



## NON-CONCURRENCE PROCESS COVER PAGE

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The U.S. Nuclear Regulatory Commission (NRC) strives to establish and maintain an environment that encourages all employees to promptly raise concerns and differing views without fear of reprisal and to promote methods for raising concerns that will enhance a strong safety culture and support the agency's mission.

Employees are expected to discuss their views and concerns with their immediate supervisors on a regular, ongoing basis. If informal discussions do not resolve concerns, employees have various mechanisms for expressing and having their concerns and differing views heard and considered by management.

Management Directive, MD 10.158, "NRC Non-Concurrence Process," describes the Non-Concurrence Process (NCP).

The NCP allows employees to document their differing views and concerns early in the decisionmaking process, have them responded to (if requested), and include them with proposed documents moving through the management approval chain to support the decisionmaking process.

NRC Form 757, "Non-Concurrence Process," is used to document the process.

Section A of the form includes the personal opinions, views, and concerns of a non-concurring NRC employee.

Section B of the form includes the personal opinions and views of the non-concurring employee's immediate supervisor.

Section C of the form includes the agency's evaluation of the concerns and the agency's final position and outcome.

NOTE: Content in Sections A and B reflects personal opinions and views and does not represent the official agency's position of the issues, nor official rationale for the agency decision. Section C includes the agency's official position on the facts, issues, and rationale for the final decision.

1. If the process was discontinued, please indicate the reason (and skip to #3):

- Non-concurring employee(s) requested that the process be discontinued
- Subject document was withdrawn

2. At the completion of the process, the non-concurring employee(s):

- Concurred
- Continued to non-concur
- Agreed with some of the changes to the subject document, but continued to non-concur

3. For record keeping purposes:

- This record is non-public and for official use only
- This record has been reviewed and approved for public dissemination

**NON-CONCURRENCE PROCESS (Continued)**

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**Section A - To Be Completed By Non-Concurring Employee**

2. Title of Subject Document Draft Regulatory Guide DG-1363, Proposed Revision 4 to Regulatory Guide 1.105, "Setpoints for Safety-Related Service"	3. ADAMS Accession Number ML20009d873
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4. Document Signer Louise Lund	5. Document Signer's Phone Number (Enter 10 numeric digits) (301) 415-0377
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6. Title of Document Signer Director, Division of Engineering	7. Office (Choose from the drop down list or fill in) RES
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8. Name of Non-Concurring Employee(s) Paul Rebstock	9. Employee's Telephone Number (Enter 10 numeric digits) (301) 415-2126
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10. Title of Non-Concurring Employee Senior I&C Engineer	11. Office (Choose from the drop down list or fill in) RES
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12.  Document Author  Document Contributor  Document Reviewer  On Concurrence

13. Name of Non-Concurring Employee's Supervisor Ronaldo Jenkins	14. Office (Choose from the drop down list or fill in) RES
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15. Title of Non-Concurring Employee's Supervisor Branch Chief, RES/DE/ICEEB	16. Supervisor's Telephone Number (Enter 10 numeric digits) (301) 415-6978
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17.  I would like my non-concurrence considered and would like a written evaluation in Section B and C.  
 I would like my non-concurrence considered, but a written evaluation in Sections B and C is not necessary.

18. When the process is complete, I would like management to determine whether public release of the NCP Form (with or without redactions) is appropriate (Select "No" if you would like the NCP Form to be non-public):  
 Yes  No

19. Reasons for the Non-Concurrence, Potential Impact on Mission, and the Proposed Alternatives

First, I would like to acknowledge the significant improvement in the 2018 version of the industry standard associated with this regulatory guide, as compared with previous versions, and the significant improvement in the NRC's regulatory guidance that would result from endorsing that revised standard. My concerns relate to specific details that I believe ought to be addressed despite the significant improvements in the standard. I believe that the treatment of these details in the present draft could lead to an undesirable reduction in safety. I heartily agree that revision of the existing regulatory guidance, published in 1999, is long overdue.

In summary, this nonconcurrency is based upon two specific concerns: 1) explicit acceptance of a 5% probability of nonconservative operation, and 2) the manner of temporal extrapolation of time-related uncertainties.

**Background**

DG-1363 is the successor to DG-1141, the previously-published draft for revision 4 of regulatory guide 1.105. Both of the concerns addressed in this nonconcurrency were adequately addressed in the version of DG-1141 that achieved concurrence and was released for public comment in 2014. Many comments were received, responses to all of the comments were developed, and DG-1141 was revised in accordance with the responses and redesignated as revision 4 of regulatory guide 1.105. On March 9, 2016 the revised regulatory guide was released for concurrence for final publication. The two provisions discussed here were addressed adequately in the concurrence version. Late in the

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concurrence process, after concurrence was essentially complete, all efforts concerning RG1.105r4 were suspended. The effort was reinitiated recently, and a new draft, DG-1363, was developed. DG-1363 cites the 2018 version of the associated industry standard, ISA 67.04.01. The 2018 version of the standard incorporates many, but not all, of the provisions of DG-1141. DG-1363 presents a “clean endorsement” of ISA 67.04.01-2018, with no exceptions or clarifications. Neither document adequately addresses either of the concerns central to this nonconcurrence.

While the current standard is a significant improvement over the previous versions, and while endorsement of it would be a dramatic improvement over the current version of the regulatory guide (which was issued in 1999 and addresses the 1994 version of the standard), the inadequate treatment of the two points cited above constitute sufficiently serious deficiencies to warrant this nonconcurrence. In my opinion, these points should be addressed in the revised regulatory guide, as they were addressed in the issued version of DG-1141 and as they were accepted in the 2016 concurrence draft of the regulatory guide. I cannot in good conscience assent to their omission.

### ***Risk-Informed Decisionmaking***

Some may claim that the provisions for which I advocate are overly prescriptive and lack adequate provision for risk-informed decisionmaking. Consideration of risk is clearly important, but the requisite assessment of risk can be credible only if the underlying facts are adequately understood. If we are to eschew a checkbox mentality, then we must adopt a mentality of deeper analytical thinking and apply it to each individual case. The trade-off does not necessarily result in simplification or reduced burden.

This regulatory guide should establish flags indicating where deeper analysis may be warranted. Those flags themselves should be rigorous, and should indicate where risk considerations might be appropriate in consideration of individual circumstances. It is in the assessment of the significance of passing by one of those flags that risk considerations should be applied, sometimes, perhaps, determining that the “violation” of a flag is, in fact, acceptable -- but that is a matter for the assessment of the safety significance of a particular limit in a particular circumstance, not for the *a priori* establishment of limits in general. Therefore, this RG should provide guidance for the rigorous development of setpoint-related limits, and leave consideration of risk to particular implementations of the guidance that it provides. Arguments to the effect that there is plenty of margin in the mechanical component capabilities, and therefore one need not worry too much about some aspect of setpoint limits, seem inappropriate at the level of the regulatory guide, where the mechanical system is not even identified let alone analyzed.

### ***Nonconcurrence Details***

#### **1. Acceptance of a 5% Probability of Nonconservative Operation**

The standard explicitly accepts a 5% probability that the analytical limit for a channel will be exceeded (final sentence in Section 4.3, on page 15). DG-1141 showed that the 95/95 criterion, together with an assumption that trippoint errors are normally distributed, results in a 2½% probability that the analytical limit will be exceeded (DG-1141 Figure 2, and associated text -- DG-1141 Figure 2 is attached to this form for reference).

A word about terminology: This write-up, as does DG-1141, makes a distinction between setpoint (the value at which a channel is *believed or measured* to trip) and trippoint (the value at which the trip *actually occurs*). Setpoints are specific known values. Trippoints include uncertainties such as measurement error, and therefore their precise values cannot be known. Trippoints can only be described statistically: for any given setpoint, there is a statistical distribution of possible trippoints. The objective of a setpoint analysis is to determine a limiting value for a setpoint such that the probability that the trippoint is nonconservative is small enough to be considered acceptable.

DG-1141 Figure 2 shows a Gaussian distribution of Actual Trippoints (ATP), such as might typically be expected for a single trip channel, along with the associated Limiting Setpoint (LSP), Analytical Limit (AL), allowances for random and bias uncertainties, and associated probabilities. Revision 2 of RG 1.105, issued in February of 1986, introduced criteria similar to the 95/95 criterion upon which Figure 2 is based. In particular, the Rev2 criterion specifically references the “±2 sigma” band (more accurately, ±1.96 sigma) typically associated with 95/95 and symmetrically

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disposed about the mean. Revision 3 further refines these criteria with specific reference to 95/95. Figure 2 therefore presents considerations tacitly recommended by the NRC for decades. Thus, the acceptable limit on the probability for a nonconservative trippoint has been tacitly established by the NRC in past revisions to RG1.105 to be 2½%.

The increase in the probability of nonconservative operation in a single channel from 2½% to 5% has been shown to result in a more than seven-fold increase in the likelihood that a safety function that employs 2/4 voting will fail to be initiated in accordance with the corresponding safety analysis, resulting in operation in an unanalyzed condition. This analysis is presented in the document identified as "95/95 and Single-Sided Setpoints," ML19239A261. The analysis is marked "DRAFT" only because it has not been formally reviewed and accepted. It is complete, and informal reviews have not resulted in any statement of concern.

A seven-fold increase in the likelihood of operation in an unanalyzed condition seems to me to be too significant for tacit acceptance without recognition or comment. In truth, the analysis also shows that, when the probability of failure of the mechanical or electrical equipment needed for the associated safety function is taken into consideration, the relative impact of 5% vs 2½% is reduced -- but it hardly seems wise to blanketly use one type of failure to excuse another.

The overt acceptance of a 5% probability of nonconservative operation also introduces an additional problem: The question of "Single-Sided Setpoints" (SSS -- this 5% vs 2½% question) has been debated for a long time, with strong opinions both in favor of their acceptance and opposing them. It was a major point of contention in the development of DG-1141. The designation itself is a misnomer, sometimes confused with one-sided vs two-sided statistical considerations such as discussed in section 9.6 of NUREG-1475, the NRC's Statistical text developed by Dan Lurie *et al.* I believe the term derives from the concept of lumping the entire 5% of ATP that fall outside the 95/95 boundaries to the nonconservative side of the mean, as opposed to the symmetrical distribution shown in the attached figure.

It should be recognized that, in all the years of debate on this matter, no explicit regulatory requirement concerning the probability of nonconservative operation has been discovered or postulated. The debate concerns what constitutes "adequate protection" and the meaning of past regulatory guidance and positions, not any explicit regulatory requirement.

DG-1141 acknowledges the connection between 95/95 and 2½%, but avoids making any explicit statement as to what the acceptable probability limit should be. This was deliberate, in recognition of the controversy over the matter and in recognition of the NRC's seemingly inconsistent history concerning this matter (SSS have sometimes been accepted, and have sometimes been rejected). This approach was found acceptable by persons on both sides of the SSS question.

Acceptance of the 5% probability explicitly endorsed in the standard would summarily accept SSS, terminate this discussion, and possibly call past NRC rejections of SSS into question.

**2. Extrapolation of Time-Related Uncertainties**

The measured setpoint for a particular instrument channel can be expected to change with time. The calibration of the sensor and other devices in the channel can change, and the value at which the channel comparator or bistable device trips can change. Changes in the measured setpoint can be related to external factors, such as the physical environment or uncertainty in the measurement and test equipment, as well as to internal considerations not attributable to any known influence. "Deviation" is the overall change in the measured setpoint due to all factors, whereas "drift" is the change that is not due to any external influence. It is not uncommon for "drift" to be cited when the actual phenomenon in question is deviation. A change observed by measurement at the beginning and end of a calibration interval constitutes deviation. Drift can be measured only under laboratory conditions and is generally specified by the instrument manufacturer and related to some specific time period that is independent of the surveillance interval.

An uncertainty analysis that takes drift into consideration would need to adjust the drift allowance to accommodate the difference between the time period over which the drift value is specified and the time period over

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which operation is expected.

A simple thought experiment shows that the amount of drift anticipated over a specified time interval can seem to be reduced by dividing the interval into subintervals and then taking the SRSS (rather than the sum) of the subinterval drifts. Since the time interval used in the drift specification is typically smaller than, and unrelated to, the limiting interval, applying SRSS as an extrapolation technique will cause the extrapolated value to be affected by this arbitrary reduction. For example, if the drift specification interval happened to be a quarter of the surveillance interval, the drift value extrapolated via SRSS would be less than what would be extrapolated if the specification interval were half of the surveillance interval, even if the drift rate were the same in both cases. Nevertheless, there has been advocacy -- inappropriate, in my opinion -- for the use of SRSS in such cases.

Although I believe that linear extrapolation should be the default approach, it is possible that some other approach may be shown to be valid in particular circumstances. The approach in DG-1141 was modified in response to public comments to allow for a scientifically-based alternative to linear extrapolation. That revised approach should be retained. The standard and DG-1363 ignore this issue altogether.

Section 4.6 of the standard addresses a measurement-based statistical approach to the estimation of setpoint deviation (referred to in the standard as "drift"). The standard uses the results of an "As-Found As-Left" Analysis (AFAL) to develop an allowance for deviation, rather than relying on manufacturer drift specifications. The standard does recognize that this is not purely a drift measurement, since it includes the effects of measurement equipment, local environments, etc. AFAL is defined by reference to a companion document, ISA 67.04.02, which has not been endorsed by the NRC. Therefore, the criteria under which AFAL is determined have not been formally reviewed or accepted by the NRC, and acceptance of AFAL would constitute acceptance of an unreviewed practice. 67.04.02 is a recommended practice, not a standard, and its development and approval do not rise to the level of a consensus standard. NRC determined many years ago that it would not be appropriate for us to endorse ISA 67.04.02 or any other "recommended practice."

***References***

Package containing all cited ADAMS documents: **ML20006f031**

DG-1141 (June, 2014) --- ML081630179

DG-1363 (February, 2020) --- ML20009d873

Response Document (RD) (from 9Mar2016 concurrence pkg) --- ML15335a085  
(ML19317D837 includes notes)


Draft Regulatory Guide 1.105r4 (from 9Mar2016 concurrence pkg) --- ML15135a255  
(ML19317d838 includes tracking to RD commitments)

Industry Standard ISA67.04.01-2018

95/95 and SSS --- ML19239a261

**20. Signature and Date of Non-Concurring Employee**

**Paul J. Rebstock**

 Digitally signed by Paul J. Rebstock  
Date: 2020.03.05 14:36:38 -05'00'

**NON-CONCURRENCE PROCESS (Continued)**

Date  
01/30/2020

**Section B - To Be Completed By Non-Concurring Employee's Supervisor**

2. Title of Subject Document

Draft Regulatory Guide DG-1363, Proposed Revision 4 to Regulatory Guide 1.105, "Setpoints for Safety-Related Service

3. ADAMS Accession Number

ML20009d873

4. Name of Non-Concurring Employee's Supervisor

Ronaldo Jenkins

5. Office (Choose from the drop down list or fill in)

RES

6. Title of Non-Concurring Employee's Supervisor

Branch Chief, RES/DE/ICEEB

7. Supervisor's Telephone Number (Enter 10 numeric digits)

(301) 415-6978

8. Comments for the NCP Reviewer to Consider

I have no comments on Section A.

9. Signature and Date of Non-Concurring Employee's Supervisor

Ronaldo Jenkins

Digitally signed by Ronaldo Jenkins  
Date: 2020.04.14 19:21:12 -04'00'

**NON-CONCURRENCE PROCESS (Continued)**

Date  
01/30/2020

**Section C - To Be Completed By NCP Coordinator**

<b>2. Title of Subject Document</b> Draft Regulatory Guide DG-1363, Proposed Revision 4 to Regulatory Guide 1.105, "Setpoints for Safety-Related Service"		<b>3. ADAMS Accession Number</b> ML20009d873
<b>4. Name of NCP Coordinator</b> Louise Lund	<b>5. Office</b> (Choose from the drop down list or fill in) RES	
<b>6. Title of NCP Coordinator</b> Division Director, RES/DE	<b>7. Coordinator's Telephone Number</b> (Enter 10 numeric digits) (301) 415-0377	

**8. Agreed Upon Summary of Issues**  
Issue 1. Acceptance of a 5% Probability of Nonconservative Operation

Where DG-1141 proposed a recommended placement of the tolerance interval such that 2.5% of the sample standard probability distribution may be allowed to exceed the analytical limit (i.e., 97.5% of the distribution to be maintained on the conservative side of the analytical limit), the Standards Committee for the development of ISA 67.04.01-2018 chose to standardize on 5% of the probability distribution exceeding the analytical limit for that standard, which the DG-1363 endorses. Mr. Rebstock believes that the use of 2.5% should be explicitly identified in DG-1363, as it was in DG - 1141.

Issue 2. Extrapolation of Time-Related Uncertainties

Regarding the estimation of drift uncertainty to be accounted for between successive surveillances, there is no generally accepted method for repeatedly and accurately predicting in advance the magnitude of drift that occurs between successive surveillances, especially when the surveillance interval significantly exceeds the manufacturer's drift performance specification interval. Mr. Rebstock believes that DG-1363 should include explicit guidance on this topic.

**9. Evaluation of Non-Concurrence and Rationale for Decision**  
I have had the benefit of hearing directly from Mr. Rebstock regarding his concerns, and also have had follow-on conversations with individuals closely involved with this issue that Mr. Rebstock asked me to contact (David Rahn and Dinesh Taneja). The issue central to this nonconcurrence has been under discussion for a long while, namely, how to treat (allocate) total instrument channel uncertainty within the space (difference) between the analytical limit and the setpoint. Mr. Rebstock's nonconcurrence is for the regulatory guide that endorses an industry consensus standard, ISA 67.04.01-2018. David Rahn is the voting member for the NRC on the ISA 67.04 Standards Committee (Committee) for this standard. Even though Mr. Rebstock is not the voting member on the ISA Committee, he has been in close coordination with the voting member over the years of the standard development and has made his views known to the voting member and to the Committee during the development of the standard. Mr. Rebstock has also expended remarkable efforts to support this aspect of the NRC nuclear safety mission, by authoring, distributing for public comments, and evaluating public comments for a previously proposed draft Revision 4 to Regulatory Guide 1.105, known as Draft Guide (DG)-1141.

Mr. Rebstock has acknowledged to me that the update to the standard that the NRC is endorsing through this revision to the regulatory guide is a major improvement to the previous version of the standard and represents a substantial position change on the Committee's part to be more responsive to the NRC's concerns in this area. Previous versions of the ISA Standard did not establish any acceptance criterion regarding the application of appropriate statistical methods for estimating the width of a tolerance interval that encompasses all the uncertainties associated with a safety system instrument channel. With the NRC staff's urging, the Committee adopted the NRC staff's tolerance interval estimation methodology identified in DG-1141, to statistically quantify the endpoints

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(boundaries) of a total instrument channel uncertainty tolerance interval at the 95/95 level. That is, the endpoints of the resulting instrument channel uncertainty tolerance interval should bound 95% of the channel uncertainty population data at a 95% confidence level. This criterion was deemed by the Committee to be one of the most critical factors influencing the determination of “adequacy” of the safety margin for the ISA standard used for establishing limiting trip setpoints. The Committee noted that adhering to this criterion provides a high degree of fidelity in accounting for random uncertainty in instrument channel performance, so that limiting setpoints may be established with sufficiently conservative margins to the analytical limit.

**Issue 1. Acceptance of a 5% Probability of Nonconservative Operation**

Where DG-1141 proposed a recommended placement of the tolerance interval such that 2.5% of the sample standard probability distribution may be allowed to exceed the analytical limit (i.e., 97.5% of the distribution to be maintained on the conservative side of the analytical limit), the Committee chose to standardize on 5% of the probability distribution exceeding the analytical limit. (The 2018 ISA standard includes the statement: “The chosen setpoint should be a value that represents the performance of the instrumentation, with a 95% probability of channel trip at or before the analytical limit is reached at a 95% confidence level.”) The consensus of the Committee members was that this placement was adequate to enable users of the standard to achieve significant conservatism in establishing sufficient margin to safety to allow for channel inaccuracies and channel drift occurring between successive surveillance intervals. The Committee considered that it is extremely unlikely for all the individual performance uncertainty terms included within the total channel uncertainty estimate to be simultaneously present within the tails of the population distribution, even under accident conditions. The Committee also noted that previous versions of RG 1.105 provided guidance for making bounding estimates of the uncertainty at a 95/95 probability/confidence level, but until the issuance of DG-1141, the RG had never specified what portion of the total instrument channel uncertainty probability distribution needed to be maintained on the non-conservative side of the analytical limit.

The Committee also observed that many existing licensee setpoint methodologies have implemented the 95% placement of the tolerance interval, and that operating experience gained since the late 1990s, indicates this methodology appears to be both safe and practical. Standardizing on a requirement for ensuring 97.5% of the population probability distribution data to be maintained on the conservative side of the analytical limit was deemed by the Committee to be overly conservative and not consistently achievable for a large segment of the nuclear industry. The Committee preferred the 95% approach as a pragmatic one, because some plants have a more limited margin available (requiring a more rigid approach that Mr. Rebstock had a significant amount of experience with), and some have a larger margins between the analytical limit and setpoint. This difference is what led to the difficulty in agreeing on this issue in the standard itself for many years before the development of the 2018 version.

The cognizant NRC staff other than Mr. Rebstock recognize that his recommended 97.5% does result in a more conservative placement of the limiting setpoint than does 95%, but they also recognize that licensees need to be practical in applying this larger allocation to minimize the likelihood of spurious actuations of safety channels when the normal process variation excursions encroach upon the channel setpoint when no actual adverse condition has occurred. In practice, staff reviewers of proposed new Technical Specification-related instrument channel setpoints and allowable values use risk insights based on an examination of existing margin between analytical limits and nominal setpoints before performing an evaluation of the proposed instrument channel uncertainty margin in detail. This use of risk insights helps to inform staff reviewers as to the effectiveness of the degree of conservatism that has been applied by applicants and licensees.

**Issue 2. Extrapolation of Time-Related Uncertainties**

Regarding the estimation of drift uncertainty to be accounted for between successive surveillances, there is no



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generally accepted method for repeatedly and accurately predicting in advance the magnitude of drift that occurs between successive surveillances, especially when the surveillance interval significantly exceeds the manufacturer's drift performance specification interval. The estimate of instrument drift between successive surveillances is important because it strongly influences the determination of allowable "As-Found" tolerance limits used as calibration inspection acceptance criteria during calibration surveillances.

Linear extrapolation of manufacturer specifications appears to produce estimates that are excessive when compared with actual instrument channel performance history, and which can result in As-Found tolerance limits that could mask a poorly performing (or broken) instrument. Although square root sum of squares methodology (SRSS) of sub-interval drift specifications appears to produce results that are more representative of actual channel performance, the use of SRSS methods for this purpose does not appear to have a strong scientific basis. In the revised ISA standard, the Committee chose to provide only general guidance for estimating drift but elected to instead provide a performance-based acceptance criterion for establishing appropriate channel performance test acceptance criteria that includes accounting for the effects of drift. A footnote in the Standard identifies that conservative estimates should be established that do not mask adverse performance. The standard also directs users to consult the ISA Recommended Practice document for additional guidance.

The Committee believes that this type of issue, methodology for estimation of drift uncertainties, should be treated as a recommended practice, not in the standard itself or the regulatory guide. I understand from Mr. Rahn that the Committee is considering Mr. Rebstock's views from DG-1141 in the development of a revised section within the recommended practice regarding drift estimation. For the NRC staff, an approach that was suggested is to include the information on how to treat uncertainties in the agency's Nuclepedia and/or a Knowledge Management NUREG.


**Conclusions**

Currently, and looking ahead, the use of newer systems will reduce the concerns with drift. The newer systems are of better quality, more precise, accurate, and stable, leading to less drift. Also, the likelihood of tripping at the tail of the distribution is very small. In using these newer systems, the industry is moving to more continuous monitoring, which incorporate self-calibration and self-diagnostics, which are capable of determining drift in real time.

In light of the substantial benefits that the revised regulatory guide will provide, as recognized by Mr. Rebstock, and that the concerns raised by Mr. Rebstock will be vetted in an appropriate venue as defined by the standards committee, as discussed above, and the improvements in this area represented by the newer systems, I am approving the current version of the document without changes. Mr. Rebstock is commended for his respectful and thoughtful approach towards bringing these key issues before the managers on concurrence.


**10. Signature and Date of NCP Coordinator**

Anita Lund

 Digitally signed by Anita Lund  
Date: 2020.05.05 16:23:30 -04'00'

**11. Signature and Date of NCP Approver**

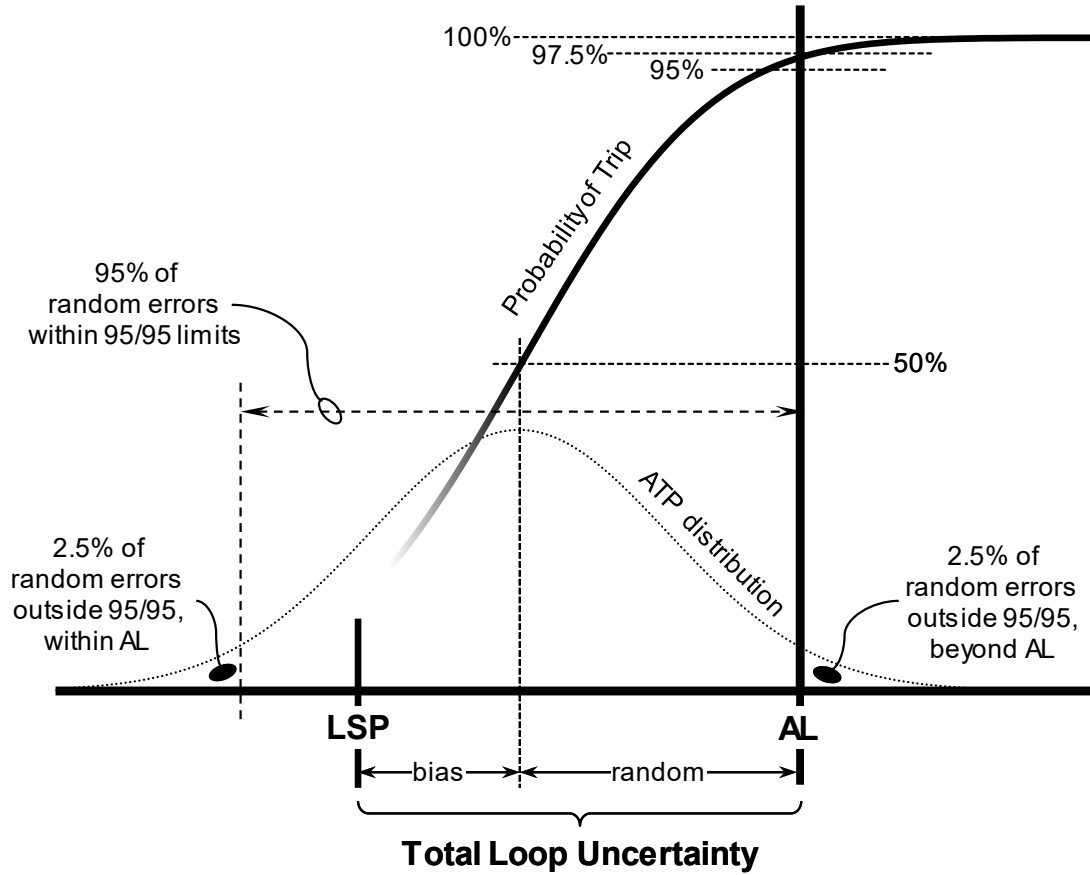
Anita Lund

 Digitally signed by Anita Lund  
Date: 2020.06.26 08:12:41 -04'00'

**Concerning:**

Draft Regulatory Guide DG-1363,

Proposed Revision 4 to Regulatory Guide 1.105, "Setpoints for Safety-Related Service"



**DG-1141 Figure 2: *Trippoint Probability Distribution***