Special Processes Institute



QUALITY BOOK

The Practical Handbook of Quality Knowledge, Methods & Tools

Konrad Burgoyne



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Quality Book

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Foreword

Quality can sometimes appear more complicated than it needs to be. There are standards, procedures, processes, tools, methods and terminology, and for someone new to quality, it can be difficult to know where to begin. Even for those with many years of experience, the breadth of the subject means there's always something new to learn.

What I like about this Quality Book is that it brings these different elements together in one place. It doesn't try to replace standards or formal training, but it makes quality more accessible and explains not only what something is, but why it matters and how it can be applied in practice.

Quality isn't just a set of rules. It's a mindset that helps us do things right every time and drives continual improvement. It reminds us that quality is also about people, the relationships we build, the trust we earn, and the shared commitment that turns good processes into great outcomes. At the heart of every process are the people who make it work.

Whether you are just beginning a career in quality, work alongside quality professionals, or have spent many years in the profession, there will be times when the answer isn't immediately obvious. I hope this book becomes something you can turn to through some of that complexity, somewhere to start, somewhere to check your thinking and somewhere to return to if you need a little direction.

And if it saves you from having to read quite so many standards twice, well, that's an extra bonus too.

Louise Blakey
Foreword to the Quality Book
2026

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1. Introduction

1.1. Purpose

The purpose of this Quality Book is to provide a practical and accessible reference for understanding and applying the principles, methods and tools of quality management. It is intended to support people at all levels of experience, from learners developing their knowledge of quality for the first time through to experienced quality professionals, engineers, auditors, managers and others seeking a practical reference for their work.

1.2. Scope

The publication brings together three complementary areas of quality:

- **Knowledge** provides the foundation for understanding quality. It explains the principles, concepts, standards, management systems, history, terminology and disciplines that underpin effective quality management.
- **Methods** describes structured approaches used to plan, assure, control, improve and verify quality throughout the product, process and organisational lifecycle.
- **Tools** provides practical techniques that can be applied to analyse data, identify and solve problems, manage risk, make decisions, control processes and drive continual improvement.

The Quality Book is intended to bridge the gap between knowing what a quality concept is and understanding how, when and why to apply it. Wherever appropriate, subjects therefore include practical guidance, examples, diagrams, tables, good practice, common pitfalls and links to related quality activities.
The publication also promotes the principle that quality is not solely the responsibility of a Quality function. Effective quality is created through the combined activities of leadership, engineering, operations, supply chain, procurement, project management and everyone involved in delivering products and services.

2. The History of Quality

2.1. Overview

Quality is not a modern invention. The need to ensure that products and services are suitable, consistent and dependable has existed for as long as people have traded goods, constructed buildings and manufactured products.

2.2. The Changing Approach to Quality

Quality has progressively developed from individual craftsmanship and final inspection into a management discipline concerned with processes, variation, prevention, risk, customer requirements, organisational performance and continual improvement. A simplified representation of this evolution is:

Craftsmanship → Inspection → Quality Control → Statistical Quality Control → Quality Assurance → Total Quality Management → Quality Management Systems → Risk-Based and Integrated Quality Management

Each stage added to rather than completely replaced what came before it. Inspection, for example, remains necessary in modern industry, but it is now recognised that inspection alone cannot create a capable process or prevent defects.

Understanding this development helps quality professionals appreciate why modern quality management places such importance on prevention, process control, evidence, leadership, customer focus and continual improvement.

2.3. What is Quality?

There is no single everyday definition that completely describes quality.
Quality may refer to:

- conformity to specified requirements;
- fitness for intended use;
- consistency of performance;
- reliability and durability;
- safety;
- customer satisfaction;

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- absence of defects;
- value;
- process capability;
- achievement of intended outcomes.

In professional quality management, quality should not simply be interpreted as meaning "the best" or the most expensive product.

A product may be inexpensive and still demonstrate excellent quality if it consistently fulfils its intended requirements. Conversely, an expensive or technically sophisticated product may demonstrate poor quality if it is unreliable or fails to meet its specified or intended requirements.

ISO 9000 provides the internationally recognised fundamentals and vocabulary used by the ISO 9000 family of quality management standards. Modern quality management therefore treats quality in relation to requirements and the characteristics of an object, rather than simply subjective perceptions of excellence.

2.4. Quality, Quality Control and Quality Assurance

These terms are related but should not be treated as interchangeable.

Concept	Primary Question	Typical Focus
Quality	Does the product, service or outcome fulfil its requirements?	Result
Quality Control	Are requirements being fulfilled?	Verification and operational control
Quality Assurance	Do we have confidence that requirements will be fulfilled?	Confidence, systems and prevention
Quality Management	How do we direct and control the organisation with regard to quality?	Overall management
Quality Improvement	How can our ability to fulfil requirements be increased?	Better performance

The development from detection toward prevention is one of the most important themes throughout the history of quality.

2.5. The Evolution of Quality

2.5.1. Early Civilisations

Quality management existed in practical forms thousands of years before the profession acquired its modern terminology. Large construction projects, organised trade and military production required:

- measurements;
- standardisation;
- defined materials;
- skilled workmanship;
- inspection;
- supervision;
- acceptance criteria.

Ancient civilisations developed systems of weights and measures and forms of standardisation because construction and commerce could not function effectively without consistency.

Historical research cited by ASQ identifies examples from ancient Rome including standardised measurement systems, standardisation of bricks and pipes and building regulations. This demonstrates that concepts now associated with specification, standardisation and conformity have very old foundations.

The lesson for the modern quality professional is important: **Quality began with the need to control variation and achieve a predictable result.**

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2.5.2. Craftsmanship and the Guild System

Before industrial mass production, products were commonly made by individual craftspeople or small groups. The person producing an item was often responsible for:

Making → Inspecting → Correcting → Delivering

The producer therefore had a direct relationship with both workmanship and reputation.
During medieval Europe, guilds established rules governing workmanship and product quality. Inspection committees could inspect products and apply marks demonstrating conformity.

Craftspeople also used identifying marks that provided traceability to the maker. These practices introduced concepts that remain familiar today:

- workmanship standards;
- competence;
- inspection;
- traceability;
- acceptance;
- reputation;
- accountability.

The craftsman effectively combined the roles that modern organisations divide between production, inspection, engineering and quality.

2.5.3. Strength of the Craft Model

Responsibility for quality was close to the person creating the product.
Limitation: Quality depended heavily on individual skill and was difficult to scale consistently as production volumes increased.

2.6. The Industrial Revolution

The Industrial Revolution fundamentally changed quality. Production moved from individual craftsmen toward factories, machinery, interchangeable components and increasingly specialised labour.

Instead of one person producing an entire product, manufacturing became divided into individual operations. This increased productivity but created a fundamental quality challenge:

Who is responsible for the quality of the finished product when many different people and processes contribute to it?

The emerging answer was inspection. Dedicated inspectors checked finished products and separated acceptable products from defective products.

The dominant model became:

Manufacture → Inspect → Accept / Reject → Rework / Scrap

This represented an important advance because acceptance criteria could be applied systematically. However, inspection primarily detected problems after they had already occurred.

This distinction eventually became fundamental to modern quality thinking:

- Inspection detects defects.
- Process control reduces their occurrence.
- Quality assurance seeks to prevent them.

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2.7. Quality People and Events

2.7.1. Scientific Management and Frederick Winslow Taylor

During the late nineteenth and early twentieth centuries, Frederick Winslow Taylor developed principles of scientific management. Taylor sought to improve productivity by studying work systematically and separating planning from execution.

Work could be:

- analysed;
- standardised;
- measured;
- divided into defined tasks;
- optimised.

This contributed significantly to modern industrial engineering and standardised work. However, separating planning, production and inspection could also distance workers from responsibility for the complete product. Quality increasingly became the responsibility of specialist inspectors. This period illustrates an important lesson:

Optimising productivity without adequately considering quality can simply produce defects more efficiently.

Modern quality management therefore seeks to integrate quality into the process rather than treating it as a separate activity performed after production.

2.7.2. Mass Production and Henry Ford

Henry Ford and the development of moving assembly-line production demonstrated the enormous potential of standardisation, interchangeable parts and process flow. Mass production required:

- repeatable components;
- controlled specifications;
- consistent processes;
- defined work;
- reliable suppliers;
- effective inspection.

Quality increasingly became a systems problem rather than simply a workmanship problem. As production volumes increased, inspecting every characteristic of every item became expensive and increasingly impractical.

Industry therefore needed better methods of understanding and controlling processes. Statistics provided the next major breakthrough.

2.7.3. Walter A. Shewhart and Statistical Quality Control

2.7.3.1. From Product Inspection to Process Control

In the 1920s, Walter A. Shewhart, working at Bell Laboratories, developed the foundations of statistical process control. Shewhart recognised that: **Every process exhibits variation.**

The critical question is whether that variation represents the normal behaviour of the process or indicates that something unusual has changed.

This led to the distinction between what are now commonly described as:

- **common-cause variation — variation inherent in the existing process system; and**
- **special-cause variation — variation resulting from an identifiable circumstance or change.**

Shewhart developed the control chart, allowing process behaviour to be evaluated statistically over time.

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2.7.3.2. Historical Change

Old approach

Make product → Inspect product → Find defect

Shewhart approach

Understand process → Measure variation → Detect abnormal behaviour → Control process → Prevent defects

This represented one of the most important transitions in the history of quality. Quality could now be managed during production rather than only after production.

Shewhart's work became the foundation for modern:

- Statistical Process Control (SPC);
- process capability;
- variation analysis;
- control charts;
- statistical quality control.

His work also strongly influenced W. Edwards Deming.

2.7.4. World War II and Statistical Quality Control

World War II created an enormous requirement for reliable military equipment produced at unprecedented scale.

Traditional 100% inspection required very large inspection resources. Statistical methods therefore became increasingly important.

Sampling inspection enabled organisations to make acceptance decisions about production lots without inspecting every individual item.

The United States military developed and adopted formal sampling approaches, including the standards that eventually became associated with MIL-STD-105.

Training in statistical quality control also expanded. The war demonstrated that quality was not merely a commercial issue. Poor quality could result in:

- equipment failure;
- loss of operational capability;
- safety consequences;
- loss of life.

This relationship between quality, reliability, safety and mission success remains particularly important within aerospace, defence, nuclear, medical and other safety-critical industries.

2.7.5. W. Edwards Deming

W. Edwards Deming became one of the most influential figures in modern quality management.
Deming was strongly influenced by Shewhart and promoted statistical understanding of processes, systems thinking and management responsibility.

After World War II, Deming worked with Japanese engineers and senior managers and became closely associated with Japan's development of modern quality management.

His philosophy challenged the idea that poor quality was primarily caused by careless workers. Instead, management was responsible for creating and improving the system in which people worked.

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Among the concepts associated with Deming are:

- understanding variation;
- systems thinking;
- continual improvement;
- management responsibility;
- long-term thinking;
- reducing dependence on mass inspection;
- improving supplier relationships;
- developing people;
- removing organisational barriers.

2.7.5.1. Deming's 14 Points

Deming's famous 14 Points for Management encouraged organisations to transform management practices rather than simply introduce more inspection.

The philosophy included ideas such as:

- creating constancy of purpose;
- adopting a new philosophy;
- reducing dependence on inspection;
- continually improving systems;
- developing training;
- improving leadership;
- breaking down barriers between departments;
- removing causes of fear;
- involving management in transformation.

These principles helped move quality from the factory inspection department toward organisational leadership.

2.7.6. The Shewhart/Deming Cycle

Shewhart's approach to learning and improvement became associated with the cycle commonly expressed as:

2.7.6.1. PLAN → DO → CHECK → ACT

- PLAN: Understand the situation, establish objectives and determine what should be done.
- DO: Implement the planned activity.
- CHECK: Evaluate results using evidence.
- ACT: Standardise successful changes or take further action based on what has been learned.

The PDCA cycle remains embedded in modern management-system thinking. Its importance lies in recognising that improvement is iterative rather than a one-time event.

2.7.7. Joseph M. Juran

Joseph M. Juran made another major contribution to the development of quality management. Juran emphasised that quality was a management responsibility and should be deliberately planned rather than expected to emerge from inspection.

He strongly promoted the concept of fitness for use. A product could conform to a drawing yet still fail to satisfy the customer's actual need. Quality therefore required understanding intended use as well as technical conformity.

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2.7.7.1. The Juran Trilogy

Juran described three fundamental managerial processes:

Process	Purpose
Quality Planning	Determine customers and their needs and establish processes capable of meeting them
Quality Control	Evaluate actual performance against objectives and address differences
Quality Improvement	Achieve improved levels of performance

This remains an extremely useful model.

PLAN QUALITY → CONTROL QUALITY → IMPROVE QUALITY

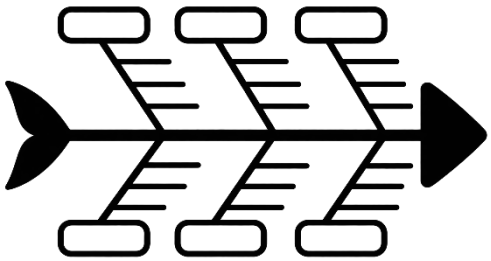
Juran also helped popularise application of the Pareto Principle to quality problems, concentrating effort on the relatively small number of causes responsible for a large proportion of problems.

2.7.8. Kaoru Ishikawa

Japanese quality expert Kaoru Ishikawa helped broaden quality participation throughout organisations.

He is strongly associated with:

- company-wide quality control;
- quality circles;
- workforce involvement;
- quality education;
- cause-and-effect analysis.



2.7.8.1. Ishikawa Diagram

The cause-and-effect diagram, also known as the fishbone or Ishikawa diagram, provides a structured way to explore possible causes of a problem.

Typical manufacturing categories include:

People | Machine | Method | Material | Measurement | Environment

Ishikawa's broader contribution was the recognition that quality should not belong exclusively to specialists. Everyone involved in a process can contribute to understanding and improving it.

2.7.9. Armand V. Feigenbaum

Armand V. Feigenbaum developed the concept of Total Quality Control.

His work emphasised that quality is affected by activities throughout the organisation, not merely manufacturing or inspection. Quality begins with customer requirements and continues through areas such as:

Design → Procurement → Manufacturing → Inspection → Delivery → Service

This helped establish the idea that quality is a cross-functional business responsibility. Feigenbaum's work was an important foundation for what later became known as Total Quality Management (TQM).

2.7.10. Philip B. Crosby

Philip B. Crosby promoted a strong prevention-based approach to quality. He became particularly associated with:

- Zero Defects;
- prevention rather than inspection;
- doing work correctly the first time;
- the cost of poor quality.

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Crosby's philosophy challenged organisations to stop treating defects as inevitable. The intention of Zero Defects should not be interpreted as a statistical claim that human beings can never make mistakes. Its more useful management meaning is: **Do not design processes around an assumption that defects are acceptable or unavoidable.**

Crosby also emphasised the financial consequences of poor quality. Failure generates costs through:

- scrap;
- rework;
- concessions;
- retesting;
- investigation;
- warranty;
- returns;
- disruption;
- customer dissatisfaction;
- lost reputation.

This helped establish quality as an economic issue, not merely a technical one.

2.7.11. Genichi Taguchi

Genichi Taguchi contributed significantly to quality engineering and robust design. Taguchi argued that quality should be designed into products and processes so that performance remains robust despite sources of variation.
He is particularly associated with:

- robust design;
- parameter design;
- design of experiments;
- reducing sensitivity to variation;
- the Taguchi Loss Function.

Traditional specification thinking often treats everything inside tolerance as equally acceptable.
Taguchi challenged this by arguing that deviation from the desired target can create increasing loss even before a formal specification limit is exceeded.

This reinforced the idea that: **conformance to tolerance is not necessarily the same as optimum quality.**

2.7.12. Shigeo Shingo

Shigeo Shingo made major contributions to manufacturing quality and operational improvement. He is particularly associated with:

- Poka-Yoke — mistake proofing;
- source inspection;
- rapid setup/changeover concepts;
- prevention of human errors becoming defects.

The fundamental principle of mistake proofing is powerful: **Where practical, design the process so that an error cannot occur or cannot progress undetected.**
This represents another major shift from detection toward prevention.

2.7.13. Taiichi Ohno and the Toyota Production System

Taiichi Ohno was a principal architect of the Toyota Production System. The Toyota approach connected quality with:

- flow;

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- waste reduction;
- Just-in-Time;
- built-in quality;
- standardised work;
- visual management;
- stopping processes when abnormalities occur;
- continuous improvement.

This demonstrated that quality and productivity do not have to be opposing objectives.

Poor quality itself creates waste through rework, inspection, delays, excess inventory and disruption. Many concepts associated with modern Lean management developed from this philosophy.

2.7.14. Masaaki Imai and Kaizen

Masaaki Imai helped popularise the Japanese concept of Kaizen internationally. Kaizen means continual or continuous improvement and emphasises frequent incremental improvements involving people throughout the organisation.

Rather than relying exclusively on major projects or technological breakthroughs, Kaizen encourages continual questioning:

- Can this process be safer?
- Can variation be reduced?
- Can unnecessary activity be removed?
- Can the work be easier?
- Can the result be more consistent?

Kaizen reinforced the concept that improvement is part of everyday work rather than an occasional management initiative.

2.7.15. The Rise of Total Quality Management

By the latter half of the twentieth century, quality thinking had moved well beyond inspection. Organisations increasingly recognised that quality depended upon:

- leadership;
- customer focus;
- process management;
- employee involvement;
- supplier relationships;
- measurement;
- prevention;
- improvement.

This became broadly known as Total Quality Management (TQM).

TQM is better understood as a management philosophy than as a single standard. Its central idea is that quality is the responsibility of the whole organisation. ASQ traces the development of total quality particularly to post-war Japanese industry and the influence of Deming, Juran, Feigenbaum and Ishikawa.

2.7.16. Quality Management Systems

As quality management matured, organisations increasingly formalised their approaches into Quality Management Systems (QMS). A QMS connects the processes needed to consistently fulfil requirements.

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A simplified model is:

Customer & Stakeholder Requirements
↓
Leadership & Planning
↓
Resources & Competence
↓
Design / Procurement / Production / Service
↓
Verification & Delivery
↓
Measurement & Customer Feedback
↓
Corrective Action & Improvement
↺
Learning feeds back into planning and operations

This represents a major historical development.

Quality is no longer merely an activity. It is a management system.

2.7.17. ISO 9000 and the Internationalisation of Quality

The ISO 9000 series was first published in 1987, providing an internationally recognised framework for quality management systems.

This was an important milestone because organisations operating across industries and national boundaries could work against a common QMS framework.

The ISO 9000 family subsequently evolved through several revisions as quality-management thinking developed.

As of 2026, ISO 9000:2026 provides the current fundamentals and vocabulary for quality management, while ISO 9001:2026 specifies QMS requirements.

ISO 9001 is applicable across sectors and organisation sizes rather than being restricted to manufacturing.

Modern ISO quality management is founded on seven Quality Management Principles:

1. **Customer focus**
2. **Leadership**
3. **Engagement of people**
4. **Process approach**
5. **Improvement**
6. **Evidence-based decision making**
7. **Relationship management**

These principles are discussed further in the Quality Book.

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2.7.18. Sector-Specific Quality Management

Generic quality-management principles have also been developed into sector-specific frameworks. Examples include:

Sector	Example Framework
General industry	ISO 9001
Aviation, Space & Defence	AS/EN/JISQ/IA 9100 series
Automotive	IATF 16949
Medical devices	ISO 13485
Rail	ISO 22163
Petroleum, petrochemical and natural gas	ISO 29001
Nuclear supply chain	ISO 19443

Contractual frameworks may also introduce additional requirements. For example, aerospace and defence contracts may require:

- First Article Inspection;
- configuration management;
- special-process control;
- supplier approval;
- traceability;
- counterfeit-part prevention;
- product safety;
- formal corrective action;
- Government Quality Assurance.

The quality professional must therefore understand both generic quality principles and the requirements applicable to the particular industry, customer and contract.

2.7.19. Six Sigma and Data-Driven Improvement

During the 1980s and 1990s, Six Sigma developed as a structured, statistically based improvement approach, initially associated particularly with Motorola and later widely adopted by other organisations. The well-known DMAIC improvement model is:

DEFINE → MEASURE → ANALYSE → IMPROVE → CONTROL

Six Sigma reinforced several historical quality principles:

- decisions based on data;
- understanding variation;
- process capability;
- root-cause analysis;
- structured improvement;
- control of improved processes.

Its statistical foundations can be traced directly back to the earlier work of Shewhart and other pioneers.

2.7.20. Lean Quality

Lean approaches place emphasis on creating value while reducing waste. Quality is integral to Lean because defects themselves are a form of waste. Common Lean concepts include:

- value;
- flow;
- pull;
- standardised work;
- visual management;
- mistake proofing;

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- workplace organisation;
- continuous improvement.

Lean and quality management therefore overlap significantly. A highly efficient process that repeatedly creates defects is not truly efficient.

2.7.21. Modern Quality Management

Modern quality management combines many ideas developed over the preceding century. A mature organisation typically seeks to move from:

Traditional Approach	Modern Approach
Inspect quality	Build quality into the process
Detect defects	Prevent defects
Blame individuals	Understand processes and systems
Correct individual failures	Eliminate root causes
Depend on inspectors	Establish process ownership
React to problems	Manage risks
Make decisions by opinion	Use evidence and data
Focus only on production	Manage the lifecycle
Manage suppliers by price	Manage supplier capability and relationships
Quality department owns quality	Everyone influences quality
Meet specification	Meet requirements and continually improve

2.7.22. Timeline of Quality Development

Period	Development	Significance
Ancient civilisation	Measurement, standardisation and inspection	Early conformity control
Medieval period	Guilds and craftsmanship	Workmanship, competence and traceability
18th–19th century	Industrial Revolution	Factory production and dedicated inspection
Late 19th century	Scientific management	Standardised and measured work
Early 20th century	Mass production	Need for repeatability and scalable quality control
1920s	Shewhart and control charts	Statistical process control
1930s–40s	Statistical sampling	Efficient acceptance and process control
WWII	Large-scale statistical quality methods	Quality becomes strategically important
1950s	Deming and Juran in Japan	Management-led quality improvement
1950s	Feigenbaum	Total Quality Control
1950s–60s	Ishikawa	Company-wide quality and quality circles
1960s–70s	Crosby, Zero Defects	Prevention and cost of quality
1960s–80s	Toyota Production System	Built-in quality, flow and waste reduction
1980s	TQM expands internationally	Organisation-wide quality
1987	ISO 9000 series	International QMS framework
1980s–90s	Six Sigma	Data-driven structured improvement
1990s onward	Lean / Lean Six Sigma	Integration of flow, waste reduction and variation control
21st century	Risk-based and integrated QMS	Quality integrated with strategy, risk and business processes
2026	ISO 9000:2026 and ISO 9001:2026	Updated international quality-management framework

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2.7.23. Quality Legends and Their Lasting Contributions

Quality Pioneer	Principal Contribution	Modern Application
Frederick W. Taylor	Scientific management	Standardised work and process measurement
Walter A. Shewhart	Statistical process control	Control charts and variation management
W. Edwards Deming	Systems thinking and continual improvement	Leadership, SPC, improvement and PDCA/PDSA thinking
Joseph M. Juran	Fitness for use and Juran Trilogy	Quality planning, control and improvement
Armand V. Feigenbaum	Total Quality Control	Enterprise-wide quality management
Kaoru Ishikawa	Company-wide quality and cause analysis	Fishbone diagrams, quality circles and employee involvement
Philip B. Crosby	Zero Defects and prevention	Defect prevention and cost of poor quality
Genichi Taguchi	Robust quality engineering	Robust design and variation reduction
Shigeo Shingo	Poka-Yoke and source inspection	Mistake proofing
Taiichi Ohno	Toyota Production System	Lean, flow and built-in quality
Masaaki Imai	Kaizen	Continual incremental improvement

These contributors should not be viewed as competing personalities whose philosophies require choosing one over another. Their work addressed different aspects of the same challenge. Modern quality management combines many of their ideas.

2.7.24. The Evolution from Detection to Prevention

Perhaps the most important lesson from the history of quality can be illustrated as follows:

Stage 1 – Inspection: Did we make a defective product?

↓

Stage 2 – Quality Control: Is the process producing acceptable products?

↓

Stage 3 – Quality Assurance: Do our processes give confidence that requirements will be achieved?

↓

Stage 4 – Quality Management: Are quality processes integrated and effectively managed throughout the organisation?

↓

Stage 5 – Continual Improvement: How can the system perform better?

↓

Stage 6 – Risk-Based Quality: What could prevent us from achieving the intended result, and what should we do before it happens?

This evolution does not mean that inspection has become unnecessary. Instead, inspection is now recognised as only one layer of quality control within a much larger system.

2.7.25. How the History Applies in Practice

Understanding quality history is not simply an academic exercise. When a quality professional encounters a problem, the history of quality provides different ways of thinking about it.

2.7.25.1. Example: Repeated Dimensional Failure

- A traditional inspection response might be: Increase inspection.
- Shewhart encourages the professional to ask: What does the process variation tell us?
- Deming encourages: Is the system creating the problem?
- Juran encourages: Was the process properly planned and controlled?
- Ishikawa encourages: What possible causes contribute to the problem?
- Crosby encourages: Why are we accepting failure and paying for poor quality?
- Shingo encourages: Can the process be mistake-proofed?

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- Taguchi encourages: Can the process or design be made less sensitive to variation?
- Modern risk-based quality management adds: Where else could this failure occur, what are its consequences and how can recurrence be prevented?

The experienced quality professional can therefore draw on multiple generations of quality thinking rather than simply applying a single tool.

2.8. Roles and Responsibilities

Modern quality management distributes responsibility throughout the organisation.

2.8.1. Leadership establishes:

- direction;
- quality policy;
- objectives;
- resources;
- culture;
- accountability.

2.8.2. Quality personnel typically provide:

- subject-matter expertise;
- assurance;
- analysis;
- facilitation;
- governance;
- independent challenge;
- auditing;
- improvement support.

2.8.3. Engineering influences quality through:

- requirements;
- design;
- tolerances;
- specifications;
- risk analysis;
- verification and validation.

2.8.4. Operations

Operations create and control the processes that produce products and services.

2.8.5. Supply Chain and Procurement

These functions influence:

- supplier selection;
- requirement flowdown;
- supplier performance;
- supply-chain risk.

2.8.6. Everyone

Everyone who performs work affecting an output has some influence on its quality. A mature quality culture therefore recognises: **Quality may be professionally supported by the Quality function, but it cannot be produced by the Quality department alone.**

2.9. Standards, Requirements and Guidance

An important distinction must be maintained when studying quality history.

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2.9.1. Mandatory Requirements

A requirement becomes mandatory when imposed by an applicable:

- law;
- regulation;
- contract;
- customer requirement;
- specification;
- organisational requirement.

2.9.2. Standards

A standard such as ISO 9001 does not automatically become a legal or contractual requirement merely because it exists. It becomes obligatory where its application is required by contract, regulation, organisational commitment or another binding mechanism.

2.9.3. Guidance

Documents such as guidance standards, professional-body publications, textbooks and quality philosophies provide useful, good practice but should not automatically be represented as contractual requirements.

For example, ISO 19011:2026 provides guidelines for auditing management systems; ISO explicitly describes it as guidance and notes that it does not itself lead to certification.

Quality professionals should therefore always distinguish:

Requirement → Guidance → Good Practice → Organisational Choice

2.10. Common Misconceptions

- "**Quality means perfection.**": Not necessarily. Quality concerns fulfiling applicable requirements and intended needs. Requirements differ according to purpose.
- "**Quality is the Quality Department's responsibility.**": Quality specialists provide expertise and assurance, but processes throughout the organisation create quality.
- "**Inspection creates quality.**": Inspection can identify nonconformity. It cannot retrospectively make the process that produced the defect capable.
- "**More inspection always means better quality.**": Additional inspection may be appropriate for risk containment, but long-term improvement usually requires understanding and controlling the process.
- "**Zero defects means mistakes can never occur.**": The useful principle is that organisations should not accept defects as inevitable or deliberately design processes around expected failure.
- "**Certification means the product is high quality.**": Management-system certification concerns conformity of the management system to specified requirements. It is not an automatic guarantee that every individual product will be defect-free.
- "**Quality costs money.**": Quality activities require resources, but poor quality also has substantial costs. Effective quality management seeks to prevent the much larger costs associated with failure, disruption and loss of customer confidence.

2.11. Common Problems and Mistakes

Organisations can repeat historical mistakes when they:

- rely excessively on final inspection;
- measure defects without investigating causes;
- treat quality as a departmental responsibility;
- focus on individual blame instead of process weaknesses;
- pursue productivity while ignoring process capability;
- accept recurring defects as normal;
- implement tools without understanding their purpose;

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- use corrective action instead of prevention;
- collect data without analysing it;
- treat certification as the objective of the QMS;
- focus on paperwork rather than process effectiveness;
- impose controls that do not correspond to risk;
- fail to capture and reuse lessons learned.

The history of quality demonstrates why these approaches are generally ineffective.

2.12. Good Practice for the Quality Professional

An effective quality professional should understand the origins of the methods being applied.

Do not simply ask:

- Which quality tool should I use?

First ask:

- What requirement are we trying to fulfil?
- What outcome is required?
- What evidence is available?
- What variation exists?
- What risk is involved?
- Is the issue with the product, process or wider system?
- Are we detecting failure or preventing it?
- What is the root cause rather than the symptom?
- How will effectiveness be demonstrated?
- How will the organisation learn from the result?

This is the practical legacy of more than a century of formal quality thinking.

2.13. Assurance and Auditing Considerations

Knowledge of quality history can also improve auditing.

- A weak audit may ask only: "Do you have the required procedure?"
- A more mature audit considers: "Does the process consistently achieve its intended result?"

This reflects the historical transition from compliance checking toward process effectiveness. Auditors should consider:

- whether processes are effective rather than merely documented;
- whether controls prevent or only detect failure;
- whether evidence supports management decisions;
- whether variation is understood;
- whether corrective actions address root causes;
- whether risks are identified and managed;
- whether lessons are retained;
- whether continual improvement is evident.

The evolution of quality therefore influences not only how organisations operate, but also how their effectiveness should be assured.

2.14. Relationship to Other Quality Knowledge

The history of quality provides the foundation for virtually every other subject in this Quality Book.

Shewhart → SPC → Control Charts → Process Capability
Deming → Systems Thinking → PDCA/PDSA → Continual Improvement
Juran → Quality Planning → Pareto → Improvement

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Ishikawa → Cause-and-Effect → Quality Circles → RCCA
Crosby → Prevention → Zero Defects → Cost of Poor Quality
Taguchi → Robust Design → DOE → Variation Reduction
Shingo → Poka-Yoke → Error Prevention
Ohno → Lean → Waste Reduction → Flow

These concepts subsequently influence modern:

QMS | APQP | FMEA | SPC | RCCA | 8D | Lean | Six Sigma | Supplier Quality | Auditing | Risk Management | Continuous Improvement

Understanding their origins helps practitioners understand why the tools exist, rather than simply learning how to complete them.

2.15. Key Takeaways

- Quality has existed for thousands of years, although formal quality management is comparatively recent.
- Quality evolved from craftsmanship to inspection, statistical control, assurance, organisation-wide management and risk-based prevention.
- Walter Shewhart established the statistical foundations for understanding process variation.
- Deming and Juran demonstrated that quality is fundamentally a management responsibility, not simply an inspection activity.
- Feigenbaum and Ishikawa helped extend quality across the entire organisation.
- Crosby reinforced prevention and the economic consequences of poor quality.
- Taguchi, Shingo and Ohno strengthened the principles of robust design, mistake prevention, built-in quality and process efficiency.
- Modern QMS standards combine many principles developed by these earlier thinkers.
- Inspection remains important, but quality cannot be inspected into a product.
- The mature objective is to design, manage and improve processes so that the correct result is produced consistently.
- Quality is not owned by the Quality department. Everyone whose work affects requirements, processes, products or services influences quality.
- Understanding quality history allows professionals to understand why modern methods and tools exist and when they should be applied, rather than using them mechanically.

2.16. Recommended Reference Framework

For further study, the following provide useful authoritative or recognised sources:

- ISO 9000:2026 — Quality management — Fundamentals and vocabulary
- ISO 9001:2026 — Quality management systems — Requirements
- ISO 19011:2026 — Guidelines for auditing management systems
- ASQ Quality Body of Knowledge
- ASQ History of Quality
- Deming — Out of the Crisis
- Juran — Juran's Quality Handbook
- Feigenbaum — Total Quality Control
- Crosby — Quality Is Free
- Ishikawa — What Is Total Quality Control? The Japanese Way
- Imai — *Kaizen*

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3. Quality Management Principles

3.1. Overview

The **Quality Management Principles (QMPs)** are the fundamental concepts that provide the foundation for effective quality management.

They describe the behaviours, values and management thinking that enable an organisation to consistently fulfil requirements, satisfy customers, manage its processes effectively and improve its performance.
The seven Quality Management Principles are:

1. **Customer Focus**
2. **Leadership**
3. **Engagement of People**
4. **Process Approach**
5. **Improvement**
6. **Evidence-Based Decision Making**
7. **Relationship Management**

These principles underpin the ISO 9000 family of quality management standards and provide a foundation for understanding how an effective Quality Management System (QMS) should operate. They should not be viewed simply as material to learn for an audit or examination. For a quality professional, they provide a **framework for thinking**.

When faced with a quality problem, process weakness, supplier issue, audit finding or improvement opportunity, the principles help the practitioner consider whether the organisation is:

- focused on the customer;
- being effectively led;
- using competent and engaged people;
- managing work as interconnected processes;
- seeking improvement;
- making decisions using reliable evidence; and
- effectively managing important relationships.

Understanding these principles helps prevent quality management from becoming a collection of disconnected procedures, forms and tools.

3.2. Why the Principles Matter

A Quality Management System can contain procedures, processes, audits, metrics, corrective actions and records while still being ineffective.

The principles provide the **reasoning behind the system**. A useful way of thinking about their relationship is:

CUSTOMER FOCUS What value and outcomes must be achieved?

↓

LEADERSHIP Where are we going and what environment is required?

↓

ENGAGEMENT OF PEOPLE Do people have the competence, authority and involvement required?

↓

PROCESS APPROACH How does the organisation consistently create the required result?

↓

EVIDENCE-BASED DECISION MAKING What does reliable information tell us?

↓

IMPROVEMENT How can performance be maintained and made better?

↕

RELATIONSHIP MANAGEMENT Which external and internal relationships influence our ability to succeed?

The principles are **interdependent**.

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For example, an organisation cannot effectively achieve customer focus without capable processes. Processes cannot operate effectively without competent and engaged people. Improvement requires reliable evidence. Supplier performance requires relationship management. All of these require leadership.

No principle should therefore be implemented in isolation.

3.3. Why Every Quality Professional Should Know Them

Quality professionals frequently use tools such as:

- audits;
- FMEA;
- 8D;
- RCCA;
- SPC;
- control plans;
- supplier assessments;
- process capability;
- First Article Inspection;
- corrective action;
- Pareto analysis.

These are important techniques, but they are **not the foundation of quality management**. The Quality Management Principles provide that foundation.

An experienced quality professional should therefore be able to move beyond: **"Which clause applies?"** and ask: **"What are we trying to achieve, and which quality-management principles should guide the way we achieve it?"**

For example, a supplier repeatedly delivering late or nonconforming products could simply be issued another corrective action.

Applying the principles encourages wider consideration:

- **Customer Focus** What is the impact on the end customer?
- **Leadership** Are appropriate priorities and resources being established?
- **Engagement of People** Do the people performing the work understand the requirements and have the necessary competence?
- **Process Approach** Which process or process interface is failing?
- **Evidence-Based Decision Making** What does the performance data actually demonstrate?
- **Improvement** Are corrective actions eliminating recurrence?
- **Relationship Management** Are customer-supplier interfaces, expectations and communications effective?

The principles therefore help the professional investigate the **system rather than simply the symptom**.

Modern connection: Leadership, Customer Focus and Improvement.
The Quality Management Principles therefore did not appear independently. They represent the consolidation of many lessons learned during the development of modern quality management.

3.4. Development within the ISO 9000 Family

Earlier editions of the ISO 9000 family were strongly associated with documented quality assurance and procedural control.

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As quality-management thinking matured, greater emphasis was placed on:

- processes;
- customers;
- leadership;
- people;
- evidence;
- improvement;
- organisational performance.

The **ISO 9000:2000** revision represented a major transition toward the process-based QMS model and was supported by **eight Quality Management Principles**.

The earlier eight principles were:

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

During development of the 2015 generation of the ISO 9000 family, these were revised and consolidated into the present **seven principles**.

Notable changes included:

- **System approach to management** becoming integrated more fully within the Process Approach;
- **Involvement of people** becoming **Engagement of People**;
- **Continual Improvement** becoming the broader **Improvement**;
- **Factual approach to decision making** becoming **Evidence-Based Decision Making**;
- **Mutually beneficial supplier relationships** becoming the broader **Relationship Management**.

This development reflects an important change in quality thinking.
Quality management became less about controlling individual activities and increasingly about understanding **organisations as interconnected systems of people, processes, information and relationships**.

3.5. The Seven Quality Management Principles

3.5.1. Customer Focus

3.5.1.1. Principle

The primary focus of quality management is fulfilling customer requirements and seeking to meet or exceed customer expectations. Without a customer or other intended recipient of an organisation's output, the concept of quality has little practical meaning.

Customer Focus therefore begins by understanding:

- Who is the customer?
- What does the customer require?
- What does the customer expect?
- What constitutes value?
- What risks could prevent successful delivery?
- Is the organisation consistently meeting those needs?
- How is customer perception changing?

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3.5.1.2. Why It Matters

Organisations ultimately depend upon their ability to deliver products or services that customers are willing to accept, use and trust.

Customer Focus influences:

Requirements → Design → Planning → Production → Verification → Delivery → Support → Feedback → Improvement

Quality professionals must therefore understand the **voice of the customer** and ensure that customer requirements are translated into effective controls throughout the organisation and, where applicable, its supply chain.

3.5.1.3. In Practice

Examples include:

- reviewing contracts and customer requirements;
- defining acceptance criteria;
- monitoring customer satisfaction;
- analysing complaints;
- investigating customer escapes;
- monitoring delivery performance;
- managing warranty information;
- obtaining customer feedback;
- considering future customer requirements;
- ensuring customer requirements are flowed down through the supply chain.

3.5.1.4. Practical Example

A supplier achieves excellent internal scrap rates but repeatedly delivers products late. Internally, the supplier may believe its quality performance is strong. From the customer's perspective, however, unreliable delivery may interrupt production. Customer Focus requires quality performance to be considered from the **customer's perspective rather than solely through internal metrics**.

3.5.1.5. Common Mistake

Treating Customer Focus as simply: "The customer is always right." That is not the principle.
The organisation must understand and fulfil agreed customer requirements while also considering applicable statutory, regulatory, safety, technical and organisational obligations.

3.5.2. Leadership

3.5.2.1. Principle

Leaders establish unity of purpose, direction and conditions in which people can contribute to achieving the organisation's quality objectives.

Quality cannot be effectively delegated entirely to a Quality Department. Leadership establishes:

- priorities;
- expectations;
- resources;
- behaviours;
- accountability;
- culture.

3.5.2.2. Why It Matters

People pay attention to what leadership consistently values.
If management states that quality is important but rewards output regardless of defects, employees receive a conflicting message.

Similarly, if corrective actions remain overdue without consequence, quality problems become normalised.

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Effective leadership aligns:

Purpose → Strategy → Policy → Objectives → Processes → People → Results

3.5.2.3. In Practice

Leadership may demonstrate commitment by:

- establishing meaningful quality objectives;
- ensuring responsibilities are understood;
- providing resources;
- reviewing QMS performance;
- supporting improvement;
- promoting customer focus;
- addressing systemic problems;
- encouraging reporting of quality concerns;
- creating an appropriate quality culture.

3.5.2.4. Practical Example

A production schedule is behind plan.

- Weak leadership may encourage: "Ship it now and sort the paperwork later."
- Effective quality leadership asks: "What is required to recover delivery while maintaining product conformity and customer requirements?"

Leadership therefore becomes most visible when **quality, cost and schedule appear to conflict**.

3.5.3. Engagement of People

3.5.3.1. Principle

Competent, empowered and engaged people at all levels are essential to an organisation's ability to create and deliver value.

People operate processes, identify abnormalities, make decisions and improve work. Quality systems therefore depend upon more than procedures. They depend upon people who:

- understand their responsibilities;
- are competent;
- understand the significance of their work;
- are able to raise concerns;
- participate in improvement;
- take ownership of outcomes.

3.5.3.2. Engagement Is More Than Training

Training alone does not demonstrate engagement. A person may be trained yet:

- not understand why the task matters;
- not feel able to stop defective work;
- not report problems;
- not participate in improvement;
- mechanically follow an ineffective instruction.

Engagement combines:

Competence + Awareness + Involvement + Empowerment + Responsibility

3.5.3.3. In Practice

Examples include:

- competence management;
- mentoring;
- quality awareness;
- improvement teams;

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- quality circles;
- employee suggestions;
- lessons learned;
- operator self-verification;
- stop-work authority;
- recognition of improvement;
- cross-functional problem solving.

3.5.3.4. Practical Example

An operator notices that a drawing dimension appears inconsistent with previous production. An engaged quality culture encourages the operator to **stop and question the requirement**.

A weak culture encourages: "**Just build what the paperwork says.**" Engagement therefore contributes directly to prevention.

3.5.4. Process Approach

3.5.4.1. Principle

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interconnected processes functioning as a coherent system. A process converts inputs into outputs.

INPUTS → ACTIVITIES → OUTPUTS

but an effective process also requires consideration of:

People | Equipment | Methods | Materials | Information | Controls | Measures | Risks

3.5.4.2. Why It Matters

Departments can appear individually successful while the overall organisation performs poorly. For example:

Sales → Contract Review → Engineering → Purchasing → Supplier → Goods In → Production → Inspection → Delivery

A weakness at any interface may affect the final result. The Process Approach therefore requires understanding:

- inputs;
- outputs;
- sequence;
- interactions;
- responsibilities;
- resources;
- criteria;
- controls;
- risks;
- measures;
- intended results.

3.5.4.3. Process Effectiveness

A process should not be judged simply by whether a procedure exists. The important question is: **Does the process consistently achieve its intended result?**

3.5.4.4. Practical Example

A purchasing process may issue purchase orders correctly, but if technical requirements are not flowed down to suppliers, the process is not fully effective. The problem may appear later as a supplier nonconformity, but the actual weakness may exist in the interface between:

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Engineering → Purchasing → Supplier

This is why process thinking is fundamental to root-cause analysis and auditing.

3.5.5. Improvement

3.5.5.1. Principle

Successful organisations maintain an ongoing focus on improvement. Processes, technology, customer expectations, risks and markets change.

An organisation that remains static may therefore become less capable even if it was previously successful.

3.5.5.2. Improvement Includes More Than Corrective Action

Improvement may involve:

- correcting problems;
- preventing recurrence;
- reducing variation;
- simplifying processes;
- eliminating waste;
- improving capability;
- introducing technology;
- improving customer experience;
- improving supplier performance;
- developing competence;
- redesigning products or processes.

3.5.5.3. Improvement Cycle

A simple improvement model is:

IDENTIFY → UNDERSTAND → CHANGE → VERIFY → STANDARDISE → LEARN

Improvement should therefore produce a demonstrable change in performance.

3.5.5.4. Typical Methods

- PDCA/PDSA;
- Kaizen;
- RCCA;
- 8D;
- Six Sigma;
- Lean;
- lessons learned;
- benchmarking;
- corrective action;
- preventive risk reduction.

3.5.5.5. Practical Example

An organisation experiences repeated incorrect part identification. Replacing incorrect labels addresses individual defects. Improvement asks:

- Why can the wrong label be selected in the first place?
- A barcode-controlled label system may eliminate the opportunity for the error.

The improvement changes the **process**, rather than repeatedly correcting the product.

3.5.6. Evidence-Based Decision Making

3.5.6.1. Principle

Decisions based on the analysis and evaluation of reliable data and information are more likely to produce desired results. Quality management involves uncertainty. Evidence reduces that uncertainty.

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3.5.6.2. Evidence May Include

- inspection results;
- test results;
- process measurements;
- SPC data;
- capability studies;
- audit evidence;
- supplier performance;
- customer complaints;
- defect trends;
- delivery performance;
- risk data;
- warranty data;
- employee feedback.

3.5.6.3. Data Is Not Automatically Evidence

Quality professionals must consider:

- Is the data accurate?
- Is the measurement system capable?
- Is the sample representative?
- Is sufficient data available?
- Is the analysis appropriate?
- Is correlation being confused with causation?
- Has uncertainty been considered?
- Is information current?

The principle is therefore not simply: **"Use data."** It is: **Use appropriate and reliable evidence to support decisions.**

3.5.6.4. Practical Example

A manager states: "Supplier A is our worst supplier." The quality professional should ask: "What evidence supports that conclusion?" A meaningful evaluation might consider:

- defect rate;
- quantity supplied;
- severity;
- customer escapes;
- delivery;
- responsiveness;
- trend;
- repeat failures.

Ten defects from ten delivered parts represent a very different situation from ten defects among one million parts. Evidence requires **context**.

3.5.7. Relationship Management

3.5.7.1. Principle

For sustained success, organisations manage their relationships with relevant interested parties, particularly those whose performance can affect the organisation's ability to create value. Modern organisations rarely operate independently. Their performance may depend upon:

- customers;
- suppliers;
- sub-tier suppliers;
- employees;
- regulators;
- shareholders;

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- partners;
- service providers;
- certification bodies;
- government organisations.

3.5.7.2. Why It Matters

An organisation may have excellent internal controls but still fail because of an incapable supplier.
Similarly, aggressive supplier management focused entirely on price may damage:

- communication;
- investment;
- responsiveness;
- innovation;
- continuity of supply.

Relationship Management does not mean avoiding accountability. It means managing important relationships deliberately.

3.5.7.3. Supplier Relationship Example

A mature supplier relationship may include:

Selection → Approval → Requirement Flowdown → Performance Monitoring → Communication → Development → Improvement

The appropriate level of management should reflect risk and importance. A supplier providing office stationery should not necessarily receive the same assurance as a supplier performing a safety-critical special process.

3.6. The Principles as a System

The seven principles are strongest when considered together.

3.6.1. Example — Repeated Customer Escape

A critical defect reaches the customer.

- **Customer Focus** Understand the impact on the customer and protect them from further escapes.
- **Leadership** Provide resources and accountability for containment and investigation.
- **Engagement of People** Involve the people who perform and understand the process.
- **Process Approach** Determine which process and interfaces allowed the failure.
- **Evidence-Based Decision Making** Analyse defect history, inspection results and process data.
- **Improvement** Remove root causes and verify effectiveness.
- **Relationship Management** Coordinate appropriately with customers and affected suppliers.

This illustrates why the principles should not be treated as seven independent statements. Together they form a **quality-management mindset**.

3.7. Relationship with PDCA

The principles also complement the Plan-Do-Check-Act cycle.

PDCA	Relevant QMP Thinking
Plan	Customer Focus, Leadership, Process Approach, Relationship Management
Do	Engagement of People, Process Approach
Check	Evidence-Based Decision Making
Act	Improvement
Throughout	Leadership, Customer Focus and Relationship Management

The relationship is not exclusive, every principle can apply throughout PDCA, but the model helps illustrate how the principles support systematic management.

3.8. Relationship with Risk-Based Thinking

Risk-based thinking asks: **What could affect the intended result?** The Quality Management Principles help determine how the organisation should respond. For example:

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- **Customer Focus** What risks could affect customer requirements?
- **Leadership** Who is accountable for managing them?
- **Engagement of People** Who understands the risk and controls?
- **Process Approach** Where within the process can failure occur?
- **Evidence-Based Decision Making** What information demonstrates the level of risk?
- **Improvement** Can the risk be reduced?
- **Relationship Management** Do external parties contribute to the risk?

Risk-based thinking and the Quality Management Principles therefore reinforce one another.

3.9. Relationship with Quality Culture

A Quality Management System describes how quality should be managed.

Quality culture influences what people actually do when nobody is watching. The principles provide an important foundation for quality culture. A strong quality culture typically demonstrates:

- leadership commitment;
- customer awareness;
- personal responsibility;
- open reporting;
- evidence-based thinking;
- collaboration;
- learning;
- prevention;
- improvement.

A weak culture may technically comply with procedures while routinely bypassing their intent. This distinction is particularly important when assessing QMS maturity.

3.10. Roles and Responsibilities

3.10.1. Top Management

Leadership has primary responsibility for establishing direction and creating conditions in which the principles can operate. This includes:

- demonstrating commitment;
- establishing policy and objectives;
- providing resources;
- promoting customer focus;
- reviewing performance;
- supporting improvement.

3.10.2. Quality Professionals

The quality professional should act as:

- facilitator;
- coach;
- analyst;
- assurance provider;
- problem-solving specialist;
- source of independent challenge.

Their role is not to **own all quality**. A mature quality professional helps other functions understand and apply the principles within their own processes.

3.10.3. Process Owners

Process owners should understand:

- intended outputs;
- inputs;

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- interfaces;
- measures;
- risks;
- responsibilities;
- improvement opportunities.

3.10.4. Employees

People performing work should understand:

- what is required;
- why it matters;
- how their work affects quality;
- when to escalate concerns;
- how they can contribute to improvement.

3.11. Standards and Quality Management Systems

The Quality Management Principles are formally associated with the **ISO 9000 family**.

- **ISO 9000:2026 Quality management — Fundamentals and vocabulary** ISO 9000 provides the fundamental concepts, principles and vocabulary for quality management systems. It is primarily a foundation and reference standard.
- **ISO 9001:2026 Quality management systems — Requirements** ISO 9001 contains auditable QMS requirements.

ISO 9001 is based upon the Quality Management Principles, but an important distinction must be understood: **The principles provide the foundation; ISO 9001 provides requirements.** The seven principles should therefore not be treated as seven additional certification clauses.

3.12. Auditing the Principles

An auditor does not normally audit the seven principles as though they were seven clauses. Instead, the principles help an auditor assess **how effectively the QMS operates**.

3.12.1. Customer Focus

Look for:

- understanding of customer requirements;
- customer feedback;
- complaints;
- customer satisfaction;
- response to changing needs.

3.12.2. Leadership

Look for:

- meaningful objectives;
- accountability;
- management involvement;
- resources;
- management review;
- quality culture.

3.12.3. Engagement of People

Look for:

- competence;
- awareness;
- involvement;
- ownership;
- willingness to report problems.

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3.12.4. Process Approach

Look for:

- defined inputs and outputs;
- process interaction;
- ownership;
- controls;
- measures;
- effectiveness.

3.12.5. Improvement

Look for:

- corrective actions;
- improvement activities;
- lessons learned;
- trends;
- demonstrated performance improvement.

3.12.6. Evidence-Based Decision Making

Look for:

- reliable metrics;
- analysis;
- trends;
- appropriate measurement;
- decisions supported by evidence.

3.12.7. Relationship Management

Look for:

- supplier management;
- performance reviews;
- communication;
- risk-based controls;
- development of important relationships.

The principles therefore help an auditor move beyond: **"Is there a procedure?"** toward **"Is the management system effectively achieving its intended results?"**

3.13. Common Misconceptions

- **"The seven principles are seven ISO 9001 requirements."** No. They provide the conceptual foundation for the ISO 9000 family. ISO 9001 contains the requirements.
- **"Customer Focus means doing whatever the customer asks."** No. Customer requirements must be understood alongside contractual, technical, statutory, regulatory, safety and other applicable obligations.
- **"Leadership means the Quality Manager."** Leadership refers particularly to organisational leadership and management responsibility. Quality cannot simply be delegated to a Quality Manager.
- **"Engagement means employees have received training."** Training contributes to competence. Engagement additionally involves awareness, participation, empowerment and ownership.
- **"Process Approach means having process maps."** A process map can help explain a process, but the principle concerns actually **managing activities as interconnected processes**.
- **"Evidence-Based Decision Making means collecting lots of data."** More data is not automatically better. Information must be relevant, reliable, appropriately analysed and understood.
- **"Relationship Management means being lenient with suppliers."** No. Effective relationships require clear expectations, appropriate controls, communication, accountability and improvement.
- **"Improvement means every KPI must continually increase."** Not necessarily. Some processes require stability, maintenance of capability or risk reduction rather than endless numerical increase.

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3.14. Common Implementation Problems

Organisations commonly weaken the principles by:

- displaying them on posters without integrating them into management practice;
- treating them as Quality Department responsibilities;
- focusing on certification rather than effectiveness;
- measuring what is easy rather than what matters;
- failing to connect objectives with customer needs;
- collecting data without analysing it;
- creating process maps that do not represent actual work;
- relying on training rather than competence;
- treating supplier management as purchase-price management;
- repeatedly correcting problems without eliminating root causes;
- rewarding behaviours that conflict with stated quality objectives.

The principles are valuable only when they influence **real decisions and behaviours**.

3.15. Good Practice

Quality professionals should use the principles as a routine mental checklist. Before implementing a new quality process, ask:

Question	Principle
Who needs the result and what do they require?	Customer Focus
Is direction and accountability clear?	Leadership
Are competent people involved?	Engagement of People
How does this interact with other processes?	Process Approach
How could performance become better?	Improvement
What evidence supports the decision?	Evidence-Based Decision Making
Which relationships influence success?	Relationship Management

This simple discipline can dramatically improve the quality of decisions.

3.16. Benefits of Applying the Principles

Effective application can contribute to:

- greater customer confidence;
- improved consistency;
- stronger leadership alignment;
- clearer responsibilities;
- improved employee involvement;
- better process performance;
- more reliable decisions;
- reduced defects and waste;
- stronger supplier performance;
- improved organisational learning;
- greater resilience;
- more effective continual improvement.

The principles should therefore be viewed as **management fundamentals rather than compliance statements**.

3.17. Limitations

The Quality Management Principles do not:

- prescribe detailed operating methods;
- replace technical standards;
- replace legal requirements;
- define product acceptance criteria;
- guarantee successful performance;

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- remove the need for professional judgement;
- specify which quality tools must be used.

They provide the **foundation upon which appropriate systems, processes, methods and tools are selected and applied**.

3.18. Key Takeaways

1. There are **seven Quality Management Principles**: Customer Focus, Leadership, Engagement of People, Process Approach, Improvement, Evidence-Based Decision Making and Relationship Management.
2. They provide the **conceptual foundation of the ISO 9000 family**.
3. They are not seven additional ISO 9001 clauses.
4. The principles are **interdependent** and should be considered as a system.
5. Every quality professional should understand them because they explain **why effective quality management works the way it does**.
6. Customer Focus establishes the purpose of quality management.
7. Leadership establishes direction, priorities and culture.
8. Engagement of People recognises that competent and empowered people create quality.
9. Process Approach moves attention from departmental activities to interconnected systems that create outcomes.
10. Improvement ensures organisations learn, adapt and become more capable.
11. Evidence-Based Decision Making encourages decisions based on reliable information rather than assumption.
12. Relationship Management recognises that organisational performance depends upon customers, suppliers and other important interested parties.
13. The principles provide a useful framework for **auditing, problem solving, supplier management, improvement, risk management and everyday quality decisions**.

4. Quality Culture

4.1. Overview

A **quality culture** is the collective set of values, beliefs, attitudes, behaviours and practices within an organisation that influence how people think about and act upon quality.

It can be thought of simply as: **How people behave towards quality when they are not being watched.**

Every organisation has a culture, whether it has deliberately created one or not. The important question is whether that culture supports or undermines the organisation's quality objectives.

A strong quality culture exists when people throughout the organisation instinctively recognise that they have responsibility for the quality of their work, understand why requirements matter, identify and report problems openly, make decisions using evidence, seek to prevent rather than hide failure, and continually look for opportunities to improve.

Quality is therefore not regarded as something performed by a Quality Department.

It becomes part of **how the organisation operates**.

4.2. What Is Quality Culture?

Organisational culture develops through shared:

- values;
- beliefs;
- behaviours;
- assumptions;
- experiences;
- expectations;

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- habits;
- leadership actions;
- accepted ways of working.

Quality culture is the part of organisational culture concerned with the achievement and improvement of quality. A useful model is:

WHAT WE SAY Policies, values, procedures and objectives
↓
WHAT LEADERS DO Priorities, decisions, resources and behaviours
↓
WHAT PEOPLE EXPERIENCE Recognition, consequences, communication and trust
↓
WHAT PEOPLE BELIEVE What really matters around here
↓
WHAT PEOPLE DO Everyday behaviours
↓
QUALITY CULTURE This explains why publishing a quality policy does not, by itself, create a quality culture. People learn what the organisation genuinely values primarily from **what it repeatedly does**, particularly when faced with pressure.

4.3. Why Quality Culture Matters

A Quality Management System establishes formal processes and controls. Culture determines how seriously people apply them. **An organisation may have**:

- ISO 9001 certification;
- documented procedures;
- inspection plans;
- trained auditors;
- FMEAs;
- control plans;
- corrective-action systems;
- sophisticated quality software;

and still have a weak quality culture.
For example, consider an operator who discovers a potentially nonconforming product shortly before an important shipment. The documented QMS may clearly require the product to be stopped and investigated.

The organisation's culture determines whether the operator thinks:
"I need to stop this and report it." Or **"Management needs this shipment out. It probably isn't serious enough to mention."** That difference cannot be controlled by documentation alone.

4.4. Quality Culture and the QMS

The relationship can be considered as:

- **QMS = How the organisation says quality should be managed**
- **Quality Culture = How people actually think and behave about quality**

The strongest organisations align the two.

4.4.1. Strong Alignment

- **QMS requirement** Report nonconformity immediately.
- **Cultural behaviour** People openly report problems and are supported for doing so.

4.4.2. Weak Alignment

- **QMS requirement** Report nonconformity immediately.
- **Cultural behaviour** People who report problems are blamed for delaying production.
- The documented system and actual culture are now in conflict.

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When this occurs repeatedly, **culture normally wins**.

4.5. Historical Development

Early formal quality management concentrated heavily on:

- inspection;
- specifications;
- procedures;
- product conformity;
- statistical control.

As quality thinking developed, pioneers including **Deming, Juran, Ishikawa and Feigenbaum** increasingly demonstrated that quality depended upon management, people and the wider organisational system.

4.6. Quality Culture in Modern Quality Management

Quality culture has become increasingly explicit within international quality-management guidance.

A major milestone was the publication of: **ISO 10010:2022 — Quality management — Guidance to understand, evaluate and improve organizational quality culture**

ISO 10010 provides guidance for evaluating, developing and improving organisational quality culture to support sustained success. It places particular emphasis on the relationship between quality culture, **leadership and engagement of people**.

The publication of **ISO 9001:2026** represents another important development. The current edition places increased emphasis on quality culture and leadership within the QMS framework.

Quality culture should therefore no longer be treated as an abstract "soft" subject sitting outside formal quality management. It is increasingly recognised as an important contributor to **QMS effectiveness and maturity**.

4.7. Characteristics of a Strong Quality Culture

A strong quality culture normally demonstrates several interconnected characteristics.

4.7.1. Customer Focus

People understand that their work ultimately contributes to satisfying customer and other applicable requirements. They understand:

- who receives their output;
- what requirements apply;
- why conformity matters;
- the consequences of failure.

Customer complaints are treated as opportunities to learn rather than simply problems to close.

4.7.2. Leadership Commitment

Leaders visibly demonstrate that quality matters. This means more than approving a quality policy.
Leaders:

- follow the same rules expected of others;
- provide appropriate resources;
- participate in quality reviews;
- challenge poor performance;
- support people who raise concerns;
- prioritise long-term capability over short-term concealment;
- make decisions consistent with stated quality values.

The most powerful demonstrations of quality culture occur when **quality, cost and delivery appear to conflict**. People remember what leaders choose.

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4.7.3. Ownership of Quality

In a strong culture: **Everyone owns the quality of their work.** This does not mean everybody performs the same quality role. Quality professionals still provide specialist:

- assurance;
- governance;
- analysis;
- auditing;
- technical support;
- independent challenge.

However, production cannot manufacture defects and expect Quality to "sort them out." Engineering cannot create ambiguous requirements and consider quality someone else's responsibility. Purchasing cannot select an incapable supplier and transfer responsibility to Supplier Quality. Ownership follows the process.

4.7.4. Speak-Up Culture

People must feel able to raise quality concerns. This includes:

- defects;
- errors;
- near misses;
- incorrect documentation;
- process deviations;
- supplier concerns;
- safety issues;
- suspected unethical behaviour.

A critical indicator of culture is therefore: **What happens to the person who reports bad news?**

If people experience blame, ridicule or negative consequences, reporting will decrease. This does not mean problems have disappeared. It may mean they have become **less visible**.

4.7.5. Just Culture and Accountability

A positive quality culture should not be confused with an absence of accountability. Organisations need to distinguish between:

- genuine human error;
- inadequate systems;
- insufficient competence;
- unclear instructions;
- process weaknesses;
- deliberate violation;
- reckless behaviour;
- intentional falsification.

Automatically blaming individuals discourages reporting. Automatically excusing every behaviour prevents accountability. A mature culture investigates **what happened and why** before determining responsibility.

4.7.6. Prevention Rather Than Detection

A strong quality culture seeks to prevent problems rather than simply detect them.

4.7.6.1. Reactive Culture

Defect → Inspect → Sort → Rework → Ship

4.7.6.2. Preventive Culture

Understand Risk → Design Controls → Monitor Process → Detect Abnormality Early → Prevent Defect

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This shift influences investment in:

- APQP;
- FMEA;
- mistake proofing;
- SPC;
- process capability;
- preventive maintenance;
- competence;
- supplier development;
- design assurance.

A culture heavily dependent upon sorting and final inspection may achieve conformity, but it has not necessarily developed mature quality capability.

4.7.7. Learning Rather Than Blame

When failure occurs, weak cultures ask: **Who caused this?**
Mature cultures first ask: **Why was this able to happen?**

This changes the investigation from:

Person → Blame → Warning → Close

toward:

Problem → Evidence → Process → Root Cause → Corrective Action → Learning

Human actions still matter, but quality professionals should avoid assuming that identifying the person involved is equivalent to identifying the root cause.

4.7.8. Evidence-Based Thinking

Strong quality cultures value facts over hierarchy. A senior manager's opinion should not automatically outweigh reliable process evidence. People are encouraged to ask:

- What does the data show?
- How was it measured?
- Is the information reliable?
- What trend exists?
- What evidence supports the conclusion?
- Have we verified effectiveness?

This directly connects quality culture with the Quality Management Principle of **Evidence-Based Decision Making**.

4.7.9. Continual Improvement

A mature quality culture does not regard compliance as the final objective.

- Compliance asks: **Are we meeting the requirement?**
- Improvement asks: **How can we perform better?**

People should be encouraged to identify:

- unnecessary activity;
- sources of variation;
- recurring problems;
- risks;
- waste;
- better methods;
- opportunities for mistake proofing.

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This connects quality culture with **Kaizen, Lean, Six Sigma, PDCA and continual improvement**.

4.7.10. Quality Culture and the Quality Management Principles

Quality culture provides the behavioural environment in which the Quality Management Principles operate and can therefore be considered the **behavioural expression of the Quality Management Principles**

Quality Management Principle	Cultural Behaviour
Customer Focus	People understand and protect customer requirements
Leadership	Leaders visibly demonstrate quality priorities
Engagement of People	People take ownership and contribute
Process Approach	Problems are understood through processes and systems
Improvement	People seek better ways of working
Evidence-Based Decision Making	Decisions are supported by reliable evidence
Relationship Management	Customers, suppliers and partners are managed collaboratively

4.7.11. What Strong and Weak Cultures Look Like

Strong Quality Culture	Weak Quality Culture
Problems are reported early	Problems are hidden
Bad news travels quickly	Bad news is softened
Quality is everyone's responsibility	Quality belongs to Quality
Prevention is valued	Inspection is relied upon
Root causes are investigated	Individuals are blamed
Leaders follow the QMS	Leaders bypass controls
Employees challenge abnormal conditions	Employees "work around" problems
Evidence drives decisions	Hierarchy or opinion dominates
Corrective actions remove causes	Actions close paperwork
Near misses are treated as learning	Near misses are ignored
Suppliers are developed and controlled according to risk	Supplier problems are repeatedly contained
Lessons are shared	Problems recur elsewhere
Improvement is routine	Improvement happens after failure
Requirements are understood	Compliance becomes a paperwork exercise

4.8. The Quality Culture Test

A simple way of understanding an organisation's culture is to consider what happens when pressure increases. Ask:

- **What happens when production is behind schedule?** Does the organisation maintain controls or quietly bypass them?
- **What happens when someone finds a defect?** Are they thanked for protecting the customer or criticised for delaying delivery?
- **What happens when an audit identifies a weakness?** Is the organisation interested in learning or simply closing the finding?
- **What happens when a senior manager is wrong?** Can evidence challenge authority?
- **What happens when a supplier repeatedly fails?** Is the systemic cause addressed or is another corrective action simply issued?
- **What happens when nobody is watching?** Are processes still followed?

These questions often reveal more about quality culture than a policy statement.

4.9. Quality Culture and Product Safety

Quality culture becomes especially important where failure can affect safety.

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Examples include:

- aviation;
- space;
- defence;
- nuclear;
- medical devices;
- pharmaceuticals;
- automotive;
- rail.

In these environments, failure to report a concern may have consequences extending far beyond scrap or rework. Personnel need to understand:

My action → Product → System → User → Potential Consequence

This requires awareness of the significance of individual work. The aviation, space and defence sector, for example, places strong emphasis on product safety, ethical behaviour and awareness within its QMS framework. A strong culture helps ensure these requirements are **lived rather than merely documented**.

4.10. Quality Culture and Ethics

Quality and ethics are closely connected. Examples of unethical quality behaviour include:

- falsifying inspection records;
- recording checks that were not performed;
- changing test results;
- knowingly shipping nonconforming product;
- hiding customer escapes;
- altering dates;
- signing another person's inspection;
- concealing supplier problems;
- intentionally bypassing approved processes.

A strong quality culture establishes that: **No delivery target, cost saving or management instruction justifies falsifying quality evidence.** Quality professionals have a particular responsibility to protect the integrity of quality information.

4.11. Roles and Responsibilities

4.11.1. Top Management

Leadership has the greatest influence on quality culture. Responsibilities include:

- establishing expectations;
- demonstrating appropriate behaviour;
- providing resources;
- promoting customer focus;
- supporting open reporting;
- reviewing performance;
- recognising positive quality behaviour;
- responding appropriately to failure.

Leadership cannot delegate organisational culture to the Quality Department.

4.11.2. Managers and Supervisors

Front-line and middle managers translate organisational values into everyday behaviour. They influence:

- priorities;
- workload;
- reactions to problems;
- recognition;

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- escalation;
- discipline;
- improvement.

A senior leadership team can promote excellent quality values, but those values may fail if local management behaves differently.

4.11.3. Quality Professionals

Quality professionals should:

- promote quality principles;
- provide independent challenge;
- use evidence;
- facilitate improvement;
- support problem solving;
- recognise systemic causes;
- protect integrity of quality information;
- coach other functions;
- escalate significant concerns appropriately.

They should avoid becoming the organisation's **quality police**. Over-policing can unintentionally reinforce the belief that Quality owns quality.

4.11.4. Employees

Personnel should:

- understand applicable requirements;
- follow approved processes;
- protect product and service conformity;
- report abnormalities;
- stop or escalate inappropriate activity where authorised;
- participate in improvement;
- maintain integrity of records.

4.12. Measuring Quality Culture

Culture cannot be represented reliably by a single metric. A combination of **leading and lagging indicators** is preferable.

4.12.1. Lagging Indicators

These describe outcomes that have already occurred:

- customer complaints;
- escapes;
- scrap;
- rework;
- warranty;
- recalls;
- audit findings;
- cost of poor quality.

4.12.2. Leading Indicators

These may reveal cultural health before major failure occurs:

- near-miss reporting;
- internal nonconformity reporting;
- employee improvement suggestions;
- corrective-action effectiveness;
- recurrence rate;

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- management participation;
- completion of improvement actions;
- quality training and competence;
- speak-up activity;
- preventive versus reactive improvement effort.

4.12.3. Important Caution

A reduction in reported nonconformities does **not automatically mean quality has improved**. For example:

Internal reports ↓
Customer escapes ↑

may indicate poor internal detection or suppressed reporting. Conversely:

Internal reports ↑
Customer escapes ↓

may indicate that employees are identifying and controlling problems earlier. Metrics therefore require **interpretation and context**.

4.13. Assessing Quality Culture

A structured assessment can consider areas such as:

- **Leadership** Do leaders consistently demonstrate quality priorities?
- **Customer Focus** Do people understand customer requirements and consequences?
- **People** Are employees competent, involved and able to raise concerns?
- **Processes** Are approved processes followed and improved?
- **Reporting** Are problems openly identified?
- **Learning** Are lessons captured and shared?
- **Decision Making** Is evidence used?
- **Improvement** Does the organisation actively prevent recurrence?
- **Relationships** Are suppliers and other interested parties effectively managed?

ISO 10010 provides guidance and example tools for organisational self-assessment of quality culture maturity.

4.13.1. A Simple Quality Culture Maturity Model

The following is a useful practical model rather than a formal ISO maturity scale.

Level	Typical Culture
1 – Reactive	Quality receives attention primarily after failure
2 – Controlled	Procedures and inspection provide basic control
3 – Managed	Processes, responsibilities and performance are systematically managed
4 – Preventive	Risk reduction, employee involvement and prevention are routine
5 – Learning	Quality, improvement and organisational learning are embedded throughout the business

- **Reactive** "Fix the defect."
- **Controlled** "Follow the procedure."
- **Managed** "Control the process."
- **Preventive** "Prevent the problem."
- **Learning** "Continuously improve the system."

The purpose of maturity assessment is not to obtain a score. It is to identify **where behaviour and systems can improve**.

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4.14. Building a Strong Quality Culture

Culture cannot normally be changed through a single initiative. A practical sequence is:

1. Understand Current Culture
↓
2. Define Desired Behaviours
↓
3. Align Leadership
↓
4. Communicate Why Quality Matters
↓
5. Develop Competence
↓
6. Empower People
↓
7. Align Processes and Incentives
↓
8. Encourage Reporting and Learning
↓
9. Measure Behaviour and Outcomes
↓
10. Reinforce and Continually Improve

Culture develops through repeated behaviour over time.

4.14.1. Incentives and Unintended Behaviour

Performance measures can unintentionally damage quality culture. For example, suppose production management is rewarded entirely for:

Units shipped per month

Employees may learn that production quantity matters more than:

- process compliance;
- inspection;
- defect reporting;
- preventive maintenance.

Better performance management balances objectives such as:

Quality + Delivery + Cost + Safety + Improvement

Quality professionals should therefore consider not only what procedures require but also **what behaviours organisational incentives encourage**.

4.14.2. Practical Example: The Friday Shipment

A critical shipment must leave on Friday. During final inspection, a dimensional characteristic is found slightly outside specification.

- **Weak Culture**
  - Production argues: "It has always worked before."
  - The inspector is pressured to accept the part.
  - Someone suggests recording the nominal value.
  - The product ships.

The organisation has demonstrated that **delivery outranks integrity**.

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- **Strong Culture**
  - The product is controlled.
  - The requirement is confirmed.
  - Engineering and Quality assess the condition.
  - If appropriate, formal concession or customer approval is obtained through the authorised process.
  - The issue is investigated.
  - Delivery impact is managed transparently.

The organisation has demonstrated: **Schedule pressure does not change the requirement.**
Employees observing this decision learn more about the organisation's quality culture than they would from hours of awareness training.

4.15. Common Misconceptions

- **"Quality culture is the responsibility of Quality."** No. Quality can facilitate and influence culture, but leadership and everyday organisational behaviour create it.
- **"Certification proves we have a strong quality culture."** Certification demonstrates conformity with the applicable certification framework. Culture concerns how people actually behave and cannot be inferred solely from possession of a certificate.
- **"If reported defects decrease, culture is improving."** Not necessarily. Reporting may have decreased rather than defects.
- **"A strong quality culture means nobody makes mistakes."** No. Mature cultures expect that problems can occur and create systems that identify, learn from and prevent recurrence.
- **"Quality culture is a soft subject."** Culture influences hard outcomes including defects, escapes, rework, safety, compliance and customer confidence.
- **"Training creates culture."** Training can develop knowledge and competence. Culture also requires leadership behaviour, systems, incentives, trust and reinforcement.
- **"No-blame means no accountability."** No. A learning culture distinguishes system weakness and human error from deliberate or reckless behaviour.

4.16. Common Problems and Mistakes

Quality-culture initiatives commonly fail when organisations:

- treat culture as a slogan;
- launch short-term campaigns;
- rely entirely on training;
- expect Quality to own the initiative;
- fail to involve leadership;
- punish people who report problems;
- reward output while criticising defects;
- measure culture using one KPI;
- conduct surveys but take no action;
- ignore middle-management behaviour;
- tolerate repeated process bypasses;
- close corrective actions without verifying effectiveness;
- accept recurring problems as normal;
- focus on audit scores rather than actual performance.

The most damaging cultural message is: **"We say one thing but reward another."**

4.17. Good Practice

Organisations seeking a strong quality culture should:

- make quality expectations clear;
- ensure leaders model expected behaviours;
- explain why requirements matter;
- give people appropriate authority to raise and stop problems;
- recognise early reporting;

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- investigate systems before assigning blame;
- make quality performance visible;
- use reliable evidence;
- share lessons learned;
- recognise prevention;
- develop quality competence;
- align objectives and incentives;
- involve suppliers where appropriate;
- verify corrective-action effectiveness;
- continually assess cultural maturity.

Most importantly: **Make doing the right thing easier than doing the wrong thing.**

4.18. Auditing and Assurance Considerations

Quality culture is difficult to audit directly because beliefs cannot simply be inspected. Auditors should therefore seek **observable evidence of behaviour**. Useful approaches include **Interview People at Different Levels** Ask:

- What happens when you find a defect?
- Can you stop the process?
- Who do you contact?
- What happens if delivery is affected?
- What quality problems concern you?
- What improvements have you been involved in?

4.18.1. Compare Answers

Significant differences between leadership and operator responses may reveal cultural weaknesses.

4.18.2. Observe Work

Compare: **Documented Process ↔ Actual Practice**

4.18.3. Examine Decisions Under Pressure

Review examples involving:

- late delivery;
- concession;
- production stoppage;
- customer escape;
- supplier failure.

These often provide strong cultural evidence.

4.18.4. Review Recurrence

Repeated findings may indicate that the organisation is **closing actions rather than learning**.

4.18.5. Examine Reporting

Very low internal defect or near-miss reporting should not automatically be interpreted positively.
Ask whether reporting mechanisms are trusted and used.

4.19. Organisational Good Practice

Organisations may voluntarily adopt practices beyond formal requirements to improve quality maturity.
The quality professional should therefore distinguish:

- **Legal / Regulatory Requirement**
- **Contractual Requirement**
- **QMS Requirement**
- **Organisational Requirement**
- **Guidance**

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- **Good Practice**

They are not automatically equivalent.

4.20. Benefits of a Strong Quality Culture

A strong quality culture can contribute to:

- earlier detection of problems;
- fewer customer escapes;
- improved customer confidence;
- improved product safety;
- reduced cost of poor quality;
- improved employee engagement;
- more effective corrective action;
- stronger continual improvement;
- better supplier relationships;
- more reliable decision making;
- improved compliance;
- greater organisational resilience;
- increased trust.

Its greatest benefit may be that problems become **visible while the organisation can still do something about them**.

4.21. Limitations

Culture is not a substitute for:

- technical competence;
- appropriate processes;
- inspection;
- verification;
- effective controls;
- engineering;
- regulatory compliance;
- independent assurance.

An organisation can have highly committed employees but still produce poor quality if its processes are technically incapable. Similarly, sophisticated systems will not compensate indefinitely for a culture that routinely bypasses them. Sustainable quality requires:

Capable Systems + Competent People + Appropriate Controls + Strong Quality Culture

4.22. Key Takeaways

1. **Every organisation has a quality culture**, whether it deliberately manages it or not.
2. Quality culture is reflected in the shared beliefs and behaviours that determine how people respond to quality in everyday work.
3. A QMS describes how quality should be managed; culture strongly influences **how it is actually managed**.
4. Leadership behaviour is one of the strongest influences on quality culture.
5. Quality belongs to **everyone whose work affects the outcome**, not solely the Quality Department.
6. People must be able to raise problems without inappropriate fear or pressure.
7. A learning culture investigates **why failure was possible**, rather than immediately looking for someone to blame.
8. A strong culture emphasises **prevention rather than dependence on detection**.
9. Evidence, openness, ethics, customer focus and continual improvement are fundamental cultural behaviours.
10. Quality culture becomes most visible when **quality, cost and delivery are under pressure**.
11. Culture should be assessed using multiple sources of evidence rather than a single score or KPI.

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12. **ISO 10010:2022** provides specific guidance for understanding, evaluating and improving organisational quality culture.
13. **ISO 9001:2026** gives greater prominence to quality culture and leadership within modern QMS requirements.
14. Certification alone does not create culture. Culture is demonstrated by what the organisation **consistently does**.
15. The ultimate indicator of a mature quality culture is that people instinctively protect the customer, the product and the integrity of the process because they understand that **quality is part of their work, not somebody else's job**.

5. Standards & Specifications

5.1. Overview

Standards and specifications are fundamental to quality management. They establish a common understanding of **what is required, what good practice looks like, how something should be performed, and how conformity can be demonstrated**.

Quality professionals work with them throughout the product and service lifecycle:

Customer Need → Requirements → Design → Specification → Procurement → Production → Verification → Acceptance → Delivery

Although the terms **standard** and **specification** are sometimes used interchangeably, they are not necessarily the same thing. A useful starting distinction is:

- **A standard establishes an agreed framework, set of rules, requirements, guidance or accepted practice.**
- **A specification defines detailed requirements that a particular product, material, process, service or system is required to satisfy.**

However, the distinction is not absolute because a **standard itself can be a specification standard** and may contain detailed technical requirements.

The quality professional therefore needs to understand the **purpose, authority, applicability and content of the document**, rather than relying solely on its title.

5.2. Why Standards and Specifications Matter

Imagine ordering a bolt simply by requesting: **"Send me a good bolt."** This provides almost no objective basis for determining conformity. Instead, the requirement might define:

- material;
- thread;
- diameter;
- length;
- tolerance;
- strength;
- coating;
- heat treatment;
- inspection;
- marking;
- certification.

The subjective concept of a "good bolt" has now been converted into **defined and verifiable requirements**. This is one of the fundamental purposes of standardisation and specification. They enable different people and organisations to share a common understanding of: **What is expected?** And **How will we know whether it has been achieved?**

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5.3. What Is a Standard?

A **standard** is an agreed document providing rules, guidelines, requirements or characteristics for activities or their results. Standards may apply to:

- products;
- materials;
- processes;
- services;
- management systems;
- terminology;
- testing;
- measurement;
- interfaces;
- safety;
- competence.

Standards are generally developed through structured processes involving relevant experts and interested parties. Examples include:

- ISO 9001 — Quality Management Systems;
- ISO 19011 — Management-system auditing;
- ISO/IEC 17025 — Testing and calibration laboratories;
- AS9100 — Aerospace, Space and Defence QMS;
- AS9102 — First Article Inspection;
- ISO 10012 — Measurement management systems;
- IPC-A-610 — Acceptability of electronic assemblies.

A standard can therefore address anything from an organisation's entire management system to the method used to perform a particular test.

5.4. What Is a Specification?

A **specification** establishes detailed requirements for something that must be provided, produced, performed or demonstrated. A specification might define requirements for a:

- product;
- component;
- material;
- process;
- service;
- software system;
- test;
- inspection;
- special process;
- interface.

For example, an engineering specification could define:

- **Material:** Aluminium alloy
- **Dimensions:** Defined drawing dimensions and tolerances
- **Finish:** Conversion coating
- **Hardness:** Defined acceptance range
- **Identification:** Required marking
- **Inspection:** Defined verification method
- **Certification:** Certificate of Conformity required

The specification provides the criteria against which conformity can be assessed.

5.5. Standards Versus Specifications

A useful practical comparison is:

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Standard	Specification
Usually establishes an agreed framework or common requirements	Usually establishes requirements for a particular application
Often developed by a recognised standards organisation or industry body	Often developed by a customer, design authority, organisation or standards body
May be broadly applicable	Usually more specific
May contain requirements, guidance or both	Typically focuses heavily on defined requirements
Often supports repeatability across many organisations	Often controls a specific product, material, process or procurement
Frequently consensus based	Does not necessarily require industry consensus
Normally voluntary until invoked	Normally mandatory when invoked by the applicable design or contract
May itself be a specification	May reference multiple standards

The most important point is: **"Standard" and "specification" describe different concepts, but they can overlap.**

Not every standard is a specification, but a standard can contain or constitute a specification.

5.5.1. Standards, Specifications, Procedures and Drawings

Quality professionals frequently encounter several related document types.

Document	Primary Purpose	Example
Standard	Establish common requirements or accepted practice	ISO 9001
Specification	Define detailed requirements	Material specification
Drawing	Define design characteristics	Engineering drawing
Procedure	Define how an organisational activity is controlled	Nonconformance procedure
Work Instruction	Explain how a specific task is performed	Assembly instruction
Test Method	Define how a test is conducted	Tensile-test method
Code of Practice	Recommend accepted professional practice	Industry installation code
Regulation	Establish legally enforceable requirements	Product safety regulation
Contract	Establish legally agreed obligations between parties	Customer supply contract

These documents may reference one another. For example:

CONTRACT
↓
Customer Quality Requirements
↓
Engineering Drawing
↓
Material Specification
↓
Process Specification
↓
Industry Standard
↓
Inspection / Test Requirement

The result is a **requirement chain**. Understanding that chain is a fundamental quality skill.

5.6. The Fundamental Principle, Requirements Must Flow

A requirement is useful only if it reaches the people and processes that need to apply it. Consider:

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Customer
↓
requires **Standard A**
↓
Prime Contractor
↓
flows relevant requirements to **Supplier**
↓
Supplier uses a **Sub-tier Processor**
↓
processor performs the controlled process.

If the original requirement is not correctly flowed down, the sub-tier may produce something that meets its own normal practice but does **not** satisfy the customer's requirement.

This is why standards and specifications are closely connected with:

- contract review;
- requirements management;
- configuration management;
- purchasing;
- supplier quality;
- inspection;
- verification;
- auditing.

5.7. A Brief History of Standardisation

Standardisation is much older than modern quality management. Human societies have always needed common references for:

- measurement;
- trade;
- construction;
- currency;
- materials;
- interchangeability.

Ancient systems of weights and measures are early examples of standardisation. Without common measurement: **A metre in one organisation could mean something different from a metre in another.** Reliable trade and engineering would become extremely difficult.

5.8. Industrialisation and Interchangeability

The Industrial Revolution dramatically increased the need for standards. Mass production required:

- standard dimensions;
- interchangeable components;
- common materials;
- consistent threads;
- standard measurement;
- repeatable manufacturing methods.

If every manufacturer used incompatible dimensions or interfaces, components could not be reliably exchanged. Standardisation therefore became essential to industrialisation.

5.9. The Development of National Standards Bodies

As industry expanded, national organisations were established to coordinate standardisation. In Britain, the organisation that became the **British Standards Institution (BSI)** originated in **1901**. The early development of engineering standards was strongly driven by the need to reduce unnecessary variety and establish common engineering practice.

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National standards increasingly provided shared technical foundations across industries.

5.10. International Standardisation

International trade created an additional problem. A national standard may work within one country, but international supply chains require compatibility across borders.

International standardisation therefore developed to establish common approaches. Important organisations include:

- **ISO International Organization for Standardization**

ISO develops international standards across a very wide range of subjects. ISO formally came into existence in **1947** following an international meeting in London in 1946. Its first standard was published in 1951 and concerned the standard reference temperature for industrial length measurement.

- **IEC International Electrotechnical Commission**

IEC develops international standards for electrical, electronic and related technologies.

- **ITU International Telecommunication Union**

ITU develops international telecommunications standards. International standardisation enables organisations in different countries to work against a common technical framework.

5.11. International, Regional and National Standards

Standards may exist at different levels.

5.11.1. International

Examples:

- **ISO**
- **IEC**

5.11.2. European

Examples:

EN standards

developed through European standardisation organisations such as:

- CEN;
- CENELEC;
- ETSI.

5.11.3. National

Examples:

- **BS** — British Standard
- **DIN** — German standard
- **ANSI** — United States standards framework

5.11.4. Industry / Sector

Examples include standards developed by:

- SAE International;
- ASTM International;
- IPC;
- API;
- IEEE;
- AIAG.

The designation often helps identify the origin and adoption of the document.

5.12. Understanding Standard Designations

Quality professionals should understand document identifiers rather than assuming similarly titled standards are different requirements. For example: **ISO 9001** is the international ISO standard. A nationally adopted version may appear as: **BS EN ISO 9001**

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This indicates adoption through the European and British standards systems. The technical content may be equivalent, although national forewords or associated information can differ. Another example:
EN 9100 and **AS/IA 9100** belong to the internationally harmonised aerospace quality-management family, although regional publication identifiers differ. Always establish:

- issuing organisation;
- standard number;
- revision;
- publication date;
- amendments;
- contractual version.

5.13. Types of Standards

Standards perform different functions.

5.13.1. Management System Standards

Establish requirements or guidance for managing an organisation or management system. Examples:

- ISO 9001 — Quality;
- ISO 14001 — Environmental;
- ISO 45001 — Occupational health and safety.

5.13.2. Product Standards

Define requirements for particular products or product families. They may address:

- dimensions;
- materials;
- performance;
- safety;
- marking;
- testing.

5.13.3. Process Standards

Define requirements or controls for performing processes.
These can be particularly important for **special processes**, where conformity may not be fully demonstrated through subsequent inspection alone.

5.13.4. Test Method Standards

Define how tests should be performed.
This improves comparability between results generated by different organisations.

5.13.5. Terminology Standards

Establish common definitions. For example:
ISO 9000 provides fundamentals and vocabulary for quality management. Common terminology prevents different organisations from assigning different meanings to important concepts.

5.13.6. Interface Standards

Establish compatibility between systems or components. Examples include:

- electrical connectors;
- communications protocols;
- screw threads;
- mechanical interfaces.

5.13.7. Codes of Practice and Guidance Standards

These describe recognised good practice rather than necessarily establishing auditable requirements.
The user must understand whether the document contains: **requirements** or **recommendations**.

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5.14. Standards Contain Different Types of Provision

A crucial quality skill is recognising the language used within a standard. In ISO documents:

- **SHALL** indicates a **requirement**. The organisation **shall**... This means the provision is required when conformity to that standard is claimed.
- **SHOULD** indicates a **recommendation**. The organisation **should**... This represents recommended practice rather than a mandatory requirement of that provision.
- **MAY** indicates **permission**. The organisation **may**...
- **CAN** typically expresses **possibility or capability**.

The distinction matters greatly during auditing. An auditor should not raise a nonconformity merely because an organisation has not followed a **"should"** recommendation unless another applicable requirement makes that recommendation mandatory.

5.15. Normative and Informative Content

Standards may contain both **normative** and **informative** material.

- **Normative** Content that forms part of the provisions necessary for applying the document.
- **Informative** Material provided for explanation, examples or supporting understanding. Typical informative content may appear in:
- notes;
- examples;
- informative annexes.

Quality professionals should not automatically convert informative guidance into mandatory requirements. This is a common auditing error.

5.15.1. Normative References

Standards frequently contain a section titled: **Normative References** These are documents referenced in a way that can be necessary for applying the standard. This differs from a bibliography or recommended reading. The quality professional should therefore identify whether another standard is:

- normatively referenced;
- informatively referenced;
- contractually invoked;
- simply useful guidance.

5.16. When Does a Standard Become Mandatory?

One of the most important concepts for quality professionals is: **Standards are generally voluntary unless something makes their application obligatory.**

ISO explicitly describes its International Standards and related deliverables as voluntary documents rather than legislation. A standard can nevertheless become binding through several mechanisms.

5.16.1. Contract

A customer contract may state: Supplier shall maintain a Quality Management System conforming to IA9100. IA9100 has now become a **contractual requirement** for that supplier.

5.16.2. Purchase Order

A purchase order may invoke a particular material or process standard.

5.16.3. Drawing

An engineering drawing may specify: Heat treatment in accordance with ABC-123. That specification is now part of the product definition.

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5.16.4. Regulation
Legislation may reference standards or provide mechanisms through which standards support regulatory compliance.

5.16.5. Organisational Requirement
An organisation may formally adopt a standard within its own QMS.

5.17. Standards Versus Customer Specifications
A customer may impose requirements that exceed the baseline requirements of an industry standard. For example:

- **Industry standard requirement** Minimum coating thickness = X
- **Customer specification** Minimum coating thickness = X + additional requirement

Where contractually agreed, the customer requirement must normally be satisfied. This leads to an important rule: **Meeting an industry standard does not automatically mean that all customer requirements have been met.** The quality professional must identify **all applicable requirements**.

5.18. Requirement Hierarchy
Organisations should establish how conflicting requirements are resolved. A simplified model might be:

LAW / REGULATION
↓
CONTRACT
↓
CUSTOMER REQUIREMENT
↓
DESIGN DEFINITION
↓
SPECIFICATION
↓
REFERENCED STANDARD
↓
ORGANISATIONAL PROCEDURE
↓
WORK INSTRUCTION

However, this should **not** be treated as a universal legal hierarchy. The actual precedence depends upon:

- jurisdiction;
- contract;
- customer requirements;
- document-specific precedence clauses.

Where requirements conflict: **Do not guess — formally resolve the conflict.**

5.19. Specifications in Engineering
Engineering specifications commonly control characteristics that cannot conveniently be represented entirely on a drawing. For example, a drawing might state: **FINISH: ABC-123 TYPE II** The specification ABC-123 may then define:

- preparation;
- process parameters;
- coating requirements;
- thickness;
- test methods;
- acceptance;
- inspection frequency;

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- records.

This prevents every drawing from reproducing the same detailed process requirements. Specifications therefore support **configuration control and standardisation**.

5.20. Process Specifications

Process specifications are particularly important where the method of manufacture affects the final product. Examples include:

- welding;
- brazing;
- heat treatment;
- plating;
- anodising;
- chemical processing;
- painting;
- adhesive bonding;
- composites processing;
- non-destructive testing.

The above examples are **special processes**. The specification may define:

Personnel + Equipment + Materials + Parameters + Environment + Qualification + Verification + Records

The objective is to control the process sufficiently to provide confidence in the resulting product.

5.21. Material Specifications

Material specifications can define:

- chemical composition;
- mechanical properties;
- physical properties;
- condition;
- heat treatment;
- dimensions;
- testing;
- certification;
- traceability.

Examples might cover:

- aluminium alloys;
- steels;
- polymers;
- adhesives;
- composites;
- plating chemicals.

Material conformity cannot be established merely by appearance. Objective evidence may therefore include:

- material certificates;
- test reports;
- batch traceability;
- independent testing.

5.22. Standards and Specifications Through the Product Lifecycle

Requirements should remain controlled throughout the lifecycle.

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CUSTOMER REQUIREMENTS
↓
CONTRACT REVIEW
↓
DESIGN REQUIREMENTS
↓
DRAWINGS & SPECIFICATIONS
↓
PURCHASE REQUIREMENTS
↓
SUPPLIER / SUB-TIER FLOWDOWN
↓
PRODUCTION CONTROLS
↓
INSPECTION & TEST
↓
ACCEPTANCE
↓
RECORDS & TRACEABILITY

A failure anywhere in this chain can result in nonconforming product even if manufacturing itself is performed correctly.

5.23. Revision and Configuration Control

A standard or specification is not defined by its number alone. Its **revision or edition matters**. For example: ABC-123 Revision C may contain different requirements from ABC-123 Revision D. Organisations should therefore control:

- document number;
- title;
- revision;
- amendment;
- approval status;
- effective date;
- source;
- applicability.

This is a configuration-management issue.

5.24. Latest Revision Is Not Always Correct

A common assumption is: **Always use the latest revision.** That is not universally correct. The contract or design definition may explicitly invoke an earlier revision.

For example: Contract requires Specification ABC-123 Rev C. Rev D may now exist, but automatically using Rev D could alter the contractual or approved product baseline. The correct question is: **Which revision is applicable to this product or contract?**

Changes should be evaluated and introduced through appropriate configuration and contractual controls.

5.25. Obsolete and Superseded Standards

Standards can be:

- revised;
- amended;
- corrected;
- superseded;
- withdrawn.

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A withdrawn standard does not automatically disappear from every existing contract. Legacy products may continue to require historical revisions. Quality professionals therefore need mechanisms for controlling **legacy standards and specifications**. This is especially important in industries with long product lifecycles such as:

- aerospace;
- defence;
- nuclear;
- rail.

5.26. Standards and Supplier Quality

Supplier quality relies heavily upon effective requirement flowdown. The purchasing organisation should determine which requirements must reach:

- direct suppliers;
- processors;
- laboratories;
- distributors;
- sub-tier suppliers.

A supplier may produce perfectly acceptable product against the **wrong specification**. That product is still nonconforming to the customer's requirement. Supplier assurance should therefore verify both: **Are they doing the process correctly?** And **Are they working to the correct requirement and revision?**

5.27. Reading a Standard Effectively

A quality professional should not begin by searching randomly for keywords. A structured approach is more effective.

5.27.1. Step 1 — Identify the Document

Confirm:

- title;
- number;
- edition/revision;
- issuing body.

5.27.2. Step 2 — Read the Scope

Determine:

- what it applies to;
- what it does not apply to;
- limitations.

5.27.3. Step 3 — Review Normative References

Identify additional documents required for correct application.

5.27.4. Step 4 — Review Terms and Definitions

Do not assume everyday meanings.

5.27.5. Step 5 — Identify Requirements

Pay particular attention to: **shall**

5.27.6. Step 6 — Separate Guidance

Identify: **should / may / can** and informative content.

5.27.7. Step 7 — Identify Evidence

Ask: **What objective evidence would demonstrate conformity?**

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5.27.8. Step 8 — Establish Applicability

Determine: **Which requirements actually apply to our product, process, organisation or contract?**

5.28. The Quality Professional's Requirement Test

Whenever encountering a requirement, ask:

- **WHAT?** What exactly is required?
- **WHY?** What is the purpose or risk being controlled?
- **WHO?** Who is responsible?
- **WHERE?** Which product, process or organisation does it apply to?
- **WHEN?** At what stage must it be applied?
- **HOW?** How will conformity be achieved?
- **EVIDENCE?** What demonstrates that the requirement was fulfilled?
- **SOURCE?** Where did the requirement originate?
- **REVISION?** Which revision applies?
- **FLOWDOWN?** Who else needs to receive the requirement?

This simple approach prevents many requirement-management failures.

5.29. Roles and Responsibilities

5.29.1. Design Authority / Engineering

Typically responsible for:

- technical requirements;
- drawings;
- design specifications;
- technical changes;
- product configuration.

5.29.2. Quality

Typically supports:

- interpretation;
- assurance;
- compliance assessment;
- auditing;
- verification;
- requirement flowdown;
- configuration assurance.

Quality should avoid unilaterally changing engineering requirements.

5.29.3. Procurement / Supply Chain

Typically responsible for ensuring applicable requirements are correctly communicated through contractual purchasing documentation.

5.29.4. Supplier

Responsible for understanding and fulfilling applicable contractual and technical requirements and flowing them to sub-tier organisations where required.

5.29.5. Configuration Management

Ensures controlled baselines, revisions and changes are appropriately managed.

5.29.6. Inspection / Verification Personnel

Verify conformity against the **applicable requirements**, not personal preference or historical practice.

5.30. Relationship with the Quality Management System

Standards and specifications interact with almost every part of a QMS. They support:

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Context and Requirements
↓
Contract Review
↓
Design Control
↓
Supplier Control
↓
Production Control
↓
Inspection & Test
↓
Nonconformity
↓
Change Control
↓
Records

They are therefore closely related to:

- configuration management;
- document control;
- contract review;
- supplier quality;
- product realisation;
- inspection;
- auditing;
- First Article Inspection;
- nonconformance;
- corrective action;
- risk management.

5.31. Auditing Standards and Specifications

Auditors should verify not only whether standards exist but whether they are **correctly identified, controlled and applied**. Useful questions include:

- **Applicability** How do you determine which standards apply?
- **Revision** How do you ensure personnel use the correct revision?
- **Access** Can users access the required document?
- **Understanding** Do personnel understand the requirements relevant to their work?
- **Flowdown** How are requirements communicated to suppliers and sub-tiers?
- **Change** How are revisions assessed and implemented?
- **Verification** How is conformity demonstrated?
- **Legacy Requirements** How are withdrawn or superseded standards controlled for legacy products?
- **Conflict** How are conflicting requirements resolved?

A powerful audit technique is: **Select one product and trace a requirement from customer contract through design, purchasing, production, supplier and inspection evidence.** This tests the effectiveness of the entire requirements-management chain.

5.32. Common Misconceptions

- **Specification and standard mean the same thing.** Not necessarily. A specification generally defines particular requirements, while a standard establishes agreed requirements, guidance or practice. However, a standard can itself be a specification.
- **Always use the latest revision.** Not necessarily. Use the revision required by the applicable contract, design baseline or controlled requirement.
- **If ISO publishes it, we must comply.** Only if the standard or relevant requirement is applicable through commitment, contract, regulation or another binding mechanism.

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- **If a supplier is certified to ISO 9001, its product meets our specification.** No. QMS certification does not automatically demonstrate conformity of a particular product.
- **If the drawing doesn't show it, it isn't required.** The drawing may reference specifications, standards, notes, customer requirements and other parts of the design definition.
- **Guidance is a requirement.** Not automatically. Recommendation and guidance should not be converted into mandatory requirements without an applicable basis.

5.33. Common Problems and Mistakes

Typical failures include:

- using obsolete revisions;
- uncontrolled copies of standards;
- incomplete purchase-order flowdown;
- misunderstanding "shall" and "should";
- treating guidance as mandatory;
- failing to read the scope;
- ignoring normative references;
- assuming certification demonstrates product conformity;
- failing to assess revised standards;
- poor configuration control;
- purchasing specifications without verifying applicability;
- copying requirements without understanding them;
- failing to flow requirements to sub-tier suppliers;
- inspectors using personal preference rather than acceptance criteria;
- assuming customer requirements are identical to industry standards.

Many apparently technical nonconformities are actually **requirements-management failures**.

5.34. Good Practice

Organisations should maintain an effective method for identifying and controlling applicable external requirements. This may include a **Standards and Specifications Register**. Useful fields include:

Field	Purpose
Document Number	Unique identification
Title	Description
Issuing Body	Source
Revision / Edition	Configuration
Publication Date	Status
Applicable Process/Product	Applicability
Requirement Owner	Responsibility
Contract Reference	Source of obligation
Supplier Flowdown	Required / Not Required
Current Status	Active / Superseded / Withdrawn
Review Date	Periodic review
Replacement Document	Where applicable

This provides traceability and reduces dependence on individual knowledge.

5.35. Benefits of Standards and Specifications

Effective use can provide:

- consistent requirements;
- repeatability;
- interoperability;
- common terminology;
- reduced ambiguity;
- easier procurement;

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- reliable acceptance criteria;
- improved safety;
- improved quality;
- efficient trade;
- improved supplier communication;
- objective auditing;
- reusable technical knowledge.

Standardisation prevents organisations from repeatedly **reinventing established solutions**.

5.36. Limitations

Standards and specifications are not automatically perfect. They can:

- become outdated;
- contain ambiguity;
- be incorrectly applied;
- conflict with other requirements;
- lag behind technology;
- be excessively prescriptive;
- be misunderstood;
- create unnecessary cost if applied without considering scope and risk.

Compliance with a standard also does not remove the need for:

- engineering judgement;
- risk management;
- regulatory compliance;
- customer understanding;
- competent personnel.

The quality professional must therefore understand both the **letter and purpose of the requirement**.

5.37. Key Takeaways

1. A **standard** establishes an agreed framework of requirements, guidelines, rules or characteristics.
2. A **specification** typically defines detailed requirements for a particular product, material, process, service or system.
3. Standards and specifications can overlap, a standard may itself contain a specification.
4. Standards create a **common language and common expectation** between organisations.
5. Standards are generally voluntary until made applicable through mechanisms such as contract, regulation, design definition or organisational commitment.
6. **Regulations and standards are not the same thing.**
7. In ISO documents, **"shall" identifies a requirement**, while **"should" identifies a recommendation**.
8. Quality professionals must distinguish **normative requirements from informative guidance**.
9. The applicable **revision or edition** is part of the requirement.
10. "Use the latest revision" is not universally correct. The applicable contractual or configuration baseline must be established.
11. Requirements must be correctly **flowed down through the supply chain**, including to relevant sub-tier organisations.
12. Product conformity cannot be established without knowing **which requirements apply**.
13. Standards and specifications are fundamental to **contract review, design, configuration management, supplier quality, production, inspection, auditing and product acceptance**.
14. A mature quality professional does not simply ask: **"Does the product look acceptable?"**
    They ask: **"What is the applicable requirement, where did it originate, which revision applies, and what objective evidence demonstrates conformity?"**

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6. Quality Management Systems

6.1. Overview

A **Quality Management System (QMS)** is the coordinated system by which an organisation directs, controls and continually improves the activities that affect the quality of its products and services. A QMS brings together:

People + Processes + Responsibilities + Requirements + Resources + Controls + Information + Evidence + Improvement

with the objective of consistently achieving intended results. A QMS should enable an organisation to answer fundamental questions such as:

- What are we required to deliver?
- Who is responsible?
- How do our processes work and interact?
- What controls are necessary?
- What competence and resources are required?
- How do we know requirements have been achieved?
- How do we identify and manage problems and risks?
- How do we measure performance?
- How do we learn and improve?

The QMS should therefore be understood as the **system by which quality is managed**, rather than simply a collection of quality procedures.

6.2. What Is a QMS?

A QMS is part of an organisation's overall management system. It provides the framework through which the organisation establishes, operates, monitors and improves the processes necessary to consistently fulfil applicable requirements. A useful simplified model is:

CUSTOMER, STATUTORY, REGULATORY & OTHER REQUIREMENTS
↓
LEADERSHIP & QUALITY POLICY
↓
OBJECTIVES & PLANNING
↓
PEOPLE, INFRASTRUCTURE & RESOURCES
↓
OPERATIONAL PROCESSES
↓
PRODUCT / SERVICE
↓
VERIFICATION & DELIVERY
↓
CUSTOMER & PERFORMANCE FEEDBACK
↓
CORRECTIVE ACTION & IMPROVEMENT
↺
LEARNING FEEDS BACK INTO THE SYSTEM

A mature QMS is therefore a **closed-loop management system**. It plans what should happen, controls what happens, evaluates what actually happened and uses the results to improve future performance.

6.3. The QMS Is Not the Standard

This distinction is fundamental. An organisation may say: "Our QMS is ISO 9001." Strictly, ISO 9001 is not the organisation's QMS.

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6.3.1. ISO 9001 is a standard containing QMS requirements.

The organisation creates and operates its own QMS to satisfy its business needs and, where applicable, the requirements of ISO 9001. Similarly:

- AS9100 does not *become* the aerospace company's QMS;
- ISO 13485 does not *become* the medical-device company's QMS;
- IATF 16949 does not *become* the automotive company's QMS.

They establish requirements around which an organisation designs and operates its management system.

A useful distinction is:

STANDARD What requirements must or should the management system satisfy?
↓
ORGANISATION'S QMS How does this organisation actually manage quality?
↓
PROCESSES How is work controlled?
↓
OBJECTIVE EVIDENCE How can we demonstrate that the system is operating effectively?

6.4. Purpose of a QMS

The primary purpose of a QMS is not certification. Its purpose is to create a **controlled, repeatable and improving system capable of consistently achieving required outcomes**.

An effective QMS should help an organisation:

- understand customer requirements;
- identify applicable statutory and regulatory requirements;
- define responsibilities;
- control processes;
- manage risks and opportunities;
- provide appropriate resources;
- establish competence;
- control suppliers;
- maintain product and service conformity;
- identify nonconformity;
- analyse performance;
- address root causes;
- learn from experience;
- continually improve.

Certification may provide external confidence in the system, but it is not the fundamental purpose of the system.

6.5. Why a QMS Matters

Without a systematic approach to quality, organisations can become dependent upon:

- individual knowledge;
- informal communication;
- inspection;
- firefighting;
- personal judgement;
- correction after failure.

This creates variation and organisational risk. For example:
Without an effective QMS "Ask John. He knows how we normally do it."

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With an effective QMS Requirements, responsibilities, processes, competence and evidence are systematically controlled.

The objective is not to remove human judgement. It is to prevent the organisation's ability to deliver quality from depending entirely upon **who happens to be at work that day**.

6.6. What Should a QMS Include?

The exact structure depends upon the organisation, its products, services, risks, customers, regulatory environment and applicable QMS requirements. However, a mature QMS normally addresses the following areas.

6.6.1. Organisational Context

The organisation should understand:

- what it does;
- who its customers and relevant interested parties are;
- applicable requirements;
- internal and external issues;
- scope of the QMS;
- key processes and their interactions.

6.6.2. Leadership

The system should establish:

- quality policy;
- responsibilities and authorities;
- leadership commitment;
- customer focus;
- accountability;
- quality culture.

Quality should be integrated into business leadership rather than delegated entirely to a Quality Department.

6.6.3. Planning

The organisation should determine:

- quality objectives;
- risks;
- opportunities;
- required actions;
- resources;
- changes that need to be controlled.

Planning converts organisational intent into controlled activity.

6.6.4. People and Competence

The QMS should ensure that people affecting quality have appropriate:

- education;
- training;
- skills;
- experience;
- competence;
- awareness;
- authority.

Training is only one possible contributor to competence.

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6.6.5. Infrastructure and Work Environment

Quality can depend upon:

- buildings;
- machinery;
- tooling;
- IT systems;
- utilities;
- environmental conditions;
- cleanliness;
- temperature;
- humidity;
- contamination control.

The QMS should ensure that necessary infrastructure and operating conditions are available and controlled.

6.6.6. Documented Information

The objective is not documentation for its own sake. Documentation should support **consistent and controlled execution of work and provide evidence where required**. See the section for detailed information on Documented Information in this publication.

6.6.7. Customer and Contract Requirements

The QMS should ensure that applicable requirements are:

Identified → Reviewed → Understood → Agreed → Communicated → Implemented → Verified

Poor contract review can create nonconformity before production even begins.

6.6.8. Design and Development

Where applicable, design processes should control:

- inputs;
- requirements;
- reviews;
- verification;
- validation;
- outputs;
- changes;
- configuration.

Quality should be **designed into the product**, rather than expected to emerge from final inspection.

6.6.9. Supplier and External Provider Control

The QMS should determine:

- what is outsourced;
- supplier approval criteria;
- requirements to be flowed down;
- risk;
- supplier monitoring;
- verification;
- corrective action;
- supplier development where necessary.

Outsourcing a process does not automatically outsource responsibility for ensuring conformity.

6.6.10. Production and Service Provision

Operational processes may need controls for:

- work instructions;
- equipment;

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- tooling;
- materials;
- process parameters;
- identification;
- traceability;
- preservation;
- special processes;
- product status;
- change control.

6.6.11. Inspection, Test and Verification

The organisation should determine:

- what must be verified;
- when;
- how;
- by whom;
- against which acceptance criteria;
- what evidence is retained.

Inspection should provide confidence in conformity but should not be regarded as the sole means of creating quality.

6.6.12. Measurement and Calibration

Where measurement affects product or process acceptance, the QMS may need to control:

- measuring equipment;
- calibration;
- verification;
- measurement traceability;
- measurement uncertainty;
- environmental conditions;
- measurement-system capability.

6.6.13. Nonconformity

The QMS should control outputs that do not meet requirements. Typical controls include:

Identify → Segregate / Control → Evaluate → Disposition → Record → Prevent Unintended Use

Depending upon the organisation, disposition may include:

- rework;
- repair;
- scrap;
- return;
- concession;
- use-as-is under appropriate authority.

6.6.14. Corrective Action

When significant or recurring problems occur, the organisation should determine:

What happened?
↓
Why did it happen?
↓
Could it happen elsewhere?
↓

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What action removes or controls the cause?
↓
Was the action effective?

Corrective action should address **causes rather than simply symptoms**.

6.6.15. Performance Evaluation
The organisation should determine whether its QMS is effective. Evidence may include:

- customer satisfaction;
- quality objectives;
- defect rates;
- process performance;
- supplier performance;
- delivery performance;
- audit results;
- cost of poor quality;
- corrective-action performance;
- trends.

6.6.16. Internal Audit
Internal audit provides independent evidence about whether the QMS:

- conforms to applicable requirements;
- is effectively implemented;
- is maintained;
- achieves intended outcomes.

A mature audit programme focuses on **process effectiveness**, not simply procedural compliance.

6.6.17. Management Review
Top management should periodically evaluate the performance and continuing suitability of the QMS.
Management review should support decisions concerning:

- performance;
- risks;
- resources;
- customer issues;
- improvement;
- changes;
- strategic direction.

It should be a **management activity**, not simply a Quality Department presentation.

6.6.18. Improvement
The QMS should learn from:

- failures;
- audits;
- customer feedback;
- data;
- risk;
- employee knowledge;
- supplier performance;
- lessons learned.

The system should become more capable over time.

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6.6.19. Process Approach

Modern QMS thinking is based strongly upon the **Process Approach**. An organisation should not be viewed simply as separate departments. Instead, it should be understood as a network of interconnected processes. For example:

CUSTOMER REQUIREMENT
↓
CONTRACT REVIEW
↓
DESIGN
↓
PURCHASING
↓
SUPPLIER
↓
PRODUCTION
↓
INSPECTION
↓
DELIVERY
↓
CUSTOMER FEEDBACK

A failure at an interface can be just as important as a failure within an individual process.

6.6.19.1. Process Inputs and Outputs

Every process can be considered as:

INPUT → ACTIVITY → OUTPUT

For example: **Purchasing**

Input Approved requirement
↓
Activity Supplier selection and purchase-order placement
↓
Output Correctly specified purchased product or service

The output from one process frequently becomes the input to another. This is why QMS effectiveness depends heavily upon **process interaction**.

6.7. PDCA and the QMS

The Plan-Do-Check-Act model provides a useful representation of a management system.

6.7.1. PLAN

- understand context;
- establish requirements;
- determine risks;
- set objectives;
- plan processes.

6.7.2. DO

- provide resources;
- develop competence;
- operate processes;
- produce products and services.

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6.7.3. CHECK

- inspect;
- monitor;
- measure;
- audit;
- analyse;
- review.

6.7.4. ACT

- correct;
- improve;
- eliminate root causes;
- update processes;
- capture lessons.

Then the cycle repeats.

PLAN → DO → CHECK → ACT → PLAN...

A QMS should therefore be **dynamic**, not a static set of procedures.

6.8. Different Quality Management Systems

There is no single QMS standard suitable for every industry. ISO 9001 provides a widely applicable baseline, while other sectors have developed additional or specialised frameworks to address particular risks. Examples include:

6.8.1. ISO 9001 — General Quality Management

ISO 9001:2026 — Quality management systems — Requirements

ISO 9001 is the world's most widely used generic QMS requirements standard. It can be applied to organisations of different:

- sizes;
- industries;
- products;
- services.

It addresses areas including:

- organisational context;
- leadership;
- planning;
- support;
- operations;
- performance evaluation;
- improvement.

The 2026 edition is the current sixth edition. ISO 9001 is intended to help organisations consistently provide products and services that satisfy customer and applicable statutory and regulatory requirements while improving the effectiveness of the QMS.

Suitable For Virtually any industry or organisation seeking a general QMS framework.

6.8.2. AS/IA 9100 / EN 9100 — Aviation, Space and Defence

The **9100 series** extends ISO 9001 with additional requirements developed for aviation, space and defence. Depending upon publication region, the standard may be designated:

- AS/IA 9100;
- EN 9100;
- JISQ 9100.

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The sector-specific requirements address the greater product, safety, configuration and supply-chain risks associated with aerospace and defence. Areas receiving additional emphasis include matters such as:

- product safety;
- operational risk;
- configuration management;
- counterfeit-part prevention;
- supplier control;
- production-process verification;
- traceability;
- special requirements;
- critical items.

Suitable For Organisations designing, developing or producing aviation, space and defence products and services.

6.8.3. AS/IA 9110 / EN 9110 — Aviation Maintenance

The 9110 standard is designed for **aviation maintenance organisations**. It builds upon the ISO 9001 foundation and introduces requirements relevant to maintenance activities.
Typical concerns include:

- maintenance safety;
- technical data;
- maintenance records;
- human factors;
- release;
- regulatory requirements.

It should not be confused with AS/IA 9100 simply because both operate within aviation.

6.8.4. AS/IA 9120 / EN 9120 — Aerospace Distribution

The 9120 standard applies particularly to distributors within aviation, space and defence supply chains. Distribution presents different risks from manufacturing. Key concerns include:

- traceability;
- preservation;
- storage;
- handling;
- supplier control;
- documentation;
- prevention of counterfeit or suspect parts;
- splitting of batches or lots.

A distributor that does not manufacture components may therefore find 9120 more appropriate than 9100.

6.8.5. ISO/IEC 17025 — Testing and Calibration Laboratories

ISO/IEC 17025:2017 — General requirements for the competence of testing and calibration laboratories.
ISO/IEC 17025 is specifically intended for organisations performing:

- testing;
- calibration;
- sampling associated with subsequent testing or calibration.

It addresses both management-system controls and **technical competence**. Important areas include:

- impartiality;
- confidentiality;
- personnel competence;
- equipment;

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- metrological traceability;
- test and calibration methods;
- sampling;
- handling of items;
- technical records;
- measurement uncertainty;
- validity of results;
- reporting.

6.8.5.1. Certification Versus Accreditation

ISO/IEC 17025 is normally associated with **laboratory accreditation**, not simply QMS certification. Accreditation assesses whether the laboratory is technically competent to perform the specific activities included within its **scope of accreditation**. This is an important distinction.

- ISO 9001 certification demonstrates conformity of a QMS.
- ISO/IEC 17025 accreditation additionally addresses competence to perform specified testing or calibration activities.

6.8.6. IATF 16949 — Automotive

IATF 16949:2016 is the principal automotive-sector QMS standard used throughout much of the global automotive supply chain. It is used in conjunction with the ISO 9001 framework and adds automotive-specific requirements. Important areas include:

- product safety;
- defect prevention;
- variation reduction;
- waste reduction;
- supplier development;
- contingency planning;
- manufacturing process control;
- customer-specific requirements.

Automotive QMS implementation is also closely associated with the **Core Tools**, including:

- APQP;
- Control Plan;
- FMEA;
- SPC;
- MSA;
- PPAP.

6.8.6.1. Customer-Specific Requirements

A particularly important automotive concept is the **Customer-Specific Requirement (CSR)**.
Meeting IATF 16949 alone may not satisfy every automotive customer. Individual OEMs may impose additional requirements that must also be identified and implemented.

6.8.7. ISO 13485 — Medical Devices

ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 13485 provides a QMS framework specifically for organisations involved with medical devices. It places strong emphasis on:

- regulatory compliance;
- safety;
- risk management;
- traceability;
- cleanliness;
- contamination control;
- validation;
- design control;

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- complaint handling;
- post-production activities.

ISO 13485 is closely connected with the regulatory environment surrounding medical devices. It should therefore not be regarded simply as ISO 9001 with a different title.

6.8.8. AQAP 2110 — NATO Quality Assurance

AQAP 2110 — NATO Quality Assurance Requirements for Design, Development and Production. AQAPs are **Allied Quality Assurance Publications**.

AQAP 2110 is primarily intended for contractual use and provides requirements intended to give the Acquirer confidence in a supplier's ability to deliver products conforming to contract requirements.
It is particularly relevant to defence procurement.

Unlike a generic voluntary management-system framework, AQAP requirements are commonly **invoked through contract**.

Depending upon the contract and applicable AQAP, requirements may include interaction with:

- the Acquirer;
- Government Quality Assurance;
- the Government Quality Assurance Representative (GQAR);
- quality planning;
- contractual risk;
- supplier controls.

For UK MOD procurement, AQAPs may be selected as contractual quality conditions according to the nature and risk of the procurement.

6.8.9. AQAP 2310 — Aviation, Space and Defence Suppliers

AQAP 2310 provides NATO QMS requirements for aviation, space and defence suppliers and is designed for situations where the supplier's QMS is based upon the 9100 framework. It is particularly relevant where **NATO contractual assurance and aerospace QMS requirements need to operate together**.

6.8.10. ISO 22163 — Railway

ISO 22163:2023 establishes railway-sector QMS requirements based upon ISO 9001:2015 with railway-specific additions. It addresses organisations supplying products and services to the railway sector. Railway-specific quality concerns include areas such as:

- project management;
- supply-chain control;
- risk;
- configuration;
- lifecycle management;
- reliability and safety.

A replacement edition is under development, so users should verify the applicable contractual edition.

6.8.11. ISO 19443 — Nuclear Supply Chain

ISO 19443:2018 applies ISO 9001 principles with additional requirements for organisations supplying products and services important to nuclear safety. A fundamental concept is the importance of **nuclear safety culture** and the control of products and services important to nuclear safety.

It is relevant to organisations within the nuclear-energy supply chain where the consequences of failure demand enhanced assurance.

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6.8.12. ISO 29001 — Oil and Gas

ISO 29001:2020 establishes sector-specific QMS requirements for product and service supply organisations in the:

- petroleum;
- petrochemical;
- natural-gas industries.

It supplements ISO 9001 with additional controls intended particularly to address sector supply-chain risks.

6.9. Comparison of Major Quality Management Frameworks

Standard / Framework	Sector	Primary Focus	Notable Additional Emphasis
ISO 9001:2026	General	Quality Management System	Customer focus, processes, leadership, risk/opportunity, performance and improvement
9100 series	Aviation, Space & Defence	Aerospace QMS	Product safety, configuration, operational risk, counterfeit prevention, supply chain
9110	Aviation Maintenance	Maintenance QMS	Maintenance safety, technical data, human factors, regulatory control
9120	Aerospace Distribution	Distributor QMS	Traceability, preservation, records, counterfeit-part prevention
ISO/IEC 17025:2017	Laboratories	Competence of testing/calibration laboratories	Technical competence, impartiality, measurement uncertainty and validity of results
IATF 16949:2016	Automotive	Automotive QMS	Defect prevention, Core Tools, product safety, supplier development, CSRs
ISO 13485:2016	Medical Devices	Medical-device QMS	Regulatory compliance, safety, risk, traceability and process validation
AQAP 2110	NATO / Defence	Contractual quality assurance	Acquirer/GQA involvement, contractual assurance and NATO-specific requirements
AQAP 2310	NATO Aerospace & Defence	Contractual aerospace quality assurance	NATO assurance integrated with 9100-based QMS
ISO 22163:2023	Railway	Railway QMS	Railway lifecycle, project and sector-specific requirements
ISO 19443:2018	Nuclear	Nuclear supply-chain QMS	Nuclear safety, safety culture and ITNS controls
ISO 29001:2020	Oil & Gas	Sector QMS	Petroleum supply-chain risk and sector-specific controls

6.10. Integrated Management Systems

An **Integrated Management System (IMS)** combines multiple management disciplines into a coherent organisational system. For example:

- **QUALITY** ISO 9001
- **ENVIRONMENT** ISO 14001
- **HEALTH & SAFETY** ISO 45001
- **INFORMATION SECURITY** ISO/IEC 27001

Common processes can include:

- document control;
- internal audit;
- competence;
- objectives;
- management review;

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- corrective action;
- risk management.

Integration can reduce duplication and encourage management to consider the organisation as a **single system**.

6.11. Certification, Accreditation and Compliance

These terms should not be confused.

- **Certification** An independent certification body assesses whether an organisation's management system conforms to a certification standard such as ISO 9001 or AS9100. The organisation may then receive certification within a defined scope.
- **Accreditation** An accreditation body formally recognises the competence of an organisation performing specified conformity-assessment activities. For example, a laboratory may be accredited to ISO/IEC 17025 for specific tests or calibrations.
- **Compliance / Conformity** An organisation may conform to a standard without obtaining third-party certification where certification is not required.
- **Contractual Approval** A customer may separately approve a supplier. Customer approval is not automatically equivalent to third-party QMS certification.

6.12. Certification Does Not Guarantee Product Quality

This is a fundamental misconception. An ISO 9001 certificate does not mean: "Every product made by this company is defect free." Certification provides confidence that the organisation has established and operates a QMS conforming to the applicable certification requirements within its certified scope. Individual product conformity must still be established through appropriate:

- process control;
- inspection;
- test;
- verification;
- records.

6.13. Scope Matters

A certificate must always be read with its **scope**. Suppose a company operates:

- Site A — machining;
- Site B — heat treatment;
- Site C — design.

A certificate covering only: "Manufacture of machined components at Site A" does not automatically demonstrate that Sites B and C are included. Quality professionals should therefore verify:

- organisation;
- site;
- standard;
- scope;
- certificate status;
- expiry / certification cycle;
- certification body;
- accreditation;
- applicable exclusions or boundaries.

Never verify supplier capability by simply seeing an ISO logo.

6.14. Customer and Contractual Requirements

A QMS standard provides only part of the requirements applicable to an organisation. The actual requirement set may be:

- **QMS STANDARD**
- **CUSTOMER REQUIREMENTS**
- **CONTRACT**

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- **DRAWINGS & SPECIFICATIONS**
- **STATUTORY / REGULATORY REQUIREMENTS**
- **SECTOR REQUIREMENTS**
- **ORGANISATIONAL REQUIREMENTS**

A company can therefore be fully certified to ISO 9001 yet still fail a customer audit because it has not complied with the customer's contractual quality requirements.

6.15. Building a QMS

A practical QMS-development sequence is:

6.15.1. Understand the Organisation

Determine:

- products;
- services;
- customers;
- interested parties;
- risks;
- regulatory environment.

6.15.2. Determine Applicable Requirements

Identify:

- QMS standards;
- contracts;
- customer requirements;
- legislation;
- regulations;
- specifications.

6.15.3. Define Scope

Establish which activities, sites and processes the QMS covers.

6.15.4. Identify Processes

Map how the organisation actually operates.

6.15.5. Define Process Ownership

Assign responsibilities and authorities.

6.15.6. Determine Controls

Establish:

- criteria;
- resources;
- competence;
- methods;
- risks;
- evidence.

6.15.7. Document What Is Necessary

Create documentation where it adds control, knowledge or evidence.

6.15.8. Implement

Operate the processes.

6.15.9. Measure

Determine whether they are effective.

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6.15.10. Audit
Independently assess conformity and effectiveness.

6.15.11. Review
Leadership evaluates system performance.

6.15.12. Improve
Address weaknesses and improve capability.

6.16. Documentation Hierarchy
Many organisations use a hierarchy such as:

LEVEL 1 — POLICY / QMS FRAMEWORK What the organisation intends to achieve
↓
LEVEL 2 — PROCESSES / PROCEDURES How activities are controlled
↓
LEVEL 3 — WORK INSTRUCTIONS How particular tasks are performed
↓
LEVEL 4 — FORMS / RECORDS / EVIDENCE What demonstrates that activities occurred

This can be useful, but it is **not a universal mandatory structure**. Modern QMS standards allow organisations considerable flexibility in determining the documented information necessary for effective operation.

6.17. A Process-Based QMS
A mature QMS should be understandable through its processes. A useful process architecture is:

- **Leadership Processes**
  - strategy;
  - objectives;
  - management review;
  - risk.
- **Customer / Operational Processes**
  - sales;
  - contract review;
  - design;
  - procurement;
  - production;
  - inspection;
  - delivery.
- **Support Processes**
  - competence;
  - maintenance;
  - calibration;
  - IT;
  - document control.
- **Assurance & Improvement Processes**
  - internal audit;
  - nonconformance;
  - corrective action;
  - data analysis;
  - continual improvement.

All should connect to the organisation's intended outcomes.

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6.18. Roles and Responsibilities

6.18.1. Top Management

Responsible for:

- QMS effectiveness;
- policy;
- objectives;
- resources;
- accountability;
- customer focus;
- quality culture.

6.18.2. Quality Function

Typically provides:

- QMS expertise;
- assurance;
- audit;
- governance;
- analysis;
- improvement support;
- independent challenge.

The Quality function should **support and assure the system rather than own every process within it**.

6.18.3. Process Owners

Responsible for:

- process performance;
- controls;
- resources;
- risks;
- measures;
- improvement.

6.18.4. Employees

Responsible for:

- following applicable controls;
- maintaining records;
- reporting problems;
- protecting conformity;
- contributing to improvement.

6.18.5. Internal Auditors

Provide independent evaluation of QMS conformity and effectiveness.

6.19. Auditing a QMS

A mature QMS audit should evaluate three things:

- **Conformity** Are applicable requirements being met?
- **Implementation** Is the documented system actually being followed?
- **Effectiveness** Does the process achieve its intended result?

For example:

- A procedure may require supplier performance reviews every month.
- Records demonstrate that the reviews occur.
- But supplier escapes continue increasing.
- The procedure is being followed, yet the process may not be **effective**.
- This distinction is fundamental to modern QMS auditing.

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6.19.1. Objective Evidence

Auditors should follow evidence through processes. For example:

Customer Requirement
↓
Contract Review
↓
Design Output
↓
Purchase Order
↓
Supplier Evidence
↓
Production Record
↓
Inspection Result
↓
Release

This approach tests whether the management system actually connects.

6.20. Common QMS Problems

Typical weaknesses include:

- QMS created primarily for certification;
- excessive documentation;
- procedures that do not reflect actual practice;
- Quality Department owning every process;
- poor process ownership;
- ineffective metrics;
- audits focused only on paperwork;
- repeated corrective actions;
- weak supplier controls;
- poor management review;
- disconnected quality objectives;
- uncontrolled local processes;
- weak requirement flowdown;
- lack of employee understanding;
- certification scope misunderstood;
- customer-specific requirements overlooked.

6.20.1. The "Paper QMS"

A particularly dangerous condition is the **paper QMS**.

This occurs when: **Documented System ≠ Actual Working System**

Employees may say: "That's what the procedure says, but this is how we really do it." The gap between documented and actual practice creates:

- audit risk;
- inconsistency;
- hidden process risk;
- weak training;
- unreliable assurance.

An effective QMS should describe and control **how the organisation actually needs to operate**.

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6.21. Common Misconceptions

- **"The Quality Department owns the QMS."** No. Top management is accountable for QMS effectiveness, while process owners are responsible for their processes. Quality provides expertise and assurance.
- **"A QMS is a set of procedures."** Procedures may form part of a QMS, but the system also includes people, processes, resources, responsibilities, controls, data and improvement.
- **"ISO 9001 tells us how to run every process."** No. It establishes requirements but deliberately allows organisations to determine methods appropriate to their context.
- **"More documentation means a better QMS."** No. Documentation should be proportionate and useful.
- **"Certification proves our products are good."** No. Certification relates to the management system and its defined scope.
- **"Passing the external audit means the QMS is effective."** Not necessarily. External certification is one source of assurance. Organisations must continually evaluate actual performance.
- **"Quality owns corrective action."** The process owner responsible for the cause normally needs to own appropriate corrective action, supported by Quality where necessary.

6.22. Good Practice

A strong QMS should be:

- **Simple** People should be able to understand how the system works.
- **Process Based** Organised around how value is created rather than departmental silos.
- **Risk Based** Controls should be proportionate to consequences and uncertainty.
- **Evidence Based** Decisions should use reliable information.
- **Integrated** Quality should form part of normal business processes.
- **Owned** Every process should have clear accountability.
- **Used** A QMS that exists only for auditors has failed its primary purpose.
- **Measured** Process effectiveness should be understood.
- **Improving** The system should learn from experience.

6.23. Benefits of an Effective QMS

An effective QMS can contribute to:

- consistent products and services;
- reduced variation;
- improved customer confidence;
- fewer defects;
- better supplier performance;
- improved traceability;
- clearer responsibilities;
- regulatory compliance;
- reduced cost of poor quality;
- improved risk management;
- better organisational knowledge;
- improved decision making;
- continual improvement.

The real value comes from **operating the system effectively**, not possessing the certificate.

6.24. Limitations

A QMS cannot compensate indefinitely for:

- poor leadership;
- inadequate technical competence;
- incapable processes;
- insufficient resources;
- unethical behaviour;
- weak quality culture.

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Certification also cannot eliminate all risk or guarantee that defects will never occur.
A QMS is a **management framework**, not a substitute for professional judgement or technical capability.

6.25. The Quality Professional's QMS Test

When evaluating any QMS process, ask:

- **PURPOSE** What is this process intended to achieve?
- **OWNER** Who is accountable?
- **INPUT** What does the process require?
- **OUTPUT** What should it produce?
- **REQUIREMENTS** Which requirements apply?
- **CONTROL** How is the process controlled?
- **RISK** What could prevent success?
- **RESOURCES** What people, equipment and information are required?
- **MEASURE** How is performance known?
- **EVIDENCE** What demonstrates conformity?
- **INTERACTION** Which other processes depend upon it?
- **IMPROVEMENT** How does the process learn and become better?

If these questions cannot be answered, the process may not be adequately understood or managed.

6.26. Key Takeaways

1. A **Quality Management System is the system through which an organisation manages quality**.
2. A QMS is not simply a collection of procedures.
3. A QMS standard such as ISO 9001 provides requirements; **the organisation creates the actual QMS**.
4. The fundamental purpose of a QMS is **consistent achievement of requirements and effective improvement**, not certification.
5. An effective QMS integrates people, processes, responsibilities, resources, controls, evidence and improvement.
6. Modern QMS thinking uses the **Process Approach, PDCA, risk-based thinking and evidence-based decision making**.
7. ISO 9001 provides a generic QMS framework applicable across sectors.
8. Sector-specific frameworks introduce additional controls appropriate to particular risks.
9. The 9100 family addresses aviation, space and defence; 9110 focuses on aviation maintenance and 9120 on aerospace distribution.
10. IATF 16949 addresses automotive quality and works alongside customer-specific requirements and automotive Core Tools.
11. ISO 13485 addresses medical-device QMS requirements with strong regulatory, safety, risk and validation emphasis.
12. ISO/IEC 17025 addresses the **competence and consistent operation of testing and calibration laboratories** and is commonly associated with accreditation rather than ordinary QMS certification.
13. AQAP requirements are particularly important in NATO and defence procurement and are commonly **contractually invoked**.
14. A single organisation may need to satisfy several QMS or management-system frameworks.
15. Certification does not guarantee individual product conformity.
16. Always examine the **scope of certification or accreditation**.
17. The best QMS is not necessarily the one with the most procedures. It is the one that enables people to **consistently understand requirements, control processes, identify problems, learn and deliver conforming products and services**.
18. A mature quality professional should never ask only: **"Do we comply with the standard?"** They should also ask: **"Is our management system actually helping the organisation consistently achieve the right result?"**

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7. Documented Information & Quality Records

7.1. Introduction

Documented information provides the **controlled knowledge and objective evidence** needed to operate, maintain and demonstrate an effective Quality Management System (QMS).

It tells people **what should be done**, supports consistent execution, and provides evidence of **what was actually done**.

Modern quality management systems use the broad term **documented information** to cover both traditional controlled documents and retained records. The amount and complexity of documentation should be appropriate to the organisation, its products and services, regulatory environment, risks, workforce competence and process complexity.

A useful principle is: **Documents guide the work. Records provide evidence of the work.**
Documentation should support effective processes and not become bureaucracy for its own sake.

7.2. What Is Documented Information?

Documented information is information that an organisation needs to **control and maintain**, together with the medium on which it is contained. It can exist in many forms, including:

- policies;
- procedures;
- process maps;
- work instructions;
- specifications;
- drawings;
- standards;
- forms and templates;
- inspection and test plans;
- control plans;
- checklists;
- electronic databases;
- ERP/MRP/QMS records;
- photographs and video;
- certificates;
- reports;
- spreadsheets;
- software-generated information;
- emails where they form part of an official decision or record;
- paper records.

The medium is less important than ensuring the information is **appropriate, available, controlled, protected and trustworthy**.

7.3. Documents and Records

Although both are documented information, their purposes differ.

Controlled Document	Quality Record
Defines what should happen	Provides evidence of what happened
Usually maintained and revised	Usually retained after completion
Subject to revision control	Normally protected from inappropriate alteration
Provides instructions or requirements	Demonstrates results or conformity
May become obsolete and be replaced	Usually remains evidence of a historical event
Example: inspection procedure	Example: completed inspection report
Example: blank checklist	Example: completed checklist
Example: drawing	Example: completed dimensional report

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For example: **Work Instruction WI-104 Rev C** tells an operator how an activity must be performed. A **completed production or inspection record** demonstrates that the activity was performed and records its results. This distinction is important because the controls needed for an instruction are not always the same as those required for historical evidence.

7.4. Why Documented Information Matters

Effective documented information supports:

- **Consistency** – activities are performed using an agreed method.
- **Knowledge retention** – important knowledge is not dependent solely on individual memory.
- **Traceability** – products, processes, materials, decisions and activities can be reconstructed.
- **Conformity** – evidence demonstrates that requirements were achieved.
- **Communication** – requirements and expectations are clearly communicated.
- **Training and competence** – controlled information supports learning and consistent working.
- **Accountability** – decisions, approvals and responsibilities can be identified.
- **Improvement** – historical information enables trends, failures and opportunities to be analysed.
- **Auditability** – objective evidence is available to demonstrate effective implementation.
- **Legal and regulatory evidence** – records may demonstrate compliance with applicable obligations.
- Good documentation therefore contributes directly to organisational knowledge, product integrity and risk management.

7.5. Documentation Hierarchy

Organisations often arrange QMS documentation into a hierarchy.

7.5.1. Level 1 – Policy and QMS Framework

Defines organisational direction and high-level commitments.
Examples:

- Quality Policy;
- QMS scope;
- Quality Manual, where used;
- governance framework;
- organisational policies.

7.5.2. Level 2 – Processes and Procedures

Defines **what happens, who is responsible and how processes interact**.
Examples:

- purchasing procedure;
- nonconformity process;
- internal audit procedure;
- design control process.

7.5.3. Level 3 – Work Instructions and Technical Controls

Defines **how specific activities are performed**.
Examples:

- manufacturing instructions;
- inspection instructions;
- test procedures;
- special process instructions;
- control plans.

7.5.4. Level 4 – Forms and Templates

Provides structured methods for capturing required information.

7.5.5. Level 5 – Records

Completed evidence resulting from processes.

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The precise hierarchy is an organisational choice. The objective is to make information **logical, accessible and proportionate**, not to create unnecessary levels of documentation.

7.6. Document Control

Controlled documents should be managed throughout their lifecycle:

Create → Review → Approve → Issue → Use → Review/Revise → Withdraw → Archive/Dispose

Controls should ensure that:

- documents are uniquely identifiable;
- title and purpose are clear;
- revision or version status is identifiable;
- appropriate personnel review and approve documents;
- current versions are available where needed;
- changes are identified and controlled;
- obsolete versions are prevented from unintended use;
- external documents are appropriately controlled;
- documents remain legible and retrievable;
- access and editing permissions are appropriate.

The level of control should reflect the **risk associated with incorrect or obsolete information**.

7.7. Document Identification

Controlled documents should normally contain sufficient information to establish their identity and status. This may include:

Information	Example
Document number	QP-014
Title	Control of Nonconforming Outputs
Revision	Rev 04
Effective date	15-Mar-26
Owner	Quality Manager
Approver	Head of Quality
Classification	Internal
Page information	Page 3 of 12

Electronic document-management systems may control some of this information automatically.
The essential requirement is that users can confidently determine:
"Is this the correct and current information for the work I am performing?"

7.8. Review and Approval

Documents should be reviewed by people with sufficient **knowledge, competence and authority**.
Approval should establish that the information is:

- technically correct;
- appropriate for its intended purpose;
- consistent with applicable requirements;
- understandable to its users;
- compatible with related processes;
- appropriately controlled. Approval should not become a ceremonial signature exercise. Approvers are accepting responsibility for the suitability of the information within their authority.

7.9. Revision and Change Control

Documents inevitably change because of:

- process improvements;
- corrective actions;
- customer requirements;
- regulatory changes;
- design changes;

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- equipment changes;
- audit findings;
- lessons learned;
- organisational changes. Changes should be controlled so that their implications are understood.

A good change process considers:

- **What changed?**
- **Why did it change?**
- **Who approved it?**
- **What else is affected?**
- **Who needs to know?**
- **When does it become effective?**
- **Is training required?**

Revision histories can provide useful traceability, but should be meaningful rather than simply stating "document updated".

7.10. Obsolete Documents

Obsolete documents present significant risk when they remain available at the point of use.
An operator following an obsolete drawing, specification or work instruction may unintentionally produce nonconforming product. Controls may include:

- electronic access to only the current version;
- withdrawal of superseded paper copies;
- clear identification such as **OBSOLETE** or **SUPERSEDED**;
- controlled archives;
- restricted access;
- automatic document-management workflows.

Historic versions may still need to be retained where they provide evidence of the requirements applicable when a product was manufactured or an activity occurred.

7.11. Documents of External Origin

Organisations frequently rely on information that they did not create.
Examples include:

- customer drawings;
- customer specifications;
- international standards;
- national standards;
- regulatory requirements;
- Defence Standards;
- supplier manuals;
- equipment manuals;
- industry specifications.

These documents may also require control. The organisation should understand:

- which external documents apply;
- their current revision status;
- where they are available;
- who monitors changes;
- how changes are assessed;
- whether changes affect products, processes or contracts.

Simply downloading a standard once does not ensure continued control.

7.12. Quality Records

Quality records provide **objective evidence** of activities performed and results achieved.

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Examples include:

- inspection reports;
- test results;
- calibration certificates;
- audit reports;
- First Article Inspection Reports (FAIRs);
- Certificates of Conformity;
- material certificates;
- training and competence records;
- manufacturing travellers or route cards;
- nonconformance reports;
- concessions and deviations;
- corrective action records;
- supplier approvals;
- process qualification records;
- maintenance records;
- management review outputs;
- risk assessments;
- validation records.

Records should provide sufficient information to understand what occurred without relying entirely upon the memory of the person who created them.

7.12.1. Good Record-Keeping Principles

Quality records should be:

- **Accurate** – reflect what actually occurred.
- **Complete** – contain all required information.
- **Legible** – understandable throughout their retention period.
- **Traceable** – linked to the relevant product, process, person or activity.
- **Contemporaneous** – recorded when the activity occurs or as soon as practicable afterwards.
- **Authentic** – attributable to the person or system that created them.
- **Retrievable** – capable of being located when required.
- **Protected** – safeguarded against inappropriate alteration, loss or damage.
- **Retained** – maintained for the required period.

A useful test is: **Could another competent person reconstruct what happened from the record?**

7.12.2. ALCOA+ Principles

Where data integrity is particularly important, organisations may apply the **ALCOA+** principles.
Records and data should be:

- **A – Attributable** Who performed or recorded the activity?
- **L – Legible** Can the information be read and understood?
- **C – Contemporaneous** Was it recorded at the appropriate time?
- **O – Original** Is it the original record or an appropriately controlled true copy?
- **A – Accurate** Does it correctly represent what occurred?

The "+" commonly extends these principles to: **Complete – Consistent – Enduring – Available**
ALCOA+ originated particularly in regulated data-integrity environments but provides useful principles for quality records more generally.

7.12.3. Correcting Records

Mistakes in records sometimes occur. Corrections should preserve the integrity of the original information.
For paper records, a typical controlled correction is to:

1. place a single line through the incorrect entry so it remains readable;

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2. enter the correct information;
3. identify the person making the correction;
4. date the correction where required;
5. provide a reason where appropriate.

Correction fluid, erasing or otherwise concealing the original information is generally poor practice for controlled quality records.

Electronic systems should provide appropriate controls such as:

- user identification;
- access permissions;
- timestamps;
- version histories;
- audit trails.

A correction should correct history, not rewrite it.

7.12.4. Electronic Records and Digital Systems

Modern QMSs increasingly rely on electronic records held within:

- ERP systems;
- electronic QMS platforms;
- databases;
- cloud platforms;
- manufacturing execution systems;
- laboratory systems;
- document-management systems;
- inspection software.

Electronic records require controls for:

Access – Security – Integrity – Availability – Backup – Recovery – Traceability

Important considerations include:

- unique user accounts;
- role-based permissions;
- change histories;
- audit trails;
- backup arrangements;
- cybersecurity;
- system validation where required;
- protection against unauthorised deletion or modification;
- long-term readability.

Moving from paper to digital records does not remove document-control responsibilities—it changes how those controls are implemented.

7.12.5. Signatures and Approvals

A signature or electronic approval represents an accountable action. Personnel should understand exactly what their approval signifies. For example, a signature may indicate:

- work performed;
- inspection completed;
- technical review completed;
- product accepted;
- document approved;

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- concession authorised.

Individuals should never sign or approve work they have not performed or appropriately verified. Electronic signatures should provide suitable assurance of identity, authority and traceability.

7.12.6. Record Retention

Not every record needs to be retained forever.
Retention requirements may originate from:

- legislation;
- regulation;
- customer contracts;
- industry standards;
- product lifecycle requirements;
- organisational policies;
- warranty periods;
- safety requirements.

A retention schedule may define:

Record Type	Owner	Storage Location	Retention	Disposal
Inspection Records	Quality	eQMS	Defined period	Controlled deletion
Training Records	HR / Function	HR System	Defined period	Controlled deletion
Calibration Records	Metrology	Calibration System	Defined period	Archive/Delete
Audit Records	Quality	eQMS	Defined period	Controlled deletion

Retention periods should be based on applicable requirements and business need rather than arbitrary convenience.

7.12.7. Storage, Preservation and Retrieval

Records must remain usable throughout their required retention period.
Consider:

- environmental damage;
- fire or flooding;
- electronic corruption;
- obsolete software or file formats;
- cybersecurity incidents;
- hardware failure;
- accidental deletion;
- unauthorised access;
- physical deterioration.

Long retention periods require consideration of **future readability** as well as simple storage. A file successfully stored for 30 years has little value if the organisation no longer has software capable of opening it.

7.12.8. Confidentiality and Information Security

Not all documented information should be freely accessible. Information may contain:

- personal data;
- intellectual property;
- customer information;
- defence or security information;
- commercially sensitive information;
- export-controlled information.

Access should therefore be based upon legitimate need and applicable legal, contractual and security requirements. Document control and information security should work together rather than operate as unrelated systems.

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7.12.9. Objective Evidence

Auditing and assurance depend heavily on objective evidence. Strong evidence might include:

Requirement → Instruction → Activity → Record → Result

For example:

Drawing requirement → Inspection instruction → Measurement performed → Inspection record → Conforming result

The existence of a procedure alone does not prove that a process is effective.
Likewise: **"We always do it that way" is not objective evidence.**

Records should support conclusions with verifiable facts.

7.13. Common Documentation Weaknesses

Common problems include:

- obsolete documents available at the point of use;
- uncontrolled local copies;
- duplicate procedures containing conflicting requirements;
- unclear revision status;
- undocumented process changes;
- incomplete records;
- missing signatures or approvals;
- retrospective completion of records;
- unexplained alterations;
- excessive reliance on spreadsheets without appropriate control;
- external standards not monitored for revision;
- records that cannot be retrieved;
- excessive documentation adding little value;
- undocumented "tribal knowledge";
- electronic systems with inappropriate access permissions;
- records retained without defined retention requirements.

Both **under-documentation and over-documentation** can create risk.

7.14. Document What Matters

An effective QMS does not measure maturity by the number of procedures it contains. Documentation should be proportionate to factors such as:

- process complexity;
- organisational size;
- competence of personnel;
- product and service risk;
- regulatory requirements;
- customer requirements;
- consequences of failure.

Where a simple visual instruction is sufficient, a twenty-page procedure may add no value. Where an activity is safety-critical or highly complex, detailed instructions and comprehensive records may be essential.

The objective is: **Enough control to achieve consistent, reliable and demonstrable results—without unnecessary bureaucracy.**

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7.15. Auditing Documented Information

When auditing documented information, do not simply ask whether a procedure exists. Follow the information through the process. Ask:

- Is the document required?
- Is the current revision being used?
- Was it appropriately reviewed and approved?
- Do users understand it?
- Does actual practice match the documented process?
- Are resulting records complete and traceable?
- Can records be retrieved?
- Are changes controlled?
- Are obsolete versions prevented from unintended use?
- Are external documents controlled?
- Are retention requirements defined?
- Are electronic records appropriately protected?

A particularly effective technique is **vertical traceability**: select an actual product, transaction or activity and trace its requirements, instructions, approvals and records through the system.

7.16. Good Practice

An effective documented-information system should ensure:

1. **People can find the information they need.**
2. **The correct information is available at the point of use.**
3. **Users can identify the current revision.**
4. **Documents are reviewed and approved by competent authorities.**
5. **Changes are controlled and communicated.**
6. **Obsolete information is prevented from unintended use.**
7. **External requirements are identified and maintained.**
8. **Records provide reliable objective evidence.**
9. **Records remain identifiable, legible and retrievable.**
10. **Electronic information is protected against inappropriate alteration or loss.**
11. **Retention and disposal requirements are defined.**
12. **Documentation remains proportionate to process and product risk.**

7.17. Key Principle

The right information, in the right place, at the right revision, for the right people—and reliable evidence that the required activities were actually performed.

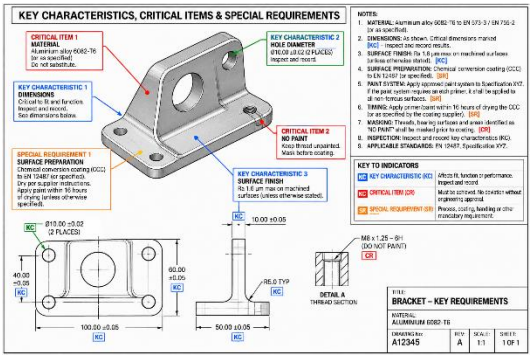
Effective document control is therefore not simply administrative control. It protects **organisational knowledge, traceability, product integrity and confidence in the evidence upon which quality decisions are made**.

8. Key Characteristics, Critical Items & Special Requirements

8.1. Introduction

Not every product requirement carries the same level of risk. Some requirements demand increased attention because variation, failure or loss of control could significantly affect:

- product safety;
- performance;
- fit, form or function;
- reliability;
- producibility;
- service life;
- regulatory compliance;
- customer requirements.



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Within aerospace and defence quality management, three important concepts are commonly used to identify and manage these higher-risk requirements:

Special Requirements → Critical Items → Key Characteristics

Although related, these terms should not be used interchangeably. A useful principle is: **Identify what matters most, understand why it matters, and apply controls proportionate to the consequence and variability involved.**

8.2. The Relationship Between the Three Concepts

The concepts can be understood broadly as:

Special Requirements: Requirements that have a **high risk of not being achieved** and therefore require consideration within operational risk management.

↓

Critical Items: Items, characteristics, functions or conditions having a **significant effect upon product realisation or use**, requiring specific actions to ensure risks are adequately managed.

↓

Key Characteristics: Attributes or features whose **variation has a significant effect** on product fit, performance, service life or producibility and therefore require specific actions to control variation.

The relationship is not simply a mandatory one-way sequence. A requirement or item may be identified through customer requirements, design analysis, operational experience, risk assessment or other technical activities. The important principle is that identification should lead to **appropriate management action**.

8.2.1. Special Requirements

A **Special Requirement** is a requirement identified as having a high risk of not being achieved and therefore requiring inclusion within the organisation's operational risk management activities. Special Requirements may originate from:

- customer requirements;
- product complexity;
- technical limitations;
- demanding performance requirements;
- new technology;
- challenging tolerances;
- unusual materials;
- manufacturing capability;
- supplier capability;
- short or demanding schedules;
- previous experience.

The defining consideration is not simply that the requirement is important, but that there is **significant risk associated with achieving it**.

8.2.1.1. Examples of Special Requirements

Examples might include:

- a dimensional tolerance close to the demonstrated capability of the manufacturing process;
- a performance requirement requiring new technology;
- an unusually demanding material property;
- a requirement dependent upon a limited supplier capability;
- a demanding delivery requirement requiring unusually short production lead time;
- a requirement involving an immature manufacturing process.

Special Requirements may therefore be **technical, operational or programme-related**, depending upon the context. Identification should occur sufficiently early to allow the organisation to plan appropriate controls.

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8.2.2. Critical Items

A **Critical Item** is an item, function, part, software element, characteristic, process or other feature having a significant effect on product realisation or use that requires specific actions to ensure the associated risks are adequately managed. Critical Items may include items affecting:

- safety;
- performance;
- reliability;
- maintainability;
- function;
- producibility;
- service life.

Examples can include:

- safety-critical components;
- fracture-critical items;
- mission-critical components;
- life-limited parts;
- critical software functions;
- critical characteristics;
- hazardous materials or processes;
- items whose failure could produce significant consequences.

The term **Critical Item** is therefore broader than a single dimensional or physical characteristic.

8.2.2.1. Critical Does Not Mean "Important"

Almost every product feature can be described as important. The term **Critical Item** should be reserved for items requiring enhanced management because of the significance of the associated consequences or risks. If everything is classified as critical: **Nothing is effectively prioritised as critical.** Over-classification can result in:

- unnecessary controls;
- excessive inspection;
- administrative burden;
- diluted attention;
- increased cost;
- difficulty identifying genuinely significant risks.

Classification should therefore be based on defined technical and risk criteria rather than personal preference.

8.2.3. Key Characteristics

A **Key Characteristic (KC)** is an attribute or feature whose variation has a significant effect on:

- product fit;
- performance;
- service life;
- producibility;

and therefore, requires specific actions for the purpose of controlling variation. The important word is: **Variation** A Key Characteristic is not merely an important dimension or requirement. It is one where **variation needs to be actively understood and controlled** because of its effect on the product or its manufacture.

8.2.3.1. Examples of Key Characteristics

Depending upon the product, Key Characteristics might include:

- a critical bore diameter;
- positional accuracy;
- surface finish;
- coating thickness;

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- bond-line thickness;
- material hardness;
- torque;
- electrical resistance;
- process temperature;
- chemical concentration;
- alignment;
- mass or balance.

A KC may relate to the **product** or to a **process parameter** where controlling that parameter is necessary to manage product variation.

8.3. Product and Process Key Characteristics

It is useful to distinguish between:

8.3.1. Product Key Characteristic

A measurable feature of the resulting product. Examples:

- diameter;
- thickness;
- hardness;
- resistance;
- surface finish.

8.3.2. Process Key Characteristic

A process parameter whose variation significantly influences the resulting product. Examples:

- furnace temperature;
- cure time;
- plating current density;
- chemical concentration;
- welding parameter.

Understanding the relationship between product and process characteristics helps organisations move from simply inspecting the output towards controlling the process that creates it.

8.4. Key Characteristics and Critical Items

A Key Characteristic may be associated with a Critical Item, but the terms are not synonymous.
For example: A flight-critical component may be classified as a **Critical Item**.

Several dimensions or material properties on that component may then be identified as **Key Characteristics** because their variation significantly influences its performance.

Therefore: **Critical Item = What requires enhanced risk management**
while: **Key Characteristic = What variation requires enhanced control**

This distinction is important when developing appropriate assurance and control strategies.

8.5. Identification

Special Requirements, Critical Items and Key Characteristics may be identified through several routes, including:

- customer designation;
- contractual requirements;
- engineering analysis;
- product safety assessment;
- design activity;
- risk assessment;
- failure analysis;
- manufacturing experience;

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- supplier experience;
- service history;
- lessons learned.

Identification should involve the appropriate technical disciplines rather than being left solely to the Quality function. Depending upon the product, this may involve:

Design + Manufacturing Engineering + Quality + Safety + Reliability + Supply Chain + Customer

8.6. Customer-Designated Characteristics

Customers may identify characteristics or items using:

- symbols;
- drawing notes;
- specifications;
- contractual requirements;
- digital product definitions;
- technical data.

These designations should be understood and appropriately flowed into the organisation's planning and control arrangements. Organisations may also identify additional characteristics internally where their own analysis identifies significant risk.

Internal identification should not remove or downgrade a customer designation without appropriate authority.

8.7. Identification on Technical Information

Where required, special characteristics may be identified on controlled technical information using defined symbols or notation. The organisation should ensure that:

- symbols are clearly defined;
- users understand their meaning;
- designations are consistently applied;
- downstream processes recognise them;
- applicable requirements reach suppliers;
- changes remain controlled.

A symbol on a drawing has little value if manufacturing, inspection or suppliers do not understand what additional action it requires.

8.7.1. Flow-Down

Identification must survive the complete product-realisation chain. For example:

Design Requirement → Drawing/Specification → Manufacturing Planning → Supplier Requirement → Process Control → Verification → Evidence

A common failure occurs when the characteristic is correctly identified at design level but loses its designation or associated controls when translated into:

- manufacturing instructions;
- purchase orders;
- supplier drawings;
- inspection plans;
- sub-tier requirements.

Where applicable, the requirement should therefore be flowed through the supply chain to the organisation actually controlling the characteristic.

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8.8. Control of Key Characteristics

Identification of a KC should lead to a defined **variation-management strategy**. Depending upon the characteristic and process, controls may include:

- process capability assessment;
- statistical monitoring;
- defined process parameters;
- increased verification;
- automated measurement;
- mistake-proofing;
- tooling controls;
- measurement-system evaluation;
- reaction plans;
- supplier controls.

The objective is not automatically to inspect every KC 100%. The objective is to establish **effective control of variation appropriate to the risk and process capability**.

8.8.1. Process Capability

Where a KC is produced by a measurable process, process capability can provide important evidence of how consistently the process operates relative to requirements. A capable process provides greater confidence that the characteristic will remain within requirements. An incapable or unstable process may require:

- investigation;
- increased monitoring;
- process improvement;
- additional controls;
- alternative manufacturing methods.

Capability indices such as **Cp and Cpk** can support this assessment where statistically appropriate, but should not be used without understanding process stability, data distribution and measurement capability. Detailed statistical methods should be selected according to the nature of the process and data.

8.8.2. Control Plans

Key Characteristics should be connected to operational controls rather than existing only on engineering drawings. A control strategy may identify:

Characteristic	Requirement	Process	Control Method	Frequency	Reaction
Bore Diameter	Drawing requirement	Machining	SPC / Measurement	Defined frequency	Stop and investigate
Coating Thickness	Specification	Plating	Process + thickness verification	Defined plan	Hold affected batch
Torque	Assembly requirement	Assembly	Controlled torque system	Each assembly	Prevent release

This provides a direct link between technical significance and operational control.

8.8.3. Reaction Plans

A control is incomplete if personnel do not know what to do when the characteristic begins to behave unexpectedly. A reaction plan should define appropriate action when:

- control limits are exceeded;
- adverse trends occur;
- process capability deteriorates;
- measurement indicates nonconformity;
- process parameters leave approved limits.

Actions may include:

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Stop → Contain → Identify Affected Product → Investigate → Restore Control → Verify → Resume

The response should consider product produced since the process was last known to be under appropriate control.

8.8.4. Measurement System

A Key Characteristic cannot be effectively controlled if the measurement system is incapable of reliably distinguishing acceptable variation from measurement error. Consider:

- measurement resolution;
- accuracy;
- repeatability;
- reproducibility;
- environmental effects;
- fixture influence;
- operator influence;
- measurement uncertainty where applicable.

The measurement strategy should be suitable for the tolerance and the decision being made. More measurement does not compensate for a poor measurement system.

8.8.5. Special Processes and Key Characteristics

Key Characteristics can exist within special processes, but the concepts should not be confused. A **special process** is characterised by limitations in verifying the resulting output fully through subsequent monitoring or measurement.

A **Key Characteristic** concerns significant variation. A special process may therefore contain important process parameters requiring enhanced control, but: **A Key Characteristic is not automatically a special process, and a special process is not automatically a Key Characteristic.**

Where the two interact, process qualification and parameter control can become particularly important.

8.8.6. First Article Inspection

First Article Inspection can provide evidence that identified product characteristics have been realised correctly using the planned production processes. However: **First Article conformity does not demonstrate continuing process control.**

A process may produce a conforming first article and later drift. For Key Characteristics, continuing control should therefore be based upon the appropriate ongoing process and variation-management strategy rather than reliance on initial verification alone.

8.8.7. Supply Chain Management

Suppliers may manufacture some of the most important characteristics within a product. Supplier controls should therefore consider:

- clear identification of applicable characteristics;
- technical understanding;
- appropriate process capability;
- suitable measurement systems;
- control methods;
- change notification;
- sub-tier flow-down;
- performance evidence.

Where significant characteristics are produced several tiers down the supply chain, effective control requires visibility beyond the immediate supplier where contractually and practically appropriate.

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8.9. Changes Affecting Critical Items and Key Characteristics

Changes involving significant items or characteristics require careful consideration. Examples include changes to:

- design;
- material;
- manufacturing source;
- manufacturing method;
- tooling;
- equipment;
- process parameters;
- inspection method;
- production location.

A change that appears minor may alter variation or introduce a new failure mechanism.
The impact on existing classifications and controls should therefore be considered as part of the change activity.

8.10. Declassification

Critical or key designation should not necessarily remain forever if evidence demonstrates that the original risk no longer exists or has fundamentally changed. However, removal should be controlled and technically justified. Questions may include:

- Why was the designation originally applied?
- What has changed?
- Is the underlying risk genuinely removed?
- Is sufficient evidence available?
- Does the customer control the designation?
- Is formal approval required?

A designation should never be removed simply because it creates additional work.

8.11. Evidence of Effective Control

An auditor or assurance professional examining a Key Characteristic should be able to follow a logical chain:

Identification → Requirement → Flow-Down → Process → Control → Measurement → Reaction → Evidence

Useful questions include:

- Why is this characteristic designated?
- Where is the requirement defined?
- How is it controlled?
- How is variation monitored?
- Is the measurement system suitable?
- What happens when control is lost?
- Are suppliers aware of the requirement?
- Is there evidence the control is effective?

The presence of a KC symbol alone demonstrates identification, not effective control.

8.12. Common Weaknesses

Common weaknesses include:

- treating Special Requirements, Critical Items and Key Characteristics as interchangeable;
- marking excessive numbers of characteristics as critical;
- failing to understand why a characteristic was designated;
- customer-designated characteristics not flowed into production;
- loss of requirements through supplier tiers;
- relying solely on final inspection;
- 100% inspection used as a substitute for process control;

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- KC symbols without defined control methods;
- no reaction plan for loss of control;
- unsuitable measurement systems;
- process capability calculated without confirming stability;
- assuming First Article acceptance demonstrates continuing capability;
- changes introduced without reassessing significant characteristics;
- designations retained indefinitely without review.

8.13. Good Practice

An effective organisation should seek to:

1. Clearly distinguish Special Requirements, Critical Items and Key Characteristics.
2. Identify them using appropriate technical and risk-based methods.
3. Understand why each designation exists.
4. Avoid unnecessary over-classification.
5. Ensure customer designations are correctly understood.
6. Maintain identification throughout product realisation.
7. Flow applicable requirements through the supply chain.
8. Connect Key Characteristics to defined process controls.
9. Focus on controlling variation rather than simply increasing inspection.
10. Ensure measurement systems are suitable for the required decisions.
11. Establish appropriate reaction plans.
12. Consider process capability where statistically appropriate.
13. Reassess controls following significant change.
14. Maintain objective evidence that the required controls are effective.

8.14. Key Principle

Identification is only the beginning: a Critical Item or Key Characteristic creates value only when its significance is understood and translated into effective controls.

The objective is not to place more symbols on drawings or generate additional inspection. It is to ensure that the **requirements and characteristics most capable of affecting product performance, safety, service life or producibility receive the level of attention necessary to manage their risk and variation throughout the product lifecycle**.

9. Quality Planning, Assurance, Control & Improvement

9.1. Introduction

Quality management is not simply inspection or the correction of problems. Effective organisations establish a coordinated approach that considers quality throughout the lifecycle of a product, service, process, project or contract. Four closely related activities provide a useful framework:

Quality Planning → Quality Assurance → Quality Control → Quality Improvement

Each performs a different function:

Activity	Fundamental Question	Primary Purpose
Quality Planning (QP)	What must be achieved and how will it be achieved?	Establish the arrangements necessary to achieve quality
Quality Assurance (QA)	How do we know those arrangements are suitable and effective?	Provide confidence that requirements will be fulfilled
Quality Control (QC)	Does the actual output meet requirements?	Determine and control conformity
Quality Improvement (QI)	How can performance become better?	Increase capability, effectiveness and efficiency

These activities should operate as an integrated system.

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Plan quality into the work, assure the arrangements, control the results and use what is learned to improve.

9.2. Quality Planning

Quality planning determines how applicable requirements will be achieved. It converts customer, contractual, technical, statutory, regulatory and organisational requirements into practical arrangements for delivering conforming outputs. Quality planning should answer questions such as:

- What must be achieved?
- What constitutes acceptance?
- Which activities influence conformity?
- What could prevent successful delivery?
- What controls are necessary?
- What verification or validation is required?
- Which resources and capabilities are required?
- What evidence will demonstrate conformity?
- Who is responsible for the activities?
- What needs to be controlled within the supply chain?

The planning effort should be proportionate to the **complexity, novelty, risk and consequence of failure** associated with the activity. A useful planning sequence is:

Requirements → Risks → Processes → Controls → Verification → Acceptance → Evidence

9.2.1. Planning Quality into the Lifecycle

Quality planning should begin early enough to influence decisions rather than being introduced after the product or process has already been established. Depending upon the application, planning may consider:

Requirements → Design → Procurement → Industrialisation → Manufacture/Service Delivery → Verification → Acceptance → Delivery → In-Service Support

Typical planning activities may include:

- requirement and contract review;
- identification of acceptance criteria;
- product and process risk assessment;
- identification of critical or key characteristics;
- manufacturing and process planning;
- supplier quality arrangements;
- inspection and test planning;
- verification and validation planning;
- First Article Inspection requirements;
- measurement strategy;
- sampling arrangements;
- process qualification;
- special process controls;
- configuration controls;
- traceability requirements;
- release arrangements;
- quality gates and review points.

Not every control is necessary for every activity. Controls should be selected because they manage a requirement or risk, not simply because they have historically been used.

9.2.2. Prevention and Detection

Effective quality planning seeks to prevent failure wherever practical rather than relying solely on detection. There is an important distinction between asking:

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"How will we detect defective output?" and **"How can we prevent the defect from being created?"**

Preventive controls may include:

- process design;
- mistake-proofing;
- automated interlocks;
- tooling controls;
- parameter limits;
- qualified processes;
- standardised methods;
- capable equipment;
- supplier development.

Detection remains necessary where appropriate, but inspection should normally form part of a wider control strategy rather than being the primary method of creating quality.

9.2.3. Quality Plans

A **Quality Plan (QP)** defines how quality requirements will be addressed for a specific product, service, project, process or contract. The organisation's QMS establishes the overall management framework. A Quality Plan applies that framework to a **specific case**.

ISO 10005, *Quality management — Guidelines for quality plans*, provides internationally recognised guidance for establishing, reviewing, accepting, applying and revising Quality Plans. It can be applied to a process, product, service, project or contract and can be used whether or not an organisation operates a management system conforming to **ISO 9001**. ISO 10005 provides guidance rather than certification requirements.

A Quality Plan should therefore not simply reproduce the Quality Manual or existing procedures.
Instead, it should explain: **How will the organisation's established management system be applied to achieve the quality requirements of this particular activity?**

9.2.4. Deliverable Quality Plans

For some contracts, particularly within defence and other highly controlled sectors, the Quality Plan may itself be a **contractual deliverable**. This is commonly referred to as a **Deliverable Quality Plan (DQP)**.

A DQP provides a contract-specific description of how the supplier intends to manage, control, assure and demonstrate conformity of the contractual deliverables. It creates the bridge between:

Contract → QMS → Project/Programme → Product/Service → Controls → Evidence

NATO procurement examples explicitly require project-specific Quality Plans rather than simply requesting a copy of the supplier's Quality Manual.

9.2.5. AQAP 2105 – NATO Requirements for Quality Plans

AQAP 2105 – NATO Requirements for Quality Plans is particularly important where NATO quality assurance requirements are contractually invoked.

AQAP 2105 establishes requirements for the preparation of contract-specific Quality Plans and is commonly used alongside other applicable Allied Quality Assurance Publications. Where AQAP 2105 is invoked contractually, the supplier should determine the exact contractual requirements, applicable AQAP edition and any customer-specific requirements.

The fundamental objective is that the Quality Plan demonstrates how the supplier will apply appropriate quality arrangements to satisfy the particular contract.

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NATO procurement documentation demonstrates AQAP 2105 being invoked specifically for Quality Plans and requiring the plan to interface the particular project with the supplier's wider quality arrangements.

9.2.6. ISO 10005 and AQAP 2105

ISO 10005 and AQAP 2105 have related but different purposes.

ISO 10005	AQAP 2105
International guidance for Quality Plans	NATO requirements for Quality Plans
Applicable across industries	Primarily associated with NATO/defence contracting
Provides guidance	Establishes requirements when contractually invoked
Can apply to a process, product, service, project or contract	Focuses on contract-specific quality planning
Supports development, review, acceptance, application and revision of Quality Plans	Supports contractual and Government Quality Assurance needs
Does not itself require certification	Compliance may become a contractual obligation

ISO 10005:2018 remains the current edition and was confirmed by ISO following systematic review in 2023.

The two approaches can complement one another: ISO 10005 provides broadly applicable quality-planning guidance, while AQAP 2105 provides the defence contractual framework where invoked.

9.2.7. Typical Quality Plan Content

The exact content should be determined by the applicable contract, customer and standards rather than copied from a generic template. Depending upon the activity, a Quality Plan or DQP may address:

- scope and applicability;
- contract, project or product identification;
- applicable requirements and standards;
- quality objectives;
- organisation, responsibilities and interfaces;
- relationship with the organisational QMS;
- customer and Government Quality Assurance arrangements;
- design and development controls;
- configuration management;
- purchasing and supplier assurance;
- sub-tier control and requirement flow-down;
- production and process controls;
- special processes;
- inspection and testing;
- verification and validation;
- First Article Inspection;
- measurement and monitoring;
- identification and traceability;
- handling, preservation and delivery;
- nonconformity and concession arrangements;
- change management;
- quality performance monitoring;
- audits and surveillance;
- release and acceptance;
- required quality evidence.

The plan should reference established organisational processes where they already provide the necessary control rather than duplicating their contents.

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9.2.8. Quality Planning Matrix

For complex products or contracts, a planning or compliance matrix can make the Quality Plan significantly more useful.

Requirement	Process / Activity	Control	Responsibility	Evidence
Product characteristics	Manufacturing	Defined process controls	Operations	Production evidence
Supplier conformity	Procurement	Supplier approval / assurance	Supply Chain / Quality	Supplier assurance evidence
Product verification	Inspection & Test	Defined acceptance activities	Quality / Operations	Inspection results
Configuration	Configuration Management	Baseline and change control	Configuration	Configuration records
Final acceptance	Product Release	Completion and conformity review	Authorised Personnel	Release evidence

This approach connects each important requirement to the method used to control it and the evidence demonstrating fulfilment.

9.2.9. Quality Plan Lifecycle

A Quality Plan should be developed early enough to influence the work. A typical lifecycle is:

Requirements Review → Develop → Review → Accept/Approve → Implement → Monitor → Revise → Complete/Close

ISO 10005 specifically addresses establishing, reviewing, accepting, applying and revising Quality Plans.
A Quality Plan should therefore be treated as a **living management tool**, not simply a document produced to satisfy a contractual milestone. Review may be appropriate following significant changes to:

- contractual requirements;
- design;
- manufacturing strategy;
- supply chain;
- processes;
- acceptance arrangements;
- organisational responsibilities;
- applicable standards.

Where customer or Government approval is required, the contractual arrangements should define the appropriate submission, review and acceptance process.

9.3. Quality Assurance

Quality Assurance (QA) is concerned with providing confidence that applicable quality requirements will be fulfilled. Rather than concentrating solely on individual products, assurance examines whether the arrangements used to produce those products are **appropriate, implemented and effective**. Assurance activities may include:

- process surveillance;
- programme or project assurance;
- internal and supplier audits;
- supplier surveillance;
- production readiness reviews;
- independent verification;
- review of quality performance;
- evaluation of corrective-action effectiveness;
- oversight of qualification and validation activities.

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Quality assurance should be based on **objective evidence and risk**, rather than assumption or administrative compliance.

9.3.1. Quality Assurance and Quality Control

QA and QC are related but should not be treated as interchangeable.

Quality Assurance	Quality Control
Provides confidence	Determines conformity
Focuses primarily on systems and processes	Focuses primarily on products, services and process outputs
Evaluates whether arrangements are suitable and effective	Evaluates results against acceptance criteria
Includes audit and surveillance	Includes inspection and testing
Seeks confidence that failure is controlled	Identifies whether requirements have been achieved

An effective organisation needs both. A product passing final inspection does not automatically demonstrate that the process producing it is well controlled.

Similarly, an apparently capable process does not remove the need for appropriate product verification.

9.4. Quality Control

Quality Control (QC) uses operational techniques to determine whether defined requirements have been fulfilled. Quality control can occur throughout production or service delivery rather than only at final inspection. Typical controls include:

- incoming verification;
- in-process inspection;
- visual examination;
- dimensional inspection;
- functional testing;
- laboratory testing;
- automated inspection;
- process monitoring;
- Statistical Process Control (SPC);
- final inspection;
- acceptance testing.

Every control should have clearly understood **acceptance criteria and reaction arrangements**.

9.4.1. Acceptance Decisions

Verification normally results in one of three broad outcomes:

- **Accept** The defined requirements have been satisfied.
- **Control as Nonconforming** A requirement has not been satisfied and the affected output must enter the appropriate nonconformity process.
- **Refer** Additional technical evaluation or authorised disposition is required before a decision can be made.

Inspection or production personnel should not informally change requirements or acceptance criteria to make an output acceptable.

9.4.2. Process Control

Quality control is most effective when applied to the process as well as the resulting output. Relevant process variables might include:

- temperature;
- pressure;
- time;
- concentration;

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- speed;
- torque;
- dimensions;
- environmental conditions;
- equipment condition;
- process capability.

Monitoring appropriate variables allows action to be taken when a process begins to change, potentially **before nonconforming product is produced**. This represents an important progression from defect detection towards process control.

9.4.2.1. Variation and Statistical Control

All processes contain variation. Quality professionals should understand:

- how much variation exists;
- whether the process is stable;
- whether the process is capable of meeting requirements;
- whether unusual variation indicates that something has changed.

Variation is often considered as:

- **Common-cause variation** – inherent within the current process.
- **Special-cause variation** – arising from a specific condition or event outside normal process behaviour.

Statistical Process Control can help identify patterns and signals that would be difficult to distinguish through individual measurements alone.

A stable process is not automatically a capable process: it may consistently produce results that do not satisfy the required specification.

9.4.2.2. Inspection Is Not Quality Creation

Inspection determines whether requirements have been achieved; it does not normally create conformity. Consider a process producing 10% defective output. If final inspection successfully detects every defect, the inspection activity may be effective, but the production process is still performing poorly. Quality maturity therefore moves progressively from:

Sort → Detect → Control → Prevent → Improve

The long-term objective should be to increase confidence in the processes producing the output rather than continually adding more inspection.

9.4.2.3. Escapes

An **escape** occurs when nonconforming output passes an intended control and progresses further than intended. An escape may occur:

- between manufacturing operations;
- through inspection;
- into another assembly;
- to another facility;
- to the customer;
- into service.

Investigation should distinguish between two important questions:

- **Occurrence:** Why was the nonconformity created?
- **Escape:** Why did the intended control fail to prevent or detect it?

The causes may be different and may require different actions.

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9.5. Quality Improvement

Quality Improvement (QI) increases the organisation's ability to achieve better results.
Improvement may address:

- conformity;
- process capability;
- reliability;
- variation;
- productivity;
- lead time;
- waste;
- customer satisfaction;
- supplier performance;
- cost;
- process effectiveness.

Improvement does not require an existing nonconformity. A conforming process can still be made safer, faster, simpler, more capable or more efficient.

9.5.1. Correction, Corrective Action and Improvement

These terms describe different activities.

Activity	Purpose
Correction	Deal with the immediate detected problem
Corrective Action	Eliminate or control the cause to prevent recurrence
Improvement	Achieve better performance beyond correcting the problem

For example:

- **Problem:** Incorrect component installed.
- **Correction:** Replace the component.
- **Corrective Action:** Remove the cause that allowed incorrect selection.
- **Improvement:** Introduce error-proofing so that incorrect selection or installation becomes inherently difficult or impossible.

9.5.2. Reactive and Proactive Improvement

Improvement can be reactive or proactive.

9.5.2.1. Reactive Improvement

Triggered by evidence such as:

- nonconformities;
- customer complaints;
- audit findings;
- failures;
- escapes;
- poor process performance.

9.5.2.2. Proactive Improvement

Triggered by opportunities identified through:

- trend analysis;
- process capability;
- risk assessment;
- benchmarking;
- employee suggestions;
- technological development;
- lessons learned;
- innovation.

A mature quality system should increasingly identify opportunities **before failure forces action**.

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9.5.3. Selecting an Improvement Method

Quality professionals have many improvement methods available, including:

- PDCA;
- 8D;
- Root Cause Analysis;
- Kaizen;
- DMAIC;
- Lean;
- Six Sigma;
- mistake-proofing;
- statistical analysis;
- process mapping;
- lessons learned.

The method should be proportionate to the **risk, complexity and significance of the problem or opportunity**. A complex methodology applied to every minor issue creates unnecessary bureaucracy. An informal investigation applied to a serious or systemic failure may be inadequate. The method is a means of solving the problem, not the objective itself.

9.5.4. Data-Driven Improvement

Effective improvement requires reliable information. Useful indicators might include:

- defect rates;
- first-pass yield;
- scrap and rework;
- process capability;
- supplier performance;
- customer complaints;
- escapes;
- warranty performance;
- recurring nonconformities;
- Cost of Poor Quality.

The desired progression is:

Data → Information → Understanding → Decision → Action → Improvement

A metric has limited value if it is repeatedly reported but never influences a decision.

9.5.5. Effectiveness

Quality activities should ultimately be judged by whether they achieve their intended result. For example:

- an audit that fails to identify significant known weaknesses may not be effective;
- an inspection system that repeatedly allows defects to escape is not effective control;
- a corrective action followed by recurrence has not achieved its intended outcome;
- a Quality Plan that is approved but ignored during delivery provides little assurance;
- a dashboard that produces large quantities of data but drives no decisions provides limited value.

The question should therefore move beyond: **"Did we complete the activity?"** to **"Did the activity achieve the intended result?"**

9.6. Integrating Planning, Assurance, Control and Improvement

The four elements should form a continuous management cycle.

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PLAN Define how requirements will be achieved and controlled.
↓
ASSURE Establish confidence that the planned arrangements are appropriate and effectively implemented.
↓
CONTROL Measure, monitor and verify actual conformity and process performance.
↓
IMPROVE Use performance, failures and opportunities to strengthen the system.
↓
FEED LEARNING BACK INTO PLANNING This final step is critical.

Lessons from production, suppliers, audits, nonconformities, customers and improvement activities should influence future Quality Plans, controls and projects.

Without this feedback loop, organisations repeatedly solve the same problems.

9.6.1. Common Weaknesses

Common weaknesses include:

- quality planning beginning after important decisions have already been made;
- Quality Plans repeating generic QMS procedures rather than addressing the specific project or contract;
- Quality Plans being produced for approval but not subsequently used;
- unclear links between requirements, controls and evidence;
- inadequate flow-down to suppliers;
- excessive reliance on final inspection;
- confusing QA with QC;
- controls that are not proportionate to risk;
- unclear acceptance criteria;
- increasing inspection instead of improving an incapable process;
- repeatedly correcting defects without eliminating their causes;
- corrective actions closed without confirming effectiveness;
- collecting performance data without acting upon it;
- failure to incorporate lessons learned into future planning.

9.6.2. Good Practice

An effective organisation should seek to:

1. Understand applicable requirements before work begins.
2. Translate important requirements and risks into appropriate controls.
3. Develop Quality Plans early enough to influence delivery.
4. Apply ISO 10005 guidance where appropriate and AQAP 2105 requirements where contractually invoked.
5. Ensure Deliverable Quality Plans are specific to the contract rather than copies of the QMS.
6. Clearly connect requirements, controls, responsibilities and evidence.
7. Flow applicable quality requirements through the supply chain.
8. Prioritise prevention over reliance on detection.
9. Use assurance to evaluate whether planned arrangements are effective.
10. Use appropriate controls to demonstrate conformity.
11. Investigate both the occurrence and escape of significant defects.
12. Use reliable data to identify trends and opportunities.
13. Confirm that corrective actions and improvements achieve their intended results.
14. Feed lessons learned back into future quality planning.

9.7. Key Principle

Quality should be planned before work begins, assured through effective processes, controlled through objective evidence and continually strengthened through learning and improvement.

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The strongest quality systems therefore do not rely on inspection to protect the customer. They progressively move from **detecting failure to controlling processes, preventing problems and continually improving the systems that create the product or service**.

10. Cost of Quality

10.1. Introduction

Cost of Quality (CoQ) is the financial impact associated with achieving required quality and dealing with the consequences when quality is not achieved. Despite its name, Cost of Quality does not mean simply **"the cost of the Quality Department."** It considers costs across the organisation arising from prevention, assurance, verification, failure and recovery.

A useful distinction is:

Cost of Quality = Cost of Conformance + Cost of Nonconformance

Understanding these costs allows an organisation to translate quality performance into a language understood throughout the business: **time, capacity, risk and money**.

The purpose of CoQ is not merely to calculate what poor quality costs. Its value comes from identifying where resources are being consumed and where investment can prevent larger losses.

10.2. Why Measure Cost of Quality?

Traditional quality metrics such as defect rates, scrap percentages and nonconformity counts are important, but they do not always demonstrate the business impact of poor performance. For example, ten minor defects may cost less than one significant customer escape.

CoQ helps organisations:

- quantify the financial impact of quality performance;
- identify hidden operational losses;
- prioritise improvement opportunities;
- justify preventive investment;
- evaluate recurring problems;
- compare the economic impact of different failure modes;
- understand supplier quality impact;
- assess trends over time;
- support management decisions.

It creates a connection between:

Quality Performance → Operational Impact → Financial Impact → Business Decision

10.3. The PAF Model

The most widely recognised approach divides quality costs into four categories:

Prevention – Appraisal – Internal Failure – External Failure

This is commonly known as the **PAF model**. These categories can also be grouped into:

10.3.1. Cost of Conformance

Money spent deliberately to achieve and demonstrate conformity. **Prevention + Appraisal**

10.3.2. Cost of Nonconformance

Money lost because requirements were not achieved. **Internal Failure + External Failure**

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The objective is not necessarily to minimise every category independently. Appropriate investment in prevention can substantially reduce much larger failure costs.

10.4. Prevention Costs

Prevention costs are incurred to prevent defects, failures and nonconformities from occurring. Examples may include:

- quality planning;
- process development;
- preventive quality activities;
- supplier development;
- process capability improvement;
- mistake-proofing;
- preventive maintenance related to quality risk;
- quality-related training;
- reliability activities;
- preventive improvement projects;
- development of effective process controls.

Prevention costs should generally be regarded as **investment in reducing future failure**, rather than simply overhead. The important question is whether the preventive activity creates sufficient value relative to the risk or cost it addresses.

10.5. Appraisal Costs

Appraisal costs arise from determining whether products, services or processes meet requirements. Examples include:

- receiving inspection;
- in-process inspection;
- final inspection;
- product testing;
- laboratory testing;
- verification activities;
- product audits;
- supplier surveillance;
- calibration associated with verification;
- acceptance testing.

Appraisal provides confidence and evidence but does not normally remove the cause of failure. An organisation heavily dependent upon inspection may therefore have high appraisal costs while still experiencing significant failure costs.

The long-term objective should be to establish sufficiently capable and controlled processes that verification effort can be **risk-based rather than excessive**.

10.6. Internal Failure Costs

Internal failure costs arise when a problem is identified before the product or service reaches the external customer. Examples include:

- scrap;
- rework;
- repair;
- retesting;
- re-inspections;
- rejected material;
- sorting activities;
- production disruption;
- unplanned investigation;

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- repeat processing;
- additional material;
- concession processing;
- engineering support caused by failure;
- downtime resulting from quality problems.

An internal defect may never reach the customer but can still consume substantial organisational resources. For this reason, simply measuring customer complaints provides an incomplete picture of quality performance.

10.7. External Failure Costs

External failure costs arise when a quality problem is discovered after the product or service has been released externally. Examples include:

- customer returns;
- warranty claims;
- field repair;
- replacement products;
- customer containment;
- sorting at customer premises;
- complaint investigation;
- recall activity;
- expedited replacement delivery;
- contractual penalties;
- additional customer assurance;
- field service;
- investigation of customer escapes.

External failures are often significantly more expensive than identifying the same defect internally because additional organisations, logistics and customer activities become involved. They may also generate consequences that are difficult to quantify financially.

10.8. The Escalating Cost of Failure

A defect generally becomes more disruptive as it progresses through the lifecycle. For example:

Prevent → Detect During Process → Detect at Final Inspection → Detect at Customer → Detect in Service

The exact cost relationship varies considerably by product and industry, so simplistic rules such as *"a defect costs ten times more at every stage"* should not be treated as universal facts.

The underlying principle, however, is important: **The later a problem is discovered, the more activities may need to be repeated, corrected, investigated or recovered.**

This is one reason early prevention and effective process control are economically valuable.

10.9. Cost of Poor Quality

Cost of Poor Quality (COPQ) generally focuses on the costs associated with failure and inefficiency resulting from inadequate quality. It commonly includes: **Internal Failure + External Failure**

Depending on the organisation's methodology, COPQ may also include other avoidable losses caused by ineffective processes. Examples include:

- scrap;
- rework;
- returns;
- repeated inspections;
- avoidable downtime;
- complaint handling;

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- failure investigation;
- supplier disruption;
- warranty;
- customer recovery.

The organisation should clearly define what is included in its COPQ measure so that trends and comparisons remain meaningful.

10.10. Visible and Hidden Quality Costs

Some quality costs are easy to identify. Others remain buried within normal departmental budgets.

10.10.1. Visible Costs

Typically easier to measure:

- scrapped material;
- warranty payments;
- replacement components;
- external sorting;
- freight;
- rework labour.

10.10.2. Hidden Costs

Often more difficult to identify:

- engineering investigation time;
- management meetings;
- production rescheduling;
- purchasing effort;
- supplier management;
- planning disruption;
- administrative processing;
- repeated approvals;
- lost capacity;
- delayed deliveries;
- additional inspections;
- customer relationship management.

Consequently, the value recorded against an NCR may represent only a fraction of the actual business cost.

10.11. The Quality Cost Iceberg

The **quality cost iceberg** is a useful way of illustrating this problem. Above the waterline are visible costs such as:

Scrap – Rework – Returns – Warranty

Below the waterline may be considerably more difficult-to-measure consequences such as:

Lost Capacity – Investigation – Delays – Expediting – Management Time – Supplier Disruption – Customer Recovery – Reputation

The iceberg is a conceptual model rather than a financial formula. Its purpose is to remind organisations that easily measured costs are not necessarily the largest or most important consequences of poor quality.

10.12. Direct and Indirect Costs

Another useful distinction is between **direct** and **indirect** costs.

10.12.1. Direct Costs

Can be reasonably attributed to a specific quality event. For example:

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- £2,000 scrapped material;
- 12 hours of rework;
- £500 laboratory retest;
- £800 replacement shipment.

10.12.2. Indirect Costs

Result from the event but are more difficult to attribute precisely. For example:

- disrupted production schedules;
- management attention;
- reduced available capacity;
- delayed programmes;
- additional supplier oversight.

Both matter, but organisations should avoid creating complex calculations that give a false impression of financial precision.

10.13. Opportunity Cost

Poor quality can consume resources that could otherwise create value. This is **opportunity cost**. If a production line spends 40 hours reworking defective product, the loss is not only the labour cost of the rework.

Those 40 hours could potentially have been used to produce conforming product.

Similarly, engineering resources repeatedly investigating preventable problems cannot spend that time developing products or improving processes. Opportunity cost can therefore reveal a business impact that traditional scrap calculations miss.

10.14. Intangible Costs

Some consequences of poor quality cannot be reliably converted into money. Examples include:

- loss of customer confidence;
- reputational damage;
- employee frustration;
- reduced supplier relationships;
- reduced likelihood of repeat business;
- management distraction;
- damage to organisational credibility.

These should not be ignored simply because they cannot be precisely quantified. Where financial measurement is unreliable, they may be better represented through appropriate risk, customer or performance indicators rather than invented monetary values.

10.15. Calculating the Cost of a Quality Event

A practical calculation should consider more than material value. For example:

COPQ Event Cost = Material + Labour + Inspection/Test + Engineering + Investigation + Logistics + Supplier/Customer Recovery + Other Direct Costs

Where appropriate, organisations may additionally evaluate downtime, lost capacity and other indirect consequences.

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10.15.1. Example

A batch failure results in: Recording only the £4,000 scrap value would significantly understate the impact.

Cost	Amount
Scrapped material	£4,000
Rework labour	£1,600
Additional inspection	£700
Engineering investigation	£1,200
Expedited replacement freight	£900
Customer support	£600
Identified COPQ	**£9,000**

10.15.2. Labour Cost

Labour cost can be calculated using an agreed organisational rate:

Labour Cost = Hours Consumed × Applicable Labour Rate

However, the organisation should define whether the rate represents:

- direct wage cost;
- fully burdened labour cost;
- standard costing rate;
- internal charge rate.

Consistency is usually more valuable for trending than attempting to calculate a theoretically perfect cost for every event.

10.15.3. Supplier Cost of Poor Quality

Supplier quality failures can create significant internal cost even when the supplier eventually replaces the defective material. Supplier-related COPQ may include:

- incoming rejection;
- production disruption;
- line stoppage;
- sorting;
- additional inspection;
- supplier investigation;
- engineering support;
- administrative effort;
- replacement freight;
- schedule recovery;
- customer impact.

A supplier replacing a £200 component free of charge does not necessarily compensate the organisation for thousands of pounds of disruption caused by that failure. Supplier performance assessment should therefore consider **impact as well as defect count**.

10.15.4. Cost of Quality Metrics

Useful metrics may include:

- **Total CoQ** Prevention + Appraisal + Internal Failure + External Failure
- **COPQ** Internal Failure + External Failure
- **COPQ as Percentage of Sales** COPQ ÷ Sales Revenue × 100
- **COPQ as Percentage of Production Cost** COPQ ÷ Production Cost × 100
- **Failure Cost per Unit** Total Failure Cost ÷ Units Produced
- **Cost per Nonconformity** Total Failure Cost ÷ Number of Nonconformities

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However, averages should be interpreted carefully. One major customer escape may distort a period containing many low-cost defects.

10.15.5. Analyse Cost, Not Just Count

Nonconformity counts alone can be misleading. Consider:

Problem	Quantity	Cost per Event	Total Impact
Minor cosmetic defect	100	£10	£1,000
Assembly failure	10	£600	£6,000
Customer escape	1	£40,000	£40,000

A Pareto chart based purely on occurrence count would prioritise the cosmetic defect. A cost-based analysis would identify the customer escape as the greatest financial impact. Both views can be useful because **frequency, severity and cost answer different questions**.

10.15.6. Trend Analysis

A single CoQ figure provides limited information. Greater value comes from monitoring trends such as:

- COPQ by month;
- internal versus external failure cost;
- supplier-related COPQ;
- COPQ by product;
- COPQ by programme;
- COPQ by process;
- COPQ by failure mode;
- prevention versus failure cost;
- recurring failure cost.

Trend analysis helps determine whether improvement activity is changing business performance rather than simply closing individual actions.

10.15.7. Pareto Analysis

Cost data is particularly useful when combined with Pareto analysis. Instead of asking:
"What defects occur most frequently?" an organisation can also ask **"Which problems cost us the most?"**

Useful Pareto analyses include:

- COPQ by failure mode;
- COPQ by supplier;
- COPQ by process;
- COPQ by product;
- COPQ by customer;
- COPQ by root-cause category.

This helps focus improvement resources where they can produce significant benefit.

10.16. The Economics of Prevention

Quality investment should be evaluated against the losses it is intended to prevent. Suppose an organisation experience recurring annual failure costs of £120,000. A £25,000 process improvement that reliably reduces those failures by £80,000 per year may provide a strong business case.

This can be expressed using measures such as:

Net Benefit = Expected Saving – Improvement Cost

and, where appropriate:

ROI = (Financial Benefit – Investment Cost) ÷ Investment Cost × 100

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Quality professionals should therefore be capable of presenting improvement proposals not only technically but economically.

10.17. Avoiding the Wrong Behaviour

Cost metrics can produce unintended behaviour if poorly designed. For example, pressure to reduce reported COPQ may encourage:

- under-reporting of nonconformities;
- incorrect cost allocation;
- inappropriate acceptance of marginal product;
- avoidance of necessary inspection;
- shifting costs between departments;
- focusing on cheap defects while ignoring high risks.

Cost should therefore inform decisions, not override safety, regulatory, contractual or technical requirements. A low-cost failure can still represent an unacceptable product-safety or compliance risk.

10.18. Quality Cost and Risk

Cost and risk are related but not interchangeable. A defect costing £100 may have serious safety implications. Another costing £20,000 may create significant financial loss but no safety consequence. Quality decisions should therefore consider factors such as:

Cost + Severity + Probability + Customer Impact + Compliance + Safety

CoQ provides one important decision-making perspective, not the sole basis for determining priority.

10.19. Data Quality

A Cost of Quality system is only useful if the underlying information is reasonably reliable. Common data sources include:

- ERP systems;
- NCR systems;
- scrap records;
- warranty systems;
- labour booking;
- supplier quality systems;
- customer complaints;
- finance systems;
- production records.

Organisations should establish consistent definitions so that different departments do not calculate quality costs differently. Perfect accuracy is rarely achievable, but consistent and transparent assumptions allow useful comparison and trend analysis.

10.20. Common Weaknesses

Common CoQ weaknesses include:

- treating Quality Department expenditure as the entire Cost of Quality;
- measuring only scrap;
- ignoring labour and investigation effort;
- ignoring supplier-generated internal costs;
- failing to distinguish internal and external failure;
- counting defects without considering financial impact;
- attempting to monetise intangible impacts without credible evidence;
- inconsistent costing methods;
- focusing solely on reducing appraisal costs;
- measuring COPQ without using it to drive improvement;
- hiding quality costs within general operational budgets;
- using cost as the sole measure of quality risk.

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10.21. Good Practice

An effective approach to Cost of Quality should:

1. Clearly define the organisation's CoQ and COPQ categories.
2. Capture meaningful costs without creating excessive administration.
3. Include more than material and scrap value.
4. Consider labour, disruption, investigation and recovery costs.
5. Separate internal and external failure where practical.
6. Understand supplier-generated COPQ.
7. Analyse financial impact alongside frequency and severity.
8. Trend costs over time rather than relying on isolated figures.
9. Use Pareto analysis to identify significant opportunities.
10. Use CoQ data to support investment and improvement decisions.
11. Maintain consistent costing assumptions.
12. Never allow financial measures to override safety, compliance or product integrity.

10.22. Key Principle

The cheapest defect is not the one that is efficiently repaired, it is the one that is prevented from occurring. Cost of Quality makes the consequences of quality performance visible to the wider organisation. Used effectively, it shifts the discussion from **"How much does Quality cost?"** to the more valuable question **"What is poor quality costing the organisation, and where should we invest to prevent it?"**

11. Process Approach, PDCA & Risk-Based Thinking

11.1. Introduction

Three closely connected concepts underpin effective modern quality management:

Process Approach → PDCA → Risk-Based Thinking

They provide a practical way of understanding how work is performed, how processes are managed and improved, and how uncertainty is considered when making decisions. The concepts are complementary:

- **Process Approach** identifies and manages interconnected activities as processes.
- **PDCA** provides a cycle for managing and improving those processes.
- **Risk-Based Thinking** ensures that uncertainty, potential failure and opportunity are considered when determining controls and priorities.

Together they encourage organisations to move away from managing departments and individual activities in isolation towards managing an **interconnected system of processes focused on achieving intended results**.

Understand the process, manage the interactions, consider the risks, evaluate the results and improve the system.

11.2. The Process Approach

A **process** is a set of interrelated or interacting activities that uses inputs to deliver an intended result.
A simple process model is:

Inputs → Activities → Outputs

For example:

Customer Requirement → Order Review & Production → Delivered Product

However, an effective process model considers more than the activities themselves. A process normally requires:

Inputs → Resources → Methods → Responsibilities → Controls → Activities → Outputs → Measures

Understanding these elements helps an organisation determine whether the process is capable of consistently achieving its intended results.

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11.2.1. From Departments to Processes

Organisations are commonly structured vertically into functions such as:

Sales | Engineering | Procurement | Manufacturing | Quality | Logistics | Finance

Customers, however, experience the organisation horizontally. A customer requirement may pass through several functions before becoming a delivered product or service. For example:

Customer → Sales → Engineering → Procurement → Production → Inspection → Logistics → Customer

Problems frequently occur at the **interfaces between functions**, rather than entirely within one department. The Process Approach therefore encourages organisations to ask:

How does workflow through the organisation from requirement to result? rather than only **Which department performs this activity?**

11.2.2. Process Elements

A well-defined process should normally have:

- **Purpose** Why does the process exist?
- **Inputs** What information, material or trigger starts or supports the process?
- **Activities** What work transforms the inputs?
- **Outputs** What product, service, information or decision results?
- **Customers** Who receive or depend upon the output?
- **Responsibilities** Who own and perform the process?
- **Resources** What people, equipment, infrastructure, information or technology are required?
- **Controls** What ensures the process operates as intended?
- **Measures** How is performance and effectiveness evaluated?
- **Risks and Opportunities** What could affect achievement of the intended result?

Thinking in these terms transforms a procedure from simply describing activities into understanding the **system that creates the result**.

11.2.3. SIPOC Thinking

A simple way to understand process boundaries is the **SIPOC** model:

Suppliers → Inputs → Process → Outputs → Customers

Element	Question
Suppliers	Who provides what the process needs?
Inputs	What enters the process?
Process	What activities transform the inputs?
Outputs	What does the process produce?
Customers	Who receives or relies upon the outputs?

The supplier and customer may be external or internal. For example, Engineering may be the internal supplier of technical information to Manufacturing, while Manufacturing may supply completed product to Inspection. SIPOC is particularly useful when establishing process scope and identifying important interfaces.

11.2.4. Process Ownership

Every important process should have clear ownership. A **Process Owner** is responsible for ensuring that the process is appropriately defined, managed and evaluated.

Typical responsibilities may include:

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- understanding the purpose of the process;
- defining process requirements;
- monitoring performance;
- managing interfaces;
- ensuring suitable resources and controls exist;
- addressing poor performance;
- identifying improvement opportunities.

Process ownership should not be confused with performing every activity within the process. A process may involve many departments while still having one clearly identified owner.

11.2.5. Process Interaction

Processes rarely operate independently. The output of one process often becomes the input to another:

Contract Review → Design → Procurement → Production → Verification → Delivery

A weakness upstream can therefore create problems much later. For example: An unclear customer requirement may lead to:

Incorrect Interpretation → Incorrect Design → Incorrect Procurement → Incorrect Manufacture → Nonconforming Product

The defect may eventually appear in manufacturing, but the originating weakness occurred much earlier. Effective quality management therefore considers the **whole process chain**, not simply where the problem was detected.

11.2.6. Process Effectiveness and Efficiency

Two useful but different concepts are:

- **Effectiveness - Did the process achieve its intended result?**
- **Efficiency - What resources were used to achieve that result?**

A process can be effective but inefficient. For example, 100% inspection may successfully prevent defective product reaching the customer but require excessive time and resources. Equally, a very fast process that repeatedly produces incorrect results may be efficient in activity but ineffective in outcome.

Quality management should first ensure **effectiveness**, then seek appropriate efficiency without compromising the intended result.

11.2.7. Process Measures

Processes should be monitored using measures that help determine whether intended results are being achieved. Measures may consider:

- quality;
- delivery;
- cost;
- productivity;
- reliability;
- cycle time;
- customer performance;
- process capability.

Good measures should support decisions. A useful distinction is between:

- **Leading Indicators** Provide early information about conditions that may influence future performance. Examples might include process stability, overdue maintenance or supplier deterioration.

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- **Lagging Indicators** Measure results after they have occurred. Examples might include customer complaints, scrap or delivery failure.

A balanced system uses both where appropriate.

11.3. PDCA

The **Plan–Do–Check–Act (PDCA)** cycle provides a structured approach for managing processes and improvement. It is strongly associated with the work of **Walter A. Shewhart** and was later widely promoted by **W. Edwards Deming**. The four stages are:



PDCA is not intended as a one-time sequence. It is a continuous cycle of learning and adjustment.

11.3.1. PLAN

The **Plan** stage establishes what needs to be achieved and how. Typical considerations include:

- intended results;
- requirements;
- responsibilities;
- resources;
- methods;
- risks and opportunities;
- controls;
- measures;
- acceptance criteria.

The purpose is to understand the activity sufficiently before execution. A weak Plan stage often results in problems being discovered later during implementation.

11.3.2. DO

The **Do** stage implements the planned arrangements. This may involve:

- performing the process;
- providing resources;
- applying defined controls;
- communicating requirements;
- collecting information;
- implementing a change or improvement.

For improvement activities, organisations may initially implement changes on a controlled or limited scale where appropriate before wider deployment.

11.3.3. CHECK

The **Check** stage evaluates what actually happened. Typical questions include:

- Were the intended results achieved?
- Did the process perform as expected?
- Were requirements fulfilled?
- What does the data show?
- Did unexpected consequences occur?
- Were assumptions correct?

Checking should compare **actual performance against planned expectations**. Without meaningful evaluation, PDCA can become simply **Plan–Do–Do–Do**.

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11.3.4. ACT

The **Act** stage determines what should happen as a result of the evaluation. Actions may include:

- standardising a successful change;
- adjusting controls;
- modifying the process;
- addressing identified causes;
- revising the plan;
- applying learning elsewhere;
- beginning another improvement cycle.

The important principle is that the results of checking should influence what happens next.

11.3.5. PDCA at Different Levels

PDCA can operate at several organisational levels.

11.3.5.1. Organisational Level

- **Plan:** strategy, objectives and resources
- **Do:** operate the management system
- **Check:** evaluate organisational performance
- **Act:** adjust and improve

11.3.5.2. Process Level

- **Plan:** define the process and controls
- **Do:** operate the process
- **Check:** monitor performance
- **Act:** improve or adjust the process

11.3.5.3. Improvement Level

- **Plan:** identify the problem or opportunity
- **Do:** test the proposed change
- **Check:** evaluate results
- **Act:** standardise, modify or reconsider

PDCA is therefore not simply an improvement tool. It is also a **management philosophy for controlling and learning from processes**.

11.4. Risk-Based Thinking

Risk-based thinking means considering uncertainty when planning, operating and improving processes.
It asks: **What could affect our ability to achieve the intended result?** This includes both:

- **Risks** Potential effects that could adversely affect results.
- **Opportunities** Circumstances that could produce beneficial outcomes.

Risk-based thinking does not require every decision to involve a formal risk assessment. The level of formality should be proportionate to the significance and complexity of the decision.

11.4.1. Risk Is Context Dependent

Risk cannot be understood solely by considering whether something might fail. The significance of risk depends upon factors such as:

- likelihood;
- consequence;
- detectability where relevant;
- exposure;
- complexity;
- uncertainty;
- existing controls;

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- customer impact;
- safety;
- regulatory impact.

The same failure may therefore represent very different levels of risk in different circumstances. For example, a cosmetic defect and an incorrectly assembled safety-critical component should not receive identical levels of control simply because both are technically nonconformities.

11.4.2. Risk-Based Thinking Is Not Risk Elimination

The objective is not to eliminate all risk. Doing so would often be impossible, prohibitively expensive or prevent useful activity. The objective is to:

Identify → Understand → Evaluate → Control → Monitor

Risk should be reduced to an appropriate level considering applicable requirements and the context of the activity. Some risks may be:

- avoided;
- reduced;
- shared or transferred;
- accepted under defined authority;
- monitored.

The appropriate response depends upon the nature of the risk.

11.4.3. Risk and Control

Controls should be proportionate to risk. A useful principle is:

Higher Risk → Stronger Assurance and Control while **Lower Risk → Proportionate Control**

This does not mean that low-risk activities require no control. It means resources should be directed intelligently rather than every activity receiving identical treatment. Risk can influence:

- inspection frequency;
- sampling;
- supplier surveillance;
- audit frequency;
- approval authority;
- validation requirements;
- process monitoring;
- contingency planning.

Risk-based control helps organisations focus resources where failure would matter most.

11.4.4. Inherent and Residual Risk

A useful distinction is:

- **Inherent Risk** The level of risk before considering the effectiveness of controls.
- **Residual Risk** The risk remaining after controls have been applied.

Conceptually:

Inherent Risk → Controls → Residual Risk

This distinction prevents an important risk from appearing insignificant simply because strong controls currently exist. It also highlights the importance of maintaining those controls. If the control fails or is removed, the underlying risk may return.

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11.4.5. Risk Ownership

Significant risks should have appropriate ownership. The **risk owner** should have sufficient responsibility and authority to understand and manage the risk. Ownership may include:

- monitoring the risk;
- ensuring controls are implemented;
- evaluating changes;
- escalating when necessary;
- reviewing residual risk.

A risk register containing numerous risks without meaningful ownership or action provides little value.

11.4.6. Opportunities

Risk-based thinking should not focus exclusively on negative outcomes. Opportunities may include:

- simplifying a process;
- adopting improved technology;
- reducing variation;
- developing suppliers;
- automating repetitive activity;
- removing unnecessary controls;
- improving customer experience;
- increasing process capability.

An opportunity should still be considered intelligently because changes intended to create benefit may introduce new risks.

11.4.7. Risk-Based Thinking and Change

Change creates uncertainty. Risk should therefore be considered when changes affect:

- design;
- suppliers;
- materials;
- processes;
- equipment;
- software;
- facilities;
- organisational responsibilities;
- inspection methods;
- production location.

The question should not simply be: **"Has the change been implemented?"** but **"What could this change affect, and have the consequences been understood?"**

This is particularly important where several individually minor changes interact.

11.4.8. Contingency Thinking

Some risks cannot be completely prevented. Organisations should therefore consider how they would respond if important disruptions occur. Examples include:

- loss of a critical supplier;
- equipment failure;
- loss of utilities;
- IT outage;
- shortage of specialist personnel;
- disruption to logistics;
- loss of critical infrastructure.

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Contingency planning asks: **"If prevention fails, how will we maintain or recover the required capability?"**
The level of contingency planning should reflect the potential impact of disruption.

11.5. Connecting Process Approach, PDCA and Risk

The three concepts become most useful when applied together.

PROCESS APPROACH Understand: **What are we trying to achieve and how does the workflow?**
↓
RISK-BASED THINKING Consider: **What could prevent or improve achievement of the intended result?**
↓
PLAN Define appropriate arrangements and controls.
↓
DO Operate the process.
↓
CHECK Evaluate performance and results.
↓
ACT Respond, standardise, correct or improve.
↓
REPEAT Use the learning to strengthen the process.

This creates an adaptive management system rather than a static collection of procedures.

11.5.1. Example – Purchasing Process

Consider a simplified purchasing process.

11.5.1.1. Process

Requirement → Supplier Selection → Purchase Order → Supplier Delivery → Receipt

11.5.1.2. Risks

Potential issues might include:

- incorrect requirements communicated;
- unsuitable supplier selected;
- requirements not flowed down;
- late delivery;
- nonconforming material.

11.5.1.3. Plan

Establish:

- supplier approval criteria;
- purchase requirements;
- verification arrangements;
- performance measures.

11.5.1.4. Do

Place and manage orders using the planned arrangements.

11.5.1.5. Check

Evaluate:

- conformity;
- delivery;
- supplier performance;
- emerging issues.

11.5.1.6. Act

Respond by:

- developing the supplier;

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- changing controls;
- adjusting surveillance;
- improving requirements;
- selecting alternative sources where appropriate.

The same thinking can be applied to almost any organisational process.

11.5.2. Common Weaknesses

Common weaknesses include:

- managing departments rather than end-to-end processes;
- unclear process ownership;
- poorly defined inputs and outputs;
- weak interfaces between functions;
- measures focused on activity rather than results;
- completing PDCA mechanically without learning;
- extensive planning with insufficient checking;
- identifying risks without managing them;
- risk registers that become administrative documents;
- applying identical controls regardless of risk;
- confusing risk identification with risk elimination;
- ignoring opportunities;
- failing to reconsider risk following change;
- measuring process efficiency while overlooking effectiveness.

11.5.3. Good Practice

An effective organisation should seek to:

1. Understand its important processes and how they interact.
2. Define meaningful inputs, outputs and intended results.
3. Establish clear process ownership.
4. Manage interfaces between functions.
5. Measure process effectiveness rather than activity alone.
6. Apply PDCA as a continuous management cycle.
7. Use evidence from the Check stage to influence subsequent action.
8. Consider risk before problems occur.
9. Apply controls proportionate to risk and consequence.
10. Understand both inherent and residual risk.
11. Assign meaningful ownership of significant risks.
12. Consider opportunities as well as threats.
13. Reassess risk when significant change occurs.
14. Use contingency planning where disruption could have significant consequences.
15. Feed operational learning back into the process.

11.6. Key Principle

A QMS should be managed as an interconnected system of processes, not as a collection of departments, procedures and individual quality activities.

The Process Approach explains **how work creates results**, PDCA provides the **cycle for managing and improving that work**, and Risk-Based Thinking ensures that **uncertainty and consequence influence how the organisation plans and controls its processes**.

Together they create a management system that is capable not only of maintaining conformity, but of **learning, adapting and improving as circumstances change**.

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12. Quality Roles, Responsibilities, Competence & Ethics

12.1. Overview

Quality is not solely the responsibility of a Quality Department. An effective Quality Management System (QMS) depends on **clear accountability, competent people, ethical behaviour and a culture in which everyone understands their contribution to conformity and customer satisfaction**.

The quality function provides specialist knowledge, assurance, governance and independent challenge, but responsibility for producing conforming products and services remains with the people and functions that perform, manage and control the work.

12.2. The Principle of Quality Responsibility

A mature organisation distinguishes between **doing quality, controlling quality and assuring quality**.

- **Everyone** is responsible for the quality of their own work and for following applicable processes and requirements.
- **Operational functions** are responsible for producing conforming outputs and controlling their processes.
- **Management** establishes objectives, provides resources, assigns responsibilities and creates the conditions necessary for effective quality performance.
- **Quality professionals** provide assurance, oversight, specialist support, verification and independent challenge.
- **Top management** remains accountable for the effectiveness of the QMS.

A useful principle is: **Quality owns the assurance system; the organisation owns quality.**
The Quality Department should therefore not become the organisation's "inspection department" or the function expected to correct every problem. Effective quality management builds prevention and control into normal business processes.

12.3. Typical Quality Roles

The structure and titles vary considerably between organisations, but common roles include:

Role	Typical Responsibilities
Quality Director / Head of Quality	Quality strategy, governance, QMS effectiveness, organisational quality performance, regulatory/customer assurance and escalation of significant quality risks.
Quality Manager	QMS implementation, audits, objectives, performance monitoring, nonconformity management, improvement and coordination of quality activities.
Quality Engineer	Product/process assurance, problem solving, RCCA, FMEA, control plans, capability, nonconformity investigation and improvement.
Supplier Quality Engineer / Manager	Supplier selection and approval, surveillance, audits, supplier performance, corrective action and development.
Manufacturing / Production Quality Engineer	Production assurance, process controls, inspections, concessions, NCRs, process capability and manufacturing improvement.
Special Processes Quality / Technical Specialist	Technical governance and assurance of processes where conformity cannot always be fully verified by subsequent inspection or test.
Quality Inspector	Inspection, measurement, verification, records, identification of nonconformities and release activities where authorised.
Quality Auditor	Independent and objective evaluation of processes, systems, products or suppliers against defined criteria.
Quality Systems / QMS Engineer	QMS documentation, certification support, internal audits, process governance, management review and standards compliance.
Metrology / Calibration Specialist	Measurement systems, calibration, measurement uncertainty, equipment control and traceability.

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Configuration / Product Assurance Specialist	Configuration identification, change control, product integrity, traceability and conformity throughout the lifecycle.
Continuous Improvement / Operational Excellence Specialist	Lean, Six Sigma, process improvement, waste reduction, capability and performance improvement.

In smaller organisations, one person may perform several of these functions. In larger or highly regulated organisations, responsibilities may be divided into highly specialised disciplines.

12.4. Quality Responsibilities Beyond the Quality Department

Quality responsibilities should be integrated throughout the organisation.

- **Top management** establishes quality policy and objectives, demonstrates leadership, provides resources and ensures the QMS achieves its intended results.
- **Engineering and Design** are responsible for translating customer and regulatory requirements into technically correct, verifiable designs and controlling design changes.
- **Procurement and Supply Chain** must ensure appropriate requirements are communicated to suppliers and that purchased products and services are appropriately controlled.
- **Operations and Manufacturing** must execute work using approved processes, competent personnel, suitable equipment and controlled instructions.
- **Inspection and Test** provide objective evidence that specified requirements have been achieved.
- **Human Resources and functional management** support identification of competence requirements, training and maintenance of appropriate competence records.
- **Employees and contractors** must understand applicable requirements, follow approved processes, protect product integrity and report problems when identified.
- The objective is a system where **responsibility follows the process**, rather than every quality-related issue being transferred to the Quality Department.

12.5. Responsibility, Authority and Accountability

These terms are related but different.

Concept	Meaning
Responsibility	The duty to perform an assigned activity or task.
Authority	The organisational power to make decisions, approve work or take action.
Accountability	Being answerable for the outcome or effectiveness of an activity.

People cannot reasonably be held accountable for activities for which they have insufficient authority or resources. Responsibilities and authorities should therefore be clearly defined through mechanisms such as:

- job descriptions;
- procedures and process maps;
- organisation charts;
- delegation or authorisation matrices;
- RACI matrices;
- inspection and approval authorities;
- competency matrices;
- terms of reference.

A **RACI matrix** can be particularly useful:

- **R – Responsible:** performs the activity.
- **A – Accountable:** owns the outcome.
- **C – Consulted:** provides expertise or input.
- **I – Informed:** needs visibility of the activity or decision.

Normally, an activity should have clearly defined accountability rather than several people assuming someone else owns it.

12.6. Competence

Competence is more than attendance at a training course. It is the demonstrated **ability to apply knowledge and skills to achieve intended results**.

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A person may have received training but still not yet be competent to perform an activity independently.

A practical competence model considers:

Knowledge + Skill + Experience + Behaviour + Demonstrated Performance

Competence requirements should be proportionate to the risk and complexity of the activity. For example, competence controls for a routine administrative activity may be relatively simple, while activities involving product safety, inspection, welding, NDT, laboratory testing or approval authority may require formal qualifications, certification, supervised experience and periodic reassessment.

12.6.1. Training vs Competence

A common QMS weakness is treating a completed training record as proof of competence.

Training	Competence
Provides knowledge or instruction	Demonstrates ability
May involve classroom or online learning	Requires application
Attendance can be recorded	Performance must be evaluated
Usually an input	Is the required outcome

Competence may be demonstrated through:

- practical observation;
- examination or testing;
- supervised work;
- qualification or certification;
- review of completed work;
- technical interview;
- witnessed demonstration;
- experience records;
- performance monitoring.

Where appropriate, personnel should only receive formal authorisation after competence has been demonstrated.

12.6.2. Competence Management Cycle

A robust competence system follows a continuous cycle:

Define → Assess → Develop → Demonstrate → Authorise → Monitor → Reassess

12.6.2.1. Define

Determine the competence required for each role or activity. Consider technical knowledge, standards, processes, equipment, safety, regulatory requirements and decision-making authority.

12.6.2.2. Assess

Compare the individual's existing capability against the required competence. This identifies competence gaps.

12.6.2.3. Develop

Address gaps through appropriate methods such as:

- training;
- mentoring;
- coaching;
- supervised practice;
- professional development;
- qualifications;
- practical experience.

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12.6.2.4. Demonstrate
Verify that the individual can apply what has been learned effectively.

12.6.2.5. Authorise
Where necessary, formally authorise the person to perform or approve defined activities.

12.6.2.6. Monitor
Monitor ongoing performance and identify deterioration, errors or changes affecting competence.

12.6.2.7. Reassess
Reassess competence periodically or following significant changes.

12.6.3. Competence Matrices
A competence or skills matrix provides visibility of organisational capability. A simple grading system might be:

Level	Example Definition
0 – Not trained	No demonstrated knowledge or experience.
1 – Awareness	Understands basic principles but cannot perform independently.
2 – Trained	Has received appropriate instruction but requires supervision.
3 – Competent	Can perform the activity independently to the required standard.
4 – Expert	Advanced knowledge; able to solve complex problems and support others.
5 – Trainer / Authority	Recognised organisational authority capable of developing or approving others.

The organisation should define its own levels clearly so that ratings are applied consistently.
Matrices can also identify **single points of failure** where only one person possesses critical competence.

12.6.4. Maintaining Competence
Competence can decline if skills are not regularly exercised or requirements change.
Reassessment may be necessary following:

- extended absence from an activity;
- process or equipment changes;
- new standards or regulations;
- significant quality escapes;
- repeated errors;
- changes in responsibility;
- expiry of qualifications or certifications;
- introduction of new technology.

Continuing Professional Development (**CPD**) helps professionals maintain and extend their knowledge throughout their careers. Useful CPD can include formal courses, technical conferences, professional qualifications, mentoring, standards review, project experience, technical reading and participation in professional bodies.

12.7. Awareness
Competence answers: **"Can this person perform the activity correctly?"**
Awareness asks: **"Do they understand why it matters?"** People should understand relevant:

- quality policies and objectives;
- customer requirements;
- product or service requirements;
- consequences of nonconformity;
- product safety implications;
- their contribution to QMS effectiveness;
- reporting and escalation responsibilities;
- ethical expectations.

A technically competent employee who does not appreciate the consequences of bypassing a control can still create substantial quality risk.

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12.8. Independence and Objectivity

Certain quality activities require an appropriate level of independence. Examples include:

- auditing;
- independent inspection;
- product acceptance;
- investigation of significant failures;
- certification activities;
- laboratory activities;
- supplier approval;
- verification and validation.

Independence does not necessarily mean belonging to a separate department. It means avoiding circumstances where conflicts of interest could compromise objective judgement. For example, an auditor should not normally audit their own work where this would undermine the impartiality of the audit.

12.9. Quality Ethics

Quality professionals regularly make decisions affecting customers, organisations, employees, safety and product integrity. Ethical behaviour is therefore fundamental. Core principles include:

- **Integrity** – act honestly and consistently with professional principles.
- **Objectivity** – base conclusions on evidence rather than personal interests or pressure.
- **Accuracy** – ensure records and reports truthfully represent what occurred.
- **Impartiality** – avoid bias and inappropriate conflicts of interest.
- **Confidentiality** – protect sensitive organisational, supplier and customer information.
- **Professional competence** – only undertake activities for which appropriate competence exists and seek assistance when necessary.
- **Accountability** – accept responsibility for professional decisions and actions.
- **Respect** – treat colleagues, customers and suppliers professionally.
- **Compliance** – respect applicable legal, regulatory, contractual and organisational requirements.
- **Courage to escalate** – raise concerns when conformity, safety, legality or integrity may be compromised.

12.9.1. Ethical Challenges in Quality

Quality professionals can experience pressure to:

- accept marginal product;
- overlook an inspection failure;
- alter or retrospectively complete records;
- reduce the severity of a nonconformity;
- close corrective actions without sufficient evidence;
- approve incomplete documentation;
- avoid reporting poor performance;
- release product to protect a delivery date;
- accept inadequate root cause analysis;
- approve suppliers despite unresolved concerns.

Commercial pressure does not remove technical or ethical responsibility. A professional response should be based on **requirements, objective evidence, defined authority and appropriate escalation**.

When requirements cannot be met, the correct approach is to use an authorised mechanism such as a concession, deviation, waiver or other formally controlled process where applicable—not to conceal or ignore the nonconformity.

12.10. Common Weaknesses

Common organisational weaknesses include:

- assuming training equals competence;
- unclear roles or overlapping accountability;

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- expired qualifications;
- inadequate competence records;
- excessive dependence on one specialist;
- insufficient auditor independence;
- Quality being treated as responsible for all product quality;
- approval authority without defined competence requirements;
- weak escalation routes;
- pressure to accept nonconforming product;
- retrospective completion of records;
- undocumented "tribal knowledge";
- competence not reassessed following change;
- ethical expectations being stated but not reinforced by management behaviour.

12.11. Good Practice

An effective organisation should be able to demonstrate that:

1. **Roles, responsibilities and authorities are clearly defined.**
2. **People understand how their work affects quality and the customer.**
3. **Competence requirements are established before assigning critical activities.**
4. **Training addresses identified competence needs.**
5. **Competence is demonstrated rather than assumed from attendance.**
6. **Critical activities have appropriate authorisation controls.**
7. **Competence is maintained and periodically reassessed.**
8. **Independent activities remain sufficiently objective and impartial.**
9. **Quality records accurately represent what occurred.**
10. **Personnel can report and escalate concerns without inappropriate pressure.**
11. **Ethical behaviour is reinforced by leadership and organisational culture.**
12. **Succession planning protects critical organisational knowledge.**

12.12. Key Principle

Quality depends on competent people being given clear responsibility, sufficient authority and the freedom to make evidence-based, ethical decisions. A strong QMS therefore does more than define processes. It ensures that the **right people, with the right competence and authority, perform those processes with integrity**.

13. Human Factors

13.1. Introduction

Human Factors is the study and application of knowledge about human abilities, limitations, behaviour and interaction with systems, equipment, environments and other people. Within quality management, Human Factors helps organisations understand **why people perform as they do and how the design of work influences quality, reliability and safety**. People do not operate independently of their environment. Performance is influenced by:

Person + Task + Equipment + Environment + Organisation + Other People

When an error occurs, identifying who made the mistake may describe **where the failure became visible**, but rarely explains why it occurred.

Human error should normally be the starting point of an investigation, not the root cause.

13.2. Why Human Factors Matters to Quality

Many quality failures involve human action somewhere in the event sequence. Examples include:

- incorrect component selected;
- operation missed;
- measurement incorrectly recorded;
- wrong programme loaded;
- fastener insufficiently tightened;

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- inspection step overlooked;
- requirement misunderstood;
- incorrect revision used;
- defect not recognised;
- information incorrectly entered.

It is easy to conclude: **"The operator made a mistake."** The more useful questions are:

- **Why was the mistake possible?**
- **What conditions influenced the person's actions?**
- **Why did the system not prevent or detect it?**

Human Factors provides a structured way of answering these questions.

13.3. Humans Are Part of the System

People should not be viewed simply as components expected to perform perfectly. Humans have valuable capabilities including:

- judgement;
- adaptability;
- problem solving;
- pattern recognition;
- creativity;
- experience;
- ability to respond to unexpected situations.

Humans also have natural limitations involving:

- attention;
- memory;
- perception;
- fatigue;
- communication;
- workload;
- consistency.

Good system design makes use of human strengths while protecting against predictable limitations. The objective is therefore not to: **"Make people stop making mistakes."**

It is to: **Design work so that errors are less likely, easier to detect and less able to cause harm.**

13.4. Error, Violation and System Failure

Not all incorrect actions have the same cause. Understanding the difference is important.

- **Error** An unintentional action or decision that does not achieve the intended result. The person intended to do the correct thing but something went wrong.
- **Violation** A deliberate departure from a known rule, procedure or requirement. A violation does **not automatically imply malicious behaviour**. People may deviate because the approved process is difficult, conflicting priorities exist, shortcuts have become normalised, or they believe another method works better.
- **System Failure** The conditions, controls or organisational arrangements allow or contribute to failure. A quality investigation should distinguish between these situations rather than classifying every event as "operator error."

13.5. Types of Human Error

A useful classification separates errors into **slips, lapses and mistakes**.

13.5.1. Slip

The intention is correct, but the action is performed incorrectly. Example: The operator intends to select Part 1234 but accidentally selects adjacent Part 1235.

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13.5.2. Lapse
Something is unintentionally forgotten or omitted. Example: An inspection step is missed after the operator is interrupted.

13.5.3. Mistake
The action is performed as intended, but the decision or understanding behind it is incorrect. Example: A technician selects an incorrect inspection method because they misunderstood the requirement.

This distinction matters because different types of error require different controls.

13.6. Active and Latent Conditions
Human Factors investigations often distinguish between **active failures** and **latent conditions**.

13.6.1. Active Failure
The action closest in time to the event. For example: **Wrong component installed.**

13.6.2. Latent Conditions
Underlying weaknesses that existed before the event. For example:
- visually similar components stored together;
- unclear labelling;
- poor lighting;
- ambiguous instructions;
- inadequate system verification;
- production pressure;
- ineffective workplace layout.

Latent conditions may remain unnoticed for months or years before combining with an active failure.

13.7. The Swiss Cheese Model
James Reason's **Swiss Cheese Model** provides a useful way of understanding organisational failure. Organisations create multiple layers of defence:

Procedure → Training → Process Control → Inspection → Final Verification

Each layer provides protection but may contain weaknesses, the conceptual "holes" in slices of Swiss cheese. Normally, one control compensates for another's weakness. Failure occurs when weaknesses temporarily align:

Hazard → ○ → ○ → ○ → Failure

The lesson is important: **Significant failures are rarely caused by one isolated mistake.** Effective investigation therefore asks why multiple controls failed to prevent or detect the event.

13.8. Performance-Shaping Factors
Human performance is influenced by the conditions in which work occurs. These are often called **Performance-Shaping Factors (PSFs)**. Important factors include:

13.8.1. Task Factors
- complexity;
- repetition;
- time available;
- sequence of activities;
- task frequency;
- precision required;
- interruptions.

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13.8.2. Individual Factors

- knowledge;
- experience;
- familiarity;
- attention;
- fatigue;
- stress.

13.8.3. Workplace Factors

- lighting;
- noise;
- temperature;
- workspace;
- accessibility;
- ergonomics.

13.8.4. Equipment and Interface Factors

- control layout;
- display design;
- software interface;
- tooling;
- equipment feedback.

13.8.5. Organisational Factors

- workload;
- supervision;
- production pressure;
- staffing;
- communication;
- priorities.

A meaningful investigation considers these conditions rather than examining the individual in isolation.

13.9. The Dirty Dozen

The **Dirty Dozen** is a widely recognised Human Factors model originating from aviation maintenance. It identifies twelve common conditions associated with human error:

Factor	Typical Quality Risk
Lack of Communication	Requirements misunderstood or information not transferred
Complacency	Familiar tasks receive insufficient attention
Lack of Knowledge	Incorrect decisions or methods
Distraction	Steps missed or sequence lost
Lack of Teamwork	Poor coordination or unclear responsibilities
Fatigue	Reduced attention and judgement
Lack of Resources	Improvisation or inadequate controls
Pressure	Shortcuts or rushed decisions
Lack of Assertiveness	Concerns not challenged or escalated
Stress	Reduced concentration and decision quality
Lack of Awareness	Consequences or wider context not recognised
Norms	Unofficial practices become accepted behaviour

The Dirty Dozen is useful as a prompt during investigation, but should not become a checklist used to automatically assign a cause.

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13.10. Fatigue

Fatigue can affect:

- concentration;
- reaction time;
- memory;
- judgement;
- visual attention;
- decision making.

Risk may increase during:

- long shifts;
- night working;
- overtime;
- repetitive work;
- high workload;
- extended periods of concentration.

Simply instructing employees to "pay more attention" does not adequately control fatigue-related risk.
The design of working patterns, task rotation, breaks, verification and automation may all need consideration.

13.11. Distraction and Interruption

Interruptions can be particularly important during sequential tasks. Consider an assembly requiring ten steps. An operator completes Step 6 and is interrupted. When returning, they believe they had completed Step 7 and restart at Step 8. The resulting error may be recorded as: **"Operator missed Step 7."** But the stronger investigation asks:

- Why was interruption possible at this stage?
- Was completed work visually identifiable?
- Could the sequence be positively tracked?
- Was there a restart protocol?
- Could the process prevent progression if Step 7 had not occurred?

This changes the focus from blame to **error-resistant process design**.

13.12. Workload and Pressure

Both excessive and insufficient workload can influence human performance.

13.12.1. Excessive Workload

Can contribute to:

- rushing;
- missed checks;
- reduced attention;
- shortcuts;
- delayed decisions.

13.12.2. Insufficient Workload

Highly repetitive or monotonous work can contribute to:

- reduced alertness;
- complacency;
- attention drift.

Production pressure is particularly important when employees perceive conflict between:

Quality – Safety – Cost – Schedule

Management behaviour strongly influences which priority people believe matters most in practice.

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13.13. Communication

Many quality problems involve incomplete, ambiguous or misunderstood information. Communication risk can occur during:

- shift handovers;
- engineering changes;
- supplier communication;
- verbal instructions;
- maintenance handovers;
- concessions;
- production changes;
- escalation of defects.

Important information should be communicated in a way that is:

Clear → Understood → Confirmed where necessary

For critical communication, simply sending information does not demonstrate that it was understood.

13.14. Workplace and Ergonomics

The physical design of the workplace can significantly influence quality. Consider:

- reach distances;
- posture;
- visibility;
- lighting;
- tool location;
- component presentation;
- display readability;
- access;
- repetitive movement.

Poor workplace design can increase the probability of:

- incorrect selection;
- missed defects;
- component damage;
- incorrect assembly;
- measurement error.

Ergonomics should therefore be considered part of process quality, not solely occupational comfort.

13.15. Human–Machine Interfaces

Increasing automation does not eliminate Human Factors. It changes the interaction. Poorly designed interfaces may create:

- confusing menus;
- similar controls;
- unclear alarms;
- excessive warnings;
- incorrect default selections;
- difficult data entry;
- poor indication of system status.

The user should be able to understand:

- **What is happening?**
- **What does the system expect?**
- **What will happen if I take this action?**
- **Has the action been successful?**

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Automation should reduce human error rather than simply transfer it to a different part of the process.

13.16. Error-Proofing

Where predictable human error could produce significant consequences, the preferred response is often to redesign the process. This is the principle behind **mistake-proofing or Poka-Yoke**. Examples include:

- connectors that fit only one way;
- fixtures preventing incorrect orientation;
- barcode verification;
- software preventing invalid entries;
- keyed components;
- automatic parameter limits;
- sensors confirming component presence.

A strong control prevents the error. A weaker control detects the error. The weakest response may simply be:

"Remind the operator to be more careful."

13.17. Visual Management

Visual controls can reduce reliance on memory and interpretation. Examples include:

- colour coding;
- shadow boards;
- clear status indicators;
- photographs of acceptable conditions;
- location markings;
- sequence indicators;
- visual limits;
- component identification.

Visual management should make the correct condition **easy to recognise**. However, colour should not normally be the only method of communicating critical information because of lighting conditions, visual impairment and other limitations.

13.18. Checklists

Checklists can reduce dependence on memory, particularly for:

- infrequent tasks;
- complex sequences;
- critical checks;
- handovers;
- inspection;
- setup activities.

A checklist is most effective when it supports the task rather than merely generating evidence that someone ticked boxes. Poorly designed checklists can create **tick-box behaviour**, where completion becomes more important than meaningful verification.

13.19. Independent Verification

For sufficiently critical activities, independent verification can provide an additional defence.
However, independence should be genuine. If a second person simply assumes the first person's work was correct and signs without meaningful verification, the additional control provides little value. Independent verification should have:

- a defined purpose;
- clear acceptance criteria;
- appropriate independence;
- sufficient time;
- access to the necessary evidence.

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Adding signatures without improving detection capability is not an effective Human Factors control.

13.20. Just Culture

A strong quality culture should distinguish between:

- unintentional human error;
- system-induced behaviour;
- reasonable judgement;
- risky behavioural choices;
- deliberate disregard of important requirements.

A **Just Culture** does not mean that nobody is accountable. It means that responses are **fair and proportionate to the behaviour and circumstances**.

If employees believe every mistake will result in punishment, they may become reluctant to report:

- errors;
- near misses;
- unsafe conditions;
- process weaknesses.

The organisation then loses valuable information about emerging risk.

13.21. Psychological Safety and Speaking Up

People closest to the work often recognise problems before management systems do. They should be able to raise concerns such as:

- unclear instructions;
- unrealistic timescales;
- defective equipment;
- questionable product;
- unsafe practices;
- recurring errors;
- ineffective controls.

The effectiveness of a reporting system depends not merely on whether it exists, but whether people **trust that concerns will be taken seriously**. Near misses and weak signals can provide valuable learning before an actual failure occurs.

13.22. Human Factors in Investigation

When human action contributed to an event, investigation should move beyond: **Who made the error?**
Consider:

- **Task** Was the task difficult, repetitive, ambiguous or unusual?
- **Information** Were instructions and requirements clear?
- **Equipment** Was equipment intuitive and suitable?
- **Environment** Did lighting, noise, temperature or workspace contribute?
- **Organisation** Were workload, staffing or schedule pressures relevant?
- **Communication** Was important information transferred effectively?
- **Controls** Why did existing controls fail to prevent or detect the error?
- **Previous Experience** Had similar events or near misses occurred before?

This provides a more useful basis for corrective action.

13.23. Weak Human Factors Corrective Actions

Weak responses commonly include:

- retrain the operator;
- brief the team;
- issue a reminder;
- tell personnel to take more care;

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- add another signature;
- create another warning notice.

These actions may sometimes be appropriate, but they are often weak when used alone because they leave the underlying error opportunity unchanged.

Before selecting retraining as corrective action, ask: **Was lack of knowledge actually the cause?** If the person already knew the correct method, repeating the same training may achieve little.

13.24. Hierarchy of Human Factors Controls

Where practical, stronger controls should be considered before relying entirely on human vigilance. A useful hierarchy is:

1. Eliminate the error opportunity
↓
2. Design the process to prevent the error
↓
3. Automatically detect or interlock
↓
4. Provide physical or visual controls
↓
5. Provide independent verification
↓
6. Provide clear instructions and checklists
↓
7. Train and communicate
↓
8. Rely on memory and attention

Controls lower in the hierarchy may still be necessary, but they generally depend more heavily upon consistent human performance.

13.25. Learning from Near Misses

A **near miss** is an event where failure could have occurred but was prevented or did not result in the full consequence. For example: An incorrect component is installed but detected before product release.

The organisation could conclude: **"Inspection worked, so there is no problem."**
A stronger response asks: **"Why was the incorrect component able to be installed?"**

Near misses provide an opportunity to improve controls before the same conditions result in a customer escape or more serious event.

13.26. Normalisation of Deviance

A potentially dangerous organisational behaviour occurs when deviations become accepted because they have not yet resulted in failure. For example: "We've always done it this way and nothing has gone wrong." Repeated success despite a weak control can create false confidence. Over time:

Deviation → Repetition → Familiarity → Acceptance → Normal Practice

This is often described as **normalisation of deviance**. The absence of previous failure does not prove that an uncontrolled practice is safe or capable.

13.27. Work as Imagined and Work as Done

Procedures describe how organisations expect work to occur. Actual operational conditions may be different. This can be considered as:

- **Work as Imagined** – how the process is designed or documented.
- **Work as Done** – how people actually perform the activity.

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Differences may arise because of:

- unavailable equipment;
- impractical instructions;
- production constraints;
- undocumented workarounds;
- changing conditions;
- accumulated experience.

The existence of a gap does not automatically mean employees are behaving incorrectly. It may reveal that the designed process does not adequately reflect operational reality. Observing actual work is therefore an important part of understanding Human Factors.

13.28. Designing for the Human

Good process design should consider predictable human characteristics from the beginning. Ask:

- Can the wrong component easily be selected?
- Can steps be performed in the wrong order?
- Does the process depend unnecessarily on memory?
- Are similar controls easily confused?
- Is critical information obvious?
- Can an interruption cause loss of position?
- Does the system provide useful feedback?
- Can an error be detected before it progresses?
- Is the task practical under real working conditions?

Human Factors is most effective when incorporated during process design rather than investigated only after something goes wrong.

13.29. Common Weaknesses

Common Human Factors weaknesses include:

- recording "operator error" as root cause;
- automatically prescribing retraining;
- assuming experienced personnel cannot make mistakes;
- relying excessively on memory;
- poorly designed interfaces;
- visually similar parts without effective controls;
- interruptions during critical activities;
- excessive warning information;
- weak shift handovers;
- normalisation of unofficial practices;
- adding inspection instead of improving process design;
- treating every violation as deliberate misconduct;
- ignoring fatigue and workload;
- failing to learn from near misses;
- procedures that do not reflect actual working conditions.

13.30. Good Practice

An effective organisation should seek to:

1. Treat people as part of the system rather than isolated causes of failure.
2. Distinguish errors, mistakes and deliberate deviations.
3. Investigate why an error was possible.
4. Consider task, workplace, equipment and organisational conditions.
5. Reduce unnecessary reliance on memory and attention.
6. Design processes to prevent predictable errors.
7. Use meaningful error detection where prevention is impractical.
8. Encourage reporting of errors and near misses.
9. Apply accountability fairly and proportionately.

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10. Observe how work is actually performed.
11. Challenge normalised workarounds and deviations.
12. Consider Human Factors when designing or changing processes.
13. Prefer stronger systemic controls over repeated reminders.
14. Verify that corrective actions actually reduce the opportunity for recurrence.

13.31. Key Principle

People make errors; well-designed systems anticipate that reality and prevent individual mistakes from becoming product failures.

When a quality event involves human action, the most valuable question is therefore rarely: **"Who made the mistake?"** It is **"Why did the system allow this mistake to occur and progress, and how can we design the work so that the same error is less likely, or unable to happen again?"**

14. Lessons Learned & Knowledge Management

14.1. Introduction

Every organisation generates knowledge through projects, production, suppliers, customers, failures, successes and everyday problem solving. The challenge is ensuring that this knowledge is **captured, understood, retained and reused** rather than disappearing when a project ends or an experienced employee leaves.

Knowledge Management (KM) is the systematic approach used to identify, create, capture, maintain, share and apply knowledge needed by the organisation.

Lessons Learned is one important part of Knowledge Management. It converts experience into knowledge that can influence future decisions and prevent organisations from repeatedly solving the same problems.

An experience only becomes a lesson learned when the learning changes future behaviour, decisions or controls.

14.2. Why Organisational Knowledge Matters

Organisations depend on knowledge to:

- understand customer requirements;
- design products and services;
- operate processes;
- solve problems;
- control risks;
- make technical decisions;
- manage suppliers;
- respond to unusual situations;
- improve performance;
- maintain continuity.

Some knowledge is formally documented. Much of it exists within people's experience. Without deliberate knowledge management, organisations can repeatedly lose valuable capability through:

- employee turnover;
- retirement;
- organisational restructuring;
- project completion;
- supplier changes;
- outsourcing;
- long gaps between similar projects;
- technology changes.

Knowledge should therefore be treated as an **organisational asset**.

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14.3. Data, Information, Knowledge and Learning

These concepts are related but different.

- **Data** Raw facts or observations. **Example:** 14 defects were recorded.
- **Information** Data given context and meaning. **Example:** 12 of the 14 defects occurred after a tooling change.
- **Knowledge** Understanding that can support decisions or action. **Example:** The revised tooling arrangement increases the probability of component misalignment.
- **Learning** Applying that knowledge to influence future behaviour or decisions. **Example:** Future tooling changes require alignment verification before production release.

The desired progression is:

Data → Information → Knowledge → Learning → Application

Simply collecting information does not guarantee organisational learning.

14.4. Explicit and Tacit Knowledge

Organisational knowledge is commonly considered in two broad forms.

14.4.1. Explicit Knowledge

Knowledge that has been captured and can be readily communicated. Examples include:

- specifications;
- technical reports;
- process instructions;
- design rules;
- databases;
- checklists;
- training material;
- lessons-learned summaries.

14.4.2. Tacit Knowledge

Knowledge held through personal experience, judgement and practical understanding. Examples include:

- recognising unusual process behaviour;
- understanding supplier capability;
- knowing which characteristics require particular attention;
- interpreting subtle technical indications;
- knowing how to resolve unusual problems.

Tacit knowledge is often difficult to capture because experienced people may perform activities instinctively without consciously recognising everything they know.

14.5. Tribal Knowledge

Tribal knowledge describes important organisational knowledge that is known informally by individuals or groups but has not been adequately captured or shared. Typical warning signs include:

- "Ask Dave—he's the only person who knows."
- "We've always done it this way."
- "It's not written down anywhere."
- "You'll learn that once you've been here a few years."

Tribal knowledge can be valuable, but uncontrolled dependence on it creates organisational risk.
The objective is not to document every detail employees know. It is to identify knowledge whose loss would materially affect **quality, safety, continuity, compliance or performance**.

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14.6. Critical Knowledge

Not all knowledge requires the same level of management. Organisations should identify **critical knowledge**, knowledge whose loss or unavailability could significantly affect their ability to operate or meet requirements. Questions may include:

- What knowledge is essential to this process?
- Who currently possesses it?
- Is it available elsewhere?
- How difficult would it be to replace?
- What would happen if it became unavailable?
- Is it adequately transferred?
- Is it current?

A simple approach can consider:

Criticality × Scarcity × Consequence of Loss

This helps prioritise knowledge-management effort.

14.7. Knowledge Sources

Organisational knowledge can come from many sources.

14.7.1. Internal Sources

- employees;
- projects;
- technical specialists;
- audits;
- investigations;
- production experience;
- improvement activities;
- design reviews;
- testing;
- previous products;
- near misses;
- customer feedback;
- supplier experience.

14.7.2. External Sources

- customers;
- suppliers;
- standards;
- regulators;
- professional bodies;
- industry publications;
- conferences;
- universities;
- research;
- benchmarking;
- external specialists.

Effective Knowledge Management considers both.

14.8. Lessons Learned

A **lesson learned** is useful knowledge derived from experience that can improve future decisions, processes or outcomes. Lessons may come from things that went wrong, but also from things that went particularly well.

- **Negative Lesson: What should we avoid or control differently next time?**

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- **Positive Lesson: What worked particularly well and should be repeated or standardised?**

Organisations that only capture failures miss valuable knowledge about successful practices.

14.9. Lesson Identified vs Lesson Learned

An important distinction exists between a **lesson identified** and a **lesson learned**.

- **Lesson Identified** The organisation understands something important from an experience.
- **Lesson Learned** That understanding has been successfully incorporated into future practice.

For example:

- **Event:** Supplier capacity was not evaluated adequately and caused programme delay.
- **Lesson Identified:** Future supplier selection should include appropriate capacity assessment.

If this statement is simply stored in a database, it remains a lesson identified. If the supplier-selection process is subsequently changed and the new approach is used on future projects, the organisation can demonstrate that learning has occurred. Therefore: **Capture is not learning. Application completes the learning cycle.**

14.10. The Lessons-Learned Cycle

A practical lessons-learned process can follow:

Experience → Capture → Analyse → Validate → Share → Apply → Verify

- **Experience** Something occurs that provides useful learning.
- **Capture** The relevant information is recorded while context is still understood.
- **Analyse** Determine why the lesson matters and where else it may apply.
- **Validate** Ensure the conclusion is accurate and supported by sufficient evidence.
- **Share** Make the knowledge available to relevant people.
- **Apply** Incorporate the learning into appropriate future activities.
- **Verify** Determine whether the learning has actually been adopted and remains useful.

Without **Apply** and **Verify**, lessons-learned systems commonly become information archives rather than learning systems.

14.11. What Makes a Good Lesson?

A useful lesson should explain more than what happened. A practical structure is:

- **Context** Where and under what circumstances did this occur?
- **Event** What happened?
- **Insight** What did the organisation learn?
- **Consequence** Why does the lesson matter?
- **Recommendation** What should be done differently or repeated?
- **Applicability** Where else could this lesson be relevant?

For example:

- **Weak lesson:** "Supplier caused late delivery."
- **Stronger lesson:** "Supplier selection evaluated technical capability but did not adequately assess production capacity. Future sourcing of comparable components should include evidence-based capacity assessment before approval."

The second statement provides knowledge that another team can actually use.

14.12. When to Capture Lessons

Lessons should not be limited to project closure.
Useful capture points may include:

- project milestones;
- design reviews;
- First Article activities;

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- production readiness;
- major changes;
- significant nonconformities;
- customer complaints;
- supplier problems;
- successful improvements;
- audits;
- project completion;
- contract completion.

Capturing learning close to the event improves the quality of the information because important context is less likely to have been forgotten.

14.13. Learning Before, During and After

Effective organisations do not wait until the end of an activity to think about lessons learned.

- **Before** Ask: **What have we learned from similar work previously?**
- **During** Ask: **What are we learning now that should influence this activity?**
- **After** Ask: **What should future teams know before doing this again?**

This creates a continuous learning cycle:

Learn Before → Learn During → Learn After → Reuse

14.14. Reuse Is the Objective

The purpose of capturing knowledge is ultimately **reuse**. Before beginning a new project, product, process or supplier relationship, teams should be able to determine:

- Have we done something similar before?
- What problems occurred?
- What worked well?
- What decisions were made?
- Which assumptions proved incorrect?
- What should we repeat?
- What should we avoid?

This can prevent substantial time and cost being spent rediscovering information that the organisation already knows.

14.15. Knowledge at the Point of Need

Knowledge is most valuable when available **where and when a decision is being made**. A large repository containing thousands of lessons has little value if users cannot find the relevant information. Knowledge should therefore be:

Relevant – Searchable – Accessible – Understandable – Current

Where practical, lessons should be connected to the processes where they are needed. For example, supplier-related lessons should be visible during supplier selection or sourcing, not only stored in a separate lessons-learned database.

14.16. Push and Pull Learning

Knowledge can be distributed in two ways.

14.16.1. Pull

Users actively search for relevant knowledge when they need it. Examples:

- searchable knowledge bases;
- technical libraries;
- previous project records.

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14.16.2. Push

Relevant knowledge is deliberately presented to users at an appropriate point. Examples:

- lessons reviewed during project kick-off;
- supplier lessons included during sourcing;
- previous failures highlighted during design review;
- applicable lessons presented during process planning.

The strongest systems often combine both approaches.

14.17. Knowledge Mapping

A **knowledge map** identifies where important organisational knowledge exists. It may identify:

Knowledge Area	Criticality	Primary Source	Backup Source	Capture Method
Special Process A	High	Technical Specialist	Engineer B	Technical guide / mentoring
Product Family X	High	Design Lead	Project Engineer	Design knowledge base
Supplier Process Y	Medium	Supplier Quality	Procurement	Supplier history
Legacy System Z	High	Engineer C	None	Urgent knowledge transfer

Knowledge mapping can reveal:

- single points of dependency;
- ageing expertise;
- missing backup capability;
- poorly captured knowledge;
- succession risks.

14.18. Knowledge Transfer

Different knowledge requires different transfer methods. Possible approaches include:

- mentoring;
- coaching;
- job shadowing;
- structured interviews;
- demonstrations;
- technical workshops;
- communities of practice;
- peer reviews;
- case studies;
- videos;
- technical notes;
- checklists;
- knowledge repositories;
- handover sessions.

Tacit knowledge is often best transferred through **interaction and experience**, rather than attempting to convert everything into written procedures.

14.19. Knowledge Loss and Succession

Knowledge risk should be considered when experienced personnel:

- retire;
- resign;
- change roles;
- move projects;
- become unavailable.

Waiting until someone's final week before attempting knowledge transfer is rarely effective. For critical knowledge, organisations should consider:

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Succession planning should focus not only on replacing the position but also on retaining the **knowledge required to perform it effectively**.

14.20. Communities of Practice

A **Community of Practice** is a group of people who share knowledge and experience around a common discipline or problem area. Examples might include communities for:

- auditing;
- supplier quality;
- metrology;
- special processes;
- problem solving;
- design assurance.

Communities can help prevent expertise becoming isolated within individual departments or sites. Their value comes from active exchange and application of knowledge rather than simply holding periodic meetings.

14.21. Learning from Success

Quality systems naturally focus attention on problems. However, successful outcomes can provide equally valuable knowledge. Questions might include:

- Why did this project perform particularly well?
- Why did this supplier transition succeed?
- Which controls prevented problems?
- Which planning decisions proved valuable?
- What should become standard practice?

Without this analysis, successful performance may be attributed simply to good fortune and the underlying practices may not be repeated.

14.22. Learning from Failure

When significant failures occur, learning should extend beyond correcting the immediate issue. Consider:

- **What happened?**
- **Why did it happen?**
- **What did we learn?**
- **Where else could the same conditions exist?**
- **Who else needs to know?**
- **What should change?**

The question **"Where else?"** is particularly powerful. A failure found on one product, process, supplier or site may reveal a weakness applicable elsewhere. Effective learning therefore moves beyond local correction towards **horizontal deployment** where appropriate.

14.23. Horizontal Deployment

Horizontal deployment means applying relevant learning beyond the location where it originated.
For example: A supplier escape identifies that a particular drawing characteristic is frequently misunderstood. The organisation should consider whether:

- other drawings contain similar requirements;
- other suppliers perform comparable work;
- other products use the same design convention;
- inspection plans contain the same weakness.

This turns a local event into organisation-wide prevention.

14.24. Knowledge Validation

Not every opinion or experience should automatically become organisational knowledge. Lessons should be evaluated to ensure they are:

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- factually supported;
- technically sound;
- sufficiently understood;
- relevant;
- not based on incorrect assumptions;
- applicable to the context in which they will be reused.

A poorly understood lesson can institutionalise the wrong behaviour. For significant technical learning, appropriate subject-matter review may therefore be necessary.

14.25. Knowledge Obsolescence

Knowledge can become outdated. **Changes to:**

- technology;
- standards;
- regulations;
- products;
- materials;
- suppliers;
- equipment;
- organisational processes

may make previous knowledge partially or completely obsolete.

Knowledge therefore requires lifecycle thinking:

Create → Use → Review → Update → Retire

A repository containing large amounts of outdated information can be more dangerous than having no information at all because users may unknowingly rely upon obsolete knowledge.

14.26. Technology and Knowledge Management

Technology can greatly improve knowledge capture and retrieval. Useful capabilities may include:

- searchable repositories;
- metadata and tagging;
- full-text search;
- linked technical information;
- collaborative platforms;
- knowledge graphs;
- intelligent search;
- automated recommendations;
- AI-assisted retrieval and summarisation.

However: **Technology stores and retrieves information; it does not automatically create organisational learning.** The organisation still needs suitable processes for validating, sharing and applying knowledge.

14.27. Artificial Intelligence and Organisational Knowledge

AI can increasingly help organisations:

- search large information collections;
- identify similar previous problems;
- summarise historical lessons;
- connect related information;
- detect patterns;
- locate specialist knowledge.

Its use should nevertheless consider:

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- confidentiality;
- intellectual property;
- access control;
- source traceability;
- validation of generated conclusions.

AI-generated information should not automatically be treated as validated organisational knowledge.

14.28. Measuring Knowledge Management

Knowledge Management can be difficult to measure directly. Useful indicators may include:

- critical knowledge areas without backup;
- lessons implemented;
- lessons reused on later projects;
- recurring failures previously identified;
- repository usage;
- knowledge-transfer completion;
- time required to locate technical information;
- percentage of relevant projects reviewing previous lessons.

The number of lessons stored is generally a poor measure of effectiveness. A repository containing 10,000 unused lessons is less valuable than 100 lessons that repeatedly improve decisions.

14.29. Barriers to Organisational Learning

Common barriers include:

- lack of time;
- information silos;
- poor search capability;
- fear of admitting failure;
- lessons written without context;
- excessive documentation;
- knowledge treated as personal power;
- lack of ownership;
- outdated information;
- weak communication between projects;
- capture occurring too late;
- failure to integrate learning into normal processes.

The most important barrier is often cultural: **An organisation may possess knowledge without behaving as though it knows it.**

14.30. Common Weaknesses

Typical weaknesses include:

- capturing lessons only at project closure;
- recording events without identifying useful learning;
- confusing a lesson identified with a lesson learned;
- large repositories with poor search capability;
- repeating previous mistakes;
- relying excessively on individual experts;
- losing knowledge when personnel leave;
- failing to capture successful practices;
- lessons without owners or applicability;
- outdated lessons remaining active;
- knowledge held within departmental silos;
- failing to deploy learning across similar products or processes;
- measuring the number of lessons rather than their use.

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14.31. Good Practice

An effective organisation should seek to:

1. Identify the knowledge required to operate important processes.
2. Recognise critical knowledge and single points of dependency.
3. Capture valuable learning close to the event.
4. Learn from successes as well as failures.
5. Distinguish lessons identified from lessons actually learned.
6. Validate significant technical knowledge before wider application.
7. Make knowledge easy to find at the point of need.
8. Review previous learning before beginning similar work.
9. Transfer important tacit knowledge before it is lost.
10. Deploy relevant learning beyond the original event.
11. Keep organisational knowledge current.
12. Integrate learning into normal processes rather than relying solely on repositories.
13. Measure application and reuse rather than simply counting stored lessons.
14. Create a culture where sharing knowledge is valued.

14.32. Key Principle

Organisations do not learn simply because their people have experiences; they learn when knowledge from those experiences is retained, shared and applied to future decisions.

The true measure of Knowledge Management is therefore not **how much information the organisation stores**, but whether the organisation can **find what it already knows, apply it when needed and avoid unnecessarily relearning the same lessons**.

15. New Product Introduction (NPI)

15.1. Definition and Fundamental Concepts

New Product Introduction (NPI) is the structured process used to take a new or significantly changed product from concept and development into controlled, repeatable production and delivery.

NPI provides the bridge between **design intent and operational reality**. It ensures that a product is not only technically capable of meeting its requirements, but can also be manufactured, inspected, supplied, supported and controlled consistently at the required **quality, cost, rate and schedule**.

Although the terminology varies between organisations and industries, NPI typically integrates activities from:

- Engineering and design
- Manufacturing and industrialisation
- Quality
- Supply chain and procurement
- Production planning
- Configuration management
- Test and inspection
- Programme/project management
- Customer and regulatory assurance
- Logistics and product support

NPI is therefore not simply a manufacturing activity or a final quality check. It is a **cross-functional product maturity process**.

15.2. Purpose of NPI

The fundamental objective of NPI is to identify and resolve problems **before they become production problems**. A well-managed NPI process provides confidence that:

The product is defined → the design is mature → the supply chain is capable → the manufacturing process is proven → verification is complete → production can proceed under controlled conditions.

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Without effective NPI, organisations risk discovering design weaknesses, manufacturing difficulties, supplier problems, inspection limitations and capacity constraints after significant investment has already been committed. This often results in:

- Late engineering changes
- Production disruption
- High levels of nonconformance
- Concessions and deviations
- Scrap and rework
- Supplier escapes
- Excessive inspection
- Schedule delays
- Cost growth
- Customer dissatisfaction

The cost and disruption associated with correcting a problem generally increase significantly as the product progresses towards production and delivery.

15.3. Typical NPI Lifecycle

There is no single universal NPI model. Organisations may use **APQP, stage-gate, product lifecycle, industrialisation or programme-specific processes**, but most contain similar maturity stages.

15.3.1. Concept and Requirements

The organisation establishes what the product must achieve and the conditions under which it will be produced and operated.
Typical considerations include:

- Customer requirements
- Regulatory and statutory requirements
- Product performance
- Reliability and maintainability
- Safety requirements
- Special requirements and critical items
- Production volumes and rate
- Target cost
- Manufacturing strategy
- Make/buy decisions
- Technology maturity
- Supply-chain capability

Requirements should be sufficiently clear, measurable and traceable to support subsequent design and verification.

15.3.2. Design and Development

The product definition develops from requirements into an engineering solution. Quality involvement at this stage is important because many future production problems originate from decisions made during design.
Activities may include:

- Design reviews
- Design FMEA
- Design for Manufacture and Assembly (DFMA)
- Tolerance assessment
- Material and process selection
- Key/critical characteristic identification
- Verification planning
- Reliability analysis
- Prototype manufacture and testing
- Configuration control

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The objective is not merely to determine whether the design **can be manufactured**, but whether it can be manufactured **repeatedly and robustly**.

15.3.3. Industrialisation and Process Development

The focus moves from defining the product to defining **how the product will be produced**. Typical outputs include:

- Manufacturing process flow
- Work instructions
- Production documentation
- PFMEA
- Control plans
- Inspection and test plans
- Tooling and fixtures
- Measurement equipment
- Special process controls
- Operator competence requirements
- Packaging and preservation requirements
- Traceability arrangements
- Production capacity planning

Processes should be designed around prevention and control rather than relying solely on final inspection to identify failures.

15.3.4. Supply Chain Readiness

Supplier maturity should develop alongside product and manufacturing maturity. Typical activities include:

- Supplier selection and approval
- Supplier capability assessment
- Quality requirement flow-down
- Supplier APQP or equivalent
- Supplier manufacturing readiness reviews
- Special process approval
- Sub-tier supply-chain control
- Capacity assessment
- FAIR/PPAP requirements
- Supplier risk management
- Long-lead material planning

A product cannot be considered production-ready if critical suppliers or sub-tier processes are not ready.

15.3.5. Product and Process Validation

Before full production, objective evidence should demonstrate that the proposed production system can manufacture conforming product. Depending on the industry, this may include:

- Prototype builds
- Engineering development builds
- Pilot production
- Production representative builds
- First Article Inspection (FAI)
- PPAP
- Process capability studies
- Measurement System Analysis (MSA)
- Special process qualification
- Functional testing
- Environmental testing

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- Reliability testing
- Production trials

The important distinction is between proving **one product can be made correctly** and demonstrating that the **production system can repeatedly make products correctly**.

15.3.6. Production Readiness

A formal readiness review is commonly conducted before authorising serial or rate production.
The review should establish whether:

Area	Typical readiness evidence
Product definition	Released and configuration controlled
Requirements	Verified and traceable
Manufacturing	Processes defined and demonstrated
Quality	Inspection and control strategy established
Supply chain	Suppliers approved and capable
Equipment	Available, validated and maintained
Tooling	Qualified and configuration controlled
Measurement	Suitable and calibrated
People	Competent and authorised where required
Materials	Approved and available
Capacity	Demonstrated against required rate
Documentation	Released and available at point of use
Nonconformities	Understood and appropriately dispositioned
FAI/PPAP	Completed where contractually required
Risks	Acceptable or supported by controlled actions

Readiness should be determined by **objective evidence**, rather than confidence that outstanding issues will be resolved later.

15.3.7. Ramp-Up and Early Production

NPI does not necessarily finish when the first production item is completed. Early production should be monitored closely to confirm that assumptions made during industrialisation remain valid at increasing production volumes. Enhanced controls may include:

- Increased inspection
- First-off verification
- Process capability monitoring
- Supplier performance monitoring
- Defect trending
- Increased engineering support
- Rapid problem escalation
- Daily/weekly production reviews

Additional controls should eventually be removed where evidence demonstrates that the normal production control system is sufficient.

15.3.8. Transition to Business-as-Usual Production

Formal NPI closure should occur when agreed maturity criteria have been achieved and responsibility can transfer to normal production governance. Closure should consider:

- Outstanding actions
- Open nonconformities
- Residual risks
- Process capability
- Supplier performance
- Production rate achievement

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- Configuration status
- Lessons learned

Unresolved issues should have defined ownership rather than disappearing with closure of the NPI project.

15.3.9. Stage-Gate Control

Many organisations control NPI using **stage gates or maturity reviews**. A gate is a formal decision point at which evidence is reviewed before progressing to the next phase. Possible decisions include:

- **GO** – maturity criteria achieved; proceed.
- **CONDITIONAL GO** – proceed subject to defined actions, owners and timescales.
- **HOLD** – insufficient evidence or unacceptable risk.

Effective gates prevent programme schedule pressure from silently becoming acceptance of technical or quality risk. A gate should therefore be an **evidence-based maturity decision**, not simply a meeting or checklist completion exercise.

15.3.10. Quality's Role in NPI

Quality should participate throughout NPI rather than becoming involved only when inspection or FAI begins. Quality provides independent assurance that appropriate controls and evidence exist across the product lifecycle. Typical responsibilities include:

- Challenging product and process risks
- Reviewing quality planning
- Supporting DFMEA/PFMEA
- Ensuring characteristics are appropriately controlled
- Assessing supplier readiness
- Reviewing inspection and test strategies
- Confirming measurement capability
- Supporting process qualification
- Reviewing FAI/PPAP evidence
- Monitoring early production performance
- Ensuring nonconformities are investigated and controlled
- Providing assurance at readiness reviews

Quality should not become the owner of every NPI activity. **Engineering owns the design, manufacturing owns the process and suppliers own their processes; Quality provides assurance that the required controls are effective.**

15.3.11. NPI Maturity

A useful principle is: **Schedule progress does not equal product maturity.**
A programme may have reached its planned production date while the product, process or supply chain remains immature. NPI maturity should therefore be demonstrated using objective indicators such as:

- Design release status
- Engineering change activity
- FMEA action closure
- FAI/PPAP status
- Process capability
- Tooling readiness
- Supplier readiness
- Open nonconformities
- Concession levels
- Yield and first-pass yield
- Scrap and rework
- Production rate

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- Test failures
- Configuration stability

The appropriate indicators depend on the product and associated risk.

15.3.12. Change During NPI

Change is normal during product introduction, but uncontrolled change is a major source of risk. Changes should be assessed for their effect on:

Design → manufacturing → tooling → inspection → suppliers → documentation → qualification → configuration → delivered product.

A seemingly minor engineering change may invalidate previous FAI, process validation, tooling, inspection programming or supplier approval. Configuration management is therefore fundamental throughout NPI.

15.4. Common NPI Failure Modes

Weak NPI programmes frequently exhibit similar behaviours:

- Quality involved too late
- Production started before design maturity
- Incomplete requirement flow-down
- Suppliers selected primarily on price or availability
- PFMEA completed as documentation rather than risk analysis
- FAI treated as proof of process capability
- Temporary concessions becoming routine
- Tooling or inspection equipment arriving late
- Production documentation released after manufacture begins
- Unresolved prototype issues carried into production
- Excessive dependence on inspection
- Capacity assumed rather than demonstrated
- Stage gates passed despite significant open actions
- Lessons from early builds not incorporated into later configurations

These are generally symptoms of insufficient **maturity, ownership or cross-functional integration** rather than isolated quality failures.

15.5. NPI and APQP

NPI and APQP are related but are not synonymous. NPI describes the broader organisational process for introducing a product into production. **Advanced Product Quality Planning (APQP)** provides a structured quality-planning methodology that can operate within that process, particularly in automotive and increasingly aerospace and other high-reliability sectors.

Similarly, tools such as **DFMEA, PFMEA, Control Plans, MSA, SPC, FAI and PPAP** support NPI but should not individually be considered the NPI process itself.

15.6. Key Principle

Successful NPI is achieved when the organisation moves from: **"We believe we can build it"** to **"We have objective evidence that we can repeatedly build, verify and deliver it under controlled production conditions."**

The effectiveness of NPI should ultimately be visible in the stability of production after launch. A mature introduction produces controlled processes, capable suppliers, stable configuration and predictable product quality, not a continuing stream of problems transferred from development into production.

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16. Advanced Product Quality Planning (APQP) & Production Part Approval Process (PPAP)

16.1. Definition and Fundamental Concepts

Advanced Product Quality Planning (APQP) is a structured, cross-functional method for planning and assuring product and process quality before full production. Its purpose is to identify requirements, risks and necessary controls early enough to prevent problems rather than discovering them during serial production.

Production Part Approval Process (PPAP) is the formal evidence and approval process used to demonstrate that the supplier understands the applicable product requirements and that the defined production process has the potential to consistently produce conforming product at the required production rate.
The relationship can be summarised as:

APQP = plan, develop, manage risk and demonstrate readiness
PPAP = compile objective evidence and obtain approval

PPAP is therefore typically an **output of the wider APQP process**, not a substitute for APQP.

16.2. Why APQP Is Important

Complex products rarely fail because of a single isolated quality activity. Problems often result from interactions between design, manufacturing, suppliers, tooling, measurement, materials, capacity and configuration. APQP provides a framework for coordinating these activities before production risk becomes embedded. Its principal objectives are to:

- Understand customer and regulatory requirements.
- Translate requirements into product and process controls.
- Identify product and manufacturing risks early.
- Establish prevention and detection controls.
- Demonstrate manufacturing and measurement capability.
- Ensure suppliers and sub-tier suppliers are ready.
- Validate production using representative conditions.
- Establish evidence of product and process readiness.
- Reduce late changes, defects, rework and customer escapes.

APQP is fundamentally a **risk-prevention and maturity-management process**, rather than a documentation exercise.

16.2.1. The APQP Lifecycle

Traditional automotive APQP is commonly represented through five overlapping phases. Industry-specific approaches may use different terminology, but the principles remain similar.

Phase	Primary Purpose	Typical Activities / Outputs
1. Plan and Define Programme	Establish requirements and objectives	Customer requirements, lessons learned, feasibility, risk, targets, timing
2. Product Design & Development	Develop and verify the product	Design reviews, DFMEA, drawings, specifications, prototypes, verification
3. Process Design & Development	Define how the product will be produced	Process flow, PFMEA, control plan, tooling, inspection strategy, work instructions
4. Product & Process Validation	Demonstrate production readiness	Production trial, MSA, capability studies, testing, dimensional results, PPAP
5. Feedback, Assessment & Corrective Action	Stabilise and improve production	Performance monitoring, variation reduction, lessons learned, corrective action

These activities normally overlap rather than occurring as isolated sequential stages.

16.2.2. The APQP Core Tools

APQP makes extensive use of complementary quality methods commonly known as the **Core Tools**.

- **APQP** Provides the overall framework for planning and coordinating product and process quality.
- **FMEA Design FMEA (DFMEA)** examines potential failures associated with the product design.

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- **Process FMEA (PFMEA)** examines potential failures associated with manufacturing and assembly processes.
- **Control Plan** Defines the controls applied to product and process characteristics, including:
  - What is controlled
  - Specification or acceptance criteria
  - Measurement or control method
  - Sampling/frequency
  - Responsibility
  - Reaction plan
- **Measurement System Analysis (MSA)** Determines whether the measurement system is sufficiently capable for its intended use. This can include Gauge R&R, bias, stability, linearity and attribute measurement analysis.
- **Statistical Process Control (SPC)** Uses process data and statistical techniques to understand variation, identify instability and maintain process control.
- **PPAP** Brings relevant evidence together to demonstrate product and production-process readiness.

The tools should form a connected system:

Requirements → DFMEA → Process Flow → PFMEA → Control Plan → Work/Inspection Instructions → Measurement & Process Data → PPAP

Traceability between these elements is important. A significant risk identified in the PFMEA, for example, should result in appropriate prevention or detection controls within the production system.

16.3. Production Part Approval Process (PPAP)

PPAP provides structured evidence that a production process has been appropriately defined and validated. PPAP should normally be based on parts produced using the intended **production process**, including representative:

- Production equipment
- Tooling
- Materials
- Operators
- Manufacturing location
- Inspection methods
- Production documentation
- Process sequence

This distinction matters because successful prototype manufacture does not necessarily demonstrate serial-production capability.

16.3.1. Typical PPAP Elements

The exact requirements depend upon the customer, industry, contract and submission level, but a PPAP package may contain:

1. Design records
2. Authorised engineering change documentation
3. Customer engineering approval, where required
4. DFMEA
5. Process flow diagram
6. PFMEA
7. Control plan
8. Measurement System Analysis studies
9. Dimensional results
10. Material and performance test results
11. Initial process studies
12. Qualified laboratory documentation
13. Appearance Approval Report, where applicable
14. Sample production parts

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15. Master sample
16. Checking aids
17. Customer-specific requirements
18. **Part Submission Warrant (PSW)**

Not every element is applicable to every product or submission.

16.3.2. PPAP Submission Levels

PPAP traditionally uses five submission levels.

Level	Typical Submission
Level 1	Part Submission Warrant only
Level 2	Warrant with product samples and limited supporting data
Level 3	Warrant with product samples and complete supporting data
Level 4	Warrant and other requirements defined by the customer
Level 5	Warrant and complete supporting data available for review at the supplier's manufacturing location

Level 3 is commonly used as the default full submission where required, although the customer determines the applicable submission requirements. A submission level primarily determines **what evidence is submitted to the customer**. It should not be interpreted as permission to omit underlying planning or evidence that remains necessary to control the process.

16.3.3. The Part Submission Warrant (PSW)

The **PSW** provides the formal summary of the PPAP submission. It typically identifies information such as:

- Part number and description
- Engineering change/revision level
- Supplier and manufacturing location
- Customer details
- Submission reason
- Applicable submission level
- Declaration of conformity
- Supporting results
- Supplier authorisation

The PSW should represent the conclusion of the approval process rather than becoming a substitute for reviewing the underlying evidence.

16.3.4. Reasons for PPAP Submission or Resubmission

PPAP may be required for a new product, but the concept also applies when changes could affect the validated production condition. Examples include:

- New part or product
- Engineering design change
- Material change
- Manufacturing process change
- New or modified tooling
- Tool refurbishment where significant
- Manufacturing location transfer
- Alternative supplier or sub-tier source
- Significant production interruption
- Changes to inspection or test methods
- Correction of a previous PPAP discrepancy

The applicable customer requirements should determine when notification, resubmission or reapproval is necessary. A useful principle is:

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Approval applies to the validated product and production configuration, not indefinitely to the part number regardless of subsequent change.

16.4. Process Capability within APQP and PPAP

Process capability studies provide evidence of how process variation compares with specification limits. Common indices include:

- **Cp** – potential capability based on process spread.
- **Cpk** – capability accounting for process centring.
- **Pp/Ppk** – performance measures commonly based on longer-term observed variation.
-

Capability targets should be defined by the applicable customer or organisational requirements rather than assumed universally.

A high capability index is also not meaningful if the process is unstable or the underlying measurement system is unsuitable. Data should therefore be interpreted in the context of **process stability, measurement capability, sample size and distribution**.

16.5. APQP in the Supply Chain

APQP should extend beyond the direct supplier where sub-tier suppliers influence product conformity. Prime organisations and customers may therefore require suppliers to demonstrate:

- APQP planning
- Sub-tier management
- Supplier readiness
- Special process controls
- Capacity
- Risk management
- Configuration control
- PPAP status
- Corrective action progress

Passing requirements down the supply chain without verifying their implementation provides limited assurance.

16.6. APQP and Aerospace

Although APQP and PPAP originated primarily from automotive quality practices, the principles have been adopted more widely. Within aerospace, **AS9145 – Requirements for Advanced Product Quality Planning and Production Part Approval Process** establishes an aerospace-specific framework for APQP and PPAP.

Aerospace implementation places particular importance on areas such as:

- Product and process risk
- Critical items and key characteristics
- Configuration control
- Production readiness
- Supply-chain management
- Process capability
- Production process validation

APQP/PPAP may operate alongside other aerospace requirements such as **AS9100**, **AS9102 First Article Inspection** and customer-specific quality requirements. These requirements serve related but different purposes and should not automatically be treated as interchangeable.

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16.7. PPAP vs First Article Inspection (FAI)

A common misconception is that PPAP and FAI are equivalent.

FAI	PPAP
Primarily verifies the product against the engineering definition	Evaluates broader product and production-process readiness
Focuses strongly on characteristics and configuration	Includes process controls, risk, measurement and capability
Provides evidence from first production representative article(s)	Provides a package of evidence concerning the production system
Aerospace commonly uses AS9102	Automotive commonly uses PPAP; aerospace may use AS9145

A conforming first article demonstrates an important result, but **one conforming article does not by itself demonstrate a capable production process**.

16.8. Effective APQP Governance

APQP should have clearly defined:

- Deliverables
- Owners
- Due dates
- Maturity criteria
- Customer requirements
- Risks and actions
- Escalation routes
- Review points
- Approval authority

Status should reflect the maturity of the evidence rather than simply whether a document exists. For example:

PFMEA completed is less meaningful than: **PFMEA reviewed against the current process, high-risk actions completed, controls transferred to the control plan and effectiveness verified.**

This distinction separates **document completion from quality maturity**.

16.9. Common APQP and PPAP Weaknesses

Typical weaknesses include:

- APQP beginning too late.
- Treating APQP as a Quality department responsibility.
- Creating documents independently with poor linkage.
- Copying previous FMEAs without meaningful review.
- Process flow, PFMEA and control plan not matching the actual production process.
- Inadequate sub-tier supplier involvement.
- Capability studies using unrepresentative production conditions.
- Measurement systems not validated before capability studies.
- Prototype evidence presented as production evidence.
- Open risks hidden by administrative completion.
- PPAP packages submitted with incomplete or contradictory data.
- Changes introduced after approval without reassessing PPAP.
- PPAP approval treated as permanent regardless of subsequent change.

16.10. What Good APQP Looks Like

Effective APQP is characterised by **early involvement, cross-functional ownership, evidence-based maturity and traceability between risk and control**. A strong APQP system should be able to answer:

What could go wrong? → How have we prevented it? → How will we detect it? → How do we know the control works? → What evidence demonstrates production readiness?

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PPAP then provides the structured evidence demonstrating that these questions have been satisfactorily addressed.

16.11. Key Principle

APQP prevents surprises; PPAP provides evidence.
Neither should become a paperwork exercise. Their value lies in establishing confidence that the product requirements are understood and that the production system is appropriately planned, validated and controlled before routine production and delivery begin.

17. DFMEA, Process Flow Diagram, PFMEA & Control Plan

17.1. Introduction

Design Failure Mode and Effects Analysis (DFMEA), Process Flow Diagram, Process Failure Mode and Effects Analysis (PFMEA), and Control Plan form a connected set of quality-planning methods used to translate product and process risk into practical controls.

They are particularly important during product and process development, APQP and industrialisation, but their value continues throughout the product lifecycle. The relationship can be viewed as:

Product Requirements → DFMEA → Process Flow Diagram → PFMEA → Control Plan → Production Instructions & Records

Each stage should inform the next. The objective is not to produce four independent documents, but to create a **traceable chain from identified risk to effective control**.

Special Processes Institute Reference: Detailed guidance on PFMEA, including its methodology, application and supporting tools, is provided separately within **SPI-06 Process Failure Mode and Effects Analysis (PFMEA) Guidebook**, **SPI-07 Understanding PFMEA – Training Publication PowerPoint**, and **SPI-08 PFMEA Workbook (Excel) Form**. See https://sp-i.org/downloads.html

Therefore, PFMEA, Process Flow Diagrams and Control Plans are introduced here primarily to explain their relationship with DFMEA rather than repeat that guidance.

17.2. Design Failure Mode and Effects Analysis (DFMEA)

17.2.1. What is DFMEA?

DFMEA is a structured, systematic method for identifying and evaluating potential failures associated with a product design before those failures occur. It asks three fundamental questions:

How could the design fail? → What would happen if it failed? → What should be done to prevent or reduce the risk?

DFMEA is proactive. It should influence the design while changes can still be made effectively rather than becoming a retrospective justification after the design has been finalised. It is applicable to:

- Complete products
- Systems
- Subsystems
- Assemblies
- Components
- Interfaces
- Functions

DFMEA should be proportionate to product complexity and risk.

17.2.2. Purpose of DFMEA

The purpose of DFMEA is to systematically evaluate design risk and use that knowledge to improve the design. It can help organisations:

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- Identify potential failure modes.
- Understand the consequences of failure.
- Identify potential design causes.
- Evaluate existing prevention and detection controls.
- Prioritise significant risks.
- Define improvement actions.
- Improve reliability, safety and robustness.
- Capture engineering knowledge.
- Support future design decisions.
- Provide relevant input into downstream manufacturing risk analysis.

The primary objective is **risk reduction through improved design**, not simply production of an FMEA document.

17.2.3. Functional Thinking

An effective DFMEA starts by understanding what the product is required to **do**.
Functions might include:

- Support a specified load.
- Maintain electrical continuity.
- Provide environmental sealing.
- Transfer torque.
- Maintain alignment.
- Prevent leakage.
- Dissipate heat.
- Provide electrical insulation.
- Resist corrosion.

Failure modes can then be considered in relation to those functions. For example:

- **Function:** Maintain environmental seal
- **Potential failure mode:** Insufficient sealing
- **Potential effect:** Moisture ingress
- **Potential cause:** Inadequate seal compression

This function-based approach is generally more effective than attempting to brainstorm defects without first understanding the intended function.

17.2.4. The DFMEA Logic

A DFMEA typically develops a logical chain:

Item / Function → Failure Mode → Effect → Cause → Existing Controls → Risk Evaluation → Action

17.2.5. Failure Mode

The manner in which the item could fail to perform its intended function. Examples:

- Fractures
- Leaks
- Overheats
- Does not engage
- Insufficient strength
- Excessive deflection
- Incorrect output

17.2.5.1. Effect of Failure

The consequence if the failure occurs. Effects should consider the next higher assembly, complete product, customer, operator or end user as appropriate.

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17.2.5.2. Cause of Failure

The design-related mechanism or reason that could create the failure mode. Examples might include:

- Insufficient wall thickness
- Incorrect material selection
- Inadequate tolerance
- Excessive stress concentration
- Poor thermal management
- Inadequate environmental protection

Causes should be sufficiently specific that meaningful actions can be identified.

17.2.6. Severity, Occurrence and Detection

FMEA methodologies traditionally evaluate three dimensions of risk:

- **Severity (S)** – how serious the effect would be.
- **Occurrence (O)** – the likelihood of the cause occurring.
- **Detection (D)** – the likelihood that existing controls will detect the issue before the failure reaches the relevant point.

Historically these ratings were often multiplied to produce a: **Risk Priority Number (RPN) = S × O × D**

RPN remains widely encountered, but it should not be used blindly. Different combinations of severity, occurrence and detection can produce the same RPN while representing very different risks. Modern FMEA methodologies may instead use approaches such as **Action Priority (AP)** to determine where action should be focused.

Regardless of the method used, the objective is not to achieve a desirable numerical score. The objective is to **identify and reduce meaningful risk**.

17.2.6.1. Prevention vs Detection

An important DFMEA distinction is between controls that **prevent a cause** and controls that **detect a problem**. For example:

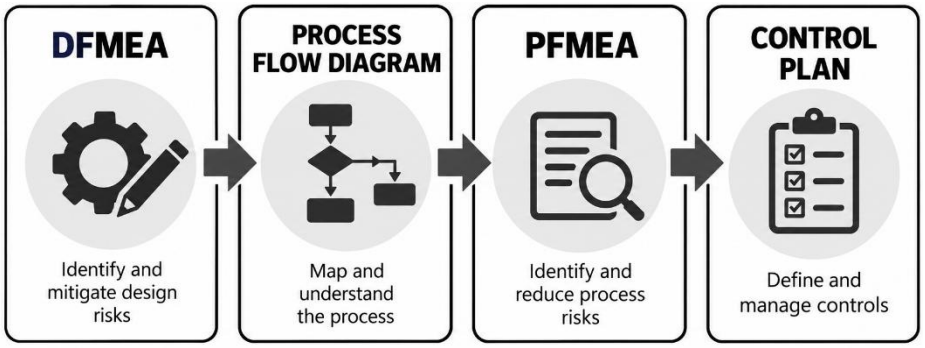
- **Prevention control:** Design rule preventing insufficient wall thickness.
- **Detection control:** Engineering analysis or physical test intended to identify inadequate strength.

Prevention is generally preferable because it reduces the opportunity for failure to occur.
Detection remains important, but relying solely on inspection or testing does not necessarily remove the underlying design risk.

17.2.7. DFMEA Inputs

Useful inputs may include:

- Customer and product requirements
- Functional analysis
- System architecture
- Drawings and specifications
- Interface requirements
- Previous product experience
- Lessons learned
- Reliability data
- Warranty and field data
- Previous nonconformities
- Engineering calculations
- Simulation and modelling
- Prototype test results
- Similar product FMEAs
- Regulatory and safety requirements



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Previous FMEAs can provide valuable knowledge, but simply copying an earlier DFMEA risks carrying forward outdated assumptions and missing new failure mechanisms.

17.2.8. Cross-Functional DFMEA

DFMEA should not normally be completed by one person in isolation. Depending on the product, useful contributors may include:

- Design engineering
- Systems engineering
- Manufacturing engineering
- Quality
- Reliability
- Safety
- Materials engineering
- Test engineering
- Service/support
- Supplier specialists

Different disciplines identify different risks. The quality of the discussion and engineering challenge is often more valuable than the completed FMEA worksheet itself.

17.2.9. DFMEA Actions

Where unacceptable or significant risk is identified, actions should be defined with clear:

- Responsibility
- Due date
- Required outcome
- Verification of completion
- Reassessment of risk

Actions should preferably address the **cause of the risk**. Possible actions include:

- Design modification
- Material change
- Tolerance improvement
- Additional analysis
- Improved environmental protection
- Design simplification
- Redundancy
- Improved interface design
- Additional verification or validation

Simply reducing a rating without implementing and verifying an effective action is not evidence that risk has reduced.

17.2.10. DFMEA Is a Living Document

DFMEA should evolve as the design and available knowledge change.
Review may be necessary following:

- Design changes
- Requirement changes
- New operating conditions
- Test failures
- Production problems
- Supplier issues
- Field failures
- Reliability findings
- New lessons learned

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A DFMEA should therefore represent the **current understanding of design risk**, not merely the state of knowledge when the document was originally created.

17.3. Process Flow Diagram

Once the product and its design risks are understood, attention turns to how the product will actually be manufactured. The **Process Flow Diagram (PFD)** defines the sequence of operations and provides the structural foundation for process risk analysis. It may include activities such as:

Receiving → Storage → Preparation → Manufacture → Special Process → Assembly → Inspection → Test → Packaging → Dispatch

The process flow should represent the **actual intended production process**, including relevant movement, inspection, rework and outsourced operations. The individual process steps then provide the basis for the PFMEA.

17.4. Process Failure Mode and Effects Analysis (PFMEA)

Where DFMEA considers: **"How could the design fail?"** PFMEA considers: **"How could the manufacturing or assembly process fail to produce the required result?"**

PFMEA analyses the operations identified within the Process Flow Diagram and considers potential process failure modes, their effects, causes, existing controls and necessary risk-reduction actions. A useful distinction is:

DFMEA	PFMEA
Focuses on product design	Focuses on manufacturing/process design
Design functions	Process functions
Design failure modes	Process failure modes
Design-related causes	Manufacturing/process-related causes
Drives design improvement	Drives process improvement and control

Manufacturing difficulty should not automatically be used to compensate for an inadequate design. Equally, a robust design does not eliminate the need for a capable manufacturing process.

17.5. Control Plan

The **Control Plan** translates identified product and process risks into the controls required during production. It defines how important characteristics and process parameters will be controlled and typically identifies:

- Characteristic or parameter
- Specification or acceptance criteria
- Measurement/control method
- Equipment or gauge
- Sample size
- Inspection/control frequency
- Responsibility
- Reaction plan

The Control Plan should reflect the significant risks identified through the preceding analysis. A PFMEA identifying a significant risk without an appropriate production control, or a Control Plan containing controls with no apparent connection to product or process risk, should prompt further review.

17.5.1. The Golden Thread

The strength of these methods comes from their connection. A well-developed quality-planning system should allow a practitioner to follow a logical thread such as:

Customer requirement

↓

Product function

↓

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DFMEA design risk
↓
Product characteristic
↓
Manufacturing operation in Process Flow
↓
PFMEA process risk
↓
Control Plan requirement
↓
Work/inspection instruction
↓
Production record and objective evidence

This is sometimes referred to as the **golden thread** of product and process quality planning. Changes to one element should therefore trigger consideration of the connected elements.

17.6. Common Weaknesses

Typical weaknesses across DFMEA, Process Flow, PFMEA and Control Plans include:

- Documents developed independently.
- FMEAs copied from previous products without adequate review.
- Failure modes described too vaguely.
- Confusing effects with causes.
- Ratings manipulated to achieve an acceptable score.
- Significant risks having no meaningful action.
- Actions recorded but effectiveness not verified.
- Process Flow not matching actual production.
- PFMEA omitting operations or outsourced processes.
- Control Plan not reflecting significant PFMEA risks.
- Production instructions contradicting the Control Plan.
- Documents not updated following change or lessons learned.
- Treating FMEA completion as an administrative milestone.

These methods only provide value when they influence **real engineering and production decisions**.

17.7. Practical Quality Principle

A useful test is to select an important product requirement and attempt to trace it through the entire system:

Requirement → Design Risk → Process → Process Risk → Control → Evidence

Then perform the exercise in reverse:

Production Control → Process Risk → Design Requirement

If that traceability cannot reasonably be demonstrated, there may be a gap between the product requirements, identified risks and production controls.

17.8. Key Principle

- **DFMEA identifies and reduces design risk.**
- **The Process Flow defines how the product will be made.**
- **PFMEA identifies and reduces manufacturing risk.**
- **The Control Plan converts those risks into operational controls.**

Their value comes not from the existence of four documents, but from the **consistent, traceable and continually maintained relationship between them**.

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For detailed PFMEA methodology and practical application, refer to the Special Processes Institute publications **SPI-06 Process Failure Mode and Effects Analysis (PFMEA) Guidebook**, **SPI-07 Understanding PFMEA – Training Publication PowerPoint**, and **SPI-08 PFMEA Workbook (Excel) Form**.

18. Metrology, Calibration & Measurement Traceability

18.1. Definition and Fundamental Concepts

- **Metrology** is the science of measurement. In quality management, it provides the principles and practices needed to ensure measurements are appropriate, reliable, comparable and understood.
- **Calibration** is the documented comparison of a measuring instrument or system against a reference of known measurement uncertainty under specified conditions. Calibration establishes the relationship between the indication of the equipment and the corresponding reference value.
- **Measurement traceability** is the property of a measurement result whereby it can be related to a stated reference through a documented, unbroken chain of calibrations, each contributing to the overall measurement uncertainty.

Together, these disciplines provide confidence that decisions based on measurement data are technically valid. A fundamental principle is: **A measurement result is only useful when there is sufficient confidence in how it was obtained and what it means.**

18.2. Why Measurement Matters

Measurement supports decisions throughout the product and process lifecycle, including:

- Product acceptance and release
- Incoming inspection
- Manufacturing process control
- Testing and validation
- Process capability assessment
- Equipment setup
- Special process control
- Laboratory testing
- Investigation of nonconformity
- Supplier assurance

If measurement is unreliable, a conforming product may be rejected or, more seriously, a nonconforming product may be accepted. Measurement therefore forms part of the **evidence on which conformity decisions depend**.

18.3. Metrology

Metrology is broader than the calibration of gauges. It considers the entire measurement process, including:

Measurand → Method → Equipment → Reference → Environment → Operator → Measurement Result → Uncertainty → Decision

The **measurand** is the quantity intended to be measured—for example, diameter, temperature, electrical resistance, torque or pressure. Metrology is commonly considered in three broad areas:

- **Scientific Metrology** Concerned with measurement standards, units and the development and maintenance of high-level measurement capability.
- **Industrial Metrology** Concerned with measurement systems used in manufacturing, inspection, testing and process control.
- **Legal Metrology** Concerned with measurements subject to statutory or regulatory requirements, such as certain measurements used in trade, safety and public protection.

Quality professionals are most frequently involved with **industrial metrology**.

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18.3.1. SI Units

Reliable measurement requires consistent definitions of measurement units. The **International System of Units (SI)** provides the internationally recognised system based on seven base units:

Quantity	SI Base Unit	Symbol
Time	second	s
Length	metre	m
Mass	kilogram	kg
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Amount of substance	mole	mol
Luminous intensity	candela	cd

Many commonly used engineering units are derived from these base units. Consistency of units is particularly important where measurements, specifications and data are exchanged between organisations.

18.4. Calibration

Calibration determines how an instrument's indication relates to a known reference. For example, a nominal 100.00 mm reference may be measured by an instrument as 100.03 mm. Calibration establishes and records the relationship between these values under defined conditions. Calibration does **not automatically mean adjustment**.

These activities should be distinguished:

- **Calibration** – determines the relationship between indication and reference.
- **Adjustment** – alters the equipment to improve its indication or performance.
- **Verification** – confirms that specified requirements have been fulfilled.

An instrument can therefore be calibrated and found outside the required acceptance criteria without being adjusted.

18.5. Measurement Traceability

Measurement traceability provides a documented connection between a measurement result and an accepted reference. A simplified traceability chain may look like:

Production measuring equipment
↓
Working reference standard
↓
Calibration laboratory reference
↓
Higher-level reference standards
↓
National / international measurement standards

Each link must be technically valid and documented, and each calibration contributes uncertainty. In the UK, national measurement standards are maintained through the **National Measurement System**, with the National Physical Laboratory (NPL) performing a major role.

Traceability should not be confused with simply possessing a calibration certificate. The **measurement result itself** must be supported by an appropriate traceability chain.

18.5.1. Calibration Hierarchy

Not every instrument needs to be calibrated directly against a national standard. Traceability is normally established through a hierarchy of increasingly accurate reference standards. The equipment used to calibrate or verify another instrument should generally provide sufficient measurement capability for the intended purpose. This creates a hierarchy such as:

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National standard → Reference standard → Working standard → Production measuring equipment → Product measurement

The appropriate hierarchy depends on the measurement, uncertainty required and associated product risk.

18.5.2. Measurement Uncertainty

No measurement is perfectly exact. **Measurement uncertainty** expresses the dispersion of values that could reasonably be attributed to the quantity being measured. Potential contributors include:

- Instrument resolution
- Calibration uncertainty
- Repeatability
- Reproducibility
- Environmental conditions
- Measurement method
- Fixturing
- Operator technique
- Reference standard uncertainty
- Temperature effects
- Equipment stability
- Workpiece condition

A result should therefore be understood conceptually as: **Measured value ± measurement uncertainty**
For example: **10.004 mm ± 0.003 mm.** The uncertainty provides important context for determining how much confidence should be placed in the measured value.

- **Accuracy, Precision and Resolution** These terms are related but should not be treated as interchangeable.
- **Accuracy** Describes closeness between a measured value and the value being measured.
- **Precision** Describes closeness between repeated measurement results. A system may be highly repeatable but consistently offset from the reference value, **precise but inaccurate**.
- **Resolution** The smallest change in indication that can be meaningfully displayed or detected by the measuring equipment. High resolution alone does not mean the measurement is accurate or suitable.

18.5.3. Measurement Capability and Tolerance

Measuring equipment should be selected according to the required measurement task. Using equipment simply because it is available or calibrated is insufficient. Consider:

Product tolerance → Required measurement capability → Appropriate equipment and method

For example, equipment with a coarse resolution may be unsuitable for assessing a very tight dimensional tolerance even if its calibration is current. Organisations sometimes use simple rules such as a **10:1 relationship between product tolerance and measurement equipment resolution or capability**, but such rules should not replace proper assessment of measurement uncertainty, process risk and the applicable requirements.

18.5.4. Measurement Decision Risk

Measurement uncertainty becomes particularly important when results approach a specification limit. Consider a specification: **10.00 ± 0.05 mm** giving limits of: **9.95 to 10.05 mm**

A result of **10.049 mm** may appear conforming. However, if the associated measurement uncertainty is significant, the true value cannot be assumed to be safely inside the specification simply from the displayed reading. This creates two important risks:

- **False acceptance** – accepting a nonconforming item.
- **False rejection** – rejecting a conforming item.

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Where appropriate, organisations may establish **decision rules or guard bands** to control these risks.

18.6. Calibration Intervals

Calibration intervals should ensure equipment remains capable throughout its period of use. Intervals may be determined from:

- Manufacturer recommendations
- Equipment stability
- Historical calibration results
- Frequency of use
- Environmental conditions
- Equipment type
- Risk associated with measurement
- Customer or regulatory requirements

A fixed annual interval is common but is not automatically appropriate for every instrument. Calibration history can provide evidence for increasing or reducing intervals where permitted.

18.7. Equipment Identification and Status

Measurement equipment should be uniquely identifiable and its status readily determined. Typical controls include:

- Unique equipment number
- Description
- Manufacturer/model
- Serial number
- Measurement range
- Resolution
- Location or custodian
- Calibration status
- Last calibration date
- Next due date
- Calibration certificate/reference
- Acceptance criteria
- Repair or adjustment history

Calibration labels can provide useful visual status, but the controlled calibration record should normally remain the authoritative source.

18.8. Control of Measuring Equipment

A robust measurement management system should address the entire equipment lifecycle:

Need identified → Selection → Acceptance → Calibration/verification → Issue/use → Protection → Periodic calibration → Maintenance → Repair → Withdrawal/disposal

Controls should protect equipment from:

- Damage
- Deterioration
- Unauthorised adjustment
- Contamination
- Incorrect storage
- Environmental exposure
- Loss of identification

Reference standards often require additional controls because failure could affect numerous downstream measurements.

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18.9. Out-of-Tolerance Calibration

One of the most important metrology controls occurs when equipment is found outside acceptable calibration limits. It is not sufficient simply to recalibrate the equipment and return it to service. The organisation should determine:

1. **What was out of tolerance?**
2. **By how much?**
3. **When might the condition have developed?**
4. **Where was the equipment used?**
5. **Which products or processes were accepted using it?**
6. **Could previous measurement decisions have been affected?**
7. **Is product containment, reinspection or customer notification required?**

This is commonly known as an **impact assessment** or retrospective assessment. The greater the measurement error and product risk, the greater the potential significance.

18.10. Environmental Control

Measurements can be affected by environmental conditions. Important influences may include:

- Temperature
- Humidity
- Vibration
- Air movement
- Cleanliness
- Electromagnetic interference
- Lighting
- Atmospheric pressure

Dimensional metrology can be particularly sensitive to temperature because both the product and measuring equipment can expand or contract. High-accuracy measurements may therefore require controlled environments and adequate stabilisation time before measurement.

18.11. Calibration Laboratories and ISO/IEC 17025

ISO/IEC 17025 specifies general requirements for the competence, impartiality and consistent operation of testing and calibration laboratories. Where external calibration services are used, organisations should consider whether the laboratory is appropriately competent for the required measurement and range. Accreditation by a recognised accreditation body provides independent evidence of competence within the laboratory's defined **scope of accreditation**.

In the UK, this role is performed by **UKAS – the United Kingdom Accreditation Service**. An accredited laboratory should not automatically be assumed competent for every calibration. The required measurement capability must fall within its applicable scope.

18.12. Calibration Certificates

A calibration certificate should be reviewed rather than simply filed. Depending on the calibration and applicable requirements, relevant information may include:

- Equipment identification
- Calibration date
- Measurement results
- Reference standards used
- Traceability information
- Environmental conditions
- Measurement uncertainty
- Calibration method
- As-found condition
- As-left condition
- Adjustments or repairs
- Statement of conformity where applicable

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- Laboratory identification
- Accreditation status and scope where relevant

Particular attention should be paid to **as-found results**, because these provide evidence of the equipment condition when it entered calibration.

18.13. Calibration vs Measurement System Analysis

Calibration and **Measurement System Analysis (MSA)** answer different questions.

- A calibration may establish: **"Does this instrument provide results appropriately related to a known reference?"**
- MSA considers: **"Is the overall measurement system suitable for this particular measurement application?"**

The measurement system includes more than the instrument:

Equipment + operator + method + fixture + environment + part + measurement process

A calibrated instrument can therefore still form part of an unsuitable measurement system.

18.14. Common Metrology and Calibration Weaknesses

Typical weaknesses include:

- Assuming calibrated means suitable for every measurement.
- Selecting equipment with inadequate resolution or capability.
- Using overdue equipment.
- Damaged equipment remaining in service.
- Calibration certificates not technically reviewed.
- Ignoring measurement uncertainty.
- No assessment when equipment fails calibration.
- Inadequate control of reference standards.
- Calibration intervals based only on convention.
- Poor traceability of equipment to inspected product.
- Uncontrolled employee-owned measuring equipment.
- Environmental effects not considered.
- Incorrect units or conversion errors.
- Calibration status labels treated as the entire calibration system.
- External laboratory accreditation assumed without checking scope.

18.15. Practical Audit Considerations

When auditing measurement control, do not only ask: **"Is this gauge calibrated?"** Follow the measurement trail:

What characteristic is being measured? → What tolerance applies? → Is this equipment suitable? → Is its calibration current? → Is traceability established? → What is the uncertainty/capability? → Is the method controlled? → Is the operator competent? → What happens if the equipment fails calibration?

This approach evaluates the effectiveness of the **measurement system**, rather than merely checking calibration labels.

18.16. Key Principle

Calibration establishes confidence in the measuring equipment; traceability connects the measurement to recognised references; metrology establishes confidence in the complete measurement process.
The objective is not to ensure that every instrument carries an in-date calibration sticker. It is to ensure that every measurement used to make an important product or process decision is **appropriate, technically valid, traceable and sufficiently reliable for its intended purpose**.

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19. Measurement System Analysis (MSA)

19.1. Definition and Fundamental Concepts

Measurement System Analysis (MSA) is the structured evaluation of a measurement system to determine whether it is sufficiently capable and reliable for its intended use. A measurement system is more than the measuring instrument. It includes the complete combination of:

Equipment + Reference Standards + Method + Operator + Part + Fixture + Software + Environment

MSA evaluates the variation introduced by this system so that an organisation can distinguish **actual product or process variation from measurement variation**.

This distinction is fundamental: **If you cannot trust the measurement system, you cannot confidently trust the decisions made from its data.**

MSA is widely associated with automotive quality and the AIAG Core Tools but its principles are applicable to any industry where measurements are used to make decisions about product conformity or process performance.

19.2. Purpose of MSA

Every measurement contains some degree of variation. MSA determines whether that variation is sufficiently small and controlled for the intended application. It helps answer questions such as:

- Can the system reliably distinguish between different parts?
- Do different operators obtain comparable results?
- Does the equipment produce consistent results?
- Does measurement performance change across its operating range?
- Does the system remain stable over time?
- Is there systematic measurement error?
- Is the system suitable for process capability or SPC analysis?
- Can inspection results be trusted when making acceptance decisions?

Without an adequate measurement system, process data can create a false impression of both conformity and process performance.

19.3. Measurement Variation

An observed measurement contains variation from both the actual product and the measurement process. Conceptually:

Observed Variation = Part-to-Part Variation + Measurement System Variation

The purpose of MSA is to understand and quantify the measurement contribution.
Measurement variation is commonly divided into:

- **Location Variation** Concerns whether measurements are correctly positioned relative to a reference value. Includes:
  - **Bias**
  - **Linearity**
  - **Stability**
  - **Width Variation**

Concerns the spread or consistency of repeated measurements. The principal elements are:

- **Repeatability**
- **Reproducibility**

Together, repeatability and reproducibility form the familiar **Gauge R&R** study.

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19.3.1. Repeatability

Repeatability is the variation observed when the **same operator measures the same part repeatedly using the same measurement system under the same conditions**. It is sometimes described as **equipment variation (EV)**. For example, if one inspector measures the same diameter ten times and obtains different results, part of that spread represents repeatability variation. Poor repeatability may be associated with:

- Instrument limitations
- Resolution
- Fixturing
- Measurement force
- Positioning
- Part condition
- Equipment wear
- Method variation
- Environmental effects

19.3.2. Reproducibility

Reproducibility is the variation in average measurements between different operators or other measurement conditions. It is often described as **appraiser variation (AV)**. For example:

- **Operator A → 10.02 mm**
- **Operator B → 10.05 mm**
- **Operator C → 10.01 mm**

A significant difference may indicate that the measurement depends too heavily on who performs it.
Potential causes include:

- Different measurement techniques
- Ambiguous instructions
- Different positioning
- Operator training
- Reading or interpretation differences
- Different measurement force
- Fixture interaction

Increasing automation can reduce some operator effects but does not automatically eliminate measurement-system variation.

19.4. Gauge Repeatability and Reproducibility (Gauge R&R)

A **Gauge R&R study** evaluates the combined contribution of repeatability and reproducibility. A typical crossed Gauge R&R study might use:

10 representative parts × 3 operators × 2 or 3 repeated measurements

The operators should measure the same parts independently, ideally in a randomised order and without seeing previous results. The selected parts should represent the expected range of actual process variation.
The study then separates observed variation into components such as:

- **Part-to-Part Variation**
- **Repeatability**
- **Reproducibility**
- **Total Measurement System Variation**

The objective is to determine how much of the observed variation is created by the measurement system rather than the product.

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19.4.1. Interpreting Gauge R&R

A commonly encountered AIAG interpretation for **% Gauge R&R** is:

% Gauge R&R	General Interpretation
<10%	Generally considered acceptable
10–30%	May be acceptable depending on application, risk, cost and other factors
>30%	Generally considered unacceptable and should be improved

These values should be treated as **guidance rather than universal acceptance criteria**.
A safety-critical characteristic, for example, may require a substantially stronger measurement system than a low-risk characteristic.

The basis of the reported percentage must also be understood—such as percentage of **study variation, process variation or tolerance**—because apparently similar percentages can represent different analyses.

19.4.2. Number of Distinct Categories (ndc)

Number of Distinct Categories (ndc) indicates how effectively the measurement system can distinguish between different levels of part variation. A system may repeat measurements reasonably well but still lack sufficient discrimination to distinguish meaningful differences between parts.

As a commonly used guideline: **ndc ≥ 5** is generally considered desirable for useful process analysis.

Higher values provide greater ability to distinguish between different levels of process output.

19.4.3. Bias

Bias is the difference between the observed average measurement and an accepted reference value.
Conceptually:

Bias = Observed Average − Reference Value

For example: Reference value = **20.000 mm** Average measured value = **20.015 mm** Bias = **+0.015 mm**
A measurement system can be highly repeatable while still having significant bias. This demonstrates why **precision alone does not establish accuracy**.

19.4.4. Linearity

Linearity evaluates whether measurement bias changes across the operating range of the measurement system. For example, an instrument may perform well around 10 mm but progressively over-read as measurements approach 100 mm. A linearity study therefore uses reference values distributed across the intended measurement range. This is particularly important when one measuring system is used across a broad range of dimensions or values.

19.4.5. Stability

Stability considers whether the measurement system maintains consistent performance over time. A reference or master part may be measured periodically and results monitored for changes. Potential sources of instability include:

- Equipment wear
- Electronic drift
- Environmental changes
- Fixture deterioration
- Contamination
- Software changes
- Maintenance
- Operator changes

A system that performs well during an initial study may not remain capable indefinitely.

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19.5. Attribute Measurement Systems

Not all measurement results are numerical. Examples of **attribute inspection** include:

- Pass / Fail
- Accept / Reject
- Defect / No defect
- Scratch / No scratch
- Correct / Incorrect
- Visual classification

Attribute MSA evaluates whether inspectors or automated systems make consistent and correct classifications. It can assess:

- **Within-appraiser agreement** – does the same inspector make the same decision repeatedly?
- **Between-appraiser agreement** – do different inspectors agree?
- **Agreement with a reference** – do inspectors agree with the known or expert classification?

This is particularly important for visual inspection, where apparently simple acceptance criteria can produce substantial variation between inspectors.

19.6. Destructive Measurement

Some measurement or test methods destroy or permanently alter the item, meaning the same part cannot be repeatedly measured. Examples may include:

- Tensile testing
- Destructive sectioning
- Peel testing
- Certain chemical analyses
- Burst testing

Traditional crossed Gauge R&R methods may therefore be inappropriate. Alternative experimental designs and statistical methods should be selected based on the measurement process.

The study should fit the measurement system, not the measurement system forced into a standard study template.

19.7. Selecting Parts for an MSA Study

Part selection can significantly affect the conclusions. Parts should normally represent the **actual range of process variation**. Selecting ten nearly identical parts can make measurement variation appear disproportionately large because there is little genuine part-to-part variation.

Conversely, deliberately selecting extremely different parts may produce misleadingly favourable results. The study design should therefore reflect the question being asked and the intended use of the measurement system.

19.8. MSA and Calibration

Calibration and MSA serve different purposes.

Calibration	MSA
Evaluates equipment against a reference	Evaluates the complete measurement system
Supports measurement traceability	Evaluates measurement capability
Primarily concerned with instrument performance	Includes equipment, people, method, parts and environment
May identify bias/error	Examines multiple sources of measurement variation

A gauge can have a valid calibration certificate and still perform poorly in an MSA. Conversely, a good Gauge R&R result does not remove the need for appropriate calibration and traceability.

The two disciplines are **complementary, not interchangeable**.

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19.9. MSA and Process Capability

MSA should generally be considered **before relying on process capability results**. If the measurement system contributes excessive variation, calculated **Cp, Cpk, Pp or Ppk** values may not accurately represent the manufacturing process. Similarly, SPC charts may indicate apparent process movement that is actually caused by measurement variation. The logical sequence is therefore:

Measurement system demonstrated suitable → Reliable data collected → Process behaviour analysed → Capability assessed

19.10. When Should MSA Be Performed?

MSA should be considered when:

- Introducing new measurement equipment
- Introducing a new measurement method
- Launching a new product or process
- Implementing APQP/PPAP
- Measuring important or critical characteristics
- Changing operators or inspection methods significantly
- Relocating or modifying measurement equipment
- Measurement results appear inconsistent
- Process capability results are questionable
- Customer requirements mandate MSA

Reassessment should also be considered when significant changes could affect the measurement system.

19.11. Improving a Poor Measurement System

A failed or marginal MSA should lead to investigation rather than simply repeating the study until an acceptable result appears. Potential improvements include:

- Better measurement equipment
- Improved resolution
- Improved fixturing
- Standardised measurement technique
- Clearer work instructions
- Operator training
- Reduced operator influence
- Improved environmental control
- Improved part positioning
- Automated measurement
- Better surface preparation
- Equipment maintenance
- Alternative measurement technology

After improvement, the study should be repeated to demonstrate effectiveness.

19.12. Common MSA Weaknesses

Typical weaknesses include:

- Assuming calibration proves measurement capability.
- Performing Gauge R&R only because a customer requires it.
- Selecting inappropriate parts.
- Using non-representative operators.
- Operators seeing previous results.
- Measurements not randomised.
- Confusing repeatability with reproducibility.
- Ignoring attribute inspection systems.
- Applying standard Gauge R&R to unsuitable destructive tests.
- Using percentage criteria without understanding their basis.
- Accepting poor MSA because the equipment is expensive or difficult to replace.

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- Conducting capability studies using an unverified measurement system.
- Repeating studies until favourable results appear rather than correcting the cause.
- Failing to reassess following significant change.

19.13. Practical Quality and Audit Considerations

When reviewing MSA, avoid asking only: **"Has a Gauge R&R been completed?"** Instead establish:

What decision is this measurement used for? → What measurement system is involved? → What variation matters? → Was the study appropriately designed? → Were representative parts and operators used? → What do the results show? → Is the system suitable for its intended purpose? → What actions were taken where it was not?

This changes MSA from a paperwork requirement into an evaluation of **measurement confidence**.

19.14. Key Principle

MSA determines whether the measurement process is good enough to make the decision being asked of it. A measurement result may contain several decimal places and appear highly precise, but precision on a display is not evidence of measurement capability.

Before using measurement data to accept product, control a process, calculate capability or drive improvement, the organisation should have sufficient confidence that: **the variation being observed belongs primarily to the product or process, not to the measurement system used to observe it.**

20. Tolerance Stack-Up Analysis

20.1. Introduction

Tolerance stack-up, also known as tolerance analysis, is the systematic evaluation of how individual dimensional and geometric tolerances combine within an assembly and influence the final functional requirement.

No manufactured feature is produced at an exact nominal dimension. Every component varies within permitted limits. When several components interact, these variations accumulate or “stack” and can affect clearance, interference, alignment, fit, preload, position, sealing, engagement and overall product performance.

A tolerance stack-up therefore answers a fundamental engineering and quality question: **Considering the permitted variation of every contributing feature, will the product still assemble and function correctly?**

Tolerance analysis should be considered during design and development rather than being used only after dimensional problems occur in production.

20.2. Purpose of Tolerance Stack-Up Analysis

Tolerance stack-up analysis is used to demonstrate that the relationship between component tolerances and the required assembly condition is understood and adequately controlled. Typical applications include:

- determining minimum and maximum assembly clearances;
- assessing potential interference between components;
- establishing dimensional interfaces between mating parts;
- determining positional or alignment variation;
- evaluating gaps, flushness and edge conditions;
- assessing bearing, shaft and bush fits;
- establishing shim requirements;
- analysing fastener and hole alignment;
- assessing seal compression;
- determining engagement depth;
- evaluating accumulated manufacturing variation;
- supporting drawing tolerance allocation;
- investigating assembly nonconformities;

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- assessing proposed concessions or deviations;
- supporting Design for Manufacture and Assembly (DFMA);
- identifying dimensions requiring tighter process control.

Tolerance analysis connects design intent with manufacturing capability. A drawing may be individually correct at component level while the resulting assembly is functionally unacceptable because the combined variation was not adequately considered.

20.3. The Tolerance Chain

A tolerance stack consists of individual dimensions that contribute to a particular functional requirement. These dimensions form a tolerance chain. or example, consider three components positioned within an enclosure:

A + B + C = Assembly Length If:

- A = 20.00 ± 0.10 mm
- B = 15.00 ± 0.05 mm
- C = 10.00 ± 0.10 mm

then the nominal assembly length is: **20 + 15 + 10 = 45.00 mm** However, the actual assembly length will vary because each component can vary. Understanding this accumulated variation is the purpose of the tolerance stack-up.

20.4. Worst-Case Tolerance Analysis

The simplest and most conservative approach is worst-case analysis. Worst-case analysis assumes that every contributing dimension could simultaneously occur at the limit that produces the most adverse assembly condition. For a simple linear stack:

$T_{(WC)} = \pm (T_1 + T_2 + T_3 + \ldots + T_n)$ Using the previous example: **$\pm(0.10 + 0.05 + 0.10) = \pm 0.25$ mm**

Therefore: **Assembly = 45.00 ± 0.25 mm**

The possible limits are therefore: **Minimum = 44.75 mm Maximum = 45.25 mm**

Worst-case analysis provides a powerful assurance: If the assembly functions at both worst-case limits, every combination of components manufactured within the specified tolerances should theoretically assemble and satisfy that particular dimensional requirement.

This makes worst-case analysis particularly appropriate for safety-critical, high-reliability, low-volume or highly consequential applications. The disadvantage is that it can result in unnecessarily tight individual component tolerances, increasing manufacturing and inspection cost.

20.5. Direction Matters

Tolerance analysis is not simply the addition of dimensions. Each dimension must be assigned according to the direction in which it affects the functional requirement. A stack may therefore be represented as:

X = A + B − C − D

The nominal result is calculated using the same signs. The analyst should establish a consistent positive direction and identify whether each dimension increases or decreases the final functional characteristic.

A useful practice is to draw the dimensional loop and use arrows to show the direction of every contributor.

20.6. Statistical Tolerance Analysis

In many production situations, it is unlikely that every component will simultaneously occur at its worst possible tolerance limit. A statistical approach may therefore provide a more realistic prediction of assembly variation. One commonly used method is Root Sum Square (RSS). For independent contributors:

$T_{(RSS)} = \sqrt{(T_1^2 + T_2^2 + T_3^2 + \ldots + T_n^2)}$

For the previous example:

$T_{(RSS)} = \sqrt{(0.10^2 + 0.05^2 + 0.10^2)}$

$T_{(RSS)}$ = approximately 0.15 mm

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The predicted assembly variation is therefore considerably smaller than the ±0.25 mm worst-case result. However, statistical tolerance analysis relies on assumptions about the underlying manufacturing processes and distributions. It should not be used simply to make an otherwise unacceptable design appear acceptable.

Process stability, centring, distribution, correlation and capability must be considered.

20.7. Worst-Case vs Statistical Analysis

Method	Principle	Advantage	Limitation	Typical Application
Worst Case	All contributors simultaneously reach adverse limits	Strong assurance and simple to understand	Can drive unnecessarily tight tolerances	Safety-critical, low-volume and high-consequence assemblies
RSS	Contributors combine statistically	More realistic for capable production processes	Depends on statistical assumptions	Stable repetitive manufacturing
Monte Carlo	Simulates large numbers of possible dimensional combinations	Handles complex distributions and relationships	Requires reliable input data and appropriate software	Complex assemblies and advanced design analysis

The analysis method should be selected according to product risk, production volume, manufacturing capability and the consequence of failure.

20.8. Gap and Clearance Analysis

Many tolerance studies determine whether a required clearance will always exist. For example:
Gap = Housing Space – Component A – Component B
Suppose:
Housing space = 50.00 ± 0.20 mm
Component A = 30.00 ± 0.10 mm
Component B = 19.00 ± 0.10 mm

Nominal gap: **50 – 30 – 19 = 1.00 mm**

Worst-case minimum gap occurs when the housing space is smallest and the components are largest: **49.80 – 30.10 – 19.10 = 0.60 mm**

Worst-case maximum gap: **50.20 – 29.90 – 18.90 = 1.40 mm**

Therefore: **Gap = 1.00 ± 0.40 mm**

If the design requires a minimum clearance of 0.50 mm, the design satisfies that requirement under the stated worst-case dimensional conditions.
This minimum/maximum approach is often easier to communicate than simply presenting a tolerance value.

20.9. Tolerance Allocation

Tolerance analysis should not merely verify existing tolerances. It can also be used to determine how the available assembly tolerance should be distributed between components. For example, if an assembly can tolerate **±0.50 mm** variation and five features contribute to the stack, allocating **±0.10 mm** to every feature may initially appear logical.

However, equal allocation is rarely optimal. Tolerance allocation should consider:

- manufacturing process capability;
- functional importance;
- measurement capability;
- material behaviour;

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- component geometry;
- supplier capability;
- production volume;
- process stability;
- cost of achieving the tolerance;
- consequences of nonconformance.

A feature easily maintained to **±0.02 mm** should not necessarily receive the same tolerance allocation as a fabricated feature for which **±0.20 mm** is difficult and expensive.

The objective is not to make every tolerance tight. The objective is to specify tolerances that are sufficiently tight to protect function, but sufficiently wide to permit economical and capable manufacture.

20.10. Relationship with GD&T

Tolerance stack-up becomes considerably more sophisticated when Geometric Dimensioning and Tolerancing (GD&T) is involved. Variation may arise not only from size tolerances but from geometric characteristics including:

- position;
- flatness;
- straightness;
- perpendicularity;
- parallelism;
- profile;
- runout;
- datum relationships.

GD&T requirements should therefore be interpreted according to the applicable drawing standard, such as ISO GPS standards or **ASME Y14.5**, rather than being treated as simple ± dimensional tolerances. Modifiers and concepts such as Maximum Material Condition (MMC), Least Material Condition (LMC), Regardless of Feature Size (RFS), bonus tolerance and datum feature mobility can significantly change the available tolerance.

A stack-up that ignores applicable geometric tolerances may substantially underestimate the true possible variation.

20.11. One-Dimensional, Two-Dimensional and Three-Dimensional Analysis

20.11.1. 1D Analysis

A one-dimensional stack considers variation along a single linear direction. This is appropriate for relatively simple conditions such as: **A + B + C – D = Gap** It is the most common form of manual tolerance analysis.

20.11.2. 2D Analysis

Two-dimensional analysis considers variation in two axes and may be required for hole patterns, angular relationships, locating features and planar assemblies. Vector relationships may need to be considered rather than simply adding linear tolerances.

20.11.3. 3D Analysis

Complex assemblies may require three-dimensional tolerance simulation. This can consider:

- multiple datum structures;
- geometric tolerances;
- assembly sequences;
- component movement;
- floating fasteners;
- angular variation;
- complex interfaces.

Specialist tolerance-analysis software or CAD-integrated tools are commonly used for these applications.

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20.12. A Practical Tolerance Stack-Up Analysis Method

A disciplined tolerance analysis should generally follow the following sequence:

1. **Define the functional requirement. Clearly identify what must be protected, such as minimum clearance, maximum gap, alignment or engagement.**
2. **Identify the interfaces. Determine which components and features influence that requirement.**
3. **Establish the tolerance loop. Trace the dimensional path from one side of the functional requirement to the other.**
4. **Select a direction convention. Assign positive and negative directions consistently.**
5. **Identify nominal dimensions and tolerances.**
6. **Include geometric contributors. Consider GD&T, datum relationships and assembly effects where applicable.**
7. **Select the analysis method. Determine whether worst-case, statistical or simulation analysis is appropriate.**
8. **Calculate the resulting variation.**
9. **Compare the result against the functional requirement.**
10. **Assess manufacturing capability. Determine whether the assumptions are realistic for the intended processes.**
11. **Optimise tolerances where necessary.**
12. **Document assumptions and conclusions.**
13. **Verify the analysis during product realisation.**

The analysis should be sufficiently documented that another competent engineer can understand what was analysed, why dimensions were included, what assumptions were made and how the conclusion was reached.

20.13. Identifying the Critical Contributors

One of the greatest benefits of tolerance analysis is identifying which dimensions dominate the assembly variation. Consider a stack containing ten dimensions. If one feature contributes 50% of the total variation, improving that feature may be considerably more effective than tightening all ten tolerances. This can guide:

- drawing optimisation;
- manufacturing process selection;
- inspection planning;
- supplier controls;
- Key Characteristic identification;
- SPC implementation;
- capability studies;
- fixture design;
- measurement strategy.

Tolerance analysis therefore supports risk-based quality planning, rather than simply being a mathematical exercise.

20.14. Relationship with Process Capability

A drawing tolerance defines what is permitted. Process capability describes what the manufacturing process actually produces. These are not the same thing.

A tolerance stack may theoretically demonstrate that an assembly will function when every component remains within drawing tolerance. However, production data may reveal that certain processes are poorly centred, unstable or incapable of reliably maintaining those tolerances.

Conversely, statistical tolerance analysis is meaningful only when its assumptions reasonably represent the manufacturing processes involved.

Process capability measures such as Cp and Cpk can therefore provide important supporting evidence when developing statistical tolerance models.

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20.15. Measurement Uncertainty

Tolerance studies should also recognise that the measured value is not the absolute true value.
Every measurement contains uncertainty. Where tolerances become small relative to the capability of the measurement system, measurement uncertainty can become a significant contributor to decision risk. The organisation should therefore consider:

- measurement equipment resolution;
- calibration;
- Gauge R&R;
- measurement uncertainty;
- operator influence;
- environmental conditions;
- measurement method;
- datum establishment;
- inspection fixture repeatability.

There is little value in specifying an extremely tight tolerance if the organisation cannot manufacture or reliably verify it.

20.16. Common Mistakes

Typical weaknesses in tolerance analysis include:

- analysing only nominal dimensions;
- adding every tolerance regardless of direction;
- overlooking geometric tolerances;
- ignoring datum relationships;
- assuming every drawing dimension belongs in the stack;
- omitting manufacturing or assembly effects;
- using RSS without understanding its statistical assumptions;
- assuming processes are perfectly centred;
- ignoring correlations between dimensions;
- tightening tolerances unnecessarily;
- using unrealistic process capability assumptions;
- overlooking measurement uncertainty;
- analysing component compliance without considering assembly function;
- performing the analysis only after production problems occur.

Another common error is double-counting variation by including dimensions that are not independent or by including a geometric effect more than once.

20.17. Best Practice

Good tolerance management begins during design rather than inspection. Tolerance stack-up should be integrated with design reviews, DFMEA, manufacturing engineering, GD&T, process capability, measurement planning and supplier quality assurance. Where a tolerance stack identifies insufficient margin, potential responses include:

- changing nominal dimensions;
- widening the available functional envelope;
- changing the datum scheme;
- reducing the number of contributors;
- tightening selected critical tolerances;
- improving manufacturing capability;
- redesigning the interface;
- introducing adjustment or shimming;
- improving locating features;
- changing assembly sequence.

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Tightening every component tolerance should generally be avoided unless technically justified. It can substantially increase manufacturing and inspection cost without addressing the true source of variation.

20.18. Quality Professional's Perspective

Tolerance stack-up is sometimes viewed as purely a design-engineering activity. In practice, it is highly relevant to Quality because it explains why individually conforming components can still create a nonconforming or non-functional assembly.

When investigating dimensional assembly problems, the Quality professional should therefore ask: **Are the individual components actually nonconforming, or is the permitted combination of conforming tolerances capable of producing the observed condition?**

That distinction is important. If all components comply with their drawings but the assembly cannot reliably meet its functional requirement, the underlying issue may be design tolerance allocation rather than manufacturing nonconformance.

Tolerance analysis therefore provides an important bridge between design intent, manufacturing capability, inspection and functional product assurance.

21. Configuration Management

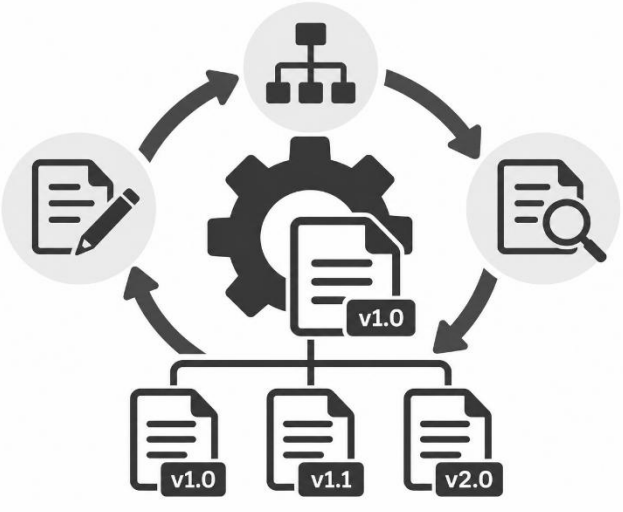
21.1. Definition and Fundamental Concepts

Configuration Management (CM) is the disciplined process used to identify, control, record and verify the functional and physical characteristics of a product, system, service or associated information throughout its lifecycle. In practical terms, Configuration Management provides confidence that an organisation can answer:

What is it? → What should it be? → What changed? → Who authorised the change? → What configuration was built, tested and delivered?

Configuration Management is particularly important where products are complex, safety-critical, highly regulated, long-lived or subject to frequent change. It applies not only to drawings and part numbers, but potentially to:

- Hardware
- Software and firmware
- Specifications
- Bills of Material (BOM)
- Manufacturing instructions
- Inspection and test requirements
- Tooling
- Processes
- Materials
- Approved suppliers
- Technical data
- Maintenance information
- Customer documentation



The fundamental objective is to maintain **control and traceability between requirements, definition, manufacture, verification and delivered configuration**.

21.2. Why Configuration Management Matters

A technically correct product manufactured to the **wrong revision** is still the wrong product. Poor configuration control can result in:

- Obsolete drawings being used.
- Incorrect components being installed.
- Unapproved software or firmware.
- Changes implemented without assessment.

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- Suppliers manufacturing to different revisions.
- Inspection against outdated requirements.
- Incompatible components or assemblies.
- Incorrect maintenance information.
- Inability to determine the configuration of delivered products.
- Previously completed verification becoming invalid after change.

Configuration Management therefore prevents uncontrolled differences between **what was designed, what was authorised, what was manufactured and what was delivered**.

21.3. The Configuration Management Process

Configuration Management is commonly structured around five related activities:

Configuration Planning → Configuration Identification → Change Control → Configuration Status Accounting → Configuration Audit

These activities operate throughout the lifecycle rather than as isolated project stages.

21.4. Configuration Management Planning

Configuration planning establishes **how configuration will be managed**. Depending on product complexity, this may be contained within a dedicated Configuration Management Plan (CMP) or incorporated into wider project or quality planning. Planning should establish:

- Roles and responsibilities
- Configuration authority
- Configuration identification methods
- Change-control process
- Baseline strategy
- Configuration status recording
- Document and data controls
- Supplier and sub-tier requirements
- Interface controls
- Configuration audit arrangements
- Records and retention
- Tools and information systems
- Customer approval requirements

The level of control should be proportionate to the product's complexity, lifecycle, regulatory environment and risk.

21.5. Configuration Identification

Configuration identification determines **what needs to be controlled** and how it will be uniquely identified. Controlled elements are commonly known as **Configuration Items (CIs)**. A configuration item might be:

- Complete product
- Assembly
- Subassembly
- Component
- Software application
- Firmware release
- Interface definition
- Drawing
- Specification
- Manufacturing dataset

Identification may include:

Part Number + Revision/Issue + Serial/Batch Number + Software/Firmware Version

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This allows a specific physical or digital item to be related to its approved definition.

21.6. Product Structure and Bill of Material

The **Bill of Material (BOM)** provides an important representation of product configuration. A structured BOM may show:

Product
↓
Major Assembly
↓
Subassembly
↓
Component
↓
Material / Part

The BOM should align with the approved product definition. Where engineering, manufacturing and service BOMs exist separately, their relationships and differences should be controlled.
Errors between BOMs, drawings, planning systems and physical product can create significant configuration risk.

21.7. Baselines

A **configuration baseline** is an approved and formally controlled reference configuration that provides a defined starting point for subsequent change. Depending on the industry and lifecycle model, organisations may establish baselines associated with:

- Requirements
- Functional definition
- Product design
- Manufacturing definition
- Production release
- As-built configuration
- As-delivered configuration

Once a baseline has been established, changes should occur through an authorised change-control process. A baseline therefore provides the answer to: **"What was the approved configuration at this point in the lifecycle?"**

21.8. Configuration Change Control

Products inevitably change. The objective of CM is not to prevent change, but to ensure that change is **identified, evaluated, authorised, implemented and recorded in a controlled manner**.
A typical change process follows:

Change Need → Change Request → Impact Assessment → Review → Approval → Implementation → Verification → Configuration Records Updated

Change terminology varies between organisations and may include:

- Engineering Change Request (ECR)
- Engineering Change Order (ECO)
- Engineering Change Notice (ECN)
- Change Proposal
- Modification
- Amendment

Regardless of terminology, the fundamental control principles remain similar.

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21.9. Change Impact Assessment

A change should not be assessed only against the document being modified. The potential effect should be considered across the wider system. For example:

Design change
↓
Could affect
↓
BOM → Tooling → Manufacturing → Supplier → Inspection → Test → Software → FAI/PPAP → Spares → Maintenance → Existing Stock → Delivered Product

Impact assessment may need to consider:

- Form, fit and function
- Safety
- Reliability
- Interchangeability
- Manufacturing process
- Tooling and fixtures
- Inspection programmes
- Test requirements
- Qualification
- FAI or PPAP
- Special processes
- Supplier requirements
- Existing inventory
- Work in progress
- Cost and schedule
- Customer approval
- Regulatory approval
- Maintenance and spares

A small drawing change can have a large lifecycle impact.

21.10. Change Effectivity

Effectivity defines when or where an approved change becomes applicable. This may be controlled by:

- Serial number
- Batch or lot
- Date
- Production order
- Software version
- Modification state

For example: **Change effective from Serial Number 00501 onwards.** Effectivity prevents ambiguity during transition between configurations. Without effective control, old and new configurations can become unintentionally mixed.

21.11. Concessions and Deviations

A concession or deviation does not normally represent a permanent change to the approved product definition. It provides controlled authorisation for a specific departure under defined conditions. The distinction is important:

- **Engineering Change** – modifies the approved configuration.
- **Concession/Deviation** – permits a controlled departure without necessarily changing the baseline definition.

Repeated concessions for the same condition may indicate that a formal design or process change should be considered.

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21.12. Configuration Status Accounting

Configuration Status Accounting (CSA) provides the records necessary to understand the current and historical configuration status. It should enable authorised personnel to determine information such as:

- Current revision
- Approved changes
- Pending changes
- Change implementation status
- Baseline status
- Serial number applicability
- Modification state
- Software/firmware version
- Concession status
- As-built configuration
- As-maintained configuration
- As-delivered configuration

Status accounting provides the **audit trail of configuration history**. For long-life products, these records may remain important for decades.

21.13. As-Designed, As-Planned, As-Built and As-Delivered

Several configuration states may exist.

- **As-Designed** The configuration defined by the approved engineering definition.
- **As-Planned** The configuration and manufacturing route intended for production.
- **As-Built** The actual configuration physically manufactured, including authorised departures where applicable.
- **As-Delivered** The configuration supplied to the customer.
- **As-Maintained** The current configuration following maintenance, repair, upgrades or modifications during service.

Ideally these states remain aligned, but where differences exist they should be **known, authorised and traceable**.

21.14. Configuration Audit

Configuration audits provide independent evidence that configuration requirements have been correctly implemented. Two concepts commonly encountered are:

- **Functional Configuration Audit (FCA)** Confirms that the configuration item has achieved its specified functional and performance requirements.
- **Physical Configuration Audit (PCA)** Confirms that the physical product corresponds with the approved product definition and associated records.

The terminology and formal requirements vary between industries and contracts, but the underlying principle is consistent: **Does the product perform as defined, and does the physical configuration match the approved definition?**

21.15. Document Control vs Configuration Management

Document control and Configuration Management are closely related but are not the same. **Document control** manages information such as:

- Approval
- Revision
- Distribution
- Access
- Obsolescence
- Retention

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Configuration Management manages the relationship between controlled information and the **actual product configuration throughout its lifecycle**.

A drawing can therefore be perfectly document-controlled while the physical product remains poorly configuration-controlled.

21.16. Configuration Management in the Supply Chain

Configuration control must extend through the supply chain where suppliers contribute to the product configuration. Suppliers may need to control:

- Customer drawing revisions
- Specifications
- BOMs
- Manufacturing instructions
- Approved processes
- Software
- Sub-tier requirements
- Engineering changes
- Effectivity
- Concessions

A common risk occurs when the customer changes a requirement but the revised configuration is not effectively communicated through every affected tier.

The key question is not merely: **"Was the change sent to the supplier?"** but **"Can we demonstrate that the correct change was understood and implemented at the correct point of effectivity?"**

21.17. Software and Firmware Configuration

Modern products increasingly combine hardware and software. Software configuration may require control of:

- Software version
- Source code
- Build configuration
- Firmware
- Libraries
- Dependencies
- Parameter sets
- Interfaces
- Release records

A product may be physically identical while behaving differently because of its software or firmware configuration. The complete product configuration must therefore consider both **physical and digital configuration** where applicable.

21.18. Configuration Management Standards

Configuration requirements appear within many industry standards and contractual frameworks. Examples include:

- **ISO 10007** – provides guidance on Configuration Management.
- **AS9100** – includes Configuration Management requirements within aerospace quality management systems.
- **EIA-649** – provides widely recognised Configuration Management principles.

Additional defence, aerospace, automotive, software and customer-specific standards may impose more detailed requirements. The applicable contractual and regulatory requirements should always determine the required level of control.

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21.19. Configuration Management and Quality

Quality professionals may provide assurance that configuration controls are operating effectively, but Configuration Management should not automatically be treated as solely a Quality department responsibility. Effective CM requires cooperation between:

- Engineering
- Configuration Management
- Manufacturing
- Quality
- Supply Chain
- Programme Management
- Production Planning
- Test
- Logistics
- Product Support

Engineering typically controls the technical definition; Configuration Management controls the integrity and status of that definition; manufacturing builds against it; and Quality provides assurance that the required controls are effective.

21.20. Common Configuration Management Weaknesses

Typical weaknesses include:

- Obsolete drawings available at point of use.
- BOM and drawing revisions not aligned.
- Changes implemented before approval.
- Changes approved but not fully implemented.
- Supplier revision status differing from customer status.
- Poor change effectivity control.
- Work in progress caught between revisions without clear disposition.
- Software versions not recorded.
- Inadequate as-built records.
- Temporary deviations becoming permanent practice.
- FAI, PPAP or qualification implications not considered after change.
- Existing inventory not assessed following design change.
- Inability to determine the configuration of delivered serial numbers.
- Document control mistaken for complete Configuration Management.

21.21. Practical Audit Approach

A powerful way to audit Configuration Management is to **trace a real configuration rather than only reviewing the procedure**. Select a delivered or production item and ask:

What is this product? → What revision should it be? → What BOM applies? → What software applies? → What changes have occurred? → Were they approved? → When did they become effective? → Did suppliers receive them? → Was verification repeated where necessary? → Can the actual as-built configuration be demonstrated?

Then select a recent engineering change and trace it in the opposite direction:

Approved Change → Product Definition → BOM → Manufacturing → Inspection/Test → Supplier → Inventory/WIP → Serial Number Effectivity → Delivered Product

This reveals whether configuration control exists **in practice rather than only in procedure**.

21.22. Key Principle

Configuration Management ensures that the right product is manufactured, verified, delivered and supported to the right approved definition and that every authorised change remains traceable.

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Its effectiveness can be tested with a deceptively simple question: **"Can we prove exactly what this product is?"** For a mature configuration management system, the answer should be supported by objective evidence covering its **definition, revision, changes, effectivity and actual as-built configuration**.

22. Counterfeit Detection, Mitigation & Avoidance

22.1. Definition and Fundamental Concepts

A **counterfeit item** is an unauthorised imitation, substitution, alteration or misrepresentation of a genuine product, material or component, intentionally presented in a way that may cause it to be mistaken for an authentic item. Counterfeiting can affect virtually any part of a supply chain, including:

- Electronic components
- Fasteners and mechanical hardware
- Raw materials and alloys
- Bearings and seals
- Adhesives and chemicals
- Electrical connectors and cable
- Batteries
- Safety equipment
- Software and firmware
- Calibration or test equipment
- Certificates and traceability records

Counterfeit prevention is particularly important in **aerospace, defence, automotive, medical, nuclear and other safety- or mission-critical sectors**, where an apparently minor component may create significant product, safety or operational risk.

The fundamental principle is: **Counterfeit assurance should focus primarily on preventing suspect material from entering the supply chain, rather than relying on inspection to discover it afterwards.**

- **Counterfeit, Fraudulent and Suspect Items** The terminology should be clearly understood.
- **Counterfeit Item** An item deliberately misrepresented as something it is not, often through false branding, identification, documentation or origin.
- **Suspect Counterfeit Item** An item for which there is objective reason to believe it may be counterfeit, but authenticity has not yet been conclusively established.
- **Fraudulent Item** An item intentionally misrepresented in relation to characteristics such as identity, condition, composition, origin, certification or performance.

The distinction is important because an organisation may need to **contain and investigate a suspect item before sufficient evidence exists to classify it conclusively as counterfeit**.

22.2. How Counterfeit Items Enter the Supply Chain

Counterfeit risk increases where the normal authorised supply chain becomes difficult to use. Common drivers include:

- Component obsolescence
- Long lead times
- Supply shortages
- Urgent programme requirements
- Allocation of scarce components
- Unauthorised distributors
- Online marketplaces
- Broker purchases
- Poor supplier controls
- Excess or surplus stock
- Unverified stock liquidation
- Weak traceability
- Cost pressure

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A frequent risk pattern is:

Urgent requirement → Authorised source unavailable → Alternative source selected → Reduced assurance → Increased counterfeit exposure

Commercial urgency should not silently reduce the required level of product assurance.

22.3. Common Forms of Counterfeiting

Counterfeiting does not always involve manufacturing a completely fake product. It may include:

22.3.1. Remarking

Original identification is removed or altered and replaced with false information. This may misrepresent:

- Manufacturer
- Part number
- Date code
- Performance grade
- Temperature range
- Military/industrial grade
- Country of origin

22.3.2. Substitution

A lower-grade, cheaper or different item is supplied in place of the specified item.

22.3.3. Used Parts Presented as New

Recovered components may be cleaned, refinished and remarked before being sold as new.

22.3.4. Reworked or Recycled Parts

Previously used or rejected components may be processed to conceal their history.

22.3.5. Material Misrepresentation

Incorrect alloy, material grade, coating or composition may be supplied with false identification.

22.3.6. Documentation Fraud

The physical item may be accompanied by altered, fabricated or reused:

- Certificates of Conformity
- Material certificates
- Test reports
- Inspection records
- Traceability documents

This is particularly significant because organisations often place substantial reliance on documentation as evidence of conformity.

22.4. Counterfeit Risk Management

Counterfeit avoidance should use a **risk-based approach**. Risk considerations may include:

- Product criticality
- Safety impact
- Supplier type
- Source of supply
- Obsolescence
- Availability
- Previous counterfeit history
- Traceability available
- Ease of counterfeiting
- Component value

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- Technology type
- Geographic supply route
- Consequence of failure

A low-risk commercial consumable purchased from its original manufacturer does not necessarily require the same controls as an obsolete safety-critical electronic component obtained through an independent broker.

22.5. Source Control – The First Line of Defence

The most effective counterfeit control is generally to purchase through an **authorised and traceable supply chain**. A preferred sourcing hierarchy might be:

Original Manufacturer (OEM/OCM)
↓
Manufacturer's Authorised Distributor
↓
Approved Supplier with Demonstrated Traceability
↓
Independent Distributor/Broker – enhanced controls required

Where the normal authorised chain cannot be used, the reason and additional assurance activities should be documented. The lower the confidence in the source, the greater the level of verification that may be necessary.

22.6. Supplier Approval and Surveillance

Counterfeit risk should form part of supplier selection and ongoing supplier assurance where relevant. Assessment may consider whether the supplier:

- Purchases from authorised sources.
- Maintains traceability to the manufacturer.
- Controls its own sub-tier suppliers.
- Has a counterfeit avoidance procedure.
- Segregates suspect material.
- Controls returned product.
- Maintains appropriate records.
- Performs risk-based authenticity testing.
- Controls obsolete and excess stock.
- Reports suspected counterfeit items.
- Trains relevant personnel.
- Prevents suspect items from re-entering the supply chain.

An approved supplier status should not eliminate the need for ongoing risk assessment.

22.7. Traceability and Provenance

Provenance is the documented history of an item's origin and movement through the supply chain. Strong provenance might demonstrate:

Manufacturer → Authorised Distributor → Supplier → Customer

Evidence may include:

- Purchase orders
- Manufacturer certificates
- Distributor records
- Lot/batch information
- Date codes
- Packaging identification
- Shipping records
- Material certificates
- Serial numbers

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Longer or unclear supply chains generally increase uncertainty. Documentation should also be assessed for **authenticity and consistency**, rather than accepted automatically because it exists.

22.8. Incoming Counterfeit Detection

Incoming inspection can provide an additional defence, particularly for higher-risk purchases. Checks may include:

22.8.1. Packaging

Look for:

- Incorrect branding
- Poor print quality
- Spelling errors
- Inconsistent labels
- Broken seals
- Incorrect packaging materials
- Suspicious relabelling

22.8.2. Identification

Confirm:

- Manufacturer
- Part number
- Lot/batch number
- Date code
- Revision
- Country of origin
- Serial number where applicable

22.8.3. Physical Examination

Look for evidence such as:

- Surface refinishing
- Grinding or sanding
- Inconsistent markings
- Incorrect fonts
- Poor engraving
- Tool marks
- Corrosion
- Contamination
- Previous installation
- Damaged terminals
- Inconsistent dimensions

No single visual characteristic should automatically be assumed to prove counterfeiting. Findings should trigger appropriate investigation.

22.9. Documentation Verification

Counterfeit detection should include the supporting documentation where required. Warning signs can include:

- Incorrect company logos
- Inconsistent fonts
- Missing information
- Altered dates
- Inconsistent part numbers
- Certificate numbers that cannot be verified
- Unexpected signatures

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- Duplicate certificates
- Conflicting lot numbers
- Unexplained changes in formatting
- Certificate details inconsistent with the physical product

Where risk warrants it, authenticity may be verified directly with the issuing organisation.

22.10. Technical Detection Methods

Higher-risk items may require specialist testing. Depending on the product, methods can include:

- Dimensional inspection
- Weight comparison
- Microscopy
- X-ray inspection
- X-ray fluorescence (XRF)
- Electrical testing
- Material composition analysis
- Hardness testing
- Coating analysis
- Decapsulation
- Dye penetrant techniques for electronic components
- Scanning acoustic microscopy
- Functional testing

Testing should be performed by competent personnel using validated methods and appropriate acceptance criteria. A test result is only useful when the method is capable of distinguishing authentic from suspect material.

22.11. Electronic Components

Electronic components represent a well-established counterfeit risk, particularly where parts are obsolete or scarce. Indicators may include:

- Remarked surfaces
- Inconsistent date codes
- Incorrect package dimensions
- Resurfacing
- Previous solder
- Damaged or reconditioned leads
- Internal construction inconsistent with known genuine devices
- Incorrect electrical performance

Standards such as the **SAE AS5553 series** address counterfeit electronic part avoidance, detection, mitigation and disposition. The **SAE AS6081 series** provides requirements particularly relevant to independent distributors of electronic parts. Applicable revisions and contractual requirements should always be verified.

22.12. Non-Electronic Counterfeit Parts

Counterfeit risk is not restricted to electronics. Mechanical and material examples include:

- Fasteners with false strength grades
- Bearings presented as premium manufacturer products
- Incorrect alloy supplied under genuine-looking certification
- Counterfeit seals
- Incorrectly certified welding consumables
- Fraudulent adhesives
- Unapproved replacement components

For mechanical items, testing may require verification of:

Dimensions + Material + Mechanical Properties + Surface Treatment + Identification + Traceability

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Visual inspection alone may not identify material substitution.

22.13. Standards and Industry Requirements

Counterfeit prevention requirements may arise from customer contracts, regulations and industry standards. Commonly encountered aerospace and defence references include:

- **IA9100** – requires processes appropriate to the organisation and product for prevention of counterfeit or suspect counterfeit parts.
- **AS5553 series** – addresses counterfeit electronic part avoidance, detection, mitigation and disposition.
- **AS6174** – addresses counterfeit material avoidance, detection, mitigation and disposition for non-electronic products/material.
- **AS6081 series** – addresses counterfeit avoidance requirements particularly for independent distributors of electronic parts.

Organisations should identify the standards and revisions specifically invoked by their customers or contracts rather than assuming every standard automatically applies.

22.14. Suspect Counterfeit Material

When an item is suspected of being counterfeit, it should normally be treated as a controlled nonconforming product. A typical response is:

Identify → Stop Use → Segregate → Quarantine → Preserve Evidence → Investigate → Determine Impact → Notify as Required → Disposition

The material should be protected from accidental use while the investigation proceeds. The organisation should also determine whether related material has already been:

- Installed
- Used in production
- Supplied to customers
- Transferred to another location

This may require wider containment.

22.15. Preventing Re-Entry into the Supply Chain

A particularly important principle is that confirmed counterfeit material should not simply be returned uncontrolled to the supplier where it could potentially re-enter commerce. Disposition should follow applicable contractual, legal and regulatory requirements and may involve controlled destruction or other measures preventing reuse.

Relevant customers, authorities or industry reporting systems may also need to be notified depending on jurisdiction and contractual requirements. Evidence should be preserved where investigation or enforcement action may follow.

22.16. Obsolescence and Counterfeit Risk

Obsolescence is a major counterfeit-risk driver. As genuine components become unavailable, organisations may increasingly rely on:

- Brokers
- Surplus stock
- Alternative manufacturers
- Long-term storage
- Redesign

Counterfeit avoidance should therefore connect with **obsolescence management**. Early identification of future obsolescence allows alternatives to be qualified before supply becomes critical.

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A planned redesign is often preferable to repeatedly purchasing increasingly uncertain stock from an uncontrolled market.

22.17. People and Awareness

Personnel involved in procurement, quality, engineering, inspection, stores and supply-chain management should understand counterfeit risks relevant to their roles. Training may include:

- Source risk
- Common counterfeit indicators
- Traceability requirements
- Escalation routes
- Quarantine controls
- Documentation verification
- Reporting responsibilities

Counterfeit prevention is not solely an incoming-inspection responsibility. Purchasing decisions made before the item arrives may have a much greater influence on risk.

22.18. Common Counterfeit Control Weaknesses

Typical weaknesses include:

- Purchasing from unknown sources because of schedule pressure.
- Assuming an approved supplier guarantees authenticity.
- Accepting certificates without verification.
- Counterfeit controls limited to electronic components.
- No risk assessment for broker purchases.
- Weak sub-tier supplier control.
- Insufficient traceability.
- Incoming inspection relying only on visual appearance.
- Lack of personnel awareness.
- Suspect material not physically segregated.
- Confirmed counterfeit product returned into an uncontrolled supply chain.
- Failure to assess products already manufactured or delivered.
- Obsolescence managed reactively rather than proactively.

22.19. Practical Audit Approach

A useful audit approach is to select a **high-risk purchased item** and trace it backwards:

Installed Product → Incoming Inspection → Supplier → Distributor → Original Manufacturer

Ask:

Can authenticity and provenance be demonstrated? → Was the source authorised? → If not, what additional controls were applied? → Were certificates verified? → Was appropriate inspection/testing performed? → Were sub-tier sources controlled?

Then examine how the organisation would respond to a suspect item:

Who stops use? → Where is it quarantined? → Who investigates? → How are affected products identified? → Who is notified? → How is re-entry into the supply chain prevented?

This tests both **prevention and response capability**.

22.20. Key Principle

Counterfeit assurance should follow a hierarchy:

Avoid → Control the Source → Establish Provenance → Verify → Detect → Contain → Report → Prevent Re-Entry

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The strongest counterfeit control is not sophisticated inspection at Goods-In. It is a **trusted, authorised and traceable supply chain** that prevents suspect material from reaching Goods-In in the first place.
Where that assurance cannot be achieved, the organisation should recognise the increased risk and apply **proportionately stronger verification and detection controls**.

23. Contract Review

23.1. Definition and Fundamental Concepts

Contract Review is the structured process used to determine whether an organisation fully understands and is capable of satisfying customer, statutory, regulatory and other applicable requirements **before committing to supply a product or service**.

Contract review is not simply a commercial check of price and delivery date. It is a cross-functional assessment of whether the organisation can actually deliver **what has been requested, under the conditions specified, with the required evidence of conformity**.

The fundamental questions are:

What has the customer asked for? → Are the requirements clear? → Can we meet them? → What risks and obligations are created? → What must be flowed into our organisation and supply chain?

A robust contract review converts customer requirements into controlled organisational commitments.

23.2. Why Contract Review Matters

Many quality problems attributed to manufacturing or suppliers actually originate much earlier because requirements were:

- Missed
- Misinterpreted
- Assumed
- Contradictory
- Not technically reviewed
- Not flowed down
- Accepted despite insufficient capability

Once a contract has been accepted, discovering that a requirement cannot be achieved can result in:

- Delivery delays
- Nonconforming product
- Concessions or waivers
- Rework and scrap
- Unplanned qualification
- Supplier problems
- Commercial disputes
- Contract penalties
- Customer dissatisfaction

Contract Review (CR) is a fundamental quality control; **inadequate or ineffective CR is frequently the root of downstream nonconformities, as misunderstood, missed or poorly flowed-down requirements become embedded in the product and process.**

Contract review therefore acts as an important **preventive control at the point of commitment**.

23.3. Contract Review Lifecycle

Contract review should not be considered a single activity performed when an order arrives. A typical lifecycle is:

Enquiry / RFQ → Requirement Review → Bid / Quotation → Negotiation → Contract / PO Receipt → Final Review → Acceptance → Requirement Flow-Down → Change Control → Delivery / Closure

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The level of review should be proportionate to the complexity, novelty, value and risk of the requirement.
A repeat order for a mature standard product may require relatively simple review, whereas a new defence or aerospace programme may require extensive technical and commercial assessment.

23.4. What Should Be Reviewed?

Contract review should consider the **complete requirement**, not just the purchase order header. Applicable information may include:

- Purchase order
- Contract
- Statement of Work (SOW)
- Drawings
- Specifications
- Customer quality requirements
- Technical data
- Applicable standards
- Delivery schedules
- Packaging requirements
- Inspection and test requirements
- Regulatory requirements
- Customer-specific requirements
- Referenced documents

A common risk occurs when a purchase order references another document which references further specifications. Requirements may therefore exist several layers below the primary contract.
The organisation should establish the **complete requirement hierarchy**.

23.5. Technical Review

Technical review determines whether the product or service can be produced in accordance with the specified requirements. Questions may include:

- Is the product definition complete?
- Are drawings and specifications available?
- Are revisions clearly identified?
- Are tolerances achievable?
- Are materials available?
- Are required manufacturing processes available?
- Are special processes required?
- Are inspection and test methods available?
- Is suitable measurement capability available?
- Are qualification requirements understood?
- Are critical or key characteristics identified?
- Are configuration requirements understood?
- Is the required technology mature?

Technical acceptance should be based on evidence of capability rather than optimism that difficulties can be resolved after award.

23.6. Quality Requirements Review

Customer quality requirements may impose obligations beyond the drawing. Examples include:

- Quality Management System certification
- First Article Inspection
- APQP/PPAP
- Inspection requirements
- Test reports
- Certificates of Conformity
- Material certification

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- Traceability
- Record retention
- Right of access
- Customer source inspection
- Special process approvals
- Supplier approval requirements
- Counterfeit prevention
- Nonconformance notification
- Change notification
- Configuration management
- Customer-specific documentation

These requirements should be identified early and incorporated into planning.
A product may satisfy every dimensional requirement while still being contractually nonconforming because required documentation, approval or process controls were not provided.

23.7. Capacity and Capability

Contract review should distinguish between **capability** and **capacity**.

- **Capability** asks: Can we technically perform the work?
- **Capacity** asks: Can we perform the required quantity at the required rate and time?

Both are necessary. Review may therefore consider:

- Equipment availability
- Production capacity
- Tooling
- Skilled personnel
- Inspection resources
- Laboratory capacity
- Supplier capacity
- Material lead times
- Competing production demand
- Planned maintenance

An organisation capable of producing ten conforming products per month may not be capable of a contractual requirement for one hundred per month.

23.8. Supply Chain Review

Requirements that depend on external suppliers should be assessed before commitment. Consider:

- Approved sources
- Material availability
- Supplier capability
- Lead times
- Special process sources
- Obsolescence
- Minimum order quantities
- Sub-tier dependencies
- Customer-mandated suppliers
- Supplier capacity

The organisation should also identify which customer requirements need to be **flowed down through the supply chain**.

A contractual requirement retained only within the prime organisation provides little protection where the relevant work is performed by a supplier.

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23.9. Requirement Flow-Down

Contract review should establish how customer requirements will reach the people and organisations responsible for satisfying them. The chain may be:

Customer Contract
↓
Internal Requirements
↓
Engineering / Manufacturing / Quality Planning
↓
Supplier Purchase Order
↓
Sub-Tier Supplier
↓
Production & Verification Evidence

Flow-down should be appropriate to the activity being performed. Simply attaching a large customer specification to every purchase order without identifying applicable requirements can create ambiguity rather than effective control.

23.10. Statutory and Regulatory Requirements

Contractual requirements do not override applicable law or regulation. Review should identify relevant obligations such as:

- Product safety
- Environmental legislation
- Export control
- Hazardous substances
- Controlled materials
- Industry approvals
- Product certification
- Security requirements

Where the organisation identifies a conflict between contractual and applicable legal or regulatory requirements, the issue should be resolved before acceptance or performance.

23.11. Clarification of Ambiguous Requirements

Ambiguity should be resolved with the customer before commitment where it could affect conformity. Examples include:

- Missing drawing revision
- Conflicting specifications
- Undefined acceptance criteria
- Different tolerances in separate documents
- Obsolete referenced standards
- Unclear delivery requirements
- Undefined inspection requirements

Assumptions should not silently become requirements.
Where clarification is obtained, it should be documented and incorporated into the controlled contractual baseline where appropriate.

23.12. Contractual Risk

Contract review should identify significant risks associated with accepting the requirement. Risks may include:

- New technology
- Aggressive schedule
- New supplier
- Single-source dependency

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- Tight tolerance
- New special process
- Unproven material
- Obsolescence
- Capacity constraint
- New regulatory requirement
- Significant qualification activity
- Customer-furnished equipment
- Incomplete technical data

Risk does not necessarily prevent contract acceptance, but significant risk should have defined **ownership, mitigation and visibility**.

23.13. Contract Acceptance

Acceptance should occur only when:

- Requirements are understood.
- Differences have been resolved.
- Capability has been established.
- Capacity has been considered.
- Applicable risks are understood.
- Required resources can be provided.
- Customer-specific requirements are identified.
- Supply-chain implications have been considered.
- Relevant approvals have been obtained.

The organisation should retain appropriate evidence of the review and resulting actions.

23.14. Contract Changes

Contract review does not end after initial acceptance. Changes may occur through:

- Revised purchase orders
- Engineering changes
- Specification revisions
- Quantity changes
- Schedule changes
- Customer amendments
- Change in regulatory requirements

Changes should be reviewed with appropriate rigour before implementation. A change should trigger consideration of its effect on:

Design → Material → Production → Tooling → Inspection → Suppliers → Configuration → Capacity → Cost → Delivery

Affected personnel and suppliers should receive the updated requirements in a controlled manner.

23.15. Verbal and Informal Customer Changes

A significant risk occurs when customer requirements are changed through:

- Telephone conversations
- Meetings
- Emails
- Informal engineering discussions

Where these communications change the contractual or technical requirement, they should be appropriately documented and incorporated into the controlled requirement before implementation. **"The customer told us to do it"** is not an effective substitute for controlled authorisation.

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23.16. Contract Review vs Order Entry

These activities should not be confused.

- **Order Entry** asks: **"Can the order be entered into the system?"**
- **Contract Review** asks: **"Can the complete requirement be satisfied?"**

Automated order-processing systems can efficiently process incorrect, incomplete or misunderstood requirements if appropriate review has not occurred.

23.17. Contract Review Responsibilities

Contract review is normally cross-functional. Depending on complexity, participants may include:

- Commercial / Contracts
- Engineering
- Quality
- Manufacturing
- Supply Chain
- Programme Management
- Finance
- Legal
- Export Control
- Product Safety

No single function necessarily understands every contractual implication. Responsibilities and approval authority should therefore be clearly defined.

23.18. Contract Review and ISO 9001 / IA9100

ISO 9001 addresses requirements for products and services within **Clause 8.2**, including:

- Customer communication
- Determining requirements
- Reviewing requirements
- Changes to requirements

IA9100 builds upon these principles for the aviation, space and defence environment and introduces additional sector-specific considerations. The applicable standard and contractual requirements should always be checked rather than treating contract review as a simple certification requirement.

23.19. Common Contract Review Weaknesses

Typical weaknesses include:

- Review limited to price and delivery.
- Quality involved only after contract award.
- Referenced specifications not reviewed.
- Customer-specific requirements missed.
- Incorrect revision accepted.
- Technical capability assumed.
- Capacity not assessed.
- Supplier capability not considered.
- Requirements not flowed to sub-tier suppliers.
- Ambiguities accepted without clarification.
- Customer changes implemented informally.
- Contract amendments not communicated internally.
- Evidence of review not retained.
- Repeat orders automatically accepted despite changed requirements.
- Contract review treated as administrative approval rather than risk prevention.

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23.20. Practical Audit Approach

Rather than reviewing only the contract-review procedure, select a real customer order and trace it. Ask:

What did the customer order? → What documents were referenced? → What revision applies? → What quality requirements exist? → Who reviewed them? → How was capability established? → What risks were identified? → What requirements were flowed internally? → What was flowed to suppliers? → Have any requirements changed?

Then follow the requirement through to the delivered product:

Customer Requirement → Contract Review → Internal Planning → Supplier Flow-Down → Production → Inspection/Test → Delivery Evidence

This establishes whether the organisation has converted contractual requirements into **effective operational controls**.

23.21. Key Principle

Contract review should establish:

Understand → Clarify → Assess → Commit → Flow Down → Control Change → Demonstrate Compliance

The purpose is not simply to prove that somebody signed a contract-review form.
A successful contract review provides confidence that **before the organisation promises to deliver, it understands exactly what it has promised and has established that the promise can realistically be fulfilled.**

24. Design & Development Assurance

24.1. Definition and Fundamental Concepts

Design and Development Assurance is the systematic application of planned controls, independent challenge and objective evidence to provide confidence that a product or service has been developed from correctly understood requirements and that the resulting design is **suitable, compliant, verified, validated and controlled**.

Design creates the solution; **Design Assurance provides confidence in the process and evidence used to demonstrate that the solution is correct**.

It should operate throughout development rather than becoming a final approval activity after the design has already been completed. A useful model is:

Requirements → Design Inputs → Design Activities → Design Outputs → Verification → Validation → Controlled Release

24.2. Purpose of Design Assurance

Design defects can be particularly costly because a single design error may be reproduced across every manufactured item. Effective Design Assurance aims to:

- Prevent requirements being misunderstood or omitted.
- Ensure appropriate design methods and controls are established.
- Provide independent challenge at appropriate stages.
- Ensure risks are identified and managed.
- Confirm verification and validation are adequate.
- Maintain traceability between requirements and evidence.
- Ensure design changes remain controlled.
- Prevent immature designs progressing prematurely.
- Capture evidence demonstrating design compliance.

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The objective is **confidence through evidence**, not additional administration.

24.3. Design and Development Planning

Before significant design activity begins, the organisation should establish how development will be controlled. Planning should consider:

- Development stages
- Responsibilities and authorities
- Required competence
- Design methods and tools
- Reviews and approval points
- Verification activities
- Validation activities
- Interfaces between disciplines
- Configuration control
- Risk management
- Customer involvement
- Supplier involvement
- Regulatory requirements
- Required records and evidence

Planning should be proportionate to the **complexity, novelty and risk** of the product. A simple modification to an established product may require considerably less assurance than development of a new safety-critical system.

24.4. Design Inputs

Design inputs define what the design must achieve. Inputs may originate from:

- Customer requirements
- Contractual requirements
- System requirements
- Functional requirements
- Performance requirements
- Interface requirements
- Safety requirements
- Reliability requirements
- Environmental conditions
- Regulatory and statutory requirements
- Applicable standards
- Manufacturing constraints
- Maintainability requirements
- Previous designs and lessons learned

Design inputs should be **clear, complete, consistent, testable and traceable**. Ambiguous or conflicting requirements should be resolved rather than interpreted silently by the designer.

Poor design input inevitably increases the risk of poor design output.

24.5. Requirements Management and Traceability

A fundamental assurance principle is the ability to demonstrate:

Where did this requirement come from? → How was it implemented? → How was it verified? → What evidence demonstrates compliance?

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A **Requirements Traceability Matrix (RTM)** or equivalent system may be used to establish these relationships. For example:

Requirement	Design Implementation	Verification Method	Evidence	Status
REQ-001	Drawing feature A	Inspection	Report 123	Verified
REQ-002	Software function B	Functional test	Test 456	Verified
REQ-003	Material specification C	Certification	Cert 789	Verified

Traceability is particularly valuable for complex products where thousands of requirements may exist across multiple systems and subsystems.

24.6. Design Outputs

Design outputs translate requirements into information from which the product can be manufactured, purchased, inspected, tested, operated and supported. Outputs may include:

- Drawings
- Models
- Specifications
- Bills of Material
- Software
- Interface definitions
- Material requirements
- Acceptance criteria
- Manufacturing requirements
- Inspection requirements
- Test specifications
- Special process requirements
- Key or critical characteristics
- Maintenance information

Outputs should provide sufficient information to ensure the product can be realised and verified without relying on uncontrolled assumptions or undocumented knowledge.

24.7. Design Reviews

Design reviews are planned, systematic evaluations of design maturity and technical adequacy. They provide an opportunity for cross-functional challenge before problems become embedded. Reviews may consider:

- Requirements maturity
- Design maturity
- Technical risks
- Interface compatibility
- Safety
- Reliability
- Manufacturability
- Inspectability
- Testability
- Maintainability
- Supply-chain capability
- Open actions
- Verification status
- Configuration status

Depending on the industry and programme, formal reviews may include concepts such as:

- **System Requirements Review (SRR)**
- **Preliminary Design Review (PDR)**
- **Critical Design Review (CDR)**
- **Test Readiness Review (TRR)**

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Names are less important than the principle: **progression should be based on demonstrated maturity and evidence**.

24.8. Independent Design Review

Effective assurance benefits from appropriate independence. A designer checking their own work can identify many errors, but independent review provides additional challenge because the reviewer is less influenced by the assumptions made during development. The required degree of independence should reflect product risk. Independent review may involve:

- Peer review
- Independent engineering review
- Quality/Design Assurance
- Safety specialists
- Customer representatives
- Independent verification teams

Independence should provide meaningful technical challenge rather than simply an additional signature.

24.9. Verification and Validation

Verification and validation are related but answer different questions.

24.9.1. Verification

"Did we design the product correctly against the specified requirements?" Verification may include:

- Analysis
- Calculation
- Inspection
- Simulation
- Review
- Testing
- Demonstration

24.9.2. Validation

"Did we design the correct product for its intended use?" Validation considers whether the resulting product performs effectively in its intended or representative operating environment.

A product can successfully pass verification against an incomplete requirement and still fail validation because the original requirement did not correctly represent the user's need. A useful distinction is:

Verification → Conformance to specified requirements

Validation → Suitability for intended use

24.9.3. Verification Methods

Different requirements require different forms of evidence. Typical methods include:

- **Inspection** – examination or measurement of physical characteristics.
- **Analysis** – engineering calculations, modelling or simulation.
- **Test** – controlled demonstration using defined conditions and acceptance criteria.
- **Demonstration** – observation of functionality or performance.
- **Review** – assessment of records, design information or supporting evidence.

The verification method should be selected based on the nature and risk of the requirement.

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24.9.4. Test Assurance

Where testing provides design evidence, the test itself should be controlled. Before relying on a test result, consider:

- Was the test article representative?
- Was its configuration known?
- Was the procedure approved?
- Were acceptance criteria defined beforehand?
- Was test equipment suitable?
- Was measurement traceability adequate?
- Were environmental conditions controlled?
- Were deviations recorded?
- Were failures investigated?
- Are results repeatable and technically defensible?

A test report is not automatically valid design evidence simply because testing occurred.

24.10. Design Risk Management

Design Assurance should confirm that technical risks are actively identified and controlled throughout development. Risk sources may include:

- New technology
- Novel materials
- Complex interfaces
- Tight tolerances
- Environmental extremes
- Software integration
- Safety-critical functions
- New manufacturing processes
- Supplier dependency
- Unproven design assumptions

Methods such as **DFMEA, reliability analysis, hazard analysis and technical risk registers** may contribute to this process. The appropriate method should reflect the product and industry.

24.11. Design for Manufacture, Inspection and Support

A design is not successful merely because it functions. Design decisions should consider whether the product can be:

Manufactured → Assembled → Inspected → Tested → Maintained → Repaired → Supported

Early engagement with manufacturing, quality, supply chain, test and support functions can identify issues that may otherwise emerge only during industrialisation or production. Examples include:

- Inaccessible inspection features
- Unnecessarily tight tolerances
- Difficult assembly sequences
- Unavailable materials
- Unachievable manufacturing processes
- Inadequate test access
- Difficult maintenance operations

Design Assurance should encourage these considerations while the design can still be economically changed.

24.12. Design Interfaces

Complex products often fail at **interfaces rather than individual components**. Interfaces may exist between:

- Mechanical systems
- Electrical systems
- Software and hardware

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- Product and operator
- Product and support equipment
- Subsystems
- Organisations
- Suppliers

Interface requirements should therefore be identified, allocated, controlled and verified.
Each individual subsystem may satisfy its own requirements while the complete system fails because the interfaces were inadequately defined.

24.13. Supplier-Designed Product

Where design responsibility is delegated to a supplier, the organisation does not automatically transfer its responsibility for assurance. Controls may include:

- Clear design authority
- Defined technical requirements
- Design review participation
- Requirements traceability
- Verification evidence
- Change approval
- Configuration control
- Access to design records
- Qualification requirements

The level of oversight should reflect the supplier's design responsibility and associated product risk.

24.14. Design Changes

Design change is inevitable, but every change can affect previously established evidence. A change should therefore consider:

Requirement → Design → Interfaces → Risk → Manufacturing → Inspection → Verification → Validation → Qualification → Configuration

The organisation should determine:

- Why the change is required.
- What is affected.
- Whether previous analysis remains valid.
- Whether verification must be repeated.
- Whether validation is affected.
- Whether customer or regulatory approval is required.
- When the change becomes effective.

A change should not be considered complete simply because the drawing has been revised.

24.15. Design Maturity

Schedule completion and design maturity are not the same. Useful indicators of maturity may include:

- Requirements stability
- Requirements verification status
- Open design actions
- Technical risk
- Design review actions
- Test completion
- Qualification status
- Engineering change rate
- Interface maturity
- Configuration stability

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A high volume of late engineering changes can indicate that a design entered industrialisation or production before sufficient maturity was achieved.

24.16. Design Assurance and Quality Assurance

Design Assurance and traditional Product Quality Assurance have related but distinct perspectives.

- **Design Assurance asks:** Is there sufficient evidence that the design process and resulting definition satisfy the applicable requirements?
- **Product/Manufacturing Quality Assurance asks:** Is there sufficient evidence that the manufactured product conforms to the approved definition?

Both are necessary. Manufacturing cannot inspect quality into a fundamentally incorrect design.

24.17. Applicable Management System Requirements

Design and development controls are addressed within **ISO 9001 Clause 8.3**. IA9100 expands these principles for aviation, space and defence applications, including sector-specific expectations concerning design planning, verification, validation and control.

Other industries may impose additional regulatory, safety, software or design-assurance requirements.
The applicable contractual and regulatory framework should therefore be established for each development.

24.18. Common Design Assurance Weaknesses

Typical weaknesses include:

- Requirements accepted without adequate clarification.
- Poor requirements traceability.
- Design Assurance involved too late.
- Design reviews becoming presentation meetings rather than technical challenge.
- Verification performed without predetermined acceptance criteria.
- Validation confused with verification.
- Test articles having uncertain configuration.
- Open design actions carried into production.
- Supplier design activities insufficiently assured.
- Interfaces poorly controlled.
- Manufacturing and inspection input obtained too late.
- Design changes not assessed against previous verification.
- Evidence fragmented across multiple systems.
- Approval based on schedule pressure rather than demonstrated maturity.
- Design Assurance treated as document approval rather than technical assurance.

24.19. Practical Audit Approach

A powerful way to assess Design Assurance is to select an important product requirement and trace it throughout development:

Customer Need → Requirement → Design Input → Design Solution → Design Output → Verification Method → Verification Evidence → Validation → Released Configuration

Then select a design change and trace its impact:

Change Request → Technical Assessment → Risk → Approval → Design Update → Affected Interfaces → Verification/Validation → Configuration Release

The question is not simply: **"Was the design reviewed?"** but **"Can the organisation demonstrate, through objective and traceable evidence, why it believes this design is correct and suitable for its intended purpose?"**

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24.20. Key Principle

Effective Design & Development Assurance creates a continuous chain of confidence:

Understand → Define → Design → Challenge → Verify → Validate → Control → Release

Its purpose is not to add another approval layer between engineering and production. It is to ensure that **requirements have been correctly translated into a controlled design and that objective evidence exists to justify confidence in that design before it is committed to production, delivery or operation.**

25. Supplier Quality Management & Supply Chain Flowdown

25.1. Definition and Fundamental Concepts

Supplier Quality Management (SQM) is the systematic management and assurance of externally provided products, processes and services to ensure they consistently satisfy contractual, technical, quality, statutory and regulatory requirements.

Supply Chain Flowdown is the controlled transfer of applicable requirements from the customer through the organisation to suppliers and, where necessary, through successive **sub-tier suppliers**. The fundamental principle is:

Outsourcing the work does not outsource accountability for conformity.

An effective supplier quality system therefore extends beyond supplier approval and incoming inspection. It should provide assurance throughout the supplier lifecycle:

Requirement → Selection → Approval → Contractual Flowdown → Planning → Surveillance → Performance Monitoring → Improvement → Change Control → Reapproval/Exit

25.2. Why Supplier Quality Management Matters

Modern organisations frequently depend on suppliers for:

- Design
- Raw materials
- Components
- Assemblies
- Special processes
- Software
- Inspection and testing
- Calibration
- Logistics
- Technical services

As outsourcing increases, a significant proportion of product risk can exist outside the purchasing organisation's direct operational control. Weak supplier assurance can result in:

- Product nonconformities
- Customer escapes
- Production disruption
- Late delivery
- Counterfeit material
- Configuration errors
- Unapproved process changes
- Poor sub-tier control
- Inadequate traceability
- Repeated concessions
- Cost and schedule growth

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Supplier Quality Management should therefore be viewed as **supply-chain risk assurance**, not merely supplier defect management.

25.3. The Supplier Quality Lifecycle

A mature SQM system manages suppliers throughout their relationship with the organisation. A typical lifecycle is:

Identify Need → Assess Risk → Select Supplier → Evaluate Capability → Approve → Define Requirements → Place Contract/PO → Assure Performance → Monitor → Develop → Reapprove / Suspend / Exit

The level of control should be proportionate to the risk associated with the product, process or service being supplied.

25.4. Supplier Segmentation and Risk

Not every supplier requires the same level of oversight. Suppliers can be classified according to factors such as:

- Product criticality
- Design responsibility
- Safety impact
- Special processes
- Product complexity
- Single-source dependency
- Supplier performance
- Financial stability
- Geographic risk
- Sub-tier dependency
- Regulatory significance
- Technology maturity
- Supply continuity
- Counterfeit exposure
- Previous quality history

This allows assurance resources to be focused where they provide greatest value. For example:

Low Risk → Standard controls

Medium Risk → Enhanced monitoring

High/Critical Risk → Formal surveillance, audits, reviews and increased governance

Supplier risk should be reviewed periodically because risk changes over time.

25.5. Supplier Selection and Approval

Supplier approval should establish whether the supplier is capable of satisfying the intended requirements **before significant work is placed**. Evidence may include:

- QMS certification
- Technical capability
- Manufacturing capability
- Capacity
- Relevant experience
- Personnel competence
- Inspection and test capability
- Special process approvals
- Calibration controls
- Configuration management
- Supply-chain controls

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- Previous performance
- Financial/commercial assessment
- Audit results

Certification to ISO 9001, AS9100 or another management system can provide useful assurance, but **certification alone does not demonstrate capability to manufacture a particular product or perform a particular process**.

25.6. Approved Supplier List

The **Approved Supplier List (ASL)** or equivalent system should identify which suppliers are authorised and, importantly, the **scope of their approval**. A supplier may be approved for:

- Specific products
- Particular processes
- Defined manufacturing sites
- Particular commodities
- Specific technologies

Approval should not automatically imply unlimited capability. Controls should exist for:

- Initial approval
- Conditional approval
- Scope changes
- Periodic review
- Suspension
- Removal
- Reinstatement

25.7. Supplier Quality Requirements Documentation

A **Supplier Quality Requirements (SQR)** document is one of the most effective mechanisms for establishing consistent supply-chain quality expectations.
Rather than repeatedly defining generic requirements on individual purchase orders, the organisation can establish a controlled supplier quality requirements document and invoke the applicable revision contractually. A good SQR should be **clear, structured, contractually usable and proportionate**.
It should distinguish between:

Requirements applicable to all suppliers
and
Requirements applicable only when invoked by product, commodity, programme or purchase order.

25.8. Recommended Supplier Quality Requirements Structure

A comprehensive SQR may address:

25.8.1. Scope and Applicability

Define:

- Who the requirements apply to
- Applicable products/services
- Order of precedence
- Definitions
- Referenced standards

25.8.2. Quality Management System

Specify required certifications or QMS expectations where appropriate. Examples may include:

- ISO 9001
- IA9100 Series
- ISO/IEC 17025
- Customer-specific requirements

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25.8.3. Contract and Requirement Review
Require suppliers to review:

- Purchase orders
- Drawings
- Specifications
- Revisions
- Quality clauses
- Delivery requirements

before accepting the work.

25.8.4. Supply Chain Flowdown
Require applicable requirements to be flowed to sub-tier suppliers.

25.8.5. Configuration and Change Control
Define requirements for:

- Revision control
- Engineering changes
- Manufacturing changes
- Process changes
- Facility relocation
- Supplier/sub-tier changes
- Notification and approval

25.8.6. Product and Process Assurance
As applicable:

- APQP & PPAP
- FAI
- Inspection
- Testing
- Process capability
- MSA
- Control plans
- Key/critical characteristics

25.8.7. Special Processes
Define applicable approval and qualification requirements, including customer or **Nadcap** approval where contractually required.

25.8.8. Nonconforming Product
Establish expectations for:

- Identification
- Segregation
- Notification
- Concession requests
- Corrective action
- Prevention of unintended use

25.8.9. Corrective Action
Define expectations for methods such as:

- Containment
- 8D & RCCA
- Effectiveness verification
- Response timescales

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25.8.10. Counterfeit Prevention

Address:

- Authorised sourcing
- Traceability
- Detection
- Suspect counterfeit reporting
- Prevention of re-entry into the supply chain

25.8.11. Traceability

Define requirements for:

- Material
- Batch/lot
- Serial number
- Process
- Personnel where applicable
- Certification

25.8.12. Inspection and Test Records

Define required evidence and acceptance documentation.

25.8.13. Records and Retention

Specify:

- Required records
- Retention period
- Storage/protection
- Accessibility
- Disposition

25.8.14. Right of Access

Where appropriate, provide controlled access for:

- Customer
- Purchasing organisation
- Regulatory authorities

to applicable facilities, records and supply-chain locations.

25.8.15. Competence and Awareness

Define expectations for personnel performing work affecting product conformity.

25.8.16. Product Safety and Ethics

Where applicable, include requirements concerning:

- Product safety
- Ethical behaviour
- reporting of concerns

25.8.17. Delivery Documentation

Clearly identify required documentation such as:

- Certificate of Conformity
- Material certificates
- Inspection reports
- Test certificates
- FAI documentation
- Special process certification

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The SQR should be periodically reviewed to ensure requirements remain **current, necessary and understandable**.

25.9. Supply Chain Flowdown

Requirements should follow the work. If a supplier outsources a process, the requirements applicable to that process should reach the organisation actually performing it. For example:

Customer
↓
Prime Organisation
↓
Tier 1 Supplier
↓
Tier 2 Special Processor
↓
Tier 3 Material Supplier

The prime organisation may not directly contract with the lower tiers, but applicable requirements still need to reach them through the contractual chain. This is particularly important for:

- Special processes
- Critical items
- Key characteristics
- Approved sources
- Counterfeit prevention
- Material traceability
- Configuration control
- Record retention
- Right of access

A strong flowdown requirement should therefore include an expectation similar to: **The supplier shall flow down applicable contractual, technical, quality and regulatory requirements to its sub-tier suppliers, including any requirement for further flowdown through the supply chain.**

25.10. Supplier Surveillance

Supplier surveillance is the **planned and risk-based oversight of supplier activity and performance**.
It provides greater assurance than waiting for defective product to arrive. Surveillance may include:

- Supplier audits
- Process audits
- Product audits
- Manufacturing readiness reviews
- APQP reviews
- FAI surveillance
- Source inspection
- Special process reviews
- Performance reviews
- Corrective action verification
- On-site quality presence

Surveillance should be based on **risk and performance**, rather than applying identical oversight to every supplier.

25.11. Supplier Surveillance Audit Programme

A mature organisation should establish a documented **supplier surveillance audit programme**. The programme should consider:

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Supplier Risk + Product Criticality + Process Risk + Previous Performance + Change + Customer Requirements

This determines:

- Which suppliers require surveillance
- Audit type
- Audit scope
- Audit frequency
- Competence required
- Follow-up activities

A risk-based programme might use: Frequency should be adjusted based on evidence rather than remaining fixed indefinitely.

25.11.1. Types of Supplier Audit

- **Quality System Audit** Assesses the supplier's management system against applicable requirements.
- **Process Audit** Follows a specific manufacturing or service process in detail.

Often more effective than a generic system audit for understanding actual product risk.

- **Product Audit** Examines product conformity and supporting evidence against defined requirements.
- **Special Process Audit** Evaluates process controls where conformity cannot be fully confirmed through subsequent inspection.
- **Focused Audit** Targets a known concern such as:
  - Configuration control
  - Calibration
  - Nonconformance management
  - Corrective action
  - Traceability

A surveillance programme should select the **audit method that addresses the risk**, rather than repeatedly conducting the same generic audit.

25.11.2. Supplier Audit Best Practice

Effective supplier audits should be:

Evidence-based → Process-focused → Risk-based → Traceable → Followed through to closure

Auditors should avoid spending the majority of audit time reviewing procedures in a meeting room. Where possible: **Follow the Product.** Select a real product and trace:

Purchase Order → Requirements → Material → Production → Special Processes → Inspection → Records → Release

This reveals how effectively the supplier's system operates in practice. Further guidance can be found in the Special Processes Institute SPI-10 Quality Auditing & Verification Guidebook.

25.12. Supplier Performance Monitoring

Supplier performance should be monitored using meaningful measures. Common indicators include:

25.12.1. Quality

- Defect rate
- PPM
- Number of nonconformities
- Customer escapes
- Repeat defects
- Concessions
- Corrective action performance

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25.12.2. Delivery

- On-time delivery
- Schedule adherence
- Lead-time performance

25.12.3. Responsiveness

- Corrective action timeliness
- Communication
- Problem containment
- Action closure

25.12.4. Assurance

- Audit performance
- FAI/PPAP performance
- Certification status
- Special process approval status

Metrics should identify **trends and risk**, not merely create supplier league tables.

25.12.5. Supplier Scorecards

Supplier scorecards can consolidate performance information into a consistent view. A scorecard may include:

Quality + Delivery + Responsiveness + Audit/Assurance + Commercial factors

Care should be taken with weighted scores. A supplier should not appear acceptable because excellent delivery performance mathematically offsets a serious product-safety or quality failure.

Some conditions should therefore trigger escalation regardless of the overall score.

25.13. Supplier Nonconformance and Corrective Action

When supplier nonconformity occurs, the immediate priority is typically:

Containment → Product Impact → Root Cause → Corrective Action → Verification of Effectiveness

Depending on significance, the organisation may request:

- Supplier Corrective Action Request (SCAR)
- 8D
- RCCA
- Recovery plan
- Increased inspection
- Controlled shipping
- On-site containment

Corrective action should address the **systemic cause**, not simply repair or replace the defective item. Repeated recurrence should trigger escalation and potentially increased surveillance.

25.14. Supplier Development

Supplier assurance should not be limited to detecting failure. Where strategically appropriate, organisations can work with suppliers to improve capability. Development activities may include:

- Process improvement
- APQP support
- PFMEA review
- Control-plan development
- RCCA coaching
- SPC implementation

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- Capacity improvement
- Special process improvement
- Quality planning
- Training

Supplier development is most effective where both organisations share data and focus on preventing recurrence and reducing variation.

25.15. Escalation and Supplier Recovery

Poor performance should trigger a structured escalation process. A typical model may progress through:

Normal Monitoring → Formal Concern → Corrective Action → Enhanced Surveillance → Supplier Recovery Plan → Executive Escalation → New Business Hold → Suspension/Removal

Escalation criteria should be defined and consistently applied. Potential triggers include:

- Repeat nonconformity
- Customer escape
- Serious safety concern
- Chronic late delivery
- Ineffective corrective action
- Loss of certification
- Unapproved change
- Counterfeit concern

The objective should be risk reduction and recovery where possible, rather than punishment.

25.16. Supplier Change Notification

Suppliers should understand which changes require notification or approval before implementation. Examples include:

- Manufacturing location
- Manufacturing process
- Material
- Design
- Tooling
- Special process source
- Sub-tier supplier
- Inspection method
- Software
- Significant equipment
- Organisational changes affecting approval

An apparently minor supplier change can invalidate previous **qualification, FAI, PPAP, process capability or customer approval**.

25.17. Receiving Inspection Is Not Supplier Assurance

Incoming inspection is one control within a wider supplier assurance system. It should not compensate indefinitely for poor supplier performance. A mature approach moves toward:

Prevent at Source → Control the Process → Demonstrate Supplier Capability → Monitor Performance → Apply Risk-Based Verification

rather than:

Receive → Inspect → Find Defect → Return → Repeat

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Inspection intensity may be increased or reduced based on supplier performance, product risk and demonstrated capability where permitted.

25.18. Supplier Quality Roles

Supplier Quality professionals frequently operate at the interface between:

- Supplier
- Engineering
- Manufacturing
- Procurement
- Quality
- Programme Management
- Customer

Their role should extend beyond processing supplier defects. Effective Supplier Quality Management involves:

Prevention + Assurance + Surveillance + Development + Escalation + Improvement

Supplier Quality should provide technical assurance while commercial ownership and contractual authority remain appropriately defined.

25.19. Applicable Quality Management Principles

ISO 9001 addresses control of externally provided processes, products and services principally within **Clause 8.4**. IA9100 adds aviation, space and defence-specific expectations relating to external providers, including increased emphasis on supplier controls and supply-chain assurance.

Customer, regulatory and contractual requirements may impose considerably more detailed obligations. The organisation should therefore define its supplier controls based on **actual product and supply-chain risk**, not simply the minimum needed to demonstrate management-system conformity.

25.20. Common Supplier Quality Weaknesses

Typical weaknesses include:

- Supplier approval based only on certification.
- Approved scope not clearly defined.
- Generic purchase-order quality clauses.
- Requirements not reaching sub-tier suppliers.
- Supplier audits conducted at fixed frequency regardless of risk.
- Audits focused on procedures rather than actual processes.
- Over-reliance on incoming inspection.
- Repeated SCARs without effective escalation.
- Supplier scorecards masking serious quality issues.
- Unapproved supplier process changes.
- Poor special-process control.
- Corrective actions closed without effectiveness verification.
- Supplier performance reviewed but no action taken.
- Surveillance reduced because of resource pressure rather than demonstrated performance.
- Tier 1 supplier assumed to control sub-tiers without evidence.

25.21. Practical Audit Approach

A powerful way to evaluate supplier quality management is to select a **critical purchased item** and trace it through the entire chain:

Customer Requirement → Internal Requirement → Purchase Order → Supplier → Sub-Tier Supplier → Manufacturing Process → Verification → Certification → Incoming Acceptance → Final Product

Ask:

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Were the correct requirements flowed down? → Did they reach the organisation performing the work? → Was supplier capability demonstrated? → What surveillance has been performed? → What does performance data show? → Have changes been controlled? → Can conformity and traceability be demonstrated?

Then select a supplier with poor performance and ask: **What changed as a result?** If the answer is **nothing**, the supplier monitoring system is measuring performance rather than managing it.

25.22. Key Principle

Effective Supplier Quality Management follows a progression:

Select → Define → Flow Down → Assure → Monitor → Develop → Escalate → Improve

The strongest supplier quality systems do not rely on finding defective product at Goods-In. They establish **clear requirements, capable suppliers, effective sub-tier flowdown, risk-based surveillance and evidence of continuing performance**.

Ultimately, the organisation should be able to demonstrate not only **who supplied the product**, but that the requirements were understood and controlled **through every relevant tier of the supply chain to the point where the work was actually performed**.

26. Goods In Inspection & Incoming Product Verification

26.1. Definition and Fundamental Concepts

Goods In Inspection, also known as **Incoming Inspection** or **Incoming Product Verification**, is the controlled process used to establish whether externally supplied products, materials and associated documentation satisfy defined requirements before they are accepted for use. Incoming verification can apply to:

- Raw materials
- Components
- Standard hardware
- Electronic parts
- Manufactured parts
- Assemblies
- Special-process outputs
- Chemicals and consumables
- Customer/Government-furnished items
- Returned or repaired product

The fundamental principle is: **Material received does not mean material accepted.** Receipt establishes physical possession. **Acceptance requires appropriate evidence that applicable requirements have been satisfied.**

26.2. Purpose of Incoming Verification

Incoming verification provides a controlled boundary between the external supply chain and internal operations. Its purpose is to:

- Confirm correct product has been supplied.
- Verify quantity and identification.
- Check condition and packaging.
- Confirm applicable documentation.
- Verify traceability where required.
- Detect obvious transportation or handling damage.
- Perform required dimensional, visual or functional inspection.
- Confirm shelf-life requirements.
- Identify suspect or counterfeit concerns.
- Prevent nonconforming material entering production.
- Generate evidence of acceptance.

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However, Goods In should be considered **one layer within supplier assurance**, not a substitute for effective supplier control.

26.3. Receipt, Inspection and Acceptance

These activities should be distinguished.

26.3.1. Receipt

Confirms that the shipment has physically arrived.
Typical activities include:

- Delivery identification
- Quantity check
- Packaging condition
- Booking into the system

26.3.2. Verification / Inspection

Determines whether specified requirements have been satisfied.

26.3.3. Acceptance

Provides authorised confirmation that the material may proceed to stores, production or another controlled status. This distinction prevents product from being used simply because it has been physically received or entered into an ERP system.

26.4. Incoming Verification Strategy

Not every incoming item requires the same level of inspection. The verification strategy should be **risk-based** and consider:

- Product criticality
- Supplier performance
- Supplier approval status
- Product complexity
- Previous nonconformities
- Process capability
- Source inspection
- FAI/PPAP status
- Traceability requirements
- Counterfeit risk
- Special processes
- Consequence of failure
- Customer requirements

A useful model is:

Product Risk + Supplier Risk + Historical Performance = Verification Level

This allows inspection effort to be focused where it provides greatest assurance.

26.4.1. Levels of Incoming Verification

Incoming controls may range from basic checks to comprehensive inspection.

26.4.1.1. Level 1 – Receipt Verification

May include:

- Correct supplier
- Correct purchase order
- Part number
- Quantity
- Packaging condition

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Suitable only where additional product verification is not required.

26.4.1.2. Level 2 – Documentation and Identity Verification

Adds checks such as:

- Revision
- Certificate of Conformity
- Material certificates
- Batch/lot identification
- Shelf life
- Traceability
- Required process certificates

26.4.1.3. Level 3 – Product Inspection

May include:

- Visual inspection
- Dimensional inspection
- Functional testing
- Material verification
- Sampling inspection

26.4.1.4. Level 4 – Enhanced Verification

For high-risk or problematic supplies, controls may include:

- Increased sampling
- 100% inspection
- Independent laboratory testing
- Material composition verification
- Counterfeit detection
- Specialist technical assessment

The appropriate level should be determined by risk rather than habit.

26.5. Purchase Order as the Verification Baseline

Incoming inspection should be performed against **defined requirements**. These may originate from:

Purchase Order → Drawing → Specification → Supplier Quality Requirements → Customer Requirements → Inspection/Test Requirements

The inspector should have access to the correct applicable revisions. Inspection without a clearly defined acceptance requirement becomes subjective.

26.6. Documentation Review

Documentation can be as important as physical inspection. Depending on the product, incoming documentation may include:

- Certificate of Conformity (CoC)
- Material certificate
- Certificate of Analysis
- Inspection report
- Test report
- FAI documentation
- PPAP evidence
- Special process certificate
- Calibration certificate
- Safety Data Sheet
- Traceability documentation

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Review should establish that documentation is:

Present → Correct → Applicable → Consistent → Traceable to the delivered product

A certificate should not be accepted simply because a document titled "Certificate of Conformity" is present.

26.7. Certificate of Conformity

A **Certificate of Conformity (CoC)** provides a supplier declaration that the supplied product conforms to specified requirements. Depending on contractual requirements, it may include:

- Supplier identity
- Customer
- Purchase order
- Part number
- Description
- Revision
- Quantity
- Batch/lot or serial number
- Applicable specifications
- Statement of conformity
- Authorised signature

A CoC is **evidence provided by the supplier**, not independent proof that every requirement has been satisfied. Its level of assurance depends on the reliability of the underlying supplier controls.

26.8. Material Certification

For raw material or material-dependent products, certification may confirm:

- Material grade
- Chemical composition
- Mechanical properties
- Heat/cast number
- Batch/lot
- Applicable specification
- Test results

Traceability should link:

Physical Material → Identification → Certificate → Material Batch/Heat → Specification

Where required by risk or contract, positive material identification or independent testing may supplement documentary evidence.

26.9. Visual Inspection

Visual inspection can identify issues such as:

- Damage
- Corrosion
- Contamination
- Poor workmanship
- Incorrect marking
- Incorrect finish
- Packaging damage
- Missing components
- Evidence of previous use
- Obvious counterfeit indicators

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Visual inspection should have defined acceptance criteria where judgement could otherwise vary between inspectors. Terms such as **"acceptable appearance"** should be supported by appropriate standards, reference samples, photographs or workmanship criteria where necessary.

26.10. Dimensional Inspection

Dimensional verification should use:

- Current product definition
- Appropriate measuring equipment
- Controlled inspection methods
- Defined sampling
- Competent personnel

Inspection should focus particularly on characteristics that are significant to product conformity and those identified through product/process risk. Measuring every dimension is not automatically better assurance if the inspection strategy is poorly targeted.

26.11. Sampling Inspection

Where 100% inspection is unnecessary or impractical, statistical sampling may be used.
A sampling plan defines:

- Lot size
- Sample size
- Acceptance criteria
- Rejection criteria
- Inspection level

Common approaches include acceptance sampling standards such as **ISO 2859-1** for attribute inspection and other industry/customer-specific methods. The sampling method should be contractually and technically appropriate. A key principle is: **Sampling does not guarantee that every item in an accepted lot conforms; it controls the statistical risk associated with the acceptance decision.**

The organisation should understand this risk rather than treating sampling as simply a method of reducing inspection workload.

26.12. AQL and Acceptance Sampling

Acceptance Quality Limit (AQL) is commonly used within sampling systems to help determine sampling plans. AQL should not be interpreted as permission for a supplier to intentionally supply a particular percentage of defective product.

The contractual requirement normally remains **conforming product**. AQL relates to the statistical acceptance methodology used to make a decision about a lot.

26.13. Reduced, Normal and Tightened Inspection

Some sampling systems permit inspection severity to change according to demonstrated supplier performance. A simplified concept is:

Good sustained performance → Reduced inspection

Normal performance → Normal inspection

Deteriorating performance → Tightened inspection

This creates a feedback mechanism between supplier performance and incoming assurance. Switching rules should be controlled rather than changed informally by inspectors.

26.14. Skip-Lot and Dock-to-Stock

High-performing suppliers may qualify for reduced incoming verification.

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- **Skip-Lot** Selected lots bypass defined inspection activities based on demonstrated performance and controlled criteria.
- **Dock-to-Stock** Material from suitably capable suppliers may move directly from receipt to approved stock with minimal incoming inspection.

These approaches should be supported by:

- Demonstrated supplier capability
- Stable performance
- Appropriate product risk
- Defined qualification criteria
- Ongoing monitoring
- Defined reinstatement criteria

Reduced inspection should represent **earned confidence**, not reduced assurance resources.

26.15. Shelf-Life Controlled Material

Products such as:

- Adhesives
- Sealants
- Paints
- Chemicals
- Resins
- Lubricants
- Some electronic or moisture-sensitive items may require shelf-life control.

Incoming checks may include:

- Manufacture date
- Expiry date
- Remaining shelf life
- Storage temperature
- Transportation conditions
- Batch/lot number
- Packaging integrity

An item can be technically correct but operationally unsuitable if insufficient usable shelf life remains.

26.16. Packaging and Preservation

Packaging protects product conformity during transport and storage. Incoming verification should consider, where applicable:

- Moisture protection
- Electrostatic discharge protection
- Corrosion prevention
- Cleanliness
- Protective caps
- Shock protection
- Temperature controls
- Tamper evidence
- Orientation requirements

Damaged packaging should prompt consideration of whether the **product itself may have been compromised**.

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26.17. Identification and Traceability

Incoming material should retain appropriate identity through receipt, inspection, storage and issue. Traceability may include:

Supplier → PO → Part Number → Revision → Batch/Lot → Serial Number → Certificate → Internal Receipt Record

Traceability becomes particularly important where material may later require:

- Recall
- Containment
- Investigation
- Product impact assessment
- Customer notification

26.18. Special Process Verification

Where supplied product has undergone special processing, incoming verification may include checking:

- Process specification
- Approved process source
- Certification
- Process batch
- Applicable approval status
- Required test results

Because special process conformity may not be fully demonstrable through subsequent inspection, **supplier and process control can be more important than Goods In inspection itself**.

26.19. Counterfeit Awareness

Incoming inspection is one defence against counterfeit or suspect counterfeit material. Potential indicators may include:

- Inconsistent markings
- Incorrect packaging
- Altered labels
- Poor-quality printing
- Conflicting date codes
- Evidence of previous use
- Unusual surface finish
- Documentation inconsistencies

However, visual inspection alone should not be considered sufficient where counterfeit risk is significant. Source control and supply-chain provenance remain stronger preventive controls.

26.20. Inspection Status

Material status should be clearly controlled. Typical statuses may include:

- **Awaiting Inspection**
- **Accepted**
- **Rejected**
- **Quarantined**
- **On Hold / Awaiting Technical Review**

Physical and electronic controls should prevent unaccepted material from being unintentionally released to production.

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26.21. Nonconforming Incoming Product

When incoming product fails verification, it should enter the organisation's controlled nonconformance process. Typical actions include:

Identify → Segregate → Record → Contain → Assess → Notify → Disposition → Corrective Action where required

The organisation should also consider:

- Other material from the same batch
- Previous deliveries
- Material already in production
- Finished product
- Other manufacturing sites
- Customer-delivered product

The scope of containment should reflect the potential risk.

26.22. Supplier Feedback and Corrective Action

Incoming inspection data should feed the wider Supplier Quality Management system. Repeated defects may justify:

- Supplier notification
- SCAR
- 8D/RCCA
- Increased inspection
- Supplier audit
- Process review
- Supplier development
- Escalation

Simply rejecting and returning defective material without addressing recurrence creates a repetitive inspection loop rather than improving supplier quality.

26.23. Inspection Planning

Incoming inspection requirements should be formally defined rather than dependent on inspector experience. An inspection plan may identify:

- Product/commodity
- Required documents
- Characteristics
- Specification limits
- Inspection method
- Sampling plan
- Measuring equipment
- Acceptance/rejection criteria
- Required records
- Reaction plan

Inspection planning should be reviewed following significant changes in supplier performance, product risk or configuration.

26.24. Digital Goods-In Systems

ERP, QMS and inspection systems can strengthen incoming verification by controlling:

- Inspection status
- Sampling requirements
- Certificate attachment
- Supplier performance
- Traceability

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- Nonconformance history
- Inspection records
- Release authority

Automation can reduce administrative errors but does not replace technical judgement. A system can automatically release incorrect product if the underlying rules are poorly designed.

26.25. Common Goods In Weaknesses

Typical weaknesses include:

- Receipt treated as acceptance.
- Inspection performed against obsolete drawings.
- Certificates checked for presence rather than content.
- Sampling plans applied without understanding statistical risk.
- Identical inspection applied to every supplier.
- Supplier performance not affecting inspection level.
- Excessive reliance on incoming inspection.
- Shelf life not checked.
- Material certificates not traceable to physical product.
- Special process certificates not verified.
- Damaged packaging ignored.
- Accepted and unaccepted material inadequately segregated.
- Inspector judgement used without defined acceptance criteria.
- Repeated supplier defects identified but not escalated.
- Inspection records insufficient to demonstrate what was actually checked.

26.26. Practical Audit Approach

A useful audit method is to select a recently accepted item from stores and trace it backwards:

Approved Stock → Goods In Acceptance → Inspection Record → Certificates → Purchase Order → Drawing/Specification → Supplier

Ask:

What was required? → What was actually checked? → Why was that level of verification selected? → Was the correct revision used? → Were certificates technically reviewed? → Was the measuring equipment suitable? → Can the batch be traced? → What would happen if the supplier's performance deteriorated?

Then select a rejected incoming item and trace:

Failure → Quarantine → Nonconformance → Supplier Notification → Containment → Corrective Action → Future Inspection Strategy

This establishes whether Goods In is simply finding defects or actively contributing to **supply-chain assurance and risk reduction**.

26.27. Key Principle

Effective incoming verification follows:

Identify → Verify Documentation → Inspect/Test as Required → Confirm Traceability → Accept or Contain → Record → Feed Back

Goods In should act as a **controlled gateway**, not the organisation's primary defence against poor supplier quality. The long-term objective should be to move from: **"Inspect quality into incoming product"** towards **"Build sufficient confidence in the supply chain that incoming verification can be intelligently targeted according to risk."**

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27. Verification, Inspection & Test

27.1. Introduction

Verification, inspection and test provide objective evidence that products, materials, processes and outputs conform to defined requirements. They form a fundamental part of product assurance and quality control, providing confidence that what has been produced or supplied is **what was specified, is acceptable for its intended use, and has been appropriately verified before release**.

Although the terms are often used interchangeably, they describe different activities:

Activity	Primary purpose	Typical question
Verification	Confirm specified requirements have been fulfilled	*Did we meet the requirement?*
Inspection	Examine or measure characteristics against acceptance criteria	*Does this characteristic conform?*
Test	Determine performance, function or behaviour under specified conditions	*Does it perform as required?*
Validation	Confirm the product is suitable for its intended use or application	*Does it meet the user's intended need?*

Verification is therefore the broader concept. Inspection and testing are two of the principal methods by which verification may be achieved.

27.2. Verification

Verification should be a **planned activity**, not simply a final check performed when manufacture is complete. The required verification activities should be determined from applicable requirements, product and process risks, criticality, previous performance and contractual or regulatory obligations. Verification may include:

- dimensional or visual inspection;
- functional or performance testing;
- material and certification review;
- configuration verification;
- review of manufacturing and inspection records;
- First Article Inspection (FAI);
- review of Certificates of Conformity (CoC);
- laboratory analysis;
- non-destructive testing;
- software or automated test;
- source inspection or customer inspection;
- process monitoring and verification;
- review of special process certification and records.

The method selected should be capable of providing sufficient confidence that the requirement has actually been satisfied. **Quality principle:** Verification should be appropriate to the risk and capable of detecting the type of nonconformity that could reasonably occur.

27.3. Inspection

Inspection determines whether defined characteristics conform to specified requirements. It may occur throughout the product lifecycle rather than only at the end of manufacture.

- **Receiving / incoming inspection** Performed on externally supplied products or materials before acceptance or release into production. The extent of inspection should consider supplier performance, product risk, certification, source inspection and other assurance controls.
- **In-process inspection** Performed during manufacture or assembly, particularly where a characteristic may become inaccessible or difficult to verify later. Examples include:
- dimensions before subsequent assembly;
- characteristics before coating or encapsulation;
- assembly orientation;
- torque verification;
- workmanship;

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- identification and traceability;
- process parameters and intermediate acceptance criteria.

27.4. Final inspection

Confirms that the completed product meets applicable requirements before release. Final inspection should not be relied upon to compensate for inadequate process control earlier in manufacture.

27.5. Inspection Planning

Effective inspection starts with understanding **what must be verified, when, how, by whom and against what acceptance criteria**. Inspection planning may be defined through:

- drawings and specifications;
- manufacturing or inspection plans;
- control plans;
- quality plans;
- route cards or travellers;
- inspection instructions;
- test procedures;
- key or critical characteristic controls;
- contractual requirements;
- regulatory requirements.

A good inspection plan clearly identifies the characteristic, requirement or tolerance, inspection stage, method or equipment, sampling level where applicable, acceptance criteria and required record. Inspection should never depend on an inspector having to guess what constitutes acceptable product.

27.6. Inspection Methods

The inspection method should be appropriate to the characteristic being assessed and sufficiently capable of determining conformity. Typical methods include:

- **Visual inspection** – workmanship, damage, contamination, identification, finish, completeness and obvious defects.
- **Dimensional inspection** – measurement of dimensions, geometry, tolerances and features using appropriate measuring equipment.
- **Attribute inspection** – determining whether a characteristic is acceptable/not acceptable or present/absent.
- **Variable inspection** – obtaining numerical measurement data that can be compared with specified limits and potentially used for statistical analysis.
- **Automated inspection** – machine vision, automated gauging, scanning or other computer-controlled inspection systems.

The limitations of the selected method should always be understood. A measurement with inadequate resolution, accuracy or capability may give the appearance of control without providing meaningful assurance.

27.7. Testing

Testing differs from conventional inspection because it normally evaluates the **function, performance, integrity or behaviour** of a product under defined conditions. Examples include:

- electrical testing;
- pressure or leak testing;
- load testing;
- environmental testing;
- functional testing;
- vibration or shock testing;
- software testing;
- destructive testing;
- material property testing;
- endurance or life testing.

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A controlled test should normally define:

Test requirement → Test method → Test conditions → Equipment → Acceptance criteria → Results → Disposition

Test procedures should specify the required conditions sufficiently to ensure repeatability. Factors such as temperature, duration, sequence, loading, stabilisation periods and equipment configuration can materially affect results. Where testing is destructive, appropriate sample selection and controls are particularly important because the tested item may not subsequently be deliverable.

27.8. Acceptance Criteria

Verification is meaningful only when acceptance criteria are established **before the result is assessed**.
Acceptance criteria may originate from:

- engineering drawings;
- specifications and standards;
- contractual requirements;
- approved design data;
- customer requirements;
- regulatory requirements;
- approved workmanship standards;
- test specifications;
- control plans.

Requirements should be clear, measurable where practical and traceable to their source.
Terms such as *acceptable*, *satisfactory*, *good condition* or *as required* should be avoided unless their meaning is objectively defined.

27.9. Sampling versus 100% Inspection

Not every characteristic necessarily requires 100% inspection. Appropriate sampling can provide an efficient means of verification where justified by risk, process capability and applicable requirements.
However, sampling is **not simply inspecting fewer parts**. A sampling plan should have a defined statistical or risk-based basis. Factors influencing the inspection level include:

- product and safety criticality;
- consequence of failure;
- characteristic classification;
- process capability and stability;
- supplier performance;
- historical defect levels;
- detectability of defects;
- contractual requirements;
- applicable standards;
- cost and practicality of inspection.

100% inspection may be appropriate for certain safety-critical, key or contractually mandated characteristics, but it should not automatically be assumed to eliminate risk. Human inspection itself can have an error rate, and repeated inspection does not correct an incapable process.

27.10. Measurement Equipment and Measurement Confidence

A recorded measurement is only useful when there is sufficient confidence in the measurement process.
Inspection and test equipment should therefore be:

- suitable for the characteristic and tolerance;
- appropriately calibrated or verified;
- identifiable;
- within its calibration status;
- protected from damage or deterioration;
- used under appropriate environmental conditions;

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- operated by competent personnel.

The relationship between the product tolerance and measurement uncertainty should also be considered. For important measurements, organisations may need to evaluate the complete **measurement system**, including equipment, operator, method, environment, fixturing and part variation. Techniques such as Measurement System Analysis (MSA) and Gauge R&R may be appropriate.
A calibration sticker alone does not demonstrate that a measurement system is suitable for its intended measurement.

27.11. Inspection and Test Records

Records provide the objective evidence that verification has taken place. Depending upon product and contractual requirements, records may include:

- part number and revision;
- serial, batch or lot number;
- characteristic inspected or tested;
- specification or acceptance criteria;
- actual measured result where required;
- pass/fail status;
- equipment identification;
- inspector or test operator;
- date;
- test conditions;
- deviations or concessions;
- associated nonconformity references.

For critical characteristics, recording only **“Pass”** may provide substantially less assurance and traceability than recording the actual measured value. Records should be legible, identifiable, retrievable, protected and retained for the required period.

27.12. First Article Inspection (FAI)

First Article Inspection is a structured verification activity used to demonstrate that the production processes, documentation and manufacturing methods are capable of producing a product that conforms to the defined engineering requirements. In aerospace and defence environments, FAI is commonly performed in accordance with **AS/EN 9102 where contractually invoked**.

FAI should not be viewed simply as an enhanced final inspection. It provides evidence that the manufacturing planning and production process have correctly realised the design requirements. Depending upon the applicable requirements, an FAI may be required for:

- initial production;
- significant design changes;
- manufacturing process changes;
- changes in manufacturing location;
- significant tooling or equipment changes;
- extended production interruptions;
- other changes capable of affecting product conformity.

The resulting **First Article Inspection Report (FAIR)** provides the documented evidence of the activity.
This section intentionally provides only an overview of FAI.

Detailed guidance covering **FAI preparation, AS/EN 9102 requirements, FAIR creation, forms, characteristic accountability and the review and approval of FAIRs** can be found in the Special Processes Institute publication: **SPI-09 – First Article Inspection Guidebook**

27.13. Verification Status and Product Release

The status of inspection and testing should remain clear throughout manufacture. Organisations should be able to distinguish between product that is:

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Awaiting verification → Accepted → Rejected → On hold / under review → Released

Unverified product should not inadvertently progress through manufacture or be delivered simply because it is physically present in an accepted-product area. Release should occur only when required verification activities have been satisfactorily completed, unless an appropriately authorised concession, deviation or other controlled approval permits otherwise.

27.14. Failed Inspection or Test

A failed inspection or test is evidence that a requirement has not been demonstrated as satisfied. The product should therefore be controlled through the organisation's nonconforming output process. Appropriate actions may include:

- segregation or controlled identification;
- creation of a nonconformance record;
- investigation;
- rework;
- repair subject to appropriate approval;
- use-as-is concession where authorised;
- scrap;
- additional inspection or containment.

Simply repeating a failed test until a passing result is obtained can conceal an underlying problem.
Where retest is permitted, the reason for the original failure should be understood and the conditions for retest controlled.

27.15. Independence and Competence

Verification personnel should be competent for the activity they perform. Competence may require knowledge of:

- drawings and specifications;
- measurement techniques;
- tolerancing;
- inspection equipment;
- test methods;
- workmanship standards;
- product-specific requirements;
- acceptance and rejection criteria.

For some products, contracts or regulatory environments, inspection or test activities may require specific qualifications, certifications or independence from the person performing the work.
Self-inspection can be effective where appropriately controlled, but should be determined according to risk rather than simply convenience.

27.16. Inspection Does Not Create Quality

Inspection is an important assurance mechanism, but it should not become the primary means of achieving product conformity. A mature quality system moves progressively from:

Detect defects → Control processes → Prevent defects → Demonstrate capable processes

Where inspection repeatedly identifies the same defect, the appropriate response is generally not simply to increase inspection. The organisation should investigate why the process continues to produce the defect and implement effective corrective or preventive controls. This distinction is fundamental: **Inspection detects whether output conforms. Process control creates the conditions for consistent conformity.**

Verification, inspection and testing therefore work most effectively when integrated with capable processes, risk management, configuration control, competent personnel, effective supplier assurance and robust corrective action.

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27.17. Key Takeaway

Verification provides evidence of conformity; inspection examines characteristics; testing demonstrates performance or behaviour. Effective assurance requires each activity to be planned, risk-based, performed using suitable methods and equipment, assessed against clearly defined acceptance criteria, and supported by reliable records. The ultimate objective is not to inspect quality into a product, but to provide objective evidence that controlled and capable processes have produced the required result.

28. Special Processes & Process Validation

28.1. Introduction

Some manufacturing and service processes require a greater level of control because the conformity of their output cannot always be fully demonstrated by subsequent inspection or testing. In these situations, assurance must be built into the **process itself** through appropriate qualification, validation, monitoring and control.

Process validation provides documented evidence that a process, when operated under defined conditions, is capable of consistently producing an output that meets specified requirements.
This principle is particularly important for **special processes**, but validation is not limited to processes formally classified as special. Any process where the output cannot be adequately verified afterwards, or where failure carries significant risk, may require validation.

Quality principle: Where conformity cannot be fully demonstrated after the process has been completed, greater assurance must be placed on controlling and validating the process that creates the characteristic.

28.2. What Is Process Validation?

Process validation is the documented demonstration that a process is capable of **consistently achieving its intended result** when operated within defined and controlled conditions. It goes beyond demonstrating that a process successfully produced one acceptable item. Effective validation establishes:

- what the process is required to achieve;
- which inputs and parameters influence the result;
- acceptable operating limits;
- required equipment, materials and resources;
- personnel competence or qualification;
- environmental requirements where relevant;
- monitoring and measurement arrangements;
- evidence that acceptable results can be repeatedly achieved;
- conditions under which the validation remains valid.

A validated process therefore has a defined **operating envelope** within which there is objective evidence that the required output can be achieved consistently.

28.3. Verification versus Validation

Verification and validation provide different forms of assurance.

- **Verification** confirms that a particular requirement has been satisfied.
- **Process validation** demonstrates that the process used to create the output is capable of consistently achieving the required result.

For example, measuring a finished component may verify that a dimension conforms. Demonstrating through controlled trials, parameter monitoring and capability evidence that the manufacturing process can repeatedly produce that dimension is process validation. Where complete verification of the resulting characteristic is impractical or impossible, process validation becomes particularly important.

28.4. When Is Process Validation Required?

The need for validation should be determined from technical requirements, applicable standards, contractual obligations and risk. Validation should particularly be considered where:

- output cannot be completely verified by subsequent inspection or test;
- verification would require destructive examination;

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- important characteristics become inaccessible after manufacture or assembly;
- deficiencies may only become apparent during service;
- process variation can significantly influence product performance;
- safety, reliability or mission-critical characteristics are created;
- the consequence of undetected failure is significant;
- regulatory, contractual or specification requirements mandate validation.

The extent of validation should be **proportionate to the complexity, uncertainty and risk associated with the process and its output**.

28.5. Special Processes

A **special process** is generally a process where the resulting output cannot be fully verified by subsequent monitoring, measurement, inspection or testing, or where deficiencies may become apparent only after the product is in use.

Such processes require increased confidence in the controls used to create the product rather than relying solely on inspection of the completed output. Special process assurance may involve:

- process qualification;
- approved procedures;
- qualified personnel;
- controlled equipment;
- defined process parameters;
- approved materials and consumables;
- environmental controls;
- process monitoring;
- representative testing;
- detailed processing records;
- periodic requalification.

Special Processes are intentionally covered only briefly within this section. For comprehensive guidance, including **special process definitions, assurance principles, qualification, control, auditing and a detailed list of recognised special processes**, refer to the Special Processes Institute publication: **SPI-01 – Special Processes Guidebook**

28.6. Understanding the Process

Effective validation starts with understanding how the process creates the required output. A process can be considered as an interaction between:

People + Equipment + Materials + Methods + Parameters + Environment + Measurement

Changes or variation in any of these factors may influence the result. Validation should therefore establish which inputs matter; how much variation is acceptable and what controls are necessary to maintain the process within its proven operating conditions. A useful principle is:

Process Inputs → Process Conditions → Process Output → Product Performance

The better this relationship is understood, the more effectively the process can be controlled.

28.7. Process Requirements and Acceptance Criteria

Before a process can be validated, its intended outcome must be clearly defined. Requirements may originate from:

- engineering drawings;
- specifications;
- customer requirements;
- process specifications;
- design requirements;

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- regulatory requirements;
- contractual requirements;
- material specifications;
- applicable standards.

Acceptance criteria should be objective and measurable wherever practical.
Validation cannot demonstrate capability against an undefined requirement. Statements such as *satisfactory*, *adequate* or *acceptable* provide little value unless the conditions defining acceptability are clearly established.

28.8. Critical Process Parameters

Not every process parameter has the same influence on the final product.
Parameters that significantly affect the ability of the process to achieve its required output should be identified and controlled. Depending upon the process, these might include:

- temperature;
- time;
- pressure;
- speed;
- electrical current or voltage;
- chemical concentration;
- flow rate;
- vacuum level;
- humidity;
- mixing ratio;
- surface preparation;
- curing conditions;
- application rate.

For each significant parameter, the organisation should understand:

What must be controlled? → What is the acceptable range? → How is it monitored? → What happens if the limit is exceeded?

Parameter limits should be supported by technical knowledge, qualification data, specifications, experimentation or other appropriate evidence. Where appropriate, normal operating limits may be established inside the absolute process limits to provide an additional control margin.

28.9. The Validated Operating Envelope

A key output from validation is understanding the conditions within which the process is known to produce acceptable results. This can be considered the **validated operating envelope**. For example, a process may have been demonstrated as capable only when performed:

- between specified temperature limits;
- using particular materials;
- on approved equipment;
- using specified tooling;
- within defined environmental conditions;
- by appropriately qualified personnel;
- using a particular process sequence.

Operating outside those conditions may mean that the original validation evidence is no longer applicable. This is why validation must be closely connected to configuration and change control.

28.10. Process Validation Lifecycle

Validation should be treated as a lifecycle rather than a one-time approval exercise. A practical sequence is:

Define Requirements → Understand Process → Assess Risk → Establish Controls → Qualify Resources → Validate → Approve → Monitor → Control Change → Revalidate

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The exact approach should reflect the process and associated risk. Validation activities may include:

- development trials;
- representative production runs;
- challenge or boundary testing;
- destructive testing;
- laboratory analysis;
- qualification samples or coupons;
- process capability studies;
- parameter studies;
- repeatability trials;
- equipment qualification;
- procedure qualification;
- personnel qualification.

The evidence should demonstrate that the process can **repeatedly achieve the required result**, not simply that one successful outcome was obtained.

28.11. Qualification and Validation

The terms *qualification* and *validation* are sometimes used interchangeably, but they can represent different concepts.

Qualification generally demonstrates that a particular resource or element is capable of performing its intended function. Examples include:

- personnel qualification;
- equipment qualification;
- procedure qualification;
- material qualification;
- facility qualification.

Validation considers whether the complete process, operating under defined conditions, is capable of consistently achieving the required outcome. A process may therefore contain several individually qualified elements while still requiring validation of their combined operation. Terminology and specific requirements should always follow applicable contractual, regulatory and industry requirements.

28.12. Equipment, Tooling and Infrastructure

Equipment used within a validated process must be capable of maintaining the conditions demonstrated during validation. Controls may include:

- equipment approval;
- calibration;
- preventive maintenance;
- tooling control;
- machine capability;
- software and programme control;
- parameter monitoring;
- alarms and interlocks;
- environmental monitoring;
- equipment qualification.

Where equipment directly controls an important process parameter, its accuracy, stability and repeatability form part of the process assurance system. A machine being calibrated or maintained does not automatically demonstrate that the **overall process is capable**.

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28.13. Personnel Competence

Some processes depend significantly upon operator skill, knowledge, judgement or technique. Controls may therefore include:

- defined competence requirements;
- formal training;
- practical demonstration;
- examinations;
- supervised experience;
- certification;
- periodic reassessment;
- continuity requirements;
- maintenance of qualification records.

Where personnel qualification is required, its scope and validity should be clearly defined.
Competence should reflect the actual work being performed rather than simply attendance at a training course.

28.14. Materials and Consumables

Materials and consumables can significantly influence process performance and should therefore be included within validation and ongoing control where relevant. Considerations may include:

- material specification;
- approved manufacturer or supplier;
- batch or lot control;
- shelf life;
- storage conditions;
- preparation requirements;
- mixing requirements;
- contamination controls;
- traceability;
- expiry dates.

Changing a material or supplier may appear insignificant but can invalidate previous validation if the material influences process performance.

28.15. PFMEA and Process Validation

Process Failure Mode and Effects Analysis (PFMEA) can support process validation by providing a structured method for identifying potential process failures, their causes and effects, and the controls necessary to prevent or detect them. Within validation, PFMEA can help identify:

- higher-risk process steps;
- important process parameters;
- potential sources of variation;
- prevention controls;
- detection controls;
- areas requiring stronger validation evidence.

Where PFMEA and control plans are used, there should be a logical relationship between them:

Process Flow → PFMEA → Control Plan → Work Instructions → Production Records

Risks identified during PFMEA should therefore be reflected in the actual controls applied to the process.
PFMEA is intentionally covered only briefly within this section.

For comprehensive guidance covering **PFMEA principles, failure modes, effects and causes, risk evaluation, prevention and detection controls, actions and practical application**, refer to the Special Processes Institute publication: **SPI-06 – Process Failure Mode and Effects Analysis (PFMEA) Guidebook**

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28.16. Process Capability and Statistical Evidence

Where outputs can be quantitatively measured, statistical techniques can provide valuable evidence that a process is stable and capable. These may include:

- control charts;
- Statistical Process Control (SPC);
- Cp and Cpk;
- Pp and Ppk;
- trend analysis;
- Measurement System Analysis (MSA).

However, statistical capability should not be confused with complete process validation.
A capable measurable characteristic does not necessarily demonstrate that every aspect of a complex process is controlled. Statistical evidence should therefore support technical understanding of the process rather than replace it.

28.17. Ongoing Process Monitoring

Validation is not complete when the validation report is approved. Processes can deteriorate or drift because of:

- equipment wear;
- tooling deterioration;
- material variation;
- environmental changes;
- personnel changes;
- maintenance;
- software changes;
- consumable degradation;
- gradual parameter drift.

Continued assurance should therefore monitor appropriate process parameters and product results.
Trend monitoring can be particularly valuable because deterioration may be identified before the process actually produces nonconforming output.

Good process control detects deterioration before the product exceeds its acceptance limits.

28.18. Process Records

Records provide evidence that production remained within the conditions established through validation.
Depending upon the process, records may include:

- equipment identification;
- operator identification;
- material and batch details;
- processing date;
- parameter readings;
- temperature or pressure profiles;
- machine programmes;
- environmental conditions;
- test results;
- inspection results;
- deviations;
- approvals;
- traceability information.

For important processes, simply recording **“Process Complete”** may provide insufficient evidence.
Records should allow the organisation to demonstrate what actually occurred during processing and whether the validated conditions were maintained.

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28.19. Change Control

One of the most important principles of process validation is maintaining control of change.
Changes should be reviewed to determine whether they affect the conditions under which the original validation was demonstrated. Examples include changes to:

- equipment;
- tooling;
- manufacturing location;
- materials;
- material suppliers;
- process parameters;
- software;
- procedures;
- process sequence;
- environmental conditions;
- inspection or test methods;
- personnel qualification requirements.

The fundamental question is: **Does the existing validation evidence remain applicable after this change?**

The response may range from documented technical review to partial requalification or complete revalidation. Changes should not be introduced into a validated process without considering their potential impact.

28.20. Revalidation

Revalidation may be required following planned change, but it can also be triggered by evidence that the existing process may no longer operate as originally demonstrated. Potential triggers include:

- significant process changes;
- customer, specification or standard requirements;
- significant nonconformities;
- customer escapes;
- adverse process trends;
- loss of capability;
- equipment replacement or major overhaul;
- relocation;
- prolonged inactivity;
- qualification expiry;
- unexpected test failures;
- audit findings.

The extent of revalidation should reflect the significance of the change or event.
Not every change requires complete revalidation, but the decision and technical justification should be documented.

28.21. Subcontracted Processes

Outsourcing a process does not remove the organisation's responsibility for ensuring that applicable requirements are satisfied. Controls for subcontracted validated or special processes may include:

- approved supplier or processor status;
- specification and revision flowdown;
- customer-approved sources where required;
- personnel qualification requirements;
- equipment and process qualification;
- sub-tier controls;
- certification requirements;
- processing records;
- change notification requirements;
- record retention;

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- right of access;
- surveillance and audit.

Where accreditation schemes such as **Nadcap** are required or used, accreditation can provide valuable independent assurance. However, accreditation does not remove the purchasing organisation's responsibility to correctly define, flow down and verify its own product and contractual requirements.

28.22. Validation Records and Evidence

Validation should produce sufficient objective evidence to demonstrate **what was validated, how it was validated and the conditions under which the validation remains applicable**. The validation package may include:

- validation plans;
- validation reports;
- applicable specifications;
- qualification results;
- trial data;
- test results;
- approved parameter ranges;
- equipment details;
- material details;
- personnel qualifications;
- risk assessments;
- capability data;
- approvals and authorisations;
- deviations;
- revalidation results.

Traceability is important. Someone reviewing the process several years later should be able to understand the scope, evidence, limitations and approved operating conditions without relying upon undocumented knowledge.

28.23. Common Process Validation Weaknesses

Typical weaknesses include:

- treating validation as a one-time test;
- demonstrating only one successful production run;
- unclear parameter limits;
- inadequate understanding of process inputs;
- validating only nominal conditions;
- poor linkage between identified risks and production controls;
- uncontrolled changes following validation;
- expired personnel qualifications;
- inadequate equipment maintenance or calibration;
- poor material and consumable control;
- incomplete validation records;
- inadequate traceability;
- relying excessively on final inspection;
- failing to reassess validation following significant process failures;
- assuming supplier accreditation removes the need for supplier control.

These weaknesses commonly occur when validation is viewed as a **documentation requirement rather than a process-control strategy**.

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28.24. What Good Process Validation Looks Like

A well-controlled validated process should allow the organisation to answer:

- **What does the process need to achieve?**
- **Which variables influence the result?**
- **What are the approved operating limits?**
- **What evidence demonstrates that the process is capable?**
- **How are those conditions controlled during production?**
- **How is process performance monitored?**
- **What happens when a limit is exceeded?**
- **What changes require review or revalidation?**

If these questions cannot be answered clearly, the validation may not provide sufficient assurance.

28.25. Key Takeaway

Where quality cannot be fully verified in the finished output, quality must be assured through control of the process that creates it.

Effective process validation establishes the conditions under which a process is capable, provides objective evidence that those conditions consistently produce acceptable results, and ensures they remain controlled throughout production. Validation should therefore be regarded as a lifecycle:

Understand → Assess Risk → Qualify → Validate → Control → Monitor → Review → Revalidate

Special Processes and PFMEA are closely related to this approach but are substantial subjects in their own right. For further detailed guidance refer to:

- **SPI-01 – Special Processes Guidebook** Detailed guidance on Special Processes, including definitions, qualification and assurance principles, auditing considerations and a comprehensive list of special processes.
- **SPI-06 – Process Failure Mode and Effects Analysis (PFMEA) Guidebook** Detailed guidance on PFMEA methodology, process risks, failure modes, effects and causes, prevention and detection controls, risk evaluation and practical application.

Download guidance resources can be accessed at: https://sp-i.org/downloads.html

29. Chemical Processing, Surface Engineering & Protective Treatments

29.1. Special Quality Focus for High Risk Processes

Chemical processing, electroplating, anodising, chemical conversion coating and painting deserve particular attention because failures are frequently **latent**. A component can look completely acceptable at final inspection at the processor and Goods-In Inspection at the customer, yet subsequently exhibit corrosion, staining, blistering, peeling, seepage or coating breakdown during storage, assembly or service.

This risk becomes greater when processing is performed by a **sub-tier supplier** and the complete technical requirements have not been flowed down through the supply chain.

29.2. Why This Subject Deserves Special Attention

Surface treatments are often regarded as the final cosmetic operation applied to an otherwise finished component. For many engineered products, this is fundamentally incorrect. A surface treatment may provide:

- corrosion protection;
- wear resistance;
- electrical conductivity or insulation;
- controlled electrical contact resistance;
- paint adhesion;
- chemical resistance;
- hardness;
- lubricity;

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- controlled friction;
- dimensional restoration;
- environmental protection;
- identification or appearance;
- preparation for subsequent bonding, painting or sealing.

Failure of the treatment can therefore result in failure of the product even though the underlying component remains dimensionally conforming. These processes are particularly vulnerable because the quality of the finished coating depends not simply upon **what material was applied**, but upon the entire processing sequence.

Cleaning → preparation → activation → treatment → rinsing → sealing/post-treatment → drying/curing → inspection → testing → handling and storage

An error at any stage may not be detectable by normal visual inspection.

29.3. Surface Treatment Is a Process — Not Simply a Material

One of the most important principles for Engineering, Procurement and Quality is: **Calling out the paint, plating or chemical material alone does not adequately define the surface treatment process.**

A drawing or purchase order may, for example, specify an approved aerospace paint by manufacturer and material specification. That defines the **paint material**, but may not adequately define:

- surface preparation;
- cleaning;
- pretreatment;
- primer;
- application method;
- number of coats;
- wet/dry film thickness;
- flash-off time;
- cure temperature and duration;
- environmental limits;
- masking;
- rework;
- adhesion requirements;
- test panels;
- periodic testing;
- acceptance criteria.

The same principle applies to plating, anodising and conversion coatings. A robust requirement should therefore invoke the appropriate **process specification**, together with the material specification where required.

This distinction is frequently missed during **design, contract review and supplier flow-down**.

29.4. The Importance of Engineering Design

Surface engineering should begin at the **design stage**, not when the completed drawing reaches the processor. Design engineers need sufficient understanding of the selected treatment to appreciate its physical and chemical limitations. Particular consideration should be given to:

- blind holes;
- deep recesses;
- narrow cavities;
- faying surfaces;
- overlapping joints;
- capillary gaps;

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- threaded holes;
- sharp internal corners;
- inaccessible surfaces;
- drainage;
- air entrapment;
- solution entrapment;
- rinsing access;
- electrical contact for electroplating;
- masking requirements;
- coating build-up;
- dimensional change;
- tolerance effects;
- surface finish;
- heat-treatment condition;
- material compatibility;
- hydrogen embrittlement susceptibility;
- galvanic compatibility;
- subsequent adhesive bonding;
- subsequent painting;
- sealing requirements.

A design can be geometrically manufacturable while being extremely difficult—or impossible—to process reliably.

29.5. Design for Drainage and Rinsing

Components entering aqueous chemical processes may be immersed in numerous chemical and rinse tanks. A blind hole can become a small chemical reservoir. During processing it may retain cleaner, acid, plating solution, anodising electrolyte or conversion chemistry. Subsequent rinsing may dilute rather than completely remove the trapped solution. After drying, apparently clean components can retain chemical residues. Later, moisture or condensation can reactivate these residues and allow them to migrate from the cavity. See SPI-502 Effective Rinsing in Surface Treatment. Possible consequences include:

staining → streaking → corrosion → blistering → paint failure → contamination of adjacent components

This explains why some surface-treatment defects become apparent **weeks or months after processing**, particularly following storage or environmental exposure.

29.6. Electroplating

Electroplating deposits a metallic coating onto a conductive substrate using an externally applied electrical current. Typical engineering coatings include nickel, chromium, zinc, zinc-nickel where permitted, copper, tin, silver and gold, depending upon the required function.

The distribution of electrodeposited material is influenced by electrical current distribution and component geometry. Plating therefore does **not necessarily deposit uniformly across a complex component**.

Edges and prominent features may receive greater deposition while recessed, threads, shielded or low-current-density areas may receive less.

29.6.1. Blind Holes, Recesses and Faying Surfaces

Designs increasingly need to consider whether the selected plating process can actually provide the required coverage. Problem areas include:

- deep blind holes;
- narrow slots;
- internal cavities;
- shielded surfaces;

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- tightly spaced features;
- faying surfaces;
- threaded areas;
- complex internal geometries.

These locations may experience:

- inadequate coating thickness;
- complete absence of coating;
- poor rinsing;
- trapped process chemistry;
- subsequent seepage;
- corrosion initiation.

Merely specifying a minimum plating thickness on the drawing does not guarantee that every geometrical location can achieve that thickness. Where internal coverage is functionally necessary, Engineering should establish whether the selected process is technically capable of achieving it.

Additional consideration should be given to excessive coating thickness in high-current-density areas, particularly on complex geometries with protruding features, sharp edges, corners and other prominent surfaces, where increased current concentration can result in localised over-plating or 'burnt' deposit.

29.6.2. Selecting the Correct Plating

Different plating systems and even different variants of nominally similar coatings can provide significantly different properties. Selection may depend upon:

- substrate material;
- corrosion environment;
- required coating thickness;
- hardness;
- wear;
- electrical properties;
- solderability;
- friction;
- lubricity;
- temperature;
- fatigue considerations;
- dimensional requirements;
- subsequent processing;
- environmental/regulatory restrictions.

For example, electroless nickel-phosphorus coatings can be specified according to requirements including thickness, hardness, adhesion, porosity and corrosion resistance; **ISO 4527** provides specification and test requirements for this coating family.

The designer should therefore specify the required **coating system and performance**, rather than assuming that the generic term "nickel plate" adequately defines the requirement.

29.6.3. Hydrogen Embrittlement

Hydrogen embrittlement is a particularly important consideration when processing susceptible high-strength steels. Hydrogen may be introduced during operations such as:

- acid cleaning;
- pickling;
- electrocleaning;
- electroplating;
- stripping/rework.

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Absorbed hydrogen can reduce ductility and contribute to delayed brittle fracture under stress.
This is particularly dangerous because a component may:

pass manufacture → pass inspection → assemble correctly → subsequently fracture in service.

Applicable specifications may therefore impose controls including material-strength restrictions, pre-processing stress relief, restrictions on cleaning methods and post-plating embrittlement-relief baking.

Hydrogen embrittlement requirements should never be left to informal processor judgement where the product or material presents a credible risk.

29.6.4. Plating Process Control

A plating requirement should invoke an appropriate controlled specification covering, where applicable:

- approved process/material;
- substrate preparation;
- plating type/class;
- thickness;
- masking;
- areas requiring or prohibiting coating;
- heat treatment;
- adhesion;
- corrosion resistance;
- hardness;
- porosity;
- hydrogen embrittlement controls;
- inspection;
- sampling;
- test coupons;
- solution control;
- periodic testing;
- process validation;
- revalidation;
- records and certification.

The process should be validated initially and subsequently maintained through appropriate **periodic testing and process control** rather than relying solely upon final visual inspection.

29.7. Aluminium Anodising

Anodising is an electrochemical process that deliberately forms a controlled oxide layer on aluminium and certain other metals. Depending upon the process, anodising can provide:

- corrosion resistance;
- wear resistance;
- electrical insulation;
- paint adhesion;
- decorative appearance;
- controlled surface characteristics.

SAE AMS2471, for example, specifies sulfuric-acid anodic treatment for aluminium-base alloys.
As with electroplating, anodising should not be regarded simply as “putting a coating on the part.” The substrate itself participates in forming the oxide layer.

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29.7.1. Common Anodising Problems

Frequent issues include:

- inadequate cleaning and caustic etching;
- poor deoxidising/desmutting;
- incorrect solution control;
- burning;
- inconsistent coating;
- poor sealing;
- staining;
- white spots or pitting;
- galvanic coupling during processing;
- colour variation;
- excessive or insufficient coating thickness;
- dimensional effects;
- contact/racking marks;
- trapped chemistry;
- inadequate rinsing;
- blind-hole seepage;
- corrosion developing after storage.

29.7.2. Rinsing

Rinsing is a critical process stage. Residual acid or process chemistry retained within holes, recesses or interfaces can subsequently cause staining and corrosion. Particular attention should therefore be paid to components containing blind holes or geometries that retain liquids. Rinsing arrangements should consider:

flow → agitation → water quality → time → temperature → contamination → part orientation → drainage

A component being immersed in a rinse tank does not itself demonstrate that adequate rinsing has occurred.

29.8. Chemical Conversion Coatings

Chemical conversion coatings chemically react with a metal surface to create a protective layer rather than simply depositing a separate coating.

They are commonly used on aluminium to provide corrosion protection and/or prepare the surface for subsequent painting.

MIL-DTL-5541, for example, covers chemical conversion coatings on aluminium and aluminium alloys and distinguishes Type I materials containing hexavalent chromium from Type II materials that do not. It also distinguishes Class 1A for maximum corrosion protection from Class 3 where low electrical resistance is required.

MIL-DTL-81706 separately controls chemical conversion **materials** used to form coatings, illustrating again the distinction between controlling the processing material and controlling the resulting coating/process.

29.8.1. Staining and Rinsing Problems

Staining is a long-standing issue associated with conversion coating processes. Potential causes include:

- insufficient rinsing or time in the rinse. See SPI-502 Effective Rinsing in Surface Treatment;
- contaminated rinse water;
- retained chemistry;
- poor drainage;
- excessive treatment such as caustic etching;
- inappropriate drying;
- solution contamination;
- handling contamination;
- blind holes and recesses.

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Where an applicable process instruction imposes a defined transfer or rinsing requirement, sometimes referred to operationally as a **“one-minute rule”**, that requirement must be understood and observed by the processor. It should not be assumed to be a universal requirement for every conversion-coating system; the controlling specification and approved process instruction determine the required sequence and timing. This distinction is important during auditing: **verify the actual specification requirement and processor instruction rather than auditing against shop-floor folklore.**

For conversion coatings subsequently painted, drying conditions also matter. **MIL-DTL-5541** specifically warns that coated parts should be allowed to dry in accordance with the chemical manufacturer's recommendation before painting because otherwise adhesion failures may occur.

29.9. Paint and Organic Coatings

Paint failures are particularly problematic because a newly painted component can appear excellent while possessing extremely poor adhesion. The weakness may not become apparent until:

- handling;
- transportation;
- assembly;
- masking removal;
- temperature cycling;
- environmental exposure;
- storage;
- service.

Typical failure modes include:

- peeling;
- flaking;
- blistering;
- cracking;
- lifting;
- corrosion beneath paint;
- poor adhesion;
- excessive film thickness;
- insufficient film thickness;
- contamination;
- incomplete cure.

29.9.1. Paint Adhesion — A Frequent Latent Failure

Paint adhesion depends heavily upon everything that occurs **before the paint is applied**. Typical causes of poor adhesion include:

- oil or grease;
- fingerprints;
- machining coolant;
- silicone contamination;
- incorrect cleaning;
- inadequate surface preparation;
- incorrect conversion coating;
- contamination between operations;
- omission of etch primer on non-ferrous surfaces where it forms part of the specified paint system;
- excessive delay between preparation and painting;
- incorrect primer;
- poor mixing;
- incorrect thinning;
- expired material;
- incorrect application;
- insufficient flash-off;

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- incorrect curing;
- unsuitable temperature or humidity.

A final visual inspection **cannot** reliably demonstrate adhesion. This is why periodic adhesion testing, process qualification and controlled test panels can be considerably more meaningful than simply inspecting whether the paint "looks good."

29.9.2. The Frequently Missing Paint Application Specification

A particularly common flow-down weakness is: **Drawing/PO:** "Paint XYZ123" but no requirement defining **how XYZ123 must be applied**.

This may leave the supplier without controlled requirements for preparation, application, curing or testing.
A robust requirement should therefore distinguish **Paint Material Specification** from **Paint Application / Process Specification** The application specification should define or reference requirements such as:

- substrate preparation;
- pretreatment;
- primer;
- mixing;
- viscosity;
- pot life;
- application method;
- film thickness;
- environmental conditions;
- flash-off;
- curing;
- adhesion;
- appearance;
- repair;
- test panels;
- periodic testing;
- acceptance criteria.

A material specification alone should not automatically be assumed to control these requirements.

29.10. Other Common Surface-Treatment Failures

Quality professionals should also be alert to:

- **Masking errors** — treatment on prohibited surfaces or absence from required surfaces.
- **Dimensional build-up** — coating thickness affecting threads, bores, fits, bearings or precision interfaces.
- **Racking/contact marks** — electrical processes require contact locations that may leave untreated or visibly marked areas.
- **Galvanic incompatibility** — an individually suitable coating may create an undesirable galvanic couple when assembled with another material.
- **Contamination** — oil, silicone, fingerprints, corrosion products and residues can severely affect subsequent treatments.
- **Process sequence errors** — performing otherwise correct operations in the wrong sequence.
- **Unapproved rework or stripping** — repeated stripping and reprocessing may affect substrate dimensions, surface condition, fatigue performance or material properties.
- **Expired chemistry/materials** — paints, sealers and processing chemicals may have shelf-life or storage requirements.
- **Incorrect water quality** — rinse-water chemistry can materially affect surface quality.
- **Bath contamination or deterioration** — concentration alone may not demonstrate that a processing solution remains capable.

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- **Poor environmental control** — temperature, humidity, airborne contamination and drying conditions can affect results.

29.11. Sub-Tier Supplier Risk

Surface treatment frequently takes place several levels below the organisation that designed the product. For example:

Customer → Prime → Tier 1 Machining Supplier → Tier 2 Surface Processor

The Tier 2 processor may never see the customer's drawing. Instead, the processor receives a purchase order generated by the machining supplier. If that PO states only: **"Anodise black"** when the drawing contains a detailed specification, type, class, thickness, masking, sealing and testing requirement, the technical requirement has effectively been lost.

This is a classic **supply-chain flow-down failure**. The supplier responsible for subcontracting the process remains responsible for ensuring that the applicable technical requirements reach the processor.

29.12. Correct Specification Flow-Down

For critical surface treatments, the purchase order and technical data should clearly identify, as applicable:

- process specification and revision;
- material specification;
- process/type/class;
- substrate;
- required thickness;
- treatment areas;
- prohibited treatment areas;
- masking;
- surface preparation;
- sealing;
- post-treatment;
- heat treatment;
- hydrogen embrittlement controls;
- appearance;
- adhesion;
- corrosion performance;
- test requirements;
- periodic tests;
- qualification requirements;
- approved processor requirements;
- certification;
- record retention;
- control of rework;
- notification/approval of process changes.

Never assume that the processor knows the design intent.

29.13. Validation, Revalidation and Periodic Testing

Special processes cannot always be fully verified by subsequent inspection. Surface treatments are a good example. The process specification should therefore establish appropriate validation and continuing verification. Depending upon the process this may include:

- adhesion;
- corrosion resistance;
- salt-spray testing;
- hardness;
- porosity;
- electrical/contact resistance;

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- coating weight;
- sealing quality;
- bend testing;
- test panels/coupons.

ISO 4527, for example, includes requirements addressing appearance, thickness, hardness, adhesion, porosity and corrosion resistance for electroless nickel-phosphorus coatings.

Measurement method also matters: **ISO 2361:2025** defines a magnetic method for electrodeposited nickel thickness and explicitly notes that it may not be suitable for electroless nickel because those coatings can be non-magnetic. This illustrates an important principle: **A measurement result is only meaningful when the measurement method is appropriate for the coating/substrate combination.**

29.14. Goods-In and Final Inspection

Visual inspection remains important but should not be mistaken for process assurance.
Incoming inspection should consider, where applicable:

29.14.1. Documentation

Verify:

- correct processor;
- specification;
- revision;
- type/class;
- certificate of conformity;
- test results;
- thickness results;
- batch/lot traceability;
- required approvals.

29.14.2. Visual condition

Look for:

- staining;
- discoloration;
- corrosion;
- pits;
- blisters;
- peeling;
- flaking;
- bare areas;
- burns;
- excessive build-up;
- contamination;
- unusual rack marks;
- seepage from holes or joints.

29.14.3. Geometry

Pay particular attention to:

- blind holes;
- recesses;
- threads;
- mating surfaces;
- edges;
- interfaces;
- masking boundaries.

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But remember: **A visually acceptable coating does not demonstrate that the process was correctly performed.**

29.15. Auditing a Surface-Treatment Processor

Auditing should follow the **actual process route**, not simply review the QMS paperwork. An effective process audit should examine the journey of a representative component:

Receipt → identification → cleaning → preparation → processing → rinsing → post-treatment → drying/curing → inspection → testing → certification → packing

Particular attention should be given to:

Audit Area	What to Examine
Contract review	Does the processor understand every specification, type and class?
Specification control	Are current authorised revisions available?
Operators	Training, competence and authorisation
Equipment	Calibration, maintenance and suitability
Chemistry	Concentration, pH, temperature, contamination and replenishment
Bath control	Analysis frequency, limits, trends and corrective action
Rinsing	**Time**, water quality, contamination, agitation, overflow and renewal
Component geometry	Blind holes, drainage, recesses and solution traps
Racking	Contact location, current distribution and damage
Masking	Approved materials, method and effectiveness
Paint	Mixing, viscosity, pot life, environment, film thickness and cure
Testing	Coupons, adhesion, corrosion, thickness and periodic tests
Traceability	Batch, tank, operator, chemistry and processing date
Rework	Stripping/reprocessing controls and Engineering approval
Nonconformance	Segregation, investigation and corrective action
Change control	Chemistry, equipment, supplier and process changes
Packaging	Protection from damage, moisture and contamination

29.15.1. Look Beyond the Certificate

One of the most important supplier-assurance lessons for chemical processing is:

A Certificate of Conformity demonstrates that a supplier has declared conformity; it does not itself demonstrate that the process was capable, correctly controlled or correctly flowed down.

For higher-risk processes, Supplier Quality should periodically examine objective process evidence behind the certificate. For example:

PO → job traveller → specification → bath record → operator → process parameters → periodic testing → special process validation → inspection result → certificate

These records should tell a consistent story.

29.16. Best-Practice Assurance Strategy

For important surface treatments, good assurance should combine four levels of control:

1. Design Assurance Confirm that geometry, material and functional requirements are compatible with the proposed treatment.

2. Technical Flow-Down Specify the correct material and process specifications, type/class, testing and acceptance requirements.

3. Process Assurance Use qualified/approved processors where required, validation, periodic testing, process audits and controlled chemistry.

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4. Product Verification Use appropriate visual, dimensional, thickness, adhesion, corrosion or other verification according to risk.

None of these controls should be expected to compensate completely for failure of another.

29.17. Warning Signs for the Quality Professional

Particular attention should be triggered when encountering requirements such as:
“Paint to match.”
“Paint black.”
“Nickel plate.”
“Anodise.”
“Chem film.”
“Protective finish.”
“Finish as previous.”

These descriptions may be insufficient unless supported by controlled technical requirements. Other warning signs include:

- processor cannot identify the governing specification;
- supplier PO differs from the drawing;
- no evidence of periodic testing;
- bath records show no trends;
- rinse control is informal;
- blind-hole components receive no special consideration;
- test coupons are not representative;
- unexplained staining is accepted as cosmetic;
- rework is routinely performed without documented controls;
- certificates omit process type/class;
- processing is subcontracted again without approval;
- supplier relies entirely upon final visual inspection.

29.17.1. When a Failure Is Found

Surface-treatment investigations should resist stopping at: **“The coating peeled.”** The investigation should trace backwards through the entire process. For example:

Paint peeled
↓
Why was adhesion inadequate?
↓
Was the substrate contaminated?
↓
Was pretreatment satisfactory?
↓
Was etch primer applied (nonferrous) prior to primer?
↓
Were process parameters within limits?
↓
Was the paint applied within the permitted time?
↓
Were temperature and humidity controlled?
↓
Was the correct application specification flowed down?
↓
Was the flash off and curing parameters correct?
↓
Was periodic adhesion testing actually performed?

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The physical defect may therefore be several process stages removed from the true root cause.

29.18. Key Quality Principle

Chemical processing and surface engineering deserve special attention because **the finished appearance can create false confidence**.

A bright plated component, clean anodised component or perfectly painted enclosure may appear completely acceptable while containing the conditions for a future failure. The strongest assurance is therefore not: **"Does the coating look acceptable?"** but **Was the correct treatment selected by Engineering, was the complete process requirement flowed down, was the component designed so that the process could be performed successfully, was the process demonstrably controlled, and is there objective evidence that the required performance continues to be achieved?**

This is particularly important for subcontracted and sub-tier processing. Many of the most difficult surface-treatment nonconformities are not discovered at the processor. They emerge **after delivery, during storage, during assembly or in service**, when corrective action is considerably more expensive and product risk is substantially greater.

For that reason, chemical processing, plating, anodising, conversion coating and painting should be treated as **engineered processes requiring lifecycle assurance, not simply finishing operations.**

30. Concession & Deviation Request

30.1. Introduction

A controlled quality system recognises that there may be circumstances where a product, process or requirement cannot be achieved exactly as originally specified. A **concession or deviation** provides a formal mechanism for evaluating and, where justified, authorising a departure from an approved requirement. Neither should be regarded as permission to ignore requirements. They are **controlled exceptions** requiring appropriate technical evaluation, risk assessment, authorisation, traceability and defined limitations.

The fundamental principle is: **A requirement remains applicable unless an appropriately authorised person or organisation formally approves a departure from it.**

Concessions and deviations should therefore be exceptional controls—not substitutes for effective planning, capable processes, correct configuration or timely corrective action.

30.2. Concession and Deviation – What Is the Difference?

Terminology varies between organisations, industries and customers, so applicable contractual definitions should always take precedence. A useful general distinction is:

30.2.1. Concession

A **concession** is permission to use or release a product or service that **does not conform to specified requirements**. It is normally associated with a condition that has already occurred.

Requirement → Nonconformity occurs → Technical evaluation → Concession requested → Approval/rejection

Example: A manufactured diameter is specified as **20.00 ±0.10 mm**, but inspection records **20.13 mm**. Rather than automatically scrapping or reworking the component, an authorised concession may be requested to determine whether the product can safely and functionally be accepted in its existing condition.

30.2.2. Deviation

A **deviation** is generally an authorised departure from a specified requirement **before the affected activity is performed or product produced**. A deviation can sometimes be referred to as a **Production Permit.**

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Requirement → Need for departure identified → Deviation requested → Approval → Controlled implementation

Example: A specified material is temporarily unavailable. Engineering proposes an technically suitable alternative before manufacture begins and requests approval to use it for a defined quantity or period.
The simplest distinction is therefore:

Concession = retrospective acceptance of a known nonconformity
Deviation = prospective approval to depart from a requirement

Organisational and contractual terminology can differ, so the governing definition must always be established.

30.3. Relationship with Nonconformity

A concession does not make the original product conforming. The product remains outside the original requirement; what changes is its **authorised disposition**. This distinction is important. A concession should therefore not be used to:

- erase a nonconformance;
- alter inspection results;
- retrospectively change the specification;
- make performance data appear conforming;
- avoid investigation or corrective action;
- conceal poor process capability.

The original requirement and actual condition should remain visible and traceable.
Where the requirement itself is permanently inappropriate, the correct response may be to formally change the drawing, specification, design or other controlled requirement rather than repeatedly raising concessions.

30.4. Applicable Standards and Requirements

Requirements for controlling nonconforming outputs and concessions appear across many quality management frameworks.

30.4.1. ISO 9001

Control of Nonconforming Outputs requires organisations to ensure that outputs that do not conform to requirements are identified and controlled to prevent unintended use or delivery.
Appropriate actions may include correction, segregation, containment, return, suspension of provision, informing the customer, or obtaining **authorisation for acceptance under concession**.

The organisation is also required to retain documented information describing the nonconformity, actions taken, concessions obtained and the authority deciding the action.

30.4.2. IA9100

IA9100 incorporates the ISO 9001 requirements while providing additional controls relevant to aviation, space and defence. Customer or design authority approval may be required before accepting nonconforming product under concession, particularly where the nonconformity departs from contractual requirements.
Organisations should also consider whether the nonconformity affects other products, processes or previously delivered product.

30.4.3. AQAP

Where NATO quality assurance requirements apply, relevant **AQAP contractual requirements** should also be considered. Contracts may establish requirements concerning nonconforming product, concessions, customer notification and Government Quality Assurance Representative involvement.

30.4.4. Customer and Contractual Requirements

Customer requirements can be more restrictive than the underlying management system standard. Contracts, drawings, specifications, supplier quality requirements and purchase orders may define:

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- who can raise a concession;
- who can approve it;
- required information;
- submission format;
- customer approval requirements;
- restrictions on shipment;
- identification requirements;
- notification requirements;
- permitted quantities;
- validity periods.

The contractual requirement should therefore always be checked before assuming internal approval is sufficient.

30.5. The Concession or Deviation Request

A request should provide enough information for the approving authority to make an **informed technical and risk-based decision**. A good request should answer:

- **What is required?**
- **What is different?**
- **How much is it different by?**
- **Why has it happened or why is the deviation needed?**
- **What product is affected?**
- **How much product is affected?**
- **What is the technical impact?**
- **What are the risks?**
- **What containment or corrective actions are being taken?**
- **What exactly is being requested?**

If these questions cannot be answered, the request may not contain sufficient information for responsible approval.

30.5.1. Minimum Information

Depending upon the product and industry, a concession or deviation request should typically identify:

- unique request/reference number;
- organisation and supplier;
- customer where applicable;
- part number;
- part description;
- drawing or specification number;
- applicable revision;
- purchase order or contract;
- serial, batch or lot numbers;
- quantity affected;
- requirement;
- actual condition or proposed departure;
- magnitude of deviation;
- location of the affected characteristic;
- inspection or test evidence;
- reason for the request;
- technical justification;
- risk assessment;
- effect on fit, form and function;
- effect on safety and reliability;
- effect on interchangeability;

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- effect on maintainability;
- effect on downstream manufacture or assembly;
- effect on configuration;
- containment action;
- corrective action reference where appropriate;
- proposed disposition;
- requested validity period or quantity;
- supporting photographs, drawings or reports;
- required approvals.

Only information relevant to the particular request should be demanded, but enough information must exist to support the decision.

30.5.2. Missing Information Is a Control Weakness

A recurring weakness in concession management is the submission of requests containing **insufficient technical information**. Examples include:

- no drawing revision;
- no identification of the actual requirement;
- stating *"out of tolerance"* without giving the measured value;
- no affected quantity;
- unknown serial or batch numbers;
- no photograph where visual evidence would help;
- no technical justification;
- no risk assessment;
- no consideration of downstream impact;
- no explanation of how the condition occurred;
- no proposed disposition;
- no indication whether additional product may be affected.

This is not simply poor paperwork. **Missing information weakens the technical decision because the approver may be accepting a risk that has not been adequately defined.**

Where information necessary to determine acceptability is missing, the request should normally be **returned for clarification rather than approved on assumption**.

A concession process that routinely accepts incomplete requests can normalise weak decision-making and transfer unidentified risk downstream.

30.5.3. State the Requirement and the Actual Condition

One of the most important elements is a clear comparison between **what should have happened and what actually happened**.

- Poor: **"Dimension out of tolerance."**
- Better: **Requirement:** Ø20.00 ±0.10 mm
- **Actual:** Ø20.13 mm
- **Deviation:** 0.03 mm above upper specification limit
- **Quantity affected:** 3 of 24 components
- **Serial numbers:** 1042, 1047, 1051

This allows the reviewer to understand the magnitude and extent of the condition immediately.
Where several characteristics are affected, each should be clearly identified rather than hidden within a general statement.

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30.5.4. Technical Assessment

Approval should be based on objective technical assessment rather than commercial pressure or convenience. Depending upon the condition, the assessment may consider:

- fit;
- form;
- function;
- safety;
- structural integrity;
- performance;
- reliability;
- durability;
- interchangeability;
- maintainability;
- appearance;
- corrosion protection;
- downstream processing;
- assembly;
- inspection accessibility;
- interface requirements;
- configuration;
- statutory or regulatory requirements.

Specialists may need to contribute where the departure affects areas such as materials, stress, design, manufacturing engineering, special processes, safety or reliability. The statement **“no impact to fit, form or function”** should be a conclusion supported by technical reasoning—not a standard phrase inserted into every request.

30.5.5. Risk Assessment

The level of assessment should be proportionate to the potential consequence of the departure. Consider:

- **Severity – What could happen if the departure causes a failure?**
- **Extent – How many products or configurations are affected?**
- **Detectability – Could associated problems remain undetected?**
- **Downstream impact – Could the condition create problems during assembly, test or service?**
- **Uncertainty – How confident are we that the condition is fully understood?**

Greater uncertainty should generally result in greater caution, not easier acceptance. Where safety, regulatory, critical or key characteristics are involved, additional authority or customer approval may be required.

30.5.6. Approval Authority

Concessions and deviations should only be approved by personnel with appropriate **authority and technical competence**. Depending upon the requirement, this may include:

- Design Engineering;
- Manufacturing Engineering;
- Quality;
- Materials Engineering;
- Safety or Reliability;
- Configuration Management;
- customer representatives;
- Design Authority;
- regulatory authorities;
- Government Quality Assurance representatives.

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A Quality function should not automatically be assumed to have authority to accept a departure from an engineering design requirement. **The authority to identify a nonconformity is not necessarily the authority to accept its technical consequences.** Approval routes should therefore be clearly defined.

30.6. Supplier Concessions

Supplier concession requests require particular discipline because the purchasing organisation must understand the condition before allowing nonconforming product into its own production system. Suppliers should not ship affected product until required approval has been obtained unless explicitly authorised by contract. A good supplier concession process should establish:

Supplier identification → Technical information → Supplier investigation → Purchasing organisation review → Appropriate technical approval → Customer approval where required → Controlled shipment

Approved product should remain traceable to the applicable concession. The concession number may need to appear on:

- delivery documentation;
- Certificate of Conformity;
- product identification;
- packaging;
- inspection records;
- receiving records.

Requirements should be defined contractually rather than assumed.

30.7. Temporary and Limited Approval

Concessions and deviations should normally have clearly defined boundaries. These may include:

- specific serial numbers;
- defined batch or lot;
- specified quantity;
- particular purchase order;
- defined manufacturing order;
- expiry date;
- defined time period;
- particular configuration.

An approval should not unintentionally become permanent. For example: **Approved for 25 units under Purchase Order XXXX only** is significantly stronger than **Approved until further notice.**

Where the departure is expected to continue, a permanent engineering or process change should normally be considered.

30.8. Identification and Traceability

Product accepted under concession should remain identifiable where required. The organisation should be capable of determining:

- which product was affected;
- which concession authorised acceptance;
- what requirement was not achieved;
- who approved the disposition;
- what limitations applied;
- where the affected product was delivered.

This becomes particularly important if later investigation determines that the original assessment was incorrect or additional risk is identified.

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30.9. Concession versus Repair and Rework

These terms should not be confused.

- **Rework** returns the product to full conformity with the original requirement.
- **Repair** restores the product to an acceptable condition but may not return it completely to the original requirement and may therefore require specific technical approval.
- **Concession** authorises acceptance or release of a known nonconforming condition.

For example:

Nonconformity → Rework → Fully conforming product

may not require a concession if the approved rework completely restores conformity and applicable requirements permit it. By contrast:

Nonconformity → Use-as-is

normally requires appropriate concession approval.

30.10. Concessions Should Not Become Normal Production

Concession data is a valuable indicator of process and management system health. Repeated concessions for the same requirement may indicate:

- incapable processes;
- inappropriate tolerances;
- weak process control;
- inadequate tooling;
- supplier capability problems;
- poor design for manufacture;
- inadequate contract review;
- ineffective corrective action;
- outdated requirements.

A concession may resolve the immediate product disposition, but it does not necessarily address the underlying cause. Repeated concessions should therefore trigger review and, where appropriate, corrective action or formal engineering change.

If the same departure is repeatedly acceptable, either the process needs fixing or the requirement may need formally reviewing. Repeated concessions should not become the unofficial specification.

30.11. Monitoring Concession Performance

Organisations should consider analysing concession and deviation data rather than treating requests as isolated events. Useful measures may include:

- number of concessions raised;
- concessions by supplier;
- concessions by product;
- concessions by requirement;
- repeat concessions;
- ageing of open requests;
- approval and rejection rates;
- average approval lead time;
- concessions by failure mode;
- concessions associated with customer escapes;
- concessions resulting in corrective action.

Pareto analysis can help identify recurring problems. Trends should be used to drive process improvement rather than simply produce management statistics.

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30.12. Urgency and Commercial Pressure

Production urgency should not reduce the technical integrity of the approval process. Statements such as:

- *"Production is waiting"*;
- *"We need to ship today"*;
- *"The customer needs the parts urgently"*;
- *"Scrapping the parts would be expensive"*

may explain the commercial context but do not provide technical justification for acceptance. The correct question remains: **Is there sufficient objective evidence and appropriate authority to conclude that the proposed departure is acceptable?**

Commercial impact may inform a decision between technically acceptable options, but it should not redefine technical acceptability.

30.13. Common Weaknesses

Common concession and deviation management weaknesses include:

- incomplete requests;
- incorrect or missing drawing revisions;
- vague descriptions;
- missing actual measurements;
- undefined affected quantities;
- inadequate traceability;
- unsupported *"no impact"* statements;
- weak risk assessment;
- approval by personnel without appropriate authority;
- shipment before approval;
- concessions remaining open indefinitely;
- repeated concessions without corrective action;
- failure to notify the customer where required;
- failure to identify affected product;
- using concessions to avoid formal engineering change;
- treating concession approval as evidence that the product actually conforms.

These should be viewed as **quality system weaknesses**, not simply documentation errors.

30.14. Best-Practice Workflow

A robust concession or deviation process can follow:

Identify → Contain → Define Requirement → Define Actual/Proposed Condition → Establish Extent → Assess Technical Impact → Assess Risk → Investigate Cause where appropriate → Obtain Required Approvals → Identify & Control Product → Release/Implement → Record → Trend → Correct Recurrence

For deviations, approval should occur **before** implementation. For concessions, affected nonconforming product should remain appropriately controlled until the disposition has been authorised.

Electronic workflow systems can strengthen control through mandatory fields, approval routing, revision control, timestamps, traceability and automatic escalation of ageing requests. However, a digital system cannot compensate for poor technical information.

30.15. What Good Looks Like

A well-managed concession or deviation should allow an independent reviewer to quickly determine:

- **What was required?**
- **What is different?**
- **Why is it different?**
- **Which product is affected?**

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- **How significant is the departure?**
- **What technical assessment was performed?**
- **What risks were considered?**
- **Who had authority to approve it?**
- **What restrictions apply?**
- **What prevents unintended use?**
- **What is being done to prevent recurrence where necessary?**

If the record cannot answer these questions, the quality of the decision may be difficult to demonstrate.

30.16. Key Takeaway

A concession or deviation is a **controlled and technically justified exception to a defined requirement**, not an administrative route around that requirement. The distinction is important:

Deviation → permission requested before departure

Concession → permission to accept a departure that has already occurred

Effective control requires complete information, objective technical assessment, appropriate risk evaluation, competent approval, defined limitations and full traceability. **Missing information is itself a weakness.** An approver cannot responsibly assess a condition that has not been adequately defined, and assumptions should never replace objective evidence.

Finally, concession data should be treated as a valuable source of improvement information. An isolated concession may represent a legitimate exception; **repeated concessions can indicate a process, supplier, design or requirement that needs more fundamental attention.**

31. Quality Audits & Checklists

31.1. Introduction

Quality auditing is a systematic, independent and evidence-based method of determining whether activities, processes and management systems **conform to defined requirements and are effectively implemented and maintained**.

An effective audit should do more than confirm that procedures and records exist. It should establish whether the process is being followed, whether controls are effective, whether requirements are being achieved and whether weaknesses or opportunities for improvement exist.

Internal auditing is a specific requirement of **ISO 9001 and AS9100 Clause 9.2**. ISO guidance emphasises that audit programmes should consider process importance, organisational change and previous audit results rather than applying the same frequency indiscriminately to every process.

Quality principle: An audit should establish not only **“Are we doing what we said we would do?”**, but also **“Is what we are doing effective?”**

This section provides an overview only. For comprehensive guidance covering audit planning, preparation, interviewing, sampling, objective evidence, findings, reporting, auditor techniques and verification activities, refer to the Special Processes Institute publication: **SPI-10 – Quality Auditing & Verification Guidebook**

31.2. Purpose of a Quality Audit

Audits provide independent information about the health and effectiveness of the management system. They can be used to determine:

- conformity with applicable standards;
- conformity with organisational procedures;
- compliance with customer and contractual requirements;
- whether processes are implemented as planned;

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- whether controls are effective;
- whether previous corrective actions remain effective;
- whether risks are appropriately controlled;
- whether improvement opportunities exist.

An audit should therefore evaluate both **conformity and effectiveness**. A process can conform to a documented procedure yet still perform poorly. Conversely, an apparently successful process may rely on informal practices that are not adequately controlled.

31.3. Types of Audit

Quality audits are commonly classified as:

31.3.1. First-party audit – Internal audit

Performed by or on behalf of an organisation on its own management system and processes.

31.3.2. Second-party audit – Supplier or customer audit

Performed by a customer, purchasing organisation or representative on another organisation within the supply chain.

31.3.3. Third-party audit – Independent audit

Performed by an independent organisation, commonly for certification or regulatory purposes. Audits may also focus on a particular:

- management system;
- process;
- product;
- project;
- supplier;
- contract;
- manufacturing activity;
- special process;
- regulatory or customer requirement.

The audit type should be selected according to the assurance objective.

31.4. ISO 9001 Internal Audit Requirements

ISO 9001 requires internal audits to be conducted at **planned intervals** to provide information on whether the QMS conforms to:

- the organisation's own QMS requirements;
- the requirements of ISO 9001;

and whether the QMS is **effectively implemented and maintained**.

The organisation must establish and maintain an audit programme covering matters such as frequency, methods, responsibilities, planning and reporting. The programme must take account of:

Importance of processes + Changes affecting the organisation + Previous audit results

Each audit must also have defined criteria and scope, use auditors selected to preserve objectivity and impartiality, report results to relevant management, address necessary correction/corrective action without undue delay and retain appropriate documented evidence.

ISO 9001 does **not** simply require every department to be audited once every year. The audit programme should reflect the organisation's processes and their relative importance and performance.

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31.5. What Needs to Be Audited?

A common misunderstanding is that internal auditing means working through the clauses of ISO 9001 once a year. A mature audit programme should instead provide appropriate coverage of the **QMS and the processes within its scope**, including applicable organisational, standard, customer, statutory and regulatory requirements. For IA9100 organisations, IAQG guidance specifically identifies the organisation's own requirements, customer requirements, statutory/regulatory requirements and applicable external standards as relevant considerations.

Depending upon the organisation, the programme may therefore include:

Area / Process	Examples of Audit Focus
QMS & Leadership	QMS effectiveness, policy, objectives, responsibilities, process management
Risk & Planning	Risks and opportunities, changes, planning, objectives
Document & Configuration Control	Current information, revisions, approvals, configuration status
Competence & Resources	Training, competence, infrastructure, work environment
Contract / Order Review	Requirement identification, feasibility, changes, flowdown
Design & Development	Inputs, outputs, reviews, verification, validation and change
Purchasing / Supplier Management	Supplier approval, performance, requirements and flowdown
Receiving / Incoming Verification	Product verification, certification, inspection and status
Production / Service Provision	Process controls, instructions, equipment, traceability
Special / Validated Processes	Qualification, parameters, personnel, equipment and records
Inspection & Test	Acceptance criteria, inspection, test and release
Monitoring & Measuring Resources	Calibration, suitability, traceability and measurement control
Nonconforming Outputs	Identification, segregation, disposition, concessions and control
Corrective Action	Root cause, actions, implementation and effectiveness
Customer Feedback	Complaints, satisfaction, escapes and trends
Performance Evaluation	KPIs, process performance, analysis and management review
Internal Audit	Effectiveness of the audit programme itself

Not every subject requires a separate audit. Several processes can be examined during a single end-to-end or process-based audit.

31.5.1. Additional IA9100 Considerations

IA9100 includes the ISO 9001 requirements but extends them for aviation, space and defence.
An aerospace internal audit programme should therefore ensure appropriate coverage of applicable IA9100-specific and sector-critical controls, such as:

- operational risk management;
- configuration management;
- product safety;
- counterfeit-part prevention;
- supplier and external-provider controls;
- production process verification;
- special requirements;
- critical items;
- key characteristics;
- identification and traceability;
- preservation;
- nonconforming product;
- customer and regulatory requirements.

IAQG guidance also highlights the importance of auditing applicable **customer, statutory and regulatory requirements**, not merely the text of AS9100 itself. The audit programme should therefore reflect **the actual aerospace QMS and its applicable requirements**, rather than becoming an annual clause-checking exercise.

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31.6. Risk-Based Audit Programming

Not every process needs to be audited at the same frequency or depth. Higher priority may reasonably be given to processes associated with:

- high product or customer risk;
- safety or critical characteristics;
- poor process performance;
- customer escapes;
- recurring nonconformities;
- previous audit findings;
- significant organisational change;
- new equipment or processes;
- new suppliers;
- increased customer complaints;
- weak corrective action;
- major changes in personnel or responsibilities.

Conversely, a mature, stable and consistently effective low-risk process may justify a lower audit frequency. ISO auditing guidance explicitly identifies higher-risk processes and those with histories of problems or nonconformities as candidates for greater audit priority. A useful principle is:

Risk + Importance + Performance + Change + Previous Results → Audit Priority

This makes the audit programme a dynamic assurance tool rather than a fixed calendar.

31.7. Audit Scope, Criteria and Objectives

Before an audit begins, its boundaries should be clear.

- **Scope** defines what is included, for example a process, department, site, product line or supplier.
- **Criteria** define what the evidence will be compared against, such as:
  - ISO 9001;
  - AS9100;
  - procedures;
  - specifications;
  - customer requirements;
  - contractual requirements;
  - regulatory requirements;
  - process instructions.

The **objective** explains what the audit is intended to establish. For example: *Determine whether the supplier approval and monitoring process is effectively implemented and provides adequate control of externally provided products and services.* Clear scope and criteria prevent audits from becoming unfocused investigations.

31.8. Objective Evidence

Audit conclusions should be based on **objective evidence**, not assumptions or personal opinion. Evidence may include:

- records;
- documents;
- system data;
- observations;
- interviews;
- inspection results;
- product examination;
- performance measures;
- traceability records;
- physical conditions.

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Good auditing frequently involves following evidence across several sources. For example:

Procedure → Interview → Actual Practice → Record → Product → Result

Agreement between these sources provides confidence that the process is operating as intended. Differences may indicate a weakness requiring further investigation.

31.9. Audit Sampling

Auditors normally examine a **sample** because reviewing every transaction, record or product is rarely practical. Samples should be selected intelligently and may include:

- recent records;
- older records;
- different personnel;
- different shifts;
- different products;
- different suppliers;
- high-risk activities;
- problem areas;
- recently changed processes.

Auditors should remember that sampling introduces uncertainty. Finding one compliant record does not demonstrate that every record is compliant, and finding one failure may justify expanding the sample to understand whether the problem is isolated or systemic.

31.10. Checklists

Audit checklists can provide valuable structure and consistency. A good checklist can:

- identify applicable requirements;
- remind the auditor of important subjects;
- provide logical audit questions;
- support evidence recording;
- improve consistency between auditors;
- assist less-experienced auditors;
- prevent important requirements being overlooked.

However: **A checklist should guide the audit, not conduct the audit.**
An auditor who simply reads questions and records **Yes/No** answers may miss significant weaknesses occurring between the questions. The auditor should be prepared to follow evidence wherever it leads.

31.10.1. Effective Audit Questions

Open questions generally produce better evidence than questions that encourage a simple yes/no response. Rather than: **“Do you calibrate this equipment?”** consider **“Show me how you know this equipment is suitable and currently approved for use.”**
Instead of: **“Are operators trained?”** consider **“How do you determine who is competent to perform this operation, and can you show me the evidence for this operator?”** Useful audit prompts include:

- **Show me…**
- **Explain how…**
- **What happens when…?**
- **How do you know…?**
- **Who is responsible for…?**
- **What evidence demonstrates…?**

These encourage demonstration of the actual process rather than confirmation of the expected answer.

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31.11. Audit Findings

Audit findings should be supported by objective evidence and clearly linked to applicable criteria. Typical outcomes may include:

- **Conformity** – evidence demonstrates the requirement is satisfied.
- **Nonconformity** – objective evidence demonstrates that a requirement has not been fulfilled.
- **Opportunity for Improvement (OFI)** – an area where improvement may be beneficial without incorrectly presenting it as a mandatory requirement.

Terminology can vary between organisations and certification schemes. A strong nonconformity normally identifies:

Requirement → Objective Evidence → Identified Gap

It should describe the problem clearly enough that someone who was not present during the audit can understand why the requirement was not satisfied.

31.12. Auditor Objectivity and Competence

Auditors should be sufficiently competent to understand:

- auditing principles;
- applicable requirements;
- relevant processes;
- evidence gathering;
- sampling;
- interviewing;
- reporting;
- identification of nonconformity.

ISO 9001 also requires auditor selection and audit conduct to preserve **objectivity and impartiality**.
The organisation should therefore avoid arrangements where individuals are effectively assessing their own work.

Technical specialists may support audits where specialist knowledge is necessary, but technical expertise alone does not automatically make someone an effective auditor.

31.13. Audit Follow-Up

Finding a problem is only part of the audit process. A complete audit cycle should include:

Plan → Audit → Report → Correct → Investigate Cause → Corrective Action where required → Verify Effectiveness → Close

Audit actions should not remain open indefinitely. Repeated findings are particularly important because they may indicate that previous corrective action addressed the immediate symptom without effectively eliminating the underlying cause.

Audit results and trends should also provide useful inputs into management review and wider improvement activities.

31.14. Common Audit Weaknesses

Typical weaknesses include:

- auditing departments instead of processes;
- auditing only against ISO/AS clauses;
- identical audit frequency regardless of risk;
- repetitive generic checklists;
- excessive yes/no questions;
- accepting statements without evidence;
- inadequate sampling;
- auditors assessing their own work;

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- failing to examine process effectiveness;
- vague findings without requirement or evidence;
- weak follow-up;
- overdue corrective actions;
- repeated findings;
- audit schedules that do not respond to performance or organisational change.

An audit programme that repeatedly reports **"no findings"** should not automatically be interpreted as evidence of an excellent QMS. It may be appropriate to review whether audits are sufficiently challenging, risk-focused and effective.

31.15. What Good Auditing Looks Like

An effective internal audit programme should be able to demonstrate:

- **What needs auditing?**
- **Why is it being audited?**
- **How was the frequency determined?**
- **What requirements apply?**
- **Is the auditor competent and impartial?**
- **What evidence was sampled?**
- **Is the process conforming?**
- **Is the process effective?**
- **What weaknesses were identified?**
- **Were actions completed and effective?**

Most importantly, audit results should provide management with useful information about the **actual condition of the management system**.

31.16. Key Takeaway

Quality auditing is not simply a compliance exercise or an annual requirement to maintain certification. It is an important **management and assurance tool** for independently evaluating whether processes conform, controls operate as intended and the QMS remains effective.

ISO 9001 and IA9100 require internal auditing at planned intervals, but an effective programme should be driven by:

Process Importance + Risk + Performance + Change + Previous Audit Results

Checklists provide valuable structure but should never restrict professional curiosity or prevent an auditor from following objective evidence.

For detailed practical guidance on **audit planning, auditor preparation, interviewing, process auditing, sampling, objective evidence, checklists, findings, reporting, corrective-action follow-up and verification techniques**, refer to the Special Processes Institute publication: **SPI-10 – Quality Auditing & Verification Guidebook**

32. Nonconformance Management & Material Review

32.1. Introduction

Nonconformance management is the controlled process used to identify, contain, evaluate, disposition and record products or outputs that **do not fulfil specified requirements**.

The immediate objective is to prevent unintended use, installation or delivery. The wider objective is to understand the extent and significance of the condition, determine an authorised disposition, maintain traceability and use the resulting information to improve the quality management system. Nonconforming product may arise at any point:

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Effective control must therefore extend beyond the traditional concept of a physical *scrap bin* or quarantine area.

Quality principle: Once conformity is uncertain, the product should be treated as nonconforming until its status has been established by appropriate authority and objective evidence.

32.2. What Is a Nonconformance?

A **nonconformance** or **nonconformity** is the non-fulfilment of a requirement. The requirement may originate from:

- drawings;
- specifications;
- contracts;
- purchase orders;
- standards;
- procedures;
- work instructions;
- inspection or test requirements;
- customer requirements;
- statutory or regulatory requirements.

Examples include:

- dimension outside tolerance;
- incorrect material;
- failed functional test;
- damaged product;
- incorrect assembly;
- missing operation;
- expired material;
- incorrect configuration;
- inadequate certification;
- unauthorised process change;
- failed special process;
- missing traceability;
- incorrect identification.

A product does not need to be physically defective to be nonconforming. **Missing evidence of conformity can itself prevent acceptance.** For example, a component may appear satisfactory but cannot automatically be accepted if required material certification, process records or traceability are missing.

32.3. Nonconforming Product versus Defective Product

The terms are related but should not automatically be treated as identical. A **nonconforming product** fails to meet a specified requirement. A **defect** generally relates to failure associated with an intended or specified use and can therefore carry additional implications regarding product function or safety.

A dimensional departure may be nonconforming without necessarily making the product functionally defective. However, only an appropriately authorised technical evaluation can determine whether the departure is acceptable.

Inspection identifies the departure; appropriate technical authority determines its significance and disposition.

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32.4. Applicable Quality Management Requirements

ISO 9001 – Control of Nonconforming Outputs requires organisations to identify and control outputs that do not conform to requirements in order to prevent unintended use or delivery. Depending upon the circumstances, actions can include:

- correction;
- segregation, containment, return or suspension;
- informing the customer;
- obtaining authorisation for acceptance under concession.

Conformity must be verified after correction where applicable.

Documented information should identify the nonconformity, actions taken, concessions obtained where relevant, and the authority deciding the action.

IA9100 incorporates these requirements while adding controls appropriate to aviation, space and defence, including stronger consideration of containment, customer notification, responsibility and authority, disposition and the potential effect on other products or previously delivered product.

Applicable contractual, customer, statutory and regulatory requirements should always be considered in addition to the management system standard.

32.5. The Nonconformance Lifecycle

A robust process can be represented as:

Detect → Identify → Contain → Record → Establish Extent → Evaluate → Disposition → Implement → Verify → Release → Analyse

Each stage has a different purpose. A weakness at any point can allow nonconforming product to unintentionally progress through production or reach the customer.

32.5.1. Identification

When a nonconformance is discovered, the affected product should be clearly identified. Identification may include:

- physical tag or label;
- electronic status;
- system hold;
- serial number;
- batch or lot identification;
- inspection status;
- nonconformance reference;
- physical segregation.

The status should be obvious enough that personnel cannot reasonably mistake the product for acceptable material. A simple principle is:

Unknown status ≠ Accepted status

Where conformity cannot be established, the product should not continue through normal production or release without appropriate control.

32.5.2. Immediate Containment

Containment protects the organisation and customer while the problem is being understood.
The first question should not simply be: **“What do we do with this item?”** It should also be **“What else could be affected?”** Containment may therefore include:

- stopping production;
- placing material on hold;

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- isolating affected stock;
- checking work-in-progress;
- checking finished goods;
- checking other batches or serial numbers;
- checking stock at other locations;
- suspending shipment;
- notifying suppliers;
- reviewing previously delivered product;
- informing the customer where required.

Containment is an immediate protective action. It should not be confused with permanent corrective action.

32.6. Quarantine

Quarantine is a controlled method of preventing nonconforming or suspect material from being unintentionally used or released while its status is unresolved.
Traditionally this involves a secure physical area, but quarantine can also be achieved through effective electronic or administrative controls.
Examples include:

- locked quarantine areas;
- controlled cages;
- designated hold locations;
- ERP/MRP stock blocks;
- electronic quality holds;
- controlled inspection status;
- restricted-access storage.

The effectiveness of quarantine depends on **control**, not simply the colour of a floor marking. A quarantine area should prevent unauthorised removal or use and maintain appropriate product protection, identification and traceability.

32.6.1. Quarantine Is Not a Storage Solution

A common weakness is allowing quarantine to become long-term storage for unresolved problems. Excessive quarantine ageing can create:

- production shortages;
- inventory inaccuracies;
- financial exposure;
- deterioration;
- shelf-life expiry;
- lost traceability;
- damaged material;
- repeated handling;
- hidden quality problems.

Organisations should therefore monitor the age and value of quarantined material and establish appropriate escalation. Useful measures can include:

Number of open items | Value | Age | Oldest item | Responsible owner | Awaiting decision from

Quarantine should be a **temporary controlled state**, not the final destination of a nonconformance.

32.7. Recording the Nonconformance

A nonconformance record should contain sufficient information for another competent person to understand **what requirement was not achieved and what was actually found**. Typical information includes:

- unique reference;
- part number and description;

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- drawing/specification and revision;
- serial, batch or lot number;
- quantity affected;
- supplier where applicable;
- manufacturing order or purchase order;
- requirement;
- actual condition;
- inspection or test evidence;
- date detected;
- process/location detected;
- person reporting;
- photographs where useful;
- immediate containment;
- related documentation.

The record should be factual and objective.
Poor: **“Part incorrect.”** Better:

- **Requirement:** Ø12.00 ±0.05 mm
- **Actual:** Ø12.09 mm
- **Quantity inspected:** 20
- **Quantity nonconforming:** 4
- **Affected serial numbers:** 104–107

The second description allows meaningful evaluation and disposition.

32.7.1. Missing Information Is a Weakness

Incomplete nonconformance records weaken the entire material review process.
Typical missing information includes:

- unidentified requirement;
- missing drawing revision;
- no actual measurement;
- unknown affected quantity;
- missing serial numbers;
- no batch traceability;
- no evidence;
- unclear location of the defect;
- inadequate containment information.

The reviewer should not have to reconstruct the problem from assumptions. **A disposition can only be as reliable as the information on which the decision is based.**

Where necessary information is missing, the record should be clarified before technical disposition.

32.8. Establishing the Extent of Condition

The visibly nonconforming item may represent only part of the problem. The organisation should consider whether the same condition could affect:

- other items in the batch;
- previous batches;
- work-in-progress;
- finished stock;
- products at another site;
- other part numbers using the same process;
- supplier stock;
- previously delivered product.

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This is commonly referred to as determining the **extent of condition**. For example, if one component is found manufactured using an incorrect drawing revision, the issue is not limited to that component. The organisation should determine **when the incorrect revision entered use and everything manufactured during that period**.

32.9. Material Review

Material review is the technical evaluation of nonconforming product to determine its appropriate disposition. The review should consider relevant factors such as:

- requirement;
- magnitude of departure;
- product function;
- safety;
- reliability;
- fit and assembly;
- interchangeability;
- downstream processing;
- maintainability;
- configuration;
- customer requirements;
- regulatory requirements;
- previous similar conditions.

The level of review should be proportionate to the significance and complexity of the nonconformance. Simple conditions may be addressed through predefined authorised dispositions, while technically significant conditions may require formal **Material Review Board (MRB)** evaluation.

32.9.1. Material Review Board – MRB

A **Material Review Board (MRB)** is a formally authorised function used to evaluate and determine the disposition of nonconforming material where the decision requires appropriate technical authority. Despite the name, an MRB does not necessarily need to be a physical meeting involving a fixed group of people. It may operate through an electronic workflow provided appropriate authorities review and approve the disposition. Depending upon the organisation and issue, MRB involvement may include:

- Quality;
- Design Engineering;
- Manufacturing Engineering;
- Materials Engineering;
- Stress Engineering;
- Safety;
- Reliability;
- Configuration Management;
- Supplier Quality;
- customer or Design Authority.

The composition should reflect the technical nature and risk of the decision.

32.9.2. MRB Authority

MRB authority should be formally defined. Not every function has authority to approve every disposition. For example:

- Quality may verify and document the nonconformance;
- Manufacturing Engineering may define an approved rework method;
- Design Engineering may assess technical acceptability;
- the Design Authority may approve certain repairs or use-as-is conditions;
- the customer may retain final concession authority.

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A fundamental principle is: **The person identifying the nonconformance does not automatically have authority to accept its consequences.**

Customer and contractual requirements should always be checked before assuming internal MRB authority is sufficient.

32.9.3. Typical Dispositions

Common dispositions include:

32.9.3.1. Rework

Action that returns the product to **full conformity with the original requirement**. After rework, the affected characteristics should be appropriately reverified.

32.9.3.2. Repair

Action that makes the product acceptable for intended use but does **not necessarily restore full conformity to the original requirement**. Repair may therefore require engineering, Design Authority or customer approval.

32.9.3.3. Use-As-Is

Acceptance of the product in its existing nonconforming condition. This normally requires appropriate technical justification and, where applicable, concession approval.

32.9.3.4. Scrap

Permanent removal of the product from its intended use. Scrapped product should be controlled to prevent accidental reuse or re-entry into the supply chain.

32.9.3.5. Return to Supplier

Nonconforming supplied product may be returned for replacement, rework, investigation or other agreed action.

The permitted dispositions and approval authorities should be defined by the organisation and applicable customer requirements.

32.9.4. Rework Instructions

Rework should be controlled. Instructions should define:

- what work is required;
- authorised method;
- equipment and tooling;
- applicable parameters;
- acceptance criteria;
- inspection or test requirements;
- necessary approvals.

Informal instructions such as: **“Clean it up and try again”** are inappropriate where the rework could influence product conformity. Following rework, the organisation should verify that the product now conforms to applicable requirements.

32.9.5. Repair

Repair requires particular care because the product may remain outside the original design definition while being considered acceptable for its intended use. A repair should therefore be based upon an appropriately authorised repair instruction or scheme. Consideration may include:

- structural integrity;
- function;
- fatigue life;
- material properties;
- corrosion protection;
- interfaces;
- interchangeability;

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- maintainability;
- future inspection;
- configuration status.

Where required, customer or Design Authority approval should be obtained before the repair is performed.

32.9.6. Use-As-Is and Concession

A **use-as-is** disposition accepts the product without physically correcting the identified departure. This should be based on appropriate technical evaluation demonstrating that the condition is acceptable for its intended application.

Where the product departs from contractual or customer requirements, a formal **concession** may be required. Concession and deviation management is covered separately within this Quality Book and should be referenced where further detail is required.

A concession does not make the product conforming—it provides authorised acceptance of the defined nonconforming condition.

32.10. Scrap Control

Scrap control is sometimes underestimated. Product designated as scrap should be controlled so that it cannot:

- accidentally return to production;
- be confused with usable stock;
- be shipped;
- be sold or transferred inappropriately;
- re-enter the supply chain as counterfeit or misrepresented product.

Depending upon product sensitivity, controls may include:

- physical destruction;
- mutilation;
- permanent marking;
- controlled disposal;
- witnessed destruction;
- disposal records.

This is particularly important for aerospace, defence, safety-critical and proprietary products.

32.11. Supplier Nonconformances

Externally supplied nonconforming product should be subject to the same disciplined control. Depending upon the issue, actions may include:

- quarantine;
- supplier notification;
- replacement;
- return;
- supplier rework;
- supplier concession request;
- containment at supplier premises;
- increased inspection;
- corrective action request;
- supplier performance impact.

The organisation should avoid automatically correcting supplier defects internally without recording them. Doing so may hide poor supplier performance and prevent the supplier from understanding and correcting its process. Supplier nonconformance data should therefore contribute to supplier performance monitoring and assurance activities.

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32.12. Previously Delivered Product

One of the most important questions following discovery of a significant nonconformance is: **"Could affected product already have been delivered?"** Where this is possible, the organisation should determine:

- affected serial or batch range;
- customers or locations;
- potential safety or functional impact;
- notification requirements;
- containment actions;
- recall or recovery requirements;
- regulatory implications.

IA9100 environments require particular attention to the effect of nonconformities on other processes or products and to timely customer notification where delivered product may be affected. Speed, traceability and clear escalation are critical.

32.13. Release from Quarantine

Nonconforming product should only leave quarantine or controlled hold when its disposition has been appropriately authorised. Before release, verify that:

- required approvals are complete;
- rework or repair has been performed where applicable;
- required inspection/test is complete;
- concessions are approved where required;
- records are updated;
- product identification is correct;
- traceability is maintained;
- ERP/MRP status is updated;
- any restrictions are communicated.

Physical release and electronic release should agree. A product physically removed from quarantine while remaining blocked electronically or electronically released while still technically unresolved, indicates weak control.

32.14. Ageing and Escalation

Open nonconformances should have clear ownership and expected resolution times. Ageing reports can identify items such as:

0–30 days | 31–60 days | 61–90 days | >90 days

The appropriate intervals will depend on the organisation. Escalation should focus not only on how long an item has been open but also its:

- product risk;
- financial value;
- production impact;
- customer impact;
- quantity;
- potential effect on delivered product.

An old low-value cosmetic issue and a newly discovered potential safety issue should not receive the same priority simply because of age.

32.15. Nonconformance Data as a Quality Indicator

Nonconformance records contain valuable information about process performance. Useful analysis may include:

- nonconformances by process;
- supplier;
- product;
- programme;

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- failure mode;
- defect type;
- cause;
- disposition;
- cost;
- age;
- customer impact;
- recurrence.

Tools such as Pareto analysis and trend charts can help identify where improvement effort should be concentrated. A mature organisation does not simply **close nonconformances**. It learns from them.

32.16. When Does a Nonconformance Require Corrective Action?

Not every individual nonconformance requires a full formal root cause investigation. The need should be based upon factors such as:

- severity;
- recurrence;
- customer impact;
- safety;
- regulatory significance;
- systemic nature;
- process performance;
- cost;
- risk of recurrence.

A simple isolated error may require correction and appropriate recording. A recurring, systemic, high-risk or customer-impacting failure may justify formal Root Cause and Corrective Action (RCCA), 8D or another structured problem-solving method.

Detailed 8D RCCA and problem-solving methods are covered in the **Special Processes Institute** **SPI-03 8D RCCA Problem Solving Guidebook**. Corrective action and preventive improvement management is covered in the next section of this publication.

32.17. Common Weaknesses

Typical weaknesses include:

- poorly identified nonconforming material;
- uncontrolled quarantine areas;
- excessive quarantine ageing;
- vague nonconformance descriptions;
- missing actual measurements;
- incomplete traceability;
- failure to establish extent of condition;
- inappropriate disposition authority;
- undocumented rework;
- repair without Design Authority approval;
- use-as-is without required concession;
- releasing product before approval;
- electronic and physical status disagreement;
- repeated defects without escalation;
- supplier defects corrected internally but never reported;
- failure to consider previously delivered product;
- poor scrap control;
- closing records before actions are actually complete.

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These are not simply administrative weaknesses. Each can create a route by which nonconforming product unintentionally progresses toward the customer.

32.18. What Good Looks Like

An effective nonconformance management system should allow the organisation to answer:

- **What requirement was not met?**
- **What was actually found?**
- **Which product is affected?**
- **Where is that product now?**
- **Could anything else be affected?**
- **Has affected material been contained?**
- **Who has authority to decide its disposition?**
- **What disposition was authorised?**
- **Has that disposition been correctly implemented and verified?**
- **Could affected product already have been delivered?**
- **Is the problem recurring?**
- **Does it require corrective action?**

If any of these questions cannot be answered, further investigation or control may be necessary.

32.19. Key Takeaway

Effective nonconformance management is much more than raising a quality record. It is a controlled lifecycle:

Identify → Contain → Record → Establish Extent → Evaluate → Disposition → Implement → Verify → Release → Learn

- **Quarantine** protects the organisation and customer while product status is unresolved.
- **Material Review and MRB** provide controlled technical evaluation and authorised disposition.
- **Rework, repair, use-as-is, return and scrap** have different meanings and should be applied using appropriate authority and controls.

Most importantly: **Nonconforming product must remain under positive control until an authorised and technically justified decision has been fully implemented.**

A strong system also looks beyond the individual item. It asks what else may be affected, whether product has already escaped, whether the problem is recurring and what the accumulated nonconformance data is telling the organisation about the effectiveness of its processes, suppliers and quality management system.

33. Corrective Action & Preventive Improvement Management

33.1. Introduction

Corrective action is the structured process used to **eliminate the cause of a nonconformity or undesirable condition so that it does not recur**. Preventive improvement goes further by using risk, trends, lessons learned and process knowledge to address weaknesses **before they become failures**. An effective quality management system should therefore operate at three levels:

Correction → Corrective Action → Preventive Improvement

- **Correction** deals with the immediate problem.
- **Corrective action** addresses why the problem occurred and prevents recurrence.
- **Preventive improvement** identifies and reduces potential weaknesses before they result in nonconformity.

Quality principle: Fixing the product resolves today's problem. Eliminating the cause helps prevent tomorrow's recurrence.

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Corrective action should not be regarded simply as completing a form or closing an audit finding. Its effectiveness is demonstrated by **sustained improvement in the process**.

33.2. Correction versus Corrective Action

The distinction is fundamental.

33.2.1. Correction

Action taken to eliminate a **detected nonconformity**. Examples include:

- reworking a component;
- replacing an incorrect document;
- recalibrating equipment;
- correcting a record;
- replacing defective material;
- retraining an operator on an immediate error.

Correction addresses: **"What must we do about the problem we have found?"**

33.2.2. Corrective Action

Action taken to eliminate the **cause of a nonconformity and prevent recurrence**. Corrective action addresses: **"Why did this happen, and what needs to change so that it does not happen again?"** For example:

- **Problem:** Incorrect component installed.
- **Correction:** Replace the incorrect component.
- **Corrective action:** Modify component identification, kitting and assembly controls so that incorrect selection is prevented.

Simply correcting the affected product does not demonstrate that corrective action has occurred.

33.2.3. What Happened to Preventive Action?

Earlier quality management systems often treated **preventive action** as a separate formal process. ISO 9001:2015 moved away from a standalone preventive-action clause and incorporated prevention throughout the QMS through **risk-based thinking**. The principle of preventive action has therefore not disappeared. Instead, organisations are expected to proactively consider:

- risks and opportunities;
- process performance;
- potential failures;
- trends;
- organisational changes;
- lessons learned;
- supplier performance;
- customer feedback;
- improvement opportunities.

Preventive improvement can therefore be considered the proactive counterpart to corrective action:

Corrective = Learn after something happened

Preventive = Act on evidence that something could happen

A mature organisation should do both.

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33.3. Applicable Quality Management Requirements

33.3.1. ISO 9001

ISO 9001 – Nonconformity and Corrective Action requires organisations to react to nonconformities and, where applicable:

- take action to control and correct them;
- deal with their consequences;
- evaluate the need for action to eliminate causes;
- review and analyse the nonconformity;
- determine causes;
- determine whether similar nonconformities exist or could potentially occur;
- implement necessary actions;
- review the effectiveness of corrective action;
- update risks and opportunities where necessary;
- make changes to the QMS where necessary.

Corrective action should be **appropriate to the effects of the nonconformity encountered**.

33.3.2. IA9100

AS9100 incorporates the ISO 9001 requirements while applying them within the aviation, space and defence environment. Organisations should additionally consider applicable customer, contractual, product-safety, regulatory and aerospace requirements when determining the extent and urgency of corrective action. Customer-specific corrective-action systems or reporting formats may also be contractually required.

33.4. When Is Formal Corrective Action Required?

Not every individual nonconformance requires a full formal root cause investigation. The response should be proportionate to **risk, significance and recurrence**. Formal corrective action should particularly be considered where there is:

- recurrence;
- customer escape;
- significant product impact;
- safety impact;
- regulatory impact;
- systemic failure;
- major audit nonconformity;
- significant supplier failure;
- repeated process failure;
- adverse trend;
- ineffective previous corrective action;
- high financial or operational consequence.

An isolated, low-risk error may require only correction and appropriate recording. Conversely, repeatedly treating recurring failures as isolated incidents is a significant management-system weakness. A useful decision principle is:

Severity + Recurrence + Systemic Risk + Customer Impact → Level of Corrective Action

33.4.1. Corrective Action Lifecycle

A practical corrective-action lifecycle is:

Identify → Contain → Understand → Determine Cause → Define Action → Implement → Verify → Standardise → Close

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The detail required at each stage should reflect the complexity and risk of the problem. The process should answer three fundamental questions:

- **What happened?**
- **Why did it happen?**
- **What has changed to prevent it happening again?**

If these cannot be answered clearly, the corrective action may not be complete.

33.5. Immediate Containment

Where a problem presents an ongoing risk, immediate containment should protect the customer and organisation while investigation continues. Containment may include:

- stopping production;
- segregating affected product;
- additional inspection;
- supplier containment;
- stock checks;
- work-in-progress review;
- shipment hold;
- customer notification;
- review of previously delivered product.

Containment is important, but it is **not corrective action**. For example: **100% inspection introduced** may be an effective temporary containment action but usually does not explain or eliminate why the defect was created.

Containment should normally remain in place until there is sufficient confidence that permanent controls are effective.

33.6. Problem Definition

Corrective action begins with an accurate definition of the problem. Poor problem statements lead to poor investigations. Weak: **“Parts are bad.”** Better **“Four of 120 components from Batch 2468 were found at final inspection with bore diameter above the drawing upper tolerance of 15.05 mm, with measured values between 15.07 and 15.11 mm.”** A useful problem definition should establish:

- what happened;
- where it occurred;
- when it occurred;
- which product/process is affected;
- how many are affected;
- what requirement was not achieved;
- actual versus required condition;
- extent of known impact.

Facts should be separated from assumptions.

33.7. Root Cause

Corrective action should address the **cause of the problem**, not simply its visible symptom. Root cause analysis seeks to understand why the conditions existed that allowed the failure to occur. Possible contributing areas include:

- process design;
- equipment;
- tooling;
- materials;
- methods;
- measurement;
- environment;
- documentation;

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- training;
- communication;
- planning;
- supplier controls;
- management system controls.

Statements such as: **“Operator error”** must not be accepted as sufficient root cause. The more useful question is: **What conditions within the process allowed a single human error to create or escape as a nonconforming output?** Always find the process that allowed the error.

33.7.1. Occurrence and Escape

A strong investigation considers two different questions:

- **Why was the problem created?** This identifies the **occurrence cause**.
- **Why was the problem not detected before reaching the next stage or customer?** This identifies the **escape or detection cause**.

For example:

- **Occurrence:** Incorrect machine offset entered.
- **Escape:** First-off verification did not require independent confirmation of the offset.

Corrective action may therefore need to address both creation and detection. Improving inspection alone may reduce escapes without preventing the defect from being produced.

33.8. Root Cause Methods

Various tools can support root cause investigation, including:

- 5 Whys;
- Ishikawa / Fishbone Diagram;
- cause-and-effect analysis;
- process mapping;
- fault tree analysis;
- Is/Is Not analysis;
- Pareto analysis;
- data analysis;
- hypothesis testing;
- direct observation;
- Gemba investigation.

The tool should suit the problem. Complex problems may require several methods rather than forcing every investigation into the same template. **5 Why** has proven the most practical tool to use in many cases and can be supported by additional investigative tools.

The objective is not to complete a root cause tool, it is to establish a **credible cause supported by evidence**.

33.8.1. Evidence-Based Root Cause

A suspected cause is not necessarily the root cause. Where practical, the investigation should demonstrate that the proposed cause:

1. can explain the observed failure;
2. is supported by available evidence;
3. can reproduce or predict the failure where appropriate;
4. disappears or is controlled when effective action is implemented.

For example, identifying *“machine wear”* as root cause should ideally be supported by evidence such as measurement, maintenance history, trend data or examination, not simply opinion.

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Root cause should be demonstrated, not selected because it sounds plausible.

33.9. Corrective Action Selection

Corrective actions should directly address the verified cause. Good corrective actions may include:

- process redesign;
- mistake-proofing;
- automated controls;
- tooling modification;
- specification clarification;
- improved maintenance;
- software controls;
- revised process sequence;
- improved supplier controls;
- improved measurement systems;
- design changes;
- strengthened verification;
- improved competency controls.

The strongest actions generally change the **system or process**, reducing dependence on individual memory or vigilance.

33.9.1. The Hierarchy of Corrective Action

Corrective actions differ in effectiveness. Where practical, preference should be given to controls that eliminate or prevent the failure rather than merely increase detection. A useful hierarchy is:

Eliminate the cause
↓
Design the failure out
↓
Error-proof the process
↓
Automatically control or detect
↓
Improve process controls
↓
Inspection / warning
↓
Training / awareness

Training can be entirely appropriate where a genuine competence gap exists, but it should not become the default corrective action for every problem.

If a trained and competent person can easily repeat the same error because the process remains vulnerable, training alone has not eliminated the underlying weakness.

33.10. Action Ownership and Timescales

Every corrective action should have:

- a clearly defined action;
- an accountable owner;
- a target completion date;
- evidence of implementation;
- appropriate status;
- effectiveness criteria.

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Actions should not remain open indefinitely. Where target dates cannot be achieved, the reason should be understood and any continuing risk appropriately controlled.

Overdue corrective actions can themselves become a useful indicator of management-system health.

33.11. Verification of Implementation

Before an action can be considered complete, there should be evidence that it was actually implemented. Evidence may include:

- revised procedures;
- changed tooling;
- updated software;
- photographs;
- completed training;
- revised inspection plans;
- updated control plans;
- engineering change records;
- new supplier controls;
- maintenance records.

Closing an action because someone states **"completed"** without objective evidence weakens the corrective-action process. Implementation, however, is only one stage. The organisation must still determine whether the action **worked**.

33.12. Effectiveness Review

An effectiveness review determines whether the corrective action has successfully prevented recurrence or otherwise achieved its intended outcome. Possible effectiveness evidence includes:

- no recurrence over a defined period;
- process capability improvement;
- reduced defect rate;
- successful audit;
- improved supplier performance;
- stable SPC results;
- successful production runs;
- absence of customer recurrence;
- reduced inspection failures;
- objective verification of new controls.

Effectiveness criteria should ideally be considered **when the action is planned**, rather than invented immediately before closure. For example:

- **Action:** Modify fixture to prevent incorrect orientation.
- **Effectiveness criterion:** No incorrect orientation during the next three production batches, confirmed through production records and audit.

33.13. Do Not Close Too Early

A common weakness is closing corrective actions immediately after implementation. For example:

Procedure revised → Action closed

This demonstrates implementation, not effectiveness. A stronger approach is:

Procedure revised → Implemented → Used in practice → Evidence collected → Effectiveness confirmed → Closed

The verification period should be proportionate to the process cycle, production frequency and risk.

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33.14. Recurrence after Closure

A repeated failure following corrective-action closure should trigger scrutiny of the previous investigation. Possible reasons include:

- incorrect root cause;
- incomplete extent-of-condition review;
- weak corrective action;
- action not fully implemented;
- ineffective effectiveness review;
- different contributing cause;
- failure to standardise the solution.

Repeated recurrence should not simply generate another identical corrective-action record. The organisation should ask: **Why did our previous corrective-action process fail to prevent this recurrence?**

33.15. Preventive Improvement

Preventive improvement uses information available within the organisation to identify potential problems before they result in nonconformity. Sources can include:

- risk assessments;
- PFMEA;
- audit observations;
- near misses;
- process trends;
- SPC;
- supplier performance;
- maintenance data;
- customer feedback;
- employee suggestions;
- lessons learned;
- benchmarking;
- reliability data;
- capability studies;
- changes to products or processes.

The objective is to recognise weak signals and act **before the control limit becomes a defect, the concern becomes an escape or the risk becomes an incident**.

33.15.1. Trend-Based Prevention

Individual events may appear insignificant when viewed separately. Trend analysis can reveal developing problems such as:

- gradually increasing defect rates;
- deteriorating Cpk;
- repeated minor supplier failures;
- increasing equipment downtime;
- increasing concession requests;
- growing nonconformance ageing;
- repeated audit observations;
- increasing customer complaints.

A mature quality system should respond to the **direction of travel**, not wait until a specification limit is exceeded.

The best corrective action is often the one that never becomes necessary because the trend was acted upon early.

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33.16. Horizontal Deployment

A corrective action may have relevance beyond the product or process where the original problem occurred. The organisation should consider: **“Where else could this same weakness exist?”**

For example, if an obsolete drawing was used because the document-control process allowed uncontrolled printed copies, the risk may exist across many products rather than only the component where it was discovered. The solution may therefore need to be deployed across:

- similar products;
- other machines;
- other departments;
- other sites;
- related suppliers;
- equivalent processes.
-

This is sometimes called **horizontal deployment** or *read-across*. It transforms local problem solving into organisational learning.

33.17. Corrective Action and Change Management

Corrective actions frequently introduce changes. Changes may affect:

- product design;
- manufacturing process;
- tooling;
- software;
- inspection;
- suppliers;
- documentation;
- personnel;
- validated processes.

These changes should therefore be subject to appropriate change control. An action intended to solve one problem should not introduce another. Where necessary, consider:

- risk assessment;
- validation;
- customer approval;
- configuration control;
- updated PFMEA;
- revised control plans;
- updated instructions;
- additional training.

33.17.1. Supplier Corrective Action

Supplier failures may require formal corrective action where the significance or recurrence justifies it. A Supplier Corrective Action Request (SCAR) may require the supplier to provide:

- containment;
- extent of condition;
- root cause;
- corrective action;
- implementation evidence;
- effectiveness evidence.

Supplier responses should be technically reviewed rather than accepted simply because all form fields have been completed. Repeated weak responses may indicate deficiencies in the supplier's own problem-solving capability and should influence supplier assurance activities.

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33.17.2. Corrective Action Performance

Corrective-action systems themselves should be monitored. Useful indicators may include:

- number of open actions;
- overdue actions;
- average closure time;
- recurrence rate;
- actions by source;
- repeat root causes;
- effectiveness failure rate;
- supplier corrective-action performance;
- ageing profile.

However, closure speed alone should not become the objective. A corrective action closed quickly but ineffectively is less valuable than a properly investigated action that achieves sustained improvement.

33.18. 8D and Structured RCCA

For significant or complex problems, organisations may use structured methodologies such as **8D (Eight Disciplines)** to manage containment, problem definition, root cause, corrective action and effectiveness. This section intentionally does not reproduce the detailed 8D methodology.

For comprehensive guidance covering **8D, Root Cause and Corrective Action (RCCA), problem definition, containment, root cause 5-Why tool, occurrence and escape causes, corrective-action selection, implementation and effectiveness verification**, refer to the Special Processes Institute publication:
SPI-03 – 8D RCCA Problem Solving Guidebook

33.19. Common Corrective-Action Weaknesses

Typical weaknesses include:

- confusing correction with corrective action;
- weak problem definition;
- treating every issue identically regardless of risk;
- accepting *"operator error"* as root cause;
- root causes based on opinion rather than evidence;
- investigating occurrence but not escape;
- excessive reliance on retraining;
- actions that do not address the identified cause;
- containment remaining permanently in place;
- overdue actions;
- closing actions without implementation evidence;
- closing immediately after implementation;
- weak effectiveness criteria;
- recurrence after closure;
- failing to consider similar products or processes;
- failing to update associated risk assessments or controls;
- treating completion of an 8D form as evidence that the problem has been solved.

These weaknesses can create the appearance of a functioning corrective-action system while the same failures continue to recur.

33.20. What Good Looks Like

An effective corrective-action record should allow an independent reviewer to answer:

- **What happened?**
- **What was done immediately to protect the customer?**
- **How far did the problem extend?**
- **Why did the problem occur?**
- **Why was it not detected earlier?**

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- **What evidence supports those conclusions?**
- **What permanent change was made?**
- **Who implemented it and when?**
- **Where else was the learning applied?**
- **How was effectiveness demonstrated?**
- **Has recurrence actually been prevented?**

If these questions cannot be answered, the corrective action may not yet be complete.

33.21. Key Takeaway

Corrective action is not the administrative closure of a nonconformance. Its purpose is to **eliminate causes and prevent recurrence**. A mature system progresses through:

Contain → Understand → Identify Cause → Improve → Verify → Learn → Prevent

Correction deals with the affected output. Corrective action strengthens the process that created it. Preventive improvement uses risk, trends and organisational learning to address weaknesses before failure occurs. The strongest organisations therefore move progressively from:

Reacting to failures → Preventing recurrence → Anticipating failure → Continually improving the system

34. Quality Tools, Methods and Practices

Quality tools, methods and practices provide structured ways to understand processes, analyse evidence, solve problems, control variation, manage risk and improve organisational performance. Their effectiveness depends on selecting a method appropriate to the problem and applying it with sufficient discipline.
A tool should never become the objective. Completing a form, diagram or analysis does not demonstrate improvement. The purpose is to generate **understanding, evidence, decisions and effective action**.

The **Special Processes Institute** provides a comprehensive range of **free, interactive web applications** covering quality management, process control, technical knowledge, quality and productivity. These practical tools complement the subjects covered in this publication by providing opportunities for **hands-on learning, application and further development**.

The webapps include the tools listed below, together with many additional resources designed for both learners and experienced professionals. **Explore the SPI Webapps: https://sp-i.org/webapps.html**

34.1. 4 Blocker

34.1.1. What It Is

A **4 Blocker** is a concise, visual management and problem-solving report that divides key information into four logical areas. There is no single universally mandated format; organisations commonly adapt the four blocks to their own needs. A typical problem-solving 4 Blocker contains:

1. **Problem / Current Situation**
2. **Analysis / Root Cause**
3. **Actions / Countermeasures**
4. **Results / Next Steps**

Other versions may show performance, issues, recovery actions and risks.

34.1.2. Purpose

The method converts complex information into a format that can be understood quickly by management, customers and cross-functional teams. It is particularly useful for:

- supplier recovery;
- production issues;
- project reporting;
- quality escapes;

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- corrective-action progress;
- improvement projects;
- executive reviews.
-

34.1.3. How to Apply

Start with a clear, quantified problem statement. Present factual evidence rather than opinion. Summarise the investigation and identified causes, define actions with owners and dates, and show objective evidence of progress or effectiveness. Charts, photographs and simple graphics are generally more useful than large amounts of text.

34.1.4. Good Practice

A 4 Blocker should be capable of being understood in several minutes without requiring a lengthy verbal explanation. Keep the information factual, current and traceable.

34.1.5. Common Mistakes

A 4 Blocker becomes ineffective when it becomes merely a status presentation. Common weaknesses include vague problem statements, excessive text, actions without owners, confusing containment with corrective action and declaring closure without effectiveness evidence.

34.1.6. Related Methods

8D, A3, 5 Why, Pareto, Ishikawa, SMART objectives and CAEV.

34.2. 5 Why

34.2.1. What It Is

5 Why analysis is a simple causal investigation technique in which the investigator repeatedly asks why an observed condition occurred. The number five is not mandatory. A valid causal chain may require three questions or considerably more than five.

34.2.2. Purpose

The objective is to move investigation away from the immediately visible symptom and towards the underlying conditions that allowed the problem to occur. Example:
Problem: Incorrect component fitted.

- Why? The operator selected the wrong component.
- Why? Two similar components were stored together.
- Why? The storage system did not differentiate similar parts.
- Why? No requirement existed for segregating look-alike components.
- Why? Look-alike part risk had not been considered during process planning.

The useful corrective action is therefore unlikely to be simply "retrain the operator."

34.2.3. When to Use

5 Why works particularly well for relatively straightforward causal chains involving:

- procedural failures;
- process breakdowns;
- human-factor issues;
- recurring manufacturing problems;
- administrative errors;
- simple equipment failures.

34.2.4. Limitations

Complex failures rarely have one linear cause. Where several causal pathways exist, combine 5 Why with Ishikawa, Fault Tree Analysis, process mapping or structured RCCA.

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34.2.5. Good Practice

Base each answer on evidence. Ask: **How do we know this is true?** Separate:

- direct cause;
- contributing causes;
- systemic cause;
- escape/detection cause.

34.2.6. Common Mistakes

The most serious mistake is stopping at human error. "Operator failed to follow procedure" explains what happened, but rarely explains why the management system permitted the failure.

34.3. 5S

34.3.1. What It Is

5S is a structured workplace organisation and visual-management methodology originating from Japanese manufacturing practice. The five elements are:

Sort — Set in Order — Shine — Standardise — Sustain.

34.3.2. Purpose

5S aims to create workplaces where abnormalities become obvious and required items can be located, used and returned efficiently. It can reduce:

- searching;
- unnecessary movement;
- clutter;
- contamination;
- incorrect tool selection;
- misplaced material;
- safety hazards.

34.3.3. Application

34.3.3.1. Sort

Remove unnecessary items from the workplace.

34.3.3.2. Set in Order

Give necessary items defined locations based on frequency and sequence of use.

34.3.3.3. Shine

Clean while inspecting equipment and workplace conditions.

34.3.3.4. Standardise

Establish consistent arrangements, visual controls and expectations.

34.3.3.5. Sustain

Maintain the system through ownership, routine review and reinforcement.

34.3.4. Important Principle

5S is **not simply workplace cleaning**. Its greatest quality value comes from making abnormal conditions visible.

34.3.5. Measures

Useful indicators include search time, missing-tool incidents, floor-space utilisation, audit performance and defects associated with workplace organisation.

34.3.6. Common Mistakes

A frequent failure is implementing an impressive 5S event followed by gradual deterioration because Sustain was never embedded into normal management.

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34.4. Six Sigma Knowledge & DMAIC

34.4.1. What It Is

Six Sigma is a data-driven improvement methodology focused on reducing variation and improving process performance. DMAIC provides its principal improvement structure:

Define – Measure – Analyse – Improve – Control.

34.4.2. Define

Establish:

- problem;
- business impact;
- customer requirements;
- scope;
- objectives;
- stakeholders;
- project boundaries.

Tools may include SIPOC, Voice of Customer and project charters.

34.4.3. Measure

Establish reliable baseline performance. Measurement systems should be validated before conclusions are drawn from their data. Typical tools include:

- MSA;
- Gauge R&R;
- capability analysis;
- process mapping;
- data collection plans.

34.4.4. Analyse

Determine relationships and causes using evidence. Methods may include:

- Pareto analysis;
- hypothesis testing;
- regression;
- Ishikawa;
- 5 Why;
- DoE.

34.4.5. Improve

Develop, evaluate and implement changes addressing verified causes.

34.4.6. Control

Ensure improvement is sustained using:

- control plans;
- SPC;
- visual management;
- standard work;
- audits;
- ownership;
- reaction plans.

34.4.7. When to Use

DMAIC is particularly valuable for complex, measurable problems involving process variation or performance gaps. It may be unnecessarily heavy for simple problems where the cause and solution are already evident.

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34.5. 8D

34.5.1. What It Is

8D is a structured team-based problem-solving methodology widely used throughout manufacturing, automotive, aerospace and supply-chain quality. The disciplines are generally:

- **D0 – Prepare & Plan**
- **D1 – Establish the Team**
- **D2 – Define the Problem**
- **D3 – Implement Interim Containment**
- **D4 – Determine Root Cause and Escape Point**
- **D5 – Select Permanent Corrective Actions**
- **D6 – Implement and Validate Actions**
- **D7 – Prevent Recurrence**
- **D8 – Recognise the Team / Close**

34.5.2. Purpose

8D provides governance around complex corrective-action investigations. Particular emphasis should be placed on distinguishing:

- **Occurrence cause** — why the defect happened.
- **Escape cause** — why existing controls failed to detect or prevent its progression.

34.5.3. When to Use

8D is appropriate for significant, recurring, systemic or customer-impacting problems. It should not automatically be demanded for every minor nonconformance.

For detailed application of the methodology, refer to the **Special Processes Institute** SPI-03 8D RCCA Problem Solving Guidebook.

34.6. A3 Report

34.6.1. What It Is

A3 problem solving originated within the Toyota Production System and takes its name from the A3 paper size traditionally used to communicate the analysis.
An A3 normally communicates:

- background;
- current condition;
- target condition;
- analysis;
- countermeasures;
- implementation;
- follow-up.

34.6.2. Purpose

The value is not the paper size. The discipline forces teams to communicate the logic connecting:

Problem → Evidence → Cause → Countermeasure → Result.

34.6.3. Best Application

A3 is particularly effective for improvement activity requiring concise communication between operational and management teams. An A3 overloaded with text defeats the purpose. Diagrams, process maps, charts and factual evidence should carry much of the message.

34.7. APQP — Advanced Product Quality Planning

34.7.1. What It Is

APQP is a structured framework for planning product and process quality before serial production.
It is strongly associated with automotive quality management and AIAG guidance, although APQP principles are applicable more widely.

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34.7.2. Typical Lifecycle

APQP commonly covers:

1. planning and programme definition;
2. product design and development;
3. process design and development;
4. product and process validation;
5. feedback, assessment and corrective action.

34.7.3. Typical Outputs

Depending on industry and customer requirements, activities may include:

- customer requirements;
- design reviews;
- DFMEA;
- process flow;
- PFMEA;
- control plans;
- MSA;
- capability studies;
- PPAP;
- production validation.

34.7.4. Key Principle

APQP should be treated as **preventive planning**, not a collection of documents completed immediately before production approval.

34.8. Community of Practice

34.8.1. What It Is

A Community of Practice is a group of people who share expertise or professional responsibility and collaborate to improve collective knowledge. Examples include communities for:

- welding;
- special processes;
- supplier quality;
- metrology;
- auditing;
- RCCA.

34.8.2. Purpose

Communities reduce organisational dependence on isolated experts and encourage lessons learned, standardisation and professional development.

34.8.3. Effective Communities

Successful communities generally require a defined purpose, knowledgeable leadership, regular engagement and mechanisms for capturing resulting knowledge. Without these, communities can become discussion forums that generate little organisational learning.

34.9. Corrective Action Effectiveness Verification — CAEV

34.9.1. What It Is

CAEV is the structured verification that implemented corrective actions have actually prevented recurrence or otherwise achieved the intended result. Implementation is not equivalent to effectiveness.

34.9.2. Method

Define effectiveness criteria **before closure**. Evidence might include:

- no recurrence over an appropriate period;
- statistical improvement;
- successful audits;

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- capability improvement;
- reduced defect rate;
- verification across similar products/processes.

The observation period should reflect the process frequency and risk. "No recurrence for one week" has little meaning where the process runs once per month.

34.9.3. Critical Principle

Corrective action should not be closed merely because every action on an action list has been completed.

34.10. Cp & Cpk — Process Capability

34.10.1. What It Is

Cp and Cpk are statistical indices used to compare process variation with specification limits.

- **Cp** represents potential capability when process centring is not considered.
- **Cpk** accounts for both variation and process location.

34.10.2. Application

Capability analysis can support:

- process qualification;
- production readiness;
- supplier assurance;
- improvement;
- control-plan development.

34.10.3. Critical Limitation

Capability indices are meaningful only where the underlying statistical assumptions are appropriate. A high Cpk calculated from an unstable process can be misleading. Therefore: **Establish process stability before interpreting capability.**

34.11. Design of Experiments — DoE

34.11.1. What It Is

DoE is a structured statistical method for deliberately changing process variables and measuring their effects on outputs. Unlike changing one factor at a time, DoE can identify **interactions between factors**.

34.11.2. Uses

Examples include determining the effects of:

- temperature;
- pressure;
- concentration;
- cure time;
- speed;
- material composition.

34.11.3. Typical Process

Define response → identify factors → select levels → design experiment → conduct controlled trials → analyse results → confirm conclusions.

DoE is particularly valuable where several process parameters interact and experimentation is practical.

34.12. Design for Manufacture — DFM

DFM applies manufacturing knowledge during product design so that products can be produced consistently, economically and robustly. Considerations include:

- manufacturing capability;
- tolerances;
- material availability;

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- tooling;
- inspection accessibility;
- process capability;
- assembly complexity;
- mistake-proofing.

DFM should begin during design development rather than after drawings have been released. A technically correct design that cannot be manufactured repeatedly within normal process capability is not a robust production design.

34.13. Fault Tree Analysis — FTA

FTA is a deductive failure-analysis technique beginning with an undesirable **top event** and logically decomposing the combinations of events capable of producing it. Logic gates such as **AND** and **OR** represent relationships between events. FTA is valuable for:

- safety analysis;
- reliability;
- complex system failures;
- aerospace;
- defence;
- engineering risk.

Unlike FMEA, which generally works forward from potential failure modes, FTA begins with an undesirable outcome and works backwards towards possible causes.

34.14. Fishbone / Ishikawa Cause Analysis

The Ishikawa or Fishbone Diagram visually structures potential causes of a problem. Manufacturing investigations commonly use categories such as:

- Man/People;
- Machine;
- Method;
- Material;
- Measurement;
- Environment.

These categories are prompts rather than mandatory rules. The method is particularly useful for preventing teams from prematurely focusing on one assumed cause.

Potential causes identified through brainstorming must subsequently be **tested against evidence**. A Fishbone diagram identifies hypotheses; it does not prove root cause.

34.15. FRACAS

34.15.1. Failure Reporting, Analysis & Corrective Action System

FRACAS is a closed-loop system for capturing failures, analysing them, implementing corrective action and feeding resulting knowledge back into engineering and operations. Typical elements include:

Failure → Record → Classify → Investigate → Correct → Verify → Trend → Learn.

FRACAS is particularly valuable in reliability-intensive industries including aerospace, defence and electronics. Its organisational value increases as the failure database matures because recurring patterns, components and failure mechanisms can be identified.

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34.16. Gemba

Gemba means the **actual place** where work occurs. Rather than attempting to understand a manufacturing problem solely from reports, the investigator goes to the process and observes reality. Good Gemba practice involves:

- **Go and see.**
- **Ask why.**
- **Show respect.**

Observe material flow, operator interaction, equipment, instructions, controls, queues and abnormal conditions. Gemba should be investigative and respectful rather than an opportunity to blame operators.

34.17. Histogram

A histogram displays the distribution of numerical observations across intervals. It can reveal:

- spread;
- centring;
- skew;
- multiple populations;
- unusual distributions;
- outliers.

Histograms are useful for understanding process behaviour but do not show the chronological sequence of observations. Run charts or control charts should therefore be used where time behaviour matters.

34.18. Is / Is Not Problem Definition

Is / Is Not analysis defines a problem by comparing where, when and under what circumstances it **occurs** against similar circumstances where it **does not occur**. Typical dimensions include:

Question	IS	IS NOT
What?	affected product	unaffected product
Where?	affected process	unaffected process
When?	occurrence period	normal period
Extent?	affected population	unaffected population

The contrasts can provide powerful clues. For example, if defects occur on Machine A but never Machine B, the differences between those machines become investigative evidence.

34.19. Jidoka — Built-in Quality

Jidoka is a Lean/Toyota principle often described as **automation with a human touch** or built-in quality. Processes should detect abnormal conditions and prevent defects from continuing downstream. Applications include:

- automatic machine stops;
- sensor detection;
- Andon alerts;
- interlocks;
- automatic rejection;
- error detection.

The philosophy is: **Do not knowingly manufacture defects and pass them to the next process.**

34.20. Kaizen

Kaizen means continuous improvement through frequent, often incremental changes involving those closest to the work. It differs from large transformation programmes by encouraging ongoing improvement as normal business activity. A practical cycle is:

Identify → Understand → Improve → Verify → Standardise → Repeat.

Successful Kaizen depends on employee participation and management support. Suggestion systems that collect ideas but rarely implement them quickly lose credibility.

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34.21. Kanban

Kanban is a visual pull-based method used to control work and inventory. A downstream requirement triggers replenishment rather than upstream processes producing indefinitely to forecast. Kanban may use:

- cards;
- bins;
- boards;
- electronic signals.

Benefits include reduced WIP, improved flow and visibility of bottlenecks. Kanban is particularly effective where demand and process behaviour are sufficiently stable to establish sensible replenishment rules.

34.22. Lean 5S Project

A Lean 5S project applies 5S as a controlled improvement activity rather than an isolated housekeeping exercise. Typical stages are:

Baseline → Sort → Reconfigure → Clean/Inspect → Visualise → Standardise → Audit → Sustain.

Before-and-after evidence and measurable benefits should be recorded.

34.23. Line of Balance

Line of Balance is a planning and production-control method particularly useful for repetitive manufacturing and assembly. It compares required production progress with actual completion across sequential operations. It helps identify:

- schedule shortfalls;
- bottlenecks;
- production imbalance;
- future delivery risk.

It is particularly valuable where multiple units progress through similar manufacturing sequences.

34.24. Measurement System Analysis & Gauge R&R

34.24.1. MSA

Measurement System Analysis determines whether the measurement process itself is suitable for its intended purpose. Sources of measurement variation may include:

- equipment;
- operators;
- method;
- environment;
- fixturing;
- part characteristics.

34.24.2. Gauge R&R

Gauge Repeatability and Reproducibility evaluates important components of measurement variation.

- **Repeatability** — variation when the same operator repeatedly measures the same characteristic using the same equipment.
- **Reproducibility** — variation associated with different operators or other reproducibility conditions.

A measurement system should be understood before relying on its data for SPC, capability analysis or acceptance decisions. Calibration alone does **not** demonstrate that a measurement system is suitable.

34.25. Material Review Board — MRB

MRB is the controlled review and disposition of nonconforming product by personnel with appropriate authority and technical competence. Possible dispositions may include:

- rework;
- repair;
- use-as-is/concession where authorised;

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- scrap;
- return to supplier.

MRB should not become a mechanism for routinely accepting poor process performance. Repeated concessions or use-as-is decisions should trigger investigation into underlying process capability, design requirements or supplier performance.

34.26. OODA Loop

OODA represents:

Observe → Orient → Decide → Act.

Originally developed in military decision theory, it provides a useful framework for decision-making in changing environments. The loop emphasises learning continuously from the results of action rather than treating decisions as isolated events.

Quality applications include containment management, supplier recovery, production disruption and rapidly developing investigations.

34.27. Pareto Analysis

Pareto analysis ranks categories by frequency, cost, impact or another meaningful measure. It helps identify the **vital few** contributors responsible for a substantial proportion of an overall problem. Typical applications include:

- defect types;
- suppliers;
- scrap costs;
- customer complaints;
- failure modes.

Pareto identifies **where to focus**. It does not establish why those problems occur.

34.28. PICK Idea Prioritisation

PICK categorises improvement ideas according to benefit and implementation difficulty. The four categories are:

Possible – Implement – Challenge – Kill.

It helps teams distinguish quick wins from expensive or low-value ideas. Decisions should be supported by evidence rather than subjective enthusiasm for particular ideas.

34.29. Poka-Yoke — Mistake Proofing

Poka-Yoke designs processes so that mistakes are prevented or detected before they become defects. Examples include:

- asymmetric connectors;
- keyed fixtures;
- part-presence sensors;
- barcode verification;
- software validation;
- torque confirmation;
- sequence interlocks.

Prevention is normally stronger than detection. Where possible: **Make the wrong action impossible rather than relying on somebody remembering not to do it.**

34.30. PPAP — Production Part Approval Process

PPAP provides documented evidence that the production process can consistently manufacture product meeting specified requirements. Depending on applicable requirements, evidence may include:

- design records;
- change documentation;

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- DFMEA;
- process flow;
- PFMEA;
- control plan;
- MSA;
- dimensional results;
- material/performance tests;
- capability evidence;
- sample parts;
- Part Submission Warrant.

PPAP should demonstrate **production readiness**, not merely document completeness.

34.31. Process Mapping & Flowcharts

Process mapping visually represents activities, decisions, interfaces and information or material flow. Useful formats include:

- basic flowchart;
- cross-functional/swim lane map;
- detailed process map;
- value-stream map.

Mapping often reveals:

- duplication;
- unclear ownership;
- loops;
- delays;
- uncontrolled handoffs;
- unnecessary approvals.

Always validate maps against what actually occurs rather than assuming documented procedures represent reality.

34.32. Product Lifecycle Management — PLM

PLM provides structured control of product information throughout its lifecycle:

Concept → Design → Development → Production → Support → Modification → Retirement.

PLM environments commonly manage:

- drawings;
- BOMs;
- configuration;
- revisions;
- approvals;
- engineering changes;
- product records.

Effective PLM supports configuration integrity and ensures users work to the correct authorised product definition.

34.33. Protecting Outcomes from Cumulative Stakeholder Compromise

Complex projects can gradually lose the characteristics that originally made them effective as multiple stakeholders request individually reasonable changes. No single compromise appears damaging, but cumulative changes can result in:

- scope drift;
- conflicting requirements;
- unnecessary complexity;

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- diluted user experience;
- excessive governance;
- design-by-committee.

Protection mechanisms include:

- clearly defined design principles;
- measurable critical requirements;
- controlled change;
- designated design authority;
- impact assessment;
- traceability to original objectives.

The key question for each proposed change is: **Does this improve the overall outcome, or merely optimise one stakeholder's local preference at the expense of the system?**

34.34. Pugh Assessment & Concept Selection

The Pugh Matrix compares alternative concepts against defined evaluation criteria using a reference or datum concept. Alternatives are typically assessed as: **Better (+), Same (S), Worse (–)** relative to the datum.

It provides structured comparison while encouraging discussion about why alternatives differ. Criteria and weighting should be established before teams become attached to particular solutions.

34.35. Quality Function Deployment & House of Quality

QFD translates customer needs into technical and process requirements. The House of Quality typically relates:

Voice of Customer → Engineering Characteristics → Relationships → Priorities → Targets.

Its purpose is to maintain traceability between what customers value and what engineering controls. QFD is particularly useful where customer requirements are qualitative and need translation into measurable technical characteristics.

34.36. Run Charts & Trend Analysis

Run charts display measurements sequentially over time. They help reveal:

- shifts;
- trends;
- cycles;
- deterioration;
- improvement.

Unlike SPC control charts, basic run charts do not normally use statistically derived control limits. They are useful exploratory tools and often provide an initial view before more formal statistical analysis.

34.37. Sampling Plans & Acceptance Sampling

Acceptance sampling uses a defined sample from a lot to support an acceptance decision. A plan typically defines:

- lot size;
- sample size;
- acceptance number;
- rejection number;
- inspection severity.

Standards such as **ISO 2859-1** and **ANSI/ASQ Z1.4** are commonly associated with attribute sampling. Sampling introduces statistical risk and should never be interpreted as proof that every item in an accepted lot conforms. Where product risk requires certainty, sampling may be inappropriate.

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34.38. Scatter Diagram / Correlation Analysis

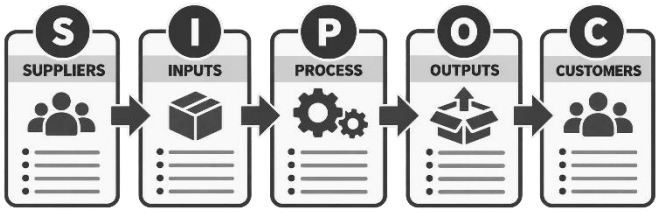
A scatter diagram plots paired observations to investigate whether two variables appear related. Patterns may suggest:

- positive association;
- negative association;
- no obvious relationship;
- nonlinear behaviour;
- unusual observations.

Correlation does **not** establish causation. A relationship should lead to further investigation rather than an automatic causal conclusion.

34.39. SIPOC Process Definition

SIPOC represents:



It provides a high-level view of process boundaries and interfaces. It is particularly useful at the beginning of improvement activity before developing detailed process maps. SIPOC answers: **What enters this process, who provides it, what happens, what leaves it and who receives the output?**

34.40. SMART Objectives

SMART provides a framework for defining effective objectives. Common interpretation:

- **Specific**
- **Measurable**
- **Achievable**
- **Relevant**
- **Time-bound**

Instead of: "**Improve supplier quality**." Use "**Reduce Supplier X's monthly incoming defect rate from 4.2% to below 1.0% by 31 December while maintaining delivery performance.**" SMART improves accountability and makes effectiveness objectively assessable.

34.41. Statistical Process Control — SPC

SPC uses statistical techniques to understand and control process variation over time. Control charts distinguish between:

- **Common-cause variation** — inherent within the existing process system.
- **Special-cause variation** — attributable to specific abnormal conditions.

A fundamental principle is that **control limits are not specification limits**. Specifications describe acceptable product requirements. Control limits describe observed process behaviour.

SPC should be accompanied by reaction plans defining what happens when abnormal behaviour is detected.

34.42. Structured Improvement Activity Management

Structured improvement management provides governance around multiple improvement activities. A typical system records:

- problem/opportunity;
- owner;
- priority;
- expected benefit;
- actions;
- milestones;
- status;
- risks;
- evidence;

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- realised benefit;
- lessons learned.

Its purpose is to prevent improvement activity becoming a collection of disconnected actions without ownership or verified benefits.

34.43. Takt Time

Takt time represents the rate at which production must operate to meet customer demand. It is based on available production time relative to required customer demand. Takt supports:

- line balancing;
- resource planning;
- staffing;
- flow design;
- bottleneck identification.

Takt time should not be confused with cycle time.

- **Takt time = required production pace.**
- **Cycle time = actual time required by the process.**

Where cycle time consistently exceeds takt time, demand cannot be met without additional capacity or process improvement.

34.44. Theory of Constraints — TOC

TOC focuses improvement on the constraint limiting overall system performance. A common five-step approach is:

1. Identify the constraint.
2. Exploit the constraint.
3. Subordinate other activities to it.
4. Elevate the constraint.
5. Repeat when the constraint moves.

Optimising every individual process does not necessarily optimise the overall system. Increasing output from a non-constraint may simply create additional WIP.

34.45. Tuckman Team Development Model

Tuckman's model describes team development through:



34.45.1. Forming

Team members establish purpose and relationships.

34.45.2. Storming

Differences, competing ideas and uncertainty emerge.

34.45.3. Norming

Working practices and relationships stabilise.

34.45.4. Performing

The team operates effectively towards shared objectives.

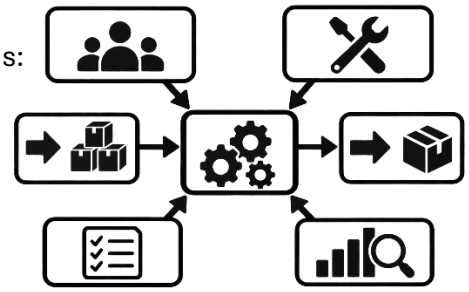
34.45.5. Adjourning

The work ends, membership changes or the team transitions to a new purpose.

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The model helps leaders recognise that disagreement during team formation is not automatically evidence of team failure.

34.46. Turtle Diagram Process Analysis



A Turtle Diagram examines a process through interconnected questions:

- **What?** — inputs and outputs.
- **Who?** — people and competence.
- **With what?** — equipment, infrastructure and resources.
- **How?** — procedures and controls.
- **How measured?** — indicators and effectiveness measures.

The process itself forms the centre of the diagram. Turtle diagrams are particularly useful in process-based auditing because they encourage auditors to examine interactions rather than simply checking individual procedural requirements.

34.47. Value Stream Mapping — VSM

Value Stream Mapping visualises the flow of material and information required to deliver a product or service. A typical exercise creates:

Current State Map → Waste Analysis → Future State Map → Improvement Plan.

VSM can expose:

- inventory;
- waiting;
- queues;
- transport;
- rework;
- information delays;
- batch processing;
- excessive lead time.

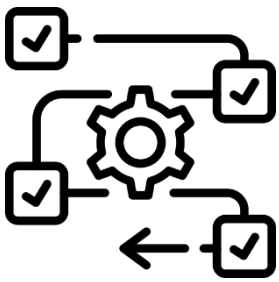
A critical distinction is made between:

- **Value-adding activity** — transforms the product/service in a way the customer requires.
- **Necessary non-value-adding activity** — currently required but does not directly create customer value.
- **Waste** — consumes resources without creating necessary value.

The objective is not merely to draw a map. The map provides evidence for redesigning the value stream.

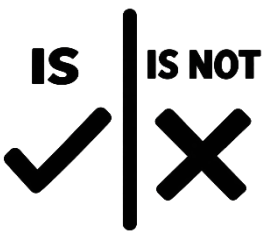
34.48. Choosing and Combining Quality Tools

Experienced quality practitioners rarely use these methods in isolation. A complex problem may require several methods in sequence. For example:



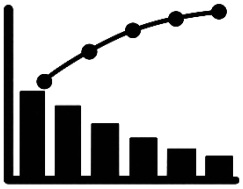
Gemba
↓
Observe the actual problem
Is / Is Not
↓
Define its boundaries
Process Mapping
↓
Understand where it occurs





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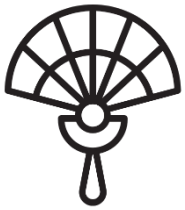


Pareto
↓
Determine where to concentrate investigation
Fishbone
↓
Develop causal hypotheses
5 Why / FTA
↓
Investigate causal pathways
MSA
↓
Verify confidence in measurement evidence
DoE / statistical analysis
↓
Test relationships where necessary
8D / A3 / DMAIC
↓
Provide overall problem-solving governance
Poka-Yoke / Jidoka
↓
Implement robust prevention
SPC / Capability Analysis
↓
Monitor resulting process behaviour
CAEV
↓
Demonstrate that corrective action remains effective.









34.49. Final Principle

Quality tools are **thinking aids, not substitutes for thinking**. The presence of a completed 8D, FMEA, Fishbone, control chart, capability study or improvement report does not demonstrate that the underlying activity was effective.

The experienced practitioner continually asks:

- **What are we trying to understand?**
- **What evidence do we need?**
- **Which method is appropriate for obtaining that evidence?**
- **What does the evidence actually tell us?**
- **What decision should follow?**
- **How will we know the resulting action worked?**

Selecting the simplest method capable of answering those questions is generally more effective than applying a complex tool simply because an organisation's procedure or template makes it familiar.

35. The Last Word

35.1. Essential Quality Knowledge for the Modern Professional

Quality is a broad and continually evolving discipline. No single publication can explore every subject in equal depth, and many areas of quality overlap with engineering, operations, supply chain, reliability, safety, software, data science and business management.

The subjects in this final section have therefore been brought together because they represent important areas of knowledge for the modern quality professional. Some have been referenced elsewhere in this book, while others represent disciplines that increasingly interact with quality as organisations become more digital, data-driven, automated and interconnected.

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The purpose is not to make the quality professional an expert in every discipline. It is to provide sufficient understanding to recognise their importance, ask the right questions, identify risks and know when specialist knowledge is required.

35.2. Customer Focus, Voice of the Customer & Customer Satisfaction

35.2.1. The Customer as the Starting and Finishing Point

Quality ultimately exists to provide confidence that products and services will satisfy requirements and perform as intended.

A technically conforming product is not necessarily a successful product if it does not meet the customer's actual need. Likewise, an organisation can achieve excellent internal quality metrics while customers remain dissatisfied.

Customer focus therefore requires more than responding to complaints. Organisations need systematic methods for understanding customer requirements, expectations, experiences and perceptions and converting these into measurable requirements and improvement activities.

35.2.2. Voice of the Customer

The **Voice of the Customer (VOC)** is the collective expression of what customers need, expect, value and experience. VOC information can originate from:

- contracts and purchase orders;
- drawings and specifications;
- customer-specific requirements;
- surveys and feedback;
- complaints;
- warranty claims;
- returns and rejects;
- customer scorecards;
- meetings and reviews;
- service and support interactions;
- market research;
- field-performance information;
- delivery performance;
- product escapes;
- lessons learned.

VOC includes both **stated requirements** and needs that may not have been explicitly stated.
For example, a customer may specify dimensional and material requirements but reasonably expect the product to arrive correctly identified, protected from damage, accompanied by appropriate documentation and fit for its intended purpose.

Quality professionals should therefore distinguish between:

What the customer specified → What the customer actually needs → What the organisation must control to consistently deliver it.

35.2.3. Translating Customer Needs

Customer statements frequently need converting into measurable characteristics.
A statement such as: “Delivery needs to be reliable.” is not directly measurable. It might be translated into:
≥98% On-Time Delivery against contractual delivery date.

Similarly: “The component must last for the expected life of the equipment.”
may result in reliability requirements, qualification testing, environmental testing or specified service-life criteria.

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Techniques such as Quality Function Deployment (QFD), requirements matrices, contract review and Critical-to-Quality characteristics can help translate VOC into measurable requirements.

35.2.4. Customer Satisfaction

Customer satisfaction should never be assessed using a single metric. Useful indicators include:

- customer complaints;
- returns;
- warranty claims;
- customer scorecards;
- product escapes;
- repeat business;
- delivery performance;
- response time;
- corrective-action performance;
- survey results;
- customer recognition or awards;
- loss of business.

An absence of complaints does **not** automatically mean that customers are satisfied.
Some dissatisfied customers simply stop buying.

35.3. Quality Objectives, KPIs & Performance Management

Quality objectives translate organisational policy and strategy into measurable expectations.
Without meaningful objectives, quality management can become reactive: organisations measure failures after they occur rather than controlling the conditions that prevent them.

35.3.1. Effective Quality Objectives

Objectives should normally be:

Specific – Measurable – Achievable – Relevant – Time-bound

Examples include:

- reduce internal scrap by 15% within 12 months;
- achieve ≥98% on-time delivery;
- reduce average corrective-action closure time below 30 days;
- reduce customer escapes by 25%;
- achieve 95% supplier corrective-action closure within agreed timescales.

Objectives should be relevant to the organisation's risks, products, customers and strategic direction.

35.3.2. Leading and Lagging Indicators

An effective performance-management system uses both.

Lagging indicators measure what has already happened:

- scrap;
- customer complaints;
- escapes;
- warranty costs;
- rejected products;
- late deliveries.

Leading indicators provide warning of conditions that may create future problems:

- overdue calibration;
- overdue corrective actions;
- supplier deterioration;
- training expiry;
- process-control violations;
- increasing inspection failures;

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- maintenance backlog;
- increasing concession requests.

A mature quality system does not merely count failures. It identifies deteriorating conditions **before they become failures**.

35.3.2.1. Beware of KPI Behaviour

Metrics influence behaviour. A target to reduce open nonconformances can unintentionally encourage premature closure.

A target to reduce inspection rejection may discourage inspectors from reporting borderline conditions. A target to maximise output may encourage production to bypass controls.

Quality professionals should therefore continually ask: **"What behaviour could this metric unintentionally encourage?"**

35.3.3. Dashboards and Trends

Good dashboards should communicate rather than decorate. They should show:

- current performance;
- target;
- trend;
- historical comparison;
- significant deviation;
- ownership;
- required action.

Trend is often more important than a single result. A metric may remain within target while deteriorating month after month.

35.4. Management Review

Management review is one of the mechanisms through which senior management determines whether the Quality Management System remains **suitable, adequate and effective**. It should not simply be an annual PowerPoint presentation prepared for an auditor.

A meaningful management review examines evidence and asks: **Is our management system actually working?**

35.4.1. Typical Inputs

Management review should consider information such as:

- previous review actions;
- customer satisfaction;
- customer complaints;
- process performance;
- product conformity;
- quality objectives;
- audit results;
- supplier performance;
- corrective actions;
- nonconformities;
- risks and opportunities;
- resource requirements;
- changes affecting the QMS;
- Cost of Poor Quality;
- delivery performance;
- improvement opportunities.

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35.4.2. Outputs

The review should result in decisions and actions concerning:

- improvement;
- resources;
- process changes;
- priorities;
- risks;
- objectives;
- responsibilities;
- investment;
- QMS changes.

Actions should have owners and timescales and should subsequently be reviewed for completion and effectiveness.

35.4.3. Management Review Test

A useful question is: **If nothing changes as a result of repeated management reviews, is management actually reviewing the system or simply observing it?**

35.5. Product Safety & Product Integrity

Quality and product safety are closely related but are not identical. Quality primarily concerns conformity and the consistent fulfilment of requirements. Product safety concerns the prevention of unacceptable risk of harm resulting from the product.

A dimensional nonconformance on a cosmetic feature may have little safety significance. The same dimensional deviation on a flight-critical component may have severe consequences.

35.5.1. Product Safety Considerations

Quality professionals should understand:

- safety-critical characteristics;
- critical items;
- special requirements;
- hazard controls;
- configuration integrity;
- traceability;
- suspect or counterfeit material;
- unauthorised substitution;
- occurrence and escalation requirements;
- change control;
- concessions affecting safety;
- preservation of safety-related records.

Product safety responsibilities should be clearly assigned and personnel should understand their responsibility to report concerns. Commercial or schedule pressure must never become justification for concealing or bypassing a product-safety concern.

35.5.2. Product Integrity

Product integrity is broader than simple inspection conformity.
It concerns confidence that the product is genuinely what it claims to be and has been produced, controlled, identified, handled and released appropriately throughout its lifecycle.
This includes protection against:

- counterfeit components;
- fraudulent documentation;
- unauthorised material substitution;
- falsified inspection results;

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- incorrect configuration;
- undocumented repair or rework;
- loss of traceability.

Quality provides an essential line of defence protecting product integrity.

35.6. Identification, Traceability, Preservation & Product Status

A conforming product can become nonconforming simply because its identity, condition or status is lost. Effective product control therefore extends beyond manufacturing.

35.6.1. Identification

Products and materials may require identification by:

- part number;
- serial number;
- batch or lot;
- heat number;
- material specification;
- revision;
- manufacturing order;
- inspection status.

Identification should remain clear throughout the product lifecycle.

35.6.2. Traceability

Traceability allows an organisation to reconstruct relevant product history. Depending upon the product, this may include:

Raw Material → Batch/Heat → Manufacturing Operations → Special Processes → Inspection → Assembly → Release → Customer

Good traceability enables rapid containment when problems occur. Without traceability, a defect affecting one batch may force an organisation to treat a much larger population as potentially suspect.

35.6.3. Preservation

Preservation includes protection against:

- corrosion;
- contamination;
- Foreign Object Debris/Damage (FOD);
- electrostatic discharge;
- moisture;
- temperature extremes;
- UV exposure;
- physical damage;
- deterioration;
- incorrect storage.

Controls may include packaging requirements, environmental storage, protective coatings, desiccants, handling requirements and shelf-life management.

35.6.4. FIFO and FEFO

FIFO – First In, First Out can help control inventory rotation. Where products have shelf lives, **FEFO – First Expiry, First Out** may be more appropriate.

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35.6.5. Product Status

At all times it should be clear whether product is:

Awaiting Inspection → Accepted → Rejected → Quarantined → Under Review → Released

Unclear status creates the possibility of unintended use. A useful principle is: **If product status cannot be demonstrated, conformity should not be assumed.**

35.7. Quality in Software, Digital Systems & Quality 4.0

Quality management increasingly operates in a digital environment. Inspection equipment automatically generates results. Manufacturing systems control processes. Algorithms analyse trends. Electronic records replace paper documentation. Artificial intelligence increasingly assists with decisions previously made solely by people.

Quality professionals therefore need to understand not only physical processes but the **digital systems upon which evidence and decisions depend**.

35.7.1. Software Quality Assurance

Software quality assurance considers whether software is developed, configured, tested, controlled and maintained in a manner appropriate to its intended use and associated risk. Relevant considerations include:

- requirements;
- verification and validation;
- configuration control;
- change management;
- cybersecurity;
- defect management;
- version control;
- testing;
- access control;
- backup and recovery.

35.7.2. Software Used for Quality Decisions

Particular attention should be given to software that influences product acceptance. Examples include:

- automated inspection;
- CMM software;
- test systems;
- SPC applications;
- automated pass/fail systems;
- laboratory software;
- calculation spreadsheets;
- measurement-data processing;
- machine-vision systems.

A measurement device can be correctly calibrated while the software interpreting its output is incorrectly configured. The entire measurement and decision chain must therefore be considered.

35.7.3. Data Integrity

Digital quality records should remain:

- attributable;
- legible;
- contemporaneous where appropriate;
- original or appropriately controlled;
- accurate;
- complete;
- protected;

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- retrievable.

Access controls, audit trails, backups and change histories become part of quality assurance.

35.7.4. Quality 4.0

Quality 4.0 describes the application of modern digital technologies to quality management. Examples include:

- connected measurement systems;
- Internet of Things sensors;
- real-time SPC;
- predictive analytics;
- machine vision;
- digital twins;
- automated inspection;
- artificial intelligence;
- machine learning;
- integrated manufacturing data;
- predictive maintenance.



The opportunity is substantial, but automation introduces new risks. Quality professionals should ask:

- **Who validated the algorithm?**
- **What data was it trained or configured against?**
- **How are incorrect decisions detected?**
- **Can the decision be traced and explained?**
- **What happens when the system fails?**

Automation does not remove the need for quality assurance. It changes what must be assured.

35.8. Reliability, Maintainability & Dependability

- Quality asks: **Does the product conform?**
- Reliability asks: **Will it continue to perform its required function for the required period under specified conditions?**

A product can pass every final inspection and still have poor reliability.

35.8.1. Fundamental Reliability Concepts

35.8.1.1. MTBF — Mean Time Between Failures

Generally applied to repairable systems and represents the average operating time between failures.

35.8.1.2. MTTF — Mean Time To Failure

Generally applied to non-repairable items and represents expected operating time before failure.

35.8.1.3. Failure Rate

Failure rate describes how frequently failures occur within a population or operating period.

35.8.2. Reliability Testing

Reliability can be evaluated using:

- life testing;
- environmental testing;
- endurance testing;
- accelerated life testing;
- Highly Accelerated Life Testing where appropriate;
- field-performance monitoring.

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35.8.3. The Bathtub Curve

A traditional reliability model identifies three broad periods:

Early Life → Useful Life → Wear-Out

Early-life failures may result from manufacturing defects or weak components. Useful-life failures are often relatively random.

Wear-out failures result from deterioration mechanisms such as fatigue, corrosion or component ageing.

35.8.4. Weibull Analysis

Weibull analysis is widely used to examine failure distributions and can help determine whether failures are dominated by early-life defects, random events or wear-out behaviour.

Quality professionals do not necessarily need to become reliability engineers but should understand what reliability data indicates and how manufacturing variation, supplier quality, process control and design decisions influence field performance.

35.8.5. Maintainability

Maintainability concerns how readily a system can be restored to operational condition following failure. Considerations include:

- accessibility;
- diagnostic capability;
- repair time;
- tooling;
- spare parts;
- maintenance instructions;
- modular replacement.

Quality, reliability and maintainability should therefore be viewed as connected elements of overall **dependability**.

35.9. Quality Statistics — Fundamentals

Statistics provide much of the mathematical foundation upon which modern quality management is built. SPC, process capability, sampling, Measurement System Analysis and Design of Experiments all depend upon statistical concepts.

Quality professionals do not need to be statisticians, but they should understand the principles sufficiently to interpret data correctly.

35.9.1. Population and Sample

A **population** represents the complete group being studied. A **sample** is a subset taken from that population. Because examining an entire population is frequently impractical, samples are used to estimate characteristics of the whole.

The usefulness of those conclusions depends heavily upon whether the sample is representative.

35.9.2. Measures of Central Tendency

- **Mean** – arithmetic average.
- **Median** – middle value when data are ordered.
- **Mode** – most frequently occurring value.

The mean can be strongly influenced by extreme values, making the median useful when distributions are skewed.

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35.9.3. Measures of Variation

Average performance alone tells only part of the story. Common measures include:

- range;
- variance;
- standard deviation.

Standard deviation provides an indication of how widely values are dispersed around their mean.
In quality management, variation is fundamental because two processes can have identical averages but very different consistency.

35.9.4. Distributions

Data may follow different statistical distributions. The **normal distribution** is particularly important because many naturally varying processes approximate its familiar bell-shaped pattern. However: **Never assume data are normally distributed simply because a calculation expects them to be.**

Process capability and other statistical methods can produce misleading conclusions when their underlying assumptions are inappropriate.

35.9.5. Confidence Intervals

A sample provides an estimate rather than perfect knowledge of a population. Confidence intervals express a range of plausible values around an estimate at a specified confidence level. Larger representative samples generally provide greater precision than small samples.

35.9.6. Correlation versus Causation

Two variables changing together does not prove that one caused the other. **Correlation identifies association—not necessarily causation.** A third variable may influence both, or the apparent relationship may be coincidental. This distinction is particularly important during Root Cause Analysis.

35.9.7. Statistical Significance versus Practical Significance

A statistically detectable difference is not automatically important to the product, process or customer. With sufficiently large datasets, extremely small differences may become statistically significant.

Quality professionals should therefore ask two questions: **Is the difference statistically credible?** And **Is the difference large enough to matter?** Both are important.

35.10. Bringing It All Together

Quality has evolved considerably from its historical association with inspection. The modern quality professional may interact with customers, suppliers, engineers, manufacturing, software developers, laboratories, reliability specialists, procurement, programme management and senior leadership, sometimes within the same working day.

No individual can be an expert in every discipline. The strength of a quality professional lies partly in understanding how those disciplines connect.

- A customer requirement becomes a specification.
- A specification becomes a design.
- A design becomes a process.
- A process creates data.
- Data provides evidence.
- Evidence supports a decision.
- The decision ultimately determines whether a product or service reaches the customer.

At every stage there is an opportunity either to **build confidence or introduce risk**. Quality therefore should not be viewed simply as a department, an inspection activity, a collection of procedures or a certification requirement.

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It is a way of managing uncertainty, controlling variation, protecting customers and ensuring that organisations consistently deliver what they have promised. Technology will continue to change the tools available to the profession. Artificial intelligence, automation, digital manufacturing, connected measurement and increasingly sophisticated data analysis will change how quality is practised.

35.11. Best Endeavour

Quality is built on standards, specifications, procedures, evidence and data. But no standard can describe every situation, no procedure can anticipate every problem, and no management system can replace professional judgement.

There will always be occasions when the answer is not obvious.

Requirements may be incomplete. Information may be limited. Commercial pressures may conflict with quality concerns. A problem may fall between organisational responsibilities. A decision may need to be made before every fact is known. In those moments, quality ultimately depends upon people.

Best endeavour is about doing the right thing.

It means applying your knowledge, experience and professional judgement to achieve the best reasonable outcome. It means asking another question when something does not look right, challenging an assumption when the evidence does not support it and speaking up when remaining silent would be easier.

It means recognising that compliance should be the **minimum expectation**, not the limit of our responsibility. Doing the right thing may mean stopping a product from progressing. It may mean admitting that a decision was wrong. It may mean reporting a problem that others would rather overlook, helping a supplier solve a difficult issue, supporting a colleague, or taking ownership of something that does not sit neatly within a job description.

It also means understanding the limits of our own knowledge. Professional judgement includes knowing when to seek advice, involve a specialist, gather more evidence or reconsider a previous decision.

Quality should never become an exercise in finding the clause, completing the form or obtaining the signature. Those things matter, but they exist to support something more fundamental: **confidence and trust**.

Customers trust organisations to deliver what was promised. Organisations trust their people to follow processes and raise concerns. Engineers trust manufacturing and suppliers to protect design intent. Users trust that products are safe, conforming and suitable for their intended purpose. That trust can take years to build and moments to lose.

Throughout a career there will also be mistakes, difficult decisions, disagreements and occasions when, with hindsight, something could have been done differently. Continuous improvement applies to people just as much as it applies to processes.
Learn from those experiences. Share the lessons. Help others develop. Be prepared to change your mind when the evidence changes. And remember that quality is ultimately about people.

The procedures we write, audits we conduct, problems we solve and improvements we make depend upon relationships built through **trust, respect, integrity and cooperation**. The relationships, experiences and friendships developed throughout a career are every bit as real as the products and processes we work to improve.

- You will not always have the perfect information.
- You will not always have the perfect process.
- You will not always make the perfect decision.

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But you can always make your **best endeavour** to understand the facts, protect the customer, support the people around you and do what you genuinely believe is right. That is perhaps the most important quality principle of all:

- **Know what is required.**
- **Understand why it matters.**
- **Use the evidence.**
- **Question what does not look right.**
- **Learn from mistakes.**
- **Treat people with respect.**
- **And always make your best endeavour to do the right thing.**



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36. Reference & Supporting Information

36.1. Glossary & Acronyms

3

3C — Concern, Cause and Countermeasure. A concise problem-solving structure used to define the problem, establish why it occurred and identify the action required to address it.

4

4 Blocker — Four-block problem-solving/reporting format. A compact visual method for presenting a problem, analysis, actions and status or results on a single page.

5

5 Why — Five Why analysis. A simple root-cause technique that repeatedly asks why a condition occurred to move from the observed problem towards its underlying cause.

5S — Sort, Set in Order, Shine, Standardise and Sustain. A workplace-organisation method used to improve order, visibility, efficiency, control and discipline.

8

8D — Eight Disciplines. A structured team-based problem-solving method covering problem definition, containment, root cause, corrective action, verification and prevention of recurrence.

A

A3 — A3 Report. A structured one-page problem-solving and improvement approach, commonly associated with Lean, that communicates the problem, analysis, countermeasures and follow-up.

Acceptance Criteria. Defined conditions that must be satisfied for a product, service, process or result to be accepted.

APQP — Advanced Product Quality Planning. A structured approach for planning product and production-process quality from concept through industrialisation and launch.

AQAP — Allied Quality Assurance Publication. NATO quality-assurance publications that may be contractually invoked for defence products, services and quality plans.

AQL — Acceptance Quality Limit. A parameter used within acceptance-sampling schemes to select sampling plans and acceptance criteria. It is not a statement that a particular percentage of defective product is acceptable in every lot.

AS9100 / IA9100 — Aviation, Space and Defence Quality Management System. Sector-specific quality-management-system requirements for aviation, space and defence organisations, building upon ISO 9001.

AS9102 — Aerospace First Article Inspection Requirement. The aerospace-sector standard governing First Article Inspection and the associated First Article Inspection Report.

AS9145 — Aerospace APQP and PPAP. An aerospace-sector standard establishing requirements for Advanced Product Quality Planning and Production Part Approval Process.

Audit. A systematic, independent and documented process for obtaining objective evidence and evaluating it against defined audit criteria.

C

C of C / CoC — Certificate of Conformity / Conformance. A supplier or producer declaration that identified product or services conform to specified requirements. The exact content and authority required depend on the applicable contract.

CAEV — Corrective Action Effectiveness Verification. The activity used to confirm that implemented corrective action has addressed the cause of a problem and is effective in preventing recurrence.

Calibration. An activity that establishes the relationship between measurement indications and recognised reference values under specified conditions; calibration does not itself mean adjustment.

Capability — Process capability. The ability of a stable process to produce output within specified requirements. Capability is commonly evaluated using statistical indices such as Cp and Cpk.

Cause. A condition, action or mechanism that contributes to or produces an observed effect or problem.

CC — Critical Characteristic. A characteristic whose variation can have a significant effect on safety, regulatory compliance, fit, function, performance or other defined critical requirements. Terminology varies by organisation and contract.

CM — Configuration Management. The disciplined control of product, system and associated information throughout the lifecycle so that approved configuration, changes, status and verification remain identifiable and traceable.

CMP — Configuration Management Plan. A plan defining how configuration identification, change control, status accounting, audits and responsibilities will be managed.

Concession. Authorised acceptance or release of a known nonconforming product or service against specified conditions. A concession does not make the original condition conforming.

Containment. Immediate action taken to protect the customer, product or process from the effects of a known or suspected nonconformity while the underlying cause is investigated.

Control Plan. A documented description of the product and process controls used to manage important characteristics, including control method, frequency, responsibility and reaction plan.

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COPQ — Cost of Poor Quality. Costs arising because requirements were not met, including scrap, rework, investigation, concessions, returns, warranty, disruption and customer impact.

Cp — Process Capability Index. A capability index comparing the width of the specification tolerance with the natural spread of a stable process without considering process centring.

Cpk — Process Capability Index accounting for centring. A capability index that considers both process variation and the position of the process mean relative to the specification limits.

Critical Item. An item whose failure or malfunction could have significant consequences and therefore requires appropriate identification, control and assurance.

CSR — Customer-Specific Requirement. A requirement established by a particular customer in addition to, or as an interpretation of, general contractual or management-system requirements.

CTQ — Critical to Quality. A measurable characteristic that is important to satisfying a customer or other defined requirement.

D

Deviation. Authorised permission to depart from a specified requirement before the affected activity is performed or product is produced. Terminology can vary by organisation or contract.

DFM — Design for Manufacture. The practice of designing products so they can be manufactured reliably, economically and consistently using capable processes.

DFMEA — Design Failure Mode and Effects Analysis. A structured analysis of potential design failure modes, their effects and causes, and the actions or controls needed to reduce design risk.

DMAIC — Define, Measure, Analyse, Improve, Control. The structured improvement cycle commonly used within Six Sigma for improving existing processes.

Documented Information. Information that an organisation is required or chooses to control and maintain, together with the medium on which it is contained.

DOE — Design of Experiments. A statistical method for planning controlled experiments so the effects and interactions of process or design factors can be understood efficiently.

F

FAI — First Article Inspection. A planned, complete and documented verification that production processes have produced an item meeting the specified product definition and applicable requirements.

FAIR — First Article Inspection Report. The documented evidence and forms used to record the results of First Article Inspection.

FEFO — First Expired, First Out. A stock-rotation principle that prioritises material or product with the earliest expiry date.

FIFO — First In, First Out. A stock-rotation principle that generally uses the oldest received stock first.

Fishbone — Fishbone / Ishikawa cause analysis. A cause-analysis technique that organises potential causes into logical categories to support structured investigation.

FMEA — Failure Mode and Effects Analysis. A structured method for identifying potential failure modes, their effects and causes, evaluating risk and establishing appropriate prevention or detection controls.

FOD — Foreign Object Debris / Foreign Object Damage. Unwanted material that can contaminate or damage a product, or the resulting damage caused by such material.

FRACAS — Failure Reporting, Analysis and Corrective Action System. A closed-loop system for recording failures, analysing causes, implementing corrective actions and monitoring recurrence or effectiveness.

FTA — Fault Tree Analysis. A deductive analysis that starts with an undesired top event and logically identifies combinations of causes that could produce it.

G

Gage R&R / Gauge R&R — Gauge Repeatability and Reproducibility. An MSA study used to estimate measurement-system variation attributable to the equipment and appraisers.

Gemba. The actual place where work is performed or value is created. Gemba activity involves observing the real process and conditions rather than relying solely on reports.

Goods-In Inspection — Incoming Product Verification. Verification activities performed on received product, material or services to determine whether specified acceptance requirements have been satisfied.

I

IAQG — International Aerospace Quality Group. The international body responsible for the 9100-series aerospace quality standards and associated sector quality initiatives.

IATF — International Automotive Task Force. The automotive-sector group associated with IATF 16949 and automotive quality-management requirements.

Inspection. Determination of conformity to specified requirements through observation, measurement, examination or other appropriate verification.

ISO — International Organization for Standardization. The international standards organisation that develops and publishes consensus-based international standards.

J

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Jidoka — Built-in quality / autonomation. A Lean principle in which abnormalities are detected and the process is stopped or controlled so defects are not knowingly passed forward.

K

Kaizen — Continual incremental improvement. A philosophy and method of making ongoing improvements through the involvement of people close to the work.

Kanban. A visual signalling method used to control workflow, replenishment or work-in-progress according to demand.

KC — Key Characteristic. A product or process characteristic whose variation has a significant influence on fit, performance, service life, manufacturability or other defined outcomes and therefore requires specific control.

KPI — Key Performance Indicator. A measure selected to monitor performance against an important objective, process or outcome.

L

Lean. An improvement philosophy focused on maximising value and reducing waste, delay and unnecessary activity across processes.

LoB — Line of Balance. A planning and control method used to compare required and actual progress across repetitive production or delivery activities.

M

MRB — Material Review Board. The authorised function or process that evaluates nonconforming product and determines or approves its disposition within defined authority.

MSA — Measurement System Analysis. Methods used to determine whether a measurement system is suitable for its intended purpose, including repeatability, reproducibility, bias, stability, linearity and attribute studies.

N

Nadcap — An industry-managed accreditation programme for special processes and other critical aerospace and defence activities.

NCR — Nonconformance / Nonconformity Report. A controlled record used to document a failure to meet a requirement and the associated containment, disposition, investigation or corrective action as applicable.

NPI — New Product Introduction. The controlled process used to move a new or significantly changed product from concept and development into capable, repeatable production or service delivery.

O

Objective Evidence. Verifiable information demonstrating that an activity occurred, a requirement was satisfied or a conclusion is supported.

OODA — Observe, Orient, Decide, Act. An iterative decision-and-action cycle used to understand changing conditions, select action and learn from the result.

P

Pareto Analysis. A prioritisation technique that orders categories by frequency, cost or other impact to identify the relatively few contributors responsible for a large proportion of the effect.

PDCA — Plan, Do, Check, Act. An iterative management and improvement cycle used to plan work, implement it, evaluate results and act on learning.

PFMEA — Process Failure Mode and Effects Analysis. FMEA applied to manufacturing, assembly or service processes to identify potential process failures, effects, causes and appropriate controls.

PLM — Product Lifecycle Management. The coordinated management of product information, definition and change across the product lifecycle.

Poka-Yoke — Mistake-proofing. A design or process-control approach intended to prevent errors or make them immediately detectable.

PPAP — Production Part Approval Process. A structured package of evidence used to demonstrate that product and production-process requirements have been understood and that the intended production process is capable of producing conforming output.

Process Approach. Managing activities as interrelated processes with understood inputs, outputs, responsibilities, resources, controls, measures and interactions.

Process Validation. Establishing objective evidence that a process can consistently achieve its intended result, particularly where the resulting output cannot be fully verified by subsequent monitoring or measurement.

Q

QFD — Quality Function Deployment. A structured method for translating customer or stakeholder needs into technical and process requirements; the House of Quality is a common QFD matrix.

QMS — Quality Management System. The coordinated framework of policies, processes, responsibilities, resources and documented information used to direct and control an organisation with regard to quality.

Quality Assurance — QA. Activities focused on providing confidence that applicable quality requirements will be fulfilled by examining whether appropriate arrangements are established, implemented and effective.

Quality Control — QC. Operational techniques and activities used to fulfil quality requirements by monitoring, measuring, inspecting and controlling outputs and processes.

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Quality Plan — QP. A document specifying how quality requirements and established management-system arrangements will be applied to a particular product, service, project, process or contract.

Quality Planning. The activity of translating requirements and risks into the processes, controls, responsibilities, verification, acceptance criteria and evidence needed to achieve conformity.

R

RCCA — Root Cause Corrective Action. A structured process for identifying the underlying cause of a problem, implementing action to remove or control that cause and verifying effectiveness.

Risk-Based Thinking. The systematic consideration of uncertainty, threats and opportunities when planning, controlling and improving activities.

Root Cause. An underlying cause that, when appropriately addressed, reduces or prevents recurrence of the problem within the defined system.

S

Sampling Plan. A defined method specifying how a sample will be selected and the criteria used to accept or reject a lot or other population.

SIPOC — Supplier, Input, Process, Output, Customer. A high-level process-mapping tool used to define the boundaries, inputs, outputs and interested parties of a process.

SMART — Specific, Measurable, Achievable, Relevant and Time-bound. A commonly used framework for defining clear and measurable objectives.

SPC — Statistical Process Control. The use of statistical techniques, particularly control charts, to understand process variation, identify instability and support process control.

Special Process. A process for which the resulting output cannot be fully verified by subsequent monitoring or measurement, or where deficiencies may become apparent only after use or service; such processes require appropriate validation and control.

Special Requirement. A requirement identified as having high risk to achievement and therefore requiring inclusion within risk-management and assurance activities.

Specification. A document or defined requirement establishing detailed criteria for a product, material, process, service, software, inspection or test.

Standard. An agreed document that provides requirements, rules, guidelines or characteristics for activities or their results.

T

Takt Time. The rate at which output needs to be completed to meet customer demand, calculated from available production time divided by required demand.

TOC — Theory of Constraints. A management approach focused on identifying and improving the system constraint that limits overall performance.

Tolerance Stack-Up. Analysis of the combined effect of individual component tolerances on an assembly, interface or functional requirement.

TQM — Total Quality Management. An organisation-wide management philosophy focused on customer satisfaction, continual improvement and participation in quality across functions.

Traceability. The ability to trace the history, application, location or relationship of an item, material, process, measurement or record through appropriate identification and records.

V

Validation. Confirmation, through objective evidence, that requirements for a specific intended use or application have been fulfilled.

Verification. Confirmation, through objective evidence, that specified requirements have been fulfilled.

VOC — Voice of the Customer. Methods used to capture and understand customer needs, expectations, feedback and priorities so they can be translated into requirements and improvement activity.

VSM — Value Stream Mapping. A Lean method for visualising the flow of material and information across a value stream to identify waste, delay and improvement opportunities.

36.2. References

Core quality-management and auditing standards

- ISO 9000 — Quality management systems — Fundamentals and vocabulary.
- ISO 9001 — Quality management systems — Requirements. Use the edition applicable to the organisation, contract and certification transition arrangements.
- ISO 10005:2018 — Quality management — Guidelines for quality plans.
- ISO 10007 — Quality management — Guidelines for configuration management.
- ISO 10010:2022 — Quality management — Guidance to understand, evaluate and improve organizational quality culture.
- ISO 10012 — Measurement management systems — Requirements for measurement processes and measuring equipment.
- ISO 19011:2026 — Guidelines for auditing management systems.

Sector and laboratory quality-management standards

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- IA/AS/EN 9100 series — Quality management systems for aviation, space and defence organisations.
- IA/AS/EN 9110 series — Quality management systems for aviation maintenance organisations.
- IA/AS/EN 9120 series — Quality management systems for aviation, space and defence distributors.
- ISO/IEC 17025:2017 — General requirements for the competence of testing and calibration laboratories.
- IATF 16949 — Quality management system requirements for automotive production and relevant service-parts organisations.
- ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes.
- ISO 19443:2018 — Quality management systems — Specific requirements for the application of ISO 9001 by organisations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety.
- ISO 22163:2023 — Railway applications — Railway quality management system — ISO 9001:2015 and specific requirements for application in the railway sector.
- ISO 29001:2020 — Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organisations.

Aerospace, defence and NATO assurance

- AS9102 — Aerospace First Article Inspection Requirement.
- AS9145 — Requirements for Advanced Product Quality Planning and Production Part Approval Process.
- AQAP 2105 — NATO Requirements for Quality Plans.
- AQAP 2110 — NATO Quality Assurance Requirements for Design, Development and Production.
- AQAP 2310 — NATO Quality Assurance Requirements for Aviation, Space and Defence Suppliers.

Measurement, inspection and acceptance sampling

- ISO 2859-1 — Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
- ISO 2361 — Electrodeposited nickel coatings on magnetic and non-magnetic substrates — Measurement of coating thickness — Magnetic method. Refer to the edition invoked by the applicable requirement.

Counterfeit prevention and electronics

- SAE AS5553 series — Counterfeit electronic part avoidance, detection, mitigation and disposition.
- SAE AS6081 series — Counterfeit electronic parts: avoidance, detection, mitigation and disposition requirements relevant to independent distribution.
- SAE AS6174 — Counterfeit material avoidance, detection, mitigation and disposition for non-electronic products/material.
- IPC-A-610 — Acceptability of Electronic Assemblies.

Surface engineering and special-process references

- ISO 4527 — Metallic coatings — Autocatalytic (electroless) nickel-phosphorus alloy coatings — Specification and test methods.
- Applicable customer, drawing, material, process and special-process specifications invoked by contract. The governing revision and any customer-specific approval or qualification requirements take precedence.

Related management-system standards referenced in the book

- ISO 14001 — Environmental management systems — Requirements with guidance for use.
- ISO 45001 — Occupational health and safety management systems — Requirements with guidance for use.
- ISO/IEC 27001 — Information security management systems — Requirements.

Automotive core-tool references

- AIAG — Advanced Product Quality Planning (APQP) and Control Plan reference material.
- AIAG — Production Part Approval Process (PPAP) reference material.
- AIAG & VDA — Failure Mode and Effects Analysis (FMEA) Handbook.
- AIAG — Measurement Systems Analysis (MSA) reference manual.
- AIAG & VDA — Statistical Process Control (SPC) reference material.

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- SPI-03 — 8D RCCA Problem Solving Guidebook.
- SPI-04 — 8D Report Template.
- SPI-05 — Understanding 8D RCCA Problem Solving – Training Publication.
- SPI-06 — Process Failure Mode and Effects Analysis (PFMEA) Guidebook.
- SPI-07 — Understanding PFMEA – Training Publication.
- SPI-08 — PFMEA Workbook (Excel) Form.
- SPI-09 — First Article Inspection Guidebook.
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