Commentary: Can AQL be Zero?

Lynn Torbeck, Torbeck and Assoc. and Suzanne Seeley, Merck

Some companies have written SOP's for sampling that set the Acceptable Quality Limit (AQL) for a critical nonconformity as 0.0%. Can an AQL be zero?

In a word: No. It is not possible for an AQL value to be zero.

To understand why, let's start with the definition of AQL. The most often used reference is ANSI/ASQ Z1.4, *Sampling Procedures and Tables for Inspection by Attributes*. On page 2, we find the definition of the Acceptable Quality Limit: "The AQL is the quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling."

Note then the average would have to be zero. If the average is zero, then all of the results would have to be zero as well, because there are no negative nonconformities. If we believe that all the nonconformities are actually zero, we would have no need for a sampling plan.

But an AQL level or limit is a requirement of CGMPs, specifically CFR 210.3(20): "*Acceptance criteria* mean the product specifications and acceptance/rejection criteria such as acceptable quality level and unacceptable quality level, with an associated sampling plan that are necessary for making a decision to accept or reject a lot or batch."

Also in 21 CFR 211.165(d), we find: "The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels."

But most important, an AQL equal to 0.0% is not statistically possible. The AQL value is determined as soon as the sample size and the acceptance number are selected. This includes "accept on zero nonconformities." The values are available from the graphs and tables in Z1.4. **Table 1** shows the true AQL values for different sample sizes and the criteria of "accept on zero" and "reject on one nonconformity."

Typically, AQL is expressed as the percent of nonconformance's (e.g., 0.0163% is 0.000163 or 163 out of one million units) for which lot acceptance has a high probability, usually 95%.

It is important to separate the business philosophy and goal of zero nonconformities from a requirement of an AQL equal to 0.0%. To that end, classifications of Critical, Major and Minor nonconformities allow a distinction based on their potential risk and impact on patient safety. Setting an AQL specification for nonconformities requires a balance between the pharmaceutical company's goal of perfection for its outgoing products and the current production capability of manufacturing technology.

The above discussion for AQL values is for processes where nonconformance levels can be sampled and estimated statistically. However, it is not recommended to assign AQL equal to 0.0% to nonconformities not allowed under any circumstances for any sample size. A classification of "None Allowed" has been recommended by author **Suzanne Seeley**.

The classification "None Allowed" is for a nonconformance, error or mistake that is unacceptable at any level. These include, for example, incorrect components such as the wrong size, color, or type of materials. While these errors may or may not affect the whole lot, they do represent a significance deviation from the intended product. If these nonconformities are found at anytime, anywhere, the entire batch is immediately rejected without further sampling or inspection. It is recommended that the term "None Allowed" be defined and used in place of AQL equal to 0.0% for this application.

To summarize, AQLs cannot be zero but the concept of "None Allowed" will meet the objective of zero nonconformities for given categories of defects.

Reference

This is an edited version of section 3.2.3 Acceptable Quality Limits from PDA.

About the Author

Lynn Torbeck is a president of Torbeck and Associates, specializing in applied statistics and designed experiments for quality assurance, quality control, validation and manufacturing under the CGMP's. Lynn was elected to the USP Expert Committee for Statistics in 2001 and 2005 and is a coauthor of USP<1010>. Lynn welcomes comments on this article. Contact him at: Lynn@Torbeck.org.

Suzanne Seeley is a Process Engineer at Merck.

Table 1 Example AQLs by Sample Size

Letter Code	Sample Size	True AQL: Single Plan
J	80	0.0641
K	125	0.0410
L	200	0.0256
M	315	0.0163
N	500	0.0103
P	800	0.00641
Q	1250	0.0041

Have Your Say

Does your company's sampling plan include AQLs for a critical noncomformity at zero?

Does "None Allow" make sense to you?

We want to know. Email us at hough@pda.org.