consistent with RIS 2006-017. Note that there are actually two LSSS: one for the As-Left setting and one for the AS-Found setting. RIS 2006-017 and the draft guidance (page 16) both point out that the "allowable value" fails to detect unexpectedly large deviation in the conservative direction, and therefore to be inadequate for the assessment of setpoint deviation.

NEI-26.4: This is a duplicate of ISA-7.8

274. NEI-26.5, B5.1, p14: Again a bias against the information presented in RIS 2006-017.

Proposed Resolution

Recommendation: Align with concepts discussed in the RIS.

The comment cites "Deviation" on "page 4." Deviation is not addressed on page 4. Staff interprets this comment as applicable to B5.1 on page 14, and as addressing "drift" as used in the RIS.

"Drift" and "Deviation" are two separate concepts. "Deviation" includes drift but also includes other changes to the measured setpoint that result from such factors as environmental changes between

measurements, and M&TE errors due to the use of different measuring equipment at different times. The RIS is written at a higher level than the guidance and does not get into these details. It uses "drift" simply as one example of something that might make a setpoint change over time.

275. NEI-26.6, B5.1, p14, footnote 6: The footnote indicates a definition for "setpoint deviation". However, "deviation" is what is provided in the glossary.

Proposed Resolution

Suggestion: Consistent use of terms

The definition of "deviation" in the glossary includes reference to "setpoint deviation." It is appropriate for the glossary to focus on the main term "deviation" without the optional modifier "setpoint."

276. NEI-26.7, A>Scope, p4b7: "… 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.

Proposed Resolution

Recommendation: Clarify which setpoints are intended, and do not expand scope from previous revisions of the RG.

See Common Theme #3: *Scope*

NEI-26.8: This is a duplicate of ISA-2.2.

277. NEI-26.9, A>Scope, p4: 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.

Proposed Resolution

Clarify wording.

See Common Theme #3: *Scope*

NEI-27.1: This is a duplicate of ISA-2.5.

278. NEI-27.2, A>Scope, p4b7: 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."

Proposed Resolution

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).

Basis for Comment or Resolution (If Needed)

Un-neccesary scope increase.

See Common Theme #3: *Scope*

NEI-27.3: This is a duplicate of ISA-7.9

279. NEI-27.4, Glossary>Drift: This is not a definition.

Proposed Resolution

Recommendation: provide a definition, perhaps from ISA.

The cross-reference is correct. “Drift” is addressed in the note concerning the definition of “Deviation.” Staff has observed many instances of the term “drift” being used when “deviation” is being discussed, and so believes that the glossary should tightly connect and contrast these terms.

NEI-27.5 duplicates ISA-7.11
NEI-27.6 duplicates ISA-2.9
NEI-27.7 duplicates ISA-2.11
NEI-27.8 duplicates ISA-2.12
NEI-27.9 duplicates ISA-7.12
NEI-27.10 duplicates ISA-2.13
NEI-28.1 duplicates ISA-3.1
NEI-28.2 duplicates ISA-3.2
NEI-28.3 duplicates ISA-3.3
NEI-28.4 duplicates ISA-3.4
NEI-28.5 duplicates ISA-3.5
NEI-28.6 duplicates ISA-3.6
NEI-28.7 duplicates ISA-3.7
NEI-28.8 duplicates ISA-3.8
NEI-29.1 duplicates ISA-3.9
NEI-29.2 duplicates ISA-3.10
NEI-29.3 duplicates ISA-3.11
NEI-29.4 duplicates ISA-4.1
NEI-29.5 duplicates ISA-4.3
NEI-29.6 duplicates ISA-4.4

280. NEI-29.7, B4.1>Fig 1 Notes, p11b8: “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.

Proposed Resolution

Recommendation: delete redundancy. Remainder of section 4.1 should be deleted and relevant information moved to the sections where the parameter is already discussed.

Section 4.1 establishes and describes the setpoint-related limits and parameters that are of interest, and describes the reasons that they are important. Section 5 provides more detailed information concerning the development of the values for those limits and parameters.

NEI-30.1: This is a duplicate of NEI-29.7.

281. NEI-30.2, B4.1>Fig 1 Notes, p11b1: "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).

Proposed Resolution

Recommendation: Include both perspectives

See Common Theme #12: *As-Left Limits*

NEI-30.3 duplicates ISA-5.3
NEI-30.4 duplicates ISA-5.4
NEI-30.5 duplicates ISA-5.5
NEI-30.6 duplicates ISA-5.5
NEI-30.7 duplicates ISA-5.6
NEI-30.8 duplicates ISA-5.7
NEI-30.9 duplicates ISA-5.8
NEI-30.10 duplicates ISA-5.9
NEI-31.1 duplicates ISA-5.10
NEI-31.2 duplicates ISA-5.11
NEI-31.3 duplicates ISA-5.12
NEI-31.4 duplicates ISA-5.13
NEI-31.5 duplicates ISA-5.13
NEI-31.6 duplicates ISA-5.14
NEI-31.7 duplicates ISA-5.15

282. NEI-31.8: 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.

Proposed Resolution

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.

See Common Theme #12: *As-Left Limits*

NEI-31.9 duplicates ISA-6.1
NEI-32.1 duplicates ISA-6.1
NEI-32.2 duplicates ISA-6.2
NEI-32.3 duplicates ISA-6.4
NEI-32.4 duplicates ISA-6.5
NEI-32.5 duplicates ISA-6.6
NEI-32.6 duplicates ISA-6.7
NEI-32.7 duplicates ISA-6.9
NEI-32.8 duplicates ISA-6.9
NEI-32.9 duplicates NEI-24.4
NEI-32.10 duplicates ISA-6.11
NEI-32.11 duplicates ISA-7.1
NEI-32.12 duplicates ISA-7.2
NEI-33.1 duplicates ISA-7.3

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283. NEI-33.2, B5.1>AFT, p15b6: Basis for “significant increase in the likelihood of spurious actions” unsupported.

Proposed Resolution

Clarify wording.

See Common Theme #11: *Deviation Assessment*

NEI-33.3: This is a duplicate of ISA-8.1.
NEI-33.4: This is a duplicate of ISA-8.2.

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284. NEI-33.5, C2b, p20: 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.

Proposed Resolution

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.

Commenter associates this comment with B5.1>AFT, p15b4, but the comment applies more directly to C2b.

See Common Theme #11: *Deviation Assessment*

NEI-33.6 duplicates ISA-8.4
NEI-33.7 duplicates ISA-8.7
NEI-33.8 duplicates ISA-8.8
NEI-33.9 duplicates ISA-8.9
NEI-33.10 duplicates ISA-8.11
NEI-34.1 duplicates ISA-8.12
NEI-34.2 duplicates ISA-8.13
NEI-34.3 duplicates ISA-8.14
NEI-34.4 duplicates ISA-9.1
NEI-34.5 duplicates ISA-9.2
NEI-34.6 duplicates ISA-9.4
NEI-34.7 duplicates ISA-9.6
NEI-34.8 duplicates ISA-9.7
NEI-34.9 duplicates ISA-9.5
NEI-35.1 duplicates ISA-9.9
NEI-35.2: duplicates ISA-9.9 (Comment is a table that is a part of the previous comment.)

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285. NEI-36.1, B4.4, p14: 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).

Proposed Resolution

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 deviation) 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.

See Common Theme #9: *Single-Sided Setpoints*

286. NEI-36.2, B5.2>LSP, p17b4: 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.

Proposed Resolution

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 needs 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].

See Common Theme #9: *Single-Sided Setpoints*

287. NEI-36.3, B5.2>LSP, p17b4: 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.

Proposed Resolution

Clarify wording.

See Common Theme #8: *95/95*

288. NEI-37.1, B5.2>LSP, p17b4: 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.

See Common Theme #9: *Single-Sided Setpoints*

289. NEI-37.2, B5.2>LSP, p17b4: The NRC needs to clearly define the probability requirement (with justification) for exceeding the AL, since that is the main purpose of the RG.

Proposed Resolution

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.

See Common Theme #9: *Single-Sided Setpoints*

NEI-37.3 duplicates ISA-10.6
NEI-37.4 duplicates ISA-10.7
NEI-37.5 duplicates ISA-10.8

290. NEI-38.1, B5.2>Fig 2 Note, p18b4: 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.

Proposed Resolution

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.

See Common Theme #9: *Single-Sided Setpoints*

NEI-38.2 duplicates ISA-11.2
NEI-38.3 duplicates ISA-11.3
NEI-38.4 duplicates ISA-11.5
NEI-38.5 duplicates ISA-2.8

291. NEI-38.6 C1a, p20: "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.

Proposed Resolution

Clarify wording.

See Common Theme #6: *Surrogate Safety Limits*

NEI-39.1: This is a duplicate of ISA-12.2.
NEI-39.2: This is a duplicate of ISA-12.3.

292. NEI-39.3, C1b, p20: This is an expansion of safety limit. The principles can be applied to ALs, but they should not be requirements.

Proposed Resolution

Recommendation: Delete C.1 as regulatory guidance as an inappropriate expansion of definitions.

See Common Theme #6: *Surrogate Safety Limits*

NEI-39.4: This is a duplicate of ISA-12.6.

293. NEI-39.5, C2b, p20: "…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.

Proposed Resolution

Recommendation: Clarify that this is needed only for a trend of tests exceeding the AFT.

See Common Theme #11: *Deviation Assessment*

NEI-39.6 duplicates ISA-12.9
NEI-39.7 duplicates ISA-12.10
NEI-39.8 duplicates ISA-12.11

294. NEI-39.9, C3b4, p21: What is the value of term "trippoint" as compared to "actual trip setpoint"?

Proposed Resolution

Suggestion: provide a reason for terminology change.

See Common Theme #16: *Setpoint vs Trippoint*

NEI-39.10 duplicates ISA-12.12
NEI-39.11 duplicates ISA-12.13
NEI-39.12 duplicates ISA-12.14
NEI-39.13 duplicates ISA-12.15
NEI-40.1 duplicates ISA-12.16
NEI-40.2 duplicates ISA-12.17
NEI-40.3 duplicates ISA-12.19

295. NEI-40.4, C4c2, p21: 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.

Proposed Resolution

Clarify wording.

See Common Theme #10: *Temporal Extrapolation*

296. NEI-40.5, C4c2, p21: 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).

Proposed Resolution

Clarify wording

See Common Theme #10: *Temporal Extrapolation*
Section C4e6 of the draft guidance simply says that the uncertainty analysis should indicate the basis for the time interval used to establish the amount of drift expected. It is not affected by the manner in which draft is determined.

NEI-40.6: This is a duplicate of ISA-13.3.
NEI-40.7: This is a duplicate of ISA-13.4.

297. NEI-40.8, C4c2, p21: The RG Draft requires the drift error to be extrapolated linearly, which is very conservative and unrealistic (Section 4c2).

Proposed Resolution

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].

See Common Theme #10: *Temporal Extrapolation*

298. NEI-41.1, C4c3, p22: 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?

Proposed Resolution

Suggestion: clarify the purpose of this section.

See Common Theme #13: *Dynamic Effects*

299. NEI-41.2, C4c3, p22: The Draft states that the dynamic effects of the process, such as transport delays be included in the uncertainty analysis (Section C4c3).

Proposed Resolution

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].

See Common Theme #13: *Dynamic Effects*

NEI-41.3: This is a duplicate of ISA-14.5.

300. NEI-41.4, C4c2, p21: If as-found/as-left analysis determines that "drift" is not, time dependent, is "drift" then not a "time related uncertainty".

Proposed Resolution

Clarify wording.

"Drift" is time-dependent by definition: it is the change in the setpoint that can only be ascribed to time and to no other source. The observed change in a setting is referred to as "deviation" rather than "drift" because it necessarily includes the influence of other factors such as changes in environmental conditions or changes in M&TE. An instrument that has no time-related uncertainty would have a drift rate of zero, but other than for digital settings a drift rate of zero seems unlikely.

301. NEI-41.5, C4b, p21: Refer to NUREG

Proposed Resolution

Clarify wording

The draft guidance is correct as-is. NUREG-1475 is one of many texts on statistical analysis, and staff does not intend to dictate which text a license should use.

NEI-41.6 duplicates ISA-13.9
NEI-41.7 duplicates ISA-13.10
NEI-41.8 duplicates ISA-13.12

302. NEI-41.9, C4c3, p22: 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.

Proposed Resolution

Delete this section

See Common Theme #13: *Dynamic Effects*

NEI-41.10 duplicates ISA-13.14
NEI-42.1 duplicates ISA-14.1
NEI-42.2 duplicates ISA-14.2
NEI-42.3 duplicates ISA-14.3
NEI-42.4 duplicates ISA-10.9(The commenter associates this comment with C4c6, but staff has determined that it more closely relates to C4b.)

NEI-42.5 duplicates ISA-14.6
NEI-42.6 duplicates ISA-16.4

303. NEI-42.7, C4c8, p22: 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.

Proposed Resolution

Clarify wording,

AFT and TLU are different things that are used differently. Each should be developed on the basis of its own usage. The reference to "comment #2" and "page 21" appear to have lost their original context and are no longer traceable.

NEI-42.8 duplicates ISA-14.8
NEI-43.1 duplicates RB-3
NEI-43.2 duplicates RB-2
NEI-43.3 duplicates ISA-15.2
NEI-43.4 duplicates ISA-15.3
NEI-43.5 duplicates ISA-15.4
NEI-43.6 duplicates ISA-15.5
NEI-43.7 duplicates ISA-15.6
NEI-44.1 duplicates ISA-15.7
NEI-44.2 duplicates ISA-15.8
NEI-44.3 duplicates ISA-15.9
NEI-44.4 duplicates ISA-15.10
NEI-44.5 duplicates ISA-15.11
NEI-44.6 duplicates ISA-15.12
NEI-44.7 duplicates ISA-15.13
NEI-44.8 duplicates ISA-16.1

304. NEI-44.9, C4h, p23: TSTF-493 requires the trending of as-found and as-left data the calibration monitoring would be redundant to this requirement

Proposed Resolution

Clarify wording.

There is no need for redundant monitoring programs. A single program could suit sets of guidance. Note that the provisions of the regulatory guide do not constitute "requirements."

NEI-44.10 duplicates ISA-16.5
NEI-44.11 duplicates ISA-16.6
NEI-44.12 duplicates ISA-16.7
NEI-44.13 duplicates ISA-16.8
NEI-44.14 duplicates ISA-16.9
NEI-45.1 duplicates ISA-16.10
NEI-45.2 duplicates ISA-6.3
NEI-45.3 duplicates ISA-16.13
NEI-45.4 duplicates ISA-16.14
NEI-45.5 duplicates ISA-17.1
NEI-45.6 duplicates ISA-17.2
NEI-45.7 duplicates ISA-17.3
NEI-45.8 duplicates ISA-17.4
NEI-46.1 duplicates ISA-17.5

NEI-46.2 duplicates RB-3
NEI-46.3 duplicates RB-2
NEI-47.1 duplicates RB-1
NEI-47.2 duplicates ISA-17.7
NEI-47.3 duplicates ISA-17.8
NEI-47.4 duplicates ISA-17.9
NEI-47.5 duplicates ISA-17.10

305. NEI-47.6, C7b3, p25: Delete this section.

Proposed Resolution

Delete this section

The referenced criterion is one of the factors used in the determination that assessment of the As-Found setpoint against the nominal setpoint, rather than against the previous As-Left setting, might be acceptable. If the As-Found Tolerance is not suitably constrained, then an NSP-based assessment may not be adequate.

NEI-47.7: This is a duplicate of ISA-18.3.

306. NEI-47.8, C7d3, p26: "… high incidence of false detections…" This is related to comment #8 on page 15.

Proposed Resolution

Recommendation: provide basis for why you think this is true. Others of us, who also think we understand statistics, disagree.

See Common Theme #11: *Deviation Assessment*

NEI-47.9 duplicates ISA-18.4
NEI-48.1 duplicates ISA-18.5
NEI-48.2 duplicates ISA-18.6
NEI-48.3 duplicates ISA-18.8
NEI-48.4 duplicates ISA-18.9

307. NEI-48.5, C7e, p26: Related to comment #1 on page 16

Proposed Resolution

Clarify wording.

The reference is unclear. NEI comments 33.6, 33.7, 33.9, 33.10, and 34.1 address allowable value as presented on page 16 of the draft guidance. See those comments and responses. See also Common Theme #7: *AV*

NuScale (comments submitted by Steven Mirsky)

308. NuScale-1, A>Scope, p4: 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~~.

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).

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. NuScale plans to 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.

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.

See Common Theme #3: *Scope*

309. NuScale-2, B2>Definitions, p8: 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.

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.

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. 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.

See Common Theme #16: *Setpoint vs Trippoint*

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310. NuScale-3, B2, p8b10: 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."~~

Reason for Change

Clarity

The sentence was modified as requested.

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311. NuScale-4, B2, p9b1: 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). Ssetpoint related technical specification limits are therefore selected so as to provide adequate protection of analytical limits.

Reason for Change

Treating Analytical Limits as surrogate Safety Limits has ramifications in definition of Safety Limits in TSs. 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.

See Common Theme #6: *Surrogate Safety Limits*

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312. NuScale-5, B3, p9b5: 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.

Reason for Change

Make it consistent with the previous paragraph.

The comment fails to recognize the present limited endorsement of the 2006 version, but the existing text does overlook the non-endorsement of the 2000 version. ***The draft was changed to '…other than selected versions of 67.04.01.***

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313. NuScale-6, B4.1>Fig 1 Notes, p10: Revise the two notes related to AFT as follows:

Potentially Excessive Deviation (see notes 3 and 4)

Reason for Change

Both notes are related to AFT.

Note 4 addresses the relationship between the value of the Analytical Limit and other values of interest. It is not directly relevant to As-Found Tolerance or to potentially excessive deviation.

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314. NuScale-7, B4.1>Fig 1, p10: Revise the parenthetical statement as follows:

(This figure is used instead of~~supersedes~~ the figure in Section 4 of ISA 67.04.01.)

Reason for Change

Reason for Change: Correctness. The RG does not supersede the ISA standard. It only explains an acceptable way to use the standard.

The suggested change was implemented (precise wording may differ).

315. NuScale-8, B4.1>Fig 1 Notes, p11b2: 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).

Reason for Change

Clarity.

Section B can contain clarifications, but not regulatory positions. Therefore the text should remain as-is.

316. NuScale-9, B4.1>Fig 1 Notes, p11b3: 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.~~

Reason for Change

For clarity and 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".

Section B can contain clarifications, but not regulatory positions. Therefore the text should remain as-is.

317. NuScale-10, B4.1>Fig 1 Notes, p11b4: 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.~~

Reason for Change

Clarity

Notes are just for interpretation of the figure. Information concerning the AV itself are provided in B5.1 (on page 16) and in C7e.

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318. NuScale-11, B4.1, p11b7: 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.

Reason for Change

Editorial comment.

Existing formatting is adequate.

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319. NuScale-12, B4.1, p11b10-11: Modify last paragraph as follows:

This RG addresses two primary considerations regarding acceptability limits on measured values for instrument setpoints:

Limits on the acceptable measured value of a setpoint:

Limiting Setpoint (LSP): the least conservative acceptable value for an as-left setpointa 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)

Reason for Change

Make the discussion consistent with the definitions provided in Section 5 of the 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. The AV discussion should be deleted in this section so that the two primary considerations (LSP and AFT) are emphasized.

This text is intended to contrast concerns related to the value of a measured value, whether As-Left or As-Found (LSP or AV), with concerns related to an observed changed in the measured value (AFT). The descriptions are not intended to be definitions, and so they reference the definitions and more complete discussions.

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320. NuScale-13, B4.1, p12b1-2: 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 intervala ~~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)~~

Reason for Change

Make the discussion consistent with the definitions provided in Section 5 of the RG. One of the goals of the RG is to clarify the use of terminology used in setpoint documents.

This is a continuation of the previous comment (Nu-Scale 12). See the response to that comment.

321. NuScale-14, B4.1, p12b5: Delete the second bullet.

Reason for Change

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.

The cited paragraph is correct as is, ***although reference to B5.1 should be added***. Staff positions are presented in Section C, and Section B only provides supporting discussions.

322. NuScale-15, B4.3, p13b6: 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. 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. 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. This point is illustrated by the as-found tolerance (AFT) shown in Figure 1. 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 ofor the anticipated deviation were overestimated, the effectiveness of the assessment would be reduced.

Reason for Change

The proposed insertions are made for clarity and a typographical error is corrected.

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.

References to the appropriate areas of the figure was added. The typo was corrected.

323. NuScale-16, B5.1>AFT, p15b6: Modify the last two sentences of the fourth paragraph as follows:

There is a tradeoff between the effectiveness of detection of malfunction induced deviation and the suppression of false detections. The width of the as-found tolerance interval is key: a narrower interval increases the sensitivity in detection of possible malfunctions, while a wider interval might mask the detection of malfunctions. 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 corresponds to a false detection rate of 5 percent for previous as-left value based evaluations. 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~~.

Reason for Change

There is no basis for linking "false detections" to "spurious actuations."

The statements were corrected.

324. NuScale-17, B5.2>LSP, p16b5: 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~~.

Reason for Change

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. The RIS 2006-17 definition of LSP should be retained as the basis for this regulatory guide.

See Common Theme #12: *As-Left Limits*

325. NuScale-18, B5.2>LSP, p17b5: Delete last sentence in the last paragraph in the subsection on Limiting Setpoint.

Reason for Change

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.

The paragraph was modified to eliminate any implication that reduction in the margin between LSP and AV would be an acceptable approach to the indicated problems.

326. NuScale-19, B5.2>Fig 2, p18: 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.

Reason for Change

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. 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.

See Common Theme #9: *Single-Sided Setpoints*

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327. NuScale-20, C4c3, p22: Delete Item c.(3).

Reason for Change

Inclusion of dynamic effects within the setpoint methodology, as required by Section C.4.c(3), is inconsistent with industry practice. 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.

See Common Theme #13: *Dynamic Effects*

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328. NuScale-21, C4c4, p22: Add clarification to Item c.(4) as follows:

Section 4.5, paragraph 2: Square Root of the Sum of the Squares (SRSS) is acceptable for combining uncertainties only if the uncertainties are statistically independent and are based on normal probability distributions that provide adequate coverage of the underlying data. Other techniques mentioned in this paragraph are not formally defined and are therefore not endorsed by NRC staff. Regardless of the method used to combine uncertainties in any particular computation, the suitability of that method for the particular application should be explained and justified. 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.

Reason for Change

Clarification of expectations that the evaluation of independence uses reasonable engineering judgment rather than a formal proof of independence.

See Common Theme #15: *SRSS*

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329. NuScale-22, C4i, p23: Modify Paragraph as follows:

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.

Reason for Change

Makes the discussion consistent with the limitations described in Section D of the RG.

Reference to RG versions was deleted. The final sentence, concerning prior NRC reviews, was modified to address review objectives rather than RG versions.

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330. NuScale-23, C6e, p25: Modify Item (e) as follows:

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.

Reason for Change

To encompass the small sample size environmental qualification testing required for digital I&C equipment by RG 1.209.

NuScale also suggests that 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.

The paragraph was modified to more clearly address the need for bounding estimates when there is a limited amount of data from observations. The examples are not needed and were deleted.

See Common Theme #14: *Additional Meetings*

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331. NuScale-24, C7c, p25: Modify Paragraph as follows:

c. In addition to the provisions of Section 6.1 of the industry standard: If the magnitude of an observed deviation exceeds the as-found tolerance but this deviation is determined to be neither acute nor chronic and therefore to be acceptable, the basis for that determination should be justified and documented. The justification should address 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 of the probability that the deviation of the observed magnitude might occur in a properly functioning channel, given the properties of the associated probability distributions. The justification should also include consideration of any similar events concerning substantially similar plant devices.

Reason for Change

It would be both impractical and inappropriate to require that all past deviations be addressed. At some point historical data loses relevance and data related to equipment that has been replaced or modified is not relevant.

The requested change was incorporated, along with a provision indicating that the basis for determining relevancy should also be included.

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332. NuScale-25, C7d2, p26: 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. 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.

Reason for Change

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. This section of the draft RG should be made consistent with BTP 7 12.

The third paragraph of B4.3 (p13 of the draft guidance) recognizes the difference in conservatism between As-Found and As-Left limits. The requested change is redundant to this and also presumes a particular calibration protocol that may not be applicable to all licensees.

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333. NuScale-26, Glossary>ATP: 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*.

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. (as opposed to the value at which the trip actually does occur under operating conditions) (See also the related discussion under "Setpoint Related Limits and Parameters." Compare with "actual trippoint.")

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*.

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. 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.

See Common Theme #16: *Setpoint vs Trippoint*

Ken Scarola (KS)

334. KS-a1, A>Regulations, p1b3: "…apply to instruments that monitor nuclear power variables and initiate protective actions – such as reactor trips or the actuation of mitigating safety systems… If… the automatic safety system does not function as required…"

    In addition to the automated actions of the safety system, this regulatory guide is also applicable to setpoints for alarms that prompt manual actions credited in the Transient and Accident Analysis (TAA) for which there is no automated action (ie. the alarms associated with Type A variables in RG 1.97). IEEE 603 defines the I&C associated with these manual actions as part of the safety system. SECY 93-087 requires these alarms to be Class 1E. Therefore, the setpoints for these alarms have as much safety significance as those for RT or ESF actuation. Current tech specs include periodic surveillance to confirm operability of instrumentation for Type A variables. But there is no definition of the setpoints or confirmation of the setpoints to generate the alarms for the associated credited manual actions. Therefore, the scope of current technical specifications is insufficient and the current scope of this regulatory guide is insufficient.

We agree that this RG can be used to support the development of limits relating to any setpoint, regardless of the manner of implementation, and without regard to whether the setpoint is addressed in TS or not. The specific text cited by the commenter applies to the Code of Federal Regulations, and should not be altered significantly.
See Common Theme #3: *Scope*
See also Common Theme #1: *Technical Specifications*

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335. KS-a2, p8 and p31: Defines "setpoint" as an "observed" value. It is contrary to industry practice to call the value observed during testing, the "setpoint". This will cause confusion. In addition, the word "setpoint" alone is ambiguous so it should not be a defined term and should not be used alone. You need more clarity in the definitions, as follows:

    Nominal Setpoint (NSP) — The actual setpoint value installed in a digital bistable or the value to which an analog bistable is calibrated. This value considers all channel uncertainties so that the accident trippoint always occurs prior to the analytical limit, which is established by the safety analysis, plus optional margin.

    Measured transition point (MTP) — The transition point of a trip, actuation or alarm bistable observed during periodic testing. The MTP has an as-found transition point (AsF) observed prior to any calibration adjustment, and an as-left transition point (AsL) observed after calibration adjustment. The acceptance criteria for AsF is defined by the as-found tolerance (AFT) and the allowable value (AV). The acceptance criteria for AsL is defined by the as-left tolerance (ALT).

    Accident transition point (ATP) — The transition point of a trip, actuation or alarm bistable that occurs during a design basis accident.

We agree that the term "setpoint" is used outside this regulatory guide broadly and often imprecisely — sometimes referring to an "objective" setting, sometimes to a measured or observed setting, and sometimes to the setting itself. For that reason, it is included among terms that are defined for specific usage in the draft, as described in section B4.1 (which is referenced in the definition). In recognition that the actual point at which the state transition occurs cannot be known with certainty (due to measurement error and other influences), the draft introduces the term "trippoint" as a random variable distributed about the measured or objective value. The additional detailed categorization proposed in the comment may be useful, but the terminology used in the draft in its present state is internally consistent and complete. Note that the proposed

redefinition of NSP as an "actual…value…to which an analog bistable is calibrated" is problematical because measurement error and other uncertainties make it impossible to know such a value with arbitrary precision.

336. KS-a3, B2, p9b2: Describes tech spec limits for as-found values. But there is another tech spec limit that applies to as-left values, which is referred to as the calibration tolerance (CT) or setting tolerance (ST). However, for consistency with AFT, this should be called as-left tolerance (ALT). The channel must be calibrated to within its ALT to ensure there is sufficient margin to accommodate expect drift over the calibration time interval. If the ALT cannot be achieved the channel is inoperable. This should be added.

The RG addresses the question of how As-Found and As-Left limits cited the technical specifications should be determined. It does not address the calibration procedures or the associated target values themselves. The paragraph cited in the comment is intended as a discussion of terminology. The staff positions concerning the as-found and as-left settings are addressed in C7 and C8, respectively, and the subject is also addressed more generally elsewhere in section B.

See Common Theme #12: *As-Left Limits*
See also Common Theme #1: *Technical Specifications*

337. KS-a4:

B4.1, p12b6: "Deviation in excess of the as-found tolerance could be an indication of … problems with the uncertainty analysis."

B5.1, p14b6: "An unexpectedly large deviation…might indicate that the data or the statistical/mathematical model on which the setpoint limits and parameters were selected might be inaccurate"

C2b: "the uncertainty analyses used to establish the criterion should be reevaluated"

C4c6: "those distributions and parameters should be corrected as appropriate"

Describing excess as-found tolerance as a potential problem with the uncertainty analysis is counterproductive, because it just adds confusion. The same could be said for deviations in response time testing or any other periodic testing. Similarly, if a system is showing signs of EMI susceptibility, even though it had met the EMI qualification envelope, a licensee would be required to address the problem. Other regulatory guides do not include any discussion of original analysis/qualification reassessment, why is it needed in this one. It is important for licensees to consider the AFT acceptance criteria for periodic testing and not a check of the uncertainty analysis. Corrective Action Programs will investigate potential problems with the uncertainty analysis if AFT acceptance criteria is frequently violated. This is a normal part of corrective actions programs.

See Common Theme #11: *Deviation Assessment*

338. KS-a5, B4.2: For digital technology there is no uncertainty in the NSP itself, because the NSP is a digital value with no uncertainty components. Therefore, it is more efficient for the periodic measurement technique to focus on the AV, AFT and ALT for the measurement calibration accuracy, not the AV and AFT for the MTP. Channels are typically calibrated at five channel calibration settings - 0%, 25%, 50%, 75% and 100% of span. The AV, AFT and ALT must be met at each channel calibration setting. Therefore, the AV, AFT, ALT that are normally defined base on the

MTP for an analog system, should be defined for each calibration setting (typically the same values for each of the five settings) for a digital system.

This technique allows a single one-step periodic surveillance (ie. CHANNEL CALIBRATION only, no additional CHANNEL OPERABILITY TEST to check setpoints), which includes stimulating the instrument and read-out of the measured value on a digital device within the system. This one-step calibration encompasses the measuring instrument, analog filtering and analog to digital conversion. In addition, this one-step periodic surveillance is applicable to all setpoints associated with that measurement channel, regardless of how many setpoints may apply to the same measurement channel. The digital setpoint values are confirmed through a periodic memory check, not a test of the channel's measurement accuracy.

Throughout this document your discussion of AV, AFT and ALT is with respect to the MTP. You need to explain that for digital technology these may be defined with respect to the five channel calibration settings, since this facilitates a more efficient periodic surveillance method.

This comment refers to the calibration process and to the structure of technical specifications, neither of which is within the scope of this RG. See Common Theme #2: *Calibration Criteria vs Setpoint Limits* and Common Theme #1: *Technical Specifications*. The impact of the use of digital technology is addressed in Section B4.2.

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339. KS-a6, B5.1>AFT, p15b3: "NRC staff considers the as-found tolerance … a limiting safety system setting as described in 10 CFR 50.36(c)(1)(ii)(A).": This statement appears contrary to Note 3 of Figure 1 and contrary to current industry practice, which use the AFT as a prompt for qualitative evaluation, and the AV as limit for operability. Note 3 of Figure 1 defines "acceptability of occasional deviation in excess of the as-found tolerance (±AFT), provided that the deviations are neither too large nor too frequent". Therefore, it would be more appropriate to say NRC staff considers the AFT, with consideration of qualitative evaluation, an LSSS.

The quotation in the comment is not complete. Staff considers AFT <u>in conjunction with a reference value</u> to constitute an LSSS. The draft includes discussions concerning the reference value. Considerations related to AV are also addressed in the draft RG. Operability is addressed in the TS themselves, and is outside the scope of the RG.

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340. KS-a7, B5.1>AFT, p15b6: "The interval should be constructed so as to encompass 95 percent of the deviations that are anticipated when there is no malfunction induced deviation:" Interval refers to time between calibrations. So it is confusing when discussed in the context of as-found tolerance. Delete "interval". The frequency of calibration (i.e. time) is a function of when transmitters can be accessed, which is typically at refueling intervals. The width of the AFT must account for the expected drift during this test interval.

In this context "interval" is a statistical term relating to a range of possible values. It is not related to time. The usage is established in the sentence prior to the one cited in the comment.

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341. KS-a8, B5.1>AV, p16b4: "The use of an allowable value in technical specifications is optional…:" This will cause industry confusion, because today the AV is the limiting value above which a channel must be declared inoperable. On the other hand, the AFT is a value used to require a qualitative evaluation of operability. It would be more appropriate to say that an AV and AFT are both required, but the AV can be equal to or greater than the AFT.

AV alone does not constitute a sufficient limit for an As-Found setpoint, because it ignores excessive deviation in the conservative direction. Such excessive deviation might not compromise safety directly, but it could be indicative of equipment malfunction or analytical or data-related problems. The As-Found tolerance described in the draft RG, together with the provisions for assessment of

any As-Found setpoint value that exceeds the limit associated with AFT, is adequate for meeting the requirements cited in the draft regulatory guide. Use of AV in addition the deviation assessment is conservative. NRC does not discourage voluntary use of AV.

342. KS-a9, B5.2, p16b5: "LSP the least conservative acceptable value for an as-left setpoint… staff considers the limiting setpoint to constitute a limiting safety system setting… the limiting setpoint is intended to be used as a limit on the as-left setting"

Glossary — Setting Tolerance "The regulatory limit for the as-left value is the limiting setpoint, regardless of the values associated with the as-left tolerance band"

Making the LSP the upper limit of the AsL is appropriate only under the following conditions (1) the setting accuracy is not included in the LSP and (2) there is no additional (optional) margin between the LSP and NSP (this margin is shown in Figure 1, and is typically applied). If the setting accuracy is included in LSP, then the as-left trippoint (AsL) can be less conservative than the LSP by the SRSS amount of the setting accuracy included in the TLU. If there is additional margin added to the NSP, then the AsL cannot exceed the setting accuracy, which typically results in a more conservative value than the LSP. Therefore, if there is margin between the LSP and NSP, then the LSSS is the AsL, which is more conservative value than the LSP.

You are deviating from the ANSI standard without recognizing that there is typically additional margin added between LSP and NSP. Because there is margin added between LSP and NSP, the AsL must be defined in terms of the NSP with an allowable calibration setting tolerance that is indicative of a properly functioning channel. This is typically a combination of the instrument calibration accuracy and rack calibration accuracy. If a channel cannot be calibrated to within the calibration setting tolerance of the NSP, then the channel is not functioning properly. Therefore, the LSP can be the upper limit of the AsL only for cases where there is no margin between LSP and NSP (and the setting accuracy is not included in the TLU). Where there is margin, the upper limit of the AsL should be the SRSS of the instrument calibration accuracy and the rack calibration accuracy.

The LSP is a theoretical value used only in setpoint calculations. Defining it as related to as-left calibration settings just adds confusion. To identify a properly functioning channel the setting tolerance must be defined with reference to the NSP. It is not sufficient to say the channel is operable if it can be adjusted within the LSP for cases where there is margin between the LSP and NSP. A properly functioning channel is only one that can be calibrated to within an acceptable tolerance of the NSP; this is the acceptance criteria for the AsL, not LSP.

See Common Theme #12: *As-Left Limits*

343. KS-a10, C4c1, p21: "the total loop uncertainty does not need to include the setting tolerance" and C8d "the total loop uncertainty does not need to include setting tolerance"

This deviation from the ANSI standard does not contribute to plant safety and just causes confusion. The purpose of setpoint calculations is to determine the NSP, not the LSP. The NSP is the numeric value set for a digital bistable and the target value for calibration of an analog bistable. The LSP is only a step along the way to defining the NSP. When determining NSP, setting tolerance is an important component of the TLU. By excluding setting tolerance from the calculation of TLU, there is likely to be more error in establishing NSP.

See Common Theme #12: *As-Left Limits*

344. KS-a11, Glossary>LTSP & NTSP: Definitions for "LTSP" and "NTSP": LTSP and NTSP should be deleted for three reasons (1) they duplicated LSP and NSP, respectively (having two acronyms for the same thing is confusing), and (2) "trip" is not used in any other setpoint name, above (3) these

setpoints apply to ESF actuation setpoints and alarm setpoints for credited manual actions, not just trip setpoints.

As discussed in B4.1, setpoint-related terminology across the industry is inconsistent and to some extent imprecise and confusing. The terminology used in the draft RG is drawn from that used in extensive discussions between NRC and industry leading to RIS 2006-017. Because ISA 67.04.01-2006 plays a prominent role in setpoint-related considerations, primary terminology from that document is recognized in the RG even if it is not used directly. ***"LTSP" and "NTSP" were removed*** from the parenthesis to the left of the dashes, but were retained in the statements concerning their usage in the industry standard.

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345. KS-a12, Glossary>AFT: Definition for "As-found tolerance (AFT)": Add: AFT is the acceptance criteria for the difference between AsF and AsL. The AFT limit is the SRSS of those uncertainty contributors expected to be present during the test and the expected uncertainty of the maintenance and test equipment used in the test.

The Glossary is intended only to define terms, not to explain their regulatory significance. This comment concerns the significance of AFT, which is addressed elsewhere in the guidance, as well as its definition. Although it is mathematically rigorous to reference the As-Found setpoint to the previous As-Left value, staff has determined that under certain circumstances referencing it to the nominal setpoint may be adequate (C7b). C7d provides criteria for the development of AFT. A more general discussion is presented in B5.1.

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346. KS-a13, Glossary>ST: Definition for "Setting Tolerance": Saying "The regulatory limit for the as-left value is the limiting setpoint" is inadequate to detect degrading channels. The setting tolerance for the AsL value should be the SRSS combination of sensor calibration accuracy and rack calibration accuracy. If the channel cannot be calibrated to the accuracy assumed in the calculation of the limiting setpoint, then it is inoperable.

The responses to several previous comments have already addressed the significance of the limiting setpoint, the nominal setpoint, and the setting tolerance. For example, see the responses to comments KS-a3, KS-a6, KS-a9, and KS-a10. An inability to calibrate a channel to the expected accuracy would certainly signal a potential problem with the channel or with the calibration equipment or process. The objective of this regulatory guide is to assist in the determination of such limits, not to establish operability criteria *per se*.

KS-b1: This is a duplicate of KS-a1.

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347. KS-b2, A>Regulations, p2b2: The focus on automatic systems with the exclusion of systems that prompt manual actions credited in the Transient and Accident Analysis, is not appropriate. These manual actions and the setpoints that generate the alarms to prompt those actions are as important as the setpoints that automatically actuated RT and ESF.

See Common Theme #3: *Scope*

KS-b3: This is a duplicate of KS-a1.
KS-b4: This is a duplicate of KS-a2.

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348. KS-b5, B2, p8b4: later you refer to this as the actual trippoint (ATP). This should be changed to accident transition point to avoid confusion.

"Trippoint" is used as a shorthand form of "Actual Trippoint," as indicated in the definition of "Actual Trippoint" on page 30. ***The text was modified*** to reduce the confusion related to these equivalent terms.

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349. KS-b6, B2, p8b7: I agree setpoint should be a fixed value and most people in industry view it that way. But as defined above, setpoint is the "observed" value. So it is not a fixed value, it varies over time due to drift and equipment failures. To avoid ambiguity change setpoint to NSP.

The sentence in question is intended to explain "trippoint" ***and was modified*** to avoid confusion concerning the term "setpoint."

350. KS-b7, B2, p9b2: There is typically another tech spec limit that applies to as-left values, which is referred to as the calibration tolerance (CT). The channel must be calibrated to within its CT to ensure there is sufficient margin to accommodate expect drift over the calibration time interval. If the CT cannot be achieved the channel is inoperable. This should be added.

See Common Theme #12: *As-Left Limits*

351. KS-b8, B4, p10: Change title to: Establishing Nominal Setpoints and Acceptance Criteria for Measured Transition Points

The requested change is not consistent with the intended organization of the draft guidance.

352. KS-b9, B4.1, p11b10: LSP is a limit on the NSP not on the measured value. Therefore, change "Limits on NSP and MTP".

See Common Theme #12: *As-Left Limits*

353. KS-b10, B4.1, p11b10: Change to "a limit on the NSP. The NSP may not be less conservative than the LSP. The LSP ensures that the ATP will always occur before the Analytical Limit."

See Common Theme #12: *As-Left Limits*

354. KS-b11, B4.1, p11b11: Change to "a limit on the Measured Transition Point (MTP). The AV allows margin to the Analytical Limit to accommodate unmeasurable uncertainties (ie. those not present during testing, such as seismic and radiation effects). MTP may not be less conservative than the AV, because.

See Common Theme #7: *AV*

355. KS-b12, B4.1, p12b1: This additional title is not needed because the AFT is also a limit on MTP, just as AV is a limit on MTP.

The cited text is a continuation of the discussion from the previous page. It is not a title. The text is correct as is.

356. KS-b13, B4.1, p11b10: or the NSP

The description in the present draft is correct.

KS-b14	duplicates KS-b11
KS-b15	duplicates KS-b12
KS-b16	duplicates KS-b13

357. KS-b17, B4.1, p12b2: This section should also describe ALT, because that is another limit for MTP.

Setting tolerance, which is another name for As-Left Tolerance, is addressed elsewhere in this draft.

358. KS-b18, B4.1, p12b4: The limiting setpoint ensures that the point at which a function is initiated will remain acceptable in the future despite all anticipated changes caused by all anticipated factors, including measurable factors, such as drift and unmeasurable factors such as changes in environment.

Staff believes that the existing wording is appropriate. The limiting setpoint is just one element of the indicated assurance.

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359. KS-b19, B4.1, p12b5: We are not concerned about the value at the time the setpoint is measured. We are concerned about the value during an accident. Change to:

"The allowable value assures that the measured drift does not exceed the value of measurable uncertainties included in the calculation to determine the limiting setpoint, above, and thereby assures that a channel would trip at an appropriate value at the time the associated safety function is needed."

Staff believes that the existing wording is appropriate. The value at the time of measurement is important because that is the value to which the other effects would be added.

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360. KS-b20, B4.1, p12b5: Change "measured value at which a function is initiated" to MTP.

The statement is correct as is. MTP is not used or defined in this regulatory guide

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361. KS-b21, B4.1, p12b6: AFT is a tolerance value, not a confirmation. Change to:

The as-found tolerance is the maximum amount by which a value can change since the last time it was tested and still be considered to be changing within the uncertainty tolerance assumed for the measurable uncertainties included in the calculation to determine the limiting setpoint, above.

This statement was modified in recognition of the first sentence of this comment. Except for this detail, the statement in the present draft is correct as is. Note that uncertainty cannot be measured, and "MTP" is neither used nor defined in this regulatory guide.

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362. KS-b22

This comment is included in KS-a4, see response there.

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363. KS-b23, B4.2, p13b3: You are missing the key point for digital technology. For digital technology there is no uncertainty in the NSP itself, because this is a digital value with no uncertainty components. Therefore, the periodic measurement technique must focus on the AV, AFT and ALT for the measurement calibration accuracy, not the AV and AFT for the MTP. Instruments are typically calibrated at five channel calibration settings - 0%, 25%, 50%, 75% and 100% of span. The AV, AFT and ALT must be met at each channel calibration setting. Therefore, the AV, AFT, ALT that are normally defined base on the MTP must be defined for each calibration setting.

The statement in the present draft is correct as is. The comment confuses the calibration process with the development and application of setpoint-related limits, which is the objective of this regulatory guide.

Also see Common Theme #2: *Calibration Criteria vs Setpoint Limits*

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364. KS-b24, B4.4, p14b5: To ensure with a probability of at least 95%...

This is an editorial change. The present draft is correct as is.

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365. KS-b25, B5.1, p14b6: Delete discussion of inaccuracy in the uncertainty calc. (see previous comment).

See Common Theme #11: *Deviation Assessment*

366. KS-b26, B5.1>AFT, p15b1: For digital systems the AFT is applied to the five channel calibration settings, not the setpoint. This comment applies throughout this section.

See Common Theme #2: *Calibration Criteria vs Setpoint Limits*

KS-b27: This is a duplicate of KS-a6.

367. KS-b28, B5.1>AFT, p15b5: I don't see this addressed in Section C.7b

C7b does present the appropriate information.

KS-b29: This is a duplicate of KS-a7.

368. KS-b30, B5.1>AFT, p15b6: I don't see the relationship to spurious actuations. Spurious actuations are the result of the NSP being too close to the normal operating limit.

The reference to "spurious actuations" is in error. The reference ***was corrected*** to refer to false detection of excessive deviation.

369. KS-b31, B5.1>AV, p16b2: This would be better explained as follows: When NSPs are determine through uncertainty calculations, uncertainties are typically divided into measurable uncertainties and unmeasurable uncertainties. The margin between the AL and AV accommodates the unmeasurable uncertainties.

Uncertainties cannot be measured. The draft is correct as is.

KS-b32: This is a duplicate of KS-b31.
KS-b33: This is a duplicate of KS-a9.

370. KS-b34, B5.2>LSP, p16b7: See comment above. This is only true for conditions 1 and 2, as explained above.

The reference appears to be to comment KS-a9. See Common Theme #12: *As-Left Limits*

KS-b35: This is a duplicate of KS-a9.
KS-b36: This is a duplicate of KS-a9.

371. KS-b37, B5.2>NSP, p18b2: Again, I see this just adding confusion, as explained above. Technicians need to know the NSP and the acceptable as-left setting tolerance, nothing more.

See Common Theme #2: *Calibration Criteria vs Setpoint Limits*
See also Common Theme #12: *As-Left Limits*

KS-b38: This is a duplicate of KS-a9.

372. KS-b39, C2b, p20: Remove text that challenges the TLU calculations. See previous comments.

See Common Theme #11: *Deviation Assessment*

KS-b40: This is a duplicate of KS-a10.

373. KS-b41

This comment is included in KS-a4, see response there.

374. KS-b42, C4c8, p22: I agree this reassessment makes sense, because the original AFT is no longer sufficient to detect instrument anomalies.

Comment noted.

375. KS-b43, C4c8, p22: "lack of need for adjustment" should be deleted because the need for adjustment is determined based on periodic calibration surveillance, not by analysis. Even an instrument that is specified for zero drift should be verified through periodic surveillance to exhibit zero drift.

The intent here is to address a potential need for modification of AFT. This does not refer to adjustment of the instrument. ***"Adjustment" was changed to "revision."***

376. KS-b44, C4e, p23: Add: A simply reference to the safety analysis where the analytical limit is specified is sufficient; a description of the safety analysis is not needed.

The cited statement was modified to avoid any implication that referenced documents should be summarized.

KS-b45: This is a duplicate of KS-a12.

377. KS-b46, Glossary>LSP: confusing to have two acronyms for the same thing. Delete LTSP.

See response to KS-a11.

KS-b47: This is a duplicate of KS-a11.

378. KS-b48, Glossary>NSP: confusing to have two acronyms for the same thing. Delete NTSP.

See response to KS-a11

379. KS-b49, Glossary>pAsL: Delete. This is the same as AsL. Having two names just adds confusion.

The term is used in the text of this draft, and should be retained in the Glossary. The distinction between AsL as established in the current calibration and pAsL as established in the previous calibration may be obvious, but staff believes that explicit recognition of the difference is warranted.

380. KS-b50, Glossary>Setpoint: There is no distinct unambiguous definition for "setpoint". So it should be deleted.

"Setpoint" is a key concept for this regulatory guide, and should be defined here.

381. KS-b51, Glossary>Setpoint: No, this is the AsF.

AsF is the As-Found Setpoint

382. KS-b52, Glossary>Setpoint: No, this is the AL.

AL is the analytical limit upon which the LSP is based. The value at which the trip actually occurs is the ATP.

KS-b53: This is a duplicate of KS-a13.

383. KS-b54, Glossary>ST: This seems to be the key difference between this reg. guide and the ANS standard. This is also a key difference from current tech specs, which require the AsL to be indicative of a properly operating channel.

The draft RG is consistent with RIS 2006-017 in this regard.

See Common Theme #12: *As-Left Limits*

384. KS-b55, Glossary>Trippoint: Both terms should not be used. Delete trippoint. Change Actuation Trippoint to Actual Transition Point to accommodate actuations and alarms, not just trips.

Both terms are used, and should remain. Note that "Actuation Trippoint" is neither used nor defined in this draft---perhaps "Actual Trippoint" was intended in the comment, but the definition of that term in the draft is correct.

Southern Company (SCo) (Comments submitted via NEI by C. R. Pierce)

385. SCo-L1: 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.

See Common Theme #3: *Scope*

386. SCo-L2: 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.

Staff acknowledges this comment. Modification of the industry standard is outside the scope of this effort.

387. SCo-L3: 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.

See Common Theme #5: *Terminology*

388. SCo-L4: 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.

See Common Theme #8: *95/95*

389. SCo-1: 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.

Proposed Resolution

Recommend endorsing ISA documents or sections and remove the redundant sections from DG-1141.

Basis for Comment or Resolution

Elimination of redundant guidance.

See Common Theme #4: *The Role of Industry Standards*

390. SCo-2, A>Scope, p4: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

The scope of this regulatory guide needs to be maintained instead of increased.

See Common Theme #3: *Scope*

391. SCo-3, B2>Definitions, p8: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

Since trippoints are not addressed in the plant Technical Specifications, the discussion in this regulatory guidance is not appropriate and complicates this guidance.

See Common Theme #16: *Setpoint vs Trippoint*

392. SCo-4, B2, p9b1: 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.

Proposed Resolution

Recommend clarifying if "safety limit" and "analytical limit" are now interchangeable terms or if there is a requirement to have margin between these terms.

Basis for Comment or Resolution

Clarifying how the terms "safety limit" and "analytical limit" were used will reduce confusion in the future.

See Common Theme #6: *Surrogate Safety Limits*

393. SCo-5, B2, p9b1: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

Delete information that is repeated in the two different sections of this guidance.

Section B provides general information and background for the guidance points presented in Section C. Both sections are needed. Some degree of duplication between these sections is to be expected.

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394. SCo-6, B3, p9: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

Removal of unnecessary information improves the guidance.

Editorial comment. Staff believes that the added information will be useful to persons less familiar with the referenced documents.

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395. SCo-7, B4.1, p10b3: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

A common terminology is needed to improve alignment within the industry.

See Common Theme #5: *Terminology*

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396. SCo-8, B4.1>Fig 1, p10: 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.

Proposed Resolution

Recommend mapping of proposed new terminology to the terminology used in the ANS/ISA 67.04.01-2006 standard.

Basis for Comment or Resolution

Terminology consistency

See Common Theme #5: *Terminology*

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397. SCo-9, B4.1>Fig 1 Notes, p11b4: 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).

Proposed Resolution

Recommend revising Figure 1, note 4 to align with Section C.7e and to improve clarity.

Basis for Comment or Resolution

Improve alignment of figure 1 with Section C.7e.

See Common Theme #7: *AV*

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398. SCo-10: 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.

Proposed Resolution

Recommend discussing the reliance of vendor data to validate assumed or anticipated error.

Basis for Comment or Resolution

Improve clarity of guidance associated with vendor data.

See Common Theme #8: *95/95*

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399. SCo-11, B4.1, p12b4,6: Consider removing the italicized statements under bullets 1 and 2. While the statements are true, the additional commentary only restates information in the bullets.

Proposed Resolution

Recommend deleting the italicized statements on page 12 underneath bullets 1 and 3.

Basis for Comment or Resolution

Redundant statement need to be removed.

The statements present the reasoning behind the bulleted provisions.

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400. SCo-12, B4.1>In Summary, p12: 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".

Proposed Resolution

Recommend revising these terms to "safety limits" and "limiting safety values" to maintain consistency in terminology.

Basis for Comment or Resolution

Maintain consistency of terminology.

"Limiting safety values" is not defined or used in the DG. In the first bullet, ***"limiting values" was changed to "analytical limits."***

401. SCo-13, B4.1>In Summary, p12b10: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

Document is not consistent on this terminology

The statements in the final and penultimate bullets ***was revised*** to clarify their applicability to the As-Found and As-Left settings, respectively. "Anticipated error in the actual trippoint" will also be clarified.

402. SCo-14, B4.1>In Summary, p13b1: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

The term "trippoint" cannot be measured.

The actual trippoint is conceptually important to this guidance. The primary criterion for the selection of the limiting setpoint is to provide adequate assurance that the actual trippoint will be no less conservative than the analytical limit, even though its exact value cannot be known.

See also Common Theme #16: *Setpoint vs Trippoint*

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403. SCo-15, B4.2, p13: 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.

Proposed Resolution

Recommend deleting Section 4.2

Basis for Comment or Resolution

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.

This section adds additional uncertainty elements that should be considered when digital systems are used, and recognizes that some of the uncertainties applicable to analog systems may not be applicable to digital systems. The technology employed can have a strong influence upon the selection of a setpoint. For example, some measurement techniques are inherently less accurate than others, or are subject to other influences, and therefore require larger margins or consideration of other sources of uncertainty.

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404. SCo-16, B4.2, p13: 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.

Proposed Resolution

Recommend working with ISA to include the information in Section 4.2 into their standard.

B.4 cannot be deleted—see the response to SCo-15.
See also Common Theme #4: *The Role of Industry Standards*
"Control and configuration of setpoints electronically" is not defined. This guidance addresses the establishment and use of setpoint-related limits. The manner of developing and maintaining setpoint-related bases, calculations, documentation, etc. are not within the scope of this regulatory guide.

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405. SCo-17, B4.3, p13b6: 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.

Proposed Resolution

Recommend referring to actual terminology used in Figure 1 for the "acceptable setpoint deviation."

Basis for Comment or Resolution

Terminology consistency

Deviation is defined as the change in the measured setpoint at the end of the surveillance interval – that is, in connection with the As-Found setpoint. See Common Theme #11: *Deviation Assessment*

406. SCo-18, B4.4, p14: 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.

Proposed Resolution

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.

Basis for Comment or Resolution

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.

See Common Theme #8: *95/95*

407. SCo-19, B5.1>Fig 2 Note, p18b4: 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.

Proposed Resolution

Recommend adding another figure for the non-idealized Gaussian case to show the wider trippoint distribution.

Basis for Comment or Resolution

Further explanation and visualization of the statistical terminology.

The comment suggests that the statement implies an excessive level of detail. The ideal/realistic question is not the point. The ***statement was modified*** to avoid excessive detail.

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408. SCo-20, C1, p20: 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.

Proposed Resolution

Recommend revising the definition "surrogate safety limit" further to delineate whether all or a subset of analytical limits are considered surrogate safety limits.

Basis for Comment or Resolution

Clarification of terminology

See Common Theme #6: *Surrogate Safety Limits*
See also Common Theme #3: *Scope*

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409. SCo-21, C3b6-7, p21: 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.

Proposed Resolution

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).

Basis for Comment or Resolution

Stating that a section is addressed does not provide usable guidance.

C3b is intended to function as an annotated set of cross-references, showing where in the Regulatory guide to find the information that clarifies the NRC position with respect to various sections of the ISA standard. The NRC position as stated in the RG should be what the licensee uses.

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410. SCo-22, C6e, p25: It would be helpful if the staff provided additional guidance on development of bounding values when the population size is small.

Proposed Resolution

Recommend increasing the guidance associated with the development of bounding values when the population sizes are small.

Basis for Comment or Resolution

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.

See Common Theme #8: *95/95*

411. SCo-23, 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.

Proposed Resolution

Recommend using standard definitions.

Basis for Comment or Resolution

Clarification of terminology

See Common Theme #5: *Terminology*

Westinghouse Electric Company (WEC) (comments submitted by James Gresham)

412. WEC-1, B4.1>Figure 1, p10:

As Westinghouse understands Figure 1, the definitions of Limiting Setpoint (LSP), Nominal Setpoint (NSP), As-Found Tolerance (AFT) and Setting Tolerance (ST), it is conceivable that with a zero margin NSP, i.e., NSP = LSP, that +ST and +AFT must equal zero in that the LSP is confirmed after the ST has been utilized (Note 1 of Figure 1) and the channel As-Found condition must be below the LSP if there is no Allowable Value (AV). While these may be suitable requirements for a calibration as a single instrument string of both sensor and process rack modules; they are overly conservative requirements when the sensor and the process racks are calibrated separately with their own ST parameter magnitudes, even when excluding ST from the Total Loop Uncertainty (TLU) to define the LSP. The Westinghouse Setpoint Methodology (WSM) is based on calibration of the sensor and the process racks separately, with independent ST and AFT for each. The ST and AFT for the sensor are independent of the NSP, i.e., about calibration points (or desired As-Left points) across the entire instrument channel span. The ST and AFT for the process racks are also independent of the NSP, i.e., about calibration points (or desired As-Left points) across the entire instrument channel span. The only ST and AFT applicable to an LSP would be associated with the trip bistable for analog process racks. As the initial definition of an operable device (sensor or process racks) is the ability to calibrate and plant calibration procedures do not allow a channel to be considered OPERABLE if a single calibration point across the instrument channel span (including the NSP for the bistable) is outside of the ST, the definition of the LSP does not exist in the WSM. Following the requirements of TSTF-493 for the periodic evaluation (trending) of As-Left and As-Found conditions for both the sensor and process racks across the entire instrument channel span and for the bistable at the NSP is sufficient for the determination of sensor or process racks operability. Even with a zero margin NSP, operability of the sensor and process racks within the TLU, and thus trip or actuation before the Analytical Limit at the required two-sided 95/95 level is assured. For this reason, Westinghouse disagrees with the proposed definition that the Limiting Safety System Setting (LSSS) is the LSP, page 16 of the proposed revision. Westinghouse suggests that a more appropriate LSSS definition for the WSM is the NSP. As noted in WCAP-17504, "Westinghouse Generic Setpoint Methodology," submitted February 2012 for review, the concept of the LSP is not considered applicable to the Westinghouse Setpoint Methodology and is not included in the evaluation process for protection system instrument channel operability. Westinghouse therefore suggests that taken together; confirmation of the sensor or process racks within the ST and verification of the As-Found condition within the AFT, with appropriate tracking or trending, are a sufficient definition of both equipment and instrument channel operability.

See Common Theme #2: *Calibration Criteria vs Setpoint Limits*.
See also Common Theme #12: *As-Left Limits*

413. WEC-2, B4.1>Notes, p11b1 and C8c, p27:

As noted in Comment (1) above, the concept of the LSP has little applicability to an instrument channel that is calibrated in two or more parts. Particularly if those parts are calibrated at multiple calibration points that do not coincide with the NSP. In reality the LSP is at most applicable only to the bistable of an analog instrument channel, there being no calibration error in a digital instrument channel setpoint for an addressable input to an algorithm. Thus, the requirement of C.8c constrains the calibration of the bistable to be one-sided, which when taking the other instrument channel uncertainties into account, is not necessary or consistent with a required two-

sided uncertainty. It also places an arbitrary, deterministic acceptance criterion on a statistical process, which if applied to the entire instrument channel is unnecessarily conservative, particularly when trended plant data demonstrates the random nature of equipment behavior, i.e., calibration and drift. Westinghouse calculations of the zero margin NSP and the LSP (without inclusion of the process rack ST); utilizing current process rack reference accuracy magnitudes conclude that the difference between the two parameters is at least an order of magnitude smaller than the reference accuracy. This suggests two things; 1) the requirement results in a one-sided calibration tolerance for the bistable, 2) the difference between the LSP and the zero margin NSP are statistically insignificant. Therefore, Westinghouse believes that the requirement of Section C.8c is not necessary and should be removed.

See Common Theme #2: *Calibration Criteria vs Setpoint Limits*
See also Common Theme #12: *As-Left Limits*

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414. WEC-3, B4.1>Notes, p12b6:

"- If a setpoint changes between tests by more than the amount anticipated, it might no longer be providing adequate protection. In addition, if a setpoint changes by more than the anticipated amount, the equipment might be malfunctioning or the calculations and assumptions by which the anticipated change was determined might not be accurate. It might be necessary to revise the calculations and to adjust the associated limits accordingly."

While the highlighted text is certainly a possibility, with an appropriately researched uncertainty calculation, the most likely cause for exceeding an AFT is malfunctioning equipment. Therefore the suggested action, revise calculations and limits, is somewhat extreme for a single occurrence. Westinghouse would agree to the action if the magnitude of change was experienced by multiple channels more than once, as demonstrated by data trending, thereby decreasing the likelihood of equipment malfunction as the cause and providing sufficient data to statistically determine a revised uncertainty calculation input and AFT. As a result, Westinghouse suggests that additional clarification is warranted, e.g. multiple channels, multiple times consistent with the plant data evaluation and trending process in order to meet the required 95/95 basis.

The highlighted text does not advocate that revision of the analysis would be necessary but rather simply reminds the reader that this must be warranted and should be considered. The reasons presented in this comment, applied and adjusted as necessary to suit a particular As-Found Setpoint, could support a conclusion that modification of the analysis is not necessary. On the other hand, multiple instances of such a finding across similar instrument loops could suggest the presence of flaws in the analysis. Note that the second paragraph of the AFT discussion on page 15 of the draft recognizes the importance of determining whether excessive deviations are "acute" or "chronic" --- or neither.

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415. WEC-4, B5.1>AFT, p15b3

"The as-found tolerance constitutes a limit on the value of the as- found setpoint. Because setpoint deviation in excess of the as-found tolerance could be an indication of incorrect operation, NRC staff considers the as-found tolerance (in combination with the reference value with which it is associated - see below) to constitute a limiting safety system setting as described in 10 CFR 50.36(c)(1)(ii)(A)."

Westinghouse has two concerns with this statement, 1) the basic wording of the proposed Regulatory Guide speaks of channel operability only in terms of the AFT with respect to the setpoint, which is a single point only evaluated explicitly with the COT. Unless the COT involves the entire instrument string, which is not the case for Westinghouse protection system designs, it ignores much of the instrument channel, i.e., the COT may involve only the bistable. Westinghouse

defines ST and AFT values for both the instrument channel sensor and process racks at multiple points across the instrument span, thus defining the operability criteria of that instrument channel at much more than the NSP. This separation, ST and AFT for sensor and process racks, results in the definition of operability criteria appropriate for the specific hardware under surveillance and removes the overshadowing effect of the sensor uncertainties on the process rack uncertainties. As a result, Westinghouse suggests that this systematic wording approach, i.e., limiting discussion to the setpoint, in the proposed Regulatory Guide is not consistent with the Westinghouse Setpoint Methodology that has been in use for many years and approved on the large majority of Westinghouse NSSS design plants at one point or another in each plant's operating history. 2) Since the Westinghouse Setpoint Methodology does not define the AFT, or instrument channel operability, at a single point, definition of the AFT as the LSSS is not appropriate. As noted in WCAP-17504, "Westinghouse Generic Setpoint Methodology," Westinghouse believes that, for the WSM, the appropriate definition of the LSSS should be the NSP.

See Common Theme #2: *Calibration Criteria vs Setpoint Limits*
See also Common Theme #12: *As-Left Limits*

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416. WEC-5, B5.2>LSP, p16b7:

"Because a setting less conservative than the limiting setpoint would not provide adequate assurance that the system would operate as required, the NRC staff considers the limiting setpoint to constitute a limiting safety system setting as described in 10 CFR 50.36(c)(1)(ii)(A)."

As per Comment (1), Westinghouse suggests that definition of the LSP as the LSSS is not appropriate for the WSM. As noted in WCAP-17504, "Westinghouse Generic Setpoint Methodology," Westinghouse believes that, for the WSM, the appropriate definition of the LSSS should be the NSP.

See Common Theme #12: *As-Left Limits*

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417. WEC-6, B5.2>ST, p18b2:

"In the approach described in this RG, the analytical limit is protected by the limiting setpoint, not by the setting tolerance."

The statement is certainly true for the proposed revision; unfortunately, it is not applicable to the Westinghouse Setpoint Methodology described in WCAP-17504, which protects the analytical limit with the NSP, in combination with the ST about the multiple calibration points across the instrument span for both the sensor and the process racks. Thus, failure to satisfy the ST at a single calibration point across the entire instrument span results in the conclusion that the instrument channel is NOT operable. Westinghouse suggests that the NRC recognize other, already approved, more conservative approaches that have been in use for many years.

See Common Theme #12: *As-Left Limits*

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418. WEC-7, B5.2>ST, p18b3:

"The nominal setpoint and setting tolerance are not usually of regulatory concern…"

Based on Comment (6) above, Westinghouse suggests this statement is not applicable to the WSM. It should be recognized that the NSP is utilized as the reference point for determination of Process Measurement Accuracy magnitudes and conversion of uncertainty terms, e.g., % ΔP to % flow, for some functions. Westinghouse suggests that utilization of the NSP in these manners defines the NSP as a basis for concluding the acceptability of an Analytical Limit and thus, as the LSSS. As it is more appropriate to define the LSSS as the NSP and initial instrument channel operability is defined

as within the ST about the multiple calibration points for both the sensor and the process racks, this would make the NSP and the ST regulatory concerns for the WSM.

See Common Theme #12: *As-Left Limits*
See also Common Theme #2: *Calibration Criteria vs Setpoint Limits*

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419. WEC-8, C2a, p20:

to reduce the potential misunderstanding of the extent of applicability of the Regulatory Guide, it would be preferable if the portions of the Technical Specifications would be defined more explicitly, e.g., all trip, actuation and operator action indication points of the specifications within Section 3.3 of NUREG-1430, NUREG-1431, NUREG-1432, NUREG-1433 and NUREG-1434, or their equivalents.

See Common Theme #3: *Scope*

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420. WEC-9, C4c2, p21:

Westinghouse suggests that an allowance should be made for other NRC approved instrument drift calculation approaches that are based on data evaluation, e.g. Generic Letter 91-04 and WCAP-17504.

See Common Theme #10: *Temporal Extrapolation*

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421. WEC-10, C4d, p22:

"Uncertainty analyses should account for all sources of error and uncertainty in the operation of each device, including… the effects of electrical noise…"

While it may be desired to include the effects of electrical noise, in general, the magnitude or occurrence of such effects are not predictable with any degree of accuracy. Therefore, the effects of electrical noise (EMI/RFI) should be precluded by appropriate design, e.g. filtering and shielding, and not be considered an uncertainty component.

If noise is filtered out it will not contribute to uncertainty. If it is not filtered out, then it would need to be accounted for, staff recognizes that this may be difficult.

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422. WEC-11, C6a, p24:

"Uncertainty data should be modeled using population statistics based on the 95/95 criterion as described under "Uncertainty Data and the 95/95 Criterion" in this RG. This applies to the individual uncertainty elements for each device and to all intermediate and final statistical results."

The individual uncertainty element for each device requirement can be met on a forward fit basis for new plant design and new hardware, at least from a Westinghouse perspective. It would be possible for new hardware for operating plants if appropriately tested hardware is purchased. However, it is not possible to meet this requirement on operating plants with hardware that was not designed or tested to the 95/95 criterion. (Westinghouse does recognize that with a conservative data evaluation process, this requirement can be met for the calibration (ST) and drift (AFT) terms for currently installed hardware.) It is possible to build conservatism into the evaluation process to address the expected weak links for this equipment, however, that would only satisfy the final statistical result. Westinghouse suggests that this aspect should be recognized by the NRC and reflected in the wording of this requirement.

See Common Theme #8: *95/95.*

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423. WEC-12, C7b1, p25:

> Westinghouse suggests that the requirement is arbitrary and unnecessary. It is expected that ST<AFT would be satisfied for a transmitter since transmitter drift is a phenomenon supported by considerable data that is expected to be several times the magnitude of the reference accuracy, at a 95/95 level. However, this requirement is not necessary and is not supported by data for process racks or bistables. There is considerable data to substantiate that process racks do not experience significant drift (with many instances of calibration data indicating As-Left = As-Found, or no change made to the process rack instrument string because the ST criterion is satisfied with margin), thus demonstrating that ST=AFT is a reasonable and expected criterion for many process rack designs – both analog and digital. Westinghouse recommends that this requirement be deleted or identified to specifically apply to sensors (principally transmitters) only.

The cited provision pertains to the assessment of AsF against NSP rather than against pAsL. The comment appears to misconstrue this as a general provision to be applied much more broadly than this.