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# NRC Staff Interpretation of 95/95 Tolerance Limits in Safety System Setpoint Analysis

NRC Public Meeting with GE-Hitachi

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# Disclaimer

- The following slides summarize the collective opinions of several members of the NRC staff concerning the interpretation of statistical representations used in the analysis of instrument channel performance. This information is being considered for use in establishing acceptance review criteria pertinent to the review of proposed instrument setpoint methodologies. The information herein represents work in progress, and does not necessarily represent the concurrence of all cognizant staff members or a final decision in this matter.

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# Regulatory Guide 1.105

- Regulatory Position C.1 of Rev. 3 (1999) of Reg Guide 1.105 states:
  - "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% probability that the constructed limits contain 95% of the population of interest for the surveillance interval selected."

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# Regulatory Guide 1.105 (continued)

- Revision 2 (1986) of Reg. Guide 1.105 stated:
  - "Paragraph 4.3 of the standard specifies the methods for combining uncertainties in determining a trip setpoint and its allowable values. Typically, the NRC staff has accepted 95% 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% 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."

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# Further Clarification Planned

- The NRC staff has recognized that these definitions and statements in the previous and current versions of RG 1.105 could be enhanced with further clarification to ensure that all licensees and NRC reviewers of safety-related instrument setpoints have a clear, common understanding of the NRC staff's concerns. The following slides represent a proposed way of providing such clarification.

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# Confidence Interval Estimation

- When the magnitude of a particular performance characteristic, (such as “power supply effect” or “drift”) of an instrument population is to be estimated, sampling of that population is performed, and the characteristic of interest is measured for each sample. The mean and standard deviation of the sample are then determined.
- One is usually interested in finding an interval around the sample mean such that there is a high probability that the actual population mean falls inside of this interval. This interval is called a *confidence interval* and the high probability is called the *confidence level*.

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# Confidence Interval Estimation

- The NRC staff position is that an acceptable confidence level to use for such estimates of instrument performance characteristics is ±1.96 σ, which is the confidence interval that is large enough to ensure, with a 95% confidence, that the true population mean actually lies within this interval.
- If the raw data sample size is not sufficiently large, (e.g., there has not been an appropriate number of tests or measurements of the characteristic of interest to support statistical test methods) the interval should be determined through best-estimate means, such as bounding assumptions supported by adequate technical justification, (e.g., documented historical operating experience) or through use of appropriate statistical means (e.g., Student's t-factors)

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# Tolerance Intervals

- Used to specify with a certain degree of confidence that a specified proportion of a population lies within a certain interval.
- The “level of confidence” of a tolerance interval is a measure of the likelihood that the calculated interval of interest does, in fact, cover at least the specified proportion of the population of interest.
- The tolerance interval that covers 95% of a population of interest with 95% confidence is used by the NRC staff as an acceptance criterion when reviewing several types of nuclear safety-related analyses.

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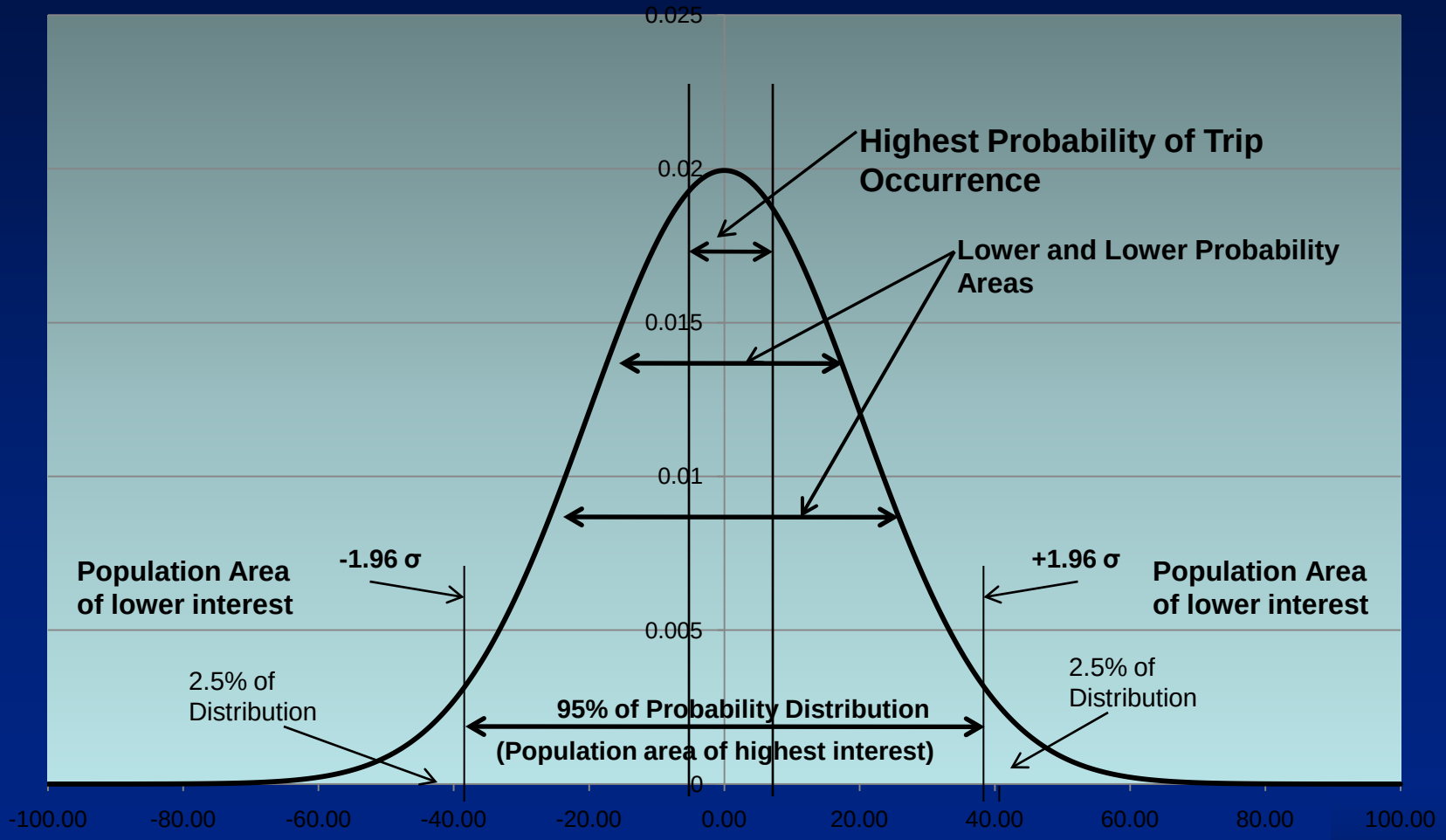
# 95% Tolerance Intervals of Interest



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# Assumptions:

- Sufficient data exists to support statistical analyses
- Data representing random error is normally distributed
- Data represents random and independent terms
- Central limit theorem/SRSS methods can be used to combine like units of standard deviations of random error
- Setpoint errors are disposed symmetrically about the mean, resulting in the highest probability of a channel trip being closest to, and symmetric about, the mean
- The highest probabilities of trip occurrence are centered close to the mean, and lower probabilities are symmetric, but further away the mean

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# 95% Tolerance Interval

- If the endpoints of the interval are being estimated based on random variables, then the level of confidence associated with a particular tolerance interval is a measure of the likelihood that the calculated interval does, in fact, cover at least the specified portion of the population.
- If the tolerance limits have been based on a statistically sufficient quantity of sample data, the confidence that the interval contains 95% of the population of interest increases.
- The NRC staff uses a confidence level of 95% as an acceptance criterion for this likelihood.

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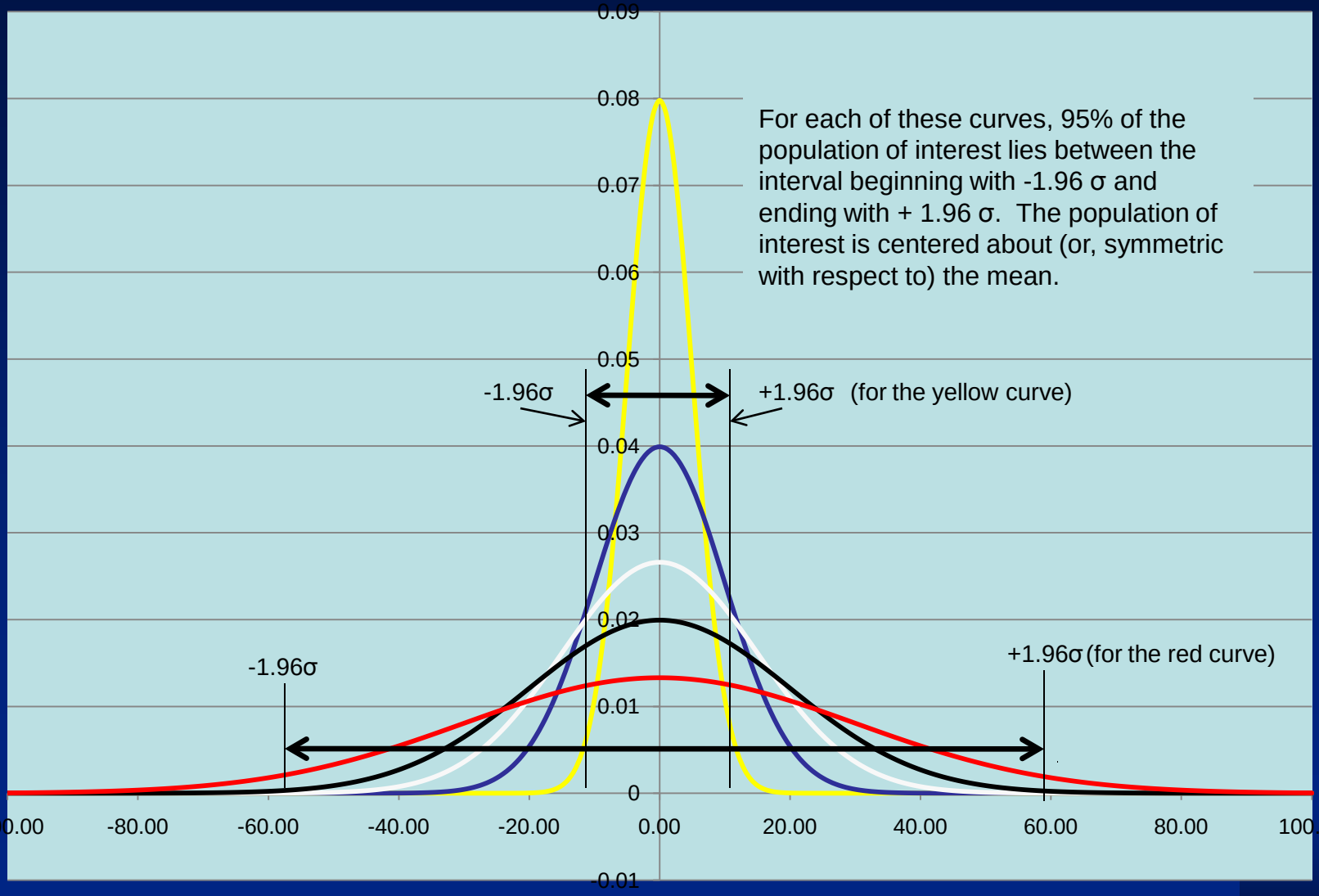
# 95% Tolerance Intervals of Interest for Various Probability Distributions



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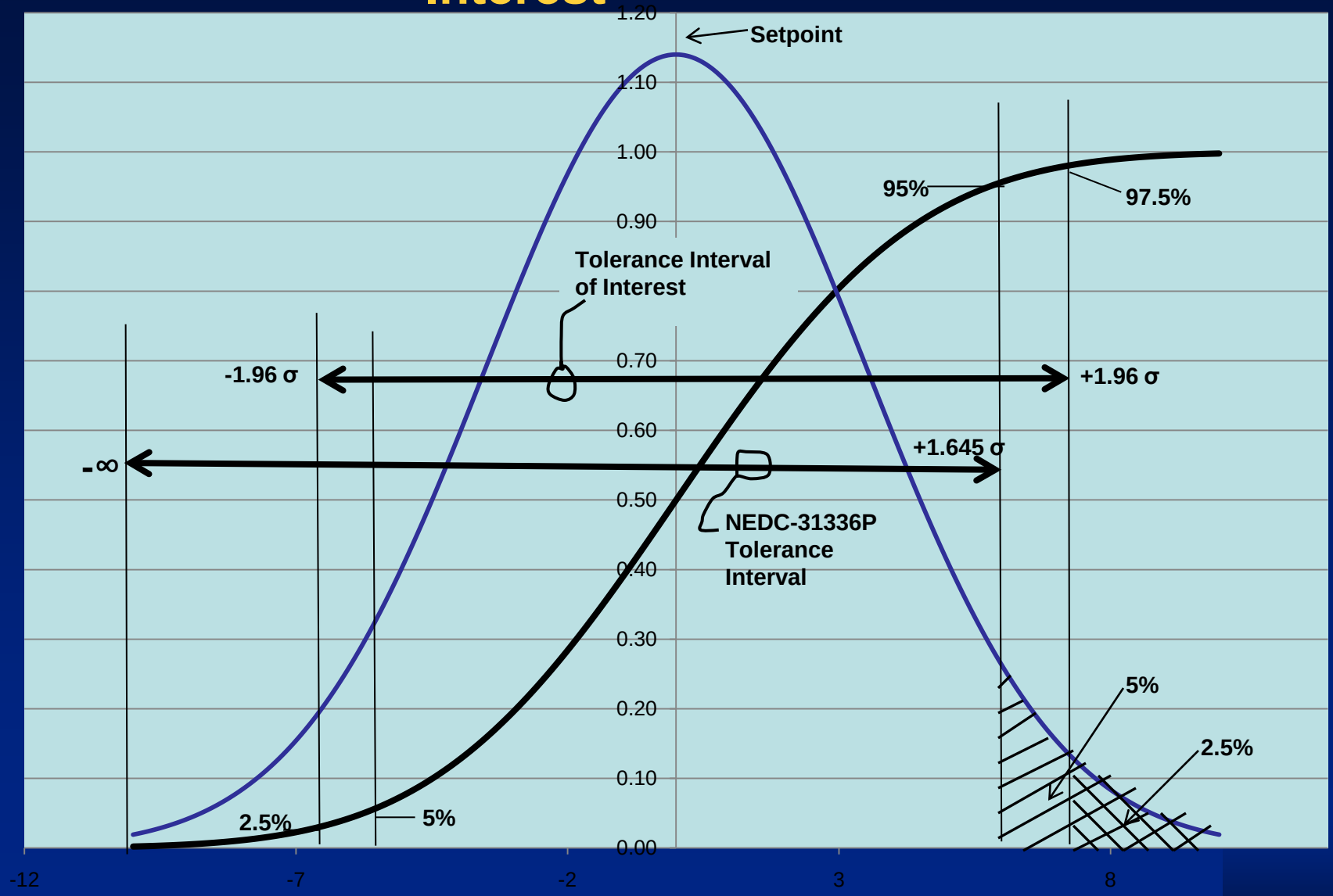
# Cumulative Probability –Interval of Interest



# Cumulative Probability

The NRC staff understanding of the tolerance interval associated with the cumulative probability of interest is that portion of the probability distribution encompassing the interval from 2.5% of the population to 97.5% of the population, totaling 95% of the population of interest.

The NRC staff understanding of the 95% tolerance limits is such that those limits are symmetric with respect to the mean. In Reg Guide 1.105 Revision 3, the NRC staff intended that the term “95/95 tolerance limit” referred to those limits reflecting a 95% confidence that the limits contain 95% of the population of interest, which is that centered around the mean, containing the highest probabilities of occurrence.

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# Probability of Failure to Trip before AL is exceeded

- Ignoring instrument channel performance bias terms, an instrument channel set at 1.96-σ away from the analytical limit, assuming the 95/95 tolerance interval definition that includes the “symmetric about the mean” criterion, has a probability of failing to trip before the analytical limit is exceeded of 2.5%.

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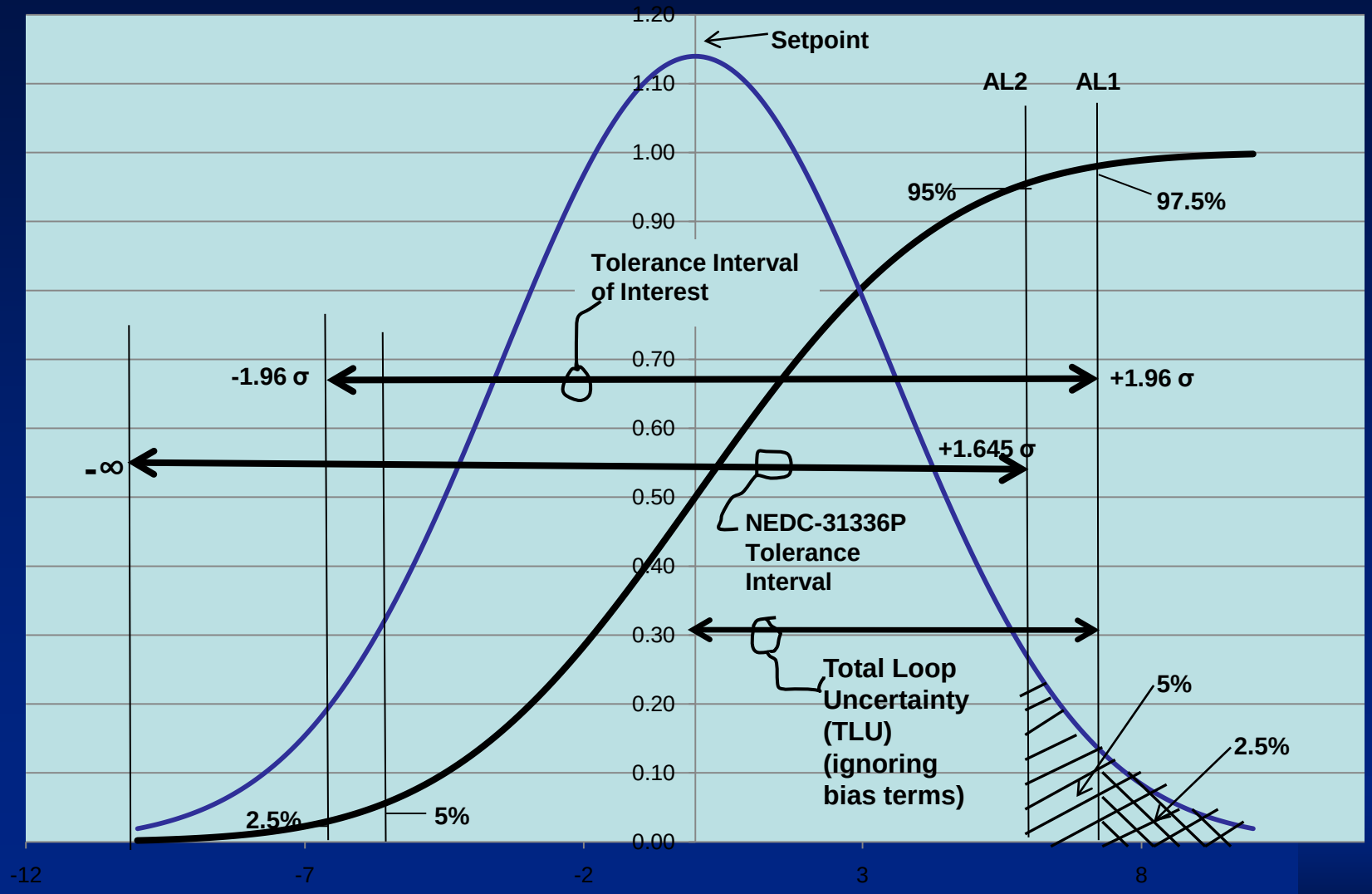
# Instrument Channel Probability of Failure to Trip before AL: 2.5%



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# Other Acceptable Approaches are Possible

- Reg Guide 1.105 represents one method of ensuring that the instrument channel will trip with a 95/95 tolerance limit before the analytical limit is exceeded.
- Other methods are also possible.
- The NRC staff would consider an instrument setpoint determination method to be adequate where it can be shown that the instrument channel will trip before the analytical limit is exceeded, and provided it can be adequately demonstrated that the "95/95 tolerance limit" is applied to ensure, with 95% confidence, that the appropriate tolerance interval contains 95% of the population of interest.