pda.org



Mastering AVI

Part8: Visual inspection life-cycle and control strategy

- Integration of visual inspection into overall manufacturing process
- Elements of lifecycle
- Particle identification/characterization
- Defect libraries as dynamic database
- AQL and control charting



Instructor Lead: Romain Veillon / Fernand Koert / Sébastien Koch

© Copyright PDA Author Romain Veillon



Mastering Automated Visual Inspection

.....control strategy is key

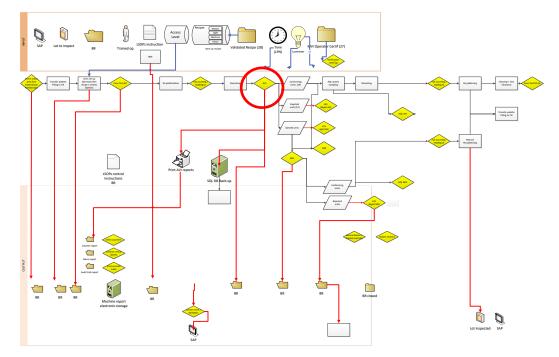




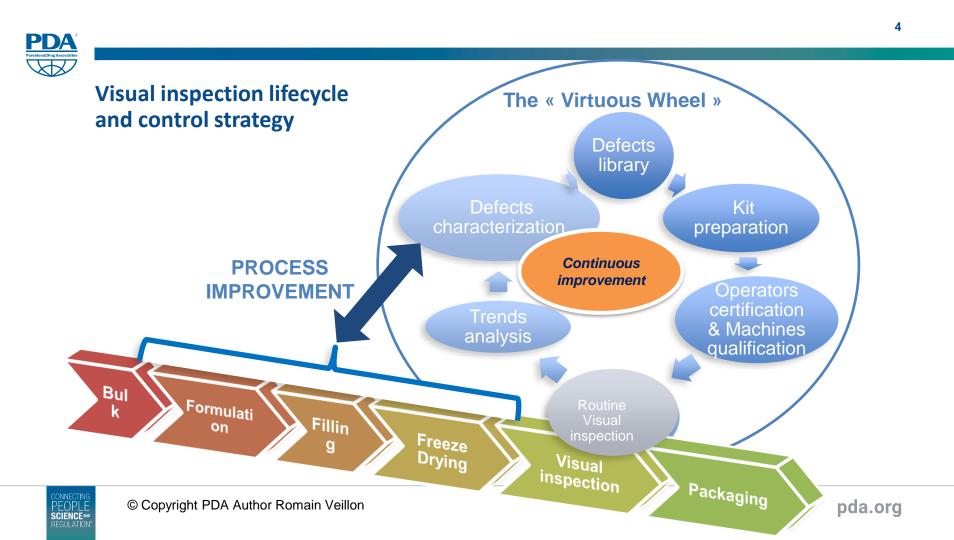




AVI Equipment is part of an overall VI process





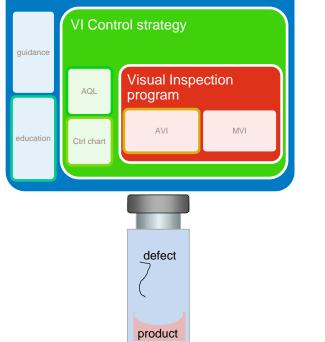




Visual inspection program in 3 layers:

- -The Core is AVI/MVI program, with strategy for DML / standard work / certification / validation
- -The control strategy with ctrl chart and AQL guarantees that VI is kept under control
- Continuous improvement is the goal of all VI activities with CAPA mngt. The Particle management is a key to success with particle control and associated WOW & education, product life cycle approach

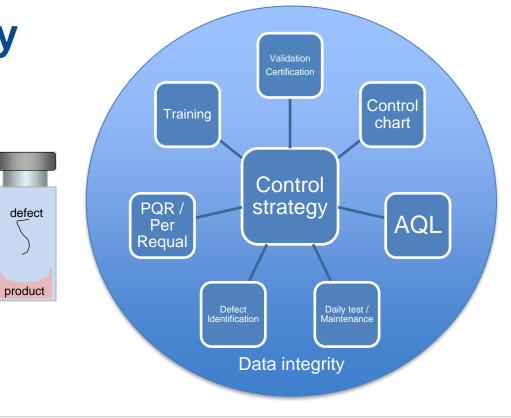








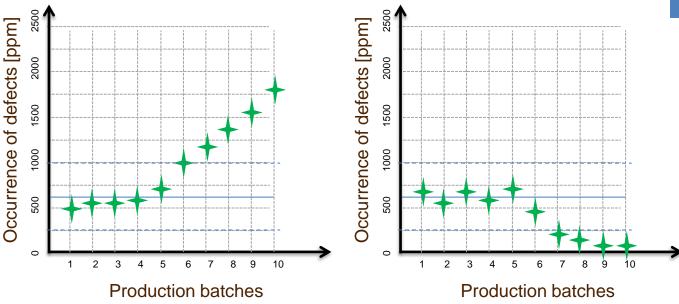
Control strategy







Why defect trending is key ?



Key take-away: SPC trend chart is a way to control absence of drift of VI process



pda.org



Why a robust SPC is key for VI?

Use of ctrl chart necessary because VI is a Markov like process (probabilistic)



$$UCL = \overline{p} + 3\sqrt{\frac{\overline{p}(1-\overline{p})}{n_i}} \qquad UCL = \overline{p} + 3\sqrt{\frac{\overline{p}(1-\overline{p})}{n_i}}$$

• 3 sigma probability follow binomial law

with 99,7% proportion of defective units

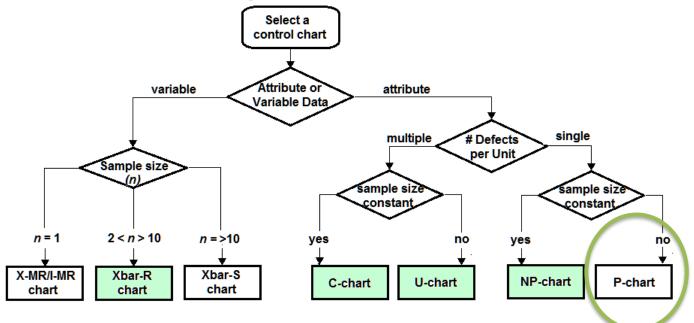


Key take-away: AVI is probabilistic So it is key to control source contamination upstream even if AVI is validated





Type of control charting



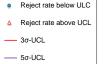


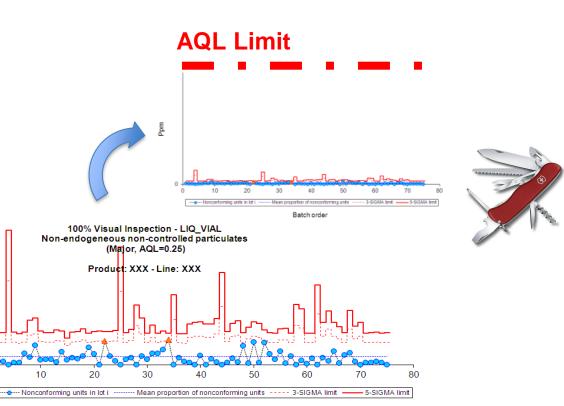


Continuous Performance Monitoring

Control Strategy- Ctrl chart

Take AWAY: Even with a low probability of detection (non NULL!!) the UCL limit is the strength of the control strategy, it has the ability to discard atypical lots in term of occurrences. It has a far lower detection than AQL Even with probabilistic detection ctrl chart can detect atypical lots





Batch order





AQL Sampling

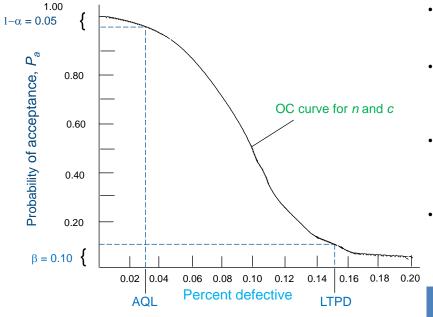
- AQL done in MVI
- AVI qualification is compared to MVI reference
- Use ISO tables
- AQL is a quality decision test
- AQL is under quality unit reponsibility



11



AQL Sampling and OC curve

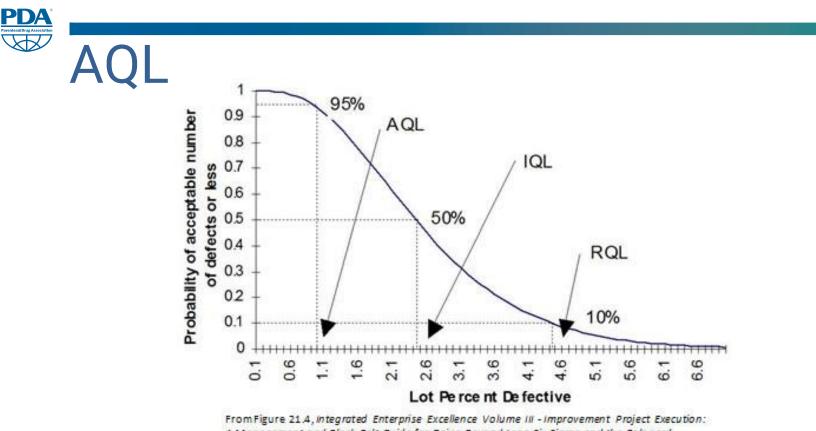


- Acceptable quality level (AQL) Acceptable fraction defective in a lot
- Lot tolerance percent defective (LTPD or RQL)
 - Maximum fraction defective accepted in a lot
- Producer's risk, α
 - Type I error = P(reject a lot|probability (defective)=AQL)
 - Consumer's risk, β Type II error = P(accept a lot| probability(defective)=LTPD or RQL)

<u>Key learning:</u> AQL are always associated to RQL in an OC curve, this is the patient risk

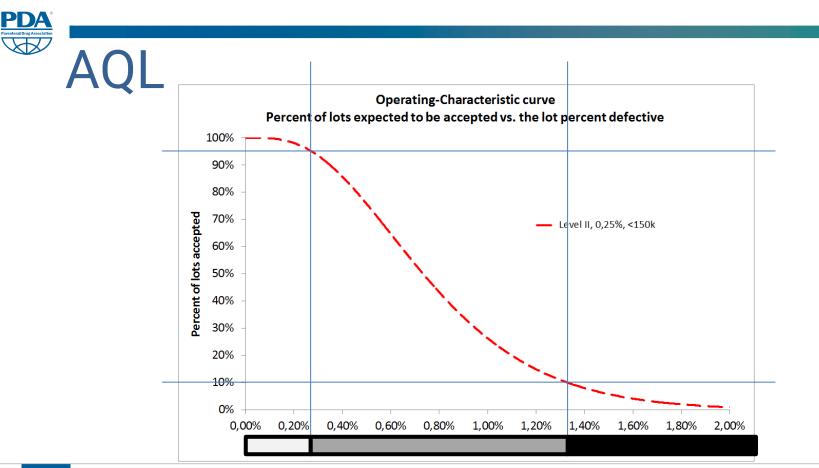


pda.org



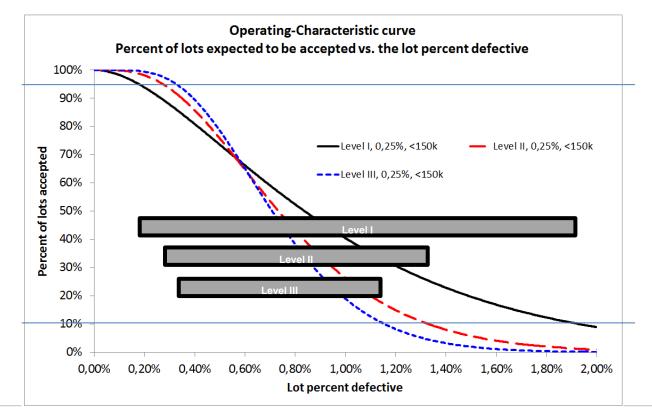
From Figure 21.4, integrated Enterprise Excellence Volume III - Improvement Project Executi A Management and Black Belt Guide for Going Beyond Lean Six Sigma and the Balanced Scorecard, Forrest W. Breyfogle III, Bridgeway Books/Citius Publishing, Austin, TX, 2008.















AQL Sampling and ISO tables

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 00
		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 R
A	2	Π	Π	Π	Π	Π	Π	Π	Π	Π	Π	Π	Π	Π	∿	0 1	Π	♦	1 2	2 3	3 4	5 6	78	10 11	14 15	21 22	30 3
в	3													Ŷ	0 1	ټ	1	1 2	2 3	3 4	5 6	78	10 11	14 15	21 22	30 31	44 4
с	5												Ŷ	0 1	ټ	∿	1 2	2 3	34	5 6	78	10 11	14 15	21 22	30 31	44 45	
D	8		-		1-11			1-11-			1-11-	1	0 1	�	₽	1 2	2 3	3 4	56	78	10 11	14 15	21 22	30 31	44 45		11
Е	13										1	0 1	ټ	∿	1 2	2 3	34	5 6	78	10 11	14 15	21 22	30 31	44 45	Ŷ		
F	20									Ŷ	0 1	↔	❖	1 2	2 3	34	56	78	10 11	14 15	21 22			介			
G	32				1-11-				1	0 1	أ	₽	12	2 3	3 4	5 6	78	10 11	14 15	21 22	Ŷ	1-11-				t- -	F1F
н	50							1	0 1	ټ	\$	1 2	2 3	34	5 6	78	10 11	14 15	21 22								
J	80						1	0 1	ټ	∿	1 2	2 3	34	56	78	10 11	14 15	21 22	俞								
к	125				111	1	0 1	ټ	\$	1 2	2 3	3 4	5 6	78	10 11	14 15	21 22	介				1-11-	- -				11
L	200				1	0 1	♦	\$	1 2	2 3	34	5 6	78	10 11	14 15	21 22	介										
м	315			1	0 1	أ	∿	1 2	2 3	34	56	78	10 11	14 15	21 22	介											
N	500		1	0 1	☆	∿	1 2	2 3	34	56	78	10 11	14 15	21 22	î												F1F
P	800	₽	0 1	ټ	\$	1 2	2 3	34	56	78	10 11	14 15	21 22	介													
Q	1 250	0 1	î	❖	1 2	2 3	34	5 6	78	10 11	14 15	21 22															
R	2 000	৵	-0-	1 2	2 3	34	56	78	10 11	14 15	21 22	৵		-11-	1	1			1	-0-		1-11-1	1-0-		1	1-0-	ΓŬ

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

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

 $\mathbf{\hat{v}}$ = Use the first sampling plan above the arrow.

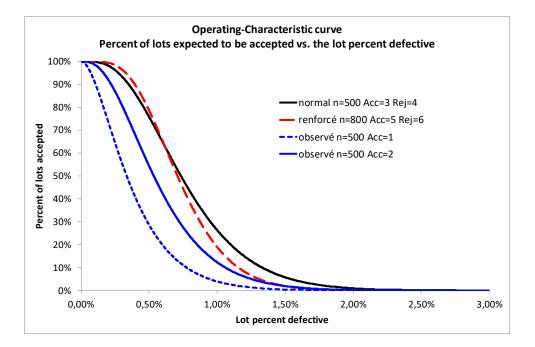
Ac = Acceptance number

Re = Rejection number



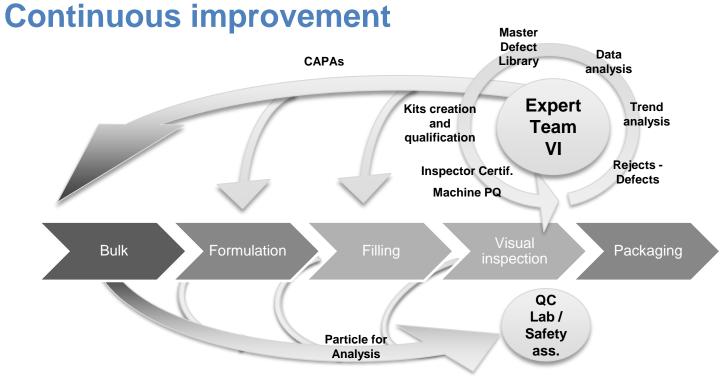


Why do we need to perform Tightened AQL in special cases ?













In this section you have learnt:

Ctrl	Integration of visual inspection into overall manufacturing process							
strat.	Elements of lifecycle							

Particle identification/ characterization

Defect libraries as dynamic database

AQL and control charting

