

Issues Management System

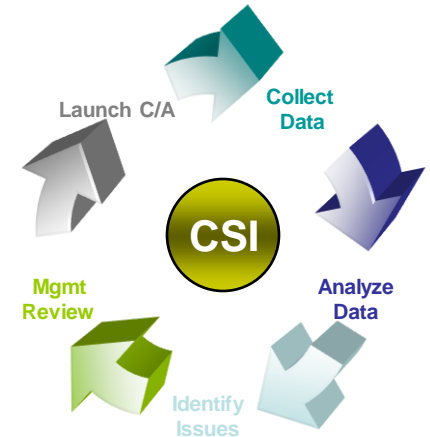
Review of Continuous Systemic Improvement Process and C/A Effectiveness Process

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Project Goals

Problem Statement:

Currently C/A are driven by individual or systemic events and not by system level performance (i.e. QC-1 Category or ISO category) and thus do not drive system level improvements, (i.e. the same categories continue to be the lowest performers).



- **Project Goals:**
 - Identify and Prioritize opportunities at the system Level
 - Evidence of sustained QC-1 Category Improvement
 - Integrated process with other business practices
 - Cost Effective

Quarterly Internal Audit Data

QC-1 Categories by Audit Type

(FY09 thru March)

Legend	
% Sig	
- if current qtr.	■
- if previous qtr.	■

Legend	
Pass %	
80-100%	■
60-79%	■
<60%	■

QC-1 Categories	Total Find.	# Opp.	Current Qtr. Sig.	# Sig.	% Sig.	FY09 Pass %	FY08 Pass %	FY07 Pass %
2.2 Quality Management Program	0				#DIV/0!	#####	100%	N/A
2.3 Organization	0				#DIV/0!	#####	100%	100%
2.4 Early and Continuous Application of Quality Principles	0				#DIV/0!	#####	100%	86%
2.5 Establishing and Validating Requirements	3	10			0.0%	70%	89%	87%
2.6 Planning	0				#DIV/0!	#####	100%	100%
2.7 Metrics	0	2			0.0%	100%	100%	N/A
3.1 Quality Improvement	1	5	1	1	20.0%	80%	100%	100%
3.2 Training	8	68			0.0%	88%	81%	87%
3.3 Design	3	24			0.0%	88%	76%	83%
3.4 Instructions/Procedures/and Drawings	35	124	2	4	3.2%	72%	72%	59%
3.5 Document Control	17	77			0.0%	78%	71%	69%
3.6 Procurement	1	7			0.0%	86%	100%	74%
3.7 Identification/ Control and Status of Items	13	202			0.0%	94%	81%	91%
3.8 Control of Processes	7	22			0.0%	68%	82%	87%
3.9 Inspection/Test/and Acceptance	8	46	1	2	4.3%	83%	79%	79%
3.10 Control of Measuring and Test Equipment	4	63		1	1.6%	94%	95%	98%
3.11 Handling/Storage/Packaging/and Delivery	3	69			0.0%	96%	82%	95%
3.12 Nonconformance	11	26			0.0%	58%	69%	68%
3.13 Corrective Action	18	49			0.0%	63%	83%	82%
3.14 Records	5	67			0.0%	93%	75%	70%
3.15 Assessment	1	5			0.0%	80%	100%	100%
3.16 Software Quality Assurance	1	6			0.0%	83%	83%	30%

Continuous Systemic Improvement Process

Quarterly review to search for potential systemic issues based on previous QAO audit results.

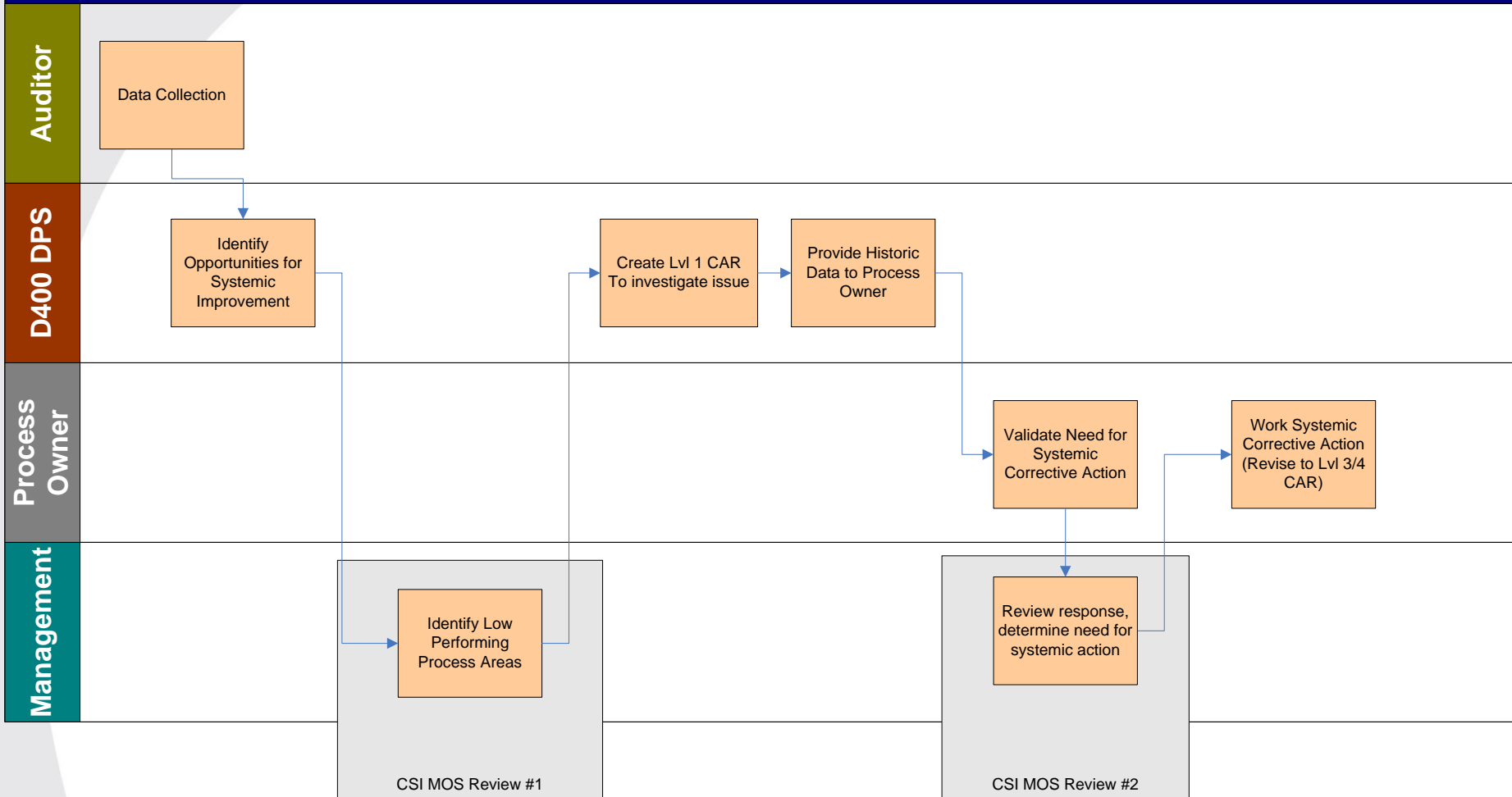
- eIAMS data analysis (Bringman/McKee/Lane)
- Data charted to show QC-1 & Command Media categories that have high incidence and future probability of audit findings

Quality management team quarterly reviews:

- CSI data to determine areas needing investigation
- Level 1 CAR responses generated by previous review

CSI Process Flow

Continuous Systemic Improvement – Systemic Issues Identification Process



CSI Data

Only categories that have had >20 opportunities (findings or observations) in last year are included.

Data is analyzed and filtered to focus on worst categories.

Ranked by: First, any multiple hits across top three categories. Then by top three in each category in conjunction w/others.

- **Worst 3 Sigma**
- **Top 3 Probability**
- **Control Chart w/down trend and 3 points OOC**

Sigma = normalized value of # passed / # opportunities over last 12 months

Probability = chance of audit finding next month based on 24 months data

Control chart = shows Sigma level month by month

CSI Data Summary

0-2=**Red**

2-3=**Yellow**

>3=**Green**

Probability%

= Higher

Probability of Audit Finding next period

Sigma Score is calculated by using the total number of Audits (Pass/Fail) / (Fail) = Sigma

Example:

TotalAudits= 107 (pass/fail)

Defects = 28 Total Fail

28/107=.214

SIGMA CALCULATOR

Enter your process opportunities and defects and press the "Calculate" button.

Switch To: [Advanced Mode](#)

Opportunities

Defects

Calculation Results

DPMO

Defects (%)

Yield (%)

Process Sigma

[Report A Problem / Make A Suggestion](#)

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provided by



Audit Category SIGMA SCORES

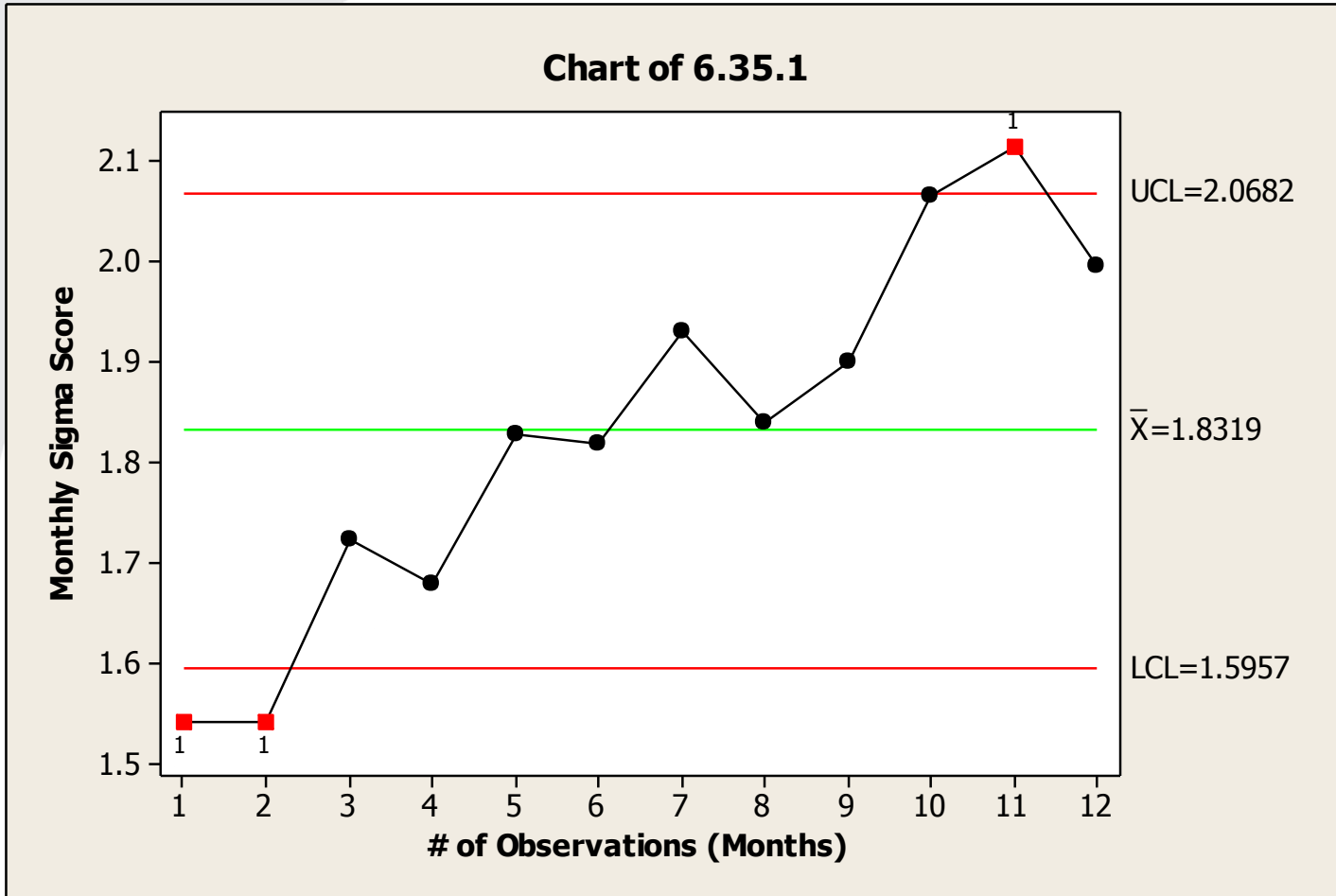
		Sigma Score	Probability of Finding Next Month*	Quarterly Categories for Review
3.10	3.10 Control of Measuring and Test Equipment	3.08	31%	
3.11	3.11 Handling/Storage/Packaging/and Delivery	2.70	58%	
3.12	3.12 Nonconformance	2.04	81%	
3.13	3.13 Corrective Action	2.13	85%	
3.14	3.14 Records	2.56	87%	
3.2	3.2 Training	2.40	57%	
3.3	3.3 Design	2.40	57%	
3.4	3.4 Instructions/Procedures/and Drawings	2.15	100%	
3.5	3.5 Document Control	2.12	97%	
3.7	3.7 Identification/ Control and Status of Items	2.48	87%	
3.8	3.8 Control of Processes	2.11	55%	
3.9	3.9 Inspection/Test/and Acceptance	2.35	77%	
4.2	Issues Management System	2.14	83%	
4.3	Command Media	1.50	53%	3
4.4	Control of Documents	1.97	95%	1
4.6	Records Management	2.30	82%	
5.8	Training	2.38	60%	
6.26	Generate Factory Instructions Tooling and Equipment	2.17	49%	
6.28	Manufacture Product per Customer Requirements	2.02	62%	
6.35	Control and Disposition of Non-Conforming Product and Material	2.10	53%	
6.36	In Process and Product Acceptance	2.71	37%	
6.52	Inventory Management	2.04	46%	
6.26.1	How to Prepare and Revise Process Plans and Shop Orders in the Manufacturing Execution System	1.84	62%	2
6.28.1	How to Initiate and Maintain Product Tracking	3.17	22%	
6.28.3	How to Verify and Handle Productive Material	6.00	12%	
6.28.5	How to Perform and Verify Manufacturing Operations	1.85	85%	4
6.28.8	How to Prepare and Complete a Production Record	2.70	12%	
6.35.1	How to Identify Non-Conforming Product	1.99	60%	5
6.36.1	How to Perform and Document In-Process and Product Acceptance	2.19	51%	
All Categories Total:		2.27		

*Probability based on 24 month data

****No findings last 12 months

6.35.1 How to Identify Non-Conforming Product

1.99	60%	trend
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(Upper Control Limit) represents a 3 x sigma upwards deviation from the mean value.

Also known as the sample **mean**. The **mean** is the average data point value within a data set.

Similar to Upper Control Limit but representing a downwards 3 x sigma deviation from the mean value of a variable.

I-MR chart, or individual and moving range chart, is a graphical tool that displays process variation over time. It signals when a process may be going out of control and shows where to look for sources of special cause variation. The I-MR chart is one of the simpler charts available to review for trends and special causes.

CSI Result Summary

? 1 - Control of Documents — KCP20080427-02 (Level 2)

✓ 2 - How to Prepare and Revise Process Plans and Shop Orders in the Manufacturing Execution System-

KCP20080193-01 (Level 4)

✓ 3 - Command Media - KCP20080351-02 (Level 3) & KCP20090049-02 (Level 2)

✓ 4 - How to Perform and Verify Manufacturing Operations

—KCP2008254-01 (Level 3) & KCP20080193-01 (Level 4)

✓ 5 - How to Identify Non-Conforming Product - KCP20090095-02
(level 3)

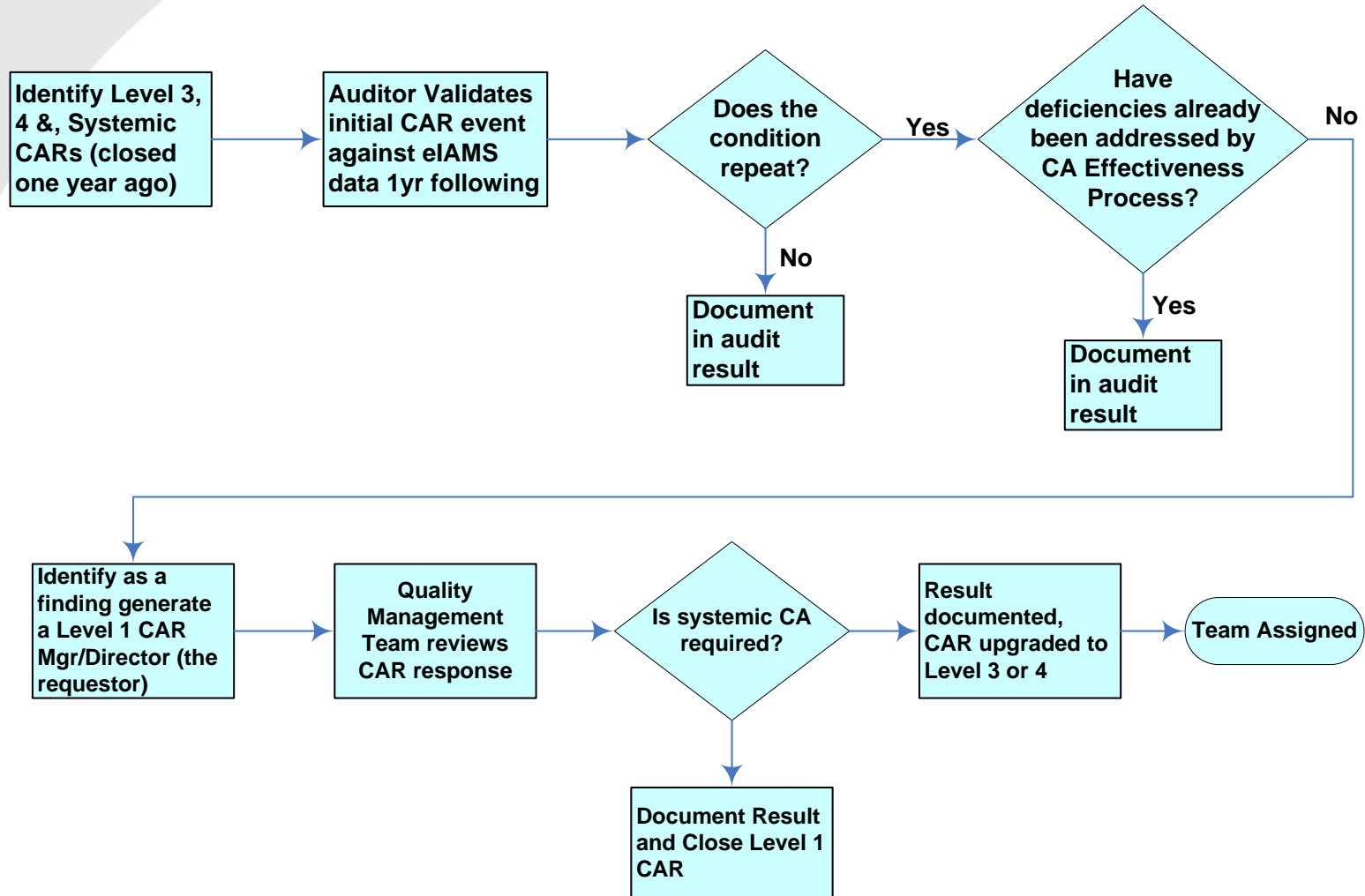
New process, still being refined, will continue to “lower the water level”.

Corrective Action Effectiveness Audit Process

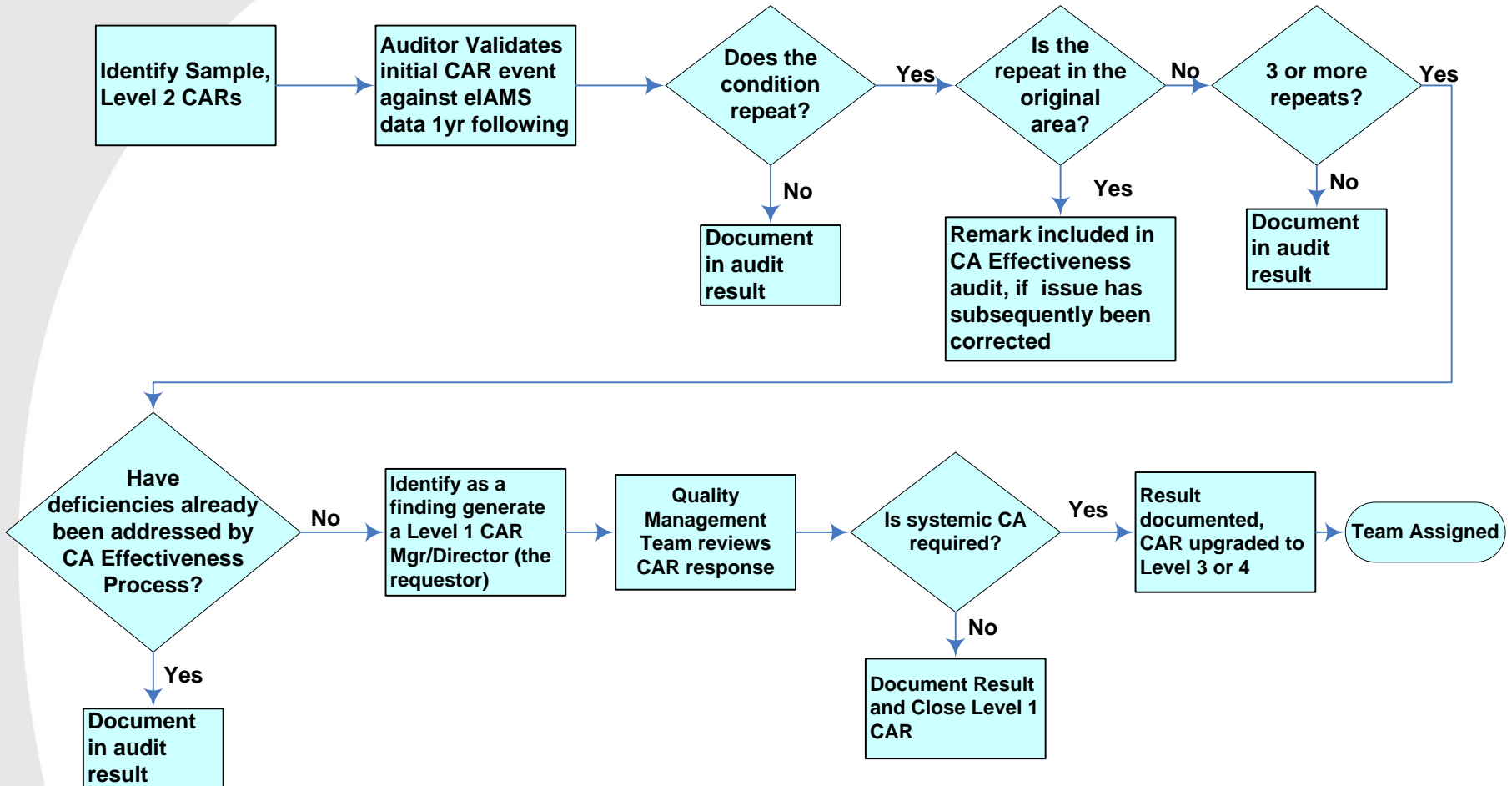
Quarterly effectiveness audits done by Assessments:

- Reviews CARs closed in quarter one year past
- Looks for repeats of events since then that show lack of C/A effectiveness
- Generate a level 1 CAR (investigation only) for any level 3, 4, or systemic issue that repeats
- Generate a level 1 CAR for any level 2 issues that have three or more repeats.
- Level 1 CARs sent to process leaders for investigation
- Quality management team reviews responses to determine if additional actions are needed.

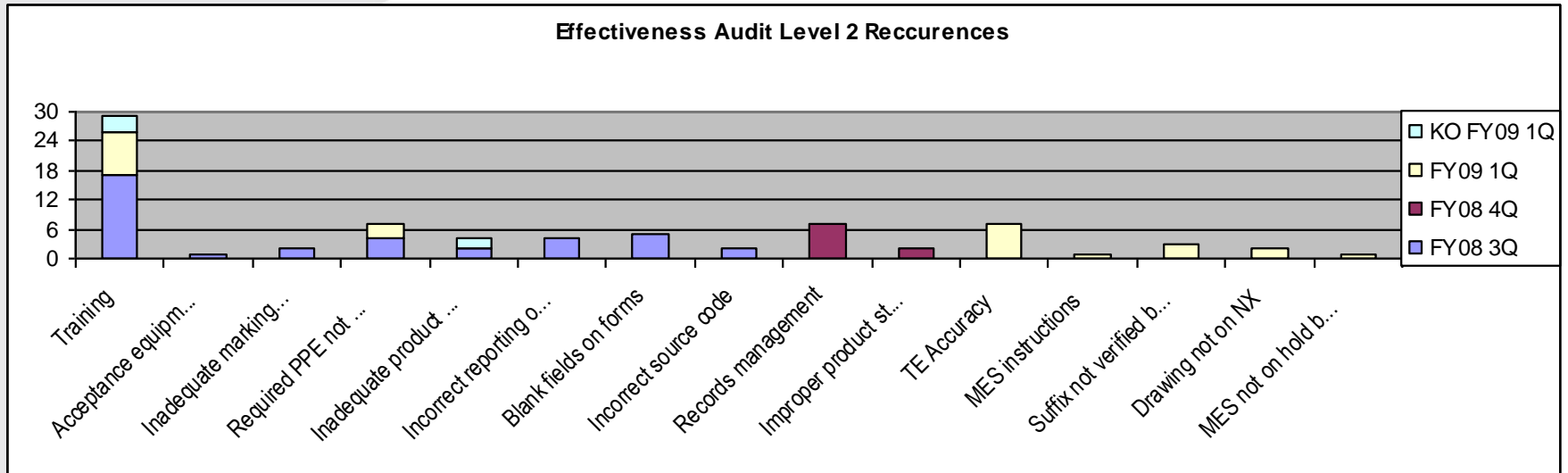
Corrective Action Effectiveness Process: Process Flow Level 3, 4 (most severe), and Systemic CARs



Corrective Action Effectiveness Process: Process Flow Level 2 (less severe) CARs



C/A Effectiveness Audit Results



KC FY09 1Q audit results (looking back to FY08 1Q)

Level 3:

Employee not wearing required PPE (3)

Level 2:

Training (9)

Acceptance equipment without required accuracy (7)

Obsolete MES instructions (1)

Drawing suffix not verified by inspector (3)

Required drawing not listed on NX (2)

Product w/past due FAR not on hold in MES (1)

No CARs created – three issues

previously identified w/CARs in work

KO FY09 1Q audit results (looking back to FY08 1Q)

Level 2:

Training (3)

Quality status identification (2)

**One level 1 CAR created for training -
KOA20080049-01**

Corrective Action Effectiveness Measurement

CAR Effectiveness Definition:

- Zero recurrence of level 3, 4, and Systemic CAR events, cause chain remains broken.
- Zero recurrence of level 2 deficiencies regardless of area or specific circumstance.

