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Recording Acceptance Sampling Results

21 CFR §820.80(e)(3) requires manufacturers to include results in records of acceptance activities. A Warning Letter (May 23, 2013) from the Baltimore District Office to Automated Ophthalmics, Inc. cited them for the format used. The letter says, "Specific test results need to be recorded. Placing an "x" mark only if the test is not within limits is not acceptable." This is not the first Warning Letter to raise the issue. The footnote refers to some others.[1,2]

The Warning Letter asserts this practice is "not acceptable" without offering an explanation. The context is 820.80(b) Receiving acceptance activities, where the firm used a sampling plan.

Many companies use an attribute sampling plan such as Z1.4 or Squeglia's c=0 plan. When dealing with measured data, the firm would convert the measurement to a pass/fail attribute by determining if the measured value is in or out of the specification. The sampling plan tells the number of items to inspect and the acceptance criteria based on the number of non-conforming items in the sample.

The Regulatory Requirement

The Warning Letter seems to assert a regulatory requirement to record the measurement, not just the attribute. However, a check of the QSR preamble doesn't support this. Preamble #147 address a comment that "recording all quantitative data is inappropriate and of little value". FDA responds by saying, the regulation requires the minimum documentation necessary to ensure the safe and effective devices and that maintain records of acceptance activities is imperative … The preamble goes on to say, "Further, the regulation does not specify quantitative data but simply requires that the results be recorded. FDA believes that it is essential for the manufacturer to maintain records which provide evidence that the product has gone through the defined acceptance activities. These records must clearly show whether the product has passed or failed the acceptance activities according to the defined acceptance criteria."

In the opinion of Ombu, the Warning Letter overreaches the regulatory requirement.

[1] The Chicago District Office cited Ohio Medical Corporation on July 22, 2009 for "There is no documentation to show inspectional results including values for measured wall thickness and results of the visual inspection; results are simply reported as passing."

[2] The Los Angeles District Office cited Phoenix Medical Devices, LLC on September 29, 2009 for "According to instruction 3.4, a summary of results are documented in the acceptance records for lead wire testing but individual test results, which would provide an accurate snapshot of actual testing, are not required."

Sampling Plans and Best Practice

On another note, the sampling procedure described above is not the best practice. Measuring data and converting it an attribute for sampling is not cost effective. The conversion throws away information and, as the result, the sample size is larger than necessary.

The best practice uses the measured values in a Z1.9 sampling plan. Typically, the Variability Unknown – Standard Deviation Method is best.

One common objection is the seemingly strange calculations used to determine the mean and standard deviation of the sample. These are artifacts from the time before the availability of hand-held calculators. The analyst laid out the data in a table format and calculated by hand, often employing a slide rule. Today, the calculations are easy to implement with a hand held calculator or spreadsheet.

The benefit of Z1.4 is a significant reduction in sample size. In Z1.9, Example 3 has a lot size of 40 units subject to Level II, Normal, AQL = 1% sampling. The sample size is 5. The corresponding Z1.4 sample size is 13. By using all the data - measured values not attributes - the variables sample size is about ⅓ of the attributes sample.