Change Management Cycle Time Improvement

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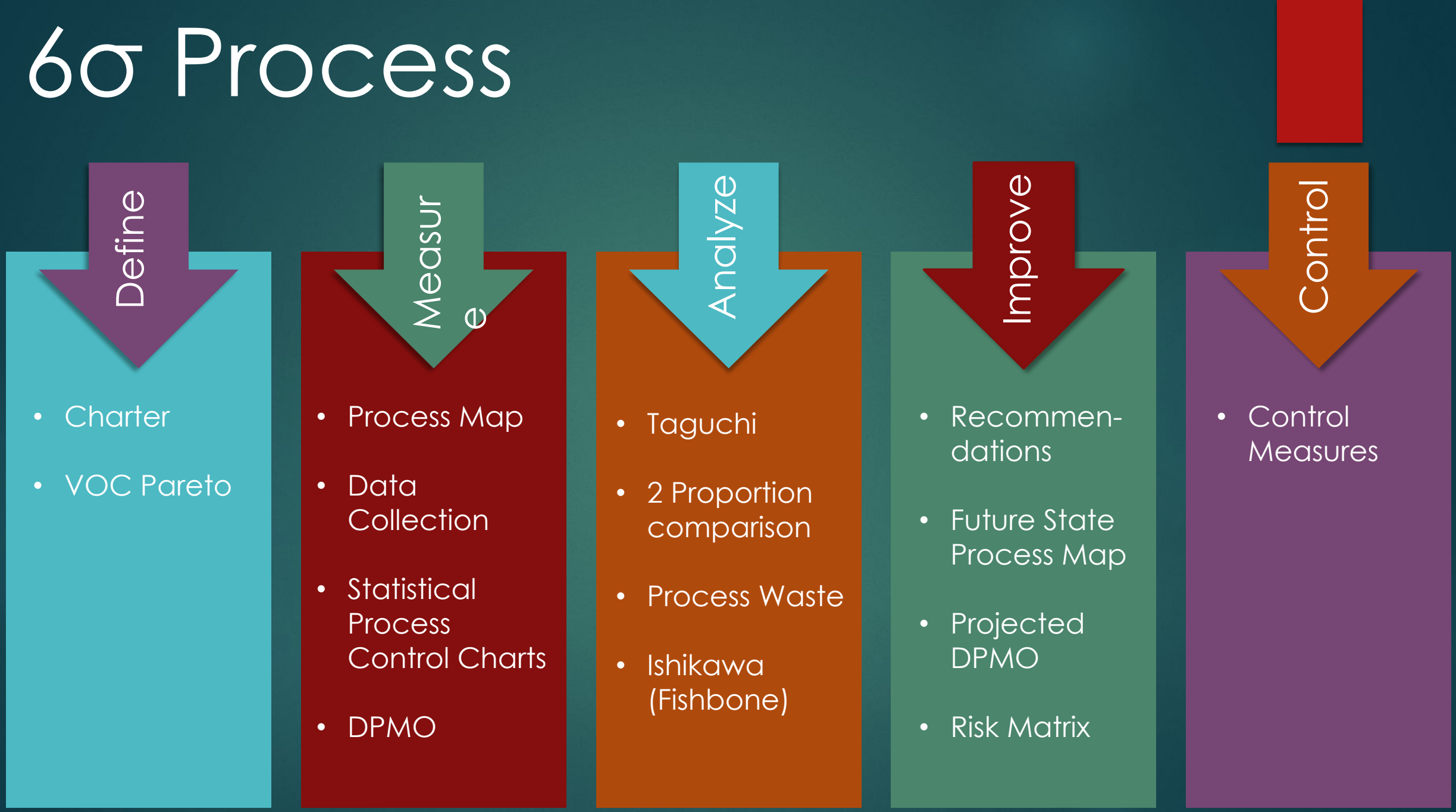
6σ Process


Define
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Future State Process Map
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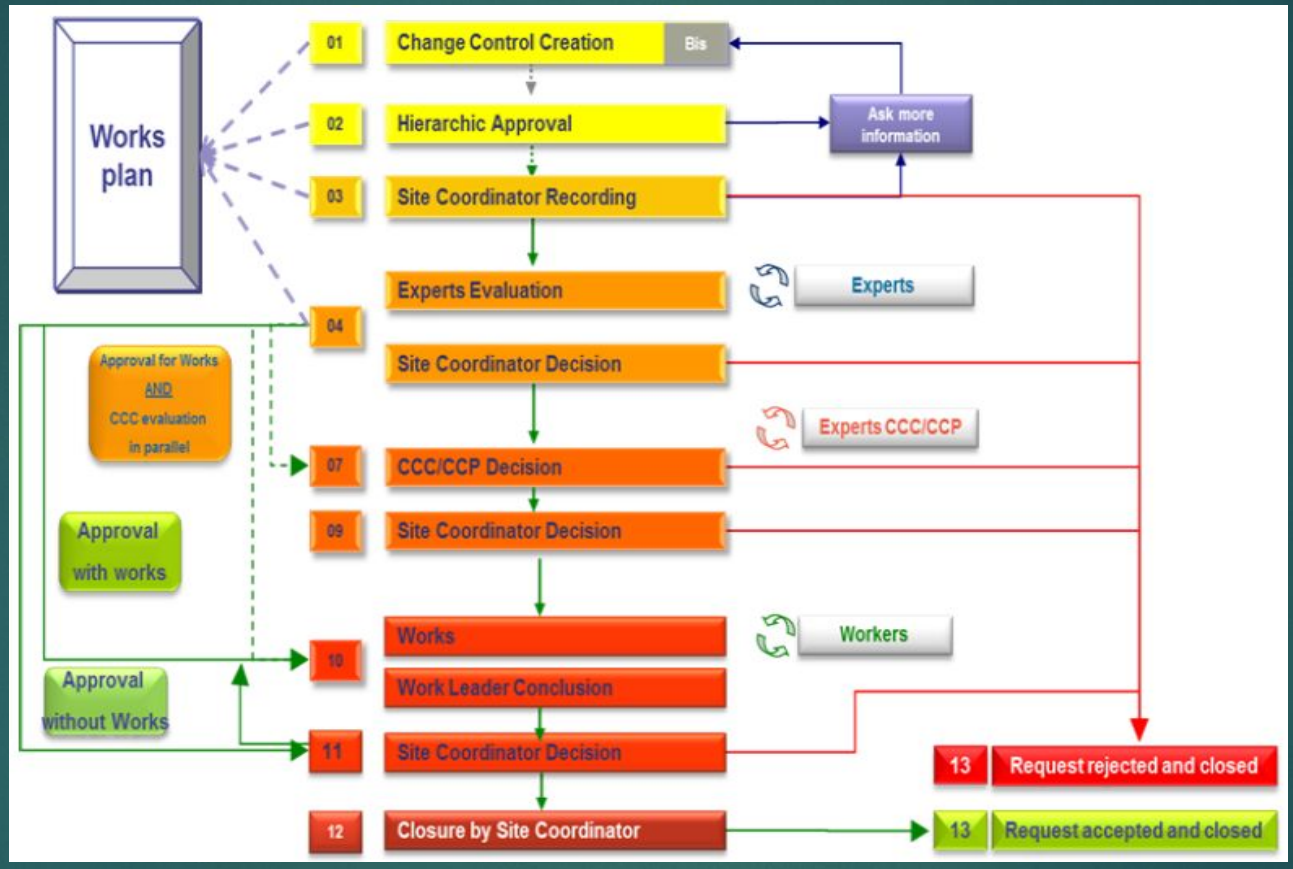
Control
Control Measures

Current State Process Map

Measure



Project Charter

Define

Process: Change Management System

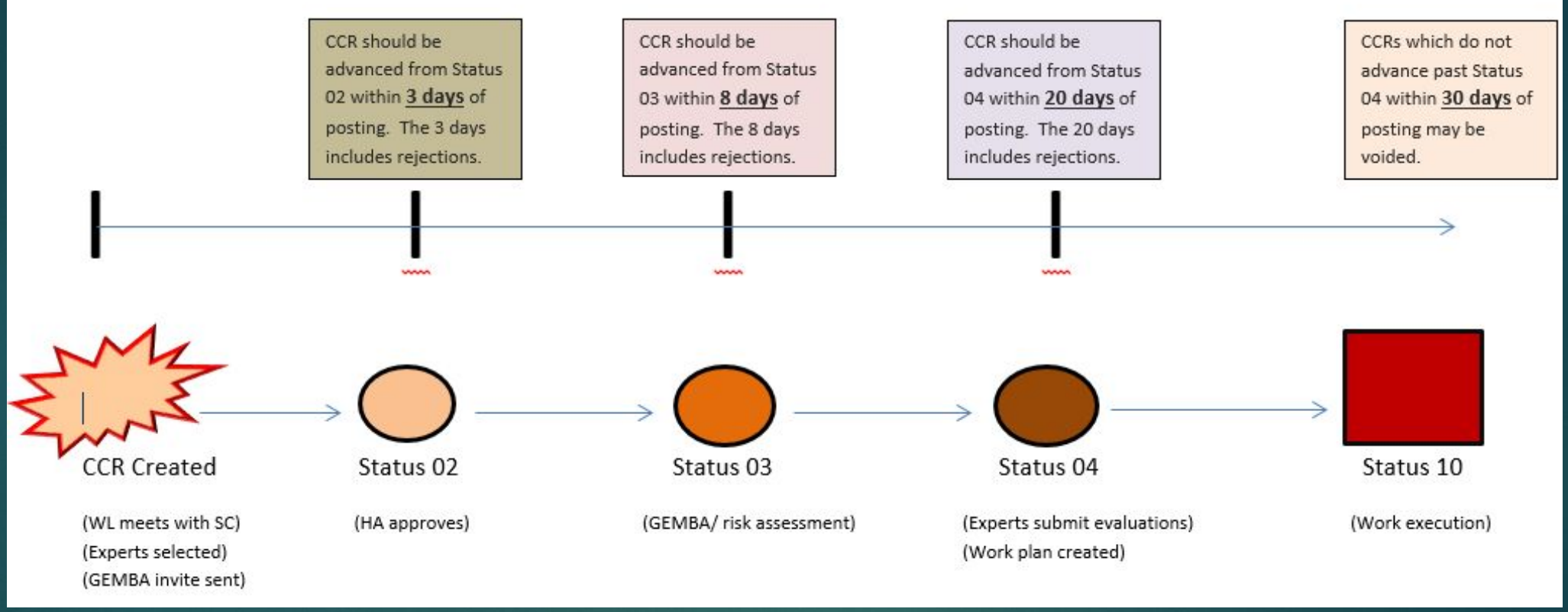
Scope: Change Control Lifecycle from Creation through Status 04 (QA Approval)

Objective: Reduce Change Control cycle time through Creation, Status 02 (Manager Approval), Status 03 (Expert Assessment) and Status 04 (QA Approval)

Metric	Current	Goal	% Improvement	Units
Cycle Time	50+ Days	≤ 20 Days	≈ 60 %	Days

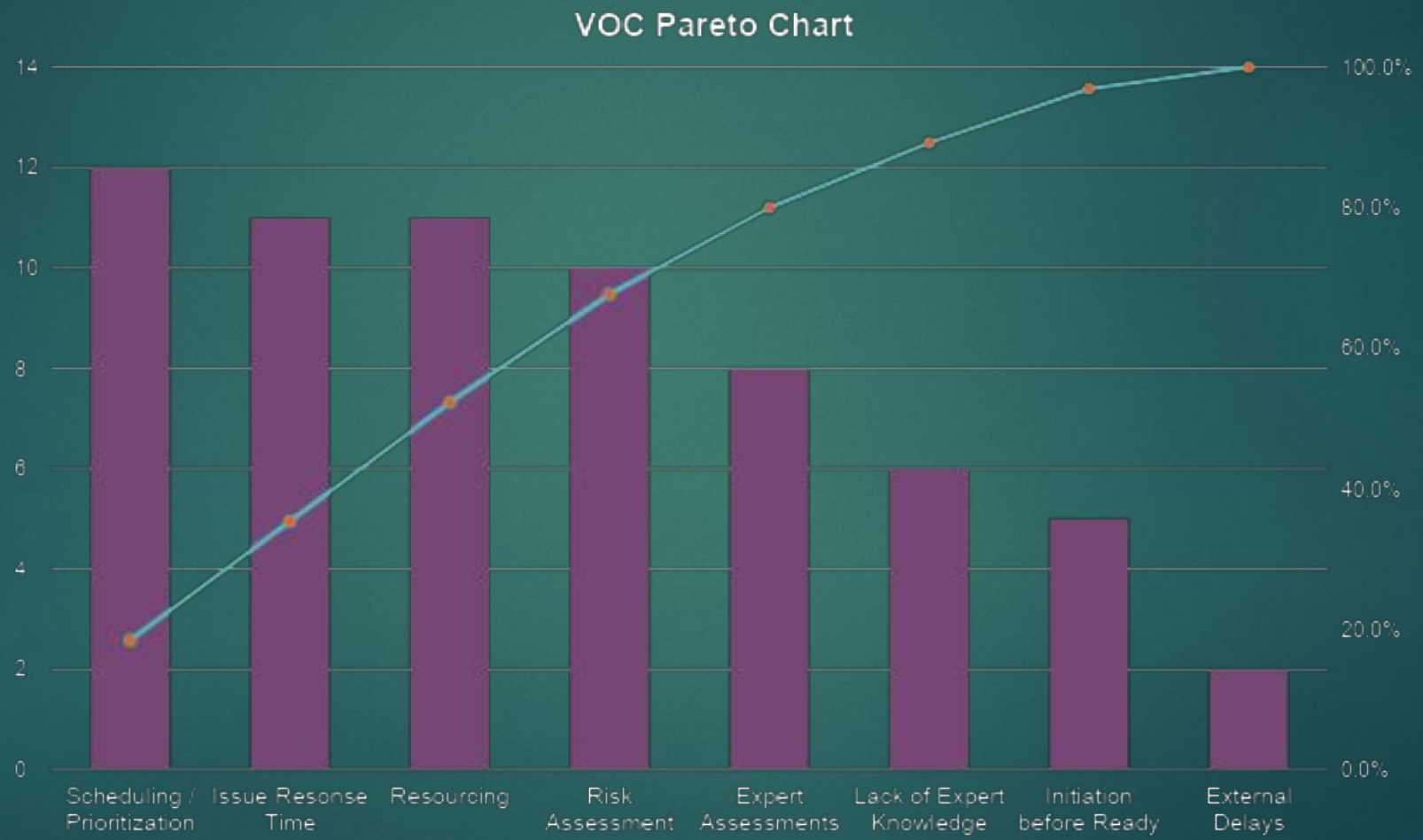
Benefits: Quicker turn around for process improvements and deviation corrective actions.

Time Line Breakdown of Key CCR Life Cycle Time Points



Voice of the Customer Pareto Chart

Define



Data Collection

Measure

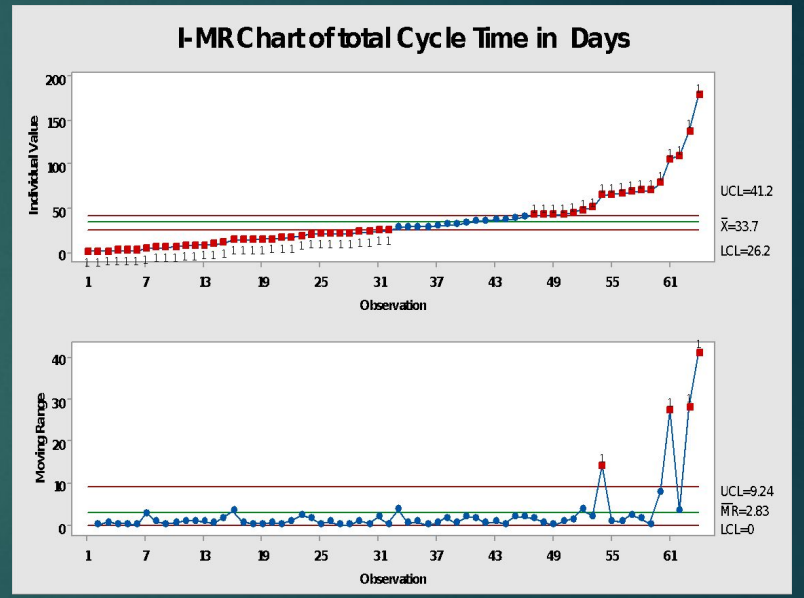
- Data pulled from Quality Systems Management Spreadsheet and Change Management Electronic System from 01APR18 through 26OCT18.
- 15 in person interviews with various roles with the Change Management System.

Data Analysis Methods:

- Cycle Time Data analyzed using 2 proportion test and Taguchi DOE.
- In person interviews analyzed using Pareto Chart.

Statistical Process Control Charts

Measure



DPMO

Measure

Defect Criteria:

Status 02	Status 03	Status 04	Total
> 3 Days	> 5 Days	> 12 Days	> 20 Days

Total Number of Change Controls: 64

Proportion of Defects: .625 (62.5%)

DPMO: .625 X 1,000,000 = 625,000

Sigma Level : 1.18

Taguchi DOE

Analyze

Day of the Week	Status 02 <3 Days	Status 03 < 5 Days	Status 04 < 12 Days	Total < 20 Days
Monday	AVG: 9.73 S/N: -13.37	AVG: 26.93 S/N: -16.28	AVG:21.62 S/N: -15.63	AVG: 42.62 S/N: -17.81
Tuesday	AVG: 6.63 S/N: -13.97	AVG: 39.53 S/N: -18.42	AVG: 16.85 S/N: -15.02	AVG: 36.15 S/N: -17.62
Wednesday	AVG: 3.03 S/N: -7.93	AVG: 25.61 S/N: -17.22	AVG: 13.84 S/N: -13.66	AVG: **27.89** S/N: **-16.30**
Thursday	AVG: 3.37 S/N: -9.48	AVG: **22.88** S/N: **-15.97**	AVG: **12.23** S/N: **-12.86**	AVG: 30.35 S/N: -16.63
Friday	AVG: **1.98** S/N: **-5.95**	AVG: 23.42 S/N: -17.13	AVG: 21.07 S/N: -16.47	AVG: 34.23 S/N: -17.67

2 Proportion Comparison

Process Waste

Analyze

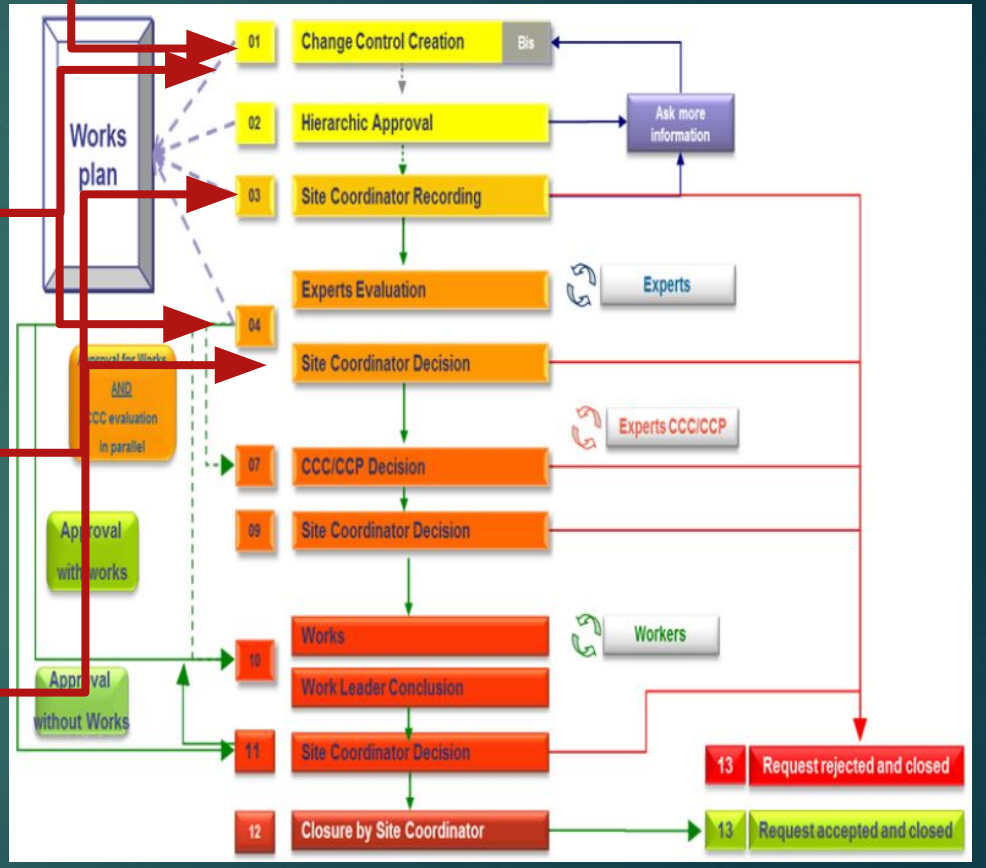
Confusion: Work Leaders unsure of change priorities.

Waiting: Waiting for problem resolution. Waiting for Approval.

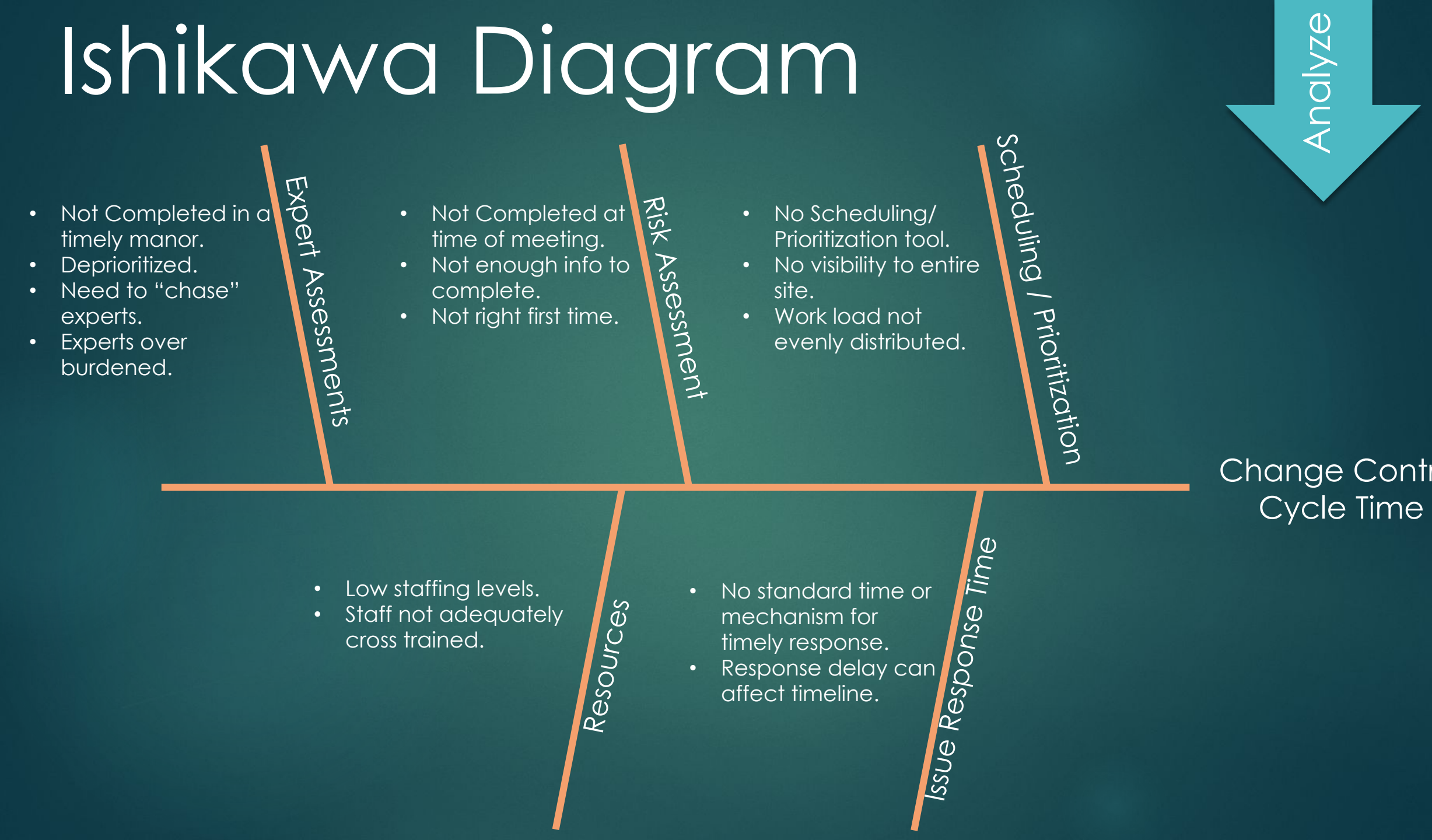
Defects: Not enough info to conduct GEMBA/RA QA rejections for errors.

Overproduction: Inconsistent level of scrutiny among QA reviewers.

Inventory: Uneven workload among staff.



Ishikawa Diagram



Recommendations

Implement the following:

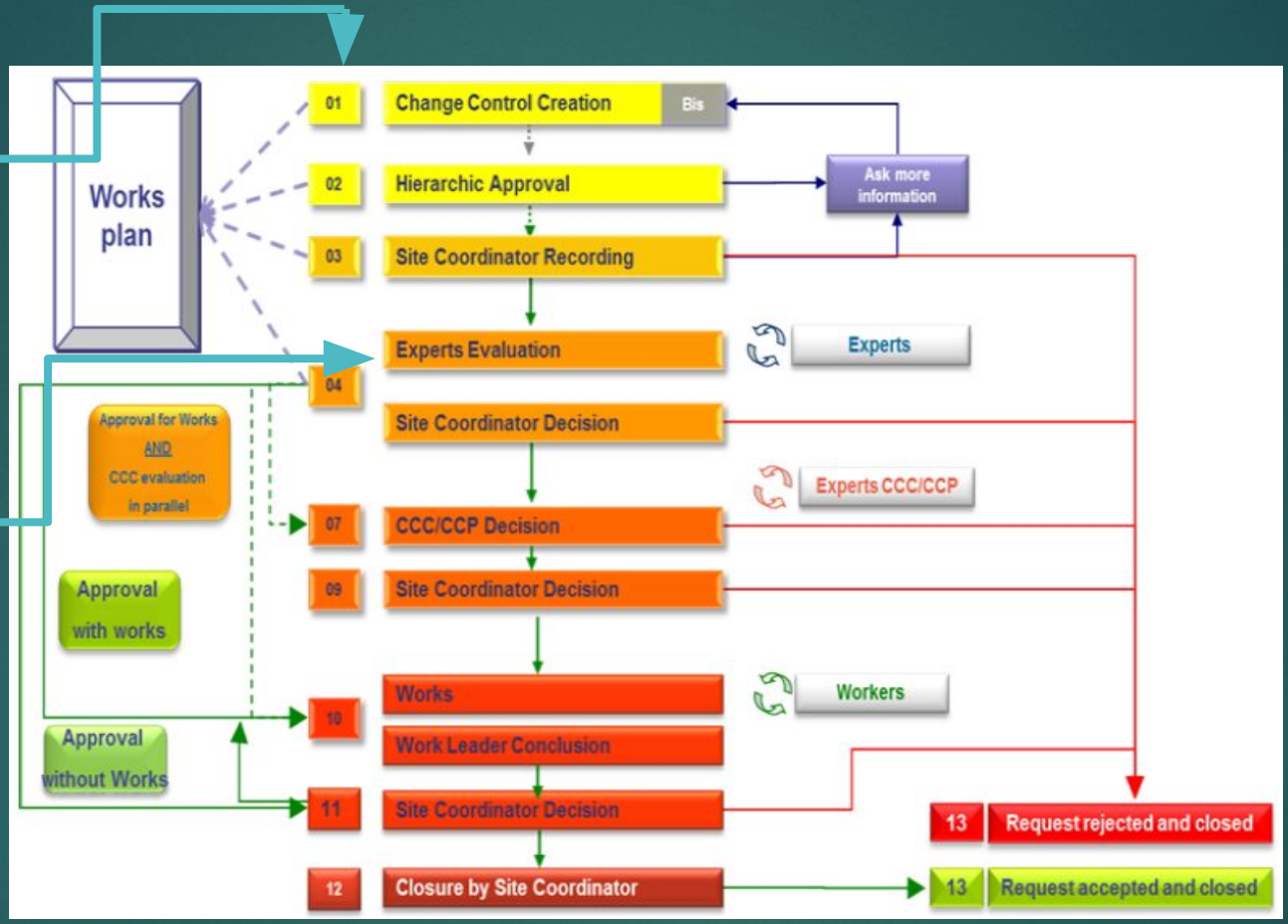
- Scheduling and prioritization tool that can manage project and resource requirements across site.
- Robust trending and escalation tool to identify problem areas and drive action.
- QA problem response tool / policy to ensure timely response to problems.
- More effective cross training methodology to raise proficiency and get employees trained into new roles faster.
- Training for Work Leaders in effective risk assessment facilitation.

Future State Process Map

Improve

Scheduling and Prioritization

Risk Facilitator Present to ensure meeting is effective and all information is completed.



More Effective Cross Training Methods.

Timely Problem Response Tool

Projected DPMO

Defect Criteria:

Status 02	Status 03	Status 04	Total
> 3 Days	> 5 Days	> 12 Days	> 20 Days

Total Number of Change Controls: xx

Proportion of Defects: xxxx

DPMO: .xxxx X 1,000,000 = xxxx

Sigma Level : xxxx

Risk Estimation Matrix

Improve

Likelihood of Occurrence	Guideline	Change Specific Criteria (Choose One)	
		☒ Failures per Operation	☐ Time between Failures*
Remote	Failure unlikely	< 3 out of every 10 operations	> 36 months
Average	Failure reasonably likely	3-6 out of every 10 operations	2-36 months
Certain	Failure very likely	> 6 out of every 10 operations	< 2 months, or unknown

		Severity		
		Minor	Moderate	Critical
Likelihood of Occurrence	Certain	Medium	High	High
	Average	Low	Medium	High
	Remote	Low	Low	Medium

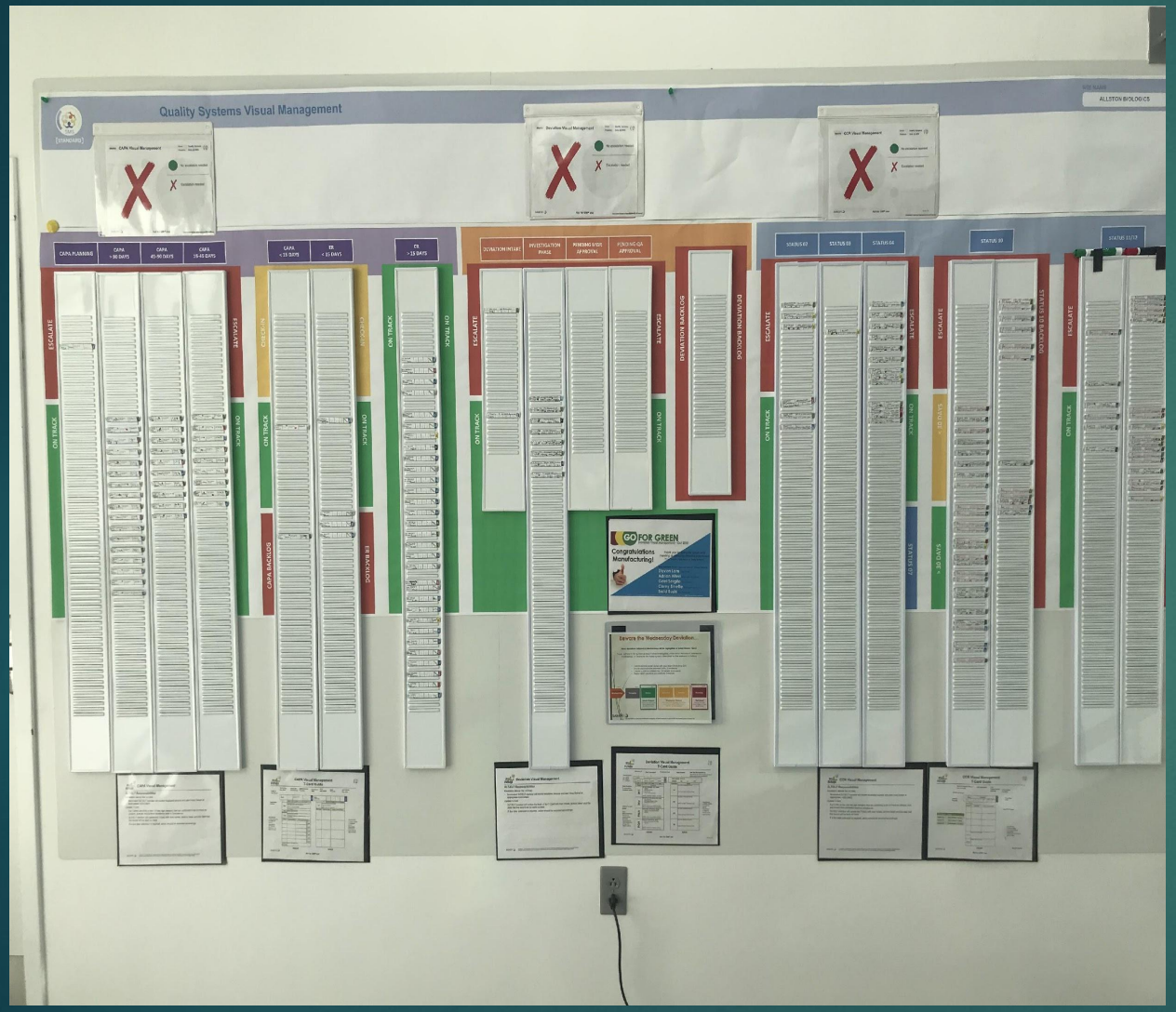
Severity	Guideline	Change Specific Criteria
Minor	Insignificant effect and/or no long-term consequences	No loss to product, no impact to SISPQ, and/or equipment failure fixable via corrective action in < 4 hours with spare parts available
Moderate	Moderately significant effect and/or medium-term consequences	Probable impact to SISPQ of 1 lot, and/or equipment failure not fixable without fabrication or will take > 4 hours
Critical	Significant effect and/or long-term or pervasive consequences	Probable impact to SISPQ of > 1 lot, and/or hazardous situation that may endanger equipment or personnel, and/or severity is unknown

Overall Risk	Acceptability
Low	The risk associated with the critical parameter is acceptable. No mitigation is required prior to implementation
Medium	The risk associated with the critical parameter may be acceptable provided additional measures are taken to mitigate the risk or appropriate justification is documented.
High	The risk associated with the critical parameter is not acceptable. Additional risk control measures are required to reduce the risk to an acceptable level.

Risk Estimation Matrix

Critical Parameter	Potential Failure	Likelihood	Severity	Overall Risk	Comments
All Change Controls make it through status 04 within 20 Days.	Faster processing time results in lower quality output.	Remote	Minor	Low	QA final approval is already in place to mitigate this potential failure.
All Change Controls are scheduled and Level Loaded through Change Control Review Board.	Change Control can me missed or overlooked by single point scheduling tool.	Remote	Minor	Low	Change Control Review Board is cross functional and reports directly to department pass up/pass down meetings ensuring transparency.

Process Controls



Control

Visual Management Board Update:

- Add Pareto Chart of reasons for cycle time excursions.
- When trend is identified, assign actions and escalate to appropriate department leadership.