October 30, 2009

Mr. Jerald G. Head
Senior Vice President, Regulatory Affairs
GE Hitachi Nuclear Energy
3901 Castle Hayne Road MC A-18
Wilmington, NC 28401

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION LETTER NO. 387 RELATED TO ESBWR DESIGN CERTIFICATION APPLICATION

Dear Mr. Head:

By letter dated August 24, 2005, GE-Hitachi Nuclear Energy (GEH) submitted an application for final design approval and standard design certification of the economic simplified boiling water reactor (ESBWR) standard plant design pursuant to 10 CFR Part 52. The U.S. Nuclear Regulatory Commission (NRC) staff is performing a detailed review of this application to enable the staff to reach a conclusion on the safety of the proposed design.

The NRC staff has identified that additional information is needed to continue portions of the review. The staff's request for additional information (RAI) is contained in the enclosure to this letter.

If you have any questions or comments concerning this matter, you may contact me at 301-415-6256 or Dennis.Galvin@nrc.gov or you may contact Amy Cubbage at 301-415-2875 or Amy.Cubbage@nrc.gov.

Sincerely,

***/RA/***

Dennis Galvin, Project Manager
ESBWR/ABWR Projects Branch 1
Division of New Reactor Licensing
Office of New Reactors

Docket No. 52-010

Enclosure:
Request for Additional Information

cc: See next page

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Distribution: See next page

ACCESSION NO.: ML093020611 NRO-002

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| **NAME** | DGalvin | ACubbage-JCruz for: |
| **DATE** | 10/30/2009 | 10/30/2009 |

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SUBJECT: REQUEST FOR ADDITIONAL INFORMATION LETTER NO. 387 RELATED TO ESBWR DESIGN CERTIFICATION APPLICATION DATED OCTOBER 30, 2009

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**Requests for Additional Information (RAIs):**
**ESBWR Design Control Document Revision 6**

| RAI Number | Reviewer | Question Summary | Full Text |
|---|---|---|---|
| 7.1-141 | Rhow S | ESBWR Setpoint Methodology (NEDE-33304P) | Based on the review of NEDE-33304P and GEH's responses to RAIs 7.1-86 and 102, NRC staff finds that GEH has not demonstrated that the ESBWR setpoint methodology, as described in NEDE-33304P, conforms to the 95/95 tolerance limit as an acceptable criterion for uncertainties specified in NRC Regulatory Guide (RG) 1.105, Revision 3. Specifically, the use of single-sided distribution and the subsequent use of the 1.645/2 factor to calculate the setpoints are not justified to demonstrate conformance to the 95/95 criterion in RG 1.105, Revision 3. This staff finding was confirmed by the Department of Energy's Oak Ridge National Laboratory (ORNL) which was contracted by the staff for a detailed evaluation. Therefore, the NRC staff requests that GEH revise NEDE-33304P to remove the reduction factor of 1.645/2 and to make corresponding changes to the supporting information. This is considered to be the staff's preferred resolution option. The evaluation prepared by ORNL is included as an enclosure.<br><br>Alternatively, GEH may provide an alternative to the RG 1.105, Revision 3 acceptance criterion and explain in sufficient detail and bases to demonstrate compliance with the relevant regulatory requirements.<br><br>This RAI supercedes and closes RAIs 7.1-86 and 7.1-102. |

# TER for GE-Hitachi's Setpoint Methodology NEDE–33304P

**M. D. Muhlheim and R. L. Schmoyer**
**Oak Ridge National Laboratory**

## 1.0 INTRODUCTION

On November 2, 2007, General Electric–Hitachi Nuclear Energy (GEH) submitted Topical Report (TR) NEDE-33304P, Rev. 0, to the Nuclear Regulatory Commission (NRC) for review (1). TR NEDE-33304P establishes the requirements and methodologies for determining and maintaining all safety-related and other important instrument setpoints for the GEH Advanced Boiling Water Reactor (ABWR) and the Economic Simplified Boiling Water Reactor (ESBWR). In response to requests for additional information (RAIs), GEH submitted a revision to NEDE-33304P for review (2). In addition to the review of TR NEDE-33304P, Rev. 1, the responses to RAI Number 7.2-36, Supplement 1 (3); RAI Number 7.1-102 (4); RAI Number 7.1-86, Supplement 1 (5); Technical Paper, "Response to NRC RAI on Use of Single-Sided Factor for Setpoint Margin" (6); and "GE New Plant Instrument Setpoint Methodology—Current Methodology" (7) were also included in the review. Because GEH's proposed setpoint methodology in TR NEDE-33304P relies on TR NEDC-31336-A (8) and its associated safety evaluation report (SER) (9), these documents were also part of the review.

GEH's proposed setpoint methodology is to use a one-sided normal distribution for those setpoint values approached from one direction. Regulatory position (1) in Regulatory Guideline (RG) 1.105, Rev. 3, (10) states that

> Section 4 of ISA-S67.04-1994 specifies the methods, but not the criterion, for combining uncertainties in determining a trip setpoint and its allowable values. The 95/95 tolerance limit is an acceptable criterion for uncertainties. That is, there is a 95 percent probability that the constructed limits contain 95 percent of the population of interest for the surveillance interval selected.

The 95/95 tolerance limit referred to in RG 1.105, Rev. 3 does not specify whether the 95/95 tolerance limit is a one-sided tolerance limit, or one end (either the upper or lower limit) of a two-sided tolerance interval. The requirement simply states that "there is a 95 percent probability that the constructed limits contain 95 percent of the population of interest for the surveillance interval selected." If the 95/95 tolerance limit refers to a two-sided test (computed under the assumption that the underlying data is normally distributed and thus symmetrical), this would imply that the one-sided tolerance limit for normally distributed data is 97.5/97.5.

## 2.0 REGULATIONS

To meet the requirements of general design criteria (GDC) 10, 13, 15, and 26, RG 1.105, Rev. 3 provides guidance for ensuring that instrument setpoints are initially within and remain within the technical specification limits.

The staff evaluated the GEH setpoint methodology based on the guidance provided in RG 1.105, Rev. 3 and Branch Technical Position (BTP) 7-12 (11) in the Standard Review Plan (SRP).

RG 1.105, Rev. 3 describes a method acceptable to the NRC staff for complying with the NRC's regulations for ensuring that setpoints for safety-related instrumentation are initially within and remain within the technical specifications. RG 1.105, Rev. 3 endorses ISA-S67.04-1994, Part 1 (12), with exceptions and clarifications. Setpoints associated with the analytical limits determined from the accident analyses are considered part of the plant's safety-related design since they are critical to ensuring the integrity of the multiple barriers to the release of fission products. Although RG 1.105, Rev. 3 endorses ISA-S67.04-1994, this review is based on ANSI/ISA-67.04.01-2006 (13) because the 1994 version is not active. However, the relevant sections of each standard—the setpoint relationships and combination of uncertainties—are the same.

SRP BTP 7-12 provides guidance on establishing and maintaining instrument setpoints.

## 3.0 TECHNICAL EVALUATION

Any methodology used to determine setpoints should ensure that an adequate allowance exists between setpoints and safety limits, such that the system initiates protective actions before safety limits are exceeded. More importantly, the methodology should demonstrate how the criterion that the staff's safety decision is based on is met and maintained throughout the calculation process.

The staff, through the RAI process requested that GEH demonstrate how it meets the guidance in RG 1.105, Rev. 3 as their methodology states. The NRC staff is concerned about

1. the validity of using the same two-sided normal data set test values typically provided by vendors to support a one-sided normal distribution setpoint determination, and

2. the justification statistically and mathematically for the multiplication factor of 1.645/2.

The methodology does not clearly quantify how its reliance on items 1 and 2 is valid nor how it meets RG 1.105, Rev. 3, criterion statistically and mathematically.

### 3.1 Data Coverage and Uncertainty Bounds

In its review of a limiting safety system setting (LSSS) trip setpoint, the NRC staff requires that all data used to establish a setpoint conforms to a normal distribution and applies 95/95 tolerance limits as an acceptable criterion such that there is a 95 percent probability that the constructed limits contain 95% of the population of interest for the surveillance interval selected. The 95/95 tolerance limit does not specify whether the 95/95 tolerance limit is a one-sided tolerance limit, as shown in Fig. 1, or one end (either the upper or lower limit) of a two-sided tolerance interval, as shown in Fig. 2. Thus, Fig. 1 shows a 5 percent upper tail where 95 percent of the data is between $-\infty$ and $1.645\sigma$. (A standard normal distribution showing the lower tail would be between $-1.645\sigma$ and $+\infty$.) Fig. 2 shows the standard normal distribution with the upper and lower 2.5 percent tails where 95 percent of the data is centered about the mean (i.e., $z = 0$) (footnote [1]). If the 95/95 tolerance limit refers to a two-sided test (computed under the assumption that the underlying data is normally distributed and thus symmetrical), Fig. 2 shows that this would imply that the one-sided tolerance limit for normally distributed data is 97.5/97.5.

[1] z is the standard normal deviate with, by definition, a mean of zero and a standard deviation of 1.

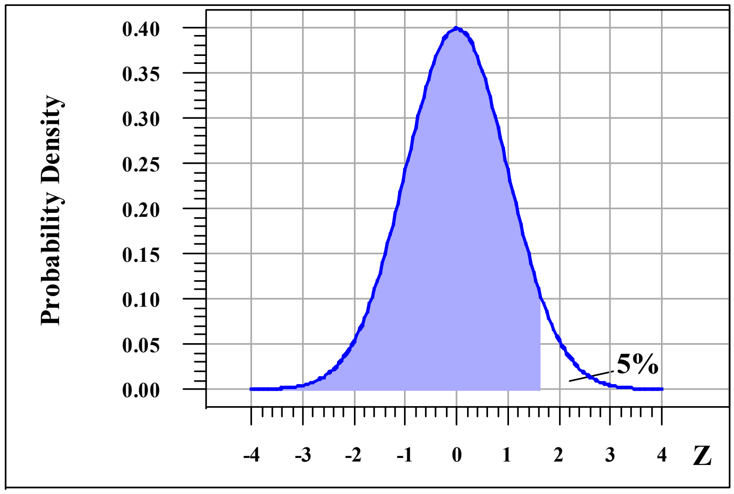


**Fig. 1. Standard normal distribution showing the 5% upper tail.**

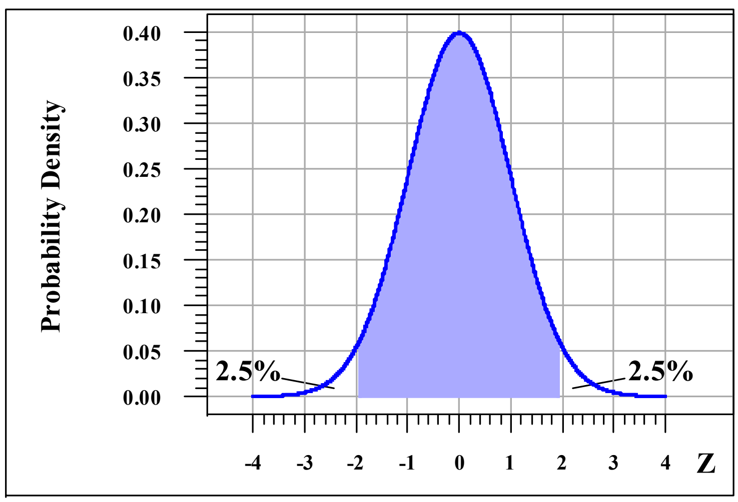


**Fig. 2. Standard normal distribution showing the upper and lower 2.5% tails.**

A setpoint is a critical value for an alarm when a measurement either exceeds it (upper limit) or falls short of it (lower limit). For many safety-related setpoints, interest is only in the probability that a single value of the process parameter is not exceeded and that the single value is approached only from one direction.

Trip setpoints must not compromise protection of the Analytical Limit (AL) and are chosen to assure that a trip or safety actuation occurs before the process reaches the AL (footnote [2]). The trip setpoint also accounts for the uncertainty associated with the expected performance of the

[2] The Analytical limit (AL) is the limit of a measured or calculated variable established by the safety analysis to ensure that a safety limit is not exceeded.

instrumentation under any applicable process and environmental conditions. The relationship between the trip setpoint, AL, and uncertainty is:

trip setpoint = AL – uncertainty

It is acceptable to combine uncertainties that are random, normally distributed, and independent by the square-root-sum-of-squares method (12, 13). For example, when two independent uncertainties, (± a) and (± b), are combined by this method, the resulting uncertainty is (± c). The margin between the trip setpoint and the analytical limit is determined by multiplying the z value (which is divided by 2 if the uncertainty is reported as a 2σ value) (footnote [3]), by the square root of the sum of the squares of the independent uncertainties:

$$c = \frac{z}{2}\sqrt{(a^2 + b^2)}$$

where

z = 1.645 for a 95/95 one-sided distribution (Fig. 1), and
= 1.96 for a 95/95 two-sided distribution (Fig. 2).

Under the symmetry implied by the normal distribution, the two-sided problem places the allowances simultaneously at both upper and lower limits. That is, the two-sided test for setpoints refers to the two tails of the normal distribution outside the 2σ limits. By definition, 5 percent of the population falls outside the ±2σ limits, such that the upper and lower tails are 2.5 percent. As shown mathematically in Section 3.2, the problem of determining a setpoint is fundamentally one-sided. The mathematics shows (Section 3.2) that the problem is inherently one-sided and that a distribution can be constructed that meets the 95/95 criterion of RG 1.105, Rev. 3. 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, for normally distributed uncertainties, 95 percent of the population will have uncertainties less than +1.645σ or greater than -1.645σ. (In Fig. 1, 95 percent of the population is less than +1.645σ).

The objective of the review of NEDE-33304P, and the associated RAIs, is to determine if the GEH setpoint methodology satisfies regulatory acceptance criteria, guidelines, and performance requirements. GEH proposes to use the 95 percent quantile of a standard normal distribution for a one-sided test rather than that for a two-sided test (i.e., multiply σ by 1.645 vs. 1.96).

GEH's setpoint methodology in NEDE-33304P applies a one-sided test because the setpoints approach the AL from only one direction—either from above or below. This interpretation of the 95/95 tolerance limit appears to satisfy the "as written" requirement in RG 1.105, Rev. 3, which states that there is a 95 percent confidence that 95 percent of the population of measurements fall within the specified limits. However, a one-sided test places <u>all</u> of the uncertainty on one side (Fig. 1) such that the probability that the AL will be exceeded can be up to 5 percent, compared to 2.5 percent for a two-sided test. In other words, GEH's methodology assumes that the 95/95 tolerance limits are applicable for either two-sided or one-sided tests. For a two-sided test, 95/95 means that 95 percent coverage is centered about the mean such that the tails are each 2.5 percent (Fig. 2). Thus, although a one-sided test meets the "as written" requirements

[3] Although the data may be reported with a 2σ uncertainty, it is the user's responsibility to avoid improper use of the vendor performance data. The vendors typically provide little information to substantiate the pedigree of the data (i.e., sample size from which it is derived, normality, etc.).

of RG 1.105, Rev. 3 in that 95% of the population measurements fall within specified limits, the question remains whether this meets the intent of RG 1.105, Rev. 3.

The difference between setpoints determined when applying the same 95/95 tolerance limit to the upper/lower end of a two-sided test and a one-sided test is shown in Fig. 3. Because the one-sided test places all of the uncertainty at one end of the distribution (as shown in Fig. 1), a one-sided test with a 95/95 tolerance limit is comparable to a two-sided test with a 90/90 tolerance limit. Consequently, the margin between the AL and the nominal trip setpoint (NTSP) decreases by ~18 percent (footnote [4]). The inherent imprecision of the data used in uncertainty calculations, the uncertainties involved in the assumption of normality, and the effects of other uncertainties and assumptions in related analyses may reduce the trip setpoint margin even further.

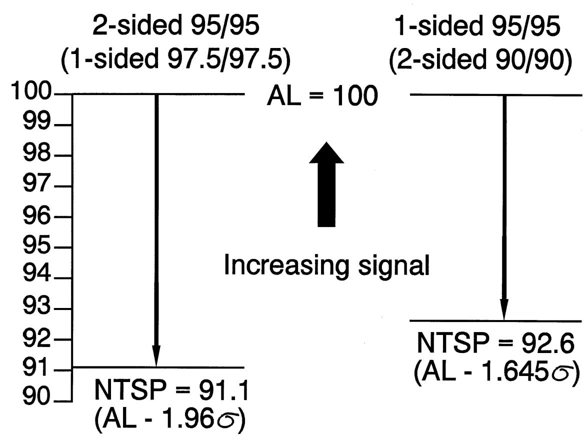


**Fig. 3. One-sided vs. two-sided 95/95 trip setpoints.**
**(AL = analytical limit and NTSP = nominal trip setpoint)**

The acceptance of a one-sided test is contingent upon the meaning of 95/95. RG 1.105, Rev. 2 (14) states

> [T]he NRC staff has accepted 95 percent as a probability limit for errors. That is, of the observed distribution of values for a particular error component in the empirical data base, 95 percent of the data points will be bounded by the value selected. If the data base follows a normal distribution, this corresponds to an error distribution approximately equal to a "two sigma" value.

The statement that "95% of the data points will be bounded by the value selected" can be met by either the one- or two-sided tests as shown in Figs. 1 and 2. The second part of the

[4] In the one-sided approach proposed by GEH, the cumulative probability function for a normal distribution attains 95 percent at a value of 1.645σ beyond the mean. Through use of this technique, a positive uncertainty calculated for a symmetrical case can be reduced while maintaining 95 percent coverage of the population when a single parameter is approached from only one direction. For example, if the original symmetric value was based on 2σ, the reduction factor is 1.645/2.00 = 0.8225 (i.e., 82.25 percent of the channel uncertainty); if the original symmetric value was based on 1.96σ, the reduction factor is 1.645/1.96 = 0.839 (i.e., 83.9 percent of the channel uncertainty).

statement—that this corresponds to an error distribution approximately equal to a “two sigma” value—applies to the two-sided test as shown in Fig. 2 because the 2σ sets the tails at 2.5 percent. Based on this, the prescribed limit of 95/95 in RG 1.105, Rev. 3 seems to refer to a two-sided test (footnote [5]), which means the tails are each 2.5 percent. The corresponding limit for a one-sided test would be 97.5/97.5. As such, the proposed setpoint methodology fails to meet the intent of RG 1.105, Rev. 3.

### 3.2 First Principles Derivation of Tolerance Limits

The purpose of this section is to describe the problem of setpoint determination in its simplest terms, so as to describe the use of statistical tolerance limits and distinguish between one- and two-sided tolerance intervals in setpoint applications. In this section, for simplicity, the setpoint determination problem is considered under the assumption that there is one instrument with no sources of uncertainty other than the time-stable measurement errors of the instrument. Additional sources of uncertainty do not affect whether a one-sided or two-sided approach is logical and appropriate, and the logic for deciding between the two approaches is clearer in a setting without them.

#### 3.2.1 Assumptions

We first consider the problem of determining a setpoint under the following somewhat simplified set of conditions:

1. A process operating condition (e.g., temperature, pressure) has *analytical limits* (ALs), that is, lower and/or upper limits that, for safety, should either be exceeded (lower limit) or not exceeded (upper limit).

2. The operating condition is monitored with a measurement instrument having normally distributed measurement errors with mean $\mu$ and standard deviation $\sigma$, where $\mu$ and $\sigma$ are typically unknown. (Measurement errors are differences between measurements and known standards.)

3. If $\mu$ and $\sigma$ were known, “reasonable” (see “Details” below) lower and upper limits for errors, L and U (percentiles), could be inferred from the standard normal distribution. (Note that generally $L < 0$ and $U > 0$; that is, L is negative and U is positive.)

4. Statistically independent estimates of the mean and variance of the measurement error distribution are available, as are the number of test measurements from which the estimates were computed (e.g., from a random sample of measurements from tests conducted with known standards by the instrument vendor).

5. Given statistically independent estimates of the mean and variance of the measurement error distribution, “reasonable” (see “Details” below) lower and upper limits for errors, L' and U' (tolerance limits), can be inferred from the standard normal distribution and a proper accounting for estimation error. (Note that generally $L' < 0$ and $U' > 0$.)

6. The instrument does not drift; it is stable over time.

[5] It appears that Rev. 3 removed some of the confusion in Rev. 2 but in turn added its own ambiguity (particularly regarding the definition of tolerance limits). For the two-sided test, the guidance in Rev. 2 and Rev. 3 are comparable.

### 3.2.2 Conclusions from Above Assumptions

The conclusions listed below follow from assumptions 1–6 above. Section 3.2.3 contains details about how they are derived.

1. For a given measurement X of the operation condition of interest, reasonable lower and upper limits for the actual operating condition are X – U' and X – L'.

2. For an upper AL, as long as X – L' < AL, it is reasonable to assume that the upper AL is not violated. For a lower AL, as long as X – U' > AL, it is reasonable to assume that the lower AL is not violated.

3. Equivalently, we can take as a one-sided upper setpoint S = AL + L' and alarm if X > S, and as a one-sided lower setpoint S = AL + U' and alarm if X < S. (The upper setpoint is defined in terms of the *lower* tolerance limit L', and the lower setpoint is defined in terms of the *upper* tolerance limit U'.)

In summary, the one-sided test for setpoints is acceptable based upon the mathematics.

### 3.2.3 Details

This section provides derivations and other details about the limits L' and U' and conclusions listed above.

A 95/95 tolerance limit means that there is a 95% confidence that 95 percent of the population of measurements fall within the specified limits. Thus, a "95/95 tolerance limit" only requires that 95 percent of the population should be covered. In particular, $(-\infty, U')$ and $(L', +\infty)$ are each 95/95 one-sided tolerance intervals.

Let X' denote the true operating value that is measured with X. Under the above assumptions, X = X' + e, where e is normally distributed with mean $\mu$ and standard deviation $\sigma$. For an upper AL (lower AL case similar), we seek a nominal upper trip setpoint S such that if X' ≥ AL, then $P(X > S) \geq 1 - \gamma$, where $\gamma = .05$ or some other reasonable value (footnote [6]). If $\mu$ and $\sigma$ were known, then it would also be known that $L = \mu - \sigma Z_{1-\gamma}$, where $Z_{1-\gamma}$ is the $1 - \gamma$ quantile of the standard normal distribution, and an S would be straightforward: $S = AL + L = AL + \mu - \sigma Z_{1-\gamma}$. In general, however, $\mu$ and $\sigma$ are unknown. We don't know $\mu - \sigma Z_{1-\gamma}$, so it has to be estimated.

Simply plugging estimates of $\mu$ and $\sigma$ into the expression $\mu - \sigma Z_{1-\gamma}$ would not properly account for statistical error in the estimation of $\mu$ and $\sigma$. To be confident that we are not overestimating $\mu - \sigma Z_{1-\gamma}$ (or, since it is typically negative, underestimating its absolute value), we need a lower confidence bound for $\mu - \sigma Z_{1-\gamma}$. Using raw data (e.g., supplied by the instrument vendor) or estimates of $\mu$ and $\sigma$, we can compute (see below) a lower $100(1-\alpha)\%$ confidence bound (footnote [7]) L' for $L = \mu - \sigma Z_{1-\gamma}$, again for some reasonable value of $\alpha$. This lower confidence

[6] For a 95/95 tolerance limit, both $\gamma$ and $\alpha = 0.05$ where $\gamma$ represents the coverage of the data and $\alpha$ represents the confidence bounds.

[7] See http://en.wikipedia.org/wiki/Confidence_limit for a discussion of confidence bounds and their relationship to statistical hypothesis testing.

bound and values above it cover everything greater than or equal to $L = \mu - \sigma Z_{1-\gamma}$ with $100(1-\alpha)$% confidence. Since everything greater than or equal to L is $100(1-\gamma)$% of the underlying normal distribution, everything greater than or equal to L' is, by definition, a $100(1-\gamma)$, $100(1-\alpha)$ tolerance bound (footnote [8]). Thus we take S = AL + L'.

By symmetry, the lower setpoint for a lower AL is S = AL + U' where U' is an upper confidence bound for $U = \mu + \sigma Z_{1-\gamma}$.

For channels that have only an upper or only a lower setpoint, the setpoint problem is inherently one-sided, and it is reasonable to determine setpoints as above. Determining a setpoint is a one-sided problem because each setpoint divides alarm conditions on one side with non-alarm conditions on the other side. If there are both upper and lower ALs, $AL_{Lower}$ and $AL_{Upper}$, however, it may be reasonable to consider both ends together. Taking $\gamma = .025$ and $\alpha = .025$, (L', U') is then a two-sided 95/95 symmetric tolerance interval for the error distribution, $AL_{Lower}$ + U', and $AL_{Upper}$ + L' are the corresponding lower and upper setpoints. This approach affords some extra safety in the same way that a two-sided confidence interval protects at both ends rather than just at the upper or lower limits.

However, the upper and lower problems can also be considered independently and handled as above with $\alpha = .05$. Because conditions at a lower setpoint are generally fundamentally different from conditions at an upper setpoint, there is generally no inherent reason that the upper and lower problems should be handled symmetrically. Besides upper and lower endpoints for one instrument channel, there are typically also multiple channels, which are generally treated independently.

Tolerance intervals are defined as "a statistical interval within which, with some confidence, a specified proportion of a population falls" (footnote [9]). This is a standard definition. More formally, for an arbitrary (not necessarily normal) cumulative distribution function F, $1-\gamma/1-\alpha$ tolerance limits are defined as follows:

One-sided upper: $P(F(U) \geq 1-\gamma) \geq 1-\alpha$
One-sided lower: $P(F(L) \leq \gamma) \geq 1-\alpha$
Two-sided $P(F(U) - F(L) \geq 1-\gamma) \geq 1-\alpha$

Note that for $\alpha$=.05 and $\gamma$=.05 these are all "95/95 tolerance limits." Because F is a cumulative distribution function, $F(-\infty) = 0$ and $F(+\infty) = 1$. Therefore $P(F(U) \geq 1-\gamma) = P(F(U) - F(-\infty) \geq 1-\gamma)$ and $P(F(L) \leq \gamma) = P(F(+\infty) - F(L) \geq 1-\gamma)$. Thus the one-sided cases are equivalent to the

[8] See http://www.itl.nist.gov/div898/handbook/prc/section2/prc263.htm, "Tolerance intervals for a normal distribution," NIST. When there are both lower and upper percentiles, the definition of tolerance limits gets a little more complicated. The term "tolerance limits" (or "tolerance intervals") generally refers to a specified amount of the underlying distribution but not to a specified part of the distribution (see for example, NIST, https://www-s.nist.gov/srmors/certificates/view_cert2pdf.cfm?certificate=4353a: "A 95/95 tolerance limit means that NIST is 95 percent confident that 95 percent of the population of [standard reference material] SRM measurements fall within the specified limits.") Thus, strictly speaking, the definition of "95/95 tolerance limits" does not entail any specification about symmetry or about which part (e.g., the symmetric middle) of the distribution need be covered—other than that 95 percent should be covered. In particular, $(-\infty, U')$ and $(L', +\infty)$ are each 95/95 one-sided tolerance intervals.

[9] http://en.wikipedia.org/wiki/Tolerance_interval.

two-sided case with one of the limits arbitrarily large or arbitrarily small. Nothing in the standard definition of tolerance limits, even in the two-sided case, assumes that the limits are symmetrical. In the two-sided case, the limits do not have to be the corresponding one sided limits but with $\alpha$ and $\gamma$ each divided by 2. Also, the definitions are independent of the underlying distribution F, which may or may not itself be symmetrical.

The regulatory position stated in RG 1.105, Rev. 3 unambiguously refers to 95/95 tolerance limits: "Section 4 of ISA-S67.04-1994 specifies the methods, but not the criterion, for combining uncertainties in determining a trip setpoint and its allowable values. The 95/95 tolerance limit is an acceptable criterion for uncertainties. That is, there is a 95 percent probability that the constructed limits contain 95% of the population of interest for the surveillance interval selected."

The "That is" qualifier essentially defines the 95/95 tolerance limit without reference to symmetry or the "center" of the underlying distribution. Since symmetry is not assumed in the standard definitions of tolerance limits, its explicit absence in the wording of RG 1.105 Rev. 3 suggests that it was never the intent.

Various approaches (as the instrument vendor providing the data in Fig. 3 pointed out) have been developed for calculating one- and two-sided tolerance intervals for the normal distribution, given a random sample of n instrument errors (e = X – X', where X' is a known standard) with mean M (corresponds to μ) and sample standard deviation S (corresponds to σ). Several methods are discussed by NIST (footnote [10]). The textbook *Statistical Intervals: A Guide for Practitioners* (15) provides a summary of approaches. A recent paper by Chakraborti and Li (16) focuses on confidence intervals for normal percentiles.

For a normal distribution, the t-distribution is used to derive tolerance bounds; in this case, the 95/95 tolerance bounds. This is done because of sampling errors in estimates of μ and σ. As mentioned at the NIST website, accurate tolerance limits based on the noncentral t-distribution can be computed, particularly now that the cumulative noncentral t-distribution has been widely implemented in computer software. For the one-sided upper case (the one-sided lower case is similar): $P( F(U) \geq 1-\gamma) = P( U \geq F^{-1}(1-\gamma) ) = P( U \geq \mu + Z_{1-\gamma}\,\sigma ) \geq 1-\alpha$. Taking U of the form U = M + kS, we determine a constant k such that $P( M + k\,S \geq \mu + Z_{1-\gamma}\sigma ) \geq 1-\alpha$ (footnote [11]), where M is the sample mean and S is the sample standard deviation.

The values of k for $\gamma = .05$ and $\alpha = .05$ and a few sample sizes are shown in Table 1. The value of k for the one-sided lower case is the negative of the value for the corresponding one-sided

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[10] http://www.itl.nist.gov/div898/handbook/prc/section2/prc263.htm.

[11] $P( M + k\,S \geq \mu + Z_{.95}\,\sigma ) = P( M - \mu + k\,S \geq Z_{.95}\,\sigma ) = P( (M - \mu) / (\sigma / n^{1/2}) - Z_{.95}\, n^{1/2} \geq -kn^{1/2}S/\sigma = P( ((M - \mu) / (\sigma / n^{1/2}) - Z_{.95}\, n^{1/2}) / (S / \sigma) \geq -kn^{1/2} ) = .95$

The constant k is fixed for a given sample size n and γ in the normal percentile $Z_{1-\gamma}$. (Here we take $\gamma = .05$.) Since $(M - \mu) / (\sigma / n^{1/2})$ is standard normal, and since $S^2 / \sigma^2$ is an independent chi-square divided by its degrees of freedom, $((M - \mu) / (\sigma / n^{1/2}) - Z_{.95}\, n^{1/2}) / (S / \sigma)$ has (by definition) a noncentral t-distribution with n−1 degrees of freedom and a noncentrality parameter $-Z_{.95}\, n^{1/2}$. Therefore, the above equality is satisfied if $-kn^{1/2}$ is the 05 percentile of this noncentral t-distribution. This determines k. A similar argument shows that k for the one-sided lower case is the negative of the value for the corresponding one-sided upper case.

upper case. For the two-sided case, apply the one-sided cases at both ends with $\gamma = .025 = .05/2$ $\alpha = .025 = .05/2$ rather than $\alpha = .05$. The interval from $\mu - Z_{.975}\,\sigma$ to $\mu + Z_{.975}\,\sigma$ obviously contains 95 percent of the distribution's probability. By Bonferroni's inequality (footnote [12]), the interval then contains both $\mu - Z_{.975}\,\sigma$ and $\mu + Z_{.975}\,\sigma$ with at least 95 percent confidence.

**Table 1. Values of k for upper tolerance bounds M + kS for several sample sizes, coverage probabilities (1 − γ), and confidence levels (1 − α)**

| n (Sample Size) | k-upper<br>1 − γ = .95<br>1 − α = .95 | k-upper<br>1 − γ = .975<br>1 − α = .95 | k-upper<br>1 − γ = .975<br>1 − α = .975 |
|---|---|---|---|
| 10 | 2.9110 | 3.4025 | 3.8009 |
| 100 | 1.9265 | 2.2758 | 2.3419 |
| 1000 | 1.7273 | 2.0520 | 2.0700 |
| Infinite | 1.6449 | 1.9600 | 1.9600 |

Table 1 clearly illustrates the effect of sample size on tolerance bounds. As $n \to \infty$, k converges to the corresponding normal quantile (estimated without error). Thus, $k \to 1.645$ for the one-sided and 1.96 for the two-sided test. This means that for a normal distribution with a sample of only 10, one needs to use 2.911 rather than 1.645 as the multiplier for a coverage probability of 95 percent with a confidence level of 95 percent.

It is typically assumed that the sample size of the vendor-reported data approaches ∞. Thus, as the sample size $n \to \infty$, k converges to the corresponding normal quantile (estimated without error). This means that as $k \to 1.645$ for the one-sided and 1.96 for the two-sided test for 95 percent confidence, 95 percent of the population measurements fall within the specified limits.

The above derivation starts with first principles and shows that the problem is inherently a one-sided problem.

### 3.3 Multiple Instruments and Drift

The error distribution of an instrument should be uniform over the instrument's range, or, if not, either separate error distribution estimates should be used for different subsets of the range, or a distribution should be estimated that represents the most variable part of the range. Similarly, the error distribution should be stable over time, or if not, it should be either re-estimated periodically to account for changes over time, or the error distribution itself should allow for variability over time. The mathematics for properly accounting for these other sources of error may involve complicated error propagation arguments and additional assumptions about the statistical distributions and independence of various components of the net error. Nevertheless, once all sources of error are properly accounted for and combined, the problem of setpoint

[12] http://en.wikipedia.org/wiki/Bonferroni_inequalities. For two events A and B, P(A U B) ≤ P(A) + P(B). Taking A as the event that L' > L and B as the even that U' < U, the probability that either event occurs is bounded by the sum of their individual probabilities: P(A U B) ≤ P(A) + P(B) = $\alpha/2 + \alpha/2 = \alpha$.

determination reduces to the problem considered in Section 3.1. The issue of one- vs two-sided approaches is the same.

### 3.4 Assumption of Normality

The error distribution might not be normal. It seems unlikely that it would be in all cases. Nonparametric statistical methods could be used to address the problem of percentile estimation without the assumption of normality. This is considered in Section 3.3.

The measurement errors in the test sample might not be statistically independent. If test measurements are not statistically independent, then M and S are not independent (even under normality), and the noncentral t-distribution argument breaks down.

The discussion in Section 3.1 and some of the calculations referred to in Section 3.2 require the assumption that there is normal distribution of measurement errors. That assumption might not hold. Because of central limit properties, sample means and many other statistical estimates have distributions that become normal as the sample size increases. However, those are large-sample properties. The statistical distribution of individual measurement errors (or of individual anything) need not be, and typically is not, normal in any given case (particularly not in each of many given cases).

Approximating distributions with normal distributions can be a useful and convenient mathematical technique, but the assumption of normality needs to be supported with data. Failure of the data to support the assumption (e.g., failure of goodness-of-fit tests) suggests that the normal approximation may be inadequate.

Assuming random, normally distributed, and independent uncertainties simplifies the statistical analyses. It is recognized that the uncertainties may not be random, the distributions may not be normal, and the uncertainties may not be independent. If the uncertainties are random, normally distributed, and independent, they can be combined using the square-root-sum-of-squares method; if the uncertainties are not random, not normally distributed, or are dependent by the arithmetic method, they may be combined using the arithmetic method. ISA 67.04.01-2006 Sections 4.5.1 and 4.5.2 describe these methods.

For example, the following data (Table 2) was read from first frequency bar chart in Fig. 4.

**Table 2. Vendor Measurement Errors (Read from Fig. 4)**

| Error | Frequency |
|---|---|
| -0.3 | 1 |
| -0.2 | 1 |
| -0.1 | 5 |
| 0.0 | 1 |
| 0.1 | 10 |
| 0.2 | 7 |
| 0.3 | 10 |
| 0.4 | 1 |
| 0.5 | 2 |

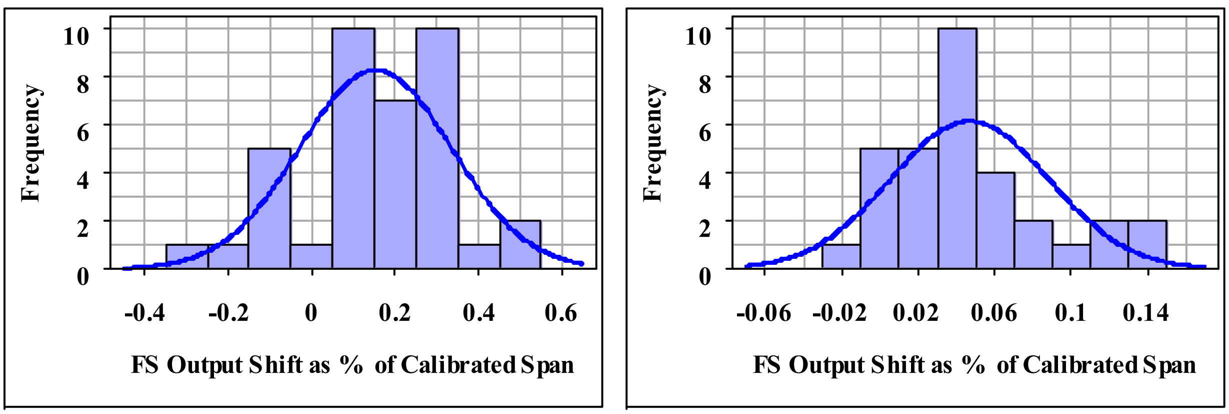


**Fig. 4. Histograms of uncertainty data. (FS is full scale.)**

Although a normal distribution was fit to the data in Fig. 4, various goodness-of-fit tests for normality all reject the assumption that the data is normal at the .05 level of significance or less (Kolmogorov-Smirnov test, p=.01; Shapiro-Wilk test, p= .049; Cramer-von Mises test, p=.009; Anderson-Darling test, p=.01). The departure from normality here may be substantial given that it is detected with so few (38) observations. The frequencies in the second bar chart in Fig. 4 also depart significantly from normal (footnote [13]).

If the normal distribution is inadequate, then some other distribution, such as the lognormal, may provide an adequate fit. Alternatively, questions about the underlying error distribution can sometimes be avoided altogether by using distribution-free statistical methods. Consider, for example, a sample of n measurement errors, $e_1$, $e_2$, $e_3$ …, $e_n$ determined by making n tests with the instrument and known standards. Instead of computing a mean and standard deviation from this sample, consider the corresponding order (i.e., sorted) statistics $e_{(1)}$, $e_{(2)}$, $e_{(3)}$ …, $e_{(n)}$. The probability that a new error e exceeds $e_{(i)}$ is (n–i+1)/(n+1), and the probability that a new error falls below $e_{(i)}$ is also i/(n+1). This can be used as the basis for distribution-free predictive

[13] For the frequencies in the second bar chart in Fig. 4: Kolmogorov-Smirnov test, p=.01; Shapiro-Wilk test, p= .01; Cramer-von Mises test, p=.005; Anderson-Darling test, p=. p=.005.

confidence limits for e, which (as in Section 3.1) can be combined with the AL for a distribution-free determination of setpoints. For example, for the 38 data points in the table, −0.3 is a 1 – 1/(38+1) = .974 lower prediction bound for the new error e. For an upper action level AL, AL + (−0.3) = AL – 0.3 could be used as an upper setpoint for the action level (footnote [14]).

### 3.5 Consistent with Previous NRC Acceptance Criteria

The NRC, in its review of NEDC-31366P, "General Electric Instrument Setpoint Methodology," stated that

> The GEH methodology utilizes single-sided distributions in the development of trip setpoints and allowable values. The staff has stated that this methodology is acceptable provided that a channel approaches a trip in only one direction…
>
> Although the staff has concluded that NEDC-31366 is an important reference document for understanding how GEH selects instrumentation setpoints, the topical report is not to be used by any plant to validate its individual setpoints. That is, each plant must provide its own plant unique analysis for its setpoints. The examples given in the topical report are used by GEH to show the safety margins and typical channel errors that might be expected. Since plants have different instruments, environments, seismic characteristics and other requirements, only examples have been provided by GEH in this topical report.

The SER on NEDC-31336 notes that "The GE[H] Setpoint Methodology utilizes single-sided distributions in the development of trip setpoints and allowable values. With the exception of using a single-sided test, these methods are reflective of industry practice and are, therefore, acceptable to the staff. The staff notes that the scope and intent of the GE[H] methodology encompasses trip setpoints only and that GE[H] states that the trip units act independently. Should the application of the GE[H] Setpoint Methodology be expanded to monitoring instrumentation, the staff expects that the methodology will be adapted to the intended application. The use of single-sided probability distributions for setpoints within the context of this topical report was found to be acceptable by the staff. The probability of a false trip (early trip) is a separate calculation when determining whether a technical specification setpoint will be satisfied."

The SER for NEDC-31366P approved the one-sided test methodology for trip setpoints, when approaching the setpoint from a single direction. This acceptance was also for setpoints with uncertainties that fit a normal distribution. It is the application of the one-sided test methodology that the NRC required to be demonstrated on plant-specific and instrument-specific bases.

### 3.6 ISA-S67.04, Part II

GEH's technical paper, in its steps for determining the setpoint margin, states that the

> [setpoint value] $X_0$ should be such that the setpoint margin between AL and X0 is 1.645-sigma. This margin assures that the setpoint is located far enough below the AL such

[14] The mean and standard deviation of the 38 errors in the sample are 0.1526 and 0.1827, respectively. For n=38, the 97.5/97.5 one-sided tolerance limit k is 2.6432, and the lower tolerance limit is 0.1526 – (0.1827 x 2.6432) = –.3303 < –0.3. Of course, the distribution-free interval is a prediction limit, not a tolerance limit.

that the area in the tail of the probability distribution curve above the AL is 5 percent. Applicability of the 1.645-sigma margin is also stated in the ISA standard (Reference 3). This margin assures 95 percent probability that the trip will occur before the AL is reached, assuming that the setpoint varies randomly with normal distribution, according to the specification.

The cited reference in the above statement (i.e., Reference 3) is ISA-RP67.04, Part II, 1994, Section 8. RG 1.105, Rev. 3, Rev. 3 does not approve ISA RP67.04.02-2000 (i.e., Part II). Thus, although when reading the technical paper it appears that Part II provides an acceptable methodology to the NRC, this is misleading.

## 4.0 FINDINGS AND CONCLUSIONS

The determination of setpoints is inherently a single-sided problem. The single-sided methodology has previously been found to be an acceptable methodology by the NRC, and this review confirms that assessment. However, the specific requirements for applying a one-sided test were not provided. That is, the coverage of the data and the confidence bounds were not specified. The question becomes whether the 95/95 limit is applicable to only the two-sided test, or is it also applicable to the one-sided test.

RG 1.105, Rev. 3 requires that "there is a 95% probability that the constructed limits contain 95 percent of the population of interest for the surveillance interval selected." RG 1.105, Rev. 3 guidance does not specify if the 95/95 tolerance limits apply to a single-sided or two-sided test. However, because RG 1.105, Rev. 2 specifies that the error distribution for 95 percent of the data points corresponds to a 2σ value, the prescribed limit of 95/95 in RG 1.105, Rev. 3 most likely refers to a two-sided test. This in turn means the tails are each 2.5 percent and the setpoints are set based on the nonconservative tail end of the distribution. The prescribed limit for a one-sided test would be 97.5/97.5. (A one-sided 95/95 test is comparable to a two-sided 90/90 test; a one-sided 95/95 test reduces the margin between the AL and the NTSP by ~18 percent.) Based on the guidance of RG 1.105, Revisions. 2 and 3, the proposed setpoint methodology proposed by GEH fails to meet the intent of RG 1.105, Rev. 3.

It is also important to understand the assumptions behind the determination of setpoints. One would have to examine the population of data from which the uncertainty values are taken to ensure the tested population was sufficient size and normally distributed to ensure the rigorous 95/95 statistical criteria are met. Because of the high cost of testing, only limited populations of instruments are typically tested. The inherent imprecision of the data used in uncertainty calculations, the uncertainties involved in the assumption of normality, and the effects of other uncertainties and assumptions in related analyses may reduce the best choice of the trip setpoint safety margin even further.

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