Some Magruder PT Committee Considerations for Using IA as an Industry Standard Allowed Dispersion

As we move towards using the IA (Investigational Allowance) as a fixed distribution within which we assess method variability, it is important that we understand where it came from. I will try to keep this short yet pertinent.

In this regard two older references have shed some light on this IA origin issue:

"Variations in Analysis of Fertilizers", Quackenbush, et al., J.AOAC, Vol 49, No 5, 1966, PP 915 - 943.

"The Background and Rational for AAPFCO Recommended Investigational Allowance", R.C. Rund, AAPFCO OP, No 28, 1975, PP 67 - 75.

In both these documents the driving imperative is to ensure compliance within the lower IA limit for NPK analysis. An acceptable sd (standard deviation) is calculated. Sometimes this is referred to as a standard error as confidence changes if more than 1 analysis is used. This sd is calculated based on experimental design using 12 industrial labs and 12 regulatory labs for mutual representation.

The salient point here is that the IA is calculated as a Normal 1 tail probability of 99% ($\alpha = 0.01$). In other words, the acceptable IA = sd * 2.33 as demonstrated in Chart A attached. We can "reverse engineer" the original sd from the given $IA_{Quackenbush}$ and call it the IAsd: IAsd = $IA_{Quackenbush}$ / 2.33

All the attached charts represent a hypothetical true value (or assigned value) of 10 units with an analytical dispersion described as the IAsd, of 1. In Chart A when the IA is applied per Quackenbush, values below 7.67 (10 - 2.33) would be considered too low.

As we move towards using the IA as a fixed industry standard allowed variation, we must also consider the upper tail of the distribution. In other words, your lab analysis is acceptable if it falls within the ± IA range shown in Chart B. If this is applied, continuing to use 99% of the data under the acceptable curve the 2 tail range will be from 7.42 to 12.58. The dilemma here is that we have lowered the acceptable low end to allow more analyses below the Quackenbush 1 tail test (see Chart B).

In order to assess upper and lower limits for IA in a Normal distribution, we have some decisions to make:

1) We can retain the Quackenbush lower limit for both upper and lower limits recognizing that we have reduced the probability (confidence) from 99% to 98% (Chart C).

2) We can adjust the confidence to 95% and reduce the acceptable range described from 8.04 to 11.96 (see Chart E). I say this because in more recent documents I have seen the IA described as a 95% confidence interval.

Here I put forward Charts B, C and E as possibilities. In light of the "New Reality" for the use of IAs as an Industry Standard having nothing to do with Guarantees.

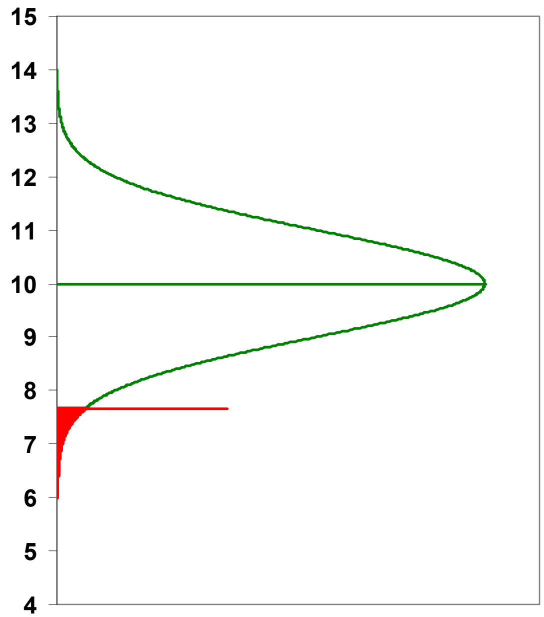
I tend to favor Chart E. Our purpose with the proposed IA metric described as "Method IA Status" is to provide labs with a tolerance alert that their result is outside of the industry standard dispersion or sort of a 95% tolerance if you will (see attached powerpoint presentation given at Bellvue, WA, Aug. 8th, 2017). In time a tighter tolerance should help to bring labs more in line with the industry standard (IA). The Z score is still available for corrective action should the result stray too far from the other participant results.

The preceding discussion does not affect the "IA Factor" for methods (described in PP presentation, Slide 6) except to alter the "IAsd = IA/2" to "IAsd = IA/2.33" (Slide 5).

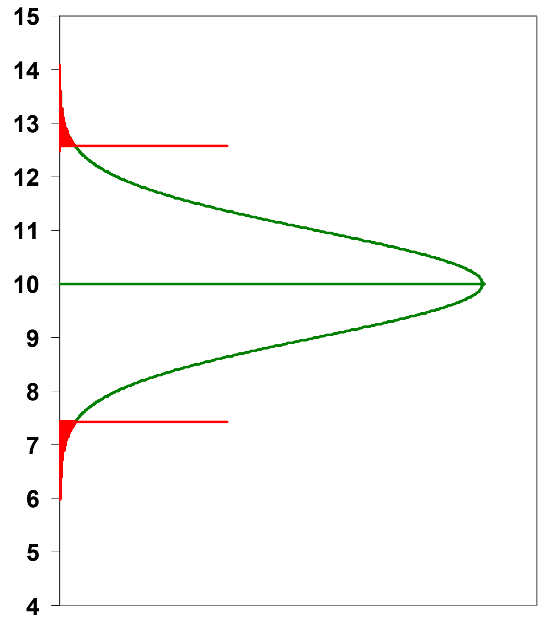
Additionally, I have assumed that the IA equations for micronutrients (slide 4) follow the same 99% lower limit 1-tail imperative as the NPK IAs described above. If any one has credible documentation on Micronutrient IAs I would appreciate it.

Dr. A. Crawford, 08/17/2017.

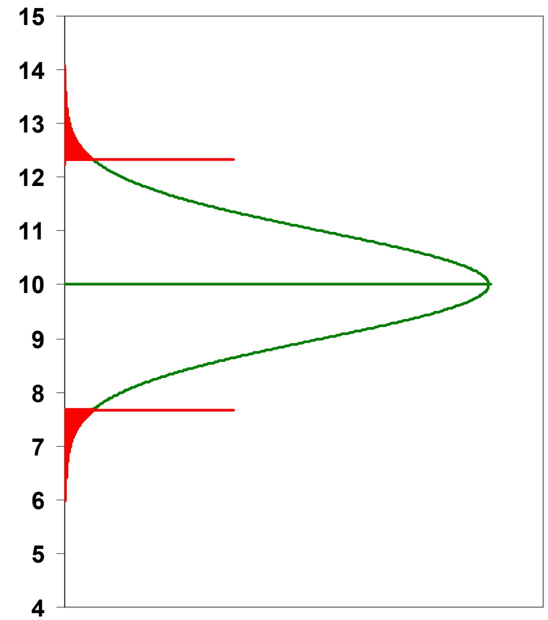
A: 99% 1 Tail, - IAsd*2.33



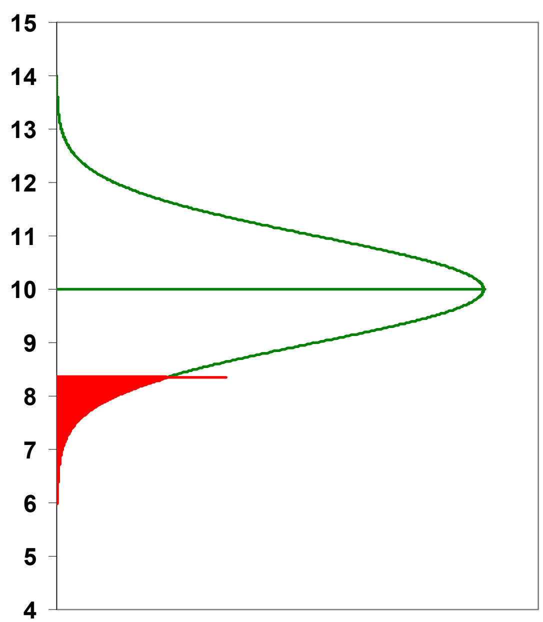
B: 99% 2 Tail, +/- IAsd*2.576



C: 98% 2 Tail, +/- IAsd*2.33



D: 95% 1 Tail, - IAsd*1.645



E: 95% 2 Tail, +/- IAsd*1.96