QIT Corrective Action Management System

Corrective and Preventive Action System

Root Cause Analysis

and

Case Study

June 2006

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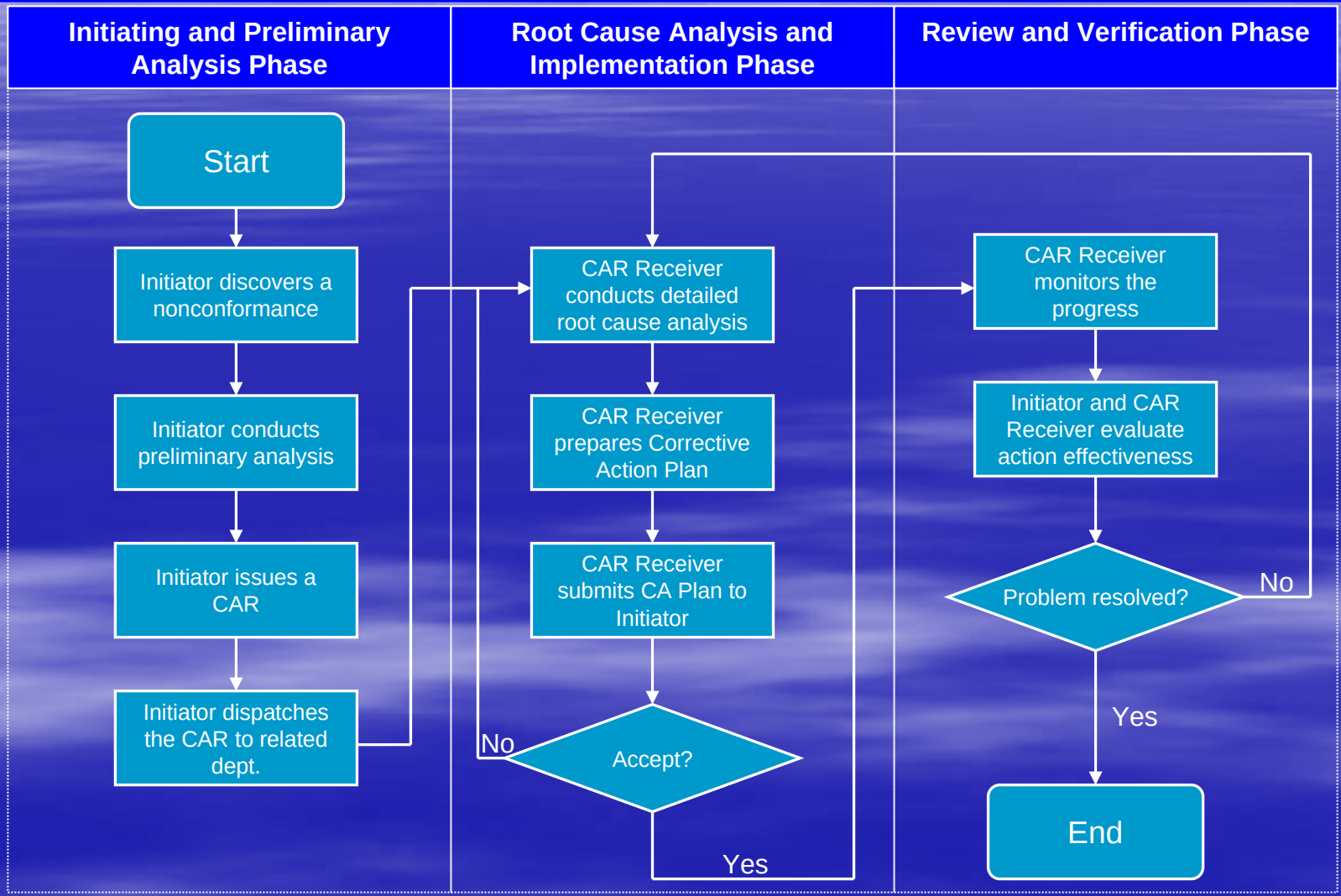
Corrective Action System Introduction

CAR System Introduction - Definition

- Corrective Action Request System
  - Also called CAR System
  - An element of ISO9000/QS9000 standards
    - "The supplier shall establish and maintain documented procedures for implementing corrective and preventive action…" (QS 9000 Element 4.14)
    - "The organization shall take corrective action to eliminate the cause of nonconformities…" (ISO9000 8.5.2)
  - Similar applications/systems:
    - Safety Action Request System
    - Supplier Corrective Action Request System
    - Action Management System for Service Sector

Primary objective: to eliminate the causes of nonconformities

CAR System Introduction - Process



CAR System Introduction – Basic Requirements

- Initiating and Preliminary Analysis Phase
  - CAR Number
  - Issuer/Originator
  - Defect Description
  - Issue Date and Deadline
- Root Cause Analysis and Implementation Phase
  - Real Root Cause
  - Action Plan, Due Date, and Representative
- Review and Verification Phase
  - Implemented Action

Root Cause Analysis

QIT's Root Cause Analysis Process

Root cause analysis is a process to establish and test the hypothesis

- Utilize the best knowledge available
  - Forming a cross-functional team
  - Data from a Knowledge Base
- Establish the theory and hypothesis
  - Qualitative approach
  - Quantitative approach
- Test the hypothesis

Forming a Cross-functional Team

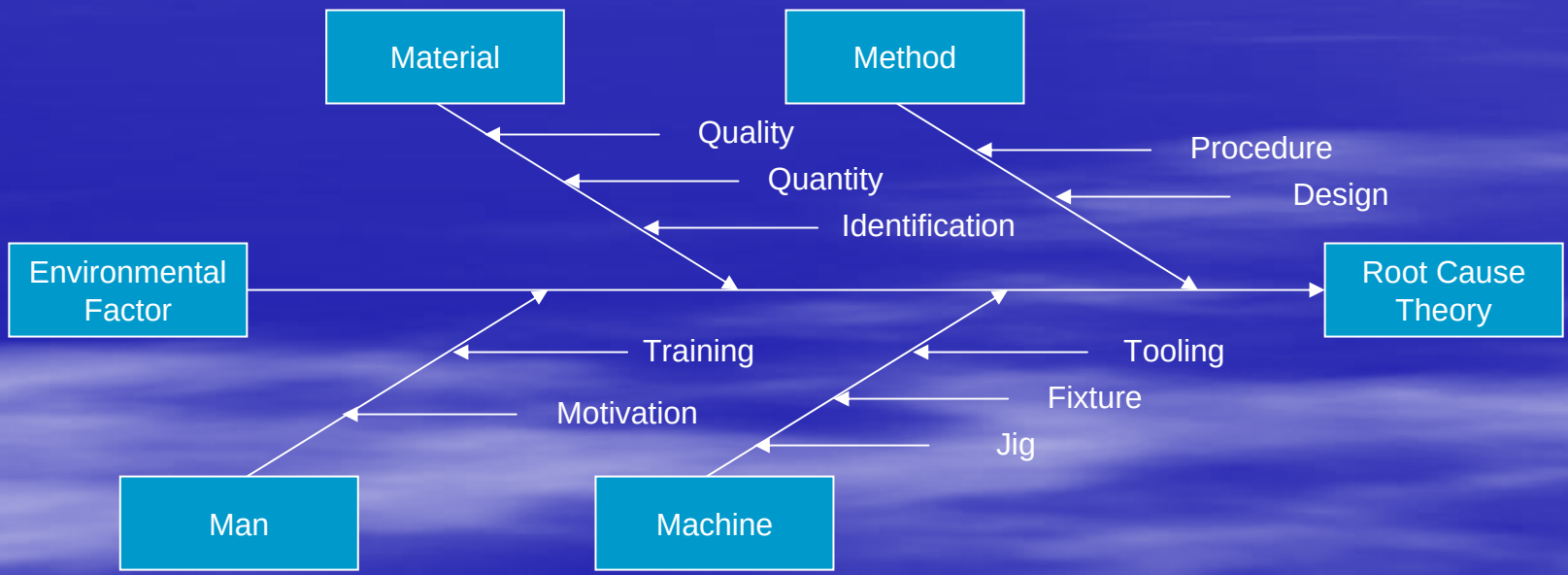
- Involving as many people from the business value stream as possible
  - Sales and Marketing
  - Engineering
  - Operation
  - Quality
  - Service
  - …

Establish the hypothesis I

- Qualitative approach
  - Proper probing to collect information
    - Where did the problem occur?
    - When did the problem occur?
    - Who is involved?
    - Why did the problem occur?
    - How did the problem occur?
  - QIT Corrective Action Management System users can also retrieve historical data from the Knowledge Base

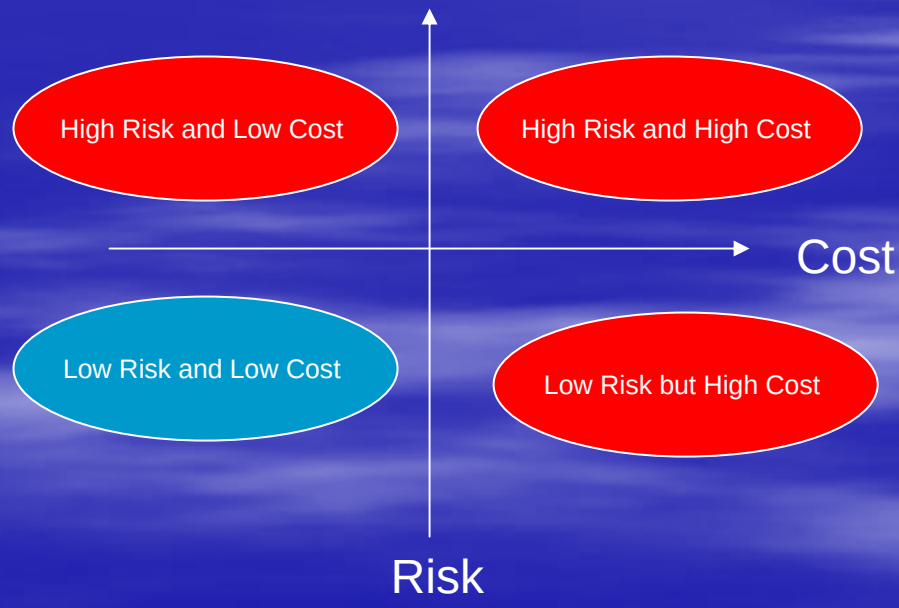
Establish the hypothesis II

- Category the contributing factors to 5 categories – Man, Machine, Material, Method, and Environmental Factor



Establish the hypothesis III

- Define all potential contributing factors of the failure, and then use Risk and Cost to weight each contributing factors
  - A cross reference of Risk and Cost
    - Risk
      - Severity
      - Occurrence
      - Currant Control
    - Cost
      - Direct Cost
      - Approval Cost
      - Other Cost



Establish the hypothesis IV

- Focus on the top 3 (high risk and high cost) contributing factors and form a theory for the failure
- For instance, in one of our customer complaint analysis
  - Man – lacking of training (Risk =50, Cost=$5k)
  - Machine – poor workmanship (Risk =50, Cost=$5k)
  - Material – N/A
  - Method – improper design of the latch (Risk =150, Cost=$50k), inappropriate assembly procedure (Risk =350, Cost=$5k), and no inspection for the latch assembly (Risk =250, Cost=$15k)
- We can then describe the theory as - The problem was caused by improper design of the latch, inappropriate assembly procedure and inspection procedure
- The next thing we need to do is to test this hypothesis

Establish the hypothesis V

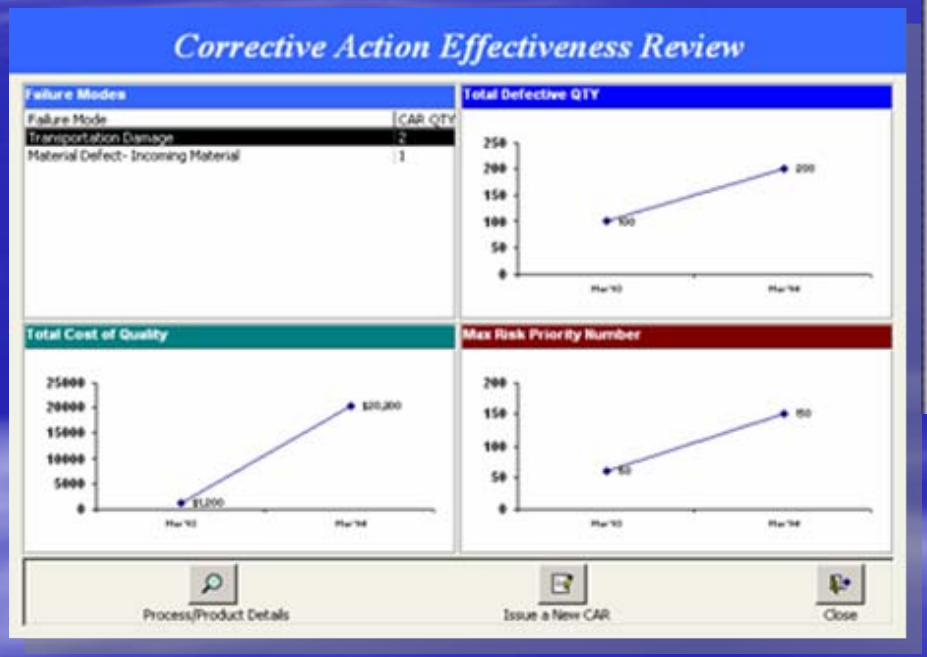
- Quantitative Approach
  - Design of Experiment (DOE)
  - Liner Regression
  - Correlation
- These statistical methods can also be used to establish a mathematical model to decipher the theory

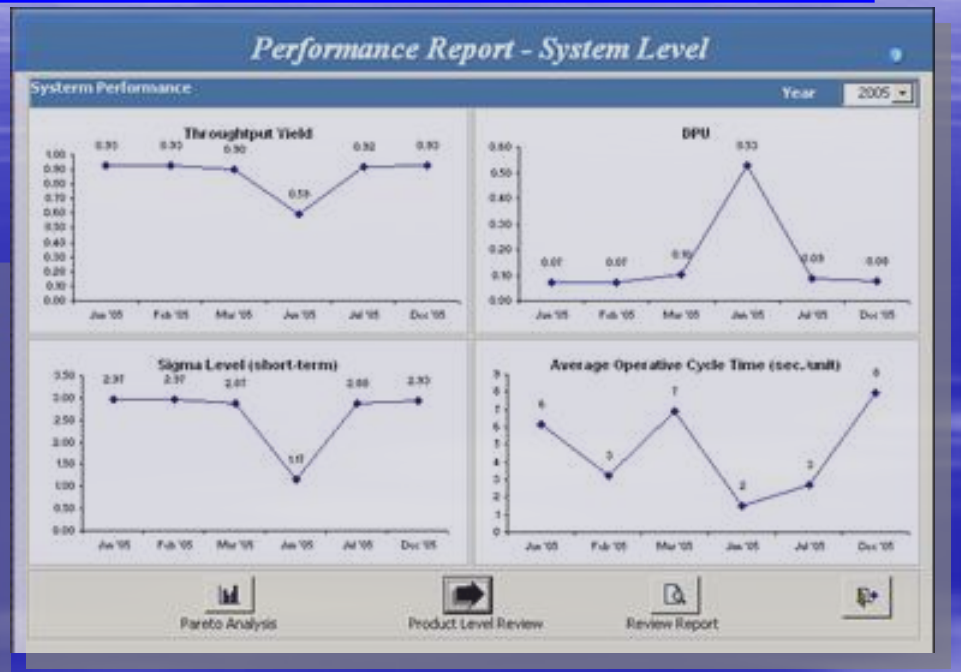
Test the Hypothesis

Test the Hypothesis

- Focus on the top three factors and implement corrective actions
- Review and verify the results. If the outcome is in a positive trend, the hypothesis is true, otherwise, it is false.
  - Yield of the production
  - Number of customer returns/complaints
  - Number of CAR issued
  - Repeated Failure Mode
- Establish a new theory based on the new data

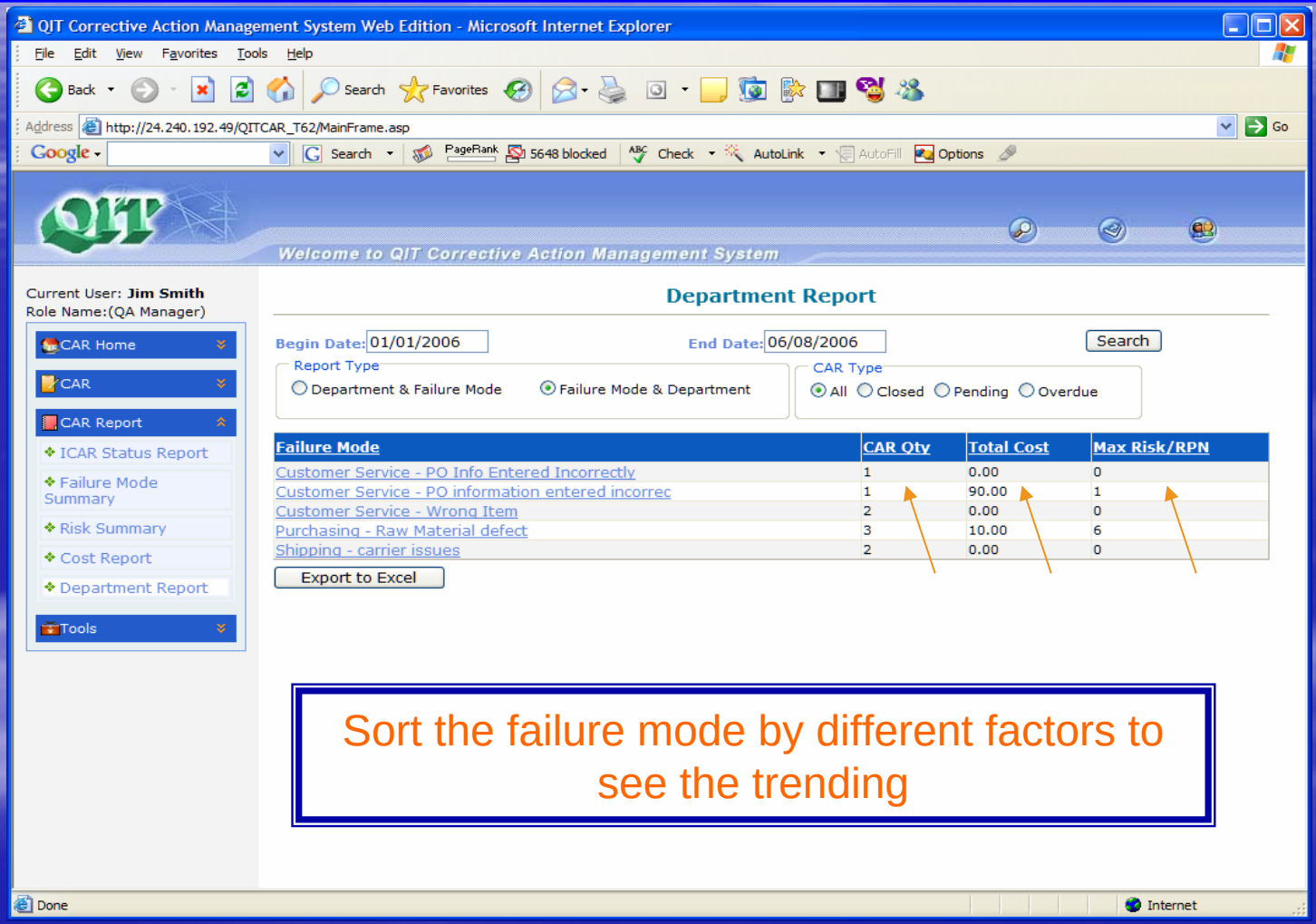
Test the Hypothesis - Example





Use the data from CAPA System or Production System to verify the action results.

Test the Hypothesis – Failure Mode Analysis



Snapshot of QIT Corrective Action System Web Edition

Common Failures in a CAR System

Common Failures

- Fail to concentrate on evaluating the CA plan, instead focus excessively on running CAR dispatching processes
  - Root Cause: primary interests were stretched thin by the comprehensive distribution processes
- Fail to use existing data to establish root cause theory and prove the theory
- Fail to use existing data to establish predict and prevent future failures and carry over best practices
  - Root Cause 1: It is hard to use a single index (risk, cost, or defective quantity) to predict future product/process behavior
  - Root Cause 2:It is an arduous and time-consuming task to summarize data

Case Study 1: A million-dollar Switch Failure

Case Study 1 – Background Information

- A US major household product company was forced to scrap millions dollars of products due to a potential fire hazard caused by a defect in a switch
- Internal investigations uncovered
  - Same problem was discovered 4 years ago
  - A CAR was issued, and the corrective action was reported completed
  - Similar failure mode still could be found in new production, but it did not catch attention because it was buried in the CAR system by other high occurrence failure modes
  - Further investigation indicated that this **high risk** problem had been encountered in similar switch designs, but it was overlooked because of the defect's low occurrence

Case Study 1 – Lesson-learned

This million-dollar problem could have been prevented

1. If results of the CAR could be monitored constantly, and information could be sent back to production promptly.
2. If the failure mode could be ranked by the failure risk category rather than the quantity of similar CARs issued
3. If the design engineer could learn from or be informed of the history and the problems of the original designs

Key functions of a CAR System:

To monitor, prioritize, and reconciliation

Case Study 2: “Do it right in the first time”

Case Study 2 – Background Information

- A division of a Fortune-500 company launched a project called “do it right in the first time”
  - Goal was to improve customer satisfaction and reduce cost
- The project failed because people were reluctant to respond to the project concept
  - “we are human being, we are not perfect, and we are bound to make mistake from time to time …”

Is it possible to always do things right the first time?

Case Study 2 Lesson-learned

- Can we always do things right the first time?
  - No, we can't. We are human being, and we tend to make mistakes
  - Wait a minute… Yes, we can, if we can learn from our pervious mistakes!
- This project could have been a huge success if employees were asked to always refer to the pervious failures as well as the best practice from the product/process history every time they took on a new project

CAR System could play a key rule in leading

Continuous Improvement projects

Perspectives Beyond ISO9000

Perspectives Beyond ISO9000

- An effective CAR System should
  - Achieve the objectives identified in ISO9000
    - To eliminate the causes of nonconformities
  - and go beyond:
    - Streamline the CAR dispatching processes
    - Monitor the action results constantly
    - Utilize various indexes to prioritize corrective actions
      - Risk, cost, defective quantity, and etc.
    - Provide product/process history and previous failures to prevent problems in new product lines

Does your current CAR System achieve these objectives?

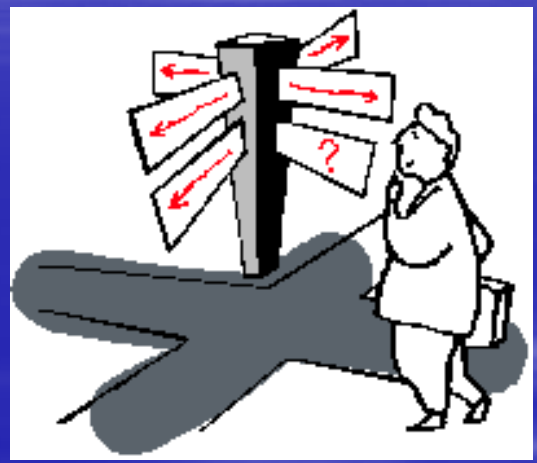
CAR System Check Sheet

Items	Yes	No
Initiating and Preliminary Study Phase		
Can the CAR System record Preliminary Root Case?		
Can the CAR System record Quality Cost?		
Can the CAR System record Failure Mode?		
Can the CAR System record Failure Risk Category?		
Root Cause Analysis and Implementation Phase		
Can the CAR System record Real Root Cause and action plans?		
Can the CAR System record user's comments and implemented actions?		
Can the CAR System record user verifications for action results?		
Monitoring and Verification Phase		
Can the CAR System prioritize CARs, utilizing Risk Category, Quality Cost, and Defective quantity?		
Can the CAR System summarize top 10 failure modes and rank them by Risk Category, Quality Cost, and Defective quantity?		
Can the CAR System report the effectiveness by using the trending of Risk Category, Quality Cost, and Defective quantity?		
Can the CAR System provide a Product/Process Knowledge Base for users to look up failure and action history?		

If you answered Yes to all these questions, then congratulations! You have a robust CAR system in place already!

If you got one or two No's, your system may need some improvements

Questions or Need Any Help?



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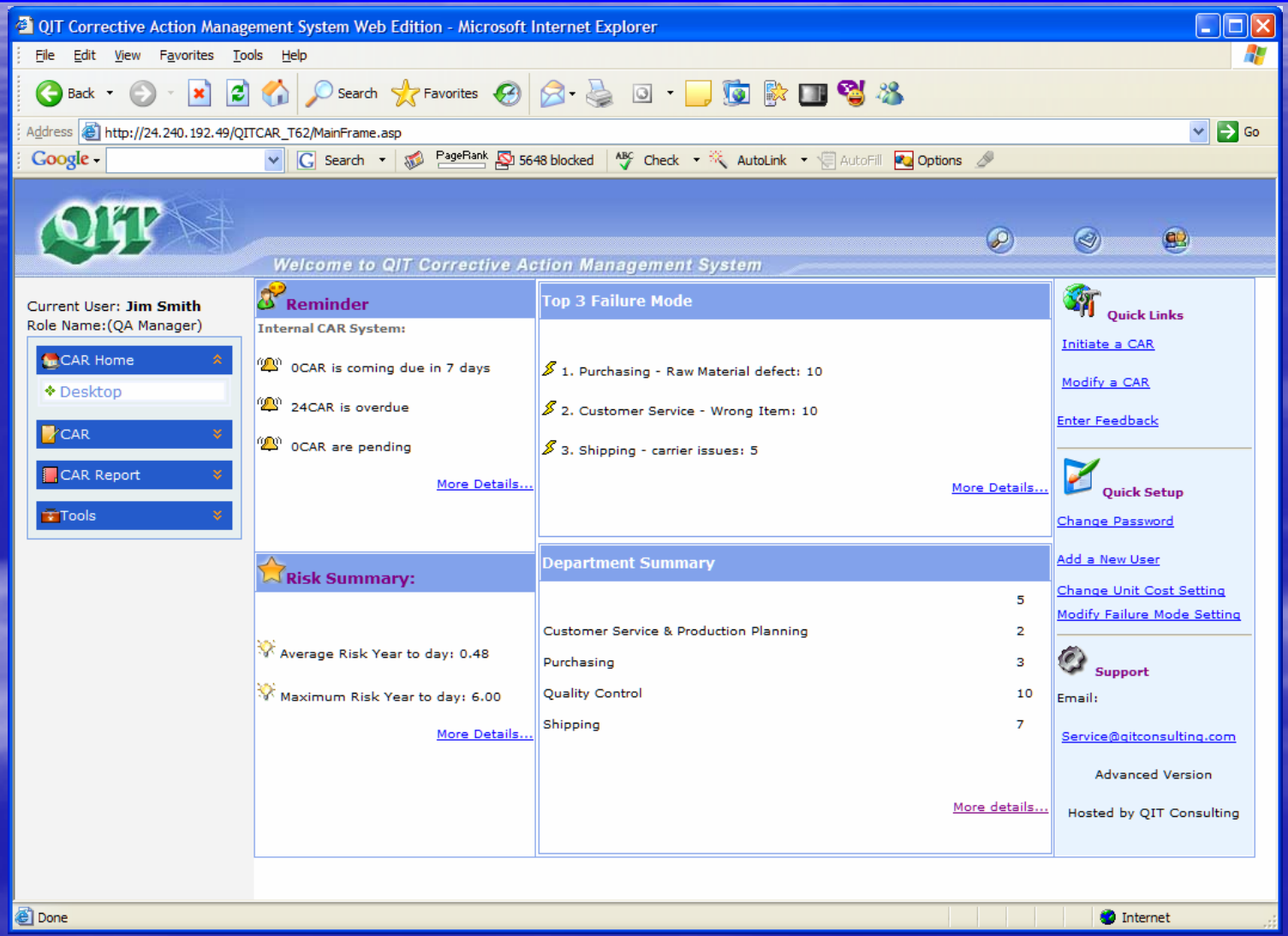
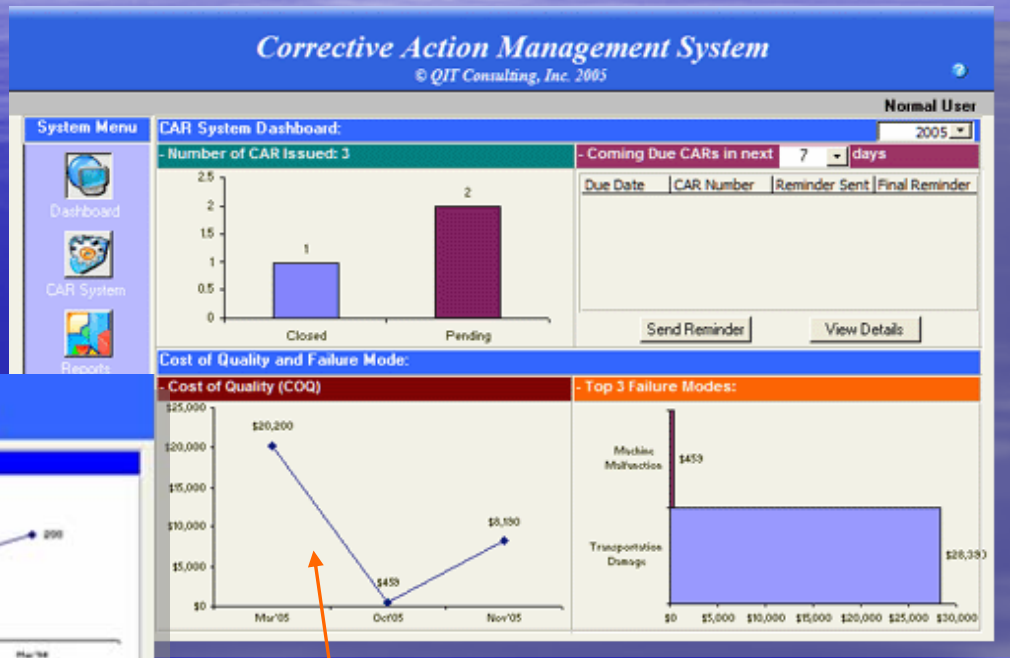
QIT Corrective Action Management System

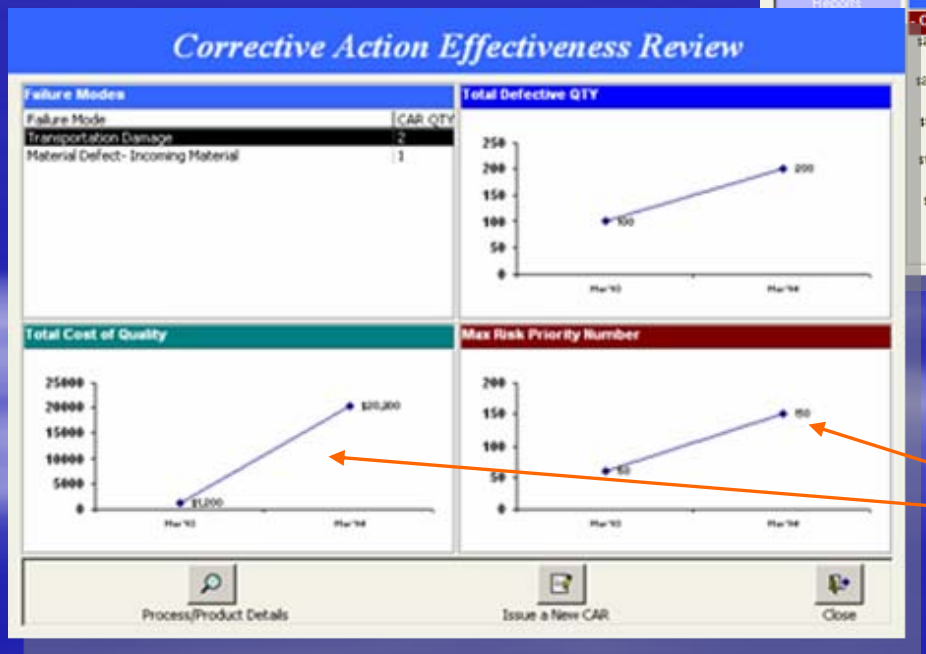
- Key Functions and Benefits
  - Easy to use and deploy
  - Reduce quality cost and quality system administrative cost
  - Issue and dispatch internal CAR, Supplier CAR, and ISO9000 Internal Audit CAR
  - Monitor corrective actions progress
  - Monitor department and supplier performance
  - Establish a Product Knowledge Base to prevent problems from happening again

QIT Corrective Action Management System Web Edition



QIT Corrective Action Management System



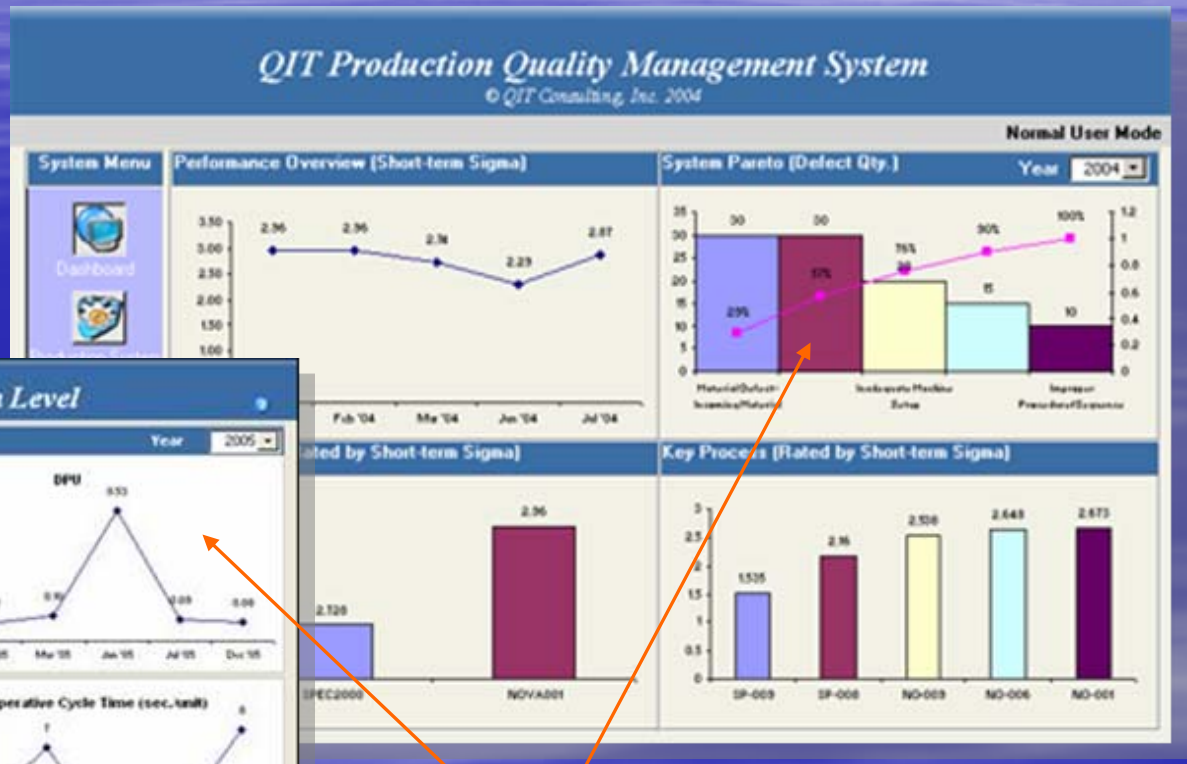


Trending of Cost and Risk to monitor quality performance

QIT Production Quality Management System

- Key Functions and Benefits
  - Easy to use and deploy. No specific 6-Sigma knowledge is needed
  - Instantly establish 6-Sigma production control
  - Reduce quality cost and 6-Sigma implementation cost
  - Use **Long-term Sigma, Short-term Sigma, Yield, Throughput Yield, Cycle Time** to report and monitor production performance
  - Report performance in System, Product, Process, and Work Order levels

QIT Production Quality Management System



The trending of Cost, Risk and Six Sigma Measurements to monitor quality performance

QIT Supplier Quality Management System

- Key Functions and Benefits
  - Easy to deploy and use
  - Reduce quality cost and improve supplier quality
  - Capture incoming inspection data
  - Report supplier Quality and Delivery Performance
  - Report supplier rolling 12-month performance
  - Supplier Report Card

QIT Supplier Quality Management System