



Acceptance Sampling and Its Application to Visual Inspection of Injectable Products

John G. Shabushnig, Ph.D.
Insight Pharma Consulting, LLC



johnshabushnig@aol.com
September 2023



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.**

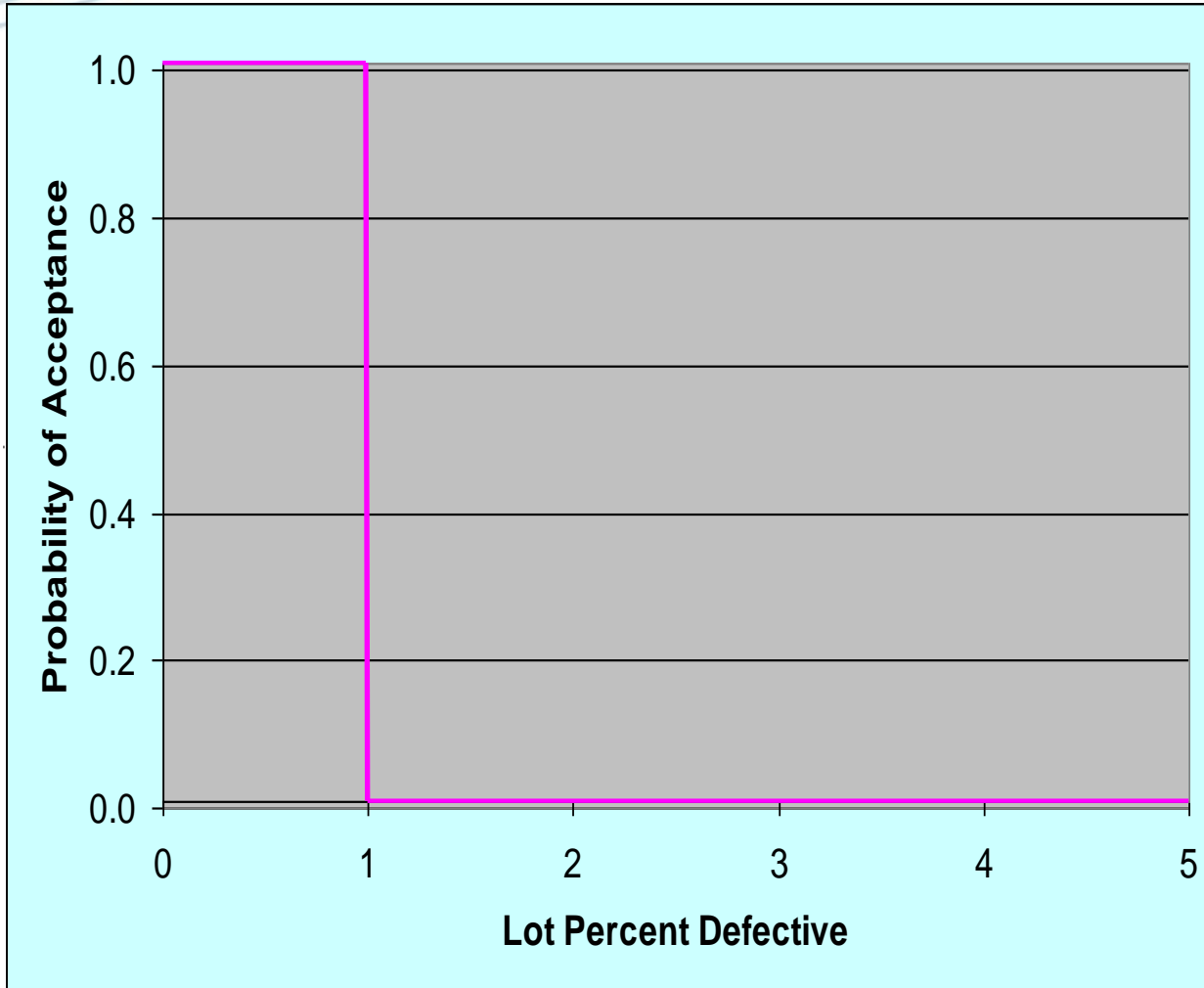


Acceptance Sampling Terms

- 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

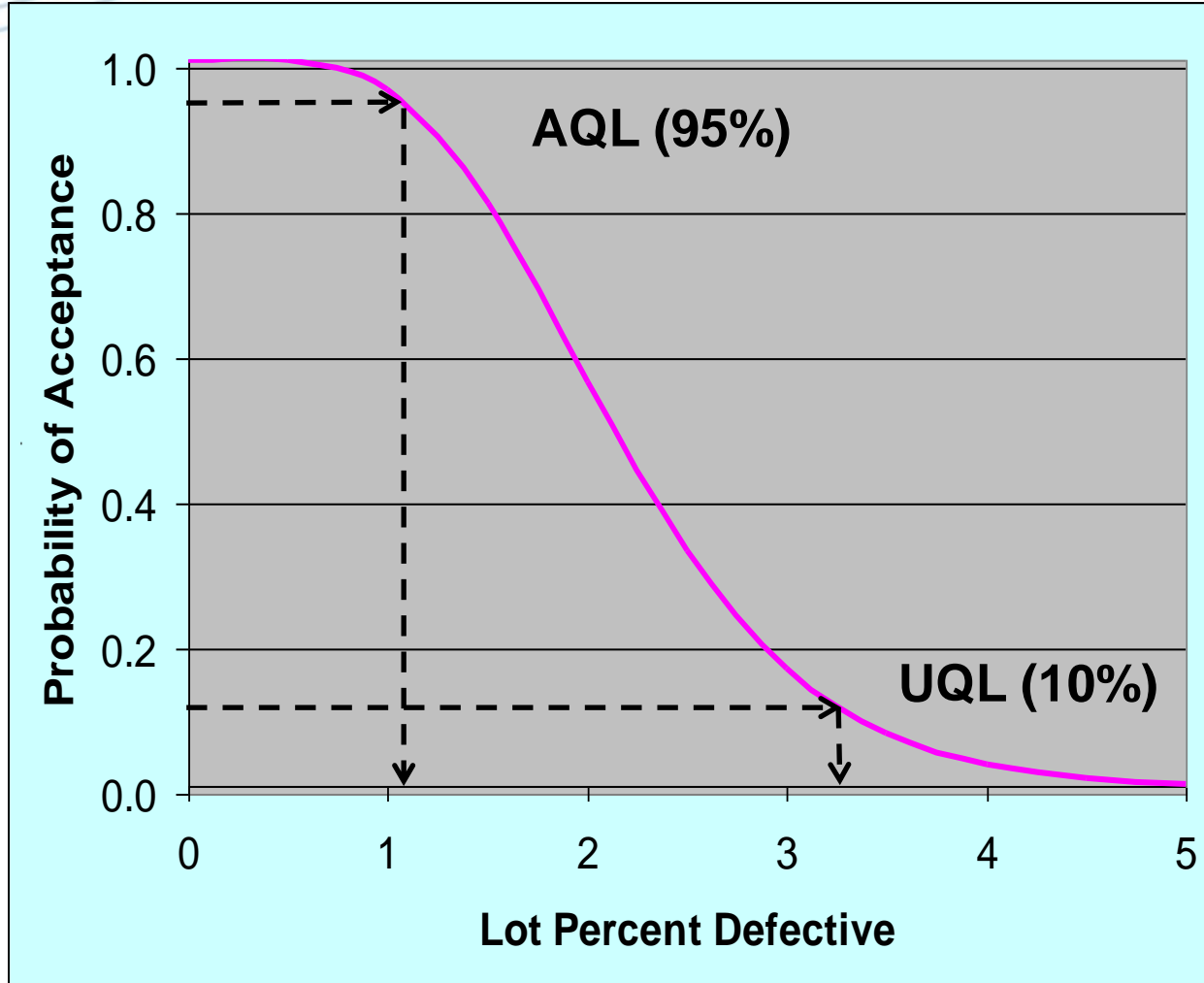


AQL = 1.0%

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 \leq the accept for the sampling plan, the lot should be accepted. When the sample contains defectives \geq to the reject number it should be rejected.

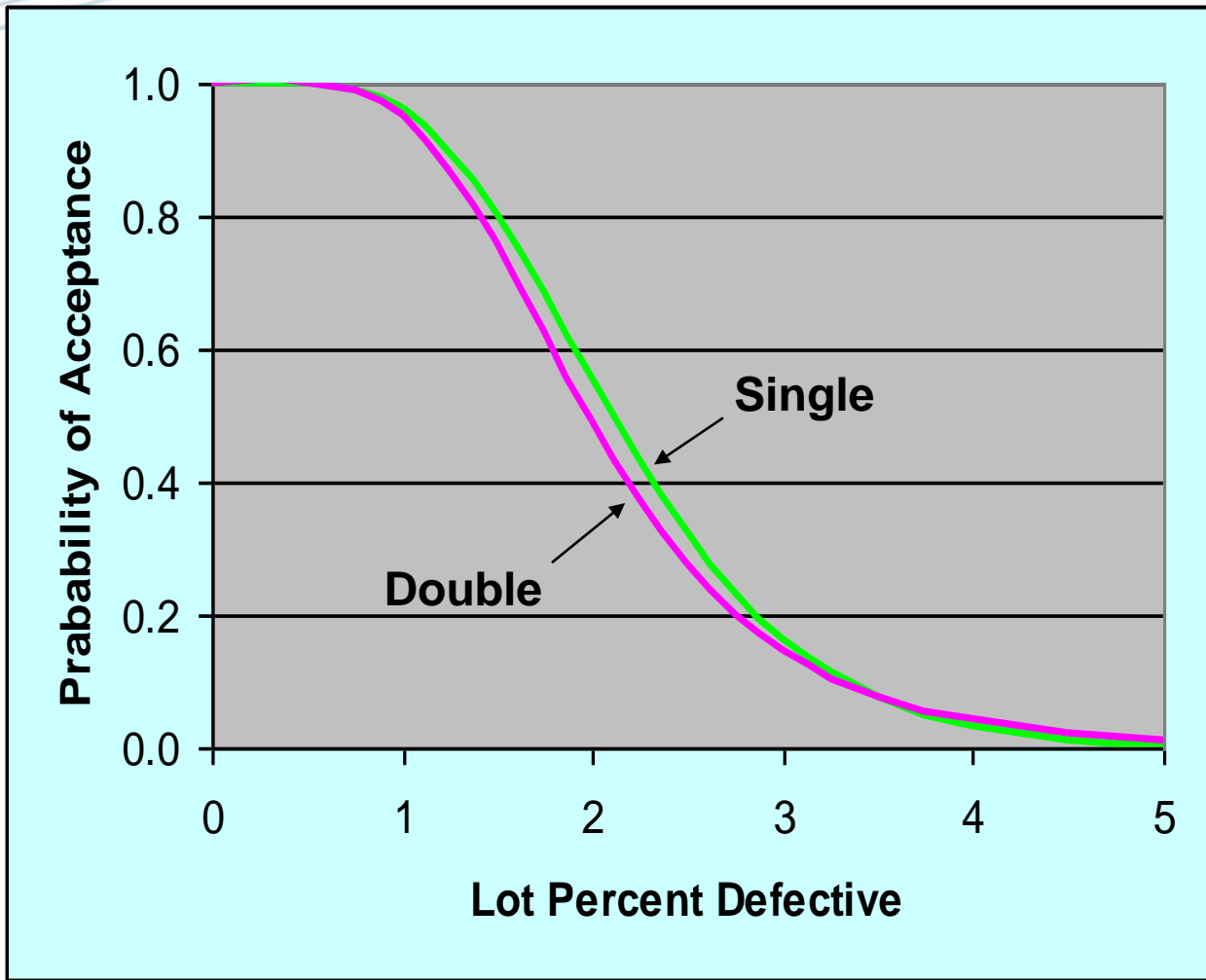


Acceptance Sampling Terms

- 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

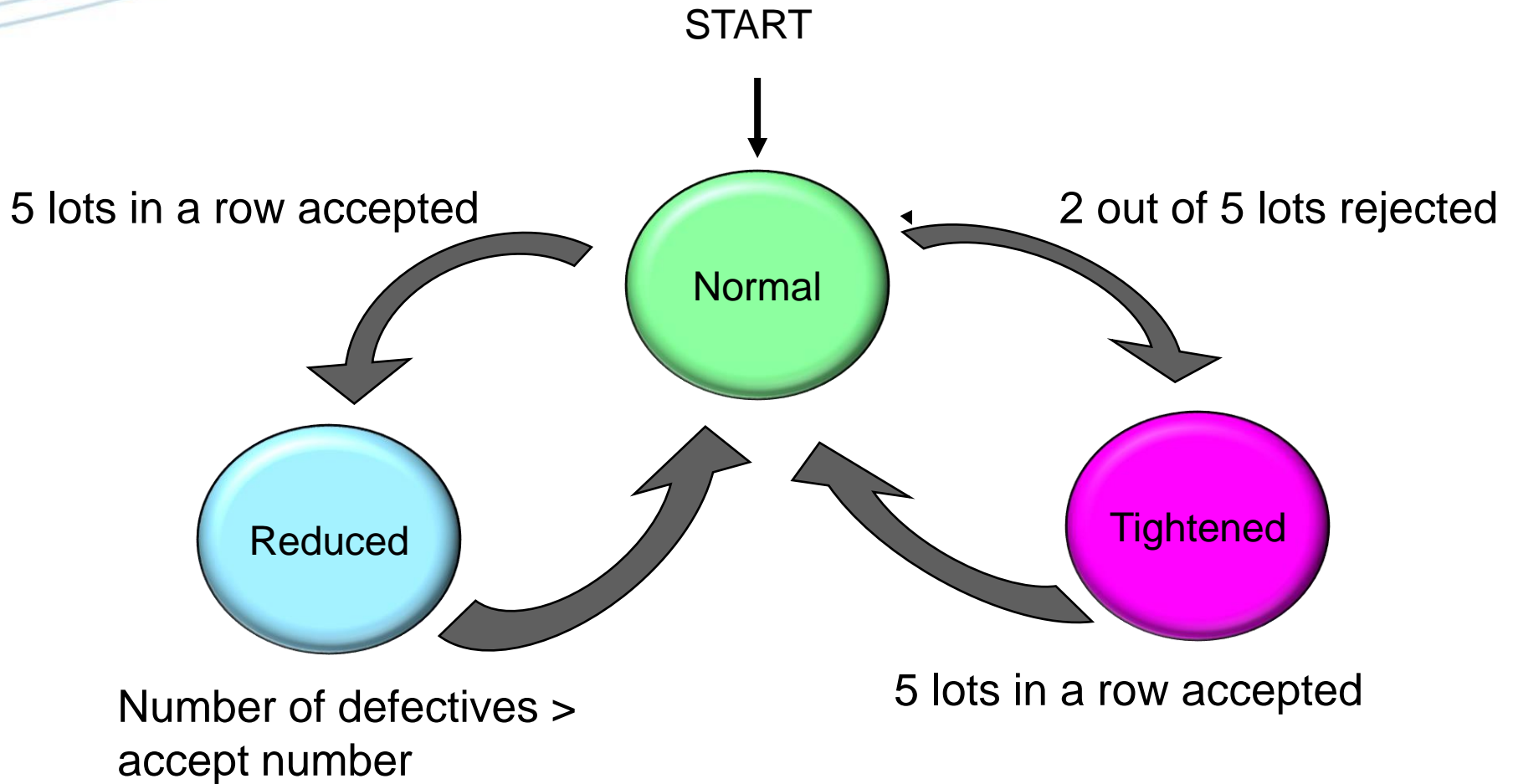


Single
 $n = 315$
 $a = 6$

Double
 $n1 = 124$
 $a1 = 1$
 $n2 = 296$
 $r1 = 6$
 $a2 = 7$
 $N = 50,000$
 $AQL = 1.1\%$
 $UQL = 3.3\%$

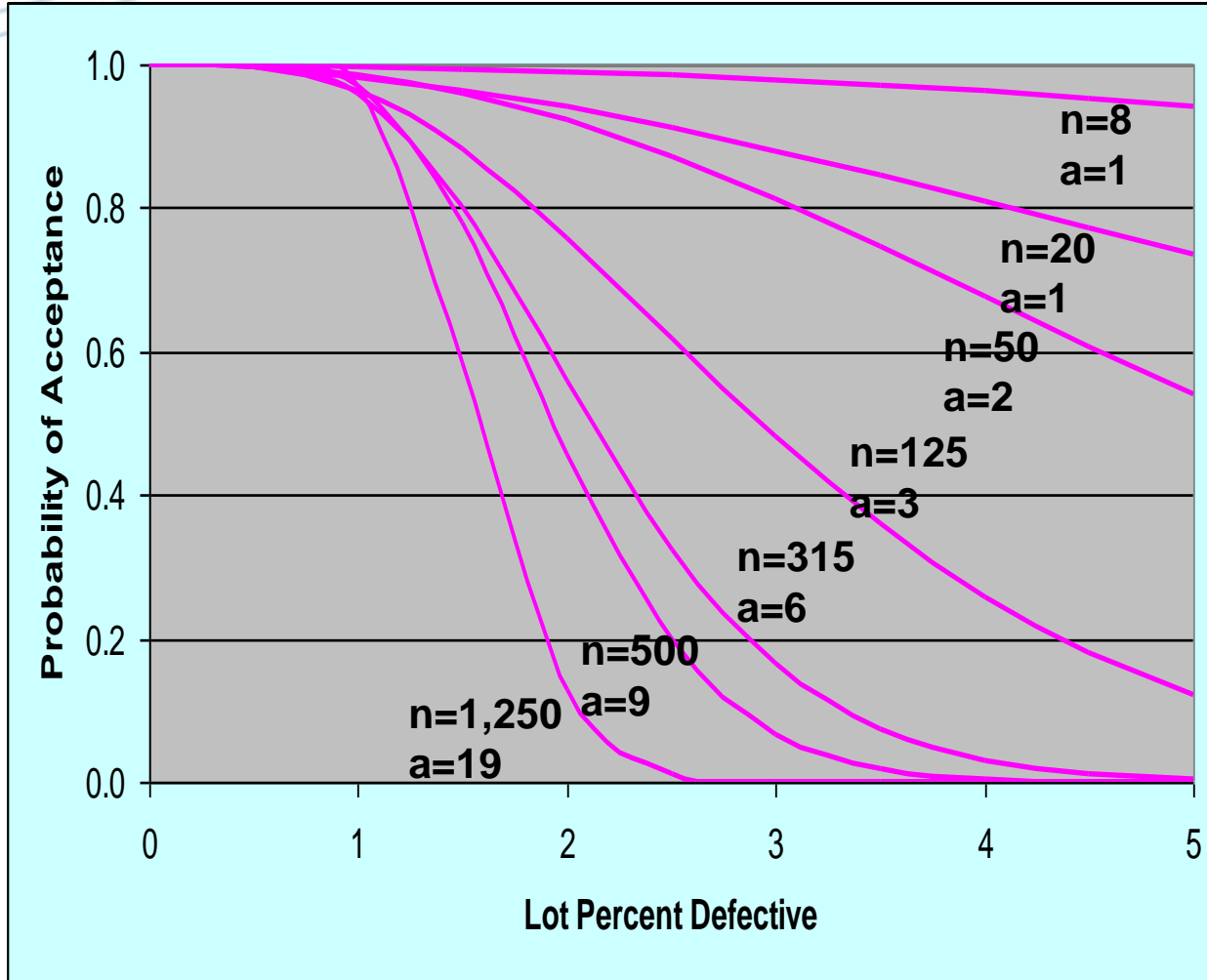


Switching Rules





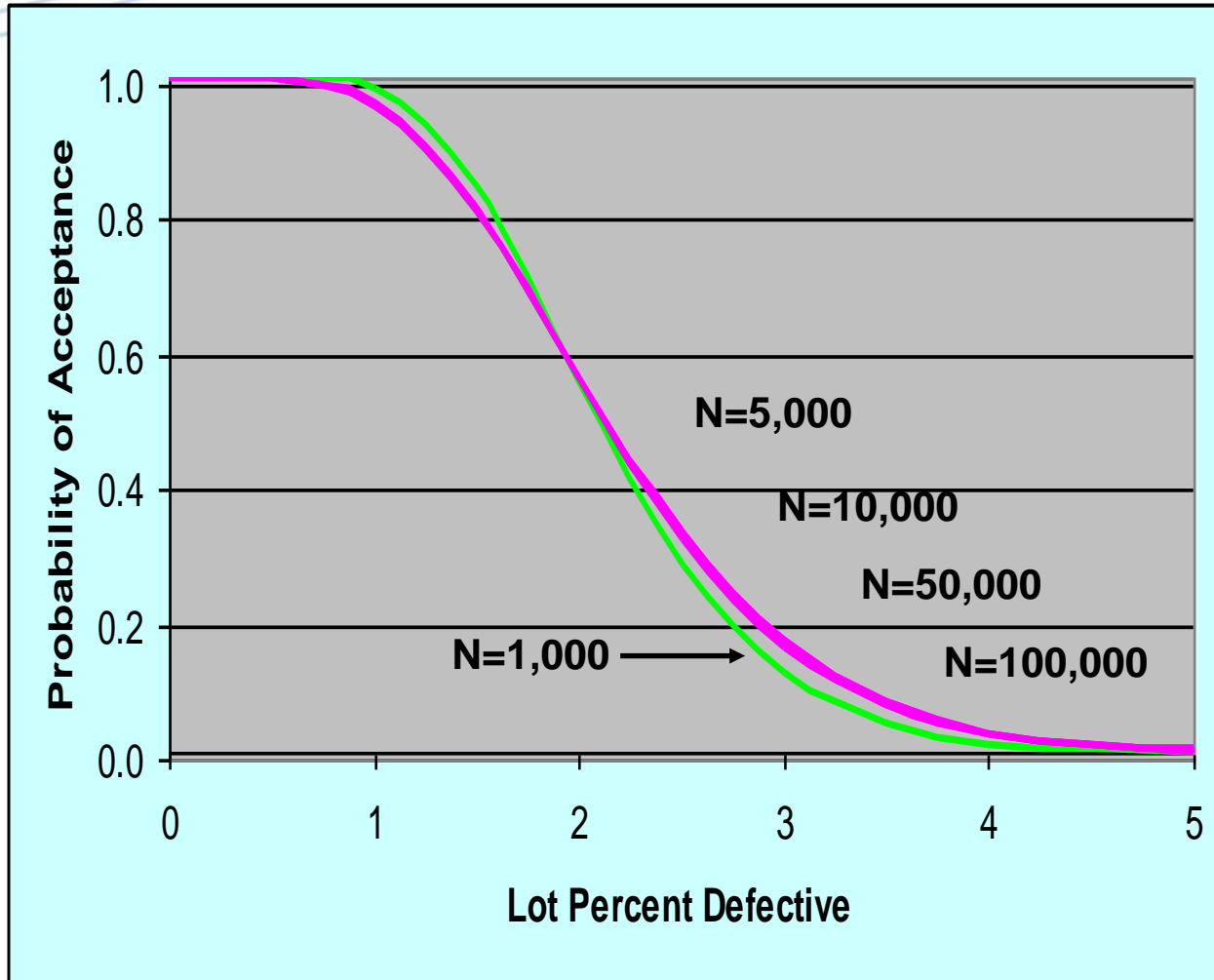
Effect of Sample Size (n)



Single
N = 50,000
AQL = 1.1%



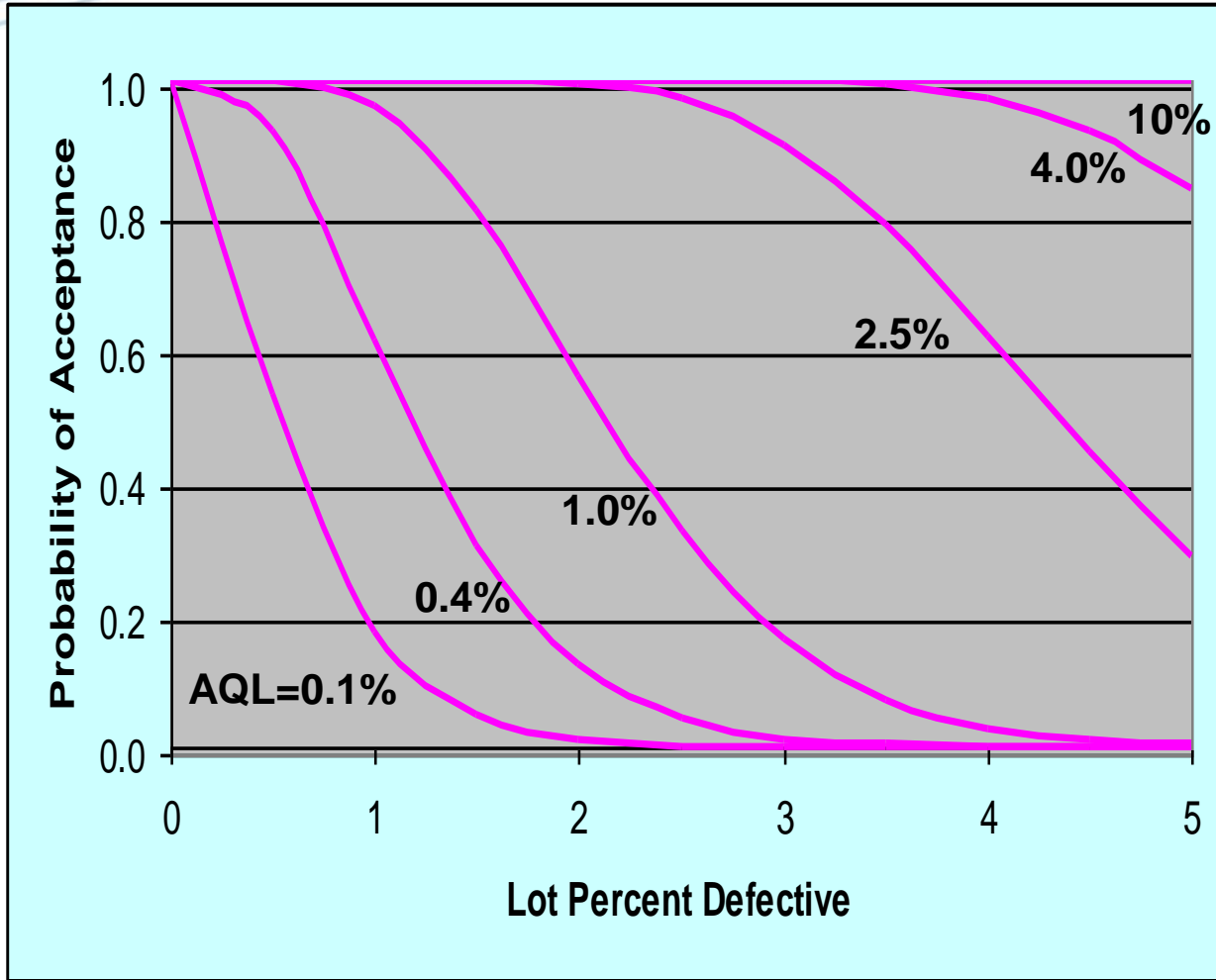
Effect of Lot Size (N)



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

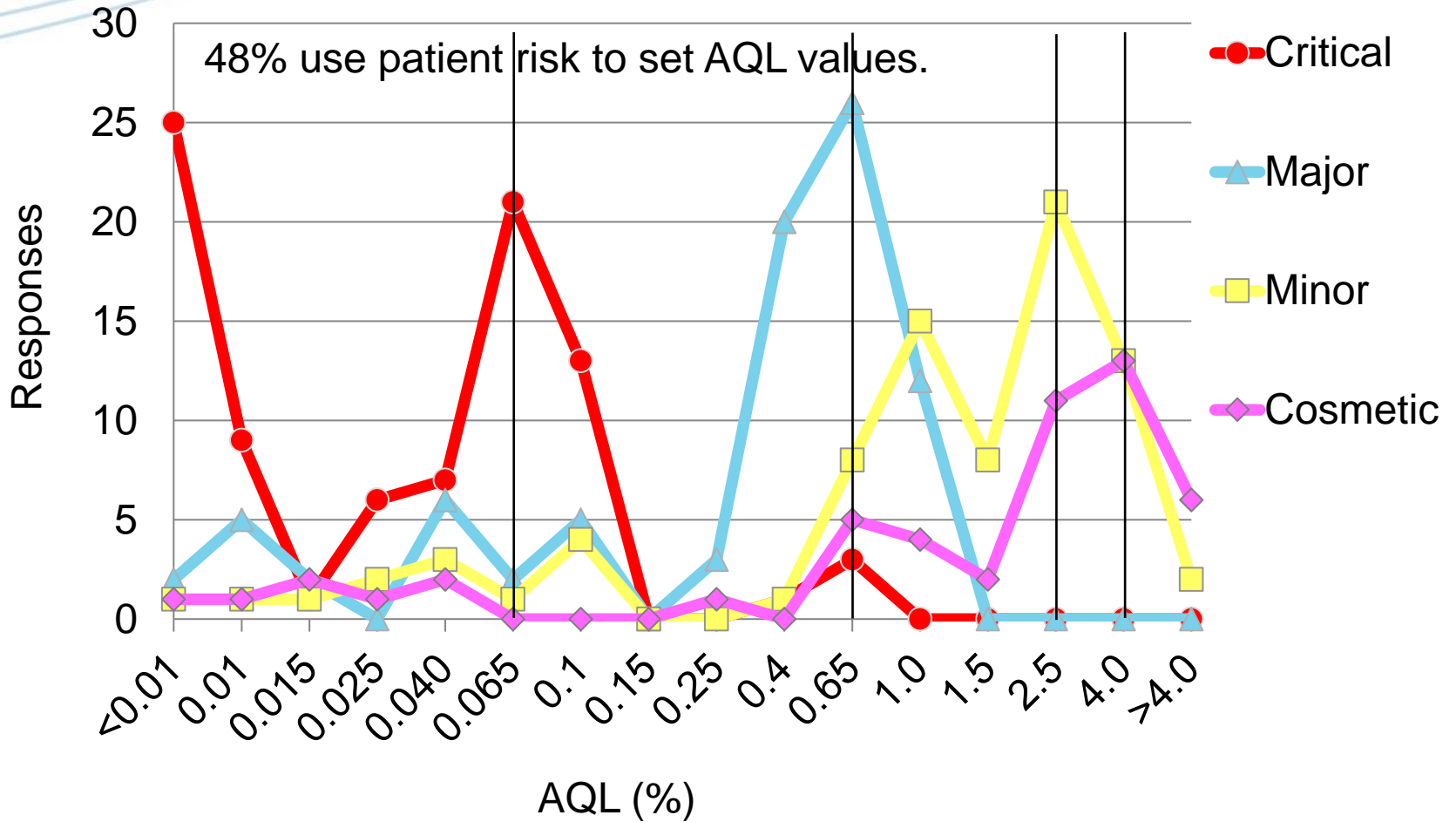
	2023	2014	2008	2003	1996
ANSI/ASQ Z1.4	63%	65%	53%	70%	90%
ISO 2859	29%	23%	11%	10%	0%
JIS Z9015	0%	7%	15%	5%	0%
Mil Std 1916	2%	3%	11%	0%	0%
Dodge Romig	1%	1%	0%	5%	0%
Other	5%	2%	10%	0%	10%

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

From 2023 PDA Visual Inspection Survey

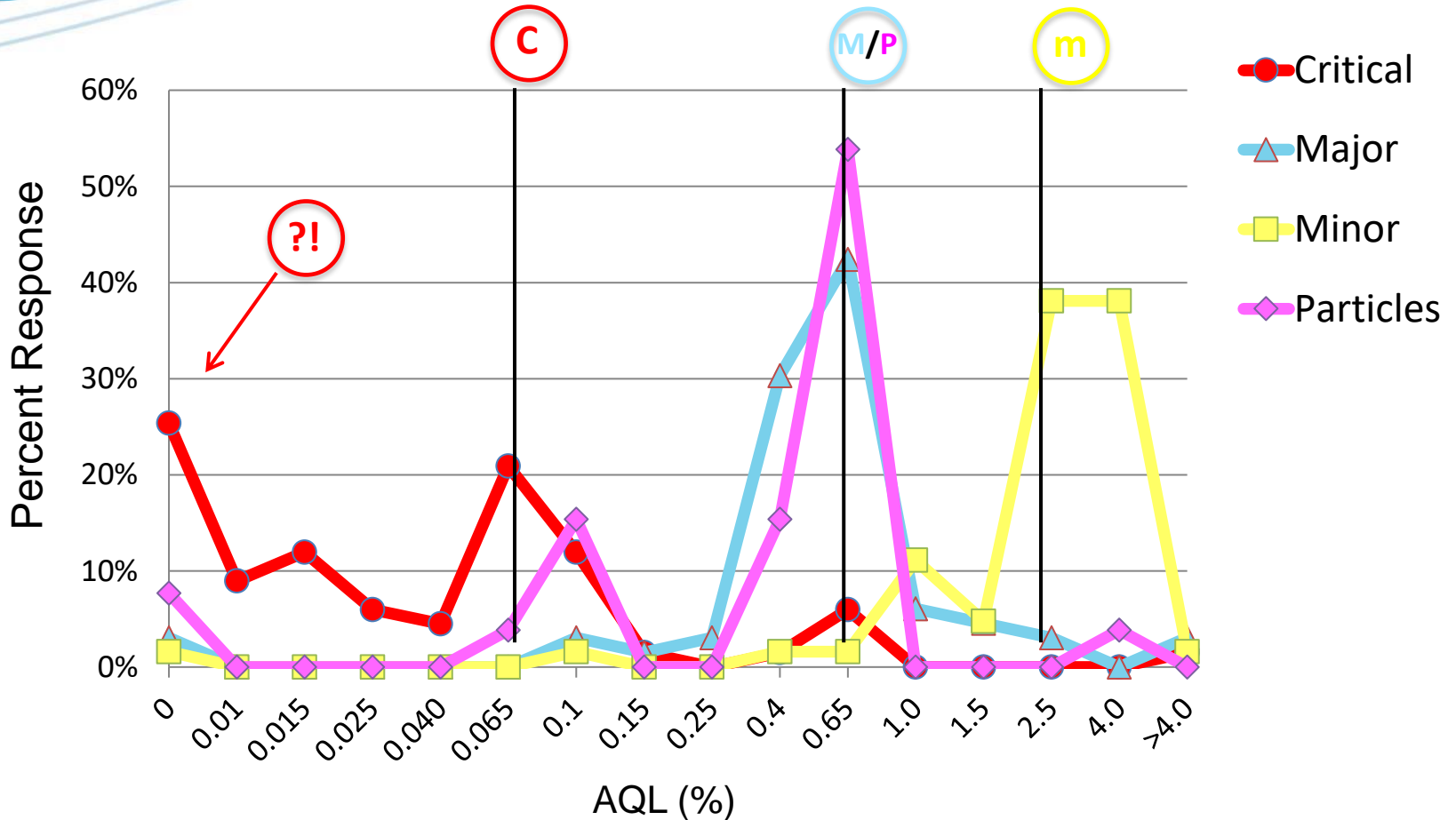


What AQL value (in %) do you use for acceptance sampling of these defect categories?





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



From 2023 PDA Visual Inspection Survey

An Introduction to Visual Inspection



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	B	
9	to	15	A	A	A	A	A	C	
16	to	25	A	A	B	B	B	D	
26	to	50	A	B	B	C	C	E	
51	to	90	B	B	C	C	C	F	
91	to	150	B	B	C	D	D	G	
151	to	280	B	C	D	E	E	H	
281	to	500	B	C	D	E	F	J	
501	to	1200	C	C	E	F	G	K	
1201	to	3200	C	D	E	G	H	L	
3201	to	10000	C	D	F	G	J	M	
10001	to	35000	C	D	F	H	K	N	
35001	to	150000	D	E	G	J	L	P	
150001	to	500000	D	E	G	J	M	Q	
500001	and	over	D	E	H	K	N	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	Ac Re
A	2	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
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	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
Q	1250	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓	↓
R	2000	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑

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

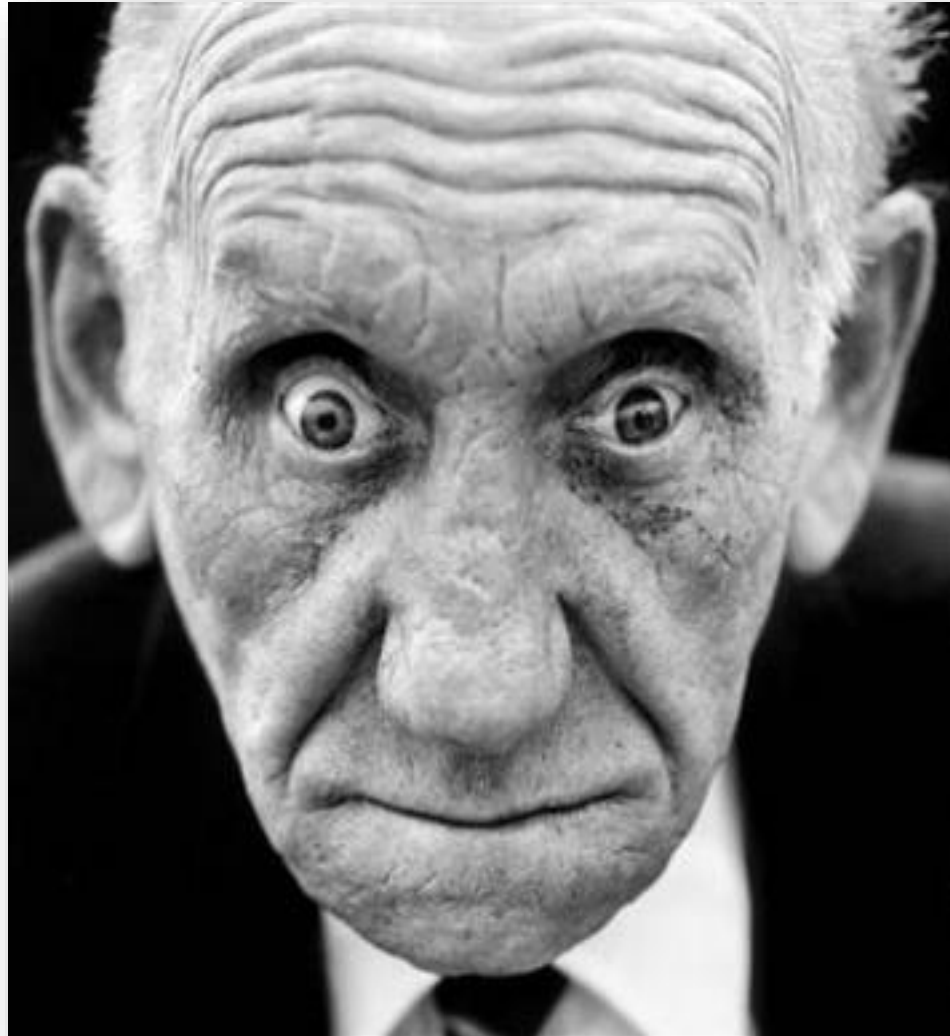


What should you do when you exceed the Accept Number?

- 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?



An Introduction to Visual Inspection

© 2023 John G. Shabushnig