

and normal deviation. The mean and standard deviation will change as more samples are collected. If the sample averages do not converge and the system is bimodal or trimodal, the system is not under statistical control and other factors require examination. This is a big problem if the variation in the individual samples is outside of the specification limits for the product.

#### **Definition and storage**

What is the sample unit? A truck may carry 44,000 lbs. of product, but what is the discrete sample unit involved? Bulk trailers present problems in how to take a representative sample. Stratification and bulk-container cleanliness issues also require resolution. Some people pull samples during unloading to make sure all sections have an equal opportunity for sampling. Manufacturers can use special equipment for taking samples from bulk trailers, and for sampling bulk bags, as well. Smaller units are easier to define and sample.

What happens to the sample after it is taken is important to consider during the sampling process. If the samples are not handled correctly, it can affect the validity of the analytical results. This is not a question of aseptic sampling technique. Will the transport and storage of lab samples differ from the actual product? As an example, if one receives raw-material samples on ice overnight, while actual raw materials are in-transit in an insulated trailer for three days from the West Coast, is the analysis valid?

#### **Get that sample**

Manufacturers have used the same sampling plans for many years. One of the older plans, U.S. Department of Defense Military Standard 105D, was first implemented in 1963 and, with revisions, is still in use. The interesting thing about MIL STD 105D is that knowledge of the suppliers' manufacturing capability is basic to the system, since the standard calls for inspecting product from processes known to be capable of meeting the specification. The simplicity of the standard is that after finding out the AQL and lot size, the sample size is given. A random-number table determines which units are selected.

Harold F. Dodge devised one way to sample product from an unknown source: randomly choose a quantity of samples equivalent to the square root of  $N$ , plus one, where  $N$  is equal to the total number units in the lot. Many companies use this method; if the noncomplying product is not uniformly distributed, a good chance exists that a company will accept a noncomplying lot.

The word random is also important. When palletized product comes in, how random are the actual samples taken? People don't like to tear down pallets; however, dishonest suppliers have been known to bury defects inside of pallets.

Remember that with large sample units, such as a bulk bag, the formula devised by Dodge does not apply unless there is a way to take a top-to-bottom sample.

Sometimes, all a company wants to know is the general average for the incoming lot. The process can be adjusted to the new average. In this case, the variation from the average causes the problem.

Be skeptical of composite samples. Do they hide unacceptable product variation? If a company receives truckloads of raw materials, but only uses a part of the truckload in each batch, it makes sense to run samples at levels that represent actual usage.

This applies to manufacturers as well as users. If a company makes

40,000 lbs. per shift and tests a sample every hour for composition, what will a user who uses 1,000 lbs. per batch of finished product and tests every batch find? This depends on the stability of the process. W.E. Deming, Ph.D., called this the economics of sampling: the cost of looking versus the cost of not looking. Companies can determine this by a breakeven analysis of the process. Flaig refers to this as the "average time to signal." This measure says that the sampling frequency should be directly proportional to the frequency of out-of-control signals of the process. The less-stable the process is, the more frequently someone will have to take samples to know what is going on.

If a company has experience with a particular type of defect, it can design a sampling program to detect it. One example is cluster sampling. According to Flaig, defects are not "randomly distributed" when they occur consistently in a specific location. It is possible to design a specific sampling plan that will detect this cluster of nonconforming material with better accuracy than with a random sampling plan.

#### **Keeping it consistent**

Many companies take samples in-process. If they understand the product and process, in-process sampling will reduce the cost associated with rejected materials. Companies first must determine what they can actually test during the run, including what physical restrictions exist to obtaining the required analyses results. Taking a sample removes a very thin slice out of the process. Does this slice represent what is happening in general? The company must determine this if it wants to rely on the in-process data.

It is possible to do 100% machine inspection of various quality factors. Some examples include label placement, label verification, fill weight, vacuum seal "duds," soluble solids, pH, color and so forth. If automatic testing is accurate and practicable, this option warrants consideration.

#### **The point of it all**

Why is the company taking samples? Some processes have built-in adjustment steps. The sample is used to determine the current composition and calculate any adjustments that are necessary. This requires taking a series of samples from several batches and determining when the mean value becomes constant. This mixing time is used on all subsequent batches. One would repeat the analysis after the adjustment until they are confident that the process works as designed. This method works well when the raw materials and/or upstream processes vary greatly, and the company wants to maintain tight finished-product specifications.

In-process sampling also can determine if the process is still in control. However, Jonathan Cryer, Ph.D., professor emeritus, department of statistics and actuarial science, University of Iowa, Iowa City, notes that an in-control process doesn't necessarily mean manufacturing is making good product. Being in statistical control and meeting specification are different issues. The machine may work as well as it can, but that might not be good enough. A company's ability to process samples usually limits sampling frequency; if that's a problem, take samples often enough to detect changes that fall outside of normal variation.

This assumes that samples are taken at the right point in production. Flaig goes further, saying that improper sampling gives misleading results. Take care that a random sample detects nonrandom behavior.

No magic number of samples applies to every situation. Direct

knowledge of the process and product are critical if one truly wants information that will lead to better quality products and more efficient processes.

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# FAQs - Frequently Asked Questions

## Acceptance Sampling Questions

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## What are the origins of the "square root of n plus one" sampling rule?

The best that I can determine is that the rule probably had its origin in the USDA in the 1920-30's. But no confirming documents exists. There are actually three versions of the rule:

1. Take the square root of the lot size to get the sample size. Accept on zero defects. This version of the rules determines the sampling plan to use.
2. Take the square root of the number of cartons, open that number of cartons and select the required number of samples from them. In this case the sampling plan including the number of samples is already determined. For example, if the sample size is 20 and 50 cartons exist,  $\text{SQRT}(50)+1=8$  cartons must be opened. Select 3 samples from 4 cartons and 2 from the remaining 4. The square root of n plus one rule is used to

obtain a representative sample.

3. Take the square root of the number of drums, sample from this number of drums and composite the samples together to run a single test. For example, if 50 drums are received, take samples from  $\text{SQRT}(50)+1=8$  drums, composite them together and measure the characteristic of interest. The rule is used again to obtain a representative sample.

Much of the discussion seems to confuse these distinct uses. Rule 1 should never be used. Sampling plans should be selected based on operating characteristics such as AQL and LTPD using tables of sampling plans like those given in my book Guide to Acceptance Sampling or one of the many standards such as ANSI Z1.4. The operating characteristic does not depend on the lot size as explained in the article "The Effect of Lot Size". Therefore, such plans can be selected independent on lot size. One reference that might be of interest is:

Keith Borland (1950), "The Fallacy of the Square Root Sampling Rule,"  
Journal of the American Pharmaceutical Association, 39, No. 7, p373-377.

This reference describes why the square root of n plus one rule should not be used to select a sampling plan.

Rule 2 and 3 represent a reasonable compromise in many cases balancing the cost of testing with the precision of the results. However, there are certainly situations rule 2 and 3 should not be used. For example, printing defects where the process could produce 100 consecutive bad units all packed in a single carton and then correct itself.

Despite the lack of justification and documentation, this rule is commonly used. For example:

GUIDE TO INSPECTIONS OF MANUFACTURERS OF  
MISCELLANEOUS FOOD PRODUCTS - VOLUME 1

"For microscopic filth, excess shell, etc., sample the square root of the number of bags in the lot. Collect a minimum of six and a maximum of eighteen subs each consisting of 900 grams (2 lbs) taken 340 grams (2/3 lb) from each of the three bags. Collect the subs in duplicate for the 702(b) portion."

"For retail size containers, sample the square root of the number of containers in the lot with a minimum of six and a maximum of 18 - 900 gram (2 lb) subs."

"Bulk containers - collect 1 pint in duplicate from each container in lot. Sample 55 gal drums on a square root basis, collecting 1 pint from a minimum of 6 and maximum of 24 in duplicate."

**Investigators Operations Manual - FDA May 1996**

Subchapter 420, Section 427.2 on random sampling states:

"Sample size is usually described in your assignment, IOM Sample

Schedule, Compliance Program, or the applicable schedules. If none of these furnish the sample size, a general rule is to collect samples from the square root of the number of cases or shipping containers but not less than 12 or more than 36 subs in duplicate. If there are less than 12 containers, all should be sampled. Discuss sample size and 702(b) requirements with your supervisor. See IOM 422.1. "

All reference to this rule has been deleted from the 2005 version.

I would love to hear from anyone who has further references, information or examples.

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## How do statistical sampling plans/concepts apply to destructive testing?

Two issues occur with destructive testing, First is the cost of testing. With destructive testing, the cost of testing is at least as great as the cost of producing the unit. However, there are cases involving nondestructive testing where the cost of testing exceeds the cost of the unit. As the cost of testing increases, economics dictate that the sample sizes be reduced lessening the protection.

The second issue is the fact that rejected lots can be rectified by 100% inspection. For destructive testing, the choice is between release and discarding (or recycling or downgrading). However, again there are cases involving nondestructive testing where the cost of performing a 100% inspection is more expensive than the potential value of the lot, so that 100% inspection is not a viable option.

I have attempted to make the case that it is not two distinct situations, destructive versus nondestructive testing, but really a continuum from inexpensive testing to very expensive testing. The impact of this is that defects types are frequently segregated not only by severity (critical, major, minor) but also by cost of testing (visual, functional) and inspected using different sampling plans. For example major visuals might be assigned an AQL of 0.25% while major functionals might be assigned an AQL of 1.0%. Since major visuals and major functionals are of the same consequence but major visuals are easier to rectify, the AQL is set lower so that one is quicker to reject them.

More on selecting sampling plans based on economics can be found in Chapter 4 of my book [Guide to Acceptance Sampling](#). One concept, I mention in the article [Classifying Defects and Selecting AQLs](#) posted on the web site is that of break even quality. The formulas I give there are for the case of nondestructive testing only. Chapter 4 gives break even qualities for the case when 100% inspection is not possible.

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## How does acceptance sampling apply to ISO 9000 and GMPs?

ISO 9000 requires "The supplier shall establish and maintain documented procedures for the inspection and testing activities set out in the quality plan ...". The Good Manufacturing Practices (GMPs) regulations issued by the FDA has a similar requirement in Subpart H, Section 820.80. The book *The FDA and Worldwide Quality Systems Guidebook for Medical Devices* by Kim Trautman compares the two sets of requirements and provides some guidance.(pages 125-137).

My own advice is:

1. The emphasis should be on defect prevention including SPC, not inspection.
2. Prevention does not eliminate the need for inspection. Most processes produce some defects and have the potential of failing. Acceptance sampling is a required part of the quality system as indicated by ISO 9001 and the GMPs.
3. Both SPC and acceptance sampling require the routine inspection of units from the process. The trick is to use the same data for both purposes. The article "[The Importance of Trending Attribute Data](#)" talks about combining SPC and acceptance sampling for attribute (pass/fail) data. Acceptance control charts can be used in the case of variables (actual measurements) data.
4. Deciding which sampling plan to use is generally based on a risk assessment. The articles on selecting valid sampling plans, "[Statistically Valid Sampling Plans](#)" and "[Selecting Statistically Valid Sampling Plans](#)", describe the rational I generally use.
5. A good tool for performing a risk assessment is an FMEA. This can be used to establish the entire control plan, of which acceptance sampling is one part. The issue is what failures could reasonable occur, are severe enough to be of concern, and for which no other means of detection are in place. In this case, acceptance sampling can be used. However, more preferable is implementation of a mistake proofing device which either prevents the defect from being produced or ensures it does not pass by undetected. In this sense, acceptance sampling is the method of last resort. FMEA's and their relationship to acceptance sampling is described in "[Methods and Tools for Process Validation](#)".

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## What are the differences between MIL-STD-105E and ANSI/ASQ-Z1.4?

ANSI/ASQ Z1.4 (1993) is nearly identical to Mil-Std-105E. There are no changes in the tables of sampling plans. The only change in the switching rules is that ANSI Z1.4 makes the use of the limit numbers for switching to reduced optional. In addition, ANSI/ASQ-Z1.4 contains additional OC curves called scheme OC curves that describe the protection provided by the switching procedure during periods of constant quality. Numerous changes where also made to the explanatory text but which do not affect any procedures.

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## Why was MIL-STD-105E and MIL-STD-414 cancelled?

ANSI/ASC Z1.4 (1993) is nearly identical to MIL-STD-105E. Likewise ANSI/ASQC Z1.9 (1993) is very similar to MIL-STD-414. Both were cancelled to reduce costs through the elimination of duplication. Many other standards were cancelled as well where nearly equivalent civilian standards existed.

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