Using Statistics in Sampling Plans – Plans that Result in Statistical Confidence

Jacakly L. Schroeder
Statistician, Validation/Quality Engineering Specialist
Jackie Schroeder
Presenter/Facilitator

• B.S. in Chemical Engineering
• M.S. in Applied Statistics
• 22 Years at 3M
• 2 Years at Dow Chemical
• Medical Devices, Drug Combo Products
• Mfg Engineer, Product Service Engineer, Supervisor, Validation Engineer, Quality Engineer
• Validation Engineer – 8 Years
• Quality Engineering Specialist/Statistician
AGENDA

• Acceptance Sampling Plan Basics and Application
• Types of Sampling Plans and Plan Selection
• Traditional Sampling vs. Modern Acceptance Sampling Techniques
• Criteria for evaluating the effectiveness of sampling plans/or schemes
• Protection offered by a statistically based sampling plan
• Interactive Exercises (Throughout)
Regulations and Sampling Plans

• Per 21 CFR 820.250 – “Sampling plans, when used, shall be written and based on a valid statistical rationale.” 

• Assumptions on which sampling plans are based shall be verified
  – We should understand how the sample is taken (random, stratified, periodic) to represent lot
    • Sample needs to be unbiased and representative of the population sampled
Acceptance Sampling

• Popularized by during WWII to test bullets
• A SQC technique, where decision to either accept or reject lot is based on sample of lot
• Main purpose is to assure the production of lots of acceptable quality
What is a Sampling Plan?

• **Purpose:**
  – Judge whether quality level of an incoming shipment or production lot is likely to be acceptable
  – Make pass/fail or accept/reject decisions

• **Important Points:**
  – Sampling plans do not estimate the quality of the lot
  – Acceptance sampling is "the middle of the road" approach between no inspection and 100% inspection
  – Sampling plans include both a sample size and acceptance criteria
Common Application

Acceptance Sampling is commonly employed when one or several of the following hold:

• Testing is destructive

• The cost of 100% inspection is very high

• 100% inspection takes too long

• Testing is the only way to detect a “bad” part
Typical Use (Receiving)

• You received a shipment of 5,000 parts from a new supplier.
• How will you decide if the quality is good enough to put in inventory?
How Will You Decide?

1. Inspect all 5,000 parts (100% inspection)

2. Put entire shipment into inventory without inspection (0% inspection)

3. Sample via a sampling plan
   Sample a portion of the shipment and if enough parts pass the acceptance criteria release into inventory
Shipper and Receiver Agreement

For smooth transfer of product, it is important that both the shipper and receiver understand and agree on:

1. What constitutes conforming and non-conforming units
2. Specification to which the discrete units of product must conform
3. Basis on which product will be accepted
   - Shipper: Understand probability that the lot will be accepted at various quality levels
   - Receiver: Understand protection that exists to prevent acceptance of nonconforming product
Basic Approach

1. Take a representative sample of n units from lot of unknown quality (p).
2. Classify each item as conforming or nonconforming.
3. Count the number that are nonconforming.
4. Compare count to accept number a.
   - If Count ≤ a: ACCEPT
   - If Count > a: REJECT
5. Record Result – Quality Record.
Attributes
• We classify items using attributes
  – A bicycle can be red, blue, or green
  – A part can be conforming or nonconforming
  – The part is visually acceptable so it passes (P) the test; otherwise it would fail (F) the test

Variables
• We measure items using variables
  – The seal strength is 75 lbs/in
  – The part diameter is 2.5 inches
  – The fill weight is 9.8 grams
  – The line speed is 100 ft/min
Considerations for Acceptance

Sampling Plan Selection

• Sampling by attributes vs. sampling by variables
• Incoming vs. outgoing inspection
• Customer Needs
• Process considerations
  – Information on available quality
  – Integrity or past experience with vendor
  – Production Type: Continuous, Lot-by-Lot, isolated lots
  – Lot size (small lots will use different distribution for estimates)
  – Inspection costs
  – Inspection procedures
• Method of correction of nonconformities
  – None, scrap, rework, 100% rectifying inspection
Types of Sampling

Definition by ISO 3534-3 (2006)

• **Acceptance Sampling Plan:**
  – Plan which states the sample sizes to be used and the associated criteria for lot acceptance; sample without replacement

• **Acceptance Sampling Schemes:**
  – A *combination of acceptance sampling plans with switching rules* for changing from one plan to another
  – Not intended to be used as individual sampling plans
Acceptance Sampling

- Devised to serve different purposes:

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Attributes Procedure</th>
<th>Variables Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guarantee consumer and producer quality levels</td>
<td>Two-point (Schilling-Johnson tables) plan Plan</td>
<td>Two-point plan (Sommers tables Modern)</td>
</tr>
<tr>
<td>Maintain quality level at same or better</td>
<td>AQL system (Mil-Std-105 or ANSI/ASQC Z1.4) ISO 2859</td>
<td>AQL system (Mil-Std-414 or ANSI/ASQC Z1.9) ISO 3951</td>
</tr>
<tr>
<td>Guarantee average quality at same or better</td>
<td>AOQL scheme (Dodge-Romig tables) Scheme</td>
<td>AOQL (Romig plan)</td>
</tr>
<tr>
<td>Rectification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduce inspection after good quality history</td>
<td>Chain sampling plan (Dodge ChSP-1 plan) Plan</td>
<td>Narrow limit gauging plan (Schilling-Sommers tables)</td>
</tr>
<tr>
<td>Check inspection after excellent quality history</td>
<td>Skip-lot sampling plan (Dodge-Perry SkSP-2 plan)</td>
<td>Double sampling plan (Sommers tables)</td>
</tr>
<tr>
<td>Compliance sampling</td>
<td>LTPD plan (Schilling LSP plan)</td>
<td>Grand-lot scheme (Schilling)</td>
</tr>
</tbody>
</table>

Neubauer—Acceptance
Sampling Facts
AQL System (1942 – 1943)

• Sampling Scheme
  – AQL System (Acceptable Quality Level); Producer’s Quality Level
  – Specify an upper limit of Quality, AQL, not to be exceeded by the producer without penalty of excessive rejected lots.
  – MIL-STD-105 came about from a need for a sampling system which did not require 100% inspection for use in testing munitions and for other destructive tests
  – Intended for stream of lots
  – Uses switching rules
AQL (Stream of Lots)

• AQL Based Sampling Scheme

• Definition of AQL:
  – When a continuous series of lots is considered, the AQL is the quality level which, for the purposes of the sampling inspection, is the limit of a satisfactory process average.

• Schemes not intended to use as individual plans.
  – Quality levels are specified in terms of AQL for the producer, while consumer protection is afforded by the switching rules which lead to tighter plans when quality is poor.
  – Designed to: Exert pressure on producer to take corrective action if quality falls below prescribed levels and to provide rewards in terms of reduced sample size for quality improvement.
Modern Acceptance Sampling
(1990’s – Present)

OC Curve
Modern Acceptance Sampling

1. Evaluate Customer Needs and Process Considerations

2. Sampling by attributes vs. sampling by variables

3. Determine appropriate statistical performance property (i.e. percent defective, defects per quantity, etc)

4. Choose sampling risks ($\alpha, \beta$), acceptable quality level (AQL) and reject performance level (RQL)

5. Develop OC Curve
Sampling Risks

• Producers Risk
  – Alpha Risk ($\alpha$)
  – Risk of rejecting good product
    • Prob (rejecting lot of AQL quality level)

• Consumers Risk
  – Beta Risk ($\beta$)
  – Risk of accepting bad quality product
    • Prob (accepting lot at RQL (LTPD) quality level)

OC curve for sampling plan quantifies these risks
Operating Characteristic (OC) Curve

• Each sampling plan has it’s own OC curve
• Graph shows probability of lot acceptance \( (P_a) \) as a function of the lot quality level \( (p) \)
• The OC curve can help us determine the plan performance
• OC curves can be used to compare sampling plans (single, double, multiple)
Every Sampling Plan Has Its Own OC Curve

Determine the chances of passing at different defective rates.

Single: n=30, a=0
Single: n=300, a=0
Single: n=3000, a=0
OC Curve Calculated Using Following Distributions (Attribute)

- **Binomial** - Used by most statistical software programs
- **Hypergeometric** - Used when sampling from a small population. Used when lot size is not significantly greater than sample size
- **Poisson** - Typically used when evaluating defects per unit rather than fraction defective
Common OC Curve Calculation

- Binomial Distribution Formula (approximate to true distribution the Hypergeometric)
  - Accurate when:
    - \( \frac{N}{n} \geq 10 \)

\[
P_a = P\{d \leq c\} = \sum_{d=0}^{c} \frac{n!}{d! (n - d)!} p^d (1 - p)^{n-d}\]

J.L. Schroeder, June 2015
## OC Curve by Binomial Formula

<table>
<thead>
<tr>
<th>Pa</th>
<th>p</th>
<th>n=</th>
<th>c=</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.998404</td>
<td>0.01</td>
<td>50</td>
<td>3</td>
</tr>
<tr>
<td>0.982242</td>
<td>0.02</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.93724</td>
<td>0.03</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.860869</td>
<td>0.04</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.760408</td>
<td>0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.647303</td>
<td>0.06</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.532735</td>
<td>0.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.425296</td>
<td>0.08</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.330337</td>
<td>0.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.250294</td>
<td>0.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.185412</td>
<td>0.11</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.134534</td>
<td>0.12</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.095766</td>
<td>0.13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.066964</td>
<td>0.14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.046047</td>
<td>0.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.031165</td>
<td>0.16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.020778</td>
<td>0.17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.013653</td>
<td>0.18</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.008848</td>
<td>0.19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.005656</td>
<td>0.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.003569</td>
<td>0.21</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OC Curve**

![OC Curve Graph](image)

- **Fraction Defective**
- **Probability of Acceptance**

J.L. Schroeder, June 2015
Modern Acceptance Sampling
Specify a Plan

• Four values may be used to characterize the OC curve

  – Sampling Risks
  • $\alpha = \text{Producers Risk}$
  • $\beta = \text{Consumer Risk}$

  – Quality Levels
  • AQL = Acceptable Quality Level
  • RQL or LTPD = Reject Quality Level or Lot Tolerance Percent Defective

J.L. Schroeder, June 2015
What is AQL?

What is routinely accepted

• The **AQL** of a sampling plan is level of quality (*percent defective, defects per hundred units, etc.*) routinely accepted by the sampling plan.

• Quality level that the **CONSUMER** feels to be the **MAXIMUM** percent defective, that for sampling purposes, can be considered the process average.

• Products or processes at or better than the AQL are passed at least 95% (1-\( \alpha \))% of the time.
What is LTPD (AKA RQL)?

What is routinely rejected

- The **LTPD** of a sampling plan is a level of quality (*percent defective, defects per hundred units, etc.*) routinely rejected by the sampling plan.
- **LARGEST** percent defective (average) which will be rejected by the producer in response to the consumers expectations.
- Products or processes at or worse than the LTPD fail most of the time.
- Protection provided by the plan.
• Sampling plan would accept every lot (100% of the time) with fraction defective less than or equal to AQL

• Sampling plan would reject every lot (100% of the time) with fraction defective greater than AQL

• Sampling does not realize the ideal OC Curve

AQL Consumer Expectation

The Quality Engineer sets the AQL
Summary

• Purpose of a sampling plan is to make accept/reject decisions
• The AQL describes what it accepts and determines the chances of passing
• The LTPD (RQL) describes what it rejects and provides consumer protection; determines the confidence statements that can be made when passing
ATTRIBUTE SAMPLING PLANS

Single Sampling Plan Example
Basic Approach

1. Take a representative sample of \( n \) units from lot of unknown quality (p).
2. Classify each item as conforming or nonconforming.
3. Count the number that are nonconforming.
4. Compare count to accept number \( a \).
   - If \( \text{Count} \leq a \), ACCEPT.
   - If \( \text{Count} > a \), REJECT.
Attribute Sampling Plans

• Choose between single or multiple sampling plans at same protection level or performance level (same LTPD)

• Multiple sampling plans were invented to give “questionable” populations another chance in order to better understand the true proportion defective
Double Sampling Plan
(For Percent Defective or Proportion Nonconforming)

START

Take a representative sample of n1 units and count number of defectives

Count ≤ a1
ACCEPT

Count ≥ r1
REJECT

Continue To Second Stage

Take second representative sample of n2 units and count the total number of defectives in both samples

Count ≤ a2
ACCEPT

Count > a2
REJECT

Resource: Dr. Wayne Taylor
Validation Sampling Plan Class - 2008
Interactive Exercise

Which LTPD\textsubscript{0.05} Plan is Best?

Single vs. Double

Defective/Nonconforming Units

- Single: \( n=300, \ a=0 \)
- Single: \( n=630, \ a=2 \)
- Double: \( n1=325, \ a1=0, \ r1=3, \ n2=580, \ a2=3 \)

Resource: Dr. Wayne Taylor
Validation Sampling Plan Class - 2008

J.L. Schroeder, June 2015
Exercise – Attribute Single Sampling Plan

- Supplier submits a lot \( N \) of 5000 items and you subject it to acceptance sampling by attributes.
- Test defines what is conforming/nonconforming.
- Sampling plan requires random sample \( n \) of 300 units from lot.
- Sampling plan defines acceptance number \( a \) and reject number \( r \).
  - Accept shipment if 0 items nonconforming \( (a = 0) \).
  - Reject shipment if 1 or more items are nonconforming \( (r = 1) \).

In symbols:
\[
N = 5000 \\
n = 300 \\
a = 0, \ r = 1
\]

Note: This plan had AQL=0.02% LTPD_{0.05}=1%
EXERCISES USING VALIDATED SAMPLING PLAN DETERMINATION SOFTWARE
Modern Acceptance Sampling
(1990’s – Present)

• H& H Servicco Corp, Stan Hilliard, www.samplingplans.com
  – 2-Point Sampling Plans (Defective Units)
    • TP105 for Attributes
    • TP414 for Variables

• Wayne Taylor Inc., Dr. Wayne Taylor, www.variation.com
Exercise – Attribute Sampling Plan

- Select AQL, RQL, alpha, beta
- Enter values into validated software program
- Assume large lot so estimate by binomial distribution
TP105 – Sample Planner for Attributes

Two Points on the OC Curve

Producer's Point
AQL = 0.0001
Alpha = 0.05

Consumer's Point
RQL = 0.05
Beta = 0.1

Calculate AQL and RQL
Calculate Alpha and Beta

1 - Alpha
Pa
Beta
OC Curve Relationships

Fixed-n decision rule

n = 45
Ac = 0

Ac/n = 0 = Maximum sample fraction defective to accept the lot
Actual Alpha = 0.004445
Actual Beta = 0.098970

Calculate n and Ac

In Fraction Defective

J.L. Schroeder, June 2015
Sampling Plan Analyzer
For Attributes

• Select New Sampling Plan
### Sampling Plan Analyzer

#### Match Single/Double Attribute Plan

#### Sampling Plan Analyzer - [untitled] - [List Sampling Plans]

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sampling Plans</th>
<th>AQL (0.95)</th>
<th>LTPD (0.10)</th>
<th>AOQL</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defective Units</td>
<td>Single: n=411, a=2</td>
<td>0.0019924</td>
<td>0.012897</td>
<td>0.00333...</td>
<td>Fraction Defective</td>
</tr>
<tr>
<td>Defective Units</td>
<td>Double: n1=193, a1=0, r1=2, n2=311, a2=2</td>
<td>0.0014725</td>
<td>0.012899</td>
<td>0.00289...</td>
<td>Fraction Defective</td>
</tr>
</tbody>
</table>

### OC Curve

**Defective Units**
- Single: n=411, a=2
- Double: n1=193, a1=0, r1=2, n2=311, a2=2
VARIABLES SAMPLING PLANS

Single Sampling Plan Example
Variables Sampling Plan

• Use normal distribution to predict the percentage of units outside of spec

Fill Volume (ml)

Resource: Dr. Wayne Taylor
Validation Sampling Plan Class - 2008
Variables – Basic Approach

START

Take a representative sample of n units, measure each unit and calculate average (X) and standard deviation (S)

Calculate \( \hat{P}_{pk} \)

\[ \hat{P}_{pk} \geq P_{pk} \]

ACCEPT Yes No REJECT

Resource: Dr. Wayne Taylor
Validation Sampling Plan Class - 2008
Exercise – Variables Sampling

Plan – Sigma Known

- Length is parameter that material must pass.
- The product standard lists the individual specification limits for length as 45 – 90 mm.
- A sigma (σ) of 4 mm has been estimated based off 3 months of data. This gives an estimated process capability (Cp) of 1.875.

\[
C_p = \frac{(USL - LSL)}{(6 \times SD)}
\]

- Select AQL, RQL, α, β
- Calculate Accept Constant (k) and Sample Size (n) or see Tables of Variables Plans (Sommers) or Jacobson Nomograph.
- Use k and n to calculate average acceptance values; where, 
  \[A_L = LSL + k\sigma; \quad A_U = UISL - k\sigma\]

In symbols:
\[
\begin{align*}
U_{ISL} &= 90 \text{ mm} \\
L_{ISL} &= 45 \text{ mm} \\
\hat{\sigma} &= 4 \text{ mm} \\
C_p &= 1.875
\end{align*}
\]

Select:
- AQL, RQL, α, β

Calculate:
- Sample size (n) and Average Accept Limits (\(A_L, A_U\))
TP414 – Sample Planner for Variables

DECISION RULE FOR A FIXED-N SAMPLING PLAN:

\[ n \quad \text{SAMPLE SIZE} = 2 \]
\[ A_L \quad \text{REJECT IF XBAR IS LESS THAN 55.2127} \]
\[ A_U \quad \text{REJECT IF XBAR IS MORE THAN 79.7873} \]
Variables Single for Defective Units

In symbols:
- $U_{\text{isl}} = 90 \text{ mm}$
- $L_{\text{isl}} = 45 \text{ mm}$
- $\text{Sigma hat} = 4 \text{ mm}$
- $C_p = 1.875$
- $AQL = 0.01\%$
- $RQL=5\%$, $\alpha=.05$, $\beta=.1$
- $k = 2.5532$
- $n=2$
- $A_L = 55.2$
- $A_U = 79.8$

SAMPLE SIZE $= 2$

$A_L$ REJECT IF $\bar{X}$BAR IS LESS THAN 55.2127

$A_U$ REJECT IF $\bar{X}$BAR IS MORE THAN 79.7873
Sampling Plan Analyzer

Match Variables to Attribute Plan

![Sampling Plan Analyzer interface](image)

Select New/Matching Sampling Plans

- **Characteristic to Inspect:** Defective Units
- **Types of Sampling Plans:**
  - Single
  - Double
  - Variables Single

**OC Curve**

![OC Curve](image)

J.L. Schroeder, June 2015
Protection Offered By A Sampling Plan
Confidence Statements

• Sampling plans are designed to demonstrate that the product tested meets a specified performance level ($LTPD_\beta$) with certain confidence (typically $1 - \beta$ or 95%).

<table>
<thead>
<tr>
<th>Sampling Plan</th>
<th>AQL</th>
<th>$LTPD_{0.05}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>$n=300, a=0$</td>
<td>0.02%</td>
<td>1%</td>
</tr>
</tbody>
</table>

— Passing the plan $n=300, a=0$ allows one to state: “With 95% confidence the defect level is below 1% defective.”
Determine Plan Protection

Make Confidence Statement

• Make Confidence Statement if pass sampling plan
  – If lot passes sampling plan, one can be 95% confident that lot percent defective is below the LTPD_β

• Passing the sampling plan n=300, a=0 allows one to state:
  – “With 95% confidence the percent nonconforming units are less than 1% defective”
  – “With 95% confidence the percent conforming units are greater than 99% conforming”

Resource: Taylor Enterprises Statistical Procedures For Medical Device Industry 2013
Statistical Confidence

• CGMP regulations regarding sampling set forth a number of requirements for validation:
  – Sampling plan must result in statistical confidence (§ 211.165(c) and (d))

Make Confidence Statement if pass sampling plan
Questions?
Contact Information

Jlaclyn L. Schroeder – 3M Company
Title: Statistician, Process Validation/Quality Specialist
E-mail: jlschroeder2@mmm.com
Work Phone: 605-696-1355

Dr. Wayne Taylor, Taylor Enterprises
Website: www.variation.com

Stan Hilliard, H & H Servicco Corp
Website: www.samplingplans.com
References


3. Acceptance Sampling and Control Class, Neubauer, 2012

4. Standards: ANSI Z1.4, ANSI Z1.9, ISO 2859-1, ISO 3951-1