Quality 101

What Is It ~ What It Is

~ What's The Problem ~

Content From GQM Advisors

'Nuclear Management Systems' Course

Management of Quality

White Paper ~ December 2024

It's my goal to provide readers and researchers what I've learned the past 50 years working in and learning about The Management of Quality. What a fascinating career in a number of business sectors making efforts to ensure basic quality principles, practices, and policies where appropriate for each application. My efforts included using the art of patience, kindness, and active listening as I helped define quality management commitments then make efforts to implement.

https://gqmadvisors.com/wp-content/uploads/2025/03/GQMadvisors-Quality-12-15-24-13pgs.pdf

Slide Deck ~ May 2025

These visual aids are intended to help readers understand, from my experiences, 'What Is It (Quality)' and put its elements into context. Each individual has their own perceptions and understanding of 'What It Is' ~ I believe this slide deck will help readers gain clarity for applications of quality principles when leading quality efforts. These slides should help when making efforts to gain consensus in a workplace setting.

Management of Quality

Abstract

In this paper, I share 50 years of working knowledge performing in high-consequence heavily regulated business sectors (mostly startups) regarding 'The Management of Quality.' Considerable content is from the GQM Advisors white paper of September 2024, (P.W. Gladieux & S.B. Kaley), *Your C-Suite & CQO, 'Is There One Common Sense Reason to Keep a CQO Out of Your C-Suite'?*[1] My insights are from extensive experience in management systems engaging in Nuclear Energy Operations (7 years, 4 power reactors ~ Entergy Operations), Supply Chain Services (more than 30 suppliers), Reactor Design Suppliers (Westinghouse Nuclear, NuScale Power, TerraPower, BWX Technologies), Large Scope Design/Build Programs (Jacobs Engineering Group, 5 years), Custom Engineered Products (12 years). These engagements were in complex management systems in high-risk / high-value sectors. I explore and pose questions regarding the critical role of 'The Management of Quality' and attempt to clarify the word 'Quality' and the role of the 'Quality Discipline' in business operations and programs. **I will consider this paper a success, if it helps one or some organizations establish their basis for adopting a definition of Quality and gaining Quality Performance Improvements in Practice.**

Management of Quality

What is Quality ? ~ The Never-Ending Question

Isn't quality a simple understanding of what you like and dislike or what works and doesn't work? Isn't it shopping and finding a sweater that fits perfectly, compliments your wardrobe, and helps you feel good? Isn't it having your favorite food on a Saturday evening with your favorite friends? If your friends pick up the tab, perhaps you've experienced 'total satisfaction.' Perhaps it's having your favorite cake with family members on your birthday. We know what it is when it comes to our personal quality of life.

Come Monday morning, we're on our way to work to make a living and contribute to the goals and objectives of a business enterprise. Isn't it true you enter an environment of requirements that must be met to achieve specified results? Are you showing up for what will be a great week or, will your week start with numerous unknowns: nagging unsolved supplier problems, needing to wear three hats because of an operational RIF two weeks ago, trying to influence the lead design engineer on your proposed solutions, or overly concerned about the procurement group always being behind schedule with a compliance audit beginning in two days. Every week, we face another week of meeting quality requirements in our work life.

Management of Quality

In Modern Times ~ Definitions Emerged

There are several quality definitions, some industry-specific, that have emerged over the past 10 decades. The most important aspect is that each person understands the applicable definition used by their employer or customer and continually pursues improvements and excellence in what work they perform. The world has improved in endless ways because of the pursuit of quality improvement. Definitions have emerged over time. There are probably others.

- For starters, quality can be represented by how time and energy is being used to accomplish tasks

- A degree of excellence

- fitness for intended use

- Conformance to requirements

- Superiority in kind

- Customer satisfaction

- Fitness for use

- Doing things right the first time

- Zero defects

- It can represent how many ISO9001 requirements are met

- The degree to which an item or process meets or exceeds the user's requirements and expectations

Management of Quality

High-Quality ~ **A Global Imperative w/ Direct Impact on Safety, Health, Environments, Cost, Schedule, Security, Profit, Consistency, Contract | Regulatory Compliance, Competition, Customer Satisfaction, & Humanity**

Quality ~ Quality ~ Qualite' ~ Qualità ~ Hinshitsu

Is There One Definition

for

*Quality Agreed On*

Throughout The World?

Does it Matter?

What's Your Definition

for

Quality?

Does it Matter?

What's Your Definition

for

Quality of Life?

Quality of Work-Life?

Does it Matter?

Management of Quality

6 Interrogatories Applied to The Management of Quality

- <u>Who</u> started the use of the word Quality?

- Who is Responsible for Quality?

- <u>What</u> is its meaning ~ Concept?

- <u>When</u> did it start its use?

- <u>Where</u> did it come from?

- <u>Why</u> is it used?

- <u>How</u> is it used & Perceived?

  - Definitions ~ How many?

  - 1 Definition ~ Can we agree?

  - Requirements ~ How many?

 - Cost of Poor Quality?

  - Measure Performance?

Quality Thinking?
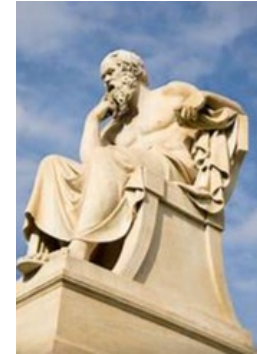
Management of Quality

You & The Management of Quality

- When did you start thinking about Quality?

- Who introduced you to Quality?

- How do you Perceive Quality?

- How do you Define Quality?

- How does Quality affect your work Products & Services?

- Do you make Quality Judgments all day?

- What do you do when Products & Services do not meet Requirements?

- What is our Policy on Quality?

- Who establishes Quality Policy?

- Who is Responsible for Quality?

CEO

Supply Chain

Management of Quality
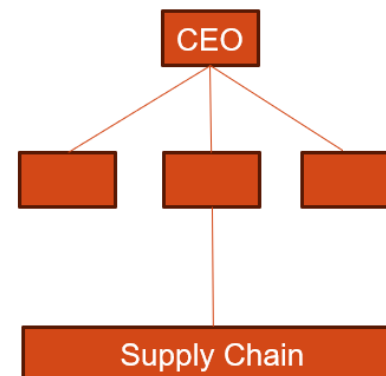
A Company & The Management of Quality

- Who defines Quality?

- Who establishes Quality Policy?

- How does Quality affect work Products & Services?

- What is done when Products & Services do not meet Requirements?

- What is our Policy on Quality?

- Do we really understand the 'Quality Language'?

- Are we 'Organized' to achieve our Quality Goals?

Management of Quality
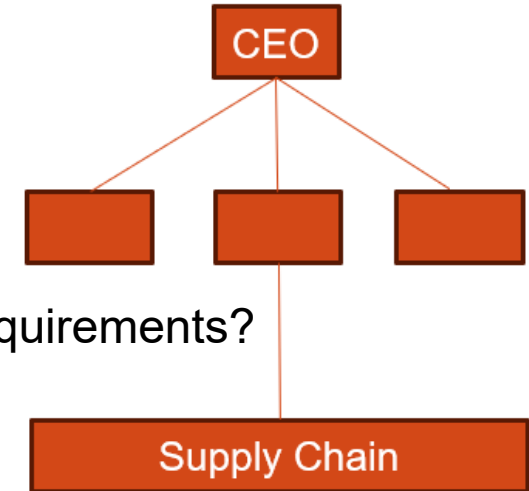
Are There Gaps in The Management of Quality?

In School, Did You Have Coursework in the principles, practices, & applications of Quality? It's highly likely the answer is no. Perhaps a few hours in statistics or inspection? There are a few universities with coursework in quality-related tools & disciplines. There are few with degree programs in quality at Masters & PhD levels. Even today, most employees have no academic coursework in Quality.

The Gap ~

With minimum to no training in quality concepts & applications, individuals entering an organization might learn something when attending orientation sessions. Some business sectors, especially those with high-risk | high-consequence products & services, provide good introductions regarding safety, quality, risk, & others. Still most individuals learn about quality by 'On-The-Job-Training.' This approach truly brings up 'Quality Culture' aspects. Will new employees be influenced in the wrong way by their peers? Will previous training in quality not align with the new employer?

Imagine the potential confusion factor, especially, when hiring employees from different Nations | Sectors | Segments | Applications with different past training in Quality? Executives should ensure highly effective training in quality & demonstrate their unconditional support as delineated in their Quality Policy.

Management of Quality

Philosophy & The Management of Quality

In School, Did You Have Coursework in ~

- Business Vision, Mission, Goals, Values
- Business Quality Policy Statement on The Management of Quality

To accelerate progress in increasing efficiencies, accuracies, timeliness, & driving down cost to provide certainty for investors & other stakeholders

VISION

MISSION

TO CREATE **INNOVATIVE, DESIGN-DRIVEN PRODUCTS** AND SERVICES THAT BRING **SIMPLICITY** TO OUR USERS.

| AMBITION | CREATIVITY | RESPONSIBILITY | HONESTY | SIMPLICITY |

FUNDAMENTAL VALUES

Management of Quality

Understanding Quality-related Terms

In School, Did You Have Coursework in ~

- Business Language ~ Terms Used by Each Discipline

- Understanding the _Reason for_ & _Use of_ these **Quality** Terms

- **Quality** The degree to which an item or process meets or exceeds the user's requirements and expectations. Most common industry definition: **Conformance to Requirements**.

- **Quality Policy** The overall quality intentions and direction of an organization regarding quality as formally expressed by top management.

- **Quality Management System (QMS)** The organizational structure, processes, procedures, and resources needed to implement quality management goals, objectives, and requirements.

Management of Quality

Understanding Quality-related Requirements

In School, Did You Have Coursework in ~

- Understanding the term **Requirement**
  - **Requirement** 1) something wanted or needed: Necessity, 2) something essential to the existence or occurrence of something else: Condition
  - Customer Contracts, Customer Quality Performance Specifications, Your Company Standards set by Policy, Industry Standards, Regulations (International, Federal, State, Local, County, Municipal)

- Other Quality-related Terms ~ Located in Multiple Sources
- Society, Industry Standards

  Quality Glossary of Terms, Acronyms & Definitions | ASQ | ASQ

  ISO 9001 - Clause 3: Terms and Definitions (iso-9001-checklist.co.uk)

Management of Quality
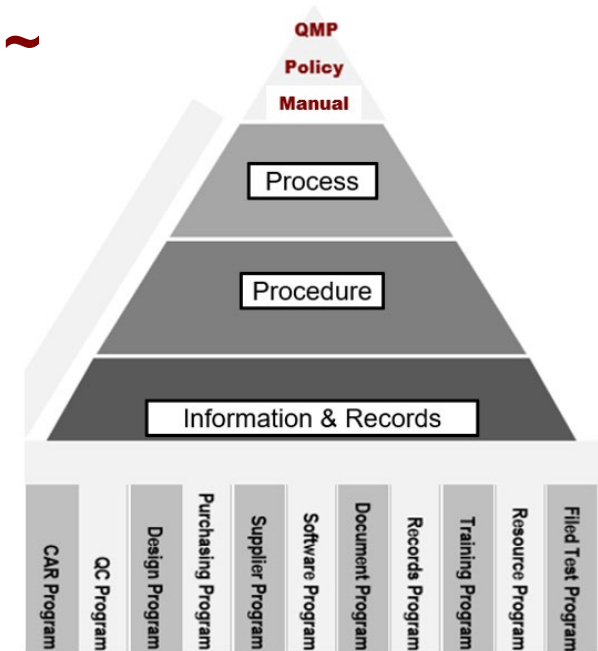
The Four Quality Disciplines

In School, Did You Have Coursework in ~

- **Quality Leadership (QL)** The Department of the Navy's definition of QL is based on W. Edwards Deming's ideas. "The application of quantitative methods and the knowledge of people to assess and improve a) materials and services supplied to the organization, b) all significant processes within the organization, and c) meeting the needs of the end-user, now and in the future." U.S. Depart Of The Navy TQL In The Fleet Theory to Practice, J.Wasik, B.Ryan, 1993, AD-A275 444 92pgs.

- **Quality Management (QM)** That aspect of the overall management function that determines and implements quality policy. Quality management includes strategic planning, allocation of resources, and systematic activities for quality such as quality planning, operations, oversight, and evaluation.

- **Quality Assurance (QA)** Those planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality.

- **Quality Control (QC)** Those actions that provide a means of control and measure of the characteristics of an item, process, or facility to established requirements (inspection or source surveillance, or both).

Management of Quality

Quality Systems | Programs

In School, Did You Have Coursework in ~

- Understanding Planning, Policies, Management Systems, Programs, Processes, Procedures, Specifications, Reports, Checklists

- Program, Project, Activity, Task ~ Analysis

- Contracts ~ Scope of Work & Legal Language

- Specification & Technical Writing

- Assessing, Auditing, ~ Performance Measurement

QMP
Policy
Manual

Process

Procedure

Information & Records

CAR Program | QC Program | Design Program | Purchasing Program | Supplier Program | Software Program | Document Program | Records Program | Training Program | Resource Program | Filed Test Program

Systems Thinking?

"Typically, Companies Have 80% Of The Core Information To Develop An Effective QMS"

Management of Quality

Quality-related Information, Data, Documents, Records

In School, Did You Have Coursework in ~

- Communications

- Information & Data Control
- Records Management

All About Records Management | (smartsheet.com)

Courtesy ARMA International

Management of Quality

Quality & The Law

In School, Did You Have Coursework in ~

- Technical Writing ~ Legal implications on word usage

- Writing Policies, Processes, Procedures, Specifications, Nonconformance Reports, Corrective Action Statements

- **Legal Liability** ~ Civil v. Criminal

- **Contract Law** ~ Compliance

- Regulatory Compliance ~ Typically CFRs

- Environmental Compliance ~ EPA & Others

- **Quality & The Law** ~ Forensic Expert

  Witnesses in many disciplines testify against

  fraudulent suppliers & materials, work

  practices, & financial fraud (Hold Suppliers to Contracts)

Terms & Definitions

Sources

Management of Quality

Sources ~ Quality Definitions

- **Quality Management Leaders ~ Quality Gurus**

- **American Society for Quality (ASQ)**

- **American Society of Mechanical Engineers (ASME)**

- **European Society for Quality (ESQ)**

- **Japanese Society for Quality Assurance (JSQA)**

- **International Organization for Standardization (ISO)**

- **International Atomic Energy Agency (IAEA)**

- **Dictionaries ~ Webster's & Merriam-Webster, Oxford, English, Cambridge, Black's Law, Ballentine's Law**

Management of Quality

Google   origin of the word quality

What is quality in one word?

What is quality in 3 words?

What word best describes quality?

What is the modern definition of quality?

What is a quality according to Aristotle?

What is the origin of quality?

What is root cause quality?

What is the prefix for the word quality?

What is the Oxford meaning of quality?

What is quality based on?

Who gave the definition of quality?

Management of Quality

Google origin of the word quality

Origin

LATIN → LATIN

qualis → qualitas

of what kind,
of such a kind

OLD FRENCH

→ qualite → quality

character,
disposition

Middle English

GREEK

poiotēs

Middle English (in the senses 'character, disposition' and 'particular property or feature'): from Old French *qualite*, from Latin *qualitas* (translating Greek *poiotēs*), from *qualis* 'of what kind, of such a kind'.

https://www.google.com/search?q=origin+of+the+word+quality&sca_esv=f6861048bb8aaca5&source=hp&ei=9PgQaK_OIaiVwbkPoZ2BgQY&iflsig=ACkRmUkAAAAaBEHBPEmZqDDUyarobp1R1eQgK_8Y9E_&ved=0ahUKEwivmIbWz_2MAxWoSjABHaFOIGAQ4dUDCA8&oq=origin+of+the+word+quality&gs_lp=Egdnd3Mtd2l6Ihpvcmlna W4gb2YgdGhlIHdvcmQgcXVhbGl0eTIFEAAYgAQyBhAAGBYYHjILEAAYgAQYhgMYigUyCxAAGIAEGIYDGIoFMgUQABjvBTIIEAAYgAQYogRIk4gBUI4bWKxYcAF4AJABAJgB6wGgAbYTqgEGMTkuNi4xuAEMyAEA-AEBmAIboALvFKgCCsICFxAAGIAEGLQCGOUCGLcDGIoFGOoCGIoDwgIdEC4YgAQY0QMYtAIY5QIYxwEYtwMYigUY6gIYigPCAhEQLhiABBiRAhjRAxjHARiKBcICCxAAGIAEGJECGJMCGJoFMgUQABjvBTIIEAAYgAQYogRIk4gBUI4bWKxYcAF4AJABAJgB6wGgAbYTqgEGMTkuNi4xuAEMyAEA-AEBmAIboALvFKgCCsICFxAAGIAEGLQCGOUCGLcDGIoFGOoCGIoDwgIRQ0QMYxwEYrwHCAg4QABiABBixAxiDARiKBcICCxAAGIAEGLEDGIoFFEC4YgASYAwzxBdKS4p6DlKSXkgcGMjAuNi4xoAen1QGyBwYxOS42LjG4B-MU&sclient=gws-wiz

Management of Quality

Google   origin of the word quality

Where did the word quality come from?

In brief. From **Latin qualitas, qualitatis ('quality')**, quality is in fact a calque of the Greek ποιότης poiótēs. In English, the Online Etymology Dictionary places its French origin around 1300.

A   Asociación Ibérica de Estudios de Traducción e Interpretación
https://www.aieti.eu › enti › quality_ENG

Quality - AIETI

What is the root of quality?

Etymology. From **Middle English qualite, from Old French qualité, from Latin quālitās, quālitātem, from quālis ("of what kind"), from Proto-Indo-European *kʷo- ("who, how")**.

Management of Quality

Google | origin of the word quality

Wiktionary, the free dictionary
https://en.wiktionary.org › wiki › quality

quality - Wiktionary, the free dictionary

What is the base word for quality?

1300, **qualite**, "temperament, character, disposition," from Old French calite, qualite "quality, nature, characteristic" (12c., Modern French qualité), from Latin qualitatem (nominative qualitas) "a quality, property; nature, state, condition" (said [Tucker, etc.] to have been coined by Cicero to translate Greek poiotēs ...

Online Etymology Dictionary
https://www.etymonline.com › word › quality

Etymology of "quality" by etymonline

What is the best definition of quality?

AI Overview

Quality, in its most basic sense, refers to the degree of excellence or the standard of something, often used to describe how good or bad something is. It can also be seen as the characteristic of a product or service that satisfies stated or implied needs, or a product/service free of deficiencies. In essence, quality is about meeting or exceeding expectations, and providing value.

Management of Quality
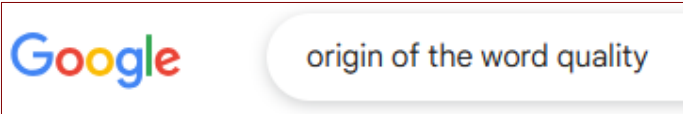
Elaboration

Degree of Excellence

Quality often implies a high standard or level of performance. A high-quality product, for example, is well-made, durable, and meets customer expectations.

Characteristics and Attributes

Quality can also refer to the specific features or traits of something, whether positive or negative. For instance, a person's "qualities" might include their honesty, kindness, or intelligence.

Conformance to Specifications

In a technical context, quality can mean a product or service meets established standards and requirements.

Customer Needs

Quality is also closely tied to satisfying customer needs, both stated and implied.

Subjectivity and Perception

Quality can be subjective, as what one person considers high quality, another may not.

Beyond Meeting Requirements

Some definitions of quality emphasize exceeding expectations and creating value for customers.

Examples

A high-quality car might have excellent engine performance, a comfortable interior, and advanced safety features.

A high-quality education would provide students with a well-rounded curriculum and experienced teachers.

A person with high-quality character would be known for their honesty, integrity, and compassion.

Management of Quality

Online Etymology Dictionary
https://www.etymonline.com › word › quality

Etymology of "quality" by etymonline

c. 1300, qualite, "temperament, character, disposition," from Old French calite, qualite "**quality**, nature, characteristic" (12c., Modern French qualité)

Wiktionary, the free dictionary
https://en.wiktionary.org › wiki › quality

quality - Wiktionary, the free dictionary

From Middle English qualite, from Old French qualité, from Latin quālitās, quālitātem, from quālis ("of what kind"), from Proto-Indo-European *kʷo- ("who, ...

Oxford English Dictionary
https://www.oed.com › dictionary › quality_n

quality, n. & adj. meanings, etymology and more

The earliest known use of the **word quality** is in the Middle English period (1150—1500). OED's earliest evidence for **quality** is from around 1300, in St. Michael.

Merriam-Webster
https://www.merriam-webster.com › dictionary › quality

QUALITY Definition & Meaning

Word History. Etymology. Noun. **Middle English** ... Browse Nearby Words. qualitied. quality. quality assurance · See all Nearby Words. Articles Related to quality ...

Asociación Ibérica de Estudios de Traducción e Interpretación
https://www.aieti.eu › enti › quality_ENG

Quality

From Latin qualitas, qualitatis ('**quality**'), **quality** is in fact a calque of the Greek ποιότης poiótēs. In English, the Online **Etymology** Dictionary places its ...

Reddit · r/etymology
5 comments · 5 years ago

When and how did 'quality' become an adjective?

I think is the way sellers speak, "high **quality**" in order to save **words**, to simplify messages, a catching eye thing in the supermarket. And ...

American Heritage Dictionary
https://www.ahdictionary.com › word › search › q=quality

American Heritage Dictionary Entry: quality

adj. Having a high degree of excellence: the importance of quality health care. [Middle English qualite, from Old French, from Latin quālitās, quālitāt-, from ...

Oxford English Dictionary
https://www.oed.com › dictionary › quality_v

quality, v. meanings, etymology and more

The earliest known use of the verb quality is in the late 1500s. OED's earliest evidence for quality is from 1579, in the writing of John Jones, physician.

YourDictionary
https://www.yourdictionary.com › quality

Quality Definition & Meaning

Origin of Quality. From Middle English, from Old French qualité, from Latin qualitatem, accusative of qualitas, from qualis ("of what kind") ...

Vocabulary.com
https://www.vocabulary.com › dictionary › quality

Quality - Definition, Meaning & Synonyms ...

The qualities of something are its distinguishing features, and those can be good or bad. The qualities you look for when buying a tightrope might include strength and pliability, but you probably wouldn't wan...

Quora
https://www.quora.com › What-is-your-definition-of-qua...

What is your definition of 'quality'? - Quora

In manufacturing, a measure of excellence or a state of being free from defects, deficiencies and significant variations. It is brought about by strict and consistent commitment to certain standards that...

Quality Digest
https://www.qualitydigest.com › magazine › nov › article

Definition of Quality | Quality Digest

This is how our readers define quality. (Note: these definitions are straight from our database and have not been edited.) "Quality itself has been defined as fundamentally relational: 'Quality is the ongoing...

Management of Quality

Google   origin of the word quality

Japanese

In Japanese, "quality" can be expressed in a few ways, but the most common are **hinshitsu (品質) and korehitsu (クオリティ)**. Hinshitsu (品質) is a more general term referring to the quality of a product or service, while korehitsu (クオリティ) is a loanword from English "quality" and is often used when referring to high-end or luxury items.

Elaboration:

Hinshitsu (品質):

This term is often used when discussing the quality of products, services, or even the quality of life. It can also be used in conjunction with other words to describe specific types of quality, such as "good quality" (良質, ryōshitsu) or "poor quality" (劣質, retsushitsu).

Korehitsu (クオリティ):

This term is a direct borrowing from English and is often used when referring to something that is considered high-end or of a high standard. You might hear it used in contexts like "high quality" (高品質, kōhinshitsu), or when discussing the quality of a product or service in terms of its aesthetics or functionality.

Beyond the words:

In Japanese culture, quality often goes beyond just functionality. Concepts like atarimae hinshitsu (当たり前品質) (taken-for-granted quality, where a product does what it's supposed to do) and miryokuteki hinshitsu (魅力的品質) (attractive quality, where a product has unique features or appeal) are also important.

Management of Quality

Definitions?

~ *On & On & On & On & On* ~

Google | origin of the word quality

What is the simplest definition of quality?

Quality is **how good something is**. If the quality of a product is high then that means that it is fit for its purpose. If the quality of an item is low that means that the product may break easily or not work properly. When people say something is a quality product that means that the product is of good quality.

Management of Quality

ASQ ~ "Q" Glossary

- **Quality Policy –** A documented statement of commitment or intent to be implemented to achieve quality.

- **Quality Management (QM) –** Managing activities and resources of an organization to achieve objectives and prevent nonconformances.

- **Quality Management System (QMS) –** A formal system that documents the structure, processes, roles, responsibilities and procedures required to achieve effective quality management.

  https://asq.org/quality-resources/quality-glossary/q?srsltid=AfmBOop0c-9Jz3O6y0yyA7JUSlbxcBFuXUQlgGxVmBC6A8zvXONqdGd7

HISTORY OF QA AND QC

Quality has been defined as fitness for use, conformance to requirements, and the pursuit of excellence. Even though the concept of quality has existed from early times, the study and definition of quality have been given prominence only in the last century.

1920s: Quality Control

Following the Industrial Revolution and the rise of mass production, it became important to better define and control the quality of products. Originally, the goal of quality was to ensure that engineering requirements were met in final products. Later, as manufacturing processes became more complex, quality developed into a discipline for controlling process variation as a means of producing quality products.

1950s: Quality Assurance and Auditing

The quality profession expanded to include the quality assurance and quality audit functions. The drivers of independent verification of quality were primarily industries in which public health and safety were paramount.

https://asq.org/quality-resources/quality-assurance-vs-control

Management of Quality

American Society for Quality (ASQ) ~ "Q" Glossary

- **Quality –** A subjective term for which each person or sector has its own definition. In technical usage, quality can have two meanings: 1) the characteristics of a product or service that bear on its ability to satisfy stated or implied needs; 2) a product or service free of deficiencies. According to Joseph Juran, quality means "fitness for use"; according to Philip Crosby, it means "conformance to requirements."

- **Quality –** The totality of features and characteristics of a product or service that bear on its ability to satisfy given needs.

- **Quality Assurance / Quality Control (QA/QC) –** Two terms that have many interpretations because of the multiple definitions for the words "assurance" and "control." For example, "assurance" can mean the act of giving confidence, the state of being certain or the act of making certain; "control" can mean an evaluation to indicate needed corrective responses, the act of guiding or the state of a process in which the variability is attributable to a constant system of chance causes. (For a detailed discussion on the multiple definitions, see ANSI/ISO/ASQ A3534-2, Statistics—Vocabulary and Symbols—Statistical Quality Control.)

  One definition of quality assurance is: all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality. One definition for quality control is: the operational techniques and activities used to fulfill requirements for quality. Often, however, "quality assurance" and "quality control" are used interchangeably, referring to the actions performed to ensure the quality of a product, service or process.

https://asq.org/quality-resources/quality-glossary/q?srsltid=AfmBOop0c-9Jz3O6y0yyA7JUSlbxcBFuXUQlgGxVmBC6A8zvXONgdGd7

Management of Quality

International Organization for Standardization (ISO)
ISO 9001 QMS & ISO 19443 NQMS - ITNS

- **Quality –** Degree to which a set of inherent characteristics [or distinguishing features] of an object", which in turn is defined as anything perceivable or conceivable, such as a product, service, process, person, organization, system or resource, "fulfils requirements."

- **Quality Policy –** Is a high-level document that outlines an organization's commitment to quality, its overall direction, and its approach to meeting customer and other applicable requirements.

- **Quality Control (QC / QA) –** QC is about detecting defects in your finished product, while QA is about preventing the defects from occurring in the first place. They're both requirements of ISO quality standards and regulations like the FDA's 21 CFR PART 820.

- **Quality Management System (QMS) –** ISO 9001 provides a framework for organizations to develop and implement a QMS, which is a set of policies, processes, and procedures designed to manage quality.

  In essence, ISO 9001 defines quality as the extent to which an object satisfies its intended purpose and the requirements placed upon it, fostering a culture of continuous improvement and customer satisfaction.

https://www.iso.org/standards.html

Management of Quality

Management System | Program Operational Elements

In School, Did You Have Coursework in ~

Quality Management System
ISO9001

5 Management Elements
1. Quality Management System (4)
2. Management Responsibility (5)
3. Resource Management (6)
4. Product Realization (7)
5. Measurement, Analysis, and
   Improvement (8)

Over 1.5 Million ISO Management System Certifications ~ Globally

Quality Certification - Get Professionally Certified | ASQ

Nuclear Quality Program
ASME / NQA-1 (10CFR50 Appendix B)

18 Criteria
1. Organization
2. Quality Assurance Program
3. Design Control
4. Procurement Document Control
5. Instructions, Procedures, and Drawings
6. Document Control
7. Control of Purchased Material, Equipment, & Services
8. Identification & Control of Mat'ls, Parts, & Components
9. Control of Special Processes
10 Inspection
11. Test Control
12. Control of Measuring and Test Equipment
13. Handling, Storage, and Shipping
14. Inspection, Test, and Operating Status
15. Nonconforming Materials, Parts, & Components
16. Corrective Action
17. Quality Assurance Records
18. Audits

Environmental Management
DOE EM-QA-001 QA Program

10 Criteria   8 Attachments
7.1 Management / Program
7.2 Management / Personnel Training and Qualification
7.3 Management / Quality Improvement
7.4 Management / Documents and Records
7.5 Performance / Work Processes
7.6 Performance / Design
7.7 Performance / Procurement
7.8 Performance / Inspection and Acceptance Testing
7.9 Assessment / Management Assessment
7.10 Assessment / Independent Assessment

Att A Certified Type B and Fissile Packaging QA Program
Att B QA Program Variance/Exemption Request
Att C Quality Assurance Implementation Plan
Att D Graded Approach
Att E Integrated Management System
Att F Suspect/Counterfeit Items Prevention
Att G Software Quality Requirements
Att H, Model Development, Use, and Validation

Management of Quality

Organizational Design ~ Organizing for Quality

In School, Did You Have Coursework in ~

- Top Management Allocate & Endorse Resources

- Executive Management Delineate & Endorse QMS Structure

- Operations & Program Management Define, Design, Implement, Upgrade, Maintain, & Improve the QMS

- Organization Disciplines Research Requirements & Manage the Requirements Baseline Matrix

- Quality Professionals QL, QM, QA, QC Assist & Advise All Organization Members

CEO

Supply Chain

Management of Quality
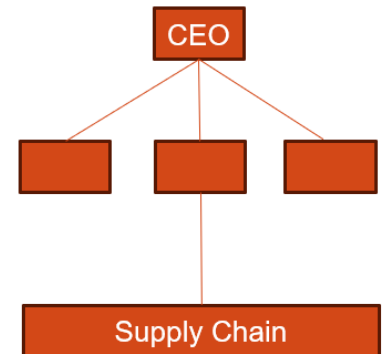
Framework Concepts for Quality Management

In School, Did You Have Coursework in ~

- **Approach** Are Quality Performance Goals and Objectives Defined and Achievable?

- **Requirements** Is the QMS "Technically Complex" and "Administratively Complex"?

- **Disciplines** Are Operation and Program Discipline Roles and Responsibilities Defined?

- **Resource Integration** Is the QMS Able to Demonstrate Effective Resource Allocations?

- **QMS Structure** How Does the QMS Look Inside the Company?

- **Infrastructure** Does the QMS Scope Encompass All Company Operating Requirements?

Quality Management System Structure

Commitment - Policy

Process

Procedure

Resource Integration

Controlled Information

Management of Quality
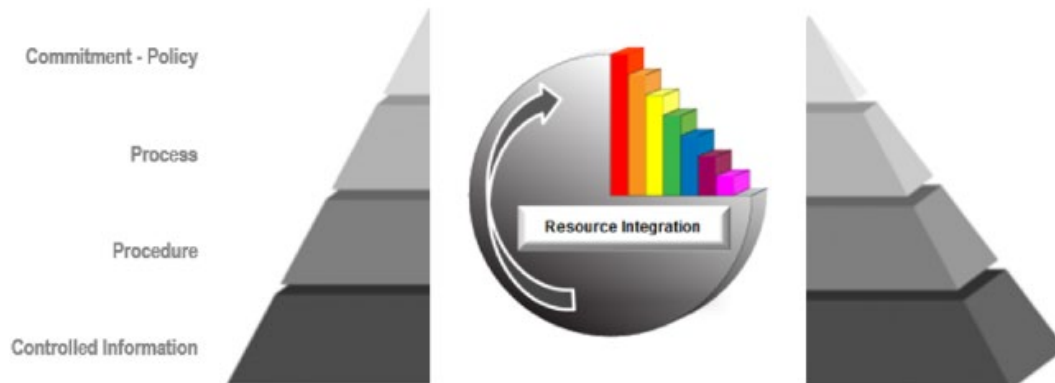
Business Process Management

In School, Did You Have Coursework in ~
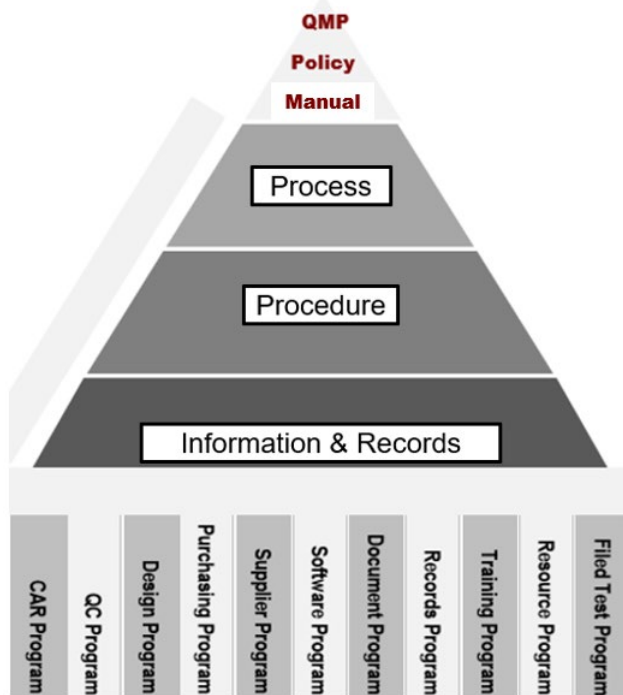
Focus on Defining Processes
~ Continually Improve ~

Management of Quality
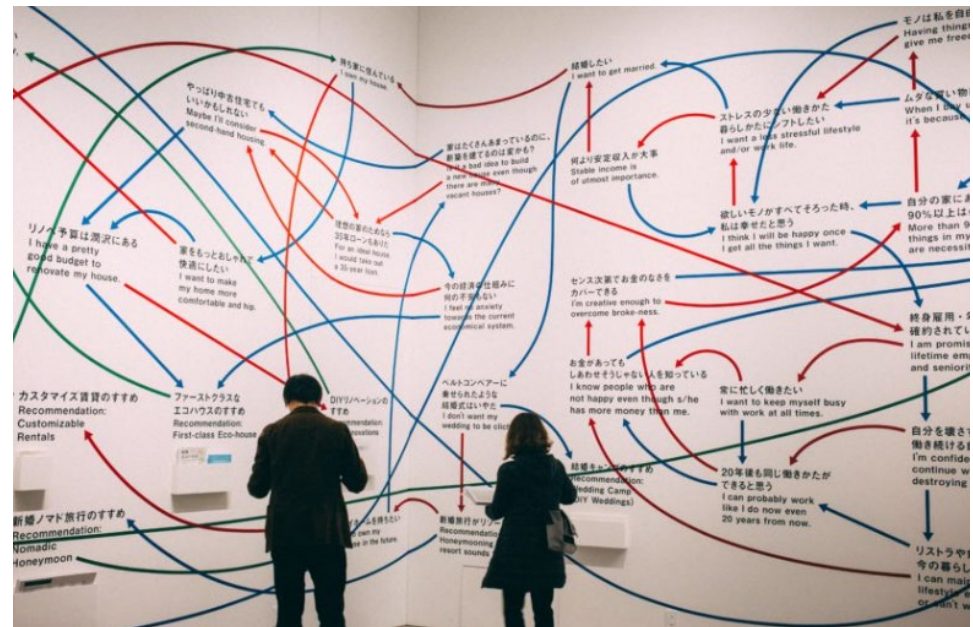
Quality-related Language & The Law

In School, Did You Have Coursework in ~

- Legal Terminology
  - Shall, Will, Must ~ Mandatory Requirement
  - Should ~ Recommended Requirement
  - May ~ Optional Requirement

Federal Employment
Law Training Group

Shall, Will, May, or Must?

📞 844-283-3584   ✉ info@feltg.com

**Shall, Will, May, or Must? |
Federal Employment Law
Training Group (feltg.com)**

~ Just Another Jobsite

Management of Quality

Supply Chain Management ~ Supplier Quality Performance

In School, Did You Have Coursework in ~

- 'A Business Critical Management Discipline'

- Performance-based Deliverables

- Surveillance | Assessment Practices?

- Sole-Source Controls??

Management of Quality
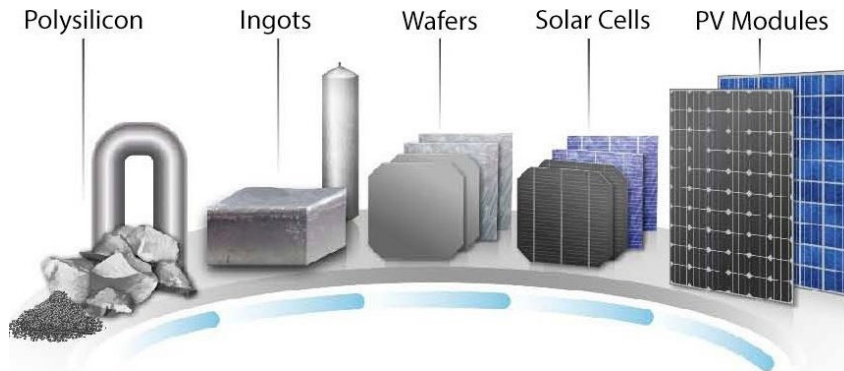
Costs of Poor Quality (COPQ)

In School, Did You Have Coursework in ~

According to the American Society for Quality (ASQ), **many companies have quality-related costs as high as 15% to 20% of sales revenue** [1] [2]. In some cases, those poor quality costs reach 40% of total operations [1]. ASQ reports that a "general rule of thumb" is to have COPQ at about 10% to 15% of operations at most [1] [3]. Effective quality improvement programs can reduce this substantially, thus making a direct contribution to profits [3].

Learn more: 1. sixsigmadaily.com   2. modusadvanced.com   3. asq.org

asq cost of poor quality - Search (bing.com)

Don't follow this approach!

QUALITY BUDGET

BUDGET AFTER A WARNING LETTER

Senior Management Should Collaborate for Success ~ CEO, Quality, Engineering, Safety, Risk, Finance, Program Management, Operations, Programs, & Suppliers

Management of Quality

Quality Timeline

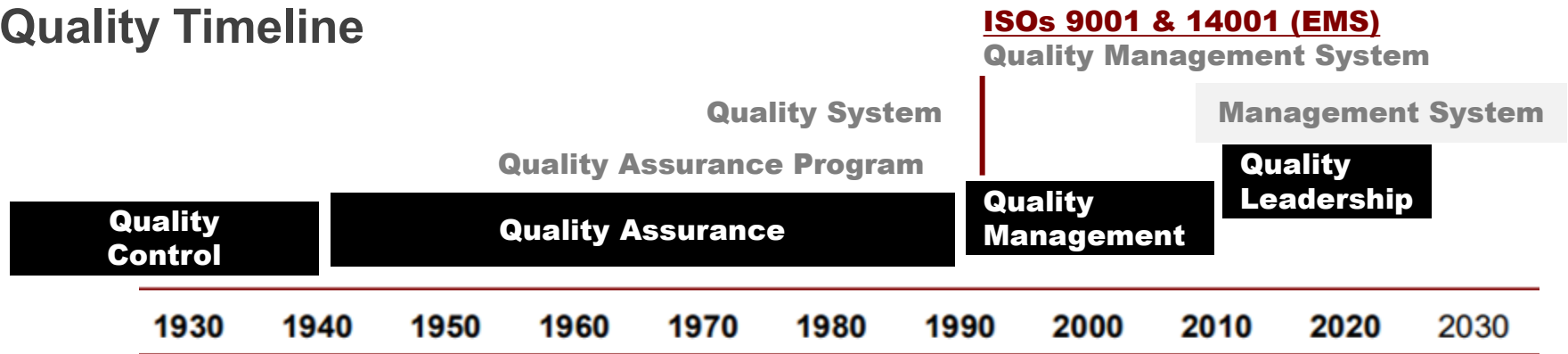**The evolution of formalizing for the Control of Quality as a business discipline had a very early beginning when people liked or disliked an item or how things were done.**

As a Profession, it took the Industrial Age to recognize the need for certain Quality-related Roles & Responsibilities. In the early 1900s, the complexities of assembly line production & assembly caused independent inspections emerge. Heating Boiler accidents & deaths from explosions essentially started Inspection & Testing Requirements. Bridges collapsing also drove the need. Soon Quality Control (Inspection | Testing) became the practice, especially for Safety-Related Products & Services.

Quality Timeline developed by GQM Advisors The following two slides depict the evolution in the use of 'Quality Management Tools' & new 'Management System Requirements Documents' (ISO 9001). The second slide depicts unfortunate 'Quality Affecting Significant Events' that have impacted lives & businesses over the past 100 plus years.

Management of Quality
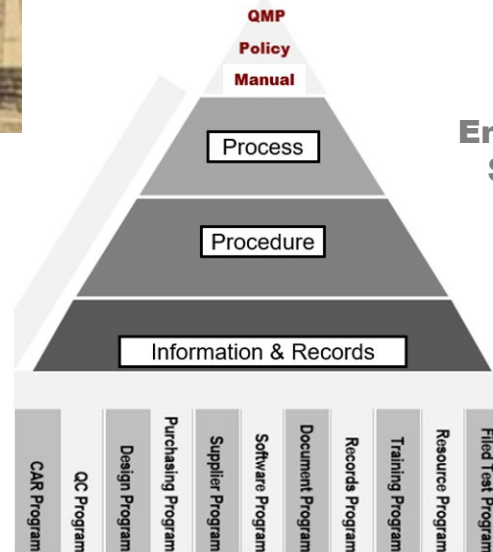
Quality Timeline

ISOs 9001 & 14001 (EMS)
Quality Management System

		Quality System		Management System
	Quality Assurance Program			**Quality Leadership**
Quality Control	**Quality Assurance**		**Quality Management**	

1930 · 1940 · 1950 · 1960 · 1970 · 1980 · 1990 · 2000 · 2010 · 2020 · 2030

'Achieve Order Out-of-Chaos'

We Need to Organize !!!

https://gqmadvisors.com/wp-content/uploads/2024/06/GQMadvisors-1900-2024-Tmln-QC-QA-QM-QL-CQO-06-10-24-R1-1sld.pdf

So, Getting Organized Began with Quality Control ?

QMP / Policy / Manual

Process

Procedure

Information & Records

CAR Program | QC Program | Design Program | Purchasing Program | Supplier Program | Software Program | Document Program | Records Program | Training Program | Resource Program | Filed Test Program

ISO 14001
Environmental Management Systems (EMS) Standard

Management of Quality

GQM advisors

MADE IN USA

1900 ~ 2020

| Quality Control | Quality Assurance | Quality Management | Quality Leadership |

QC | QA | QM | QL

Quality's Path to Leadership

Quality Affecting Significant Events

- 1912 RMS Titanic Atlantic Ocean (UK)
- 1941 World War II Mass Production (U.S.)
- 1955 Post-War Aerospace (U.S.)
- 1955 Naval Nuclear Program (U.S.)
- 1955 Atoms for Peace (Global Effort)
- 1960 Global Space Race (NASA, U.S.)
- 1968 Commercial Nuclear Power (U.S.)
- 1979 TMI Unit 2 (Pennsylvania, U.S.)
- 1984 NRC NUREG-1055 Report to Congress
    Nuclear Industry Quality / Safety /
    Management Failures (U.S.)
- 1986 Challenger Shuttle (U.S.)
- 1986 Chernobyl (Russia)
- 1988 Piper Alpha Oil Spill (North Sea)
- 1989 Exxon Valdez Oil Tanker Spill
    Prince William Sound (Alaska, U.S.)
- 2001 911 (New York City, U.S.)
- 2002 Prestige Oil Spill (Spain)
- 2002 Davis Besse' Reactor Head (Ohio, U.S.)
- 2003 Columbia Shuttle (U.S.)
- 2008 Metrolink Train (Southern CA, U.S.)
- 2008 B2 Bomber Crash (U.S.)
- 2010 Deepwater Horizon BP Oil Spill, Gulf of
    Mexico, 87 Days, (UK)
- 2011 Fukushima Daiichi (Japan)
- 2020 Coronavirus Pandemic Global COVID19

Conformance to Requirements
"Quality is Free concept 1979"
Dr. Philip B. Crosby

U.S. Quality Leaders Emerge
- Dr. Walter A. Shewhart
- Dr. Armand V. Feigenbaum
- Dr. Joseph M. Juran
- **Dr. W. Edwards Deming's Period of Influence**
  - 'System of Profound Knowledge'
  - Encompassed System, Variation, Knowledge, Psychology
  - 4 Lenses of Reference

Quality Management Tools
Risk Mitigation, SixSigma, QFD, FEMA, PDCA, C&E Diagraming, SPC, Control Charts, Remote Audits, Design / Contract Assurance, Lean, Process Mapping, Software, Modeling, Self-Assessments, CAPA, Drone Site Monitoring, Robot Inspections, Cyber Security, Others

2000 Work Cultures Emerge as Key Element to QMS Effectiveness

1990 Shift from 'Error Detection' to 'Error Prevention'

1990 U.S. Dept of Navy CNO Enacted Total Quality Leadership Concepts & Practices to Selected Fleet Units. *Goal: Process Improvements.* [1]

Quality Leadership   **Who's Your ~ Chief Quality Officer ?**

1977 DOE Formed

1971 OSHA Formed

Quality Assurance Emerges

1958 NASA & DARPA Formed

1957 First U.S. Nuclear Power Plant

"Cost of Poor Quality" U.S. Military Suppliers

Increased Emphasis on Quality | Safety

Inspection / Testing

Mass Production

1913, U.S. DOL Created

World War II

1911, U.S. ASME BPVCs Boiler / Pressure Safety

QC / SPC In - Process Inspection

1907, 60 Workers Died in Pittsburgh Factories

1884, U.S. BLS Collects Data

QRs

Self - Inspection   **Productivity Studies (SPC)**

Quality Control

1987 Quality Management Systems (QMS)
- ISO 9001 QMS Certifications 1.4 Million
- U.S. Baldrige Quality Performance Program (Department of Commerce)
- Quality Management Consultants

Complex Software

Quality Management

Quality Assurance

Complex Engineered Products / Systems / Structures

Challenger Shuttle, U.S.
1986 Accident

Chernobyl, Russia
Nuclear Power Plant
1986 Accident

Three Mile Island, U.S.
Nuclear Power Plant
1979 Accident

Exxon Valdez, Prince William Sound
1989 Oil Tanker Spill, Alaska, U.S.

911, Twin Towers, U.S.
2001

Columbia Shuttle, U.S.
2003 Accident

BP Deepwater Horizon, UK
2010 Oil Spill

Fukushima Daiichi, Japan
Nuclear Power Plant
2011 Accident

Management Systems
Industry & Government - Driven
- Environmental / Health / Safety Mgt
- Enterprise / Information Mgt
- Integrated Mgt
- Requirements Mgt
- Risk Mgt
- Emergency Prep Mgt
- Supply Chain Mgt
- Process Hazards Mgt
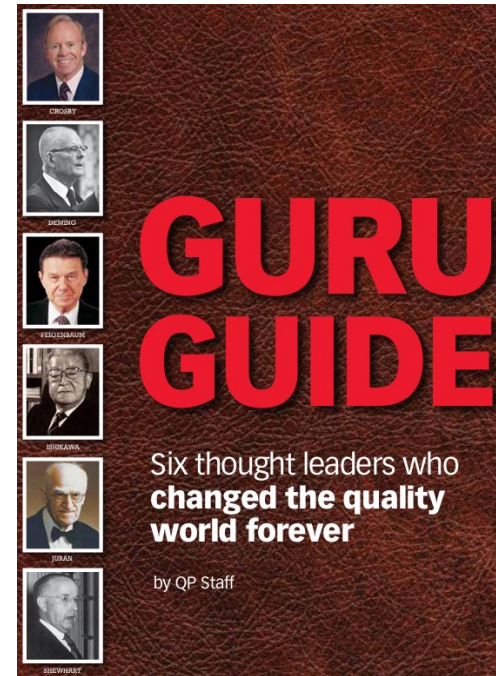- Cybersecurity Mgt

Quality 4.0
~ Digital ASQ

COVID-19
Global Pandemic

QRs
Quality Requirements

QRs

| 1900 | 1910 | 1920 | 1930 | 1940 | 1950 | 1960 | 1970 | 1980 | 1990 | 2000 | 2010 | 2020 | 2030 | 2040 | 2050 |

https://gqmadvisors.com/wp-content/uploads/2024/06/GQMadvisors-1900-2024-Tmln-QC-QA-QM-QL-CQO-06-10-24-R1-1sld.pdf

Management of Quality

Quality Thought Leaders ~ 2024, NZOQ

- Conformance to requirements ~ Philip B. Crosby

- Meeting or exceeding customer expectations ~ Dr. W. Edwards Deming

- Quality is the customers perception of what quality is, not what a company thinks it is ~ Armand V. Feigenbaum

- Emphasizes a customer-centric, holistic, and continuous improvement approach ~ Kaoru Ishikawa

- A product meets customer needs leading to customer satisfaction ~ Dr. Joseph Juran

- Conformance to requirements & Price of nonconformance ~ Walter A. Shewhart

- Eight product quality dimensions ~ performance, features, reliability, conformance, durability, serviceability, aesthetics and perceived quality. Garvin's (1984; 1987)
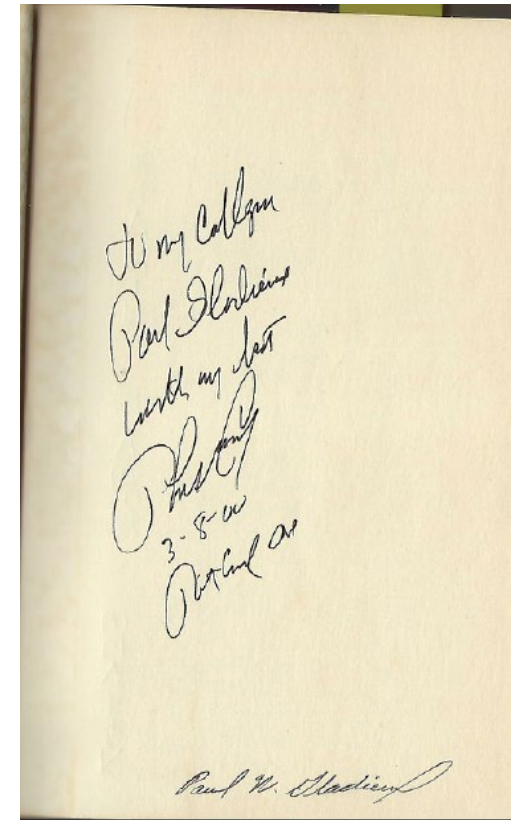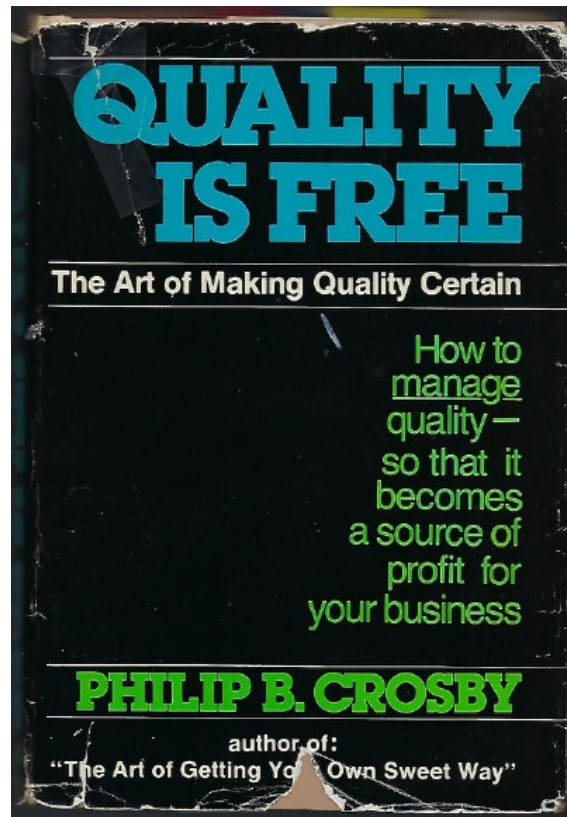

https://nzbef.org.nz/wp-content/uploads/2019/05/Guide-6-Thought-Leaders-who-Changed-the-Quality-World-Original.pdf

Management of Quality

'Quality is Free' ~ 1979, Phillip B. Crosby

Caution!!!   Remember, Don't Judge a Book by Its Cover !!!

It's possible this is the only one in circulation with the title on the spine printed upside down !!!

Management of Quality

'Quality is Free' ~ 1979, Phillip B. Crosby

'The Art of Making Quality Certain' How to Manage Quality ~ So that It Becomes a Source of Profit for Your Business'

He Explains in Simple Terms ~ **How 'Quality is Conformance to Requirements'**

In an article 'What are Requirements' he explained the basis for acceptable Product & Service deliverables. The insight aspect of the way he explains this concept is by expressing Requirements in Numbers. He proposed the idea of how many requirements it takes to run your company. Today, smart companies use a Requirements Management Matrix to establish baseline requirement sources & implement a simple Requirements Accounting Process. It can be managed using MS.Excel for small companies.

How many Requirements (Those that Affect the Quality of Your Products & Services) are the basis for your Operations & Programs? One, Two, Three, Ten Million?

Do you think the CEO, COO, CFO, CTO, CIO, with advisory guidance by your CQO, would know how many Requirements drive your organization?
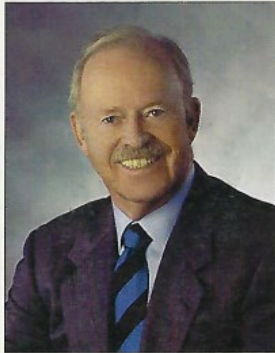
Management of Quality

'Creating A Reliable Organization' ~ 2000

"Creating A Reliable Organization"

An Evening with

Philip B. Crosby

Wednesday March 8, 2000

presented by
ASQ Portland Section 0607
Intel Corporation
and
The Oregon Quality Award

American Society for Quality
ASQ

intel®

OREGON QUALITY AWARD

"Creating A Reliable Organization"

Program Description

Management's most important job is creating a reliable organization. That is, one where all transactions are completed correctly and you have built relationships with employees, suppliers, and customers. The purpose of all this is to have an organization that can be trusted to do what it has agreed. From answering the inquiry to giving the customer what has been promised – the place works.

The Quality professional's job is to help management create this pragmatic culture. They do that through: "Policy, Education, Requirements, and Insistence."

In a reliable organization everyone is oriented toward preventing problems rather than chasing and trying to solve them. The organization is efficient and profitable.

This is not a world where organizations can afford old-fashioned Quality Control and Quality Assurance as their primary way of operating. They need Quality Management.

Adopting Quality Management is the equivalent of graduating from financial management by taking money in and out of a cigar box, to the sophisticated computer driven management of today.

Join Mr. Crosby and your peers for an informative, thought-provoking and enjoyable evening.

Philip B. Crosby is a preeminent leader who has revolutionized quality movements throughout the world. He draws on over 40 years of "hands on" management experience to provide a thoughtful and stimulating discussion of management's role in causing their organizations, their employees, their suppliers, and themselves to be successful.

Mr. Crosby has published thirteen books, all of which have been best sellers. His first business book, *Quality Is Free*, has sold over 2.5 million copies. He created the renowned Zero Defects concept, and has been credited with beginning the quality revolution in the United States and Europe. Mr. Crosby's latest book is his autobiography, *Quality and Me*, published in 1999.
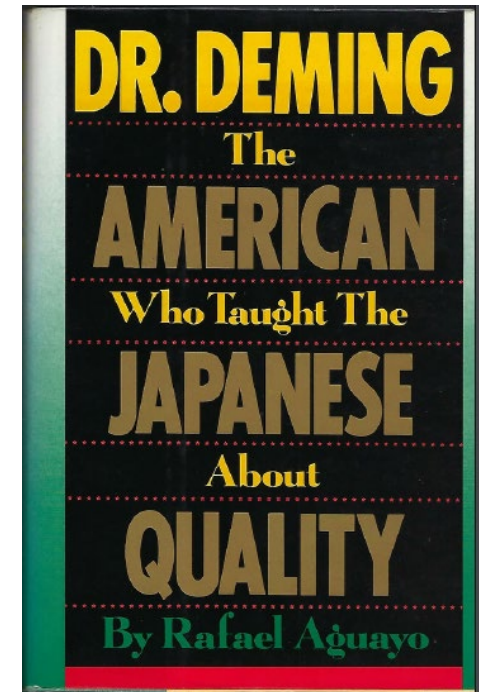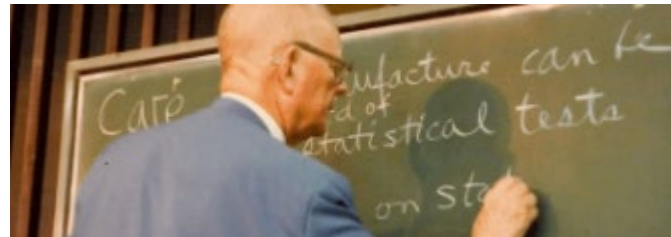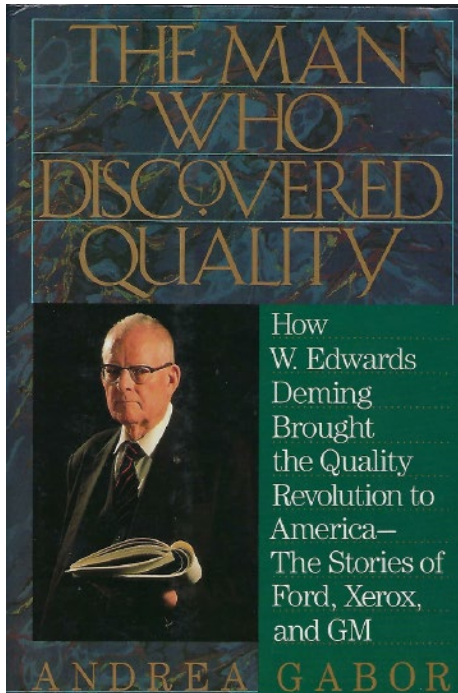
PHILIP CROSBY Associates II, Inc.

www.philipcrosby.com

Management of Quality

Dr. W. Edwards Deming

America's Father of Quality Management
Both Books ~ 1990

The W. Edwards Deming Institute

Management of Quality

Dr. W. Edwards Deming

Quality Thinker & Thought Leader

Dr. Deming was preoccupied with why things do not behave as predicted. All systems (be they the equipment, the process or the people) have variation, but he argued that it is essential for managers to be able to distinguish between special & common causes of variation. He developed a theory of variation ~ that special causes of variation are usually easily attributable to quickly recognizable factors such as changes of procedure, change of shift or operator etc.; but that common causes will remain when special causes have been eliminated (normally due to design, process, or system).

These common causes are often recognized by workers, but only managers have the authority to change them to avoid repeated occurrence of the problem. Deming estimated that management was responsible for more than 85% of the causes of variation. This formed his central message to the Japanese.

Management of Quality

Is Quality Just a Word We Use?

Tom Taormina, CMC, CMQ/OE, BMSM – More than 50 Years
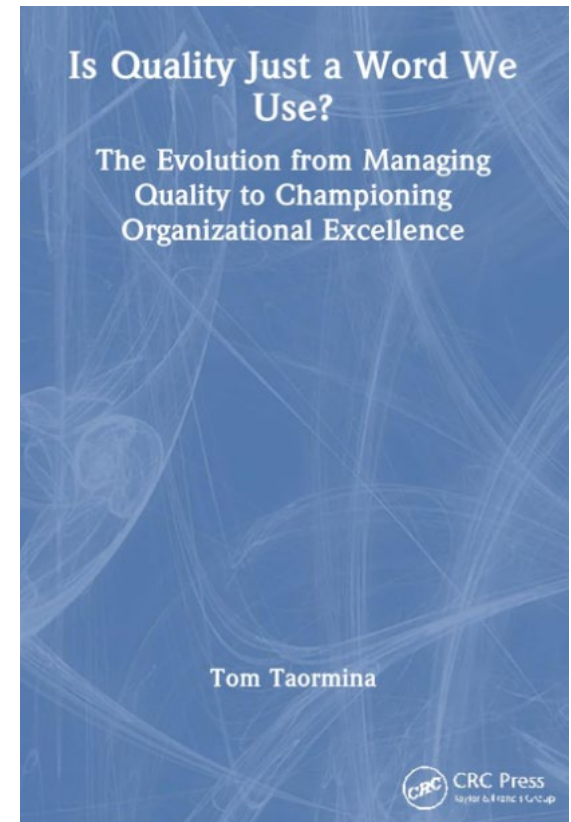
Consultant | Expert Witness | Author | GQM Advisor

tom@tomtaormina.com

There's thousands of articles, hundreds of books, hundreds of webinars, hundreds of consultants & advisors, numerous university & private courses, hundreds of thousands of quality professionals, numerous sectors | segments, thousands of applications, millions of perceptions, & thousands of opinions on Quality & its Management.

- Has the dust settled ~ Is there one definition?

- Will there be one more definition to emerge?

- If we asked 100 random persons ~ how many definitions would we hear?

- Will there ever be one definition?

https://www.amazon.com/Quality-Just-Word-We-Use/dp/1032879653

This 2025 book presents a groundbreaking model for quality professionals to drive revolutionary changes in business management, empowering them to eliminate defects & enhance their impact on business success, attracting professionals in fields such as quality assurance, quality management, risk management, & manufacturing management as well those involved in litigation.

Is Quality Just a Word We Use?
The Evolution from Managing Quality to Championing Organizational Excellence

Tom Taormina

CRC Press

Management of Quality

What's Your Definition of Quality?

Does it Align With Your Workplace Products & Services?

Is Quality Clear in Your Vision, Mission, Value, Policy Statements?

True Operational & Program Effectiveness ~ Excellence

Requires A Consensus & Consistent Use Of Your Definition & Application

Requires Deliberate Focus On The Management of Quality

Management of Quality

GQM advisors

Who Defines Quality in Your Organization?

Why is it Critical to Have a Clear & Consistent Definition of Quality?

High-Risk & High-Consequence Safety-Related Products & Services Must be Designed, Produced, & Supplied in the Best Form & Function as Possible for End Users.

Engineers & Designers are 'The Specifiers' of Quality-Level Requirements & Performance Expectations for Safety-Related Products & Services for Protecting Life, Safety, Health, Security, & Environments.

Image Being in a Plane at 40K Feet NOT DESIGNED for the Highest Quality & Safety?

~ Executives & Specifying Engineers Define Quality in the U.S. Industry ~

Management of Quality

Paul W. Gladieux ~ Professional Goal

'My goal is to assist anyone making efforts to properly define 'The Management of Quality' in any sector, segment, application. Please contact me if you have questions, comments, or need assistance.'

https://gqmadvisors.com/professional-resources/advisors/#teamMember8

Paul W. Gladieux, CEO | CQO | Founder – More than 45 Years
**GQM Advisors, Management Systems Professional**

Expertise
Expertise encompasses all aspects of defining, designing, requirements baselining, structuring, writing, deploying, and upgrading effective management systems in multiple sectors. Systems range from simple commercial to complex high-hazard safety-related requiring: requirements management matrix development, large-scope information management systems (data/documents/records/reports), complex multi-site assessments and sustaining analysis. Mastery in baselining management system startups, upgrades, turnarounds. Working knowledge of national/international codes, standards, regulations, and stipulations encompassing U.S. ASME, U.S. DOE Orders, ISO Standards, U.S. NRC Regulations/NUREGs/CFRs, IAEA Standards, U.S. Baldrige Performance Criteria, and others. Over 10K hours engaged in management system assessments (1983 ASME/NQA-1 Nuclear Lead Assessor certified, and 1994 U.S. and UK ISO QMS Lead Assessor certified - six sectors). Service marked 'GQM Advisors Management Systems Focused on Quality Since 1991.'

GQM ADVISORS WAS FOUNDED IN 1991 on the belief the "Management of Quality is a fundamental responsibility of everyone engaged in the delivery of products & services." We are a group of leading Independent Quality-focused Professionals with a reputation of mastery & excellence in deploying the Four Quality Disciplines > QL, QM, QA, & QC. The Group understands that all business disciplines must be quality-focused for an organization to achieve annual goals & objectives delineated in its Quality Management System (QMS).

Arizona	Nevada	Tennessee
California	New Jersey	Texas
Colorado	North Carolina	Utah
Florida	Ohio	Virginia
Georgia	Oregon	Washington
Michigan	South Carolina	Washington, DC

Canada

Netherlands

United Kingdom

Since 1991

Since 1974

https://gqmadvisors.com/professional-resources/advisors/
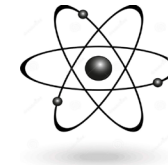
Advisors collective expertise exceeds 1,000 years encompassing more than 50 Business Sectors | Segments | Applications. Our established relationships in various industries, societies, agencies, business peer groups, & supply chains enables us to align the never-ending mix of management systems baseline requirements in virtually any operation and program environment. Our experiences vary & span a 50-year period beginning in the early 1970s.

Global Quality Management Advisors

Management Systems

~ Focused on Quality ~

Paul W. Gladieux
CEO | CQO | Founder
Lynchburg, VA USA
503-939-4498 C

34 Years ~ Serving Clients

Since 1991

https://gqmadvisors.com/

GQM **advisors**