Acceptance Sampling and Its Application to Visual Inspection of Injectable Products

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

johnshabushnig@aol.com
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An Introduction to Visual Inspection

How Do We Inspect?

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

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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

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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.

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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.
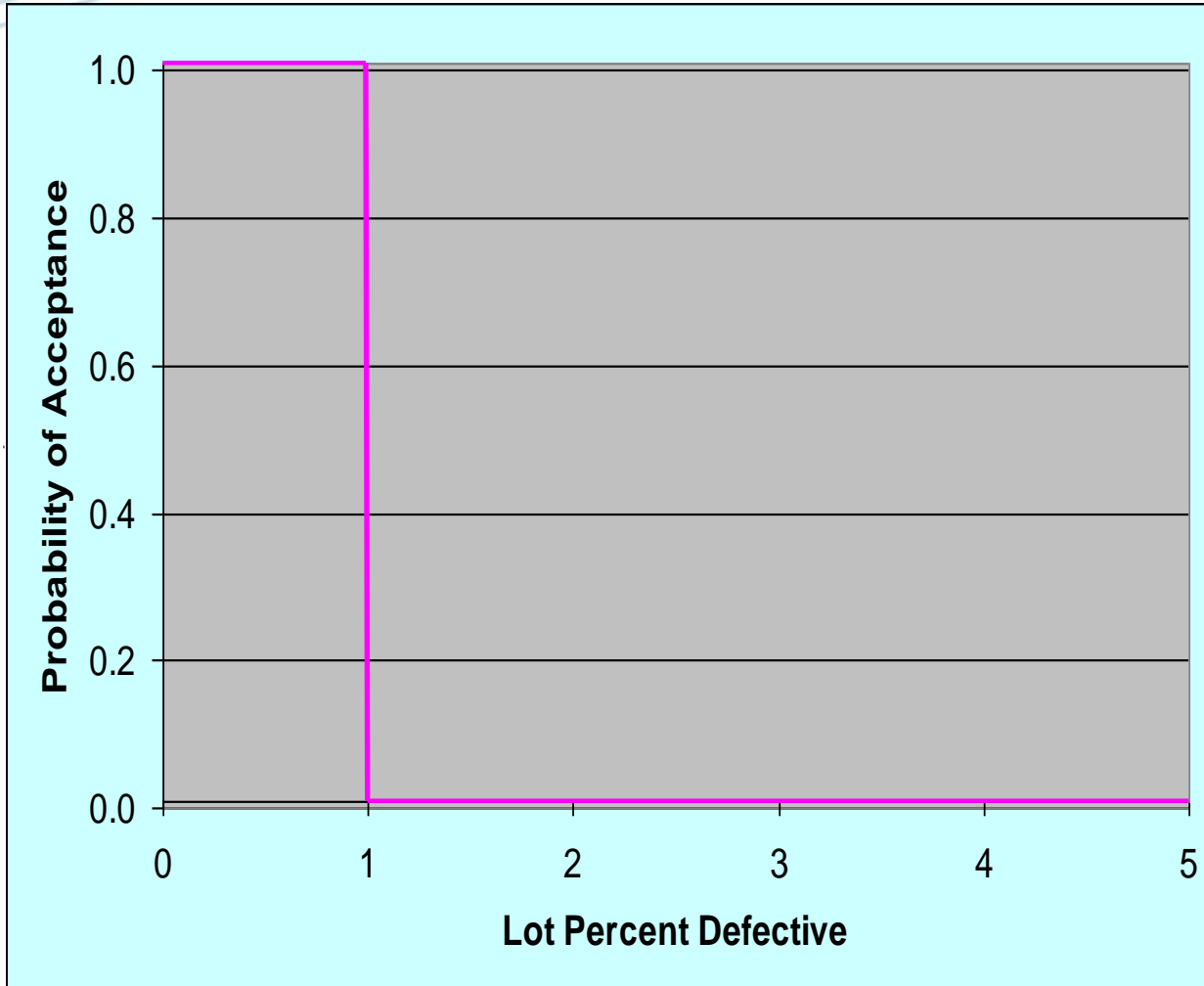
Acceptance Sampling Terms

- 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.
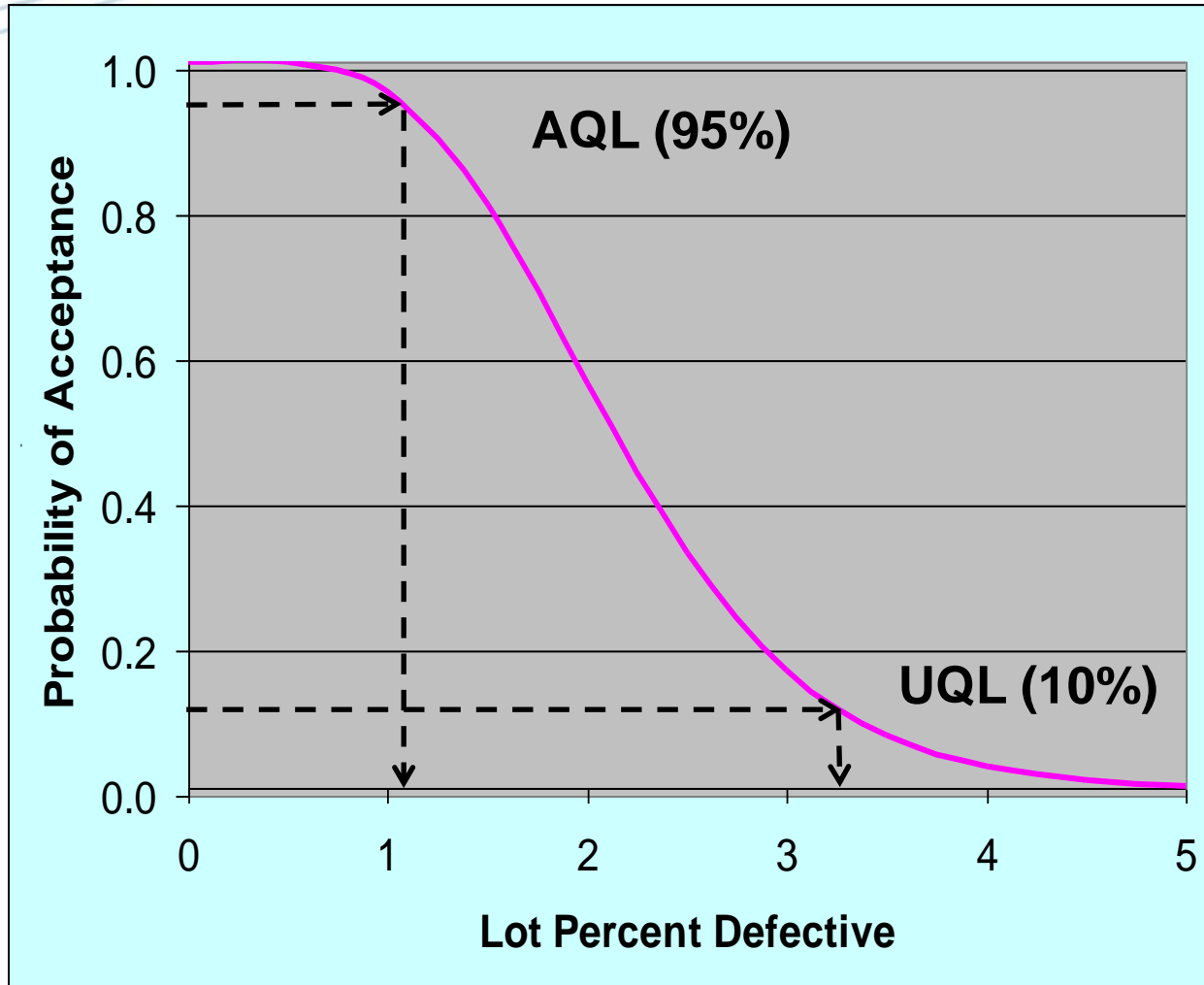
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Ideal Operating Characteristic Curve

AQL = 1.0%

UQL = 1.0%

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Operating Characteristic Curve

Single

N = 50,000

n = 315

a = 6

AQL = 1.1%

UQL = 3.3%

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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.
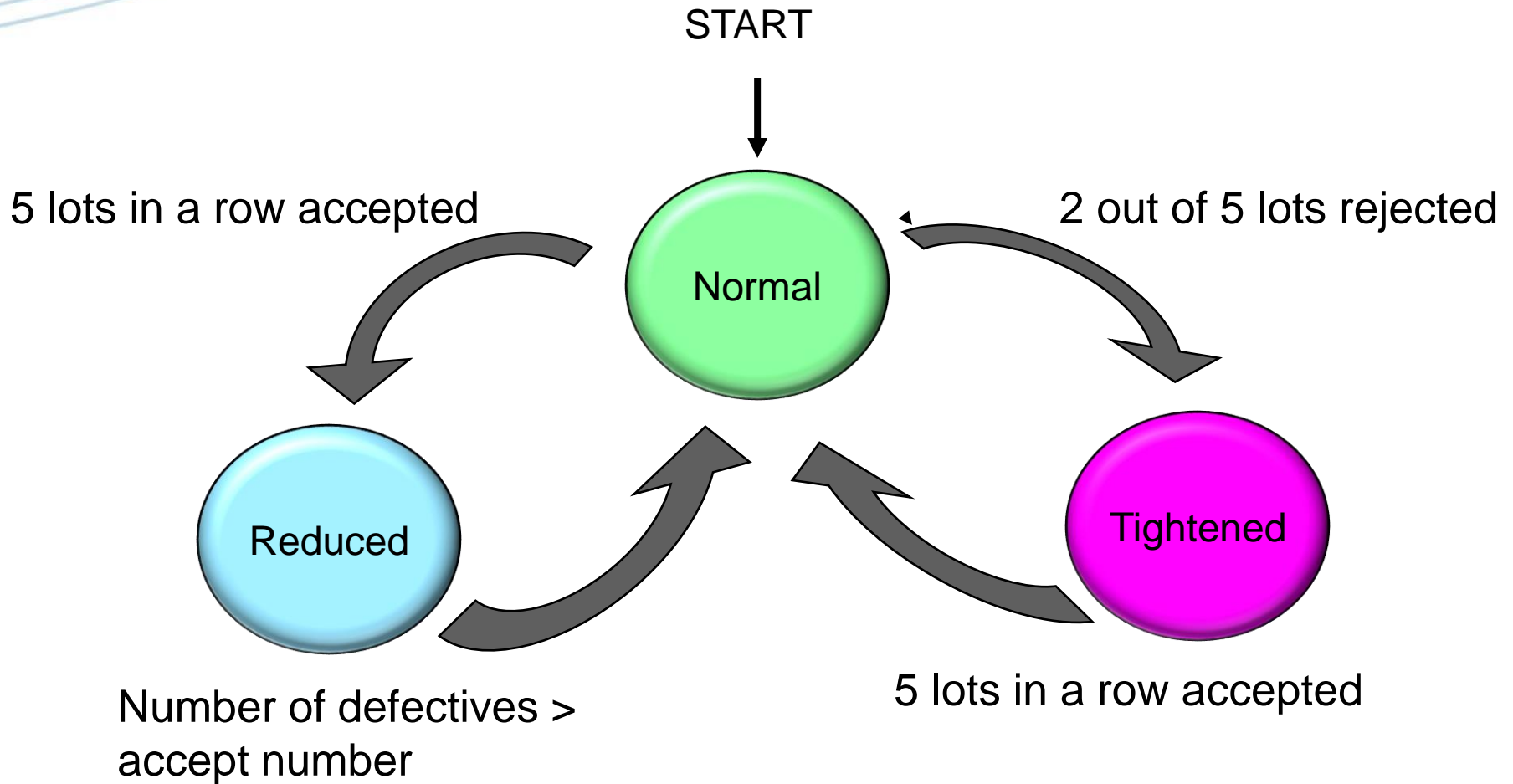
Acceptance Sampling Terms

- 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.
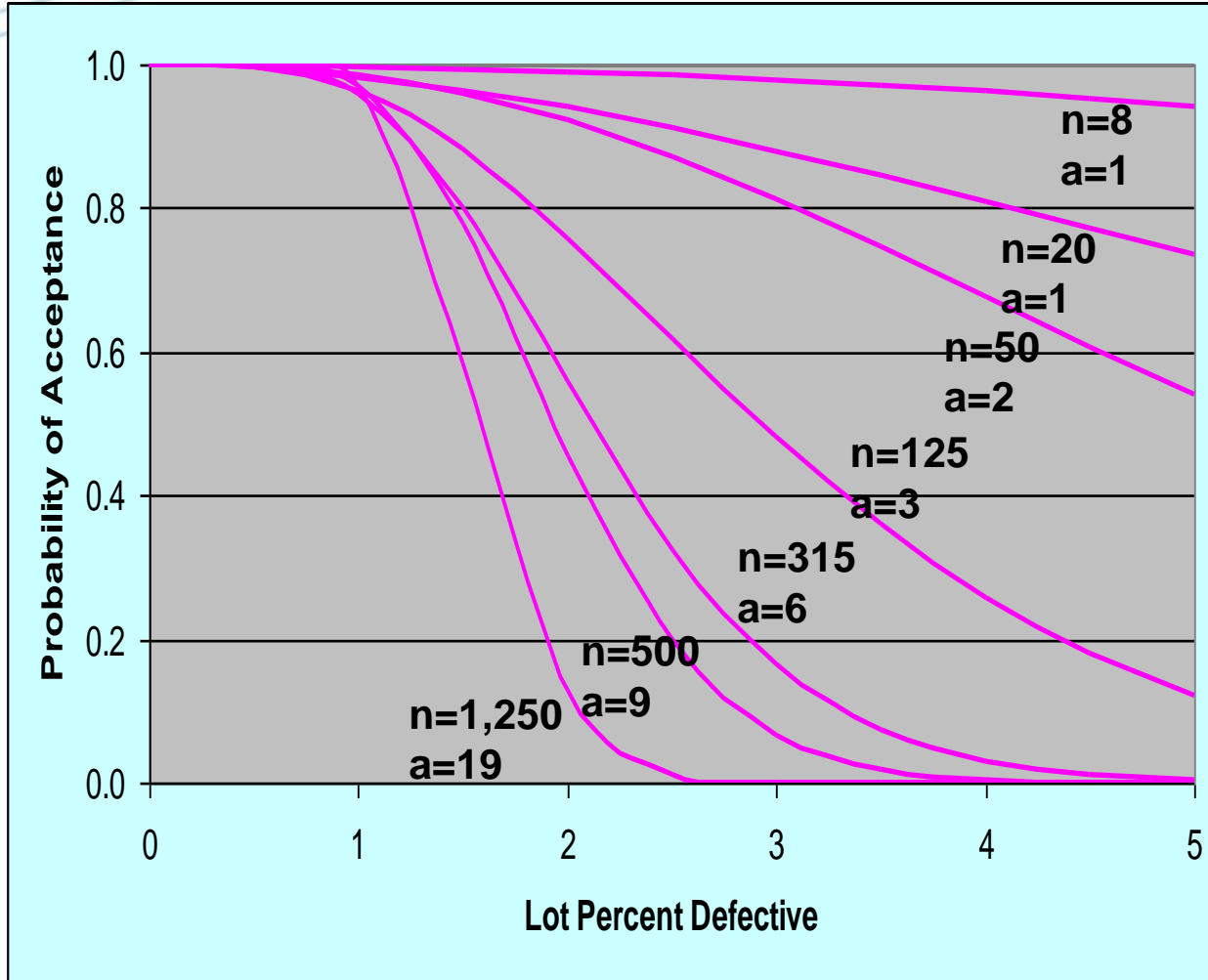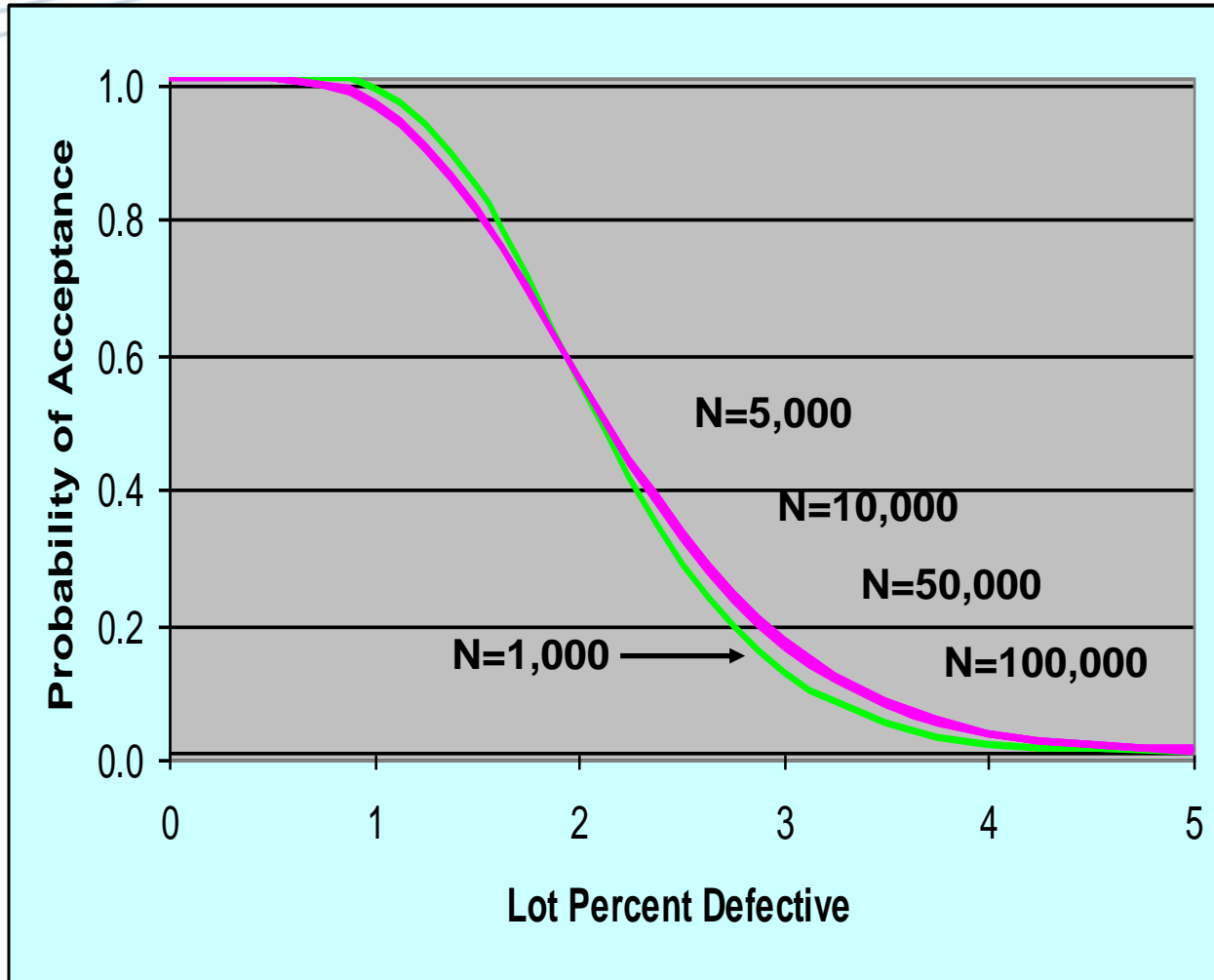
Switching Rules

START

5 lots in a row accepted

2 out of 5 lots rejected

Normal

Reduced

Tightened

Number of defectives >
accept number

5 lots in a row accepted

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Effect of Sample Size (n)

Single

N = 50,000

AQL = 1.1%

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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

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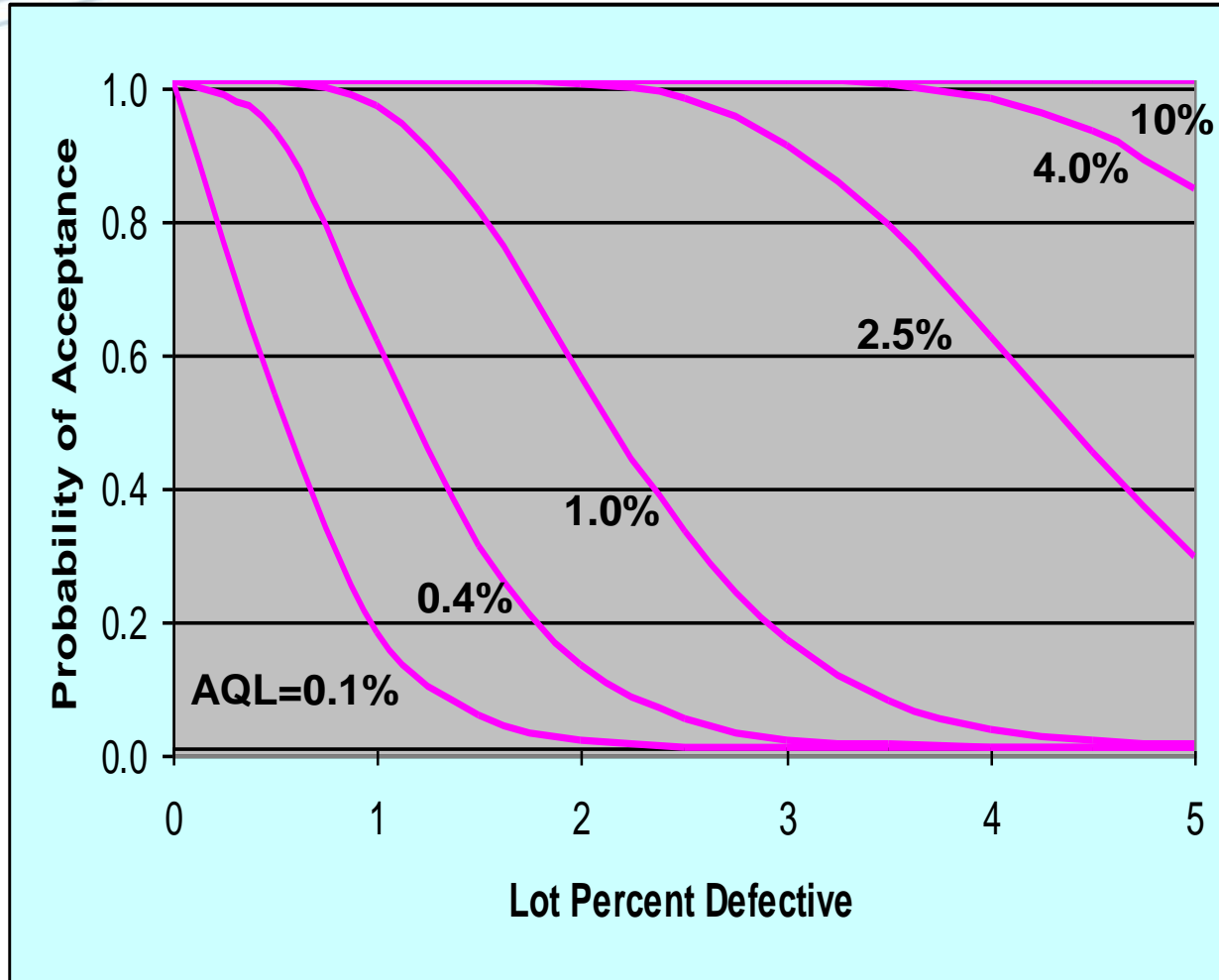
Standard Sampling Plans

- 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)
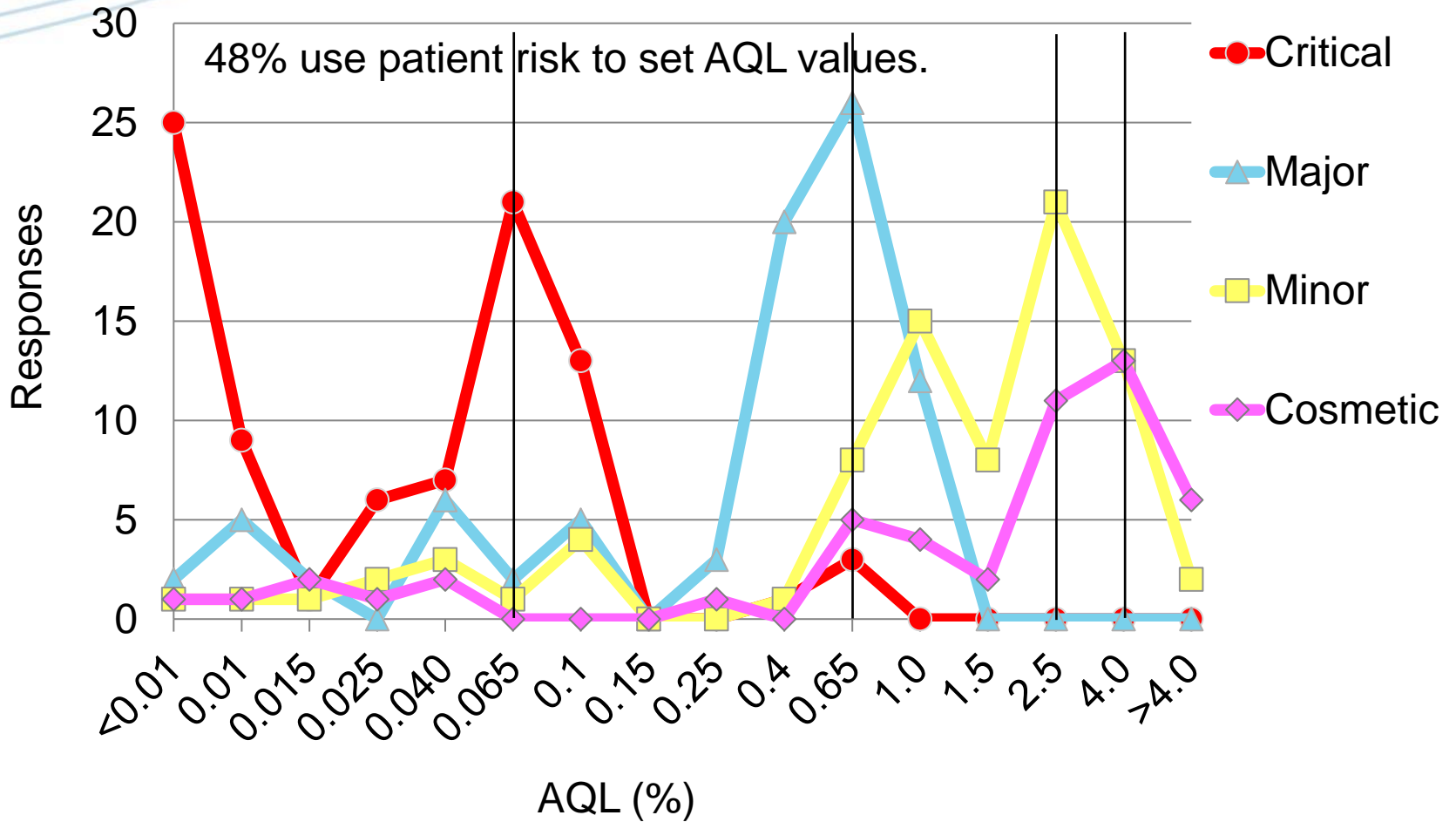- Mil Std 1916
  - Zero accept plans

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Sampling Plans

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

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

48% use patient risk to set AQL values.

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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

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ANSI Z1.4 Sampling Table

Sample Collection

- Random

- Stratified

  – Subgroups

- Periodic

  – Simple procedure

  – Easy to automate

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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
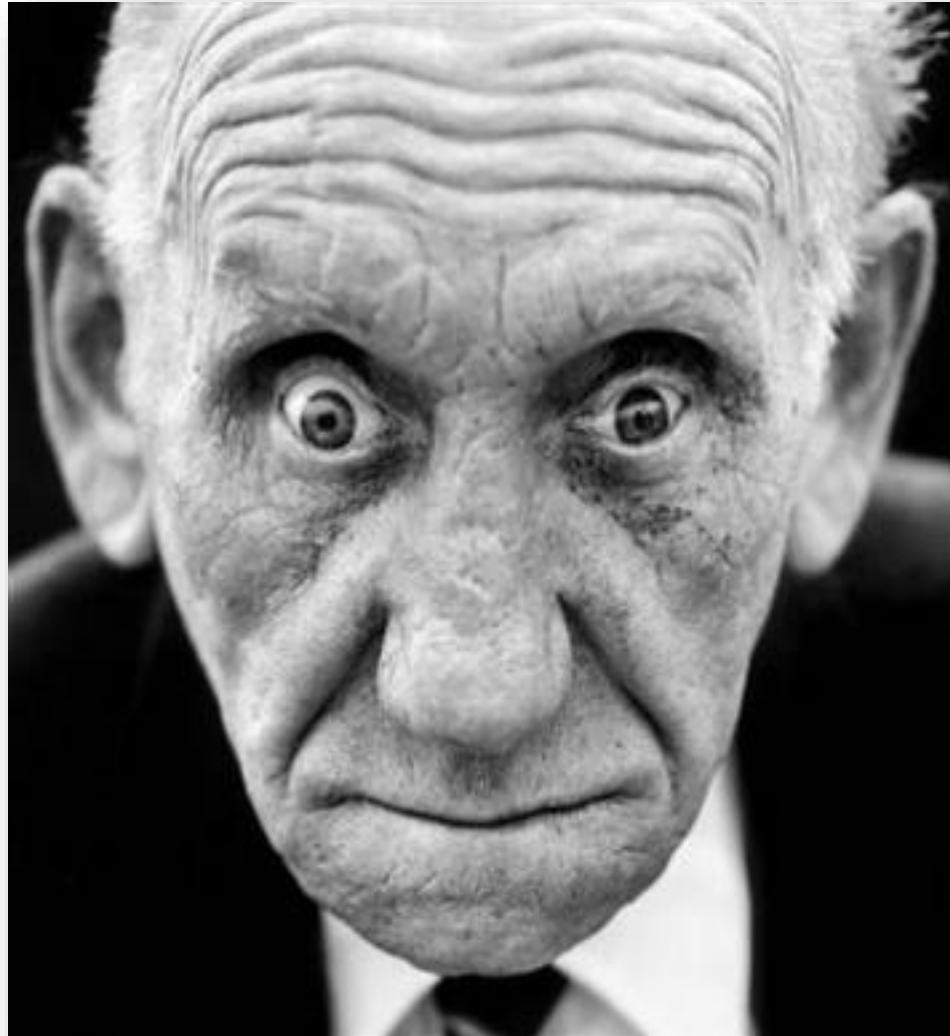   - Manufacturing or Inspection process

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

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