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General Comment

The NRC staff is commended on clarifying the mathematically incorrect assumptions in DG-1141. However, Section B should clarify whether the desired statistical objective for licenses and applicants is a tolerance interval rather than a confidence interval as requirements for safety-related instrument setpoints. (See https://www.graphpad.com/support/faq/the-distinction-between-confidence-intervals-prediction-intervals-and-tolerance-intervals/#:~:text=If%20you%20set%20the%20first,wider%20than%20a%20prediction%20interval).

The incorrect assumptions center on Figure 2 in DG-1141. For example, characterization of the as-found trip setpoint in terms of an error band reflects a deterministic not a probabilistic engineering expectation. Trip setpoint which is subject to the various random based uncertainties would be expected to be found within the total loop uncertainty as defined in the ISA Standard Section 4.4. Similarly, given the nonrandom terms in Equation 2 of the ISA Standard the assumption of a normal distribution is an incorrect one. Lastly, the notion that 21/2% probability can be assigned or allocated to one side or another of a distribution runs contrary to the laws of probability.

On confidence intervals (https://en.wikipedia.org/wiki/Confidence_interval)

A 95% confidence level does not mean that for a given realized interval there is a 95% probability that the population parameter lies within the interval (i.e., a 95% probability that the interval covers the population parameter). According to the strict frequentist interpretation, once an interval is calculated, this interval either covers the parameter value or it does not; it is no longer a matter of probability. The 95% probability relates to the reliability of the estimation procedure, not to a specific calculated interval. Neyman himself (the original proponent of confidence intervals) made this point in his original paper:

"It will be noticed that in the above description, the probability statements refer to the problems of estimation with which the statistician will be concerned in the future. In fact, I have repeatedly stated that the frequency of correct results will tend to . Consider now the case when a sample is already drawn, and the calculations have given [particular limits]. Can we say that in this particular case the probability of the true value [falling between these limits] is equal to ? The answer is obviously in the negative. The parameter is an unknown constant, and no probability statement concerning its value may be made..."

Deborah Mayo expands on this further as follows:

"It must be stressed, however, that having seen the value [of the data], NeymanPearson theory never permits one to conclude that the specific confidence interval formed covers the true value of 0 with either (1)100% probability or (1)100% degree of confidence. Seidenfeld's remark seems rooted in a (not uncommon) desire for NeymanPearson confidence intervals to provide something which they cannot legitimately provide; namely, a measure of the degree of probability, belief, or support that an unknown parameter value lies in a specific interval. Following Savage (1962), the probability that a parameter lies in a specific interval may be referred to as a measure of final precision. While a measure of final precision may seem desirable, and while confidence levels are often (wrongly) interpreted as providing such a measure, no such interpretation is warranted. Admittedly, such a misinterpretation is encouraged by the word 'confidence'."

A 95% confidence level does not mean that 95% of the sample data lie within the confidence interval.

A confidence interval is not a definitive range of plausible values for the sample parameter, though it may be understood as an estimate of plausible values for the population parameter.

A particular confidence level of 95% calculated from an experiment does not mean that there is a 95% probability of a sample parameter from a repeat of the experiment falling within this interval.

Bottom Line: If the NRC expects licensees or applicants to meet a statistical limit with respect to the Analytical Limits in nuclear power plant technical specifications then a tolerance interval should be required rather than a confidence interval.