Session 8:

Sampling and Acceptable Quality Limits (AQL)

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Objectives

- Understand what you can infer from sample testing
- Understand how to choose a sample size and make inferences about the finished product from ISO 2859-1
- Learn options for conducting and interpreting sample tests during production

What is Statistics?

- Set of techniques for reducing large quantities of numerical data to a size and form which can be interpreted
- Provides formal rules for interpretation
- Intuitive interpretation may be done from summary statistics or graphs

Why Statistics Are Important

- The acceptability of your finished product is assessed by testing a sample
- Testing samples during production ensures good quality and helps eliminate waste
- Sampling approach based on production stage

Statistics, Certification, and Prequalification

- Under ISO 13485, Clause 8, factories must collect and analyze appropriate data for:
  - Conformity to requirements
  - Trends in production
  - Opportunities for corrective action

Why Do Sampling and Not 100% Testing?

- Many tests are destructive, so 100% testing is impossible
- Testing is costly
- Testers get bored and lose concentration

Statistics in Acceptance Testing

How statistical concepts are used in ISO 4074

What is the Aim of the Tests in ISO 4074?

- Purchasers must accept a small proportion of noncomplying condoms because no manufacturer can make perfect condoms
- The standard limits the proportion of noncomplying condoms to:
  - 1.5% for inflation
  - 0.25% for holes
- These limits are called the AQL

Acceptable Quality Limit (AQL)

- MAXIMUM acceptable proportion defective in production process (specified in ISO 4074 for each test)
- Frequency of lot rejections increases as process average exceeds AQL
- Manufacturers expected to make the process average as low as possible
- (The process average is the long term average proportion defective)

How Are the Tests Assessed?

- The test for holes inherently an attributes test
- The inflation test is turned into an attributes test
- Sample sizes and pass/fail limits can be calculated BUT
- Most people use tables in standards, especially ISO 2859-1

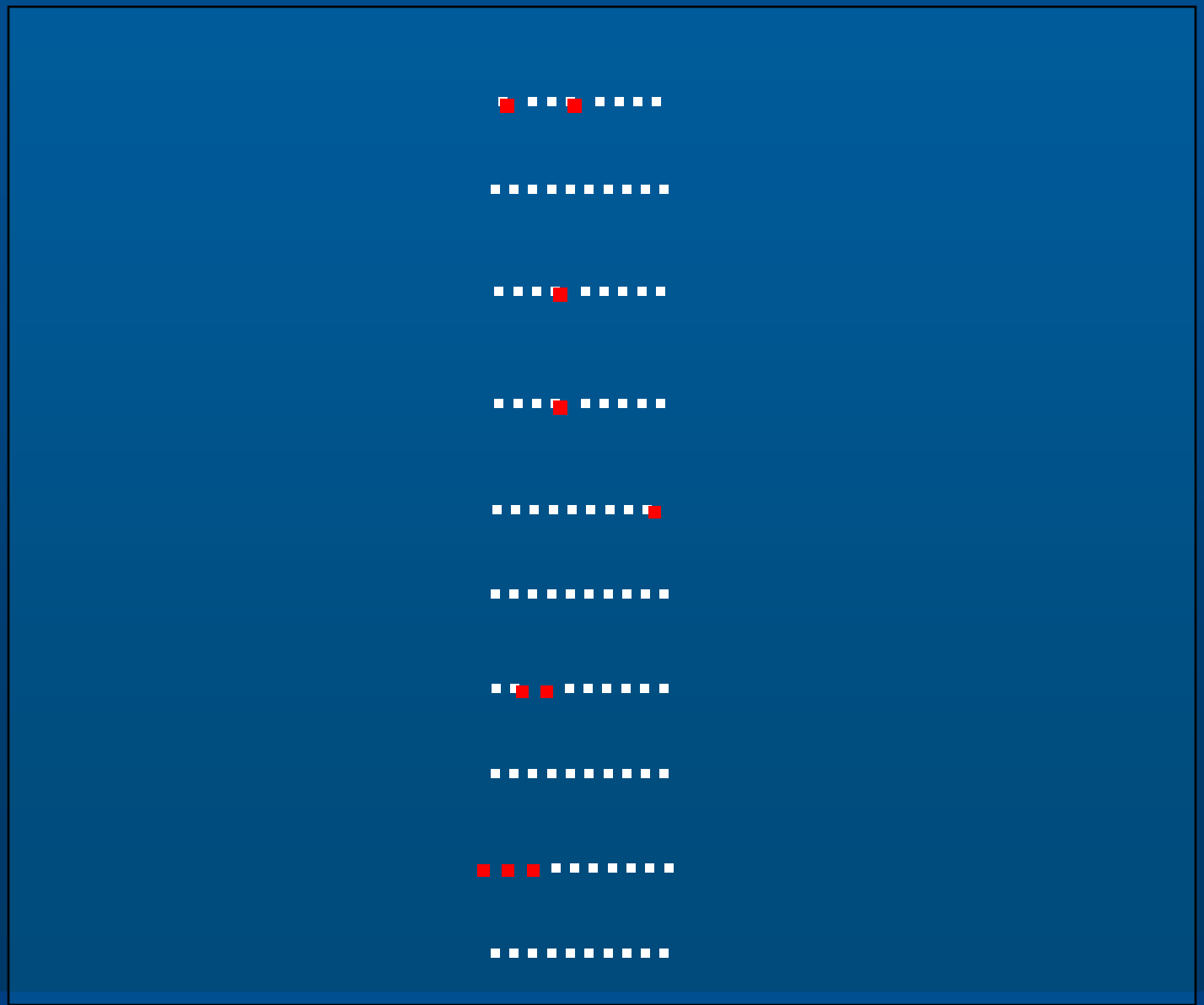
Example Using the Holes Test

- Do our condoms pass the holes test?
- Postulate “null hypothesis” that condoms just meet the requirements
- Calculate the probability of finding 0, 1, 2, 3, 4…….holes
- If the probability of finding more than x holes is less than (say) 5%, and you find more than x holes, then sufficient to say the lot fails

Sampling Example

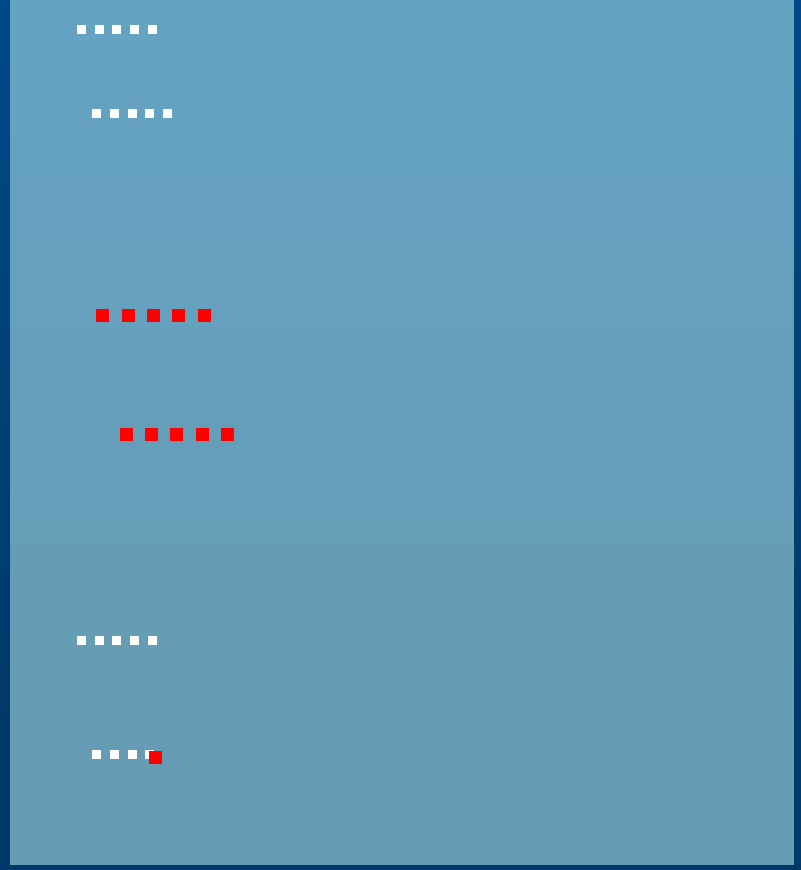
- There’s a box with 100 things in it
- You can’t see into the box, but you can reach in
- Some of the things are red; some are white
- You reach in and take ten things out randomly
- What will you get?

Sampling Example



Sampling Result

Could be any of:



- All white OR
- All red OR
- OR any number of red things between 2 and 9
- The most likely outcome is: 1 red one and 9 white ones
- But the result may or may not be indicative of the what's in the box

Sampling “Error”

- The smaller the sample, the more “fuzzy” the result
- Can reduce risk of “error” by using larger sample
- From the binomial distribution, you can calculate the sample size needed to give any chosen risk of rejecting a marginal batch, and of accepting a batch that has a given level of defects

Possible Outcomes of Sample Test

Test result ► / Product ▼	Sample passes (accept hypothesis)	Sample fails (reject hypothesis)
Product is good	Correct decision	Type 1 or α error
Product is bad	Type 2 or β error	Correct decision

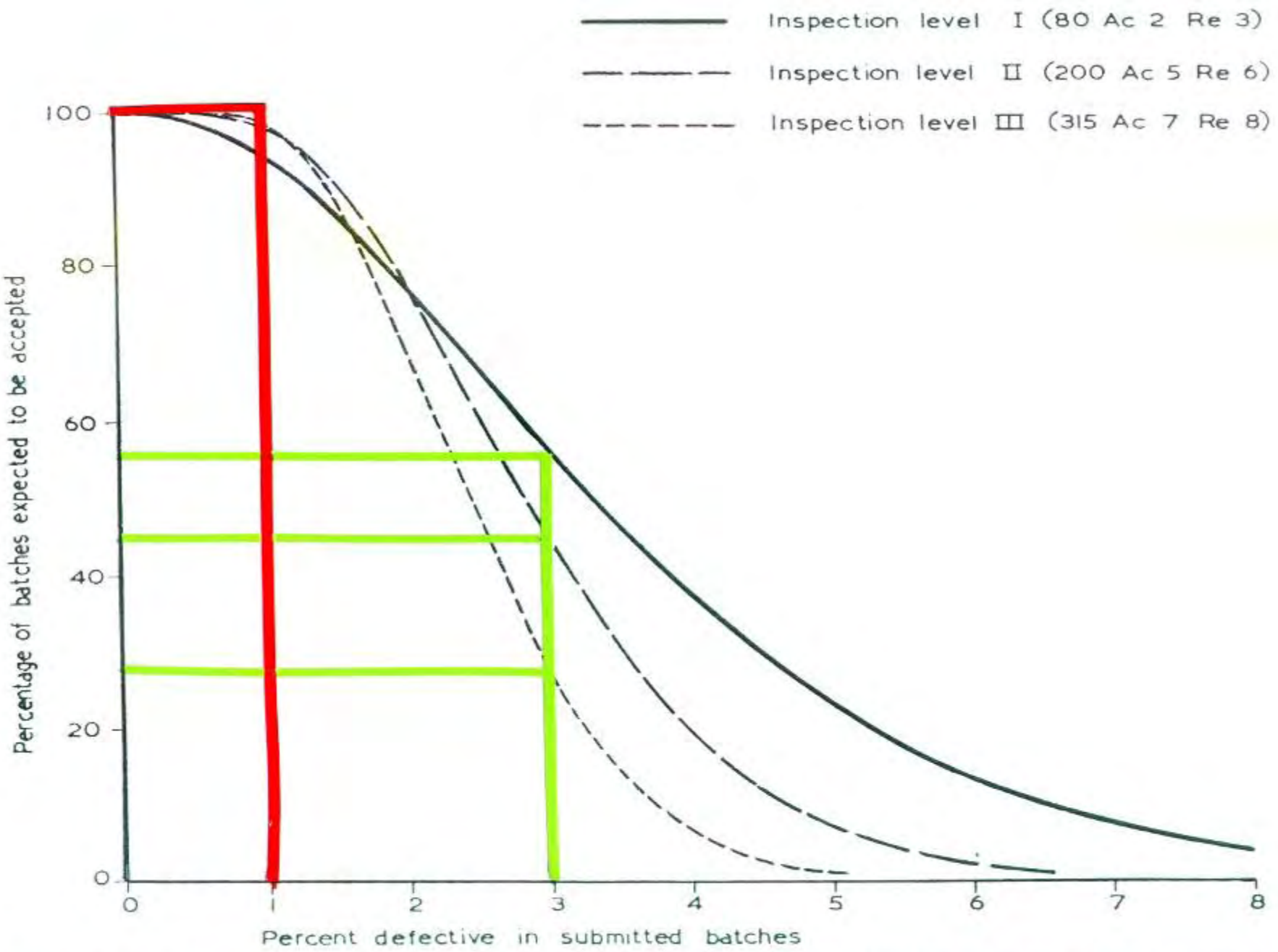


Fig. 12. COMPARISON OF OC CURVES FOR DETERMINING INSPECTION LEVEL. AQL 1% DEFECTIVE, NORMAL INSPECTION

Questions?

Ways to Choose Sampling Plans

- Do a calculation based on Type 1 and Type 2 error risks
- Use ISO 2859–1
- Use ISO 2859–2 (receipt testing)
- Use ISO 2859–3 (skip-lot schemes)
- Choose custom scheme
- ISO 2859–1 is most commonly used

Sampling in Practice

- Use standards for sample sizes and accept/reject criteria (ie don’t do the maths yourself)
- For attributes testing, ISO 2859-1 is commonly used for final release inspection
- Generally requires 95% to 99% certainty that the product is bad before rejecting it

Sampling Choices

- How certain do we need to be that an accepted batch really is good?
  - This determines the “inspection level”
  - ISO 2859–1 allows seven levels
  - ISO 4074 stipulates inspection levels for each test
- ISO 4074 requires use of ISO 2859-1

More Sampling Choices…

- Which method of sampling do we want?
  - Single, double, or multiple?
- Do we use normal, tightened, or reduced sampling?

Inspection Levels

- Three levels for general use:
  - **GII**: default choice
  - **GIII**: for critical defects
  - **GI**: if cost dictates
- Four “special” levels: **S1** to **S4**
  - Use these for less important properties

Single, Double, or Multiple Sampling?

- Overall outcome is the same
- Multiple sampling requires fewest samples; single requires most
- With very good or very bad batches, multiple sampling requires very few samples
- With marginal batches, multiple requires the most samples
- Single sampling is simplest to implement; double, next; multiple, most complex

Normal, Tightened, or Reduced?

- Sampling starts with *normal* sampling
- If two out of any five consecutive batches fail, ISO 2859–1 REQUIRES a change to *tightened* inspection
- After five batches in a row pass, then you can switch back to *normal* inspection
- These switches are mandatory

Normal, Tightened, or Reduced?
(continued)

- You MAY implement *reduced* sampling if the sampling score is >30:
  - Normally this means ten consecutive batches have passed on normal inspection one step tighter than required, and production sampling is continuous
- If a batch fails, or if production becomes irregular, then you must switch back to *normal* sampling

Steps for Using ISO 2859–1

- Know the AQL for the test
- Choose the inspection level or follow product standard or specification
- Know the batch size
- Go to the first table and get the code letter
- Decide on single, double, or multiple
- Look at the test history to decide on normal, tightened, or reduced
- Go to the appropriate table to find sample size and pass/fail numbers

Table 1 - Sample size code letters (see 10.1 and 10.2)

Lot size	Special inspection levels				General inspection levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	E	F
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1 200	C	C	E	F	G	J	K
1 201 to 3 200	C	D	E	G	H	K	L
3 201 to 10 000	C	D	F	G	J	L	M
10 001 to 35 000	C	D	F	H	K	M	N
35 001 to 150 000	D	E	G	J	L	N	P
150 001 to 500 000	D	E	G	J	M	P	Q
500 001 and over	D	E	H	K	N	Q	R

Table 2-A — Single sampling plans for normal inspection (Master table)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																										
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45
C	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧
D	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧	⇧
E	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧	⇧	⇧
F	20	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧
G	32	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧
H	50	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
J	80	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
K	125	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
L	200	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
M	315	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
N	500	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
P	800	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
Q	1 250	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
R	2 000	⇧	⇧	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

Table 3-A — Double sampling plans for normal inspection (Master table)

Sample	Sample size	Cumulative sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																								
			0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400
			Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
			⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	*	⇩	⇩	*	*	*	*	*	*	*
First	2	2															⇧		0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16
Second	2	4														*		⇩	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27
First	3	3															⇩	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	17 22
Second	3	6														*	⇧	⇩	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27	37 38
First	5	5													⇩	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	17 22	25 31	
Second	5	10												*	⇧	⇩	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27	37 38	56 57	
First	8	8											⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	17 22	25 31		
Second	8	16											*	⇩	⇧	⇩	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27	37 38		
First	13	13										⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16					
Second	13	26										*	⇩	⇧	⇩	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27				
First	20	20									⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16						
Second	20	40									*	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27						
First	32	32								⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16							
Second	32	64								*	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27							
First	50	50							⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16								
Second	50	100							*	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27								
First	80	80					⇩	⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16									
Second	80	160					*	⇧	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27									
First	125	125				⇩	⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16										
Second	125	250				*	⇧	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27										
First	200	200			⇩	⇩	⇩	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩
Second	200	400			*	*	⇧	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27										
First	315	315		⇩	⇩	⇧	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
Second	315	630		*	⇧	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27												
First	500	500	⇩	⇩	⇩	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
Second	500	1 000	*	⇧	⇩	⇧	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27													
First	800	800	⇩	⇩	⇩	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
Second	800	1 600	*	⇧	⇩	1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27														
First	1 250	1 250	⇧	⇧	0 2	0 3	1 3	2 5	3 6	5 9	7 11	11 16	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧	⇧
Second	1 250	2 500			1 2	3 4	4 5	6 7	9 10	12 13	18 19	26 27															

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

Table 4-A — Multiple sampling plans for normal inspection (Master table) (*continued*)

Sample size code letter	Sample	Sample size	Cumulative sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																											
				0,010		0,015		0,025		0,040		0,065		0,10		0,15		0,25		0,40		0,65		1,0		1,5		2,5		4,0		6,5	
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
H	First	13	13	⇩		⇩		⇩		⇩		⇩		⇩		⇩		*		⇧		⇩		#	2	#	2	#	3	#	4	0	4
	Second	13	26																					0	2	0	3	0	3	1	5
	Third	13	39																					0	2	0	3	1	4	2	6
	Fourth	13	52																					0	2	1	3	2	5	4	7
	Fifth	13	65																					1	2	3	4	4	5	6	7
J	First	20	20															⇧		⇩		#	2	#	2	#	3	#	4	0	4
	Second	20	40																			0	2	0	3	0	3	1	5	1	6
	Third	20	60															*				0	2	0	3	1	4	2	6	3	8
	Fourth	20	80																			0	2	1	3	2	5	4	7	5	9
	Fifth	20	100											⇩		⇩		⇩		⇩		1	2	3	4	4	5	6	7	9	10
K	First	32	32													⇧		⇩		#	2	#	2	#	3	#	4	0	4	0	5
	Second	32	64																	0	2	0	3	0	3	1	5	1	6	3	8
	Third	32	96											*						0	2	0	3	1	4	2	6	3	8	6	10
	Fourth	32	128																	0	2	1	3	2	5	4	7	5	9	9	12
	Fifth	32	160									⇩		⇩		⇩		⇩		1	2	3	4	4	5	6	7	9	10	12	13
L	First	50	50											⇧		⇩		#	2	#	2	#	3	#	4	0	4	0	5	1	7
	Second	50	100															0	2	0	3	0	3	1	5	1	6	3	8	4	10
	Third	50	150											*				0	2	0	3	1	4	2	6	3	8	6	10	8	13
	Fourth	50	200															0	2	1	3	2	5	4	7	5	9	9	12	12	17
	Fifth	50	250							⇩		⇩		⇩		⇩		1	2	3	4	4	5	6	7	9	10	12	13	18	19
M	First	80	80									⇧		⇩		#	2	#	2	#	3	#	4	0	4	0	5	1	7	2	9
	Second	80	160													0	2	0	3	0	3	1	5	1	6	3	8	4	10	7	14
	Third	80	240							*						0	2	0	3	1	4	2	6	3	8	6	10	8	13	13	19
	Fourth	80	320													0	2	1	3	2	5	4	7	5	9	9	12	12	17	20	25
	Fifth	80	400	⇩		⇩		⇩				⇩		⇩		1	2	3	4	4	5	6	7	9	10	12	13	18	19	26	27

Sample size code letter	Sample	Sample size	Cumulative sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																											
				10		15		25		40		65		100		150		250		400		650									
				Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re								
H	First	13	13	0	5	1	7	2	9	⇧		⇧		⇧		⇧		⇧		⇧		⇧									
	Second	13	26	3	8	4	10	7	14																						
	Third	13	39	6	10	8	13	13	19																						
	Fourth	13	52	9	12	12	17	20	25																						
	Fifth	13	65	12	13	18	19	26	27																						
J	First	20	20	1	7	2	9	⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧									
	Second	20	40	4	10	7	14																								
	Third	20	60	8	13	13	19																								
	Fourth	20	80	12	17	20	25																								
	Fifth	20	100	18	19	26	27																								
K	First	32	32	2	9	⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧									
	Second	32	64	7	14																										
	Third	32	96	13	19																										
	Fourth	32	128	20	25																										
	Fifth	32	160	26	27																										
L	First	50	50	4	10	⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧									
	Second	50	100	7	14																										
	Third	50	150	13	19																										
	Fourth	50	200	20	25																										
	Fifth	50	250	26	27																										
M	First	80	80	⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧		⇧									
	Second	80	160	7	14																										
	Third	80	240	13	19																										
	Fourth	80	320	20	25																										
	Fifth	80	400																												

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

* = Use the corresponding single sampling plan (or alternatively use the double sampling plan below, where available).

++ = Use the corresponding double sampling plan (or alternatively use the mutliple sampling plan below, where available).

\# = Acceptance is not permitted for this sample size.

Table 10-L-2 — Sampling plans for sample size code letter L

Type of sampling plan	Cumulative sample size	Acceptance Quality Limit, normal inspection (in percent nonconforming and nonconformities per 100 items)																	
		< 0,065	0,065	0,10		0,15	0,25	0,40	0,65	1,0	1,5		2,5		4,0		6,5	> 6,5
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
Single	200	⇓	0 1				1 2	2 3	3 4	5 6	7 8	8 9	10 11	12 13	14 15	18 19	21 22	⇑
Double	125	⇓	*	use	use	use	0 2	0 3	1 3	2 5	3 6	4 7	5 9	6 10	7 11	9 14	11 16	⇑
	250			code	code	code	1 2	3 4	4 5	6 7	9 10	10 11	12 13	15 16	18 19	23 24	26 27	
				letter	letter	letter												
Multiple	50	⇓	*	K	N	M	# 2	# 2	# 3	# 4	0 4	0 4	0 5	0 6	1 7	1 8	2 9	⇑
	100						0 2	0 3	0 3	1 5	1 6	2 7	3 8	3 9	4 10	6 12	7 14	
	150						0 2	0 3	1 4	2 6	3 8	4 9	6 10	7 12	8 13	11 17	13 19	
	200						0 2	1 3	2 5	4 7	5 9	6 11	9 12	11 15	12 17	16 22	20 25	
	250						1 2	3 4	4 5	6 7	9 10	10 11	12 13	15 16	18 19	23 24	26 27	
		< 0,10	0,10		0,15	0,25	0,40	0,65	1,0	1,5		2,5		4,0		6,5		> 6,5
		Acceptance Quality Limit, tightened inspection (in percent nonconforming and nonconformities per 100 items)																

⇑ = use next preceding sample size code letter for which acceptance and rejection numbers are available

⇓ = use next subsequent sample size code letter for which acceptance and rejection numbers are available

Ac = Acceptance number

Re = Rejection number

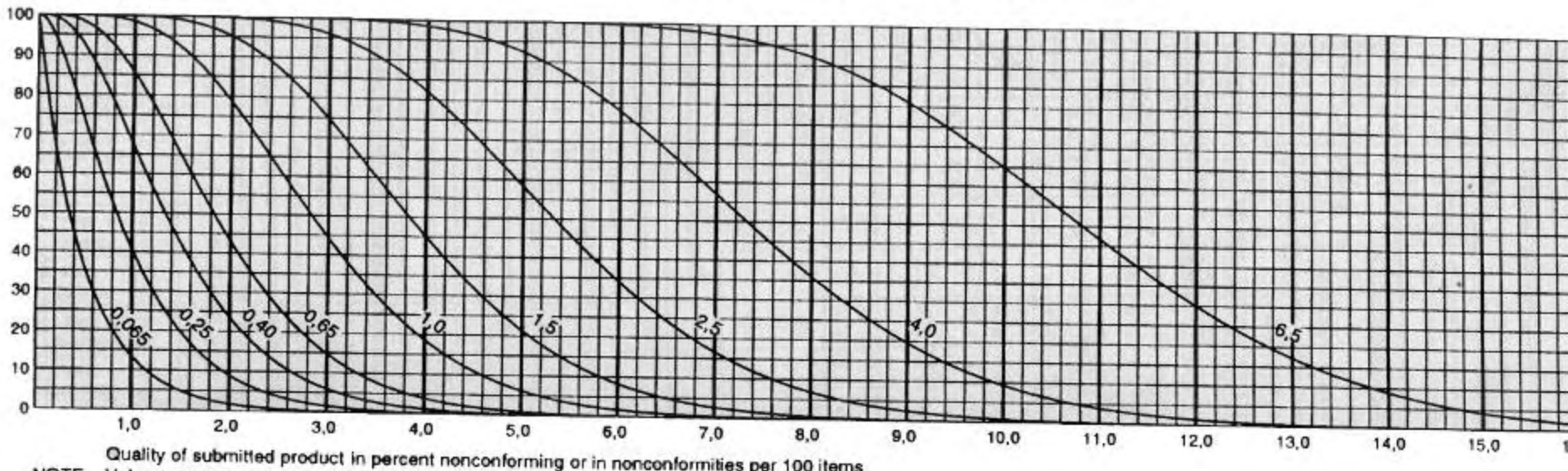
* = use single sampling plan above (or alternatively use code letter P)

\# = acceptance not permitted at this sample size

Table 10-L — Tables for sample size code letter L (Individual plans)

Chart L Operating characteristic curves for single sampling plans

(Curves for double and multiple sampling are matched as closely as practicable)



NOTE Values on curves are Acceptance Quality Limits (AQLs) for normal inspection.

Table 10-L-1 — Tabulated values for operating characteristic curves for single sampling plans

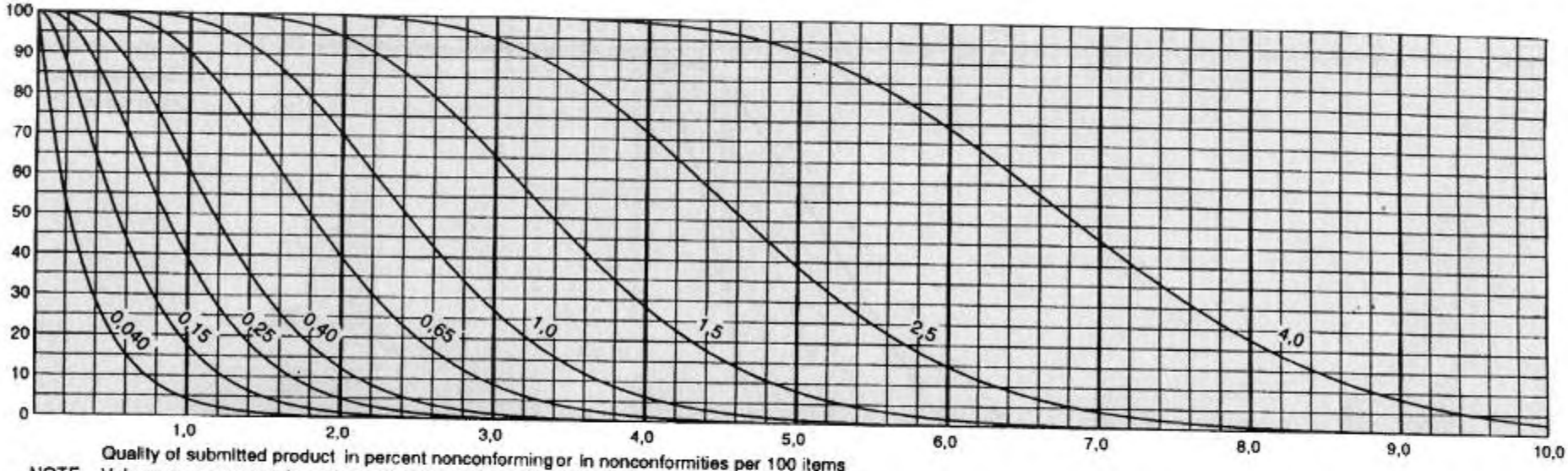
P_a	Acceptance Quality Limit, normal inspection (in percent nonconforming and nonconformities per 100 items)																							
	0,065	0,25	0,40	0,65	1,0	1,5		2,5		4,0		6,5	0,065	0,25	0,40	0,65	1,0	1,5		2,5		4,0		6,5
	p (in percent nonconforming)												p (in nonconformities per 100 items)											
99,0	0,00503	0,074	0,219	0,414	0,900	1,47	1,77	2,42	3,10	3,80	5,28	6,43	0,00503	0,074	0,218	0,412	0,893	1,45	1,75	2,39	3,05	3,74	5,17	6,29
95,0	0,0256	0,178	0,410	0,686	1,31	2,01	2,37	3,11	3,89	4,68	6,31	7,57	0,0256	0,178	0,409	0,683	1,31	1,99	2,35	3,08	3,84	4,62	6,22	7,45
90,0	0,0527	0,266	0,552	0,875	1,58	2,34	2,73	3,54	4,36	5,20	6,91	8,22	0,0527	0,266	0,551	0,872	1,58	2,33	2,72	3,51	4,32	5,15	6,84	8,12
75,0	0,144	0,481	0,864	1,27	2,11	2,99	3,43	4,33	5,23	6,15	8,00	9,40	0,144	0,481	0,864	1,27	2,11	2,98	3,42	4,31	5,21	6,12	7,95	9,34
50,0	0,346	0,838	1,33	1,83	2,83	3,83	4,33	5,33	6,32	7,32	9,32	10,8	0,347	0,839	1,34	1,84	2,84	3,83	4,33	5,33	6,33	7,33	9,33	10,8
25,0	0,691	1,34	1,95	2,54	3,69	4,81	5,36	6,46	7,55	8,63	10,8	12,4	0,693	1,35	1,96	2,55	3,71	4,84	5,40	6,51	7,61	8,70	10,9	12,5
10,0	1,14	1,93	2,64	3,31	4,59	5,82	6,42	7,60	8,76	9,91	12,2	13,8	1,15	1,94	2,66	3,34	4,64	5,89	6,50	7,70	8,89	10,1	12,4	14,1
5,0	1,49	2,35	3,11	3,83	5,18	6,47	7,10	8,33	9,54	10,7	13,1	14,8	1,50	2,37	3,15	3,88	5,26	6,57	7,22	8,48	9,72	10,9	13,3	15,1
1,0	2,28	3,27	4,14	4,93	6,42	7,82	8,50	9,82	11,1	12,4	14,8	16,6	2,30	3,32	4,20	5,02	6,55	8,00	8,70	10,1	11,4	12,7	15,3	17,2
	0,10	0,40	0,65	1,0	1,5		2,5		4,0		6,5		0,10	0,40	0,65	1,0	1,5		2,5		4,0		6,5	
	Acceptance Quality Limit, tightened inspection (in percent nonconforming and nonconformities per 100 items)																							

NOTE Binomial distribution used for entries corresponding to inspection for nonconforming items, Poisson for inspection for number of nonconformities.

Table 10-M — Tables for sample size code letter M (Individual plans)

Chart M Operating characteristic curves for single sampling plans

(Curves for double and multiple sampling are matched as closely as practicable)



NOTE Values on curves are Acceptance Quality Limits (AQLs) for normal inspection.

Table 10-M-1 — Tabulated values for operating characteristic curves for single sampling plans

P_a	Acceptance Quality Limit, normal inspection (in percent nonconforming and nonconformities per 100 items)																							
	0,040	0,15	0,25	0,40	0,65	1,0		1,5		2,5		4,0	0,040	0,15	0,25	0,40	0,65	1,0		1,5		2,5		4,0
	p (in percent nonconforming)												p (in nonconformities per 100 items)											
99,0	0,00319	0,047	0,139	0,262	0,570	0,929	1,12	1,53	1,95	2,40	3,33	4,05	0,00319	0,047	0,138	0,261	0,567	0,923	1,11	1,51	1,94	2,37	3,28	3,99
95,0	0,0163	0,113	0,260	0,435	0,833	1,27	1,50	1,97	2,46	2,96	3,99	4,78	0,0163	0,113	0,260	0,434	0,830	1,26	1,49	1,96	2,44	2,94	3,95	4,73
90,0	0,0334	0,169	0,350	0,555	1,00	1,48	1,73	2,24	2,76	3,29	4,37	5,20	0,0334	0,169	0,350	0,554	1,00	1,48	1,72	2,23	2,74	3,27	4,34	5,16
75,0	0,0913	0,305	0,549	0,805	1,34	1,89	2,17	2,74	3,32	3,90	5,07	5,95	0,0913	0,305	0,548	0,805	1,34	1,89	2,17	2,74	3,31	3,89	5,05	5,93
50,0	0,220	0,532	0,848	1,16	1,80	2,43	2,75	3,38	4,02	4,65	5,92	6,87	0,220	0,533	0,849	1,17	1,80	2,43	2,75	3,39	4,02	4,66	5,93	6,88
25,0	0,439	0,853	1,24	1,62	2,35	3,06	3,41	4,11	4,81	5,49	6,86	7,87	0,440	0,855	1,24	1,62	2,36	3,07	3,43	4,13	4,83	5,52	6,90	7,92
10,0	0,728	1,23	1,68	2,11	2,92	3,71	4,09	4,85	5,59	6,33	7,77	8,84	0,731	1,23	1,69	2,12	2,94	3,74	4,13	4,89	5,64	6,39	7,86	8,95
5,0	0,947	1,50	1,99	2,44	3,31	4,13	4,54	5,33	6,10	6,86	8,36	9,46	0,951	1,51	2,00	2,46	3,34	4,17	4,58	5,38	6,17	6,95	8,47	9,60
1,0	1,45	2,09	2,64	3,15	4,11	5,01	5,44	6,29	7,12	7,93	9,51	10,7	1,46	2,11	2,67	3,19	4,16	5,08	5,52	6,40	7,24	8,08	9,71	10,9
	0,065	0,25	0,40	0,65	1,0		1,5		2,5		4,0		0,065	0,25	0,40	0,65	1,0		1,5		2,5		4,0	
	Acceptance Quality Limit, tightened inspection (in percent nonconforming and nonconformities per 100 items)																							

NOTE Binomial distribution used for entries corresponding to inspection for nonconforming items, Poisson for inspection for number of nonconformities

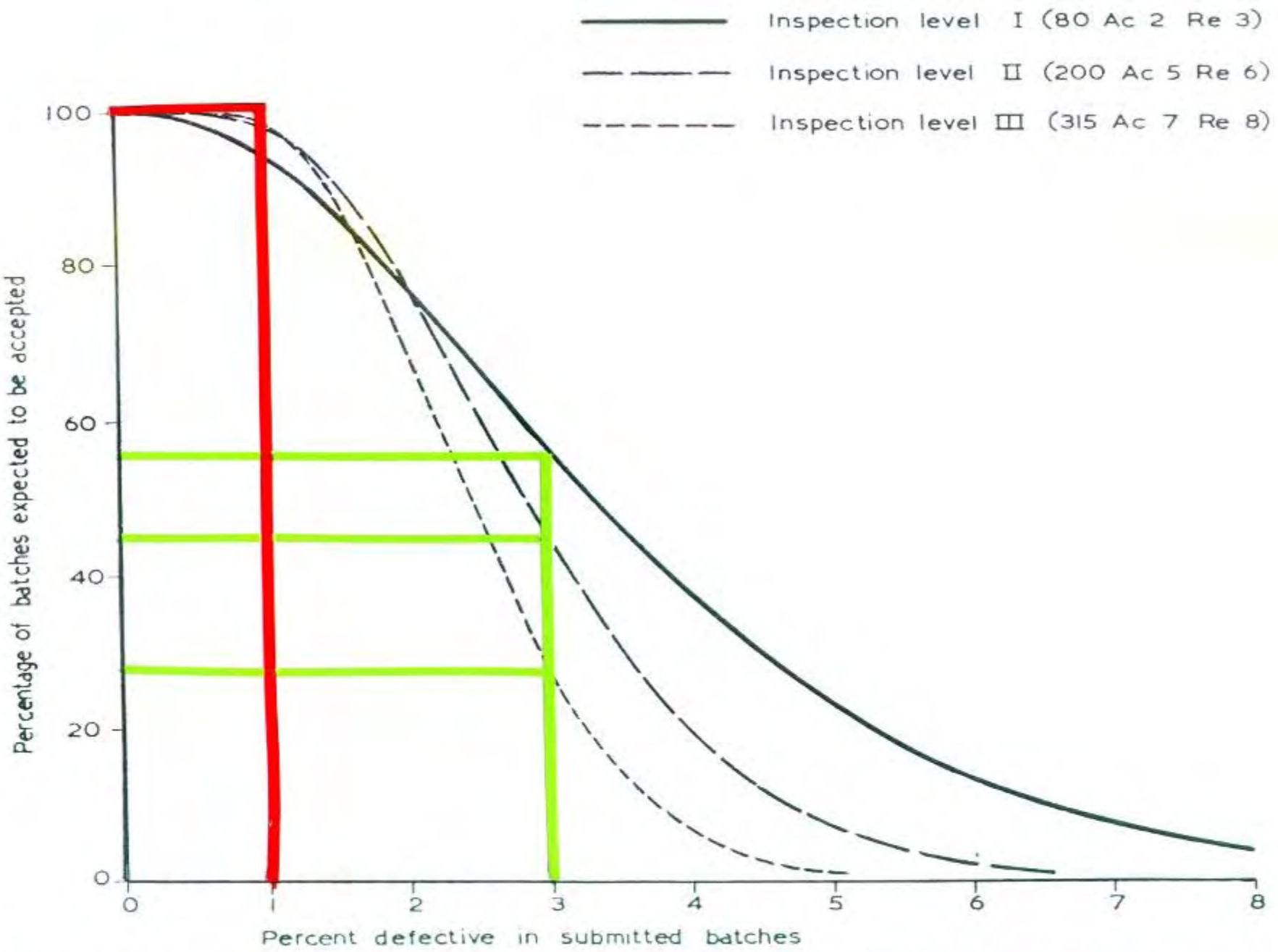


Fig. 12. COMPARISON OF OC CURVES FOR DETERMINING INSPECTION LEVEL. AQL 1% DEFECTIVE, NORMAL INSPECTION

Effectiveness of Sample Testing

- Very bad batches will most likely be rejected
- Good batches will most likely be accepted
- Marginally unacceptable batches are more likely to be accepted than rejected
- BUT – if you are operating at, say 1.5 times the AQL, you can expect say 10% percent rejections

Passing the Tests

- If the process average equals the AQL, ***1 lot in 20*** to ***1 in 100*** will be rejected
- To ensure that products are almost never rejected due to chance, the process average should be 0.3 times the AQL

Questions?

Small Group Exercise

In-Process Testing

Why Test During Production?

- As condoms move through production, investment in them grows
- Good to identify problems early in the process
- Better to get information by sublot and take corrective action if needed

Attributes and Variables Tests

- The tests in ISO 4074 are all attributes tests
- Information is lost in transforming data for assessment on the basis of variables

Attributes and Variables Tests (continued)

- Attributes tests good for regulatory purposes
- Loss of data usually means larger samples
- For manufacturing purposes, use of the actual data (variables) yields more information from smaller sample size
- ISO 3951: sampling by variables

Approaches to Using Variables in Manufacturing

- Use ISO 3951

  Two variants:

  - The s method
  - The sigma (σ) method

- Use control charts (also good for attributes)

ISO 3951

- Analogous to ISO 2859–1
- Uses same AQLs
- Uses same inspection levels
- Uses similar switching rules
- Relies on normal or near-normal distribution
- Variants
  - **s method**: if the process SD is not known
  - **Sigma (σ) method**: if the process SD is known

Using ISO 3951

- Establish acceptability limits
- Know your sublot size
- Select your sampling level
- Find the sample size
- Calculate the quality statistics
- Look at limits in ISO 3951 tables

Using ISO 3951: Sample Size

Table I-B — Sample size code letters and sample sizes for normal inspection

Method		"s"	"a"									
Acceptable quality level		All AQL	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10,0
Sample size code letter	B	3	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
	C	4						2	2	2	2	3	3
	D	5					2	2	2	3	3	3	4
	E	7			2	2	3	3	3	4	4	5	5
	F	10		3	3	3	4	4	4	5	5	6	7
	G	15	4	4	4	5	5	6	6	7	8	9	11
	H	20	5	5	6	6	7	7	8	9	10	12	14
	I	25	6	6	7	8	8	9	10	11	13	15	17
	J	35	8	9	9	10	11	12	14	15	18	20	24
	K	50	11	12	13	14	16	17	19	22	25	29	33
	L	75	16	17	19	21	23	25	28	32	36	42	49
	M	100	22	23	25	27	30	33	36	42	48	55	64
	N	150	31	34	37	40	44	49	54	61	70	82	95
	P	200	42	45	49	54	59	65	71	81	93	109	127

Equivalent attributes sample (ISO 2859)	
Code letter	Sample size
B	3
C	5
D	8
E	13
F	20
G	32
H	50
—	—
J	80
K	125
L	200
M	315
N	500
P	800

ISO 3951: s Method Normal

"*s*" method

Table II-A — Single sampling plans for normal inspection (master table) : "*s*" method

Sample size code letter	Sample size	Acceptable quality level (normal inspection)										
		0,10	0,15	0,25	0,40	0,65	1,00	1,50	2,50	4,00	6,50	10,00
		k	*k*	*k*	*k*	*k*	*k*	*k*	*k*	*k*	*k*	*k*
B	3								1,12	0,958	0,765	0,566
C	4						1,45	1,34	1,17	1,01	0,814	0,617
D	5					1,65	1,53	1,40	1,24	1,07	0,874	0,675
E	7			2,00	1,88	1,75	1,62	1,50	1,33	1,15	0,955	0,755
F	10		2,24	2,11	1,98	1,84	1,72	1,58	1,41	1,23	1,03	0,828
G	15	2,42	2,32	2,20	2,06	1,91	1,79	1,65	1,47	1,30	1,09	0,886
H	20	2,47	2,36	2,24	2,11	1,96	1,82	1,69	1,51	1,33	1,12	0,917
I	25	2,50	2,40	2,26	2,14	1,98	1,85	1,72	1,53	1,35	1,14	0,936
J	35	2,54	2,45	2,31	2,18	2,03	1,89	1,76	1,57	1,39	1,18	0,969
K	50	2,60	2,50	2,35	2,22	2,08	1,93	1,80	1,61	1,42	1,21	1,00
L	75	2,66	2,55	2,41	2,27	2,12	1,98	1,84	1,65	1,46	1,24	1,03
M	100	2,69	2,58	2,43	2,29	2,14	2,00	1,86	1,67	1,48	1,26	1,05
N	150	2,73	2,61	2,47	2,33	2,18	2,03	1,89	1,70	1,51	1,29	1,07
P	200	2,73	2,62	2,47	2,33	2,18	2,04	1,89	1,70	1,51	1,29	1,07

Use of ISO 3951

- Use s method (simpler, fewer assumptions)
- Remember assumption of normality
- Acceptability limits must be determined
- Even if not used, gives a good guide to sample size for control charts

Control Charts

- A simple, visual method of keeping track of product quality
- You plot mean and SD results (or number of holes) as a function of time (or sublot)
- You establish warning and action levels in advance
- You observe the control chart for trends

Control Charts
(continued)

- Proven for reducing scrap rate
- Effective for defect prevention
- Prevents unnecessary process adjustments
- Provides diagnostic information
- Shows stability of important parameters over time
- Easy to draw in spreadsheets

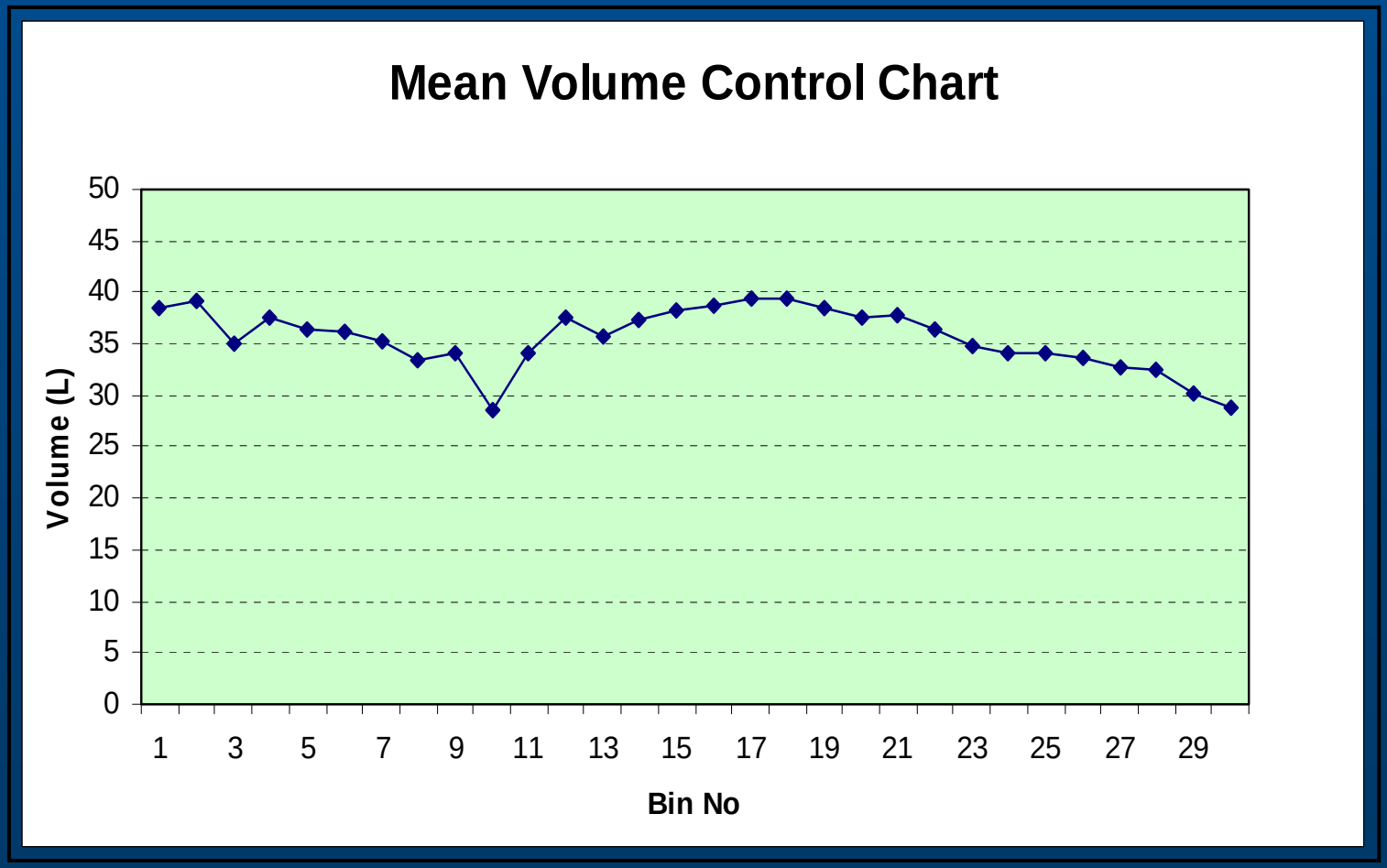
Types of Control Charts

- Shewhart control chart
  - Checks on whether process is in statistical control
- Acceptance control chart
  - Uses accept/reject
- Adaptive control chart
  - Employs predictive methods to vary process conditions

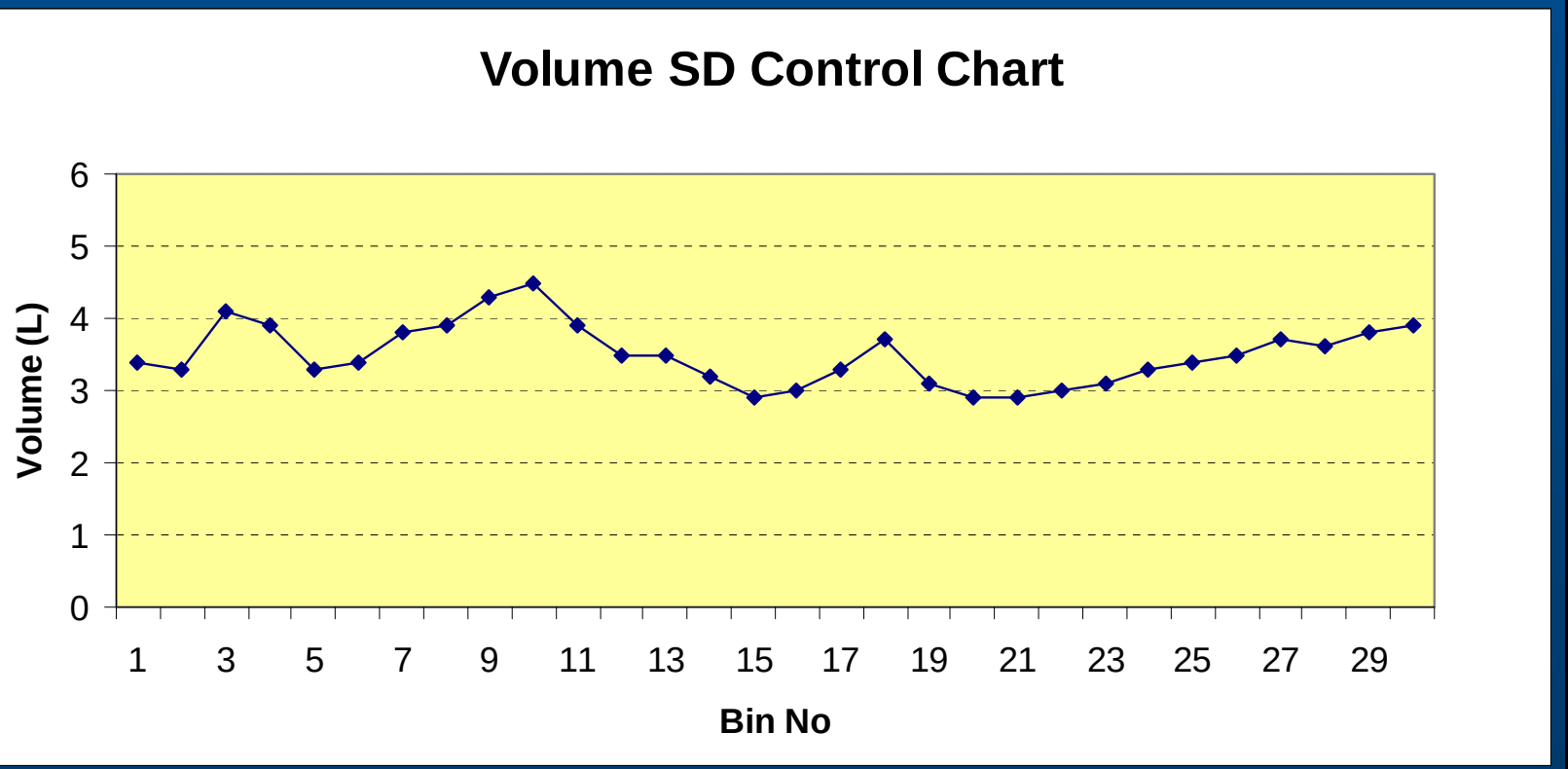
Data Plotted in Control Charts

- Mean
- Range
- Standard deviation
- Proportion or percent
- Counts, counts per unit, etc.
- Quality scores

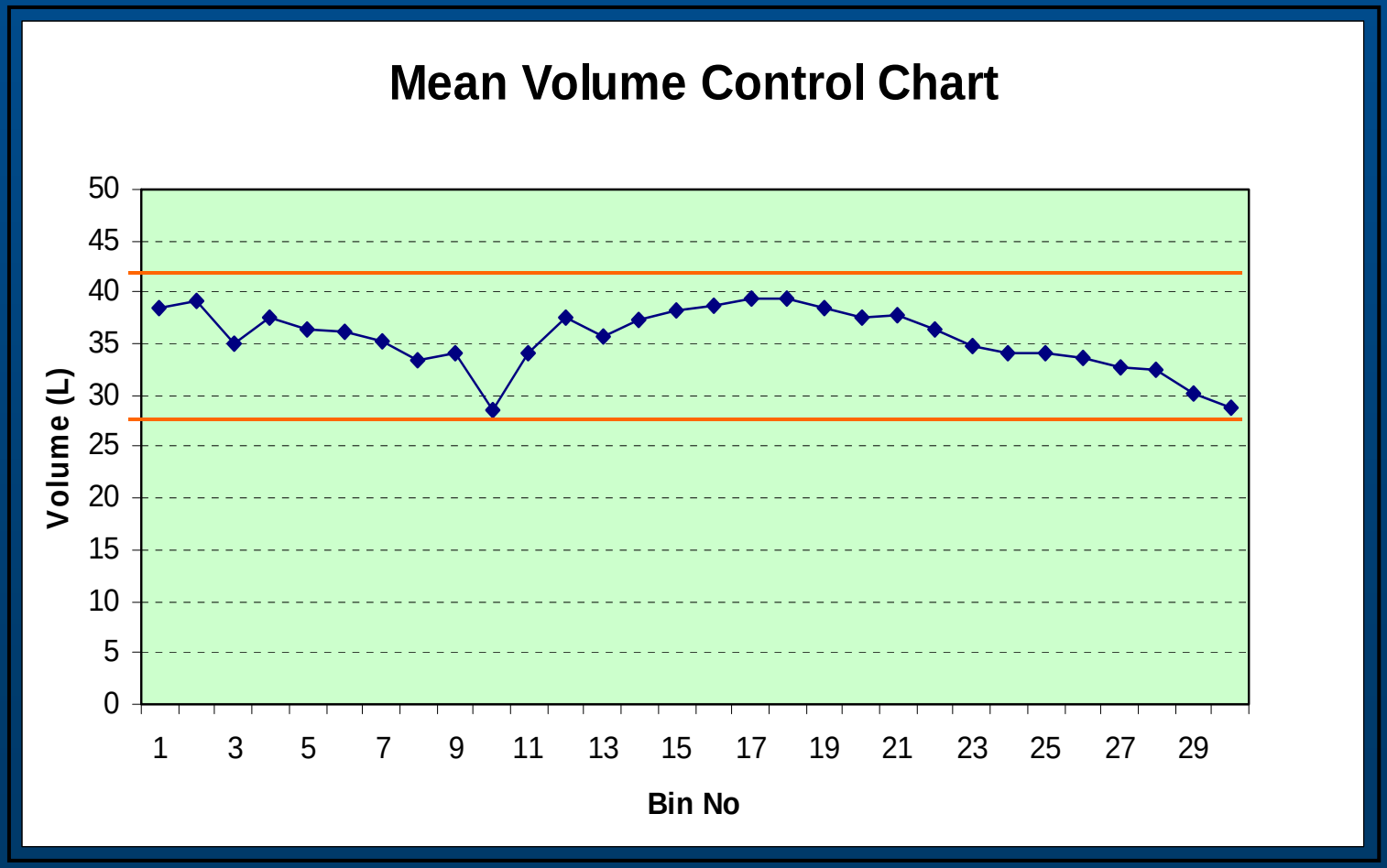
Basic Volume Control Chart



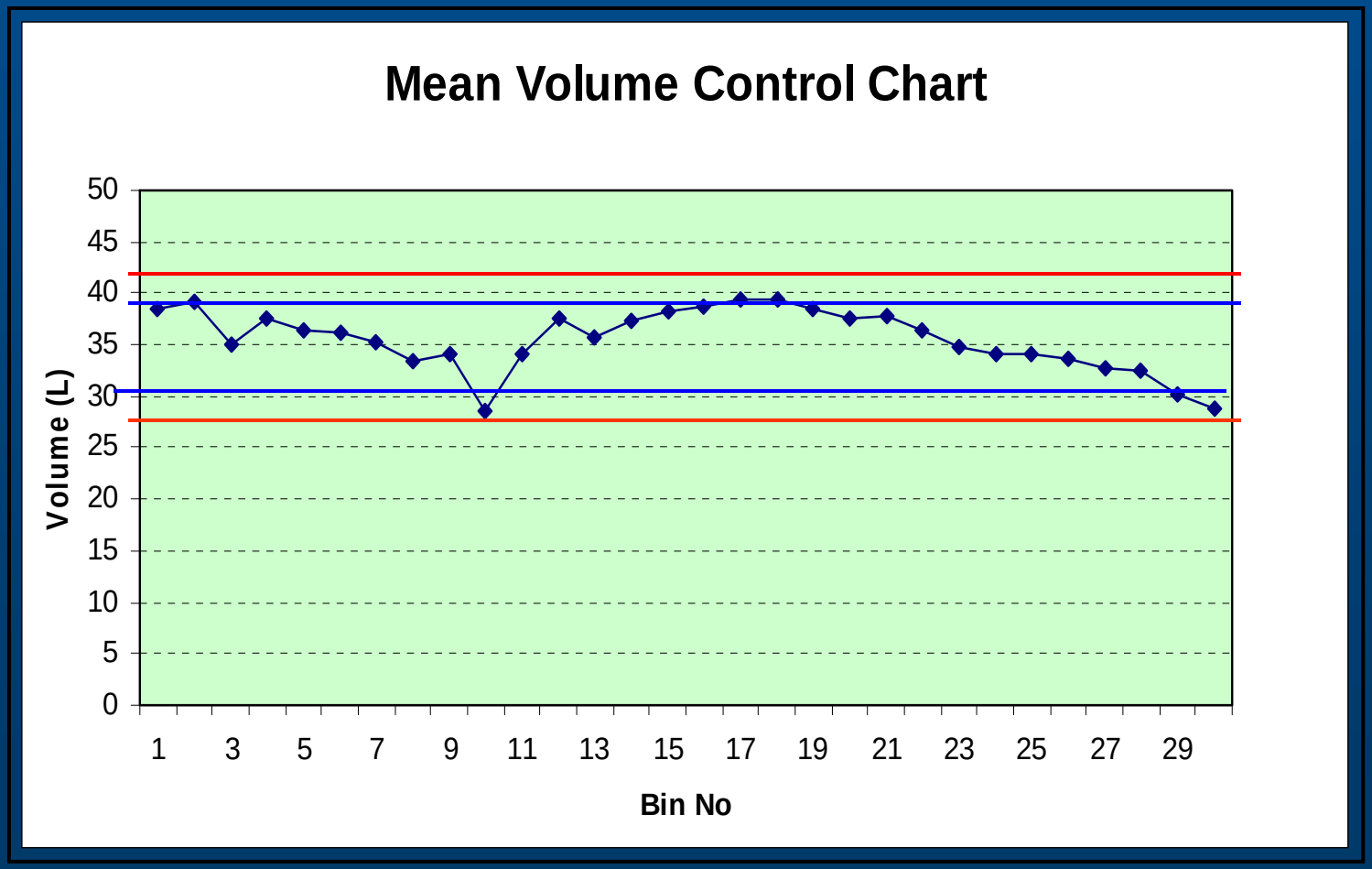
Volume SD Control Chart



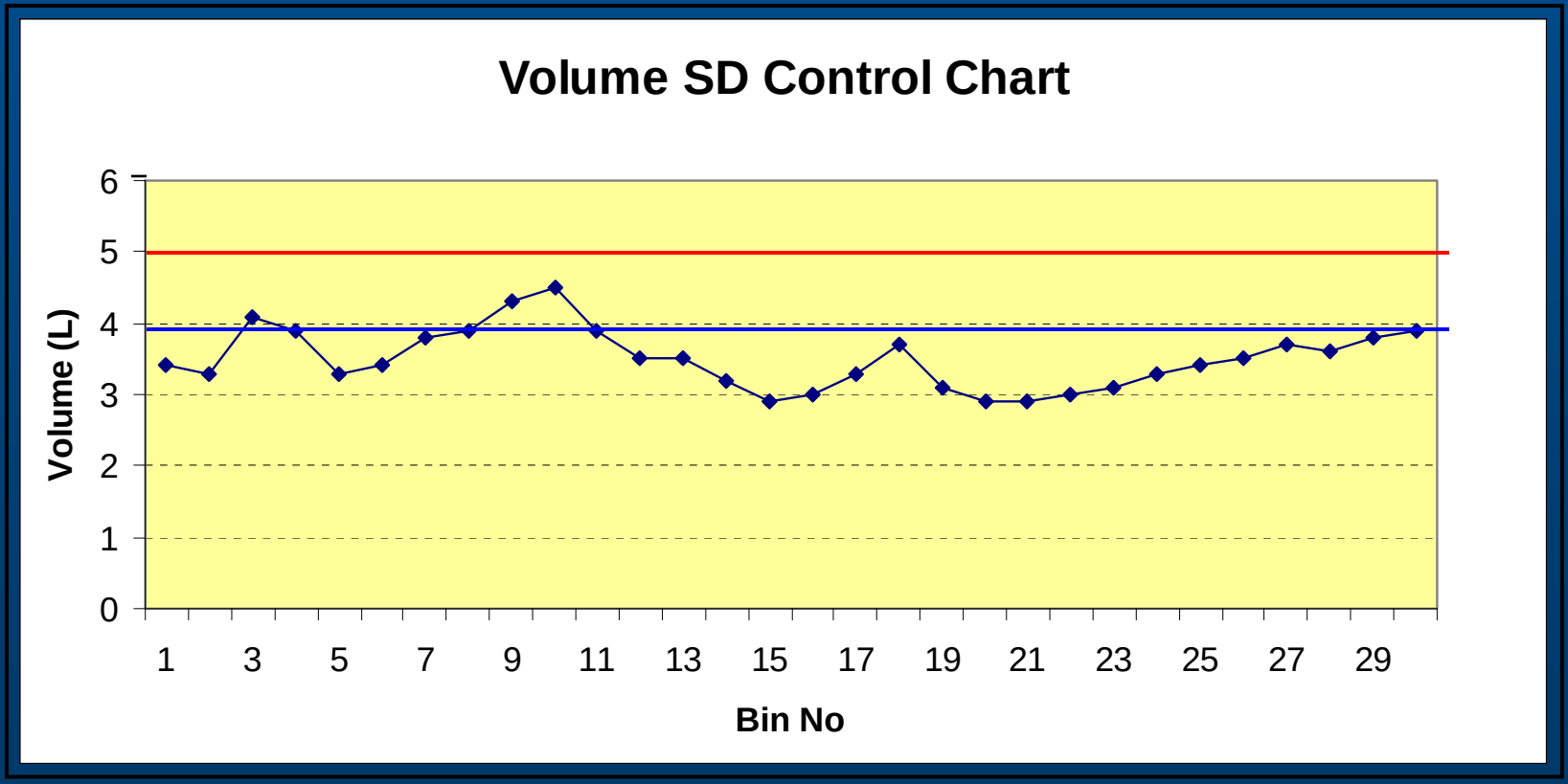
Volume Control Chart With Action Limits



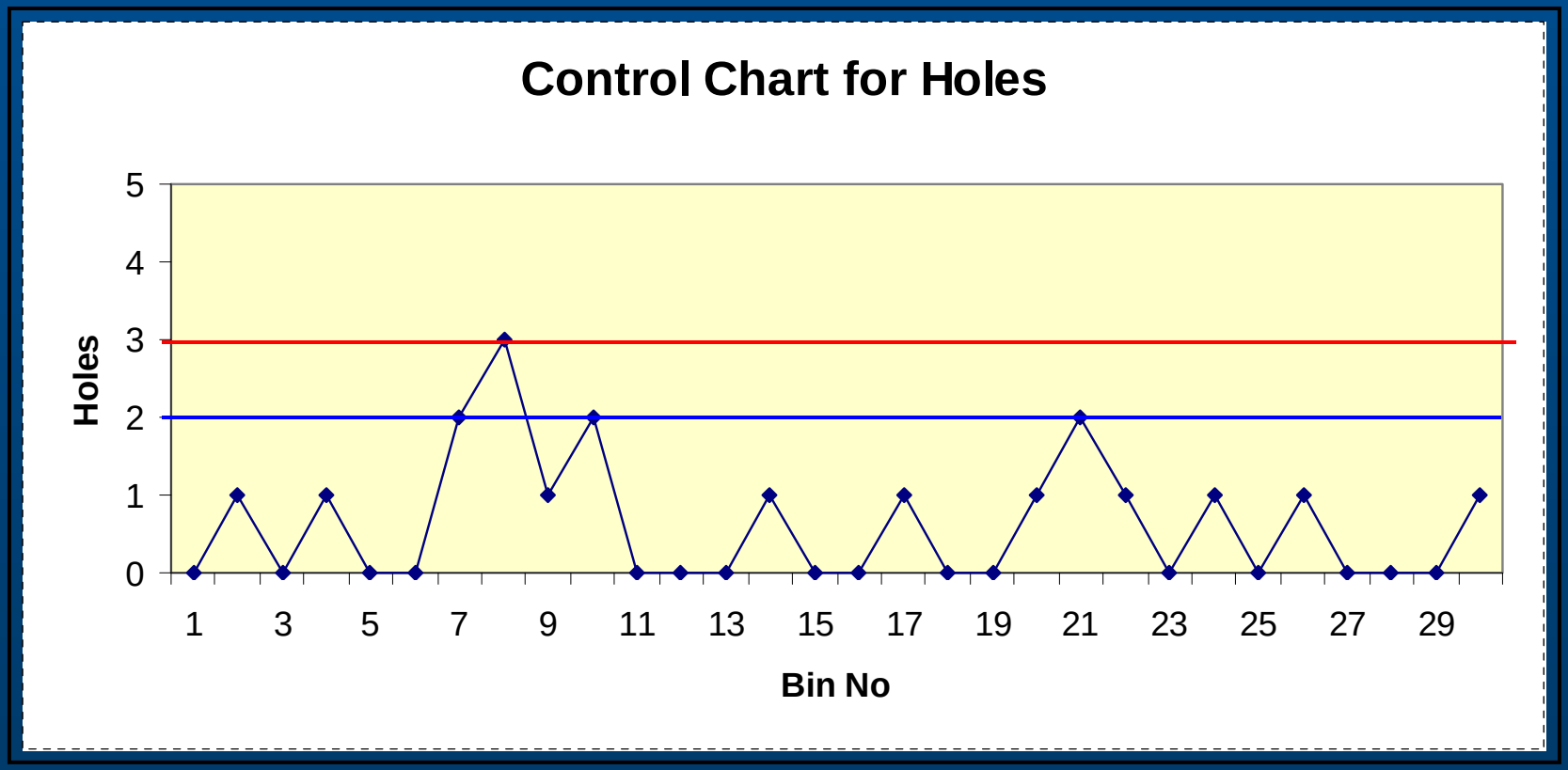
Volume Control Chart With Warning and Action Limits



Volume SD Control Chart With Warning & Action Limits



Control Chart for Holes



Interpreting Control Charts

- Needs to be adapted to the process and the chart
- Typical rules—take action if:
  - 1 or more points outside the action limit
  - A run (~7 points) trending towards limit
  - 2 of 3 consecutive points outside warning limit
  - 4 of 5 consecutive points beyond 1σ limit
  - Anything else unusual

Setting Limits for Variables and Attributes

- Limits in examples were 2σ for warning, 3σ for action
  - σ refers to SD of means
- Other limits may be appropriate in some circumstances
- Limits for SD are best set by experience
- The wider the limits, the more tolerant the control

Other Techniques

- Add moving average to control charts
- Construct control chart using only moving average
- Use a cumulative sum (CUSUM) control chart
  - Looks at totals over a run of bins
  - Can detect relatively small shifts in process average much earlier than Shewhart charts

Small Group Exercise

Statistics Session
Group Exercise

1. In the final release test for holes, a factory tests 315 condoms per lot. The results for a series of lots are shown on the next page. Indicate which ones pass and which ones fail.

2. Examine the sampling tables, and describe the difference between normal and tightened inspections in terms of sample size and pass/fail limits.

3. A factory has a bin size of 9000. It wants to check on its product bin by bin before foiling, using ISO 2859-1 and the same inspection levels as in ISO 4074. The release batch size is 24 bins.

   - If they use single sampling, what are the sample sizes for holes and inflation and what are the pass/fail limits?

   - How many condoms per batch are tested in this process? How does it compare with final release testing?

   - As a result of technical improvements, they were able to raise the speed of the machine, and the bin size was raised to 11,000 (the batch is still 24 bins). What are the new sample sizes and pass/fail limits?

4. Repeat Question 3, using a double sampling plan.

5. Use the tables and graphs in ISO 2859-1 to estimate the probability that a sample with 1 percent holes will be accepted for both the bin sizes above and for the whole batch. The tables and graphs you need are located after the multiple sampling tables and are organized by sample size.

6. Return to Question 3 and use the tables from ISO 3951 to see what the sample size would be if we were using the s method for inflation.

Lot No.	Holes	Result?
9324591	1	
9324592	0	
9324593	1	
9324594	2	
9324595	1	
9324596	3	
9324597	2	
9324598	1	
9324599	2	
9324600	3	
9324601	2	
9324602	1	
9324603	0	
9324604	1	
9324605	2	
9324606	1	
9324607	0	
9324608	1	
9324609	1	
9324610	1	
9324611	2	
9324612	1	
9324613	2	
9324614	1	
9324615	1	
9324616	0	
9324617	1	
9324618	0	
9324619	3	
9324620	2	
9324621	2	
9324622	1	
9324623	2	
9324624	3	
9324625	2	
9324626	1	
9324627	1	
9324628	1	
9324629	0	
9324630	1	
9324631	0	
9324632	2	

Overview of ISO 3951 Sampling Methods: s, Sigma, and R

ISO 3951

- Analogous to ISO 2859-1.
- Uses same AQLs.
- Uses same inspection levels.
- Uses similar switching rules.
- Variants:
  - s method: if the process Standard Deviation (SD) is not known.
  - σ method: if the process SD is known.
  - R method: if the sample size is < 10.

Using ISO 3951

1. Know your sublot size (e.g., 6000).
2. Select your sampling level (e.g., GI).
3. Find the sample size (depends on AQL for Φ method).
4. Establish acceptability limits.
5. Calculate the quality statistics.
6. Look at limits in ISO 3951 tables.

Using the s Method

1. Determine the specification limits in advance.
   - There may be one or two, U and L.
   - Example: 45 and 20 L volume.
2. Test the sample.
3. Calculate the mean (x), the SD (s), and the "quality statistics" (QU and QL) as follows.
4. Compare QU and QL with the limits (k) given in the appropriate table of ISO 3951.
   - Both values must be greater than the value of k for the sample to be acceptable.

$$Q_U = \frac{U - \bar{x}}{s}$$

$$Q_S = \frac{\bar{x} - L}{s}$$

$$\bar{x} = mean$$

$$s = SD$$

Using the Sigma Method

- Use exactly the same method as for the s method, but use the sample size and tables for the σ method.
- As σ, U, L, and k are known in advance, the only unknown is the mean.
- Thus, for the upper limit, the sample is acceptable if the mean <U-k σ.

Using the R Method

Same as above method if sample <10