



Mount Wachusett
Community College

AQS 200 Conducting Root Cause Investigations

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Start near. Go far.



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AQS 200

Conducting Root Cause Investigations

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COURSE OBJECTIVE

- Students will learn problem solving skills and methods used in industry, both manufacturing and service, to investigate and correct the issues faced in a real-world setting.
- Students will apply the tools, analyze the data and evaluate the results to demonstrate an understanding of root cause analysis.



SYLLABUS

Week	Lecture Topic	Week	Lecture Topic
1	Quality Principles Overview/Review	9	Problem Cause Data Analysis
2	Manufacturing/Service Processes Problem Selection	10	Problem Cause Data Analysis
3	Problem Solving	11	Root Cause Identification
4	Root Cause Analysis	12	Root Cause Elimination Solution Implementation
5	Problem Understanding	13	Current Methodologies – <i>PDCA, Six Sigma DMAIC</i>
6	Problem Cause Investigation	14	Current Methodologies – <i>7 Step, 8D</i>
7	Problem Cause Data Collection	15	Final Exam - Cumulative
8	Midterm		



QUALITY OVERVIEW

- Quality is an important component of cost of goods sold or services provided.
- Tracked through multiple measures.
- Lack of quality can lead to product and company failure.

Space Shuttle Challenger

<https://www.youtube.com/watch?v=j4JOjcDFtBE>

Volkswagen Scandal

<https://www.youtube.com/watch?v=CQ4irwe3ZDk>

“Deflategate”

https://www.youtube.com/watch?v=VZ_S8F3mKFE

WHAT IS ROOT CAUSE?

- **Root Cause** – fundamental (true) reason a product or process nonconformance occurred
- **Root Cause Analysis (RCA)**
Structured investigation (review) aiming to identify (determine) the true cause of a product or process nonconformance (problem) AND the actions necessary to eliminate it.

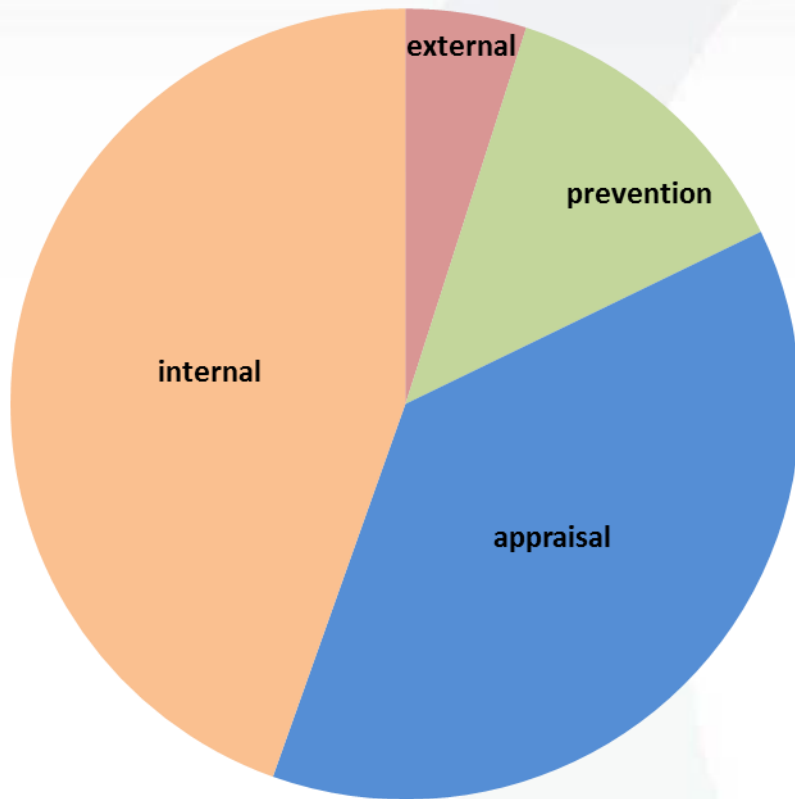
QUALITY - Review

- Dictionary definition
 - : how good or bad something is
 - : a characteristic or feature that someone or something has
 - : a high level of value or excellence
- Manufacturing / Service – relative concept

Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.

**Quality is determined by the Customer (end-user)
based on their expectation and needs.**

Cost of Quality



- Internal
 - Scrap, Rework
- Appraisal
 - Material Receipt Measurement
 - In-process/Final Inspection
- Prevention
 - Improvement, Planning
- External
 - Returns, Warranty

GENERAL QUALITY PRINCIPLES

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based decision making
- Relationship management

REFERENCE: ISO 9001:2015

QMS – PRINCIPLES (ISO 9001:2015)

- **Customer Focus**

- understand current and future customer needs
- meet customer requirements
- strive to exceed customer expectations

Organizations depend on their customers.

- **Leadership**

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership
- **Engagement of People**
People at all levels of an organization and their full involvement enables their abilities to be used for the organization's benefit
- **Process Approach**
Desired result is achieved more efficiently when activities and related resources are managed as a process

QMS – PRINCIPLES (ISO 9001:2015)

- Customer Focus
- Leadership
- Engagement of People
- Process Approach

- **Improvement**

Continual improvement of the organizations overall performance should be a permanent objective of the organization

- **Evidence-based decision making**

Effective decisions are based on the analysis of data and information

- **Relationship Management**

An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value

GENERAL QUALITY PRINCIPLES

Root Cause Investigations - Problem Solving

- ISO 9001:2015
 - Customer Focus
 - Leadership
 - Engagement of People
 - Process Approach
 - Improvement
 - Evidence-based decision making
 - Relationship management

QUALITY MANAGEMENT SYSTEMS

VOLUNTARY

- **ISO 9001:2015** (General Requirements)
- **ISO 13485:2003** (Medical Devices)
- **ISO/IEC 17025:2005** (Calibration Laboratories)
- **ISO/TS 16949:2009** (Automotive)
- **AS9001C** (Aerospace)
- **ISO 22000:2005** (Food Safety)
- **ISO E14001:2004** (Environmental Management)

QUALITY MANAGEMENT SYSTEMS

REGULATORY (mandatory)

- **US FDA**
 - **21 CFR Part 820** (Medical Devices)
 - **21 CFR Part 210/211** (Pharmaceutical Manufacture)
 - **21 CFR Part 58** (Laboratory Practices)
 - **21 CFR Part 312** (Clinical Practices)
 - **21 CFR Part 600/601/610** (Biologics)

Quality Management System Overview

Overview of
ISO 9001:2015(E)

Quality management systems - Requirements

Quality Management System Overview

Why review Quality Management System requirements?

To gain knowledge & a fundamental understanding of business process requirements, process interactions & relationships for use during root cause analysis.

Quality Management System Overview

ISO 9001:2015 --

- Section 4.0 Context of the organization
- Section 5.0 Leadership
- Section 6.0 Planning
- Section 7.0 Support
- Section 8.0 Operation
- Section 9.0 Performance evaluation
- Section 10.0 Improvement

4.0 Context of the Organization

4.4 Quality management system and its processes

- Identify:
 - The processes, the sequence and their interactions
 - Required inputs and expected outputs
 - Criteria & methods for monitoring performance
 - Needed resources, responsibilities & authorities
 - The risks & opportunities
- Evaluate processes
- Implement changes needed to achieve intended results
- Improve processes & system
- Maintain & retain documented information

* Reference ISO 9001:2015(E)

5.0 Leadership

5.1.2 Customer focus

- Determine, understand & consistently meet requirements
- Determine & address risks & opportunities
- Maintain focus on enhancing customer satisfaction

5.3 Organizational roles, responsibilities & authorities

- Conforming to requirements (i.e., system, ISO)
- Processes meet intended outputs
- Reporting on the performance of the system & opportunities for improvement
- Promoting customer focus
- Maintaining integrity of system when changes are planned and made

* Reference ISO 9001:2015(E)

6.0 Planning

6.1 Identify risks & opportunities

- Take actions to address the risks & opportunities
- Monitor & evaluate the effectiveness of actions taken

6.3 Planning of Changes

- Consider potential consequences of changes, impact to integrity of system?
- Resources needed
- Responsibilities & authorities

* Reference ISO 9001:2015(E)

7.0 Support

7.1 Resources – internal versus external

- People
- Infrastructure: buildings, utilities, equipment, communication, information technology, transportation
- Environment: suitable socially, psychologically, & physically (i.e., temperature, light, noise, hygiene)
- Monitoring & measuring resources: calibration, traceable measurement standards, equipment identified with calibration status, validity of previous measurements evaluated when equipment is found out of tolerance
- Organization knowledge: necessary for operation of processes, used & shared (IP, lessons learned, standards, academia)

* Reference ISO 9001:2015(E)

8.0 Operation

8.2 Requirements for products and services

8.3 Design & development of products & services

- Inputs / Controls /Outputs
 - *Identify the results to be achieved*
 - *Reviews: evaluate if defined results are being met*
 - *Verification: ensures design output meets design input requirements*
 - *Validation: ensures products and services meet specified application or intended use requirements*

8.5 Production & service provision

- Control / Identification Post-Delivery

8.6 Release of products and services

- Establish verifications of product and service at appropriate stages to ensure requirements have been met
- Verifications must be completed prior to release of products and services unless authorized and as necessary by the customer
- Retain documented information showing conformance with acceptance criteria and person authorizing release

* Reference ISO 9001:2015(E)

8.0 Operation

8.7 Control of nonconforming outputs (Investigations start here)

- Identify & control nonconforming outputs to prevent inadvertent use or release
- Take appropriate actions to resolve non-conformance:
 - Correction : if correction is made, you must verify that nonconforming outputs were corrected
 - Segregation, return, suspension
 - Inform the customer
 - Obtain approval for waiver/concession
 - Retain documented information showing nonconformance, actions taken & authorities responsible for actions

* Reference ISO 9001:2015(E)

9.0 Performance Evaluation

9.1 Monitoring, measurement, analysis & evaluation

9.2 Internal audit

9.3 Management review

Source of investigations

* Reference ISO 9001:2015(E)

10.0 Improvement

Investigations / Root Cause Analysis

10.2 Nonconformity & corrective action

- Assess need for action to eliminate the cause, the **root cause**, of the non-conformance in order to prevent recurrence by:
 - Reviewing & analyzing the non-conformance
 - Identify root cause
 - Assess if similar non-conformances could exist or occur

10.3 Continual improvement

- Review the results of outputs from management reviews and analysis & evaluation to identify opportunities for improvement

* Reference ISO 9001:2015(E)

