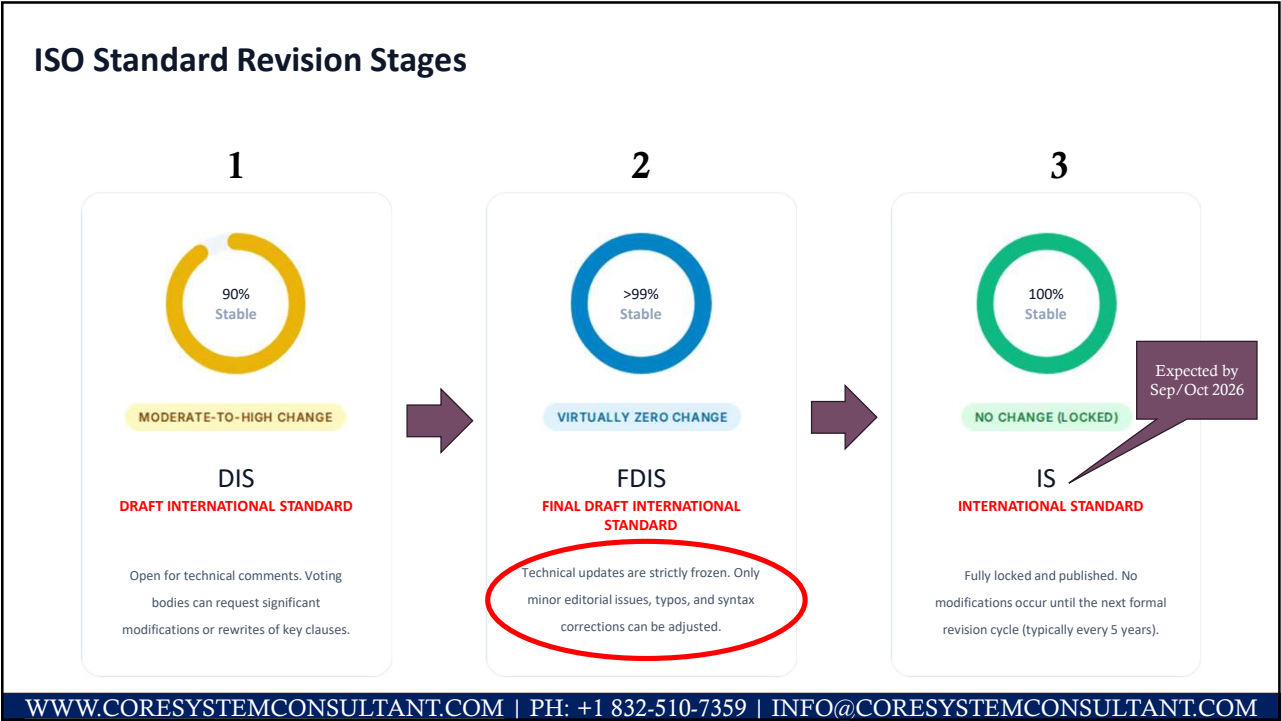




## ISO 9001:2026 Evolution: The Future of Quality Management

### ISO 9001:2015

#### STRATEGIC CONTEXT & RISK



##### Risk-Based Thinking

Primary logic for planning and addressing potential issues.



##### General Context Issues & Basic Awareness

Organization's environment considered generally; basic human awareness.

| Feature          | ISO 9001:2015                                                                                            |
|------------------|----------------------------------------------------------------------------------------------------------|
| Primary Logic    |  Risk-Based Thinking    |
| Org. Environment |  General Context Issues |
| Human Factors    |  Basic Awareness        |

### ISO 9001:2026

#### CULTURE, ETHICS, & OPPORTUNITY



##### Quality Culture & Ethical Behaviour

Explicitly addresses shared values, attitudes, and practices regarding quality and ethical behavior in leadership and awareness requirements.



##### Climate Change as Core Requirement

Mandatory determination of climate change as a relevant issue for the organization.



##### Shift to Opportunity-Based Thinking

Adds "Opportunity-based thinking" to achieve beneficial effects on system performance.



##### Separation of Risks & Opportunities

Clearly distinguishes risks from opportunities, requiring separate analysis and action plans.



##### Strengthened Management of Change

Reinforces requirements for system changes to ensure achievement of intended results.

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## What is Climate Change?

### 1) DEFINITION

LONG-TERM SHIFTS IN TEMPERATURES AND WEATHER PATTERNS.



HISTORICAL PATTERNS      MODERN SHIFTS

### 2) THE BIG PICTURE

RAPID ENVIRONMENTAL SHIFTS HAPPENING NOW.



Modern changes are occurring at an accelerated pace compared to historical patterns.

### 3) KEY INDICATORS

#### KEY ENVIRONMENTAL INDICATORS



##### RIISING TEMPERATURES AND EXTREME WEATHER

Increasing air and ocean temperatures leading to severe storms, floods, and hurricanes.



##### SEVERE HEATWAVES AND DROUGHT

Prolonged periods of extreme heat that disrupt natural cycles and safety.



##### SHIFTING ESSENTIAL RESOURCES

Growing scarcity of fresh water and a decline in available fertile land.

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### Climate Change vs Quality Management System

**Determination of Relevance**

Organizations must now determine if climate change is an internal or external issue that affects their ability to achieve intended results or any related demand by interested parties and accordingly the controls to counter any such issues.

- Pharmaceutical Sector:** A pharmaceutical company that requires consistent temperature and humidity for its production lines might identify **increasingly frequent extreme heatwaves** as a relevant issue. If the current cooling infrastructure cannot handle these peaks, it could lead to product nonconformity.
- Logistics and Supply Chain:** A shipping / transport company might determine that **rising sea levels or increased storm frequency or natural disasters** is a relevant issue because it threatens its **ability to meet delivery schedules** through sea/land routes (conformity of service).

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### Ethical Behaviour vs Quality Culture

**Ethical Behaviour**

- Definition:** Ethical behaviour involves **transparency, honesty, and integrity** in all professional interactions and decision-making processes.

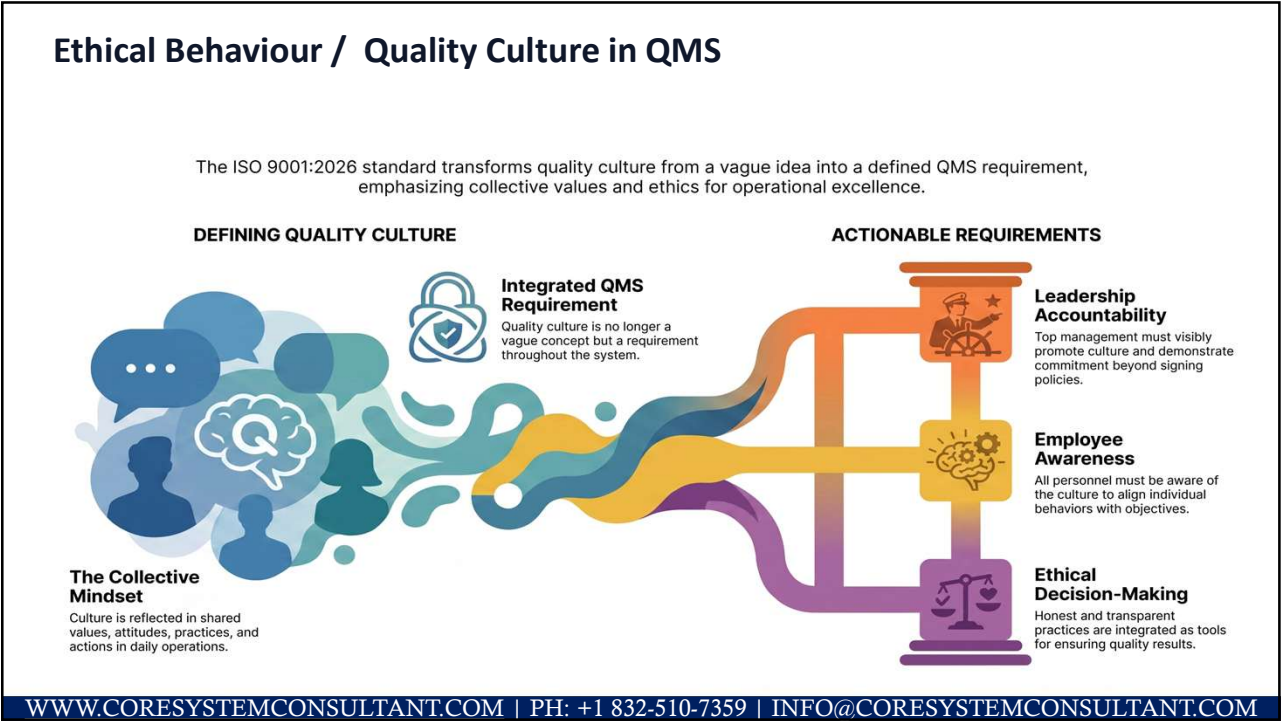
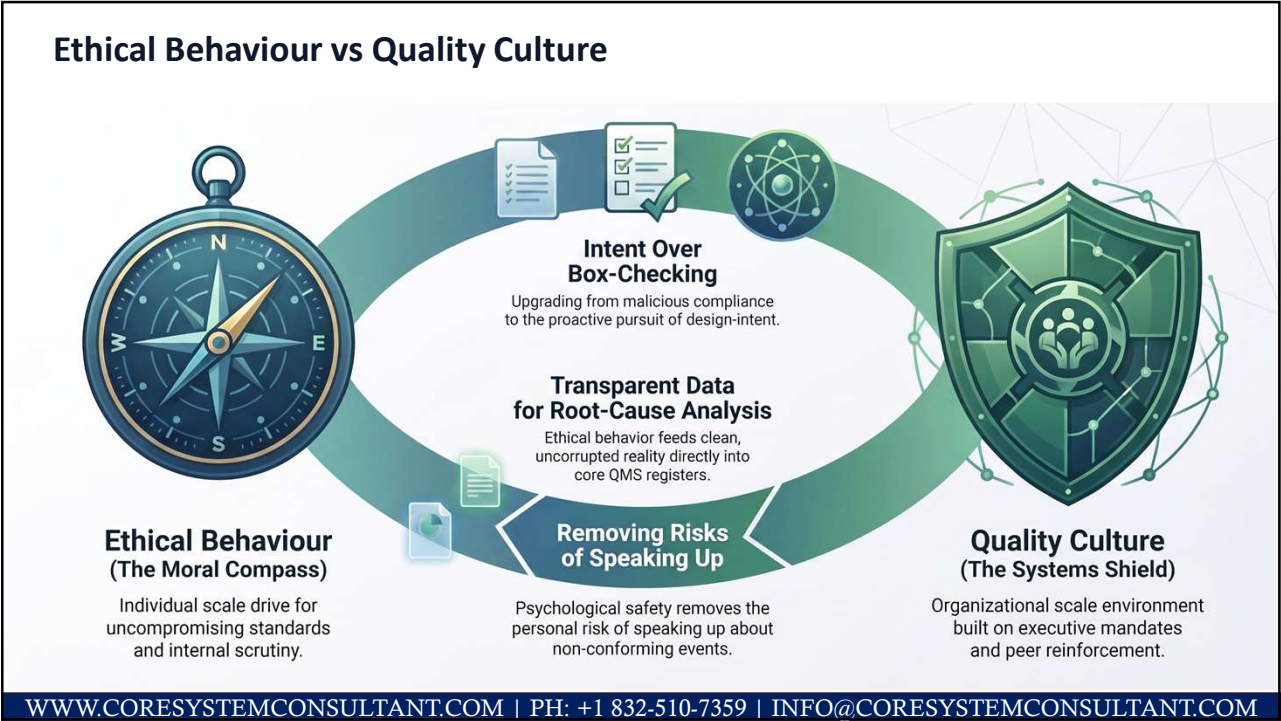


**Quality Culture**

- Definition:** Quality culture is the collective **shared values, attitudes, and practices** that determine how an organization makes decisions regarding quality. It is the "way we do things around here" when no one is watching.

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### Risk Based Thinking vs Opportunity Based Thinking

**Risk-Based Thinking:** Focused on **preventing undesired results** and dealing with uncertainty that could have a negative impact.

**Opportunity-Based Thinking:** Focused on **pursuing desired results** by identifying circumstances that allow for beneficial effects on performance.

**Major Change:** The 2026 edition **separates these two concepts**. While the 2015 version often treated them together, the new standard requires distinct analysis for each to ensure opportunities for growth are not overshadowed by risk mitigation.

**ISO 9001:2015**

6.1 Actions to address risks and **opportunities**

6.1.1 – no title

6.1.2 – no title

➔

**ISO 9001:2026**

6.1 Actions to address risks and opportunities

6.1.1 Determining risks and opportunities

6.1.2 Actions to address risks

**6.1.3 Actions to address opportunities**

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### Risk Based Thinking vs Opportunity Based Thinking



**Risk-Based Thinking**

**Focus:** Preventing the undesired.

**Action:** Implementing preventive controls to minimize negative effects, deviations, and nonconformities.

**Opportunity-Based Thinking**

**Focus:** Pursuing the desired.

**Action:** Exploiting favorable circumstances to innovate, adopt new practices, launch new products, or improve productivity.

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### Risk Based Thinking vs Opportunity Based Thinking

RISK-BASED THINKING

- **FOCUS:** Preventing undesired results.
- **INDUSTRY TRIGGER:** An automotive supplier identifies the severe threat of a cyberattack targeting its newly automated warehouse systems.
- **EXECUTION:** Implementation of advanced, localized software firewalls and redundant data backups (Defensive Action).

OPPORTUNITY-BASED THINKING

- **FOCUS:** Pursuing desired results.
- **INDUSTRY TRIGGER:** The same automotive supplier recognizes a surging global market demand for Electric Vehicles (EV).
- **EXECUTION:** Aggressive investment in specialized workforce training for EV-component assembly to capture new market share (Offensive Action).

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### Change Management

#### Change Management: ISO 9001 2015 vs. 2026

ISO 9001:2015

STATIC: Planned Manner



Follow a plan.

Focus on Process Compliance



Implement changes as planned.



Follow procedures.

ISO 9001:2026

ACTIVE: Ensuring Effectiveness



Achieve intended results.

Focus on Measurable Results



Communicate Changes



Monitor & Evaluate Effectiveness



Review Final Results

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### Few Other Changes...

Clause 6.1.2 now includes a note stating that determined risks can specifically include those related to the ability to provide conforming products and services **during and after a disruption** (also in 8.2.1e)

Maintain and Retain Documented Information is all replaced with 'available' as Documented Information

Few structural changes for better clarity like:

**ISO 9001:2015**

- 10 Improvement
- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement

➔

**ISO 9001:2026**

- 10 Improvement
- 10.1 Continual improvement
- 10.2 Nonconformity and corrective action

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### Transition timeline from ISO 9001:2015 to ISO 9001:2026

The timeline consists of a horizontal line with four circular markers. Below the line, from left to right, are three boxes: 'DRAFT PHASE Dec 2025', 'STANDARD GOES LIVE Sept 2026', and 'SUNSET MILESTONE Sept 2029'. Above the line, between the first and second markers, is a box for 'FINAL REVIEW Mid 2026'. A large blue arrow points from the 'DRAFT PHASE' box to the 'STANDARD GOES LIVE' box. The 'SUNSET MILESTONE' box is circled in red.

**DRAFT PHASE**  
Dec 2025

Draft International Standard (DIS) approved by member countries, finalizing the core structure.

**FINAL REVIEW**  
Mid 2026

FDIS final textual modifications, technical polishing, and administrative comment resolutions.

**STANDARD GOES LIVE**  
Sept 2026

Official public release of ISO 9001:2026. This launches the formal three-year transition window.

**SUNSET MILESTONE**  
Sept 2029

Final transition deadline. All legacy ISO 9001:2015 certifications expire and lose official validity.

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