Acceptance Sampling and Its Application to Visual Inspection of Injectable Products

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How Do We Inspect?

- 100% inspection
  - Manual Inspection
  - Automated Inspection
- Acceptance Sampling

Sampling vs. 100% Inspection

- Sampling preferred when:
  - Test is destructive
  - Test cost is high
  - Lot size is very large
- 100% Inspection preferred:
  - To remove low numbers of randomly distributed defects
  - When risk of a defective unit is high

Acceptance Sampling Terms

- Acceptance Sampling
  - Inspection of a sample from a lot to decide whether to accept the lot.
- Lot Size (N)
  - The total number of items to be considered together for acceptance or rejection.
- Sample Size (n)
  - The number of items selected at random from the lot for testing or inspection.

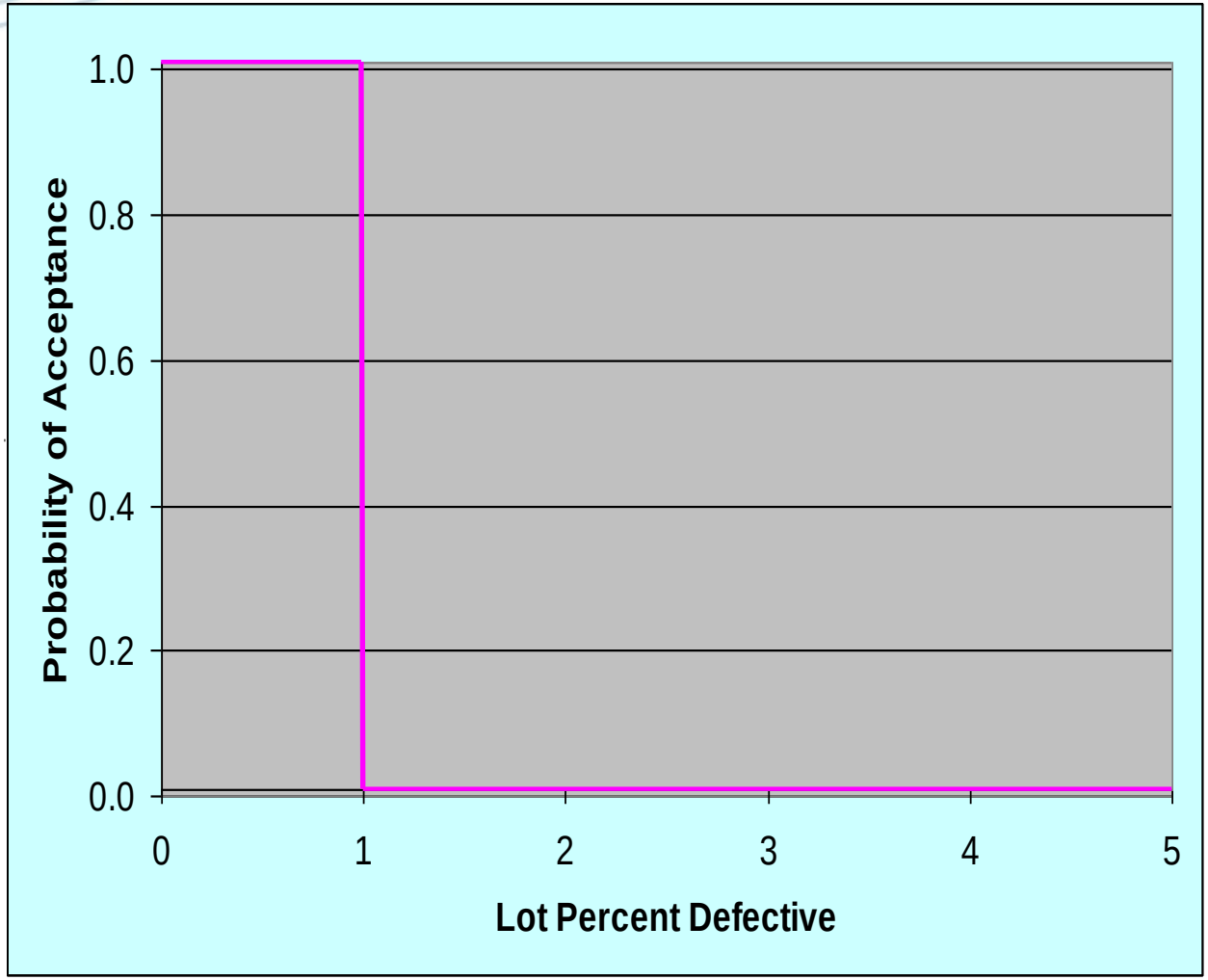
Acceptance Sampling Terms

- Acceptable Quality Limit (AQL)
  - The defect level that will be routinely accepted by the sampling plan. 95% of the time, lots of this quality will be accepted. Defines the producer's risk.
- Unacceptable Quality Limit (UQL) or Lot Total Percent Defective (LTPD)
  - The defect level that will be routinely rejected by the sampling plan. 90% of the time, lots of this quality will be rejected. Defines the customer's (patient's) risk.

Acceptance Sampling Terms

- Operating Characteristic (OC) Curve
  - A plot of the probability of accepting a lot (y-axis) versus the lot percent defective (x-axis). This curve is descriptive of the protection provided by a given sampling plan.

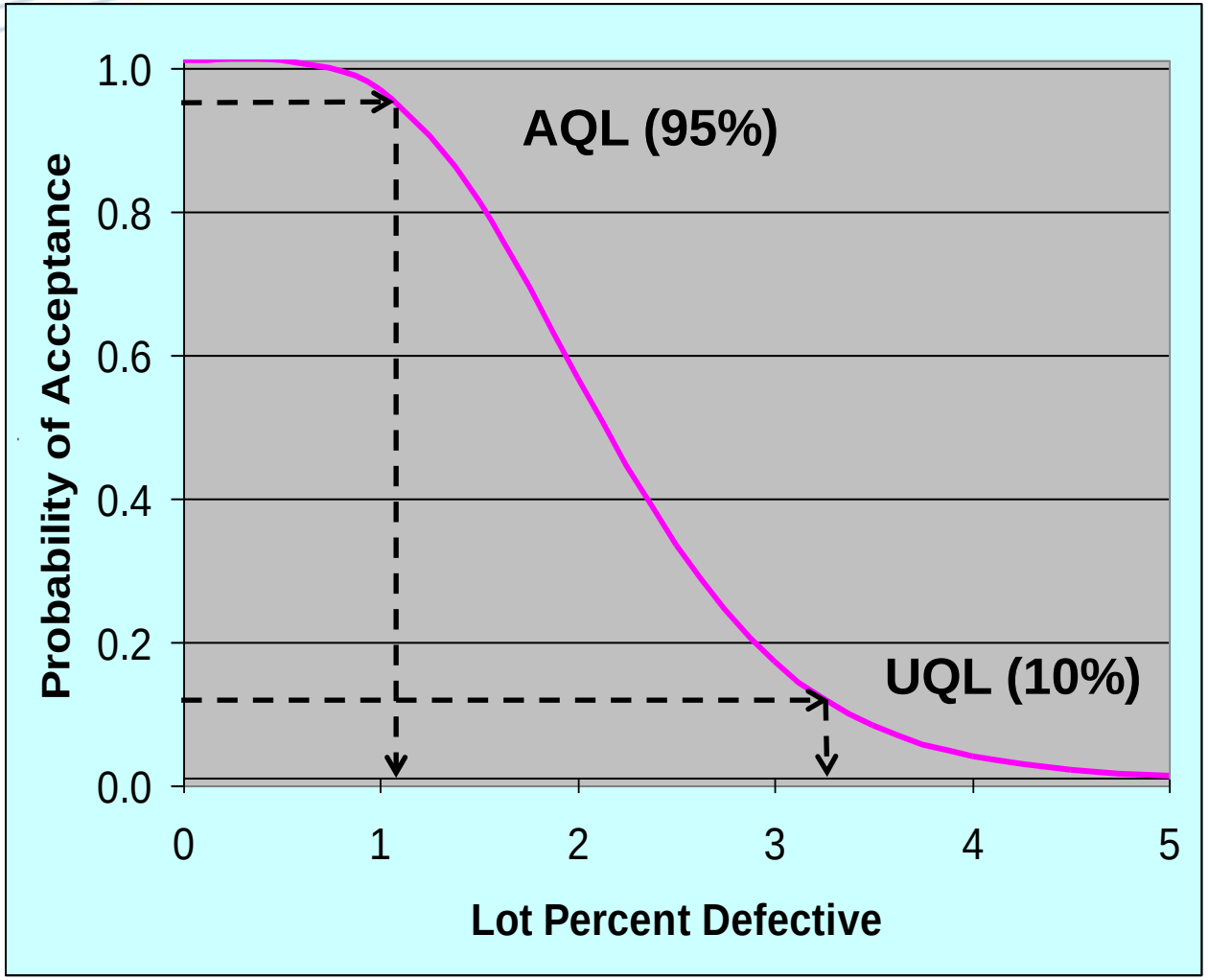
Ideal Operating Characteristic Curve



AQL = 1.0%

UQL = 1.0%

Operating Characteristic Curve



Single

N = 50,000

n = 315

a = 6

AQL = 1.1%

UQL = 3.3%

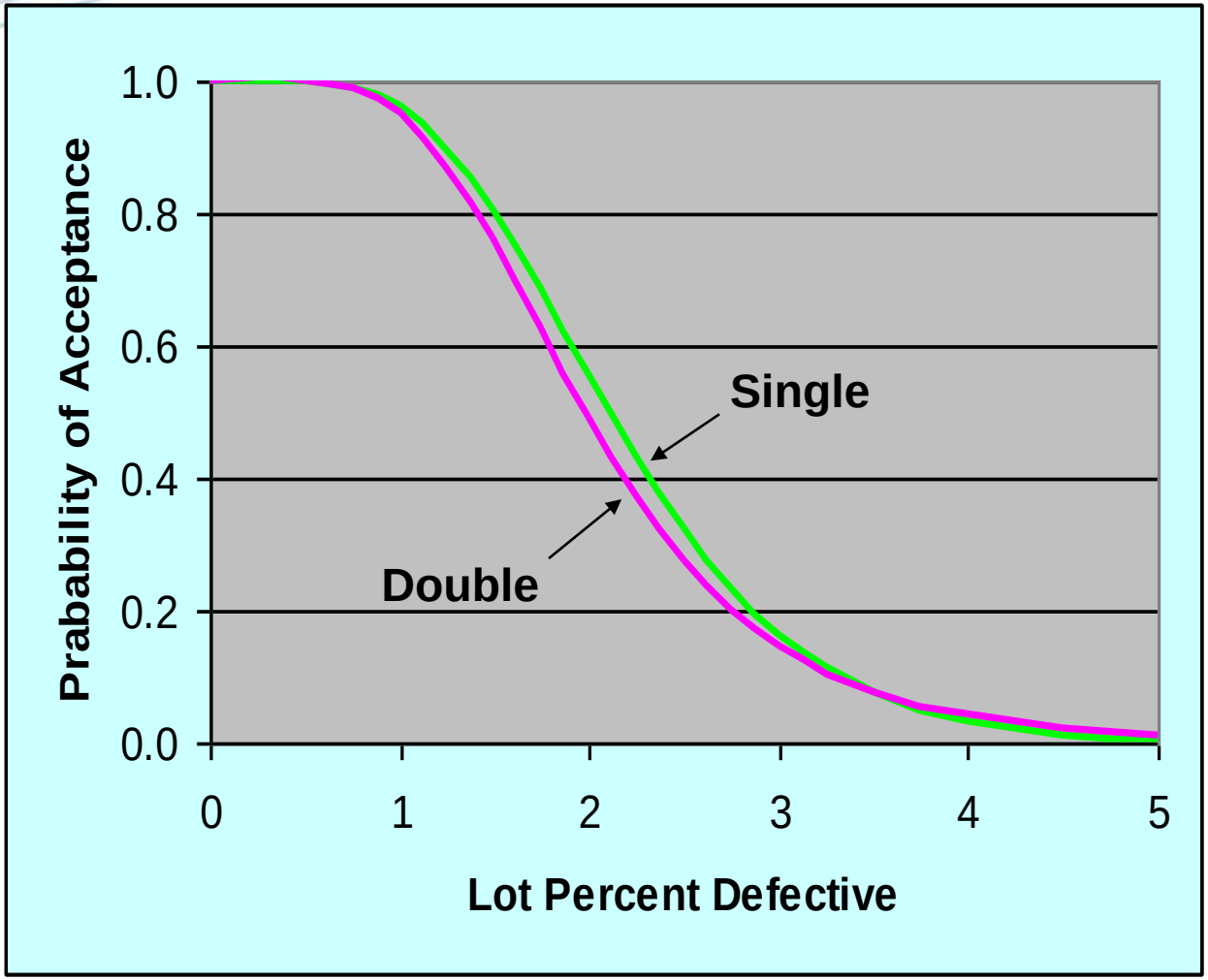
Acceptance Sampling Terms

- Sampling Plan
  - Defined by the sample size (n) and the accept number (a) for a given lot size (N). Performance is shown by the operating characteristic curve and values for AQL and LTPD.
- Accept (a)/Reject (r) Number
  - When the sample contains defectives <= the accept for the sampling plan, the lot should be accepted. When the sample contains defectives >= to the reject number it should be rejected.

Acceptance Sampling Terms

- Single Sampling Plan
  - Sampling inspection in which the decision to accept or reject a lot is based on the inspection of a single sample.
- Double Sampling Plan
  - Sampling inspection in which the inspection of the first sample leads to a decision to accept the lot, reject it or take a second sample. The inspection of the second sample, when required, then leads to a decision to accept or reject the lot.

Single vs. Double Sampling Plan



Single

n = 315

a = 6

Double

n1 = 124

a1 = 1

n2 = 296

r1 = 6

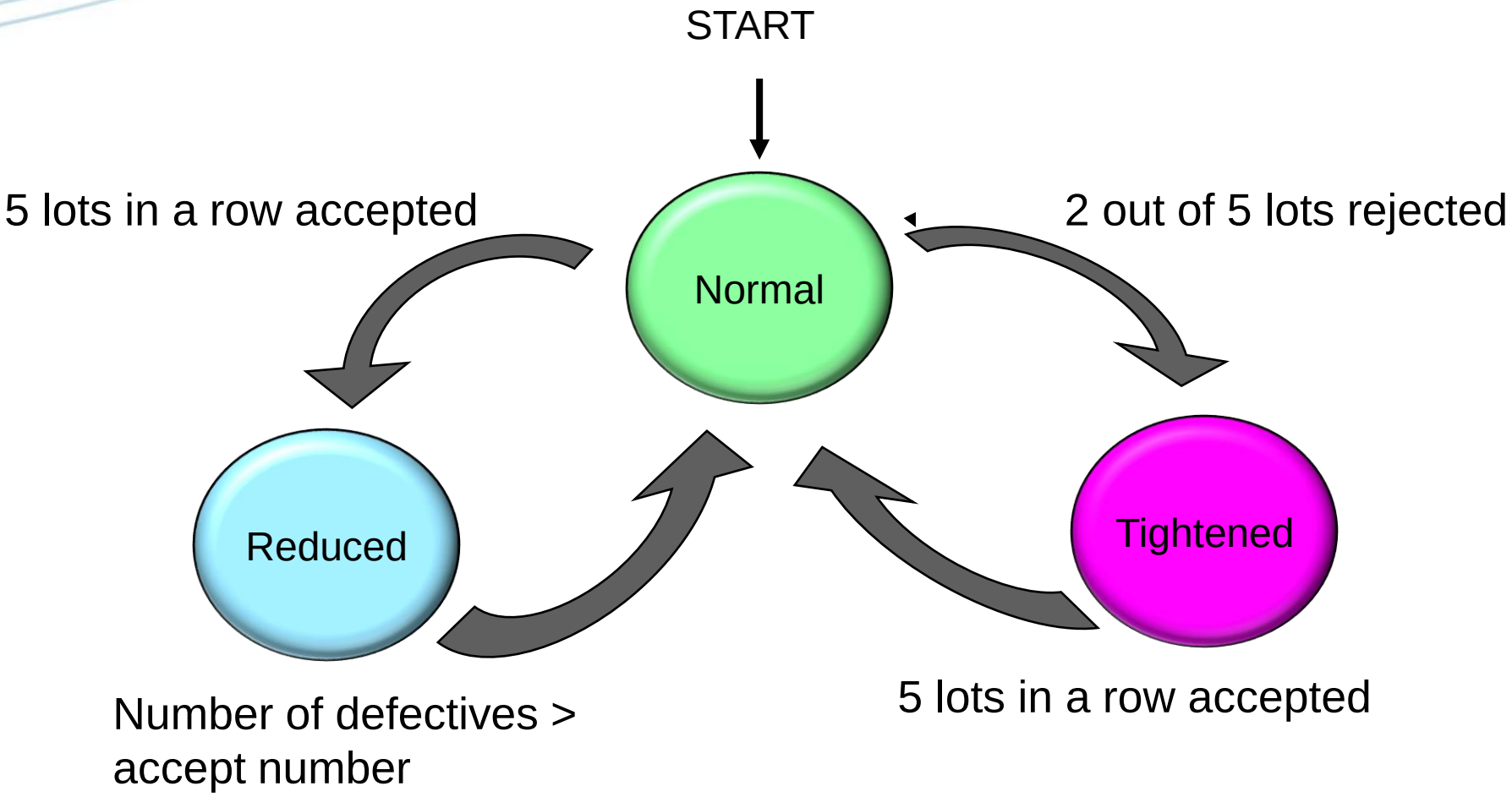
a2 = 7

N = 50,000

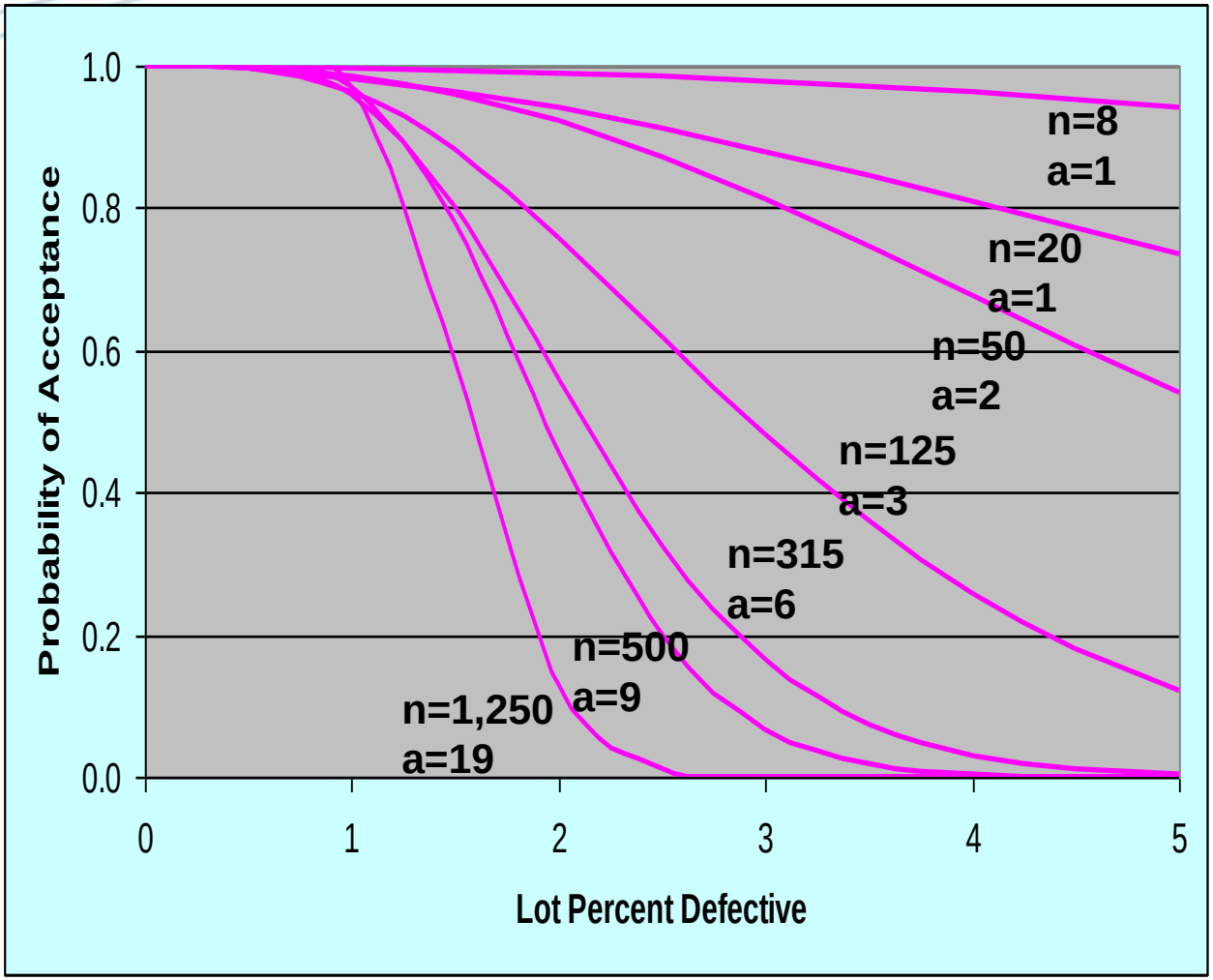
AQL = 1.1%

UQL = 3.3%

Switching Rules



Effect of Sample Size (n)

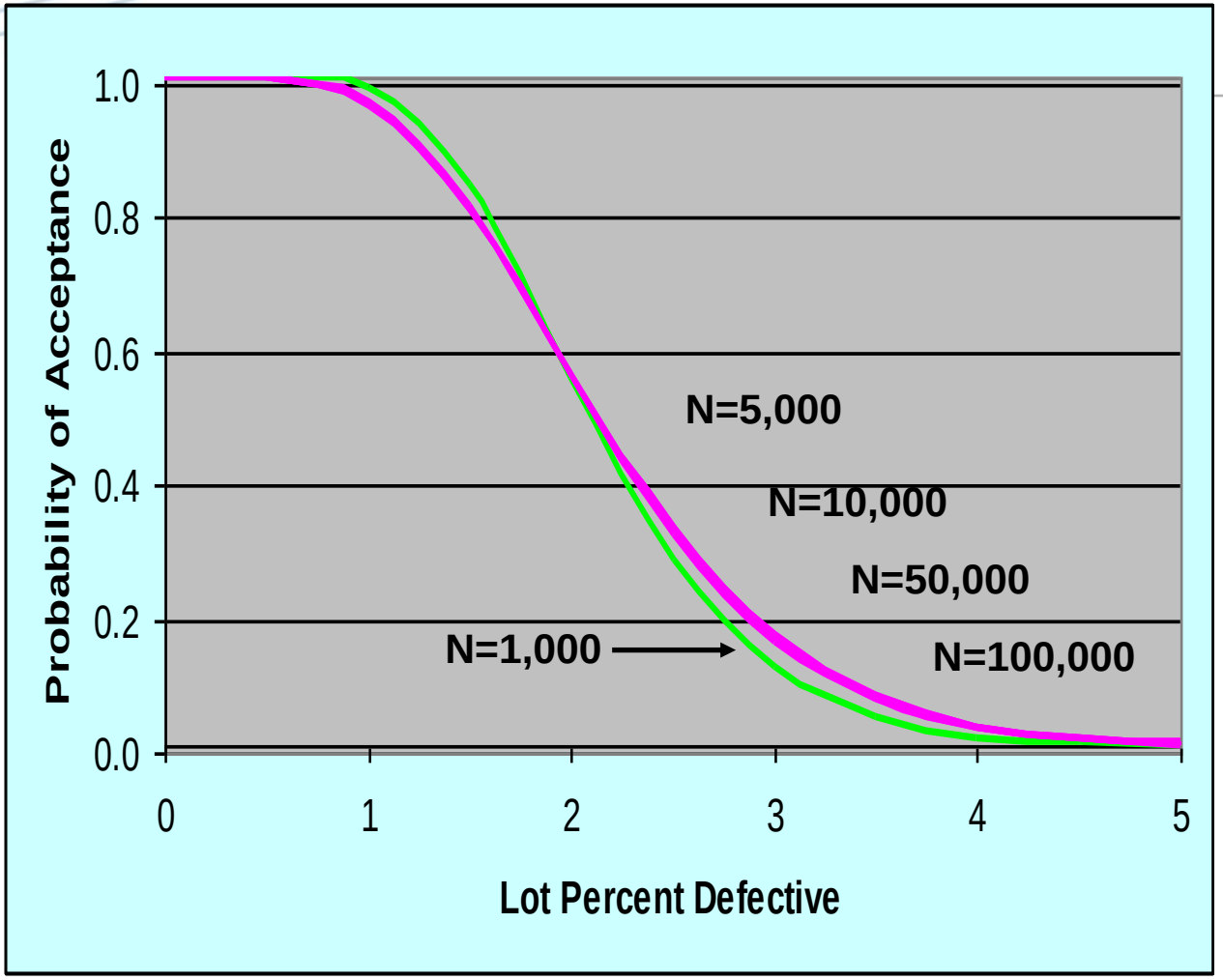


Single

N = 50,000

AQL = 1.1%

Effect of Lot Size (N)



Single

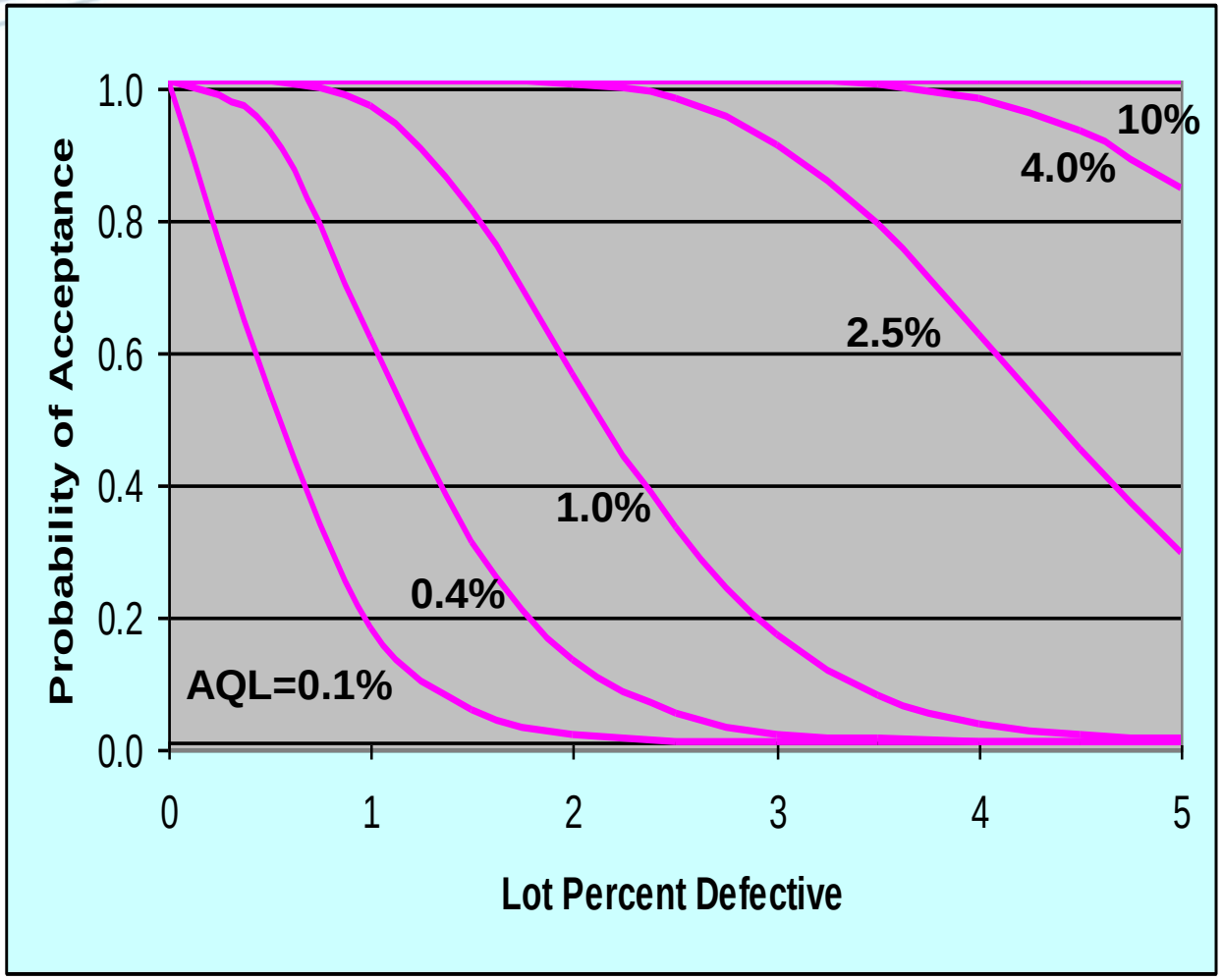
n = 315

a = 6

AQL = 1.1%

UQL = 3.3%

Effect of AQL



Single

N = 50,000

n = 315

Standard Sampling Plans

- Mil Std 105e “Sampling Procedures and Tables for Inspection by Attributes”
  - Discontinued in 1991
- ANSI/ASQ Z1.4-2003 (R2013) “Sampling Procedures and Tables for Inspection by Attributes”
  - ISO 2859-1:1999
  - JIS Z 9015-1:2006
- Dodge-Romig
  - Average Outgoing Quality Limit (AOQL)
- Mil Std 1916
  - Zero accept plans

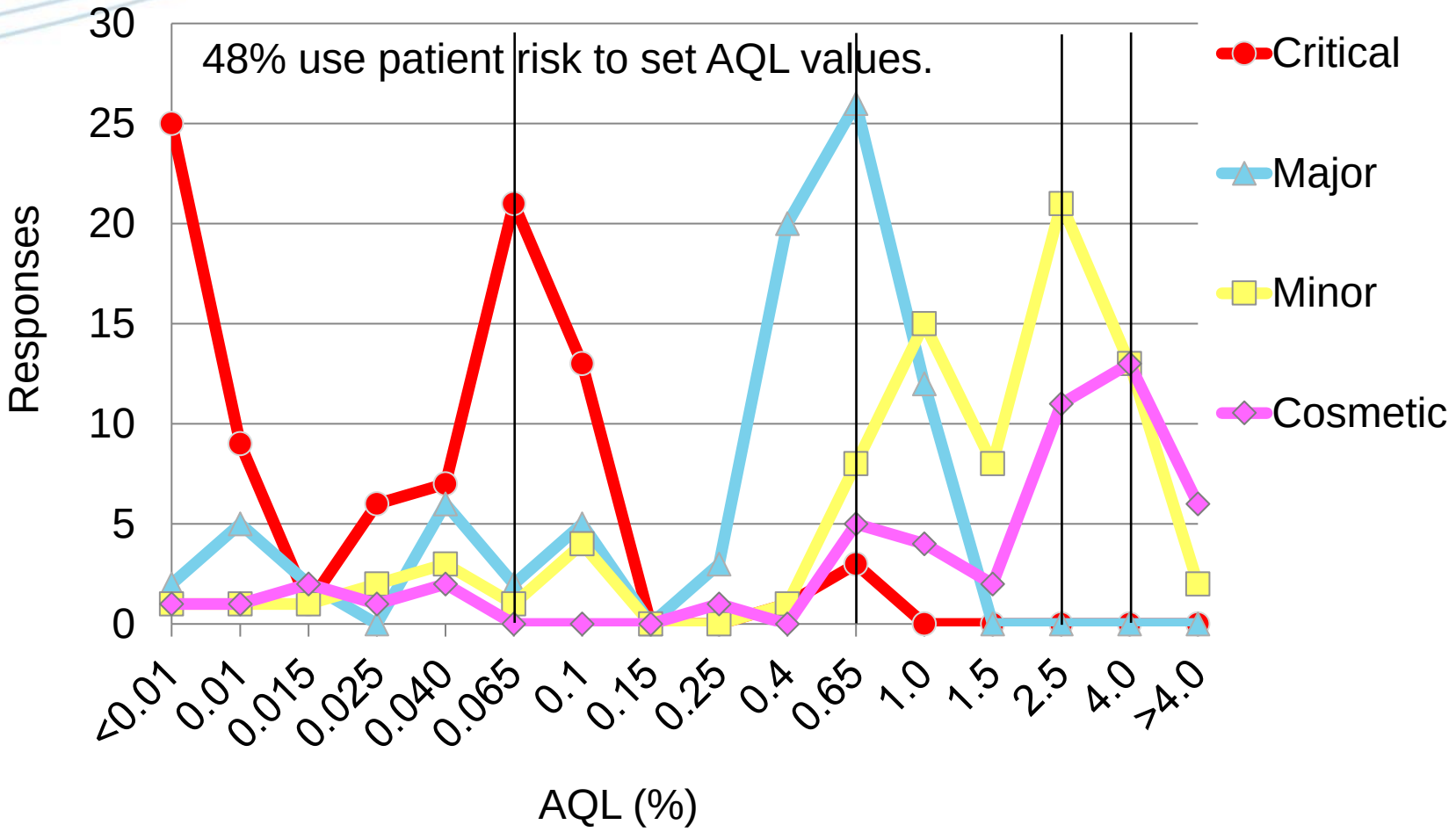
Sampling Plans

	2023	2014	2008	2003	1996
ANSI/ASQ Z1.4	**63%**	65%	53%	70%	90%
ISO 2859	**29%**	23%	11%	10%	0%
JIS Z9015	**0%**	7%	15%	5%	0%
Mil Std 1916	**2%**	3%	11%	0%	0%
Dodge Romig	**1%**	1%	0%	5%	0%
Other	**5%**	2%	10%	0%	10%

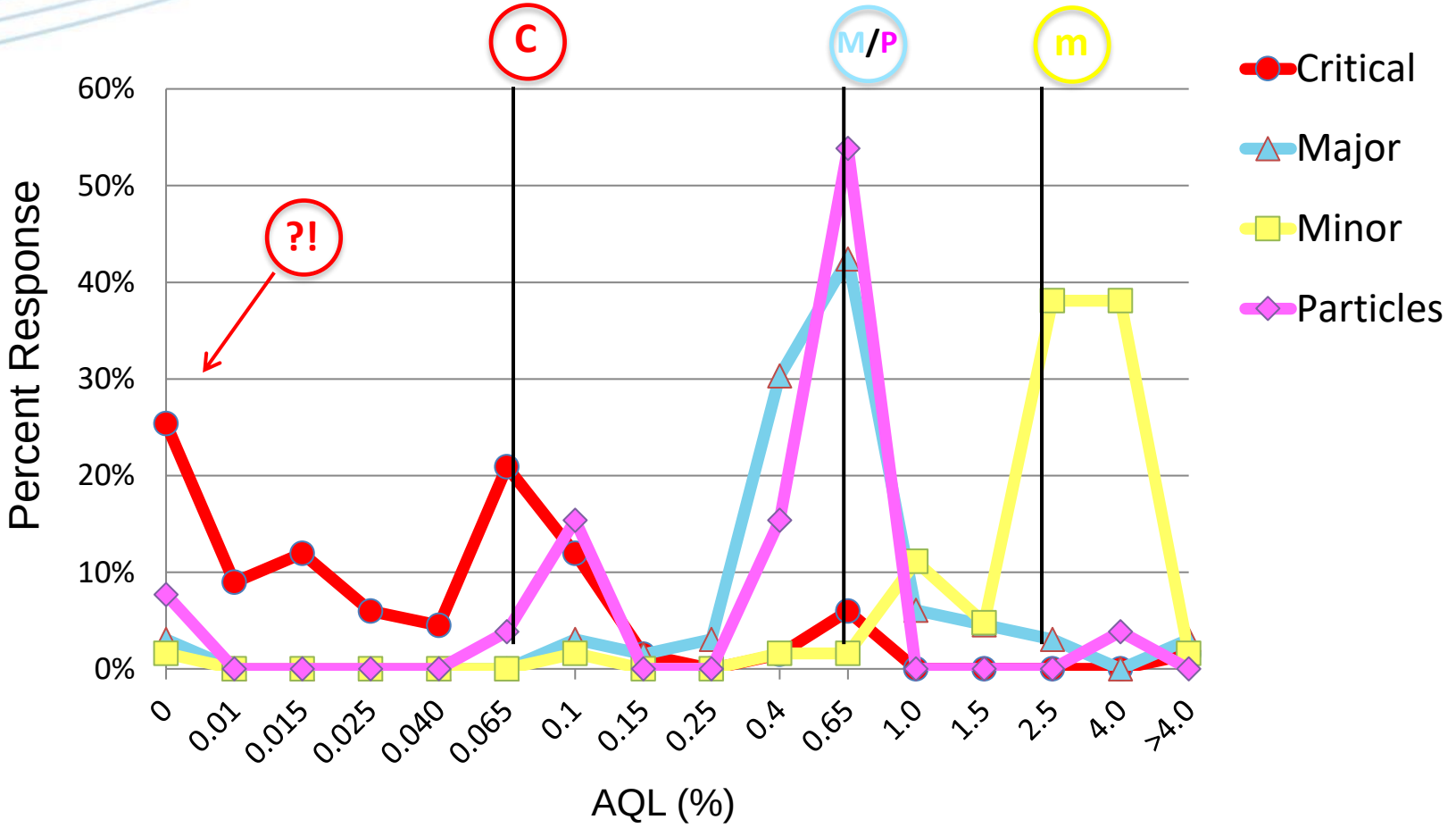
Other: 2x100% inspection, plan based on AQL and RQL

From 2023 PDA Visual Inspection Survey

What AQL value (in %) do you use for acceptance sampling of these defect categories?



What AQL value (in %) do you use for acceptance sampling of these defect categories?



From 2023 PDA Visual Inspection Survey

ANSI Z1.4 Sampling Table

Lot or batch 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 1200	C	C	E	F	G	J	K
1201 to 3200	C	D	E	G	H	K	L
3201 to 10000	C	D	F	G	J	L	M
10001 to 35000	C	D	F	H	K	M	N
35001 to 150000	D	E	G	J	L	N	P
150001 to 500000	D	E	G	J	M	P	Q
500001 and over	D	E	H	K	N	Q	R

ANSI Z1.4 Sampling Table

Sample size code letter	Sample size	Acceptable Quality Levels (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		1000	
		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	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																							⇧	⇩			1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	30	31	44	45	⇩			
F	20																							⇧	⇧			1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	30	31	44	45	⇩			
G	32																	0	1	⇩		⇩		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	⇩											
H	50																	⇧	⇩			⇧	⇩	1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	⇩											
J	80																	⇧	⇧			⇧	⇧	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											⇧	⇩	⇩		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	⇩																	
M	315											⇧	⇧	⇧		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	1250	0	1	⇧	⇧	⇧		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	⇧																							
R	2000	⇧		⇧		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	⇧																							

⇩ = Use first sampling plan below arrow. If sample size equals, or exceeds, lot or batch size, do 100 percent inspection.

⇧ = Use first sampling plan above arrow.

Ac = Acceptance number.

Re = Rejection number.

Sample Collection

- Random
- Stratified
  - Subgroups
- Periodic
  - Simple procedure
  - Easy to automate

How should a sampling plan be used?

- As a Safety Net
  - 100% inspection is not 100% effective
  - To detect new defect types with automated systems
  - To detect a process shift
    - Manufacturing or Inspection process

What should you do when you exceed the Accept Number?

- Investigate (Always)
  - Inspection Process
  - Manufacturing Process
- Reinspect (Sometimes)
  - When it is appropriate (based on investigation)
- Reject Lot (Sometimes)
  - When reinspection is not successful

Any Questions?